

Document Title

**Summary of the residues in or on treated products, food and feed for
Isoxaflutole**

Data Requirements

**EU Regulation 1107/2009 & EU Regulation 283/2013
Document MCA**

Section 6: Residues in or on treated products, food and feed

According to the guidance document SANCO 10181/2013 for
preparing dossiers for the approval of a chemical active substance

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Version history

Date	Data points containing amendments or additions ¹ and brief description	Document identifier and version number

¹ It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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CA 6 RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED

Isoxaflutole (RPA 201772) is an herbicidal active substance. In early 1996, the original Annex II dossier was submitted to the Netherlands being the designated Rapporteur Member State. The representative use supported for the peer review process was pre-emergence treatment of maize at a rate of 100 g a.s./ha in northern and southern Europe.

The EU MRLs for isoxaflutole were established in Annexes II and IIIB of Regulation (EC) No 396/2005 in 2008.

On 03 July 2009, EFSA provided a first reasoned opinion on isoxaflutole, which excluded the metabolite isoxaflutole-benzoic-acid (RPA 203328) from the residue definition. This was considered in Regulation (EC) No 459/2010. All existing EU MRLs are established for the sum of isoxaflutole and its metabolite diketonitrile-isoxaflutole (RPA 202248), expressed as isoxaflutole.

On 25 February 2013, EFSA provided a second reasoned opinion on isoxaflutole, reviewing all the existing MRLs for isoxaflutole, according to Article 12 of Regulation (EC) No 396/2005.

In this renewal of approval dossier, the "safe uses" in maize and sweet corn will be presented.

CA 6.1 Storage stability of residues

Under KCA 6.1/01 and /02, the storage stability study of isoxaflutole residues was described for maize raw agricultural commodities (grain, silage and fodder) and maize processed commodities (flour, meal, grits, starch and refined oil). The results of this study indicate that the residues of isoxaflutole (sum of isoxaflutole, RPA 202248, and RPA 203328) are stable in corn matrices when stored under freezer conditions for 3 months (processed commodities) and for 5 months (raw agricultural commodities).

New studies submitted for renewal application

Report:	KCA 6.1/03; [REDACTED] B. J. 2012; M 442915-01
Title:	Stability of residues of isoxaflutole and its metabolite RPA 202248 during frozen storage in several raw agricultural commodities
Report No:	RAISP012
Document No:	M 442915-01-1
Guidelines:	not specified; not specified
GLP/GEP:	yes

I Materials and Methods

A study was started in 2012 to investigate the stability of isoxaflutole and RPA 202248 residues in oranges, pinto beans, soybean seeds and sugarcane over a storage period of 24 months. The document M-442915-01-1 reports the results of the study until approximately 6 months of storage. A final report will be issued in 2014 covering a storage period of 24 months.

The orange and pinto bean samples used in this study were purchased at a local market, the soybean seed sample was a generic control sample from [REDACTED] sample archives and the sugarcane samples were harvested in [REDACTED], California by a [REDACTED] employee.

Prior to stability set up, the analytical method was tested on each matrix. Performance was evaluated to ensure no residues through analysis of one control sample and one corresponding fortified control sample for each matrix. The results from this evaluation identified that the control samples were suitable for use in this study. Additionally, 3 recoveries per matrix were performed.

The homogenized untreated sample materials were individually spiked with isoxaflutole and RPA 202248 at a fortification level of 0.1 mg/kg for all matrices. The samples were stored in high density polyethylene centrifuge bottles in a freezer typically at -25 to -10 °C.

Control samples were also stored along with the storage stability (stored spiked) samples. Some of them were freshly fortified at 0.1 mg/kg with a mixture of isoxaflutole and RPA 202248 and analyzed along with the storage stability samples.

Residues of isoxaflutole and its metabolite RPA 202248 were analyzed by LC/MS/MS, using method IS-004-P10-01 with minor modifications. After addition of 1% formic acid in water to the homogenized plant matrices, residues of isoxaflutole and RPA 202248 were extracted with methanol. The extract was filtered and isotopic internal standards were added to the extract, which was then diluted with 1% formic acid in water and analyzed by LC/MS/MS. The limit of quantification (LOQ) of the method IS-004-P10-01 is 0.01 mg/kg.

Zero-day analysis sets consisted of one control sample and three procedural fortifications for each analyte (individual fortifications). For the other storage intervals (1, 3 and 6 months) analysis sets consisted of one control sample, two procedural fortifications (mixed fortifications) and two stability fortifications for each analyte (individual fortifications).

II. Findings

For each compound, the obtained recovery means for the method validation were in the acceptable range of 70–110% with RSD < 20%. The results are shown in [Table 6.1-1](#).

Analytical method performance during the course of the study was monitored through concurrent analysis of freshly fortified control samples along with stability samples. For each compound, the obtained recovery means were in the acceptable range of 70–110% with RSD < 20%. The results are shown in [Table 6.1-2](#).

The storage stability results for isoxaflutole and RPA 202248 are detailed in [Table 6.1-3](#) to [Table 6.1-7](#). The residue levels of isoxaflutole and RPA 202248 in the control samples were always found to be below the limit of detection (LOD) of 0.005 mg/kg.

III. Conclusions

The storage stability results indicate that isoxaflutole converts onto RPA 202248 over time. After 6 months of storage, 36% of RPA 202248 was found in pinto beans samples spiked with isoxaflutole, 9% in sugarcane, 21% in orange and 25% in soybean seed. However, there is no significant loss of RPA 202248 in any of the tested matrices stored under freezer conditions for at least 6 months. Overall, total residues of isoxaflutole (comprising isoxaflutole and RPA 202248) remain stable for at least 6 months in 4 crop groups:

- the high acid content crop group, represented by orange
- the high protein content crop group represented by pinto beans
- the high oil content crop group represented by soybean seed
- the high water content crop group represented by sugarcane.

The preliminary results for a longer storage period of 12 months indicate that total residues of isoxaflutole (comprising isoxaflutole and RPA 202248) remain stable for at least 12 months in these 4 crop groups. The final report covering a storage period of 24 months should be available by end of May 2014.

Table 6.1 – 1: Method validation

Commodity	Spike level (mg/kg)	Sample size (n)	Isoxaflutole			RPA 202248		
			Recoveries (%)	Mean (%)	RSD (%)	Recoveries (%)	Mean (%)	RSD (%)
Oranges	0.1	3	83, 89, 84	85	3.8	77, 81, 78	79	2.6
Pinto Beans	0.1	3	83, 80, 85	83	3.0	84, 83, 86	84	1.8
Soybean seed	0.1	3	89, 88, 87	88	1.1	82, 81, 80	81	4.2
Sugarcane	0.1	3	97, 90, 89	92	4.7	84, 80, 79	81	3.3

RSD: relative standard deviation

Table 6.1 – 2: Concurrent (freshly fortified) recoveries

Commodity	Spike level (mg/kg)	Sample size (n)	Isoxaflutole			RPA 202248		
			Recoveries (%)	Mean (%)	RSD (%)	Recoveries (%)	Mean (%)	RSD (%)
Oranges	0.1	9	92, 86, 85,	80	1.6	73, 74, 72,	82	4.2
			92, 92, 93,			78, 80, 93,		
			93, 87, 88			93, 87, 87		
Pinto Beans	0.1	9	94, 95, 95,	88	1.1	72, 81, 81,	83	8.7
			95, 91, 87,			90, 92, 89,		
			87, 75, 67			90, 78, 67		
Soybean seed	0.1	9	80, 83, 81,	86	6.9	75, 73, 71,	80	6.4
			93, 95, 83,			78, 79, 84,		
			85, 86, 86			84, 86, 86		
Sugarcane	0.1	9	93, 94, 92,	89	6.6	76, 75, 74,	81	10.1
			77, 82, 91,			71, 78, 91,		
			93, 91, 86			92, 89, 87		

RSD: relative standard deviation

Table 6.1 – 3: Storage stability of Isoxaflutole in orange (samples spiked with Isoxaflutole)

Commodity	Storage period (Days)	Residue Level in Stored Spiked Sample		Average % Recovery	Day 0 Normalized % Recovery ^b	Average % of Fresh Concurrent Recoveries ^a	Average Corrected % Recovery ^c
		mg/kg	% of nominal spiking level				
Isoxaflutole							
Orange	0*	0.0916	92	88	100	88	-
		0.0864	86				
		0.0854	85				
	31	0.0936	93	91	103	92	99
		0.0892	89				
	96	0.0882	88	88	100	93	95
		0.0884	88				
	188	0.0742	74	74	84	88	84
0.0726		73					
RPA 202248							
Orange	0	na	na	na	-	73	-
	31	na	na	na	-	79	-
	96	na	na	na	-	93	-
	188	0.0204	20	21	-	87	24

Sum of Isoxaflutole and RPA 202248							
Orange	0*	0.0916	92	88	100	-	-
		0.0864	86				
		0.0854	85				
	31	0.0926	93	91	103	-	99
		0.0892	89				
	96	0.0882	88	88	100	-	95
		0.0884	88				
	188	0.0946	95	94	107		108
0.0934		93					

na : not analysed

* 0-day values are procedural recoveries only (mean of three replicate analyses)

^a Mean of two replicate analyses

^b Normalized recovery = (Average recovery in stored sample / Average recovery in stored sample at day 0) x 100%. (Recalculated using rounded values for average recoveries presented in this table. Thus the values may slightly differ from those shown in the report.

^c Corrected percent recovery = (Average % recovery in stored spiked sample / Average of fresh concurrent recoveries) x 100.

Table 6.1 – 4: Storage stability of isoxaflutole in pinto beans (samples spiked with isoxaflutole)

Commodity	Storage period (Days)	Residue Level in Stored Spiked Sample			Day 0 Normalized % Recovery ^b	Average % of Fresh Concurrent Recoveries ^a	Average Corrected % Recovery ^c
		mg/kg	% of nominal spiking level	Average % recovery			
Isoxaflutole							
Pinto Beans	0*	0.0935	94	95	100	95	-
		0.0953	95				
		0.0951	95				
	36	0.0696	70	71	75	97	73
		0.0706	74				
	94	0.0594	59	56	62	88	67
		0.0584	58				
	184	0.0498	50	49	52	71	69
0.0478		48					
RPA 202248							
Pinto Beans	0*	na	na	na	-	81	-
		na	na				
		na	na				
	36	0.0310	31	31	-	90	34
		0.0310	31				
	94	0.0358	36	36	-	73	49
		0.0362	36				
	Sum of Isoxaflutole and RPA 202248						
Pinto Beans	0*	0.0935	94	95	100	-	-
		0.0953	95				
		0.0951	95				
	36	0.0696	70	71	75	-	73
		0.0706	74				
	94	0.0904	90	90	95	-	101
		0.0894	89				
	184	0.0856	86	85	89	-	118
0.0840		84					

na : not analysed

* 0-day values are procedural recoveries only (mean of three replicate analyses)

^a Mean of two replicate analyses

^bNormalized recovery = (Average recovery in stored sample / Average recovery in stored sample at day 0) x 100%. Recalculated using rounded values for average recoveries presented in this table. Thus the values may slightly differ from those shown in the report.

^cCorrected percent recovery = (Average % recovery in stored spiked sample / Average of fresh concurrent recoveries) x 100

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Table 6.1 – 5: Storage stability of isoxaflutole in soybean seed (samples spiked with isoxaflutole)

Commodity	Storage period (Days)	Residue Level in Stored Spiked Sample			Day-0 Normalized % Recovery ^b	Average % of Fresh Concurrent Recoveries ^c	Average Corrected % Recovery ^c	
		mg/kg	% of nominal spiking level	Average % recovery				
Isoxaflutole								
Soybean seed	0*	0.0800	80	81	100	81	-	
		0.0830	83					
		0.0814	81					
	35	0.0762	76	76	94	94	81	
		0.0758	76					
	94	0.0722	72	72	89	87	86	
		0.0720	72					
	183	0.0577	58	58	72	86	67	
		0.0571	57					
	RPA 202248							
	Soybean seed	0	na	na	na	-	74	-
		35	na	na	na	-	79	-
94		na	na	na	-	82	-	
183		0.0244	24	25	-	86	29	
		0.0248	25					
Sum of Isoxaflutole and RPA 202248								
Soybean seed	0*	0.0800	80	81	100	-	-	
		0.0830	83					
		0.0814	81					
	35	0.0762	76	76	94	-	81	
		0.0758	76					
	94	0.0722	72	72	89	-	86	
		0.0720	72					
	183	0.0821	82	82	101	-	96	
		0.0819	82					

na : not analysed

* 0 day values are procedural recoveries only (mean of three replicate analyses)

^a Mean of two replicate analyses

^b Normalized recovery = (Average recovery in stored sample / Average recovery in stored sample at day 0) x 100%. Recalculated using rounded values for average recoveries presented in this table. Thus the values may slightly differ from those shown in the report.

^c Corrected percent recovery = (Average % recovery in stored spiked sample / Average of fresh concurrent recoveries) x 100

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Table 6.1 – 6: Storage stability of isoxaflutole in sugarcane (samples spiked with isoxaflutole)

Commodity	Storage period (Days)	Residue Level in Stored Spiked Sample			Day-0 Normalized % Recovery ^b	Average % of Fresh Concurrent Recoveries ^a	Average Corrected % Recovery ^c	
		mg/kg	% of nominal spiking level	Average % recovery				
Isoxaflutole								
Sugarcane	0*	0.0932	93	93	100	93	-	
		0.0942	94					
		0.0920	92					
	29	0.0808	81	82	88	80	97	
		0.0816	82					
	95	0.0938	94	93	101	92	102	
		0.0928	93					
	185	0.0750	75	77	83	85	87	
		0.0782	78					
	RPA 202248							
	Sugarcane	0	Na	na	na	-	-	-
		29	na	na	na	-	75	-
95		na	na	na	-	92	-	
185		0.00864 0.00870	9 9	9	-	88	88	
Sum of Isoxaflutole and RPA 202248								
Sugarcane	0*	0.0932	93	93	100	93	-	
		0.0942	94					
		0.0920	92					
	29	0.0808	81	82	88	80	102	
		0.0816	82					
	95	0.0938	94	93	101	92	102	
		0.0928	93					
	185	0.0750	84	86	90	85	97	
		0.0869	87					

na : not analyzed

* 0 day values are procedural recoveries only (mean of three replicate analyses)

^a Mean of two replicate analyses

^b Normalized recovery = (Average recovery in stored sample / Average recovery in stored sample at day 0) x 100%. Recalculated using rounded values for average recoveries presented in this table. Thus the values may slightly differ from those shown in the report.

^c Corrected percent recovery = (Average % recovery in stored spiked sample / Average of fresh concurrent recoveries) x 100

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Table 6.1 – 7: Storage stability of RPA 202248 in orange, pinto beans, soybean seed and sugarcane (samples spiked with RPA 202248)

Commodity	Storage period (Days)	Residue Level in Stored Spiked Sample			Day-0 Normalized % Recovery ^b	Average % of Fresh Concurrent Recoveries ^c	Average Corrected % Recovery ^e	
		mg/kg	% of nominal spiking level	Average % recovery				
Orange	0*	0.0730	73		100	73	-	
		0.0738	74	73				
		0.0716	72					
	31	0.0722	72		97	79	-	
		0.0698	70	71				
	96	0.0750	75		103	93	81	
		0.0754	75	75				
	188	0.0672	67		96	94	88	
		0.0716	72	70				
	Pinto Beans	0*	0.0817	82		100	81	-
			0.0807	81	81			
			0.0807	81				
36		0.0814	81		100	92	88	
		0.0802	80	81				
94		0.0736	74		97	90	85	
		0.0746	75	75				
184		0.0762	76		95	73	105	
		0.0766	77	77				
Soybean seed		0*	0.0746	75		100	74	-
			0.0728	73	74			
			0.0758	75				
	35	0.0666	67		94	79	84	
		0.0660	66	67				
	94	0.0738	74		101	84	89	
		0.0740	75	75				
	183	0.0758	76		105	86	91	
		0.0804	80	78				
	Sugarcane	0*	0.0769	76		100	75	-
			0.0749	75	75			
			0.0743	74				
29		0.0730	73		96	75	95	
		0.0698	70	70				
95		0.0768	77		103	92	84	
		0.0766	77	77				
185		0.0765	77		104	88	89	
		0.0794	79	81				

na : not analysed

* 0 day values are procedural recoveries only (mean of three replicate analyses)

^a Mean of two replicate analyses

^b Normalized recovery = (Average recovery in stored sample / Average recovery in stored sample at day 0) x 100%. Recalculated using rounded values for average recoveries presented in this table. Thus the values may slightly differ from those shown in the report.

^c Corrected percent recovery = (Average % recovery in stored spiked sample / Average of fresh concurrent recoveries) x 100

Overall, total residues of isoxaflutole (comprising isoxaflutole and RPA 202248) remain stable for at least 6 months in 4 crop groups:

- the high acid content crop group, represented by orange
- the high protein content crop group represented by pinto beans
- the high oil content crop group represented by soybean seed
- the high water content crop group represented by sugarcane.

The preliminary results for a longer storage period of 12 months indicate that total residues of isoxaflutole (comprising isoxaflutole and RPA 202248) remain stable for at least 12 months in these 4 crop groups. The final report covering a storage period of 24 months should be available by end of May 2014. It will be promptly submitted for consideration in the evaluation, as agreed on the pre-submission meeting with representatives of ICPS on the 23rd of October 2013 in Milano.

Report:	KHIA 8.1.1 /01; [REDACTED] . I-2014;M-442915-02-1
Title:	Stability of residues of isoxaflutole and its metabolite RPA 202248 during frozen storage in several raw agricultural commodities
Report No:	RAISP012
Document No:	M-442915-02-1
Guidelines:	<ul style="list-style-type: none"> - US EPA Residue Chemistry Test Guideline OPP 15860.1380: Storage Stability Data - OECD Test Guideline 506: Stability of Pesticide Residues in Stored Commodities - OECD Testing and Assessment #72/Series on Pesticides #39 - OECD Testing and Assessment #64/Series on Pesticides #39 - EU Directive 91/414/EEC, No. 7032/VI/93, rev.5: Appendix H - PMRA Dir98-02, Section 5, Storage Stability Data - APVM Residue Guideline No8: Stability of Residues in Storage
GLP/GEP:	yes

Materials and methods

A study was started in 2012 to investigate the stability of isoxaflutole and RPA 202248 residues in representative commodities - a high oil content commodity (soybean seed), a high protein content commodity (pinto bean), a high acid content commodity (orange) and a high water content commodity (sugarcane) - over a storage period of 24 months at 20°C ± 5°C.

The control materials used for fortification were purchased from local markets on 2012-01-31, transferred from laboratory sample archives on 2012-02-03 or locally harvested on 2012-02-13. The homogenized untreated sample materials were separately spiked with isoxaflutole and RPA 202248 at a fortification level of 0.10 mg/kg for all matrices, stored in high density polyethylene centrifuge bottles typically at -20 ± 5°C, then later analyzed at the nominal storage intervals of 0, 1, 3, 6, 12, 18 and 24 months.

Concurrent recovery experiments at fortification levels of 0.10 mg/kg were also performed for each analyte at each storage interval. In addition, concurrent recovery at fortification levels of 0.01 mg/kg were also performed for each analyte and matrix at the 24 month interval to demonstrate method reliability at the limit of quantitation (LOQ).

At each storage interval isoxaflutole and its metabolite RPA 202248 were determined independently in the stored unfortified control samples and in the stored spiked samples by LC/MS/MS according to Method No. IS-004-P10-01 with some acceptable deviations. Residues were extracted with methanol. The extract was filtered, and an isotopic internal standard was added to the extract, which was then diluted with 1% formic acid in water and analyzed by LC/MS/MS. The limit of quantification (LOQ) of the method IS-004-P10-01 is 0.01 mg/kg.

Findings

The analytical method used to quantify residues of isoxaflutole and RPA 202248 was tested on each matrix prior to stability set-up by performing a set of 3 recoveries at 0.10 mg/kg. For each compound, the obtained recovery means were in the acceptable range of 70 – 110% with RSD < 20% (see Table 6.1-1).

Table 6.1-1: Method validation

Commodity	Spike level (mg/kg)	Sample size (n)	Isoxaflutole			RPA 202248		
			Recoveries (%)	Mean (%)	RSD (%)	Recoveries (%)	Mean (%)	RSD (%)
Oranges	0.1	3	83, 89, 84	85	3.8	77, 81, 78	79	2.6
Pinto Beans (dry)	0.1	3	83, 80, 85	83	3.0	84, 83, 86	84	1.8
Soybean seeds	0.1	3	89, 88, 87	88		82, 81, 80	81	2.5
Sugarcane	0.1	3	97, 90, 89	92	4.7	84, 80, 79	81	3.3

RSD: relative standard deviation

Concurrent recoveries were conducted at the nominal storage intervals of 0, 3, 6, 12, 18 and 24 months. For this purpose, stored control samples were independently, freshly fortified with isoxaflutole and RPA 202248 at 0.10 mg/kg. The corresponding results are detailed in Table 6.1-2 and Table 6.1-3.

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Table 6.1-2: Concurrent recoveries for isoxaflutole in oranges, pinto beans, soybean seeds and sugarcane

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Recoveries (%) ^a	Mean (RSD)
Oranges	0.1	0	3	92, 86, 85	88 (4.3)
	0.1	31	2	92, 92	92
	0.1	96	2	93, 93	93
	0.1	188	2	87, 88	88
	0.1	377	2	90, 87	89
	0.1	567	2	83, 85	84
	0.01 ^b	738	2	86, 90	88
	0.1	738	2	86, 85	85
Pinto beans (dry)	0.1	0	3	94, 95, 95	94 (0.6)
	0.1	36	2	95, 99	97
	0.1	94	2	87, 88	88
	0.1	184	2	79, 67	71
	0.1	374	2	70, 76	70
	0.1	578	2	82, 83	82
	0.01 ^b	737	2	79, 77	73
	0.1	737	2	72, 72	69
Soybean seeds	0.1	0	3	80, 83, 81	81 (1.9)
	0.1	36	2	93, 94	94
	0.1	94	2	83, 85	84
	0.1	183	2	86, 86	86
	0.1	374	2	70, 74	72
	0.1	577	2	76, 79	78
	0.01 ^b	736	2	74, 72	73
	0.1	736	2	73, 71	72
Sugarcane	0.1	0	3	93, 94, 92	93 (1.1)
	0.1	36	2	77, 82	80
	0.1	95	2	91, 93	92
	0.1	185	2	91, 86	89
	0.1	375	2	83, 92	88
	0.1	564	2	77, 76	77
	0.01 ^b	735	2	86, 84	85
	0.1	735	2	85, 89	87

^a Corrected for control contribution, if any.

^b Used to demonstrate method reliability at the LOQ only, and therefore not used for statistical purposes

Table 6.1-3: Concurrent recoveries for RPA 202248 in oranges, pinto beans, soybean seeds and sugarcane

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Recoveries (%) ^a	Mean (RSD)
Oranges	0.1	0	3	73, 74, 72	73 (1.4)
	0.1	31	2	78, 80	79
	0.1	96	2	93, 93	93
	0.1	188	2	87, 87	87
	0.1	377	2	89, 85	87
	0.1	567	2	81, 83	82
	0.01 ^b	738	2	82, 94	83
	0.1	738	2	89, 86	88
Pinto beans (dry)	0.1	0	3	87, 81, 81	83 (0.7)
	0.1	36	2	90, 93	92
	0.1	94	2	89, 90	90
	0.1	184	2	79, 67	73
	0.1	374	2	73, 75	74
	0.1	578	2	90, 81	86
	0.01 ^b	737	2	82, 91	86
	0.1	737	2	88, 77	83
Soybean seeds	0.1	0	3	75, 73, 75	74 (1.6)
	0.1	36	2	78, 79	79
	0.1	94	2	84, 84	84
	0.1	183	2	86, 86	86
	0.1	374	2	70, 70	70
	0.1	577	2	77, 80	79
	0.1	736	2	81, 79	80
	0.10	736	2	81, 78	80
Sugarcane	0.1	0	3	76, 75, 74	75 (1.3)
	0.1	36	2	71, 78	75
	0.1	95	2	91, 92	92
	0.1	185	2	89, 87	88
	0.1	375	2	90, 92	91
	0.1	564	2	81, 78	80
	0.01 ^b	735	2	91, 87	89
	0.10	735	2	86, 92	89

^a Corrected for control contribution, if any.

^b Used to demonstrate method reliability at the LOQ only, and therefore not used for statistical purposes

The residue levels of isoxaflutole and RPA 202248 in the control samples were always found to be below 0.003 mg/kg.

The results for isoxaflutole and RPA 202248 in stored spiked samples are detailed in Table 6.1-4 to Table 6.1-8.

Table 6.1-4: Stability of isoxaflutole residues in oranges following storage at -20 ± 5°C

Commodity	Storage period (Days)	Residue Level in Stored Spiked Sample			Day-0 Normalized % Recovery ^b	Average % of Fresh Concurrent Recoveries ^a	Average Corrected % Recovery ^c
		mg/kg	% of nominal spiking level	Average % recovery			
Isoxaflutole							
Orange	0 *	0.0916	92	87.7	100		
		0.0864	86				
		0.0854	85				
	31	0.0926	93	91.0	104	92	99
		0.0892	89				
	96	0.0882	88	88.0	100	93	95
		0.0884	88				
188	0.0742	74	73.5	84	88	84	
	0.0726	73					
377	0.0756	76	73.5	84	89	83	
	0.0706	71					
567	0.0616	62	60.5	69	84	72	
	0.0594	59					
738	0.0550	55	55.5	63	85	85	
	0.0558	55					
RPA 202248							
Orange	0	na	na	na	-	-	-
	31	na	na	na	-	-	-
	96	na	na	na	-	93	-
	188	0.0204	20	19.5	-	87	23
		0.0208	21				
	377	0.0190	19	19.0	-	87	22
		0.0193	19				
	567	0.0200	20	19.5	-	82	25
0.0228		23					
738	0.0304	30	31.0	-	88	35	
	0.0318	32					
Sum of isoxaflutole and RPA 202248							
Orange	0 *	0.0916	92	87.7	100	-	-
		0.0864	86				
		0.0854	85				
	31	0.0926	93	91.0	104	-	99
		0.0892	89				
	96	0.0882	88	88.0	100	-	95
		0.0884	88				
	188	0.0946	95	94.0	107	-	107
0.0934		93					
377	0.0946	95	92.5	105	-	105	
	0.0899	90					
567	0.0816	82	82.0	94	-	97	
	0.0822	82					
738	0.0854	85	86.5	99	-	100	
	0.0876	88					

na : not analysed

* 0-day values are procedural recoveries only (mean of three replicate analyses)

^a Mean of two replicate analyses

^b Normalized recovery = (Average recovery in stored sample / Average recovery in stored sample at day-0) x 100%.

^c Corrected percent recovery = (Average % recovery in stored spiked sample / Average of fresh concurrent recoveries) x 100.

Table 6.1-5: Stability of isoxaflutole residues in pinto beans following storage at -20 ± 5°C

Commodity	Storage period (Days)	Residue Level in Stored Spiked Sample			Day-0 Normalized % Recovery ^b	Average % of Fresh Concurrent Recoveries ^a	Average Corrected % Recovery ^c
		mg/kg	% of nominal spiking level	Average % recovery			
Isoxaflutole							
Pinto Beans (dry)	0 *	0.0935 0.0953 0.0951	94 95 95	94.7	100	-	-
	36	0.0696 0.0706	70 71	70.5	74	97	73
	94	0.0594 0.0584	59 58	58.5	62	88	86
	184	0.0498 0.0478	50 48	49	52	71	69
	374	0.0484 0.0474	48 47	47.5	50	70	68
	578	0.0346 0.0352	35 35	35.0	37	78	45
	737	0.0342 0.0328	34 33	33.5	35	73	46
RPA 202248							
Pinto Beans (dry)	0	na	na	na	-	-	-
	36	na	na	na	-	-	-
	94	0.0310 0.0310	31 31	31.0	-	90	34
	184	0.0358 0.0362	36 36	36.0	-	90	49
	374	0.0406 0.0406	41 40	40.5	-	74	55
	578	0.0440 0.0452	44 45	44.5	-	86	52
	737	0.0456 0.0440	46 41	43.5	-	82	53
Sum of isoxaflutole and RPA 202248							
Pinto Beans (dry)	0 *	0.0935 0.0953 0.0951	94 95 95	94.7	100	-	-
	36	0.0696 0.0706	70 71	70.5	74	-	73
	94	0.0904 0.0804	90 89	89.5	95	-	100
	184	0.0856 0.0840	86 84	85.0	90	-	118
	374	0.0890 0.0878	89 88	88.5	93	-	123
	578	0.0786 0.0804	79 80	79.5	84	-	97
	737	0.0798 0.0774	80 74	77.0	81	-	99

na : not analysed

* 0-day values are procedural recoveries only (mean of three replicate analyses)

^a Mean of two replicate analyses

^b Normalized recovery = Average recovery in stored sample / Average recovery in stored sample at day-0) x 100%.

^c Corrected percent recovery = (Average % recovery in stored spiked sample / Average of fresh concurrent recoveries) x 100

Table 6.1-6: Stability of isoxaflutole residues in soybean seed following storage at -20 ± 5°C

Commodity	Storage period (Days)	Residue Level in Stored Spiked Sample			Day-0 Normalized % Recovery ^b	Average % of Fresh Concurrent Recoveries ^a	Average Corrected % Recovery ^c
		mg/kg	% of nominal spiking level	Average % recovery			
Isoxaflutole							
Soybean seed	0 *	0.0800	80	81.3	100		
		0.0830	83				
		0.0814	81				
	35	0.0762	76	76.0	93	94	
		0.0758	76				
	94	0.0722	72	72.0	89	84	86
		0.0720	72				
	183	0.0577	58	57.5	71	86	67
		0.0571	57				
	374	0.0494	49	50.5	52	72	70
		0.0516	52				
	577	0.0346	35	35.0	43	78	47
		0.0348	35				
	736	0.0228	23	24.0	30	72	33
0.0252		25					
RPA 202248							
Soybean seed	0	na	na	na	-	-	-
	35	na	na	na	-	-	-
	94	na	na	na	-	84	-
	183	0.0244	24	24.5	-	86	28
		0.0248	25				
	374	0.0306	31	31.0	-	70	44
		0.0312	31				
	577	0.0444	44	44.5	-	79	54
		0.0414	41				
	736	0.0486	48	48.0	-	80	60
0.0468		47					
Sum of isoxaflutole and RPA 202248							
Soybean seed	0 *	0.0800	80	81.3	100	-	-
		0.0830	83				
		0.0814	81				
	35	0.0762	76	76.0	93	-	81
		0.0758	76				
	94	0.0722	72	72.0	89	-	86
		0.0720	72				
	183	0.0800	82	82.0	101	-	95
		0.0819	82				
	374	0.0800	85	81.5	100	-	114
		0.0828	83				
	577	0.0790	79	79.5	95	-	99
		0.0782	76				
	736	0.0714	71	71.5	88	-	93
0.0720		72					

na : not analysed

* 0-day values are procedural recoveries only (mean of three replicate analyses)

^a Mean of two replicate analyses

^b Normalized recovery = (Average recovery in stored sample / Average recovery in stored sample at day-0) x 100%.

^c Corrected percent recovery = (Average % recovery in stored spiked sample / Average of fresh concurrent recoveries) x 100

Table 6.1-7: Stability of isoxaflutole residues in sugarcane following storage at -20 ± 5°C

Commodity	Storage period (Days)	Residue Level in Stored Spiked Sample			Day-0 Normalized % Recovery ^b	Average % of Fresh Concurrent Recoveries ^a	Average Corrected % Recovery ^c
		mg/kg	% of nominal spiking level	Average % recovery			
Isoxaflutole							
Sugarcane	0 *	0.0932	93	93.0	100		
		0.0942	94				
		0.0920	92				
	29	0.0808	81	81.5	88	80	102
		0.0816	82				
	95	0.0938	94	93.5	101	92	102
		0.0928	93				
185	0.0750	75	78.0	82	89	86	
	0.0782	78					
375	0.0794	79	78.0	84	88	89	
	0.0766	77					
564	0.0642	64	69.5	68	77	82	
	0.0626	63					
735	0.0694	69	70.5	76	81	81	
	0.0724	73					
RPA 202248							
Sugarcane	0	na	na	na	-	-	-
	29	na	na	na	-	-	-
	95	na	na	na	-	92	-
	185	0.00864	9	10	-	88	10
		0.00870	9				
	375	0.0108	11	11.5	-	91	13
		0.0118	12				
564	0.0122	13	12.5	-	86	16	
	0.0122	12					
735	0.0142	14	14	-	89	16	
	0.0150	15					
Sum of isoxaflutole and RPA 202248							
Sugarcane	0 *	0.0932	93	93.0	100	-	-
		0.0942	94				
		0.0920	92				
	29	0.0808	81	81.5	88	-	102
		0.0816	82				
	95	0.0938	94	93.5	101	-	102
		0.0928	93				
185	0.0866	84	85.5	92	-	96	
	0.0869	87					
375	0.0902	90	89.5	96	-	102	
	0.0884	88					
564	0.0767	77	78.0	82	-	98	
	0.0748	75					
735	0.0836	84	85.5	92	-	97	
	0.0874	87					

na : not analysed

* 0-day values are procedural recoveries only (mean of three replicate analyses)

^a Mean of two replicate analyses

^b Normalized recovery = (Average recovery in stored sample / Average recovery in stored sample at day-0) x 100%.

^c Corrected percent recovery = (Average % recovery in stored spiked sample / Average of fresh concurrent recoveries) x 100



Table 6.1-8: Stability of RPA 202248 residues in oranges, pinto beans, soybean seed and sugarcane following storage at $-20 \pm 5^\circ\text{C}$

Commodity	Storage period (Days)	Residue Level in Stored Spiked Sample			Day-0 Normalized % Recovery ^b	Average % of Fresh Concurrent Recoveries ^a	Average Corrected % Recovery
		mg/kg	% of nominal spiking level	Average % recovery			
Orange	0 *	0.0730	73	73.0	100	-	-
		0.0738	74				
		0.0716	72				
	31	0.0722	72	71.0	103	93	81
		0.0698	70				
	96	0.0750	75	75.0	103	93	81
		0.0754	75				
	188	0.0672	67	69.5	108	87	80
0.0716		72					
377	0.0800	80	79.7	108	87	91	
	0.0784	78					
567	0.0810	81	82.0	107	90	90	
	0.0832	83					
738	0.0854	85	85.0	116	88	97	
	0.0848	85					
Pinto Beans (dry)	0 *	0.0817	82	81.3	100	-	-
		0.0807	81				
		0.0807	81				
	36	0.0811	81	77.5	99	92	88
		0.0802	80				
	92	0.0736	74	74.5	92	90	83
		0.0746	75				
	184	0.0763	76	76.5	94	73	105
0.0766		77					
374	0.0754	75	74.5	92	74	101	
	0.0742	74					
578	0.0829	82	79.0	97	86	92	
	0.0756	76					
738	0.0752	75	76.5	94	82	94	
	0.0780	78					
Soybean seed	0 *	0.0746	75	74.3	100	-	-
		0.0728	73				
		0.0750	75				
	35	0.0666	66	66.0	90	79	84
		0.0660	66				
	94	0.0738	74	74.5	100	84	89
		0.0746	75				
	183	0.0758	76	78.0	105	86	91
0.0804		80					
377	0.0696	70	70.0	94	70	100	
	0.0702	70					
577	0.0800	80	77.0	104	79	97	
	0.0740	74					
736	0.0694	69	70.0	94	80	88	
	0.0714	71					

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Table 6.1-8: Stability of RPA 202248 residues in oranges, pinto beans, soybean seed and sugarcane following storage at $-20 \pm 5^\circ\text{C}$ (contd)

Sugarcane	0 *	0.0763	76	75.0	100	-	-
		0.0749	75				
		0.0743	74				
	29	0.0730	73	71.5	95	75	95
		0.0696	70				
	95	0.0768	77	77.0	103	92	-
		0.0766	77				
	185	0.0768	77	78.0	104	88	89
0.0794		79					
375	0.0820	82	81.0	108	97	-	
	0.0804	80					
564	0.0826	83	82.5	110	80	103	
	0.0818	82					
735	0.0832	83	84.5	83	95	-	
	0.0860	86					

* 0-day values are procedural recoveries only (mean of three replicate analyses)

^a Mean of two replicate analyses

^b Normalized recovery = (Average recovery in stored sample / Average recovery in stored sample at day 0) x 100%

^c Corrected percent recovery = (Average % recovery in stored spiked sample / Average of fresh concurrent recoveries) x 100

Conclusion

Isoxaflutole (RPA 201772) is not stable, degrading to its metabolite RPA 202248 (isoxaflutole diketone nitrile) during frozen storage. After 24 months of storage, 43.5% of RPA 202248 (uncorrected recovery values) was found in pinto beans samples spiked with isoxaflutole, 14.5% in sugarcane, 31.0% in orange and 48.0% in soybean seed. However, residues of the metabolite RPA 202248 (isoxaflutole diketone nitrile) are stable in all commodities evaluated during frozen storage. For samples fortified with isoxaflutole alone, the sum of isoxaflutole and its metabolite RPA 202248 demonstrate that the total residues are stable. Therefore, the total residue of concern (isoxaflutole and its metabolite RPA 202248) is stable (stability recoveries ^a 70%, corrected for procedural recoveries) for at least 24 months (738-days for oranges, 737-days for pinto beans (dry), 736-days for soybean seeds, and 735-days for sugarcane) in frozen storage at $-20 \pm 5^\circ\text{C}$.

Overall, total residues of isoxaflutole (comprising isoxaflutole and RPA 202248) remain stable for at least 24 months in 4 crop groups:

- the high acid-content crop group represented by orange
- the high protein-content crop group represented by pinto beans
- the high oil-content crop group represented by soybean seed
- the high water-content crop group represented by sugarcane.

In view of these data, it is very unlikely that total residues of isoxaflutole (comprising isoxaflutole and RPA 202248) would behave differently in maize matrices.



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

Nevertheless, Bayer CropScience is initiating a new study on maize matrices to verify this. The corresponding study plan is available under KCA 6.1/04. An interim report covering 12 months of storage should be available in Jan/Feb 2015. It will be promptly submitted for consideration in the evaluation, as agreed on the pre-submission meeting with representatives of ICPS on the 27th of October 2013 in Milano.

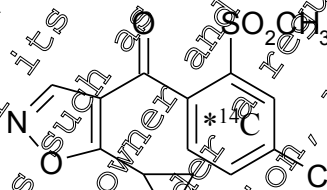
Report:	[REDACTED] x: [REDACTED] 2013;M-472509-01
Title:	Storage stability of isoxaflutole (RPA 201772, RPA 202248 and RPA 203328) in field corn grain and forage
Report No:	M-472509-01-1
Document No:	M-472509-01-1
Guidelines:	OPPTS 860.1380 - storage stability data. OECD guideline for the testing of chemicals No. 506, stability of pesticide residues in stored commodities, Oct 2007. PMRA residue chemistry guidelines, regulatory directive 98-02, section 5, storage stability data, June 1998
GLP/GEP:	yes

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**CA 6.2 Metabolism, distribution and expression of residues****CA 6.2.1 Plants**

Isoxaflutole (AE B197278, RPA 201772, IFT) is a broad-spectrum herbicide for weed control in maize/corn, sweetcorn, sugarcane, chickpea and poppy, and is also being developed for use in p-hydroxyphenyl pyruvatedioxygenase (HPPDase) tolerant soybean. The mode of herbicidal activity of IFT is the inhibition of HPPDase. IFT inhibits the biosynthesis of an essential co-factor of phytoene desaturase with the consequent inhibition of carotenoid synthesis. This inhibition results in severe chlorophyll bleaching in broadleaf weed species.

As part of the development programme for the herbicide Isoxaflutole the distribution and expression of residue in plant have been investigated using ^{14}C Isoxaflutole uniformly labelled in the phenyl ring position.



(ISO)- name (approved)

Isoxaflutole

IUPAC name: (5-cyclopropyl-4-(2-methylsulfonyl-4-(trifluoromethyl)benzoyl) isoxazole

CAS number:

141117-29-0

Company code:

RPA 201072 (AE B197278)

In non GAP investigations the phenyl ring label was determined to be the most appropriate radio labeling position. Only a small part is differentiated from the molecule resulting in a cyanomethyl cyclopropyl ketone (RPA 202304). This compound was determined to be rather unstable under alkaline conditions rapidly forming the widely occurring cyclopropane carbocyclic acid (RPA033852). Additionally radioactivity from the isoxazole ring label was shown to be rapidly released from the plant as volatile ^{14}C compounds. Therefore studies with a cyclopropyl ring label were not conducted (see also point 6.2.1/08 and 6.2.1/09).



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

Report:	4; ;2006;M-268739-01
Title:	The metabolism of [phenyl-UL- ¹⁴ C]-Isoxaflutole in corn with post-emergence application
Report No:	MEUBY003
Document No:	M-268739-01-2
Guidelines:	US EPA OPPTS 860.1300; not specified
GLP/GEP:	yes

This study was designed to determine the amount and nature of the residue of [phenyl-UL-¹⁴C]-isoxaflutole in corn as the result of a post-emergence application in combination with the safener cyprosulamide (AE 0001789).

Materials and Methods

Corn plants at V2 stage were treated with [phenyl-UL-¹⁴C]-isoxaflutole (8.35 mCi/mmol) at a rate of 211 g ai/ha, which is 1.6 times the maximum anticipated annual field application rate. Raw agricultural commodities (RACs) consisted of forage, sweet corn, stover, and grain. Sweet corn consisted of kernels plus cobs with husks removed (K+CWHR). Total residues in raw agricultural commodities were determined by combustion. Residues were characterized as extractable with acetonitrile/water mixtures or non-extractable (fiber). Metabolites were identified and quantified by reverse-phase high performance liquid chromatography (HPLC) and confirmed by LC/MS-MS.

Results

Total radioactive residues (TRR, expressed as isoxaflutole equivalents) were 0.134 ppm in forage, 0.010 ppm in sweet corn, 0.100 ppm in stover and 0.015 ppm in grain. Extractable and non-extractable residues in each RAC (raw agricultural commodity) were summarized in table 6.2.1/02-1. The majority of the residues were extractable (77.3-96.3% of TRR). After processing, the organosoluble fractions were analyzed by HPLC. The aqueous soluble fractions of forage and stover were further investigated using base hydrolysis and the resulting organosoluble components were analyzed by HPLC.

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Table 6.2.1/02-1: Total Radioactive Residues in RACs Resulting from Post-emergent Treatment of Corn at a Rate of 211 g Isoxaflutole/ha

RAC	Total Residue		Extractable Residue		Non-extractable Residue (NER)	
	Ppm	%TRR	ppm	%TRR	Ppm	%TRR
Forage	0.081	92.9	0.075	7.1	0.006	6.0
	0.156	ND	ND	ND	ND	ND
	0.164	ND	ND	ND	ND	ND
Mean	0.134					
Sweet corn (K+CWHR)	0.010	96.3	0.009	3.3	0.001	0.0
Stover	0.120	87.9	0.106	12.1	0.015	1.7
	0.101	ND	ND	ND	ND	ND
	0.078	ND	ND	ND	ND	ND
Mean	0.100					
Grain	0.015	77.2	0.012	22.8	0.004	4.0

ND = not determined

The metabolic profiles of the residues identified from the RACs are shown in Table 6.2.1/02-2. Analysis of the extractable residues showed a qualitatively similar metabolic profile in all RACs. The principle residues were identified as RPA 203328, with lesser amounts of RPA 202248. In all analyzed matrices the majority of the residue could be identified (67.2 - 72.8% of TRR). The largest single unidentified residue in any matrix was 0.005 ppm.

Table 6.2.1/02-2: Summary of Metabolite Identification

Compound	Forage		Sweet corn		Stover		Grain	
	%TRR	Ppm	%TRR	Ppm	%TRR	Ppm	%TRR	Ppm
Isoxaflutole	--	--	--	--	--	--	--	--
RPA 202248	--	--	6.0	0.001	4.0	0.005	9.8	0.001
RPA 203328	67.2	0.056	60.9	0.005	63.3	0.076	63.0	0.010
Total identified	67.2	0.056	67.4	0.006	67.3	0.081	72.8	0.011

-- not detected

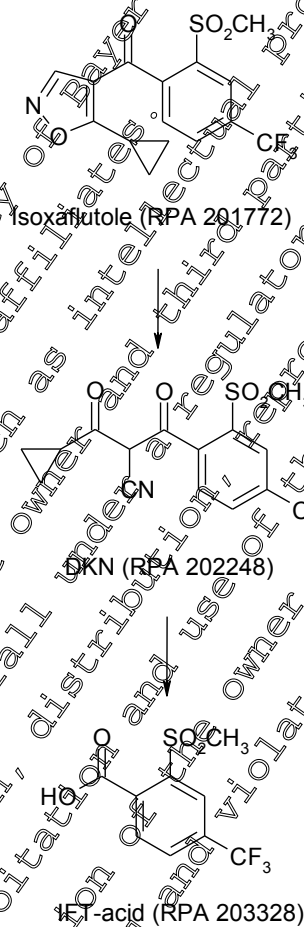
Conclusions

The nature of the residue and its distribution in corn was studied following post-emergent application of [¹⁴C]-isoxaflutole in combination with the safener cyprosulfamide (AE 0001789). The principle residue was identified as RPA 203328, with much smaller amounts of RPA 202248. RPA 203328 was also recovered from alkaline hydrolysis of water-soluble conjugates.

In the previous corn metabolism study ([REDACTED] 1995), [¹⁴C]-isoxaflutole was applied to corn (without safener) using both pre-plant incorporated and pre-emergent methods.

In all RACs, the same two metabolites were detected and RPA 203328 was similarly in far greater quantity than RPA 202248. Application of isoxaflutole post-emergence has no significant effect on its metabolism profile.

Figure 6.2.1-1: Metabolic Pathway of Isoxaflutole in Corn



The same metabolic profile was observed in both corn metabolism studies. A hydrolytic attack on isoxaflutole promoted isoxazole-ring opening to form RPA 202248 which is a diastereomere to isoxaflutole. Further hydrolytical cleavage of the carbonyl bridge and loss of the complete isoxazole moiety lead to the corresponding benzoic acid derivative, RPA 203328, via a Retro-Claisen type reaction. Both of these metabolites are well known to occur as a result of plant metabolism, soil metabolism, soil photolysis, aqueous photolysis, and rat metabolism.



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Report:	7: ;2009;M-368555-01
Title:	The metabolism of [phenyl-UL- ¹⁴ C]isoxaflutole in soybean with pre-plant and post-emergent application
Report No:	MEISP002
Document No:	M-368555-01-1
Guidelines:	US EPA OPPTS 860.1300 PMRA Ref.: DACO 6.2, Plants OECD Ref.: OECD Guideline for the Testing of Chemicals 501: Metabolism in Crops;not specified
GLP/GEP:	yes

This study was designed to investigate the nature of the [phenyl-UL-¹⁴C]isoxaflutole (IFT) derived residues in HPPD tolerant soybean as the result of a pre-plant or a post-emergent application. The maximum anticipated seasonal application rate for a pre-plant or a post emergent application on HPPD tolerant soybean is 105 g a.i./ha per year. The treatment regime for this study was a single pre-plant or post-emergent application at a nominal rate of 330 g a.i./ha. This represents an exaggeration rate of 3.1X the maximum seasonal rate to insure adequate residue levels for identification of metabolites.

Methods

The pre-plant (PP) and post-emergent (PE) application were both applied, via hand held sprayer, using [phenyl-UL-¹⁴C]-isoxaflutole (42.24 µCi/mmol) at a rate of 330 g a.i./ha. The pre-plant (PP) application was made directly to soil prior to planting. The post-emergent (PE) application was applied uniformly to the soybean plants at the full flowering stage (BBCH 65). The soybean plants were grown inside a greenhouse and were fertilized, watered and treated with maintenance chemicals as necessary to maintain healthy plant growth. The raw agricultural commodities (RACs) of forage at BBCH 75 (50% of pods have reached final length and continuation of pod filling), as well as hay and seed at BBCH 99 (full maturity, above ground plant parts are dead and seeds are dry and hard) were harvested, homogenized and radioassayed.

Identification and quantitation of the residues in forage, hay and seed extracts were accomplished by using reverse phase high performance liquid chromatography (HPLC) and liquid chromatography/mass spectrometry-mass spectrometry (LC/MS-MS) and by comparison of the mass spectral data to that of authentic reference standards when available.

Findings

For both, the pre-plant application and post-emergent application, HPLC analysis of the formulated treatment solutions were conducted. It could be shown that the [phenyl-UL-¹⁴C]-isoxaflutole was stable during preparation and treatment.



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Table 6.2.1/03-1: Total Radioactive Residues in the Different Commodities

Matrix	Determined by combustion (TRR _C)		As sum of extracts plus remaining solids (TRR _E)	TRR _E as % of TRR _C
	1.0 X*	3.1 X	3.1 X	3.1 X
	Ppm	ppm	Ppm	%
Pre-Plant / Forage	0.086	0.0268	0.291	100
Pre-Plant / Hay	0.159	0.492	0.493	100
Pre-Plant / Seeds	0.048	0.157	0.157	100
Post-Emergent / Forage	4.235	13.28	10.733	82
Post-Emergent / Hay	0.573	7.775	6.11	91
Post-Emergent / Seeds	0.084	0.259	0.257	99

*extrapolated from 3X results

All percentages of identified metabolites were based on the sum of extracted radioactive residues plus the radioactive residues remaining in the extracted solids. The majority of the residues (93% to 91% of the TRR_E) after a pre-plant application were extractable, and only 7% to 5% of the TRR_E (0.020 to 0.008 ppm) remained as bound residue.

The majority of the residues (90% to 92% of the TRR_E, 0.679 to 0.242 ppm) after a post-emergent application were extractable, and only 3% to 5% of the TRR_E (0.054 to 0.008 ppm) were not extractable.

Metabolite identification by HPLC with radio detection resulted in the data shown by table 6.2.1/03-2 and table 6.2.1/03-3. Identification rates were high (83% - 96% of TRR_E) for all commodities after pre plant application as well as after post-emergent application.

Table 6.2.1/03-2: Summary of Characterization and Identification of Radioactive Residues in the Pre-Plant Soybean Matrices Treated with [phenyl-UL-¹⁴C]-isoxaflutole.

Compound	Forage		Hay		Seed	
	%TRR _E	Ppm	%TRR _E	Ppm	%TRR _E	ppm
IFT	--	--	--	--	--	--
IFT-Amide	53	0.154	13	0.062	8	0.013
RPA 202248	15	0.038	13	0.066	17	0.027
RPA 203328	27	0.078	56	0.278	66	0.105
Total Identified	93	0.270	82	0.406	92	0.144

Table 6.2.1/03-3: Summary of Characterization and Identification of Radioactive Residues in the Post-Emergent Soybean Matrices Treated with [phenyl-UL-¹⁴C]-isoxaflutole.

Compound	Forage		Hay		Seed	
	%TRR _E	Ppm	%TRR _E	Ppm	%TRR _E	ppm
IFT	72	7.757	25	0.411	--	--
IFT-Amide	--	--	3	0.055	8	0.020
RPA 202248	18	1.943	21	0.334	24	0.061
RPA 203328	6	0.627	38	0.608	62	0.160



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Total identified	96	10.327	87	1.409	94	0.246
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The identified metabolites were RPA 202248, RPA 203328, and IFT-Amide. Metabolic degradation of isoxaflutole is rapid with between 66% and 18% of the TRR_E being observed in the forage, hay and seed as RPA 203328 and RPA 202248. The IFT-Amide can be found in soybean seed at a level of 8% of TRR_E, independent of the application regime. Nevertheless, in soybean seed residues of IFT amide stay below 0.01 mg/kg when extrapolated to the 1X dose rate. In forage and hay, where IFT amide can be found in higher amounts with pre-plant application than with post emergent application, the maximum residues are 0.021 mg/kg in hay and 0.051 mg/kg in forage (based on 1x dose rate).

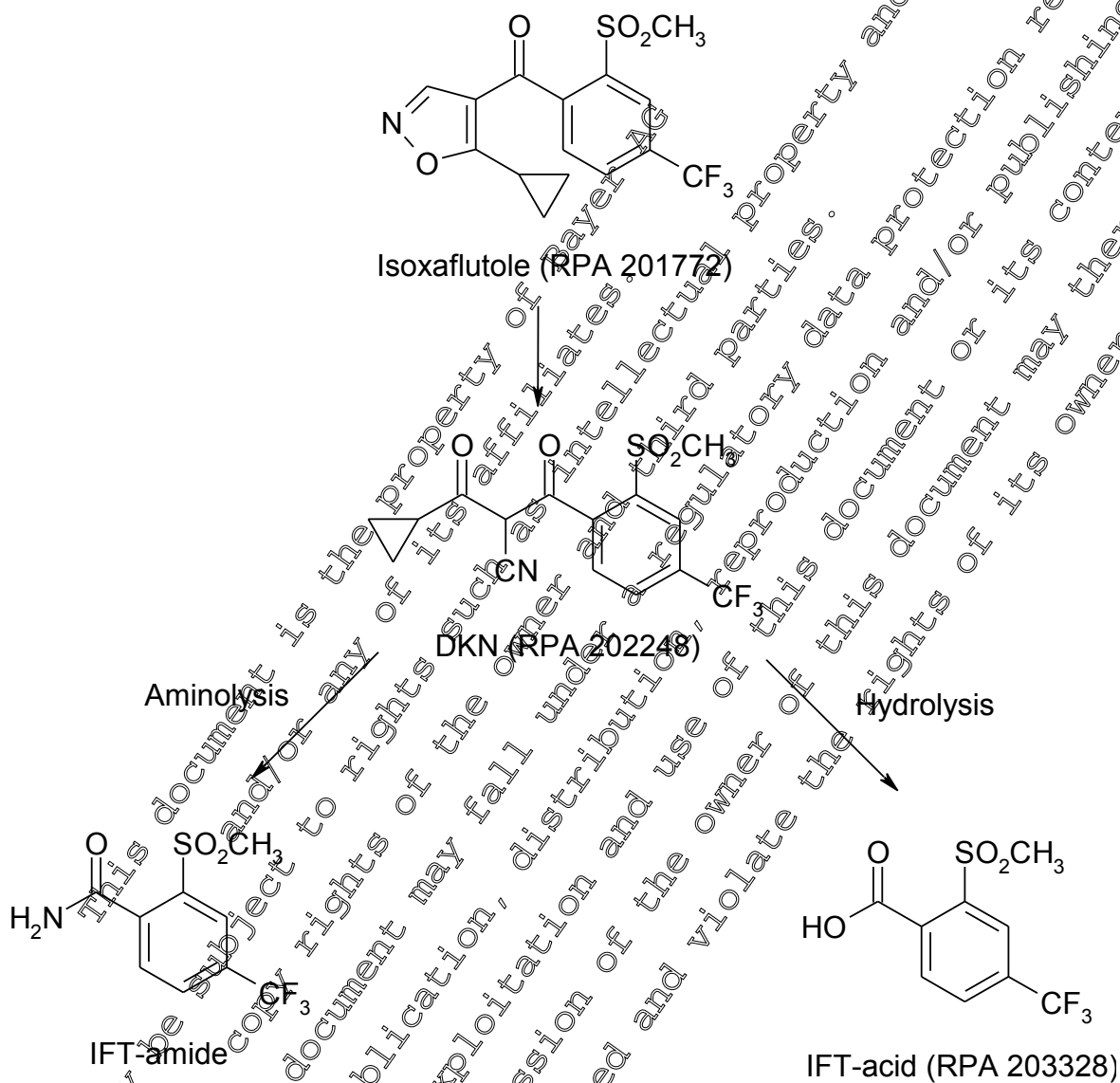
The proposed metabolic pathway for the [phenyl-¹⁴C]-isoxaflutole in HPPD tolerant soybean is shown in Figure 6.2.1/03-1. The isoxazole ring of isoxaflutole undergoes metabolic cleavage resulting in RPA 202248, which is isomeric with the parent. RPA 203328 and IFT-Amide result from oxidation of the isoxazole moiety. The oxidation products of isoxaflutole RPA 203328, RPA 202248, and IFT-amide were observed in all RACs, indicating that the oxidation is the main route of metabolism for the parent compound.

The three metabolites forming the major part of the residue were already known from previously performed metabolism studies.

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Figure 6.2.1-2: Metabolic Pathway of Isoxaflutole in Soybean



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Report:	[REDACTED]; [REDACTED]; [REDACTED]; 2000;M-211481-01
Title:	(14C)-Isoxaflutole: Metabolism in wheat
Report No:	C026477
Document No(s):	Report includes Trial Nos.: 16862 RPAL16862 M-211481-01-1
Guidelines:	EU (=EEC): 96/68 EC, 6.1; USA (=EPA): OPPTS 860, 1300; Deviation not specified
GLP/GEP:	yes

Materials and Methods

Seven cylindrical (80 cm diameter, 60 cm deep, 3mm thick) UPVC containment vessels with bases were buried in the ground at [REDACTED], UK. Each vessel was filled with the local soil, a sandy silt loam, and fitted with a 10 cm long plastic tube to facilitate drainage and leachate removal. A representative soil sample was analysed to determine its physico-chemical properties. The soil was tilled to approximately 7.5 cm to simulate commercial seeded preparation. All seven vessels were planted with wheat seeds (*Triticum aestivum*) in January 1999.

¹⁴C -isoxaflutole uniformly labeled in the phenyl ring position was used in this study. An isoxaflutole treatment solution with a radiochemical purity of 100.0% and 98.8% confirmed by High Performance Liquid Chromatography (HPLC) and Thin Layer Chromatography (TLC) respectively, and a specific activity of 2527 Bq/μg (151645 dpm/μg) was prepared in acetonitrile. All glassware used for treatment preparation was soaked in 0.1M hydrochloric acid for several hours, rinsed with deionised water and acetone and air dried prior to use. Whenever possible, plastic pipettes and vials were used for sample processing and storage. This procedure was necessary because isoxaflutole is known to be unstable in the presence of OH⁻ ions extracted from glass vessels used for sample processing.

The treatment solution was applied to immature wheat plants (BBCH 30) at a field rate of 55 g ai/ha using a customized agricultural sprayer. Control wheat plants were grown in the area surrounding the treatment vessels to monitor re-assimilation of any volatile ¹⁴C species arising from isoxaflutole metabolism by the adjacent treated wheat crop. The wheat plants were grown to maturity outdoors under ambient environmental conditions. During the course of the study, fertilisers, crop protection chemicals (excluding any closely related to the test substance) and irrigation were used as necessary to ensure crop vigour.

At interim harvest (growth stage BBCH 59 - 73) the hay was weighed, frozen and then homogenised. The final harvest plant was separated into grain, chaff, straw and stubble. Each plant part was weighed and homogenised fresh. The total radioactive residue (TRR) was determined by combustion of representative aliquots of homogenised plant material. Sample aliquots were combusted in a continuous flow of oxygen producing radioactive carbon dioxide. The radioactive carbon dioxide was



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trapped in a convoluted reaction column filled with Carbosorb E and flushed into a scintillation vial with Perma Fluor.

Chaff and stubble are not regarded as raw agricultural commodities, therefore these plant parts were not extracted to determine the nature of residue. Representative subsamples of homogenised hay and grain were extracted by maceration with acetonitrile and acetonitrile / water. A subsample of homogenised straw was extracted by soaking in water followed by maceration in acetonitrile and acetonitrile / water, and finally soxhlet extraction with dichloromethane / glacial acetic acid.

Quantitative measurement of radioactivity in solutions was carried out by liquid scintillation counting (LSC) following solubilisation of the samples in an LSC cocktail.

Following concentration, the combined plant part extracts were subjected to quantitative and qualitative analysis by reverse-phase HPLC employing certified reference standards as chromatographic retention time markers. Metabolite identification of a representative interim harvest hay extract was confirmed, by Liquid Chromatography - Mass Spectrometry - Mass Spectrometry (LC-MS/MS).

Findings

No radioactivity (< 0.004 mg/kg) was present in the control wheat plants grown in the area surrounding the [¹⁴C]-isoxaflutole treated crop indicating that only negligible quantities of volatile ¹⁴C-compounds were formed from isoxaflutole metabolism by the treated wheat crop.

In hay a total of 92.4% (0.159 mg/kg) of the TRR was extracted. A total of 96.5% (0.056 mg/kg) of the final harvest grain TRR was extracted. A total of 89.0% (0.095 mg/kg) of the TRR in harvest straw could be extracted.

Table 6.2.1/04-1: Total Radioactive Residue of ¹⁴C-Isoxaflutole in Treated Wheat Plants

Sample material	Total Radioactive Residue (TRR) (mg/kg)	Extractable (% TRR)	Extractable (mg/kg)	Non extractable (% TRR)	Non extractable (mg/kg)
Hay	0.17	92.4	0.159	7.6	0.013
Grain	0.058	96.5	0.056	3.5	0.112
Straw	0.107	89.0	0.095	11.0	0.012
Chaff	0.07	-	-	-	-
Stubble	0.078	-	-	-	-

The major component of the extracted radioactivity in both plant parts was RPA 203328, accounting for 0.055 mg/kg (95.8% of the TRR) and 0.084 mg/kg (79.1% of the TRR) in grain and straw respectively. Low levels of RPA 202248 (0.011 mg/kg, 9.9% of the TRR) were also present in the final harvest straw extracts. No remaining isoxaflutole could be detected in the harvest commodities wheat grain and straw.



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Table 6.2.1/04-2: Composition of Residues Extracted from ¹⁴C-Isoxaflutole Treated Wheat Plants

Sample Material	RPA 203328		RPA 202248		Isoxaflutole		Bound Residues	
	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR
Hay	0.112	65.0	0.036	20.9	0.011	6.5	0.013	7.5
Grain	0.155	95.8	nd	nd	nd	nd	0.002	0.5
Straw	0.084	79.1	0.011	9.9	nd	nd	0.042	11.0

Conclusion

Following a single post-emergence application to immature wheat plants isoxaflutole is rapidly metabolised to RPA 202248 and RPA 203328. In summary, low radioactive residues (0.058 - 0.107 mg/kg) were present in wheat grain and straw at final harvest. The majority of these radioactive residues were extractable (> 89%). These extractable radioactive residues comprised entirely of RPA 203328 demonstrating a rapid decline of isoxaflutole. The results of the study are in line with previous metabolism studies.

Report:	[REDACTED]; 1999; M-211498-01
Title:	(14C)-RPA 201772: Metabolism in sugarcane
Report No:	C026486
Document No(s):	Report includes Trial Nos.: 10316 M-211498-01
Guidelines:	EU (=EEC): 96/68/EC, 6.1; USEPA (=EPA): 0171-4; not specified
GLP/GEP:	yes

Materials and Methods

This metabolism study was carried out to determine the quantity and nature of the residue, following one treatment to pre and post emergence grown sugarcane. Solutions of [¹⁴C]-Phenyl-isoxaflutole with a radiochemical purity of >97% by HPLC and a specific activity of 2.525 MBq/mg (151,500 dpm/μg) were prepared and applied to sugarcane soil and plants at two application rates, pre-emergence at a field rate of 200g/ha (active ingredient) and, post-emergence at a field rate of 150g/ha, in acetonitrile solutions by spraying.

The plots used in this study were located in [REDACTED], Brazil. Two plots were allocated for the pre and post-emergence treatments, two plots were nominated as controls and a final plot acted as a spacer plot. To avoid possible contamination, the pre and post-emergence plots were made with steel plate containment vessels of 1.5 m area and 1.5 m depth. The containment vessels were 1.2 m in-ground and were filled with a sandy loam soil. The plots were in a netting enclosure to prevent access by birds and small animals. The sugarcane variety SP 79-1011 was selected for this study as a typical variety grown in Brazil. The planting was staggered to enable the pre- and post-emergence plots to be treated on the same day. The sugarcane plants were grown outdoors under ambient environmental conditions. During the course of the study no fertilisers or crop protection chemicals were applied. Irrigation and



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hand weeding were used as necessary to ensure crop vigour. The sugarcane plants were grown to maturity. As residues were expected to be very low in the harvest commodities additional interim samples were taken at approximately 1 and 3 months after planting. Following final harvest, the leaves were separated from the sugarcane. Both plant parts were weighed, frozen, homogenized and combusted to determine the Total Radioactive Residue (TRR).

Prior to plot treatment, the spray distribution of the pre-emergence treatment was checked by filter papers. The treatment solutions were sprayed onto the plots using a PLC sprayer. Control plots were treated with acetonitrile only. Prior to treatment the application solutions were assayed for radioactivity content by liquid scintillation counting (LSC). From these results the amount of [¹⁴C]-isoxaflutole in the application solutions was calculated. The actual percentages of target treatment rate per plot were 104.9% for pre emergence and 88.8% post emergence respectively. Radiopurities of the treatment solutions were determined immediately before application. At each harvest, the sugarcane plants from each plot were placed in labeled plastic bags and transported frozen to [redacted] Agriculture Ltd., [redacted], [redacted], UK for storage until they were further processed. Except at the final harvest, the leaves were separated from the cane before transportation. Cane and leaves were combusted directly following homogenization and following extraction as necessary. All sample combustions were performed using an automated sample oxidiser and absorption by a scintillation cocktail. The radioactivity in the resultant solution was quantified by liquid scintillation counting LSC. For each scintillation cocktail quench correction curves were prepared.

Extractions were done by maceration and soxhlet extraction with acetonitrile. Subsequent extraction was done by maceration with acetonitrile-water, maceration with diluted acid and/or base and reflux at 60°C.

Quantitative analysis was performed by reversed phase HPLC with mass selective detection using 2 channel multiple reaction monitoring (MRM). The presence of isoxaflutole (RPA 201772) and its metabolites RPA 202248 and RPA 203328 was confirmed by co-chromatography with certified reference standards and confirmed by LC-MS detection.

Table 6.2.1/050: MRM Transitions Used for Confirmation of Metabolite Identity

Compound	Isoxaflutole (RPA 201772)	RPA 202248	RPA 203328
MRM transition	358 → 79	358 → 79	267 → 223

Findings

The final harvest TRRs in whole sugarcane were <0.001 mg/kg for both post-emergence and pre-emergence samples. Therefore these samples were not further processed.

Table 6.2.1/05-2: Distribution of Radioactivity in Sugarcane Final Harvest Samples

Plant Part	TRR (mg/kg)	
	Pre-emergence	Post-emergence
Leaves	0.003	0.001
Cane	0.001	<0.001



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Whole Plant	0.001	<0.001
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Extraction of radioactivity and elucidation of the metabolic profile was, due to low residues, done only for the first interim sampling and the second interim sampling of the pre-emergence application. The residue in the pre-emergence treated crop of the first interim sampling was 0.119 mg/kg while in the post-emergence treated crop the residue was 0.176 mg/kg. Extractability of the residue was high with >90% being solubilised from each sample.

At the second interim harvest 95 days after emergence only the pre-emergence samples contained a significant TRR (0.147 mg/kg). This TRR was higher than the 40 days pre-emergence treated sample possibly due to the size of the representative crop sampled. Again >90% was extracted.

Table 6.2.1/05-3: Extractability of Residues from ¹⁴C-Isoxaflutole Treated Whole Sugarcane Plants

Sugarcane harvest matrix	Total Radioactive Residue (mg/kg)	Extracted (%)	Extracted (mg/kg)	Bound Residues (%)	Bound Residues (mg/kg)
<i>First Interim</i>					
Pre-emergence	0.1188	96.7	0.1137	4.5	0.0051
Post-emergence	0.1757	90.4	0.1587	9.6	0.0170
<i>Second Interim</i>					
Pre-emergence	0.1473	93.5	0.1377	6	0.0096
Post-emergence	0.0065	na	na	na	Na
<i>Final Harvest</i>					
Pre-emergence	0.0008	na	na	na	na
Post-emergence	0.0004	na	na	na	na

na – not analysed

At the first interim sampling the major component of the extracted radioactivity in both crops was RPA 203328 accounting for 0.102 mg/kg (85.9% of the TRR) and 0.117 mg/kg (66.5% of the TRR) in the pre and post-emergence treated crops respectively. In addition the post-emergence treated crops also contained low levels of parent (0.019 mg/kg, 10.8% of the TRR) and RPA 202248 (0.004 mg/kg, 2.2% of the TRR). In both crops a number of polar species were detected (two species in post and one in pre-emergence) accounting for 0.019 mg/kg (10.9% of the TRR) in the post-emergence samples and 0.012 mg/kg (9.8% of the TRR) in the pre-emergence samples. Analysis of the extracted radioactivity of the second interim sampling showed that RPA 203328 was the major component present accounting for 0.138 mg/kg (93.5% of the TRR).

Table 6.2.1/05-4: Composition of Residues Extracted from ¹⁴C-Isoxaflutole Treated Whole Sugarcane Plants

Sugarcane harvest matrix	TRR (mg/kg)	RPA 200072		RPA 202248		RPA 203328		Unknowns	
		(mg/kg)	(%)	(mg/kg)	(%)	(mg/kg)	(%)	(mg/kg)	(%)
<i>First Interim</i>									
Pre-emergence	0.1188	nd	nd	nd	nd	0.1021	85.9	0.0117	9.8
Post-emergence	0.1757	0.0189	10.8	0.0039	2.2	0.1168	66.5	0.0191	10.9
<i>Second Interim</i>									
Pre-emergence	0.1473	nd	nd	nd	nd	0.1377	93.5	nd	nd

nd – not detected



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Total identification rates between 79.8 and 93.5 % of the TRR can be observed.

Conclusion

The results indicate that after application to sugarcane metabolism of isoxaflutole is very rapid. At final harvest the total TRR in both pre and post-emergence treated crops was extremely low (<0.001 mg kg/1). Residues in sugarcane at commercial harvest are likely to be very low due to growth dilution and possibly further metabolism. The pathway of degradation seen in this study is similar to that observed before (Figure 6.2.1-1, metabolism in corn).

Report:	[redacted]; 2009-M-360799-01
Title:	Metabolism of [phenyl-14C]isoxaflutole in poppies
Report No:	MEF-09/499
Document No:	M-360799-01
Guidelines:	OECD 501; US EPA OPP'S 860.1300; Canadian PMRA Ref. DACO 6.3; Japanese MAFF 12 Nounan 8147; EU 90/414/EEC amended by 96/68/EC; not specified
GLP/GEP:	yes

Executive summary

The metabolism of 14C isoxaflutole in poppy plants was investigated following pre-emergence application to soil at a rate of 100 g a.s./ha (3 days after sowing of poppy seeds) in combination with the non-labeled s.e.ener of prosulfamide admixed at a 1-to-1 ratio. The plants were grown to maturity in an open vegetation hall under outdoor conditions. At harvest, poppy seeds, seed bolls with upper stem (the top 15 cm of the plants) and poppy straw were sampled, analysed for the content of total radioactive residues (TRR) and extracted with acetonitrile/water. The extracts were concentrated and analyzed by HPLC, TLC and HPLC-MS with aid of co-chromatographed reference items.

The TRR amounted to 0.056 mg active substance equivalent/kg (mg equ/kg) in seeds, to 0.779 mg equ/kg in seed bolls and upper stem and to 0.725 mg equ/kg in straw. More than 90 % of TRR could be extracted by conventional extraction from each plant matrix. The extracted residue components were comprised of isoxaflutole-benzonic acid, RPA 203328, as the predominant residue component accounting for 66 – 94 % of TRR in different crop samples. Isoxaflutole-diketonitrile, RPA 202248, was a minor component in seed bolls and upper stem and in straw (2 – 4 % of TRR), but not detectable in seeds. Up to four minor components could also be detected, none of them exceeding 10 % of TRR or 0.03 mg equ/kg. The parent substance isoxaflutole could not be detected in any plant part. The rate of identification accounted for 66 – 96 % of TRR. The proportion of non-extractable residues was in the range of 2.2 – 8.5 % of TRR.

Material and methods



Test plant and test site: Poppy plants were cultivated in a plant container (surface area approx. 1 m²) filled with sandy loam soil. The container was placed in open vegetation hall covered by a glass roof and enclosed by a metal net to protect the plants from birds and wild animals. Poppy seeds of the species *Papaver somniferum* (cultivar *Mieszko*) were sown three days before soil treatment with the test substance.

Spray mixture and spray procedure: SC 480 blank formulation containing the respective amount of non-labelled safener cyprosulfamide was added to [phenyl-UL-¹⁴C] isoxaflutole and homogenized using a small ball mill. The ratio isoxaflutole-to-safener was 1 to-1. Addition of water finally resulted in the spray mixture. Spray treatment of the bare plant soil was conducted using a controlled track sprayer equipped with a flat fan nozzle. To protect the surroundings from radioactive contamination the plant container was enclosed by a plastic foil. After spraying, the protecting foil and the spraying device were rinsed with methanol to detect spray losses. Numerical subtraction of these losses from the initial amount resulted in the actual spray rate slightly exceeding (8%) the nominal rate of 100 g as/ha. Homogeneity of the spray application was checked using small paper filter discs evenly distributed on the soil surface.

Sampling and sample work-up: At maturity (BBCH stage 89-92, 110 days after soil treatment), poppy seeds, the seed bolls including a part of the upper stem and straw were harvested. Seed bolls with 10 – 15 cm of the upper stem were cut from the rest of the plants. The seed bolls were opened with a scalpel to release the seeds and then shred into pieces of 1 – 2 cm length. The rest of the plants comprising of the straw fraction, were cut off just above the soil surface and shred into pieces of 2 – 3 cm length. The total weight of each sample was determined. The samples were homogenised by a Polytron homogeniser with aid of liquid nitrogen using Aliquots of each homogenised sample material were combusted in a biological sample oxidizer and the formed ¹⁴CO₂ absorbed in an alkaline scintillation cocktail for rough determination for the total radioactive residues (TRR). ¹⁴C-Radioactivity was measured by liquid scintillation counting (LSC). Quench correction was automatically conducted by the counter using shift recording of the endpoint or inflexion point of the Compton spectrum of an external standard.

Extraction and clean-up of the extracts: Further aliquots were three times extracted with acetonitrile/water 4/1 (v/v) using a blender. The sum of the radioactivity in the extracts and the extracted solids resulted in an exact figure of TRR. Combined extracts were cleaned-up using solid phase extraction on a RP18 cartridge. Percolate and rinse (elution with a small amount of acetonitrile/water 4/1 to complete percolation) were concentrated and profiled by radio-HPLC. In order to desorb potential less polar radioactive residues, the cartridge was finally rinsed with methanol/tetrahydrofuran 1/1. As this last fraction did not contain relevant amounts of radioactivity it was not further investigated.

Methods of metabolite identification: Identification of residue components was achieved by HPLC-MS and HPLC and/or TLC co-chromatography with authentic reference items. HPLC was conducted



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using a RP (reversed phase)18 column (250 x 4.6 mm, particle size 5 µm, operated at 40°C) that was eluted by a gradient mixture of water/formic acid (99/1, v/v) and acetonitrile. TLC was conducted on high performance plates HPTLC Si 60 F₂₅₄ (normal phase) and HPTLC RP18W F₂₅₄ (reversed phase) and each with two solvent mixtures for development. Non-labeled reference standards were detected by quenching of the fluorescence light of the plates when irradiated by UV light. Radioactive peaks were detected by radioluminography using an imaging device. For HPLC/MS analysis the compounds eluted from a RP18 column were ionized by electro-spray (ESI) and pre-collected on an orbitrap ion trap.

LOQ and storage conditions: The limit of quantification (LOQ) in HPLC analysis depended on the matrix and ranged between 0.001 and 0.013 mg equ/kg for the extracts from seeds, seed bolls and upper stem and straw. All samples and non-aqueous extracts were stored in a freezer at a temperature of ≤-18°C.

Findings

Following pre-emergent application of ¹⁴C-labelled isoxaflutole to poppies at a use rate of approximately 100 g as/ha the measured total radioactive residues (TRR) at maturity are presented in Table . The TRR values in different plant parts were calculated by numerical addition of the radioactivity in extracts and the respective extracted solids.

Table 6.2.1/06-1: Total Radioactive Residues (TRR) in Different Parts of Poppies Following Pre-emergent Treatment of ¹⁴C-isoxaflutole at a Use Rate of 108 g as/ha

Matrix	Application	BBCH at harvest	PHI* [days]	TRR [mg equ/kg]
Seeds	soil treatment 3 days after sowing; growth stage BBCH 00, 108 g a.s./ha	approx. 89-92	110	0.056
Seed bolls and upper stem				0.779
Straw				0.725

* PHI: pre-harvest interval

The poppy matrices were extracted with acetonitrile/water resulting in an almost complete extraction. More than 90% of TRR could thus be extracted from each matrix and the non-extractable residues accounted for < 9% of TRR.

Extracted residues were identified by HPLC/MS and co-chromatography using HPLC and TLC with authentic reference standards.

Table 6.2.1/06-2 presents the resulting composition of residues in poppy matrices.

The parent substance isoxaflutole was not observed in poppies. Isoxaflutole-benzoic acid (RPA 203328) proved to be the predominant residue component in each poppy matrix (66.0% of TRR in seeds, 94.3% of TRR in seed bolls and upper stem, and 88.7% of TRR in straw). Isoxaflutole-



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diketonitrile, RPA 202248, was observed as a minor metabolite in seed bolls and upper stem and in straw not exceeding 5% of TRR.

Up to four minor metabolites were detected in seeds, none of them exceeding 0.004 mg equ/kg and amounting to a maximum of 0.029 mg equ/kg in poppy straw. The non-extractable residues were low and did not reach 10% of TRR.

Table 6.2.1/06-2: Composition of Residues in Different Parts of Poppies Following Pre-emergent Treatment of ¹⁴C-Isoxaflutole at a Use Rate of 108 g a.s/ha

Poppy matrix	Seeds		Seed Bolls and Upper Stem		Straw	
	TRR [mg as equ/kg]	0.056	0.779	0.779	0.725	0.725
	% of TRR	mg equ/kg	% of TRR	mg equ/kg	% of TRR	mg equ/kg
Isoxaflutole-benzoic acid	66.0	0.037	94.3	0.734	88.7	0.643
Isoxaflutole-diketonitrile	---	---	2.1	0.016	3.2	0.026
Subtotal identified	66.0	0.037	96.4	0.751	92.3	0.670
unknown 1	5.4	0.003	1.0	0.008	4.0	0.029
unknown 2	2.5	0.001	---	---	---	---
unknown 3	2.1	0.002	0.4	0.003	---	---
unknown 4	1.1	0.004	---	---	---	---
Subtotal characterised*	77.1	0.010	1.4	0.011	4.0	0.029
Analysed extract	83.7	0.047	97.8	0.762	96.3	0.699
Not analysed	1.8	0.004	---	---	0.5	0.003
Total extractable	91.5	0.051	97.8	0.762	96.8	0.702
Non-extractable residues	8.5	0.005	2.2	0.017	3.2	0.023
Accountability	100.0	0.056	100.0	0.779	100.0	0.725

* characterised by their relative polarity based on the HPLC elution pattern



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From the known metabolites two metabolic reactions can be derived:

Hydrolytic cleavage of and opening of the isoxazole ring of isoxaflutole resulting in isoxaflutole-diketonitrile, RPA 202248.

Further hydrolysis of isoxaflutole-diketonitrile forming isoxaflutole-benzoic acid, RPA 203328 which was the major metabolite in all poppy samples.

The metabolic transformations of isoxaflutole in poppies follows the same route as seen previously in other crops and is shown in figure 6.2.1-1 (metabolic pathway in corn).

Conclusion

Metabolism of isoxaflutole in poppies followed the same route as seen before in several other plant metabolism studies, i.e. ring opening of the isoxazole ring and hydrolytic split off of the formed diketonitrile group.

Supportive data I

The following study is presented to underline that the presence of the safener cyprosulfamide has no impact on the nature of the residue of isoxaflutole in plants.

Report:	2002;M-210791-01
Title:	Effects of safener AE 0001789 on metabolism of isoxaflutole (IFT) (RPA 201772) in maize Code: AE 0001789 and (U-14C-phenyl)RPA201772
Report No:	C021215
Document No:	M-210791-01-1
Guidelines:	Deviation not specified
GLP/GEP:	no

This study was conducted to demonstrate the effects of the safener cyprosulfamide (AE 0001789) on the metabolism of isoxaflutole (IFT, RPA 201772) in maize. In literature it is supposed that the safener induces the activity of herbicide detoxifying enzymes (J. Davis and J. C. Caseley, 1999). In plants and soil IFT is rapidly converted to a diketonitrile (RPA 201772) derivative by opening the isoxazole ring but nothing is known about the enzyme(s) involved in degrading DKN, the active herbicide component of IFT, to the inactive benzoic acid derivative (RPA 203328).

Materials and Methods

Zea mays (corn variety Lorenzo) plants are cultivated before, during and after application of compounds in a growth chamber under the following conditions: 16 h full light at 26°C, 8 h dark at 18°C, 70% humidity

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After imbibition in water over night corn seeds were put into pots with Seramis clay granulate. In these pots seedlings grew for 3 days before they were transferred with their primary roots into 3.5-ml vials. Only roots and not the kernels were exposed to the compound solution. The vials included 3 ml of a nutrient solution with 0.5 µg/ml ¹⁴C-IFT alone or in combination with safener (1 µg/ml). Pure radio labeled IFT was used without formulation. Cyprosulfamide was applied as WP20 formulation. The seedlings were incubated for 24 h. During that time roots and shoots approximately duplicated their weight and an uptake of 1 ml to 2 ml of the application solution was observed. After 24 h incubation the seedlings were transferred into beakers filled with nutrient solution (without IFT or safener). In these beakers plants grew for further 3 days in the plant chamber. To check whether mono-oxygenase inhibitors 1-aminobenzotriazole (ABT) and piperonyl butoxide (PBO) antagonise safener activity of cyprosulfamide also treatment solutions containing ABT or PBO were tested. After treatment the seedlings of those inhibitor-treated plants were transferred to nutrient solution which also contained ABT or PBO. Symptoms on leaves of maize plants were compared 3 days after treatment.

Because of the variability of safener effects among single plants, plant material from 50 plants (shoots, seeds, roots) was bulked for preparation of one sample. Samples treated either with [¹⁴C]-IFT alone or in combination with safener or cyprosulfamide were harvested three days after treatment. The samples were extracted to recover the absorbed [¹⁴C]- activity and were analysed to determine the levels of the two known IFT metabolites DKN and BA.

The plant material was homogenised using an Ultra Turrax. The homogenates were centrifuged and filtered. The pellets were dispersed in acetonitrile/water (80/20, v/v), again centrifuged and evaporated to dryness. The residues were dissolved in acetonitrile/water (50/50, v/v), the solutions were filtered and the filtrates were concentrated for approx. 12 hours in a 37°C incubator. Next day the concentrates were mixed with 10% TEA (v/v) and three times partitioned in ethyl acetate. In the ethyl acetate fraction about 60% of the radioactivity could be determined. Ethyl acetate partitioning resulted in more defined peaks with shoot and root extracts at radio-TLC but without changing the ratio of metabolite peaks to each other. For seed extracts a partitioning was omitted.

Five to 10-µl samples of the filtrates or the ethyl acetate fractions were subjected to radio-TLC analysis. The metabolites were separated by their R_f values. The radioactive spots were located and their radioactivity was measured using an automatic TLC-linear analyser. The peaks were integrated and the radioactivity was quantified against ¹⁴C labeled standards.

Amounts of radioactivity were quantified by liquid scintillation counting (LSC), either directly in the washing solutions or extracts, or after combustion of the plant samples.

Samples were combusted using the Biological Oxidizer and the resulting [¹⁴C] carbon dioxide was trapped and counted in a liquid scintillation analyser.

Findings

Three days after treatment those plants previously incubated with ¹⁴C-isoxaflutole alone had partially bleached leaves. Maize plants previously incubated with ¹⁴C-isoxaflutole in combination with safener cyprosulfamide showed a clear reduction of leaf damage. A pre-incubation with the safener for 5 hours prior to the incubation with the safener/isoxaflutole mixture does not visibly improve safener effects on shoots.



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After three days seeds incorporated clearly more radioactivity than shoots and roots. No IFT was detectable due to the rapid conversion to the diketonitrile derivative. In safener treated plants the total amount of radioactive compounds in shoots was lower, in seeds higher compared to plants treated with the ¹⁴C-IFT/safener combination. Additionally plants treated with the ¹⁴C-IFT/safener combination show a lower ratio of the active ¹⁴C-DKN to the inactive ¹⁴C-BA derivative of isoxaflutole than plants treated with ¹⁴C-isoxaflutole alone. In seeds and roots no differences in the ratios between the metabolites of isoxaflutole could be demonstrated and only small enzymatic degradation of DKN to the inactive benzoic acid derivative was observed.

Table 6.2.1/07-1.: Distribution of the Recovered Radioactivity Between the Different Plant Parts

Matrix	Treatment	
	Isoxaflutole [%]	Isoxaflutole + Safener [%]
Shoots	30.2	25.5
Seeds	42.1	44.3
Roots	27.8	26.2

To check the distribution of radioactivity within the remaining seed parts of the young plants about 1-2 mm slices from the middle of seeds (longitudinal sections) were analysed using a phosphoimager. The results indicated a concentration of radioactivity in the transition area between root and shoot and only a small distribution into the endosperm (not shown). These results were confirmed by separate combustion of the transition area between root and shoot and endosperm tissue indicating that the safener effects mechanisms which are responsible for the translocation of DKN from the root system into the shoot system. Because of the lower translocation rate the enzymes involved in detoxification could be able to reduce the amount of toxic DKN more rapidly and prevent toxic effects. Until now nothing is known about a conversion of DKN into a more polar intermediate prior to the inactive benzoic acid derivative and no intermediate could be demonstrated by TLC analyses in extracts of all tissues.

In experiments with the mono-oxygenases inhibitors ABP (1-aminobenzotriazole) and PBO (piperonyl butoxide) no visible reduction of safener effects on maize leaves could be demonstrated.

Conclusion

Application of safener cyprosulfamide (AE 0001789) in combination with isoxaflutole resulted in a lower DKN/BA ratio in maize shoots three days after treatment. This means that the safener cyprosulfamide induces further breakdown of the IFT- diketonitrile metabolite to the known benzoic acid derivative. No change in the DKN/BA ratio could be documented in seeds and roots of safener-treated plants. Additionally only minimal metabolisation of DKN to BA was observed in seeds and roots in comparison to shoots after both treatments. The highest accumulation of radioactive compounds was identified in seeds and not in shoots or roots three days after treatment. The amount of radioactive isoxaflutole metabolites in shoots was significant lower in safener-treated plants. This indicates that the translocation of DKN from the root system into the shoot system could be one of the



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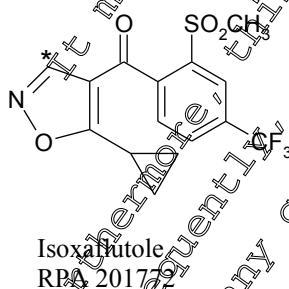
processes affected by the safener. Finally, no evidence could be produced that mono-oxygenase are involved in safening effects of cyprosulfamide.

Supportive data II

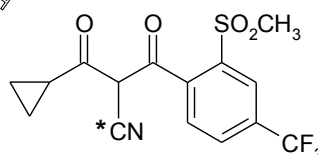
In the development phase of isoxaflutole attempts were made to determine the primary metabolic pathway and identify degradation products in plants. In the course of this also the absorption, translocation and metabolism of ¹⁴C-isoxazole ring labeled isoxaflutole was investigated in tolerant maize following root application through a nutrient solution. The following extract from studies 200.170 (M-274733-01-1) and 200.275 (M-274674-01-1) summarizes these metabolism results. The studies are preliminary studies done during early development phase and therefore were never designed as full guideline metabolism study. Nevertheless the studies can provide some information on the fate of ¹⁴C-isoxazole ring labeled metabolites and therewith give a reason for the sole choice of ¹⁴C-phenyl ring label position in the available full metabolism studies.

Report:	[redacted]; [redacted]; 1993; M-274733-01
Title:	Isoxazoles: ¹⁴ C-RPA 201319 and RPA 201772. Absorption, translocation and metabolism in maize, Ipomoea sp. and Abutilon theophrasti
Report No:	M-274733-01-1
Document No:	M-274733-01-1
Guidelines:	not specified
GLP/GEP:	no

Report:	[redacted]; [redacted]; 1993; M-274674-01
Title:	Isoxazoles: RPA 201772. Plant metabolism studies. Primary degradation pathways in maize, Ipomoea and Abutilon theophrasti
Report No:	M-274674-01-1
Document No:	M-274674-01-1
Guidelines:	not specified
GLP/GEP:	no



Isoxaflutole
RPA 201772



Isoxaflutole - diketonitrile
RPA 202248



Materials and Methods

Seeds of maize (var. Artus) were germinated in moist vermiculite and the young seedlings were transferred to brown 50ml nutrient culture bottles containing half strength Long Ashton nutrient solution. The seedlings were grown in a growth chamber maintained at 25°C day, 20°C night, 16h photoperiod and a light intensity of 420 $\mu\text{mol m}^{-2} \text{s}^{-1}$ PAR, provided by a combination of fluorescent and incandescent bulbs. The relative humidity (RH) was held constantly at 60%. At the time of treatment the maize plants were at two-leaf growth stage. The seedlings were carefully selected for uniformity before treatment.

Culture bottles were filled with 50ml of nutrient solution containing 0.5 $\mu\text{g/ml}$ (study 200.170, M-274733-01-1) or 0.25 $\mu\text{g/ml}$ (study 200.275, M-274674-01-1) ^{14}C -isoxazolo. The roots of the seedlings were immersed in the solution for 3 days by supporting the seedlings with a foam top fitted to the bottle so that only roots were in contact with the treatment solution. Each culture bottle contained two (study 200.170, M-274733-01-1) or three (study 200.275, M-274674-01-1) seedlings of maize.

At harvest, the plants were removed from the nutrient solution and the roots were rinsed. The root rinse and unabsorbed ^{14}C treatment solution in each bottle were combined, made up to 50ml and 0.2ml aliquots were radioassayed to estimate total ^{14}C taken up by the roots during a 3 day exposure period. One lot of plants were sectioned into roots and shoots, weighed and frozen until analysis. Another lot of plants were transferred to fresh untreated nutrient solution and maintained in the growth chamber for further 4 days prior to harvest.

Extraction and analysis with study 200.170, M-274733-01-1: For each sampling time point the shoots of 6 plants of maize were subsequently homogenised in acetone and methanol (or acetone) containing 1% acetic acid by ultraturax for 3-4 min at maximum speed. The extracts were filtered and washed. After the second extraction the filter cakes were dried at room temperature and the unextracted activity in each sample was determined by combustion. The acetone/methanol extracts of each sample were combined and 1ml aliquots were radioassayed.

The solvent extracts and ^{14}C -nutrient solutions were reduced via vacuum evaporation to a volume of approximately 5ml and stored frozen until analysis. To prepare the stored samples for HPLC analysis they were further reduced under a constant stream of nitrogen. The resulting supernatant liquids were filtered through 0.22 μm pore nylon filters and subsequently injected to a 'Spectra Physics HPLC System1 connected to a 'Berthold Radiodetector LB506.

Several putative degradation products of isoxaflutole (RPA 201772) such as amide, dione and benzoic acid were cochromatographed with the plant extracts.

Extraction and analysis with study 200.275, M-274674-01-1: At each harvest, the shoots of 12 plants of maize were homogenized subsequently for 3-4 min in acetone and acetone containing 1% acetic acid at a maximum speed of an 'Ultraturax' homogeniser. The extracts were filtered and washed with acetone. Radioactivity of the combined extracts was radioassayed, and the radioactivity in the air dried filter cake was determined by combustion.

The acetone extracts were concentrated to the aqueous phase and the pH was adjusted to <3.0 with hydrochloric acid. Afterwards the extract was liquid/liquid partitioned with ethyl acetate and radioactivity was measured in organic and aqueous fraction. A major proportion of the radioactivity



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was recovered in the ethyl acetate fraction. The organic fraction was concentrated and chromatographed by TLC whereas the aqueous fraction was concentrated and hydrolysed with 0.1N HCl at 60°C for 18h. The resulting hydrolysate was subject to liquid/liquid partitioning with ethyl acetate and the radioactivity in organic and aqueous fractions were determined as before. The ethyl acetate extracts were finally concentrated and chromatographed. In all experiments, the final aqueous fractions contained negligible amounts of radioactivity and were discarded.

Closed System ¹⁴C₂I-trap experiment (study 200.170, M-274733-01-1)

The possible degradation of ¹⁴C-RPA 201772 and RPA 201819 with the release of either ¹⁴C₂ or other volatile ¹⁴C products was assessed in trap experiments. Nine plants (3 plants per bottle) were exposed to nutrient solution containing 0.5 µg/ml RPA 201772 and were placed in air tight glass jars in a greenhouse. After 3 days, the plants were transferred to fresh solution and maintained in the jar for further 4 days. The jars were connected to four traps, the first two traps contained 10% KOH (100ml) and the last two traps contained 80% methanol. The solutions in the traps were replaced every day and 1ml aliquots were radioassayed. After 7 days, the recovery of root absorbed activity inside the plants was determined and compared to the airborne radioactivity recovered in traps.

Results

Absorbed isoxaflutole was readily converted to the corresponding diketonitrile. Analysis of root and shoot extracts of plants show rapid degradation to the diketonitrile with a half-life of < 1h as soon as it is absorbed by the roots forming a number of polar metabolites.

Study 200.170, M-274733-01-1

Only approximately 50% of the absorbed radioactivity remained detectable in the shoot after 3 days. Further loss of absorbed radioactivity was observed from the treated plants kept in normal nutrient culture for 4 consecutive days. The total recovery of absorbed radioactivity after 7 days, averaged 32% containing 5% of absorbed radioactivity as diketonitrile, 22% of absorbed radioactivity as ¹⁴C-polar metabolites whereas 2% remained unextracted. The time course of ¹⁴C-recovery in KOH traps confirms that the loss of absorbed ¹⁴C from maize plants was due to the release of ¹⁴CO₂. Unfortunately it has been found that ¹⁴CO₂ trapping system used in study 200.170 (M-274733-01-1) was only 70% efficient. After 7 days the total recovery including ¹⁴CO₂ recovered in traps averaged for 73% (89% corrected for trap efficiency) of the absorbed radioactivity in maize.

Table 6.2.1/09-1: Distribution of the Recovered Radioactivity Between Different Compartments

Matrix	Recovery in % of absorbed radioactivity		¹⁴ C ₂ -trap experiment after 3 + 4 days
	after 3 days	after 3 + 4 days	
DKN in root extract	7.5	2.2	-
DKN in shoot extract	18.1	5.1	-
Unidentified polar metabolites	22.9	22.2	-



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Matrix	Recovery in % of absorbed radioactivity		¹⁴ CO ₂ -trap experiment
Total radioactivity in extracts	48.5	29.5	30.1
Unextracted in root	0.4	0.3	5.6
Unextracted in shoot	1.3	1.7	
Total radioactivity recovered in plant	50.2	31.5	35.7
Loss of absorbed radioactivity	49.8	68.5	64.3
Recovered in ¹⁴ CO ₂ -trap	-	-	53.5 (53.5)*
Total recovery including ¹⁴ CO ₂ trap	-	-	73.2 (69.3)*

*corrected for efficiency of ¹⁴CO₂ trap

Study 200.275_M-274674-01-1

In [isoxazole ¹⁴C]-RPA 201772 treated maize, in addition to rapid loss of the radioactivity from the shoot as ¹⁴CO₂, 15% of the absorbed radioactivity was associated with at least three labeled metabolites. The metabolite 4 and 5 appear to co-chromatograph with the benzoyl ketonitrile (RPA 204219), and the cyclopropyl ketonitrile (RPA 202304), respectively in the TLC systems examined. As these metabolites occur in extracts at low levels (< 15%), separation and identification was difficult.

Discussion and Conclusion

In plants treated with ¹⁴C-isoxazole ring labeled isoxaflutole (RPA 201772), the diketonitrile with its label at the CN moiety degraded to polar products with a significant loss of absorbed activity, mostly as ¹⁴CO₂. The loss of absorbed activity averaged 50% after 3 days and 69% after 7 days. ¹⁴C-polar metabolites at day 7 averaged 23% in maize respectively and was associated with at least 5 different compounds. Bound residues slowly increased between day 3 and day 7 from 1.7% to 2 %.

From these results it can be concluded that in a full metabolism study with the isoxazole ¹⁴C labeled isoxaflutole at commercial harvest the predominant part of the ¹⁴C-isoxazole ring label would be lost as volatile compounds. Metabolites with close structural relationship to the active ingredient such as the diketonitrile, the benzoyl ketonitrile (RPA 204219), and the cyclopropyl ketonitrile (RPA 202304) would also be visible with the phenyl ring label. The amount of approximately 20 % of the absorbed dose after 7 days for the other, polar metabolites (at least three + RPA202304) will be further reduced by continued transformation to volatile compounds and incorporation to bound residues in the consecutive days. Additionally they are very small compounds containing only carbon, oxygen and nitrogen atoms and will thus be common metabolites mostly with also natural appearance.

Overall Summary on Plant Metabolism of Isoxaflutole

The metabolism of ¹⁴C-isoxaflutole uniformly labeled in the phenyl ring position was investigated in corn for a pre-plant incorporated and a pre-emergence application as well as for a post-emergence



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application in combination with the safener cyprosulfamide (AE 0001789). Furthermore studies were conducted in HPPD tolerant soybean as the result of a pre-plant or a post-emergent application. The metabolism of isoxaflutole in wheat was investigated after a single post-emergence application to immature plants. Also the metabolism in sugarcane was monitored after pre and post emergence treatment with isoxaflutole. Additionally the degradation of isoxaflutole in poppy plants following pre-emergence application to soil was investigated. Finally a study to demonstrate the effects of the safener cyprosulfamide on the metabolism of isoxaflutole in maize plants was reported.

No studies with ¹⁴C label in the isoxazole ring position were initiated. The isoxazole part is decomposed from the molecule very rapidly forming very small common or volatile metabolites.

Radioactive residues were low with only small amounts of the active ingredient isoxaflutole found, indicating a rapid decline of IFT. No isoxaflutole active ingredient was observed in the raw agricultural commodities for human consumption. Extraction efficiencies were high for all matrices observed consequently amounts of bound residues were generally below 10% of the TRR.

The same metabolic profile was observed in all metabolism studies. A hydrolytic attack on isoxaflutole promoted isoxazole-ring opening to form IFT diketonitrile (DKN, RPA 202248) which is a diastereomere to isoxaflutole. Further hydrolytical cleavage of the carbonyl bridge and loss of the complete isoxazole moiety lead to the corresponding benzoic acid derivative IFT-benzoic acid, RPA 203328), only in soybean also the corresponding aminolysis to IFT-amide could be observed. The two major metabolites IFT-diketonnitrile and IFT-benzoic acid occur as a result of crop metabolism, soil metabolism, soil photolysis, aqueous photolysis, and rat metabolism.

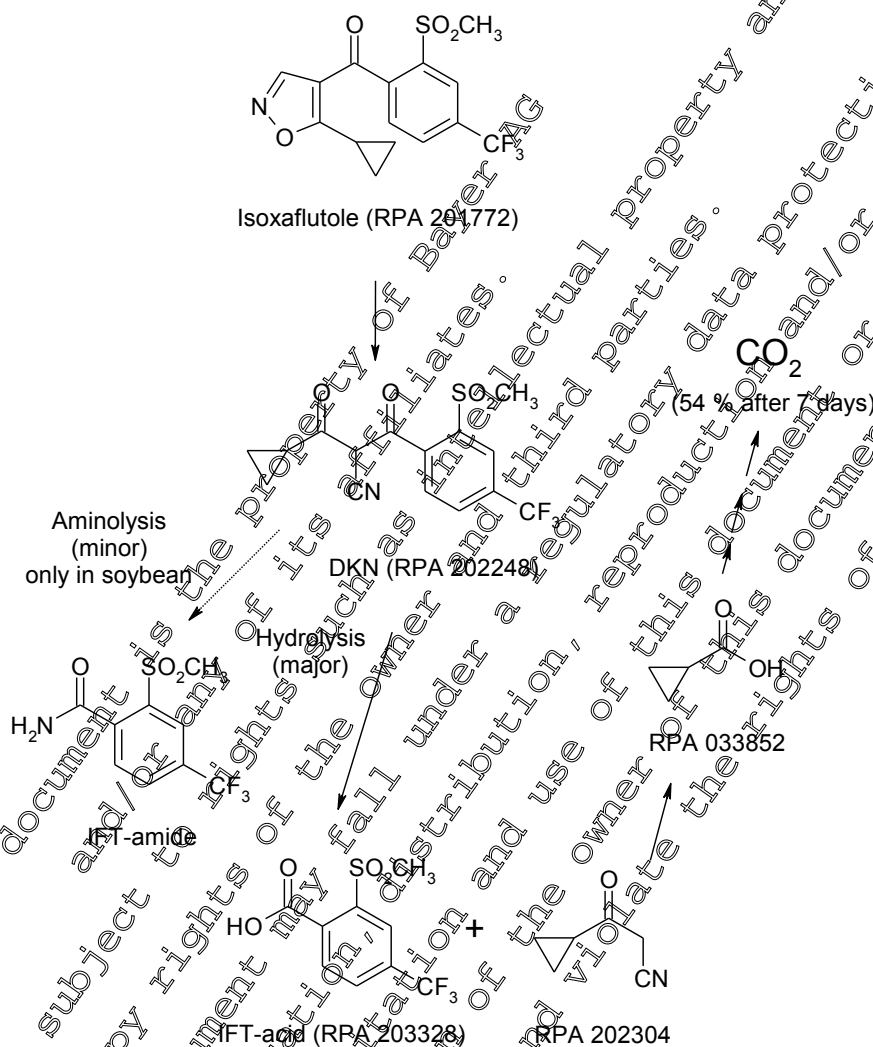
Application of safener cyprosulfamide in combination with isoxaflutole demonstrates that the safener cyprosulfamide only quantitatively affects the breakdown of the diketonnitrile metabolite of isoxaflutole to the known benzoic acid derivative. The amount of radioactive metabolites in shoots was significant lower in safener-treated plants. No qualitative changes could be observed along the principle root of metabolization. Finally, no evidence could be produced that mono-oxygenases are involved in safener effects of cyprosulfamide.

The proposed metabolic pathway for the [phenyl-¹⁴C]-isoxaflutole in plant is shown in figure 6.2.1-3.

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Figure 6.2.1-3: Metabolic Pathway of Isoxaflutole in Plants



CA 6.2.2 Poultry

No additional data available

CA 6.2.3 Lactating ruminants

No additional data available

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CA 6.2.4 Pigs

Following oral administration ¹⁴C-isoxaflutole has been shown to be rapidly absorbed and metabolized by Phase I type reactions in rat, goat and hen. The main product eliminated in both urine and faeces in the rat and goat and in the excreta of chicken was the diketone nitrile derivative (DKN/RPA 202248). Elimination was observed to be relatively rapid in all three species with very low to moderate levels of radioactive residues being found in the tissues at the time of sacrifice, with the higher levels being located in the principal organs of metabolism and excretion, the liver and kidney.

Therefore it can be concluded that the principal pathway of metabolism is the same in goat, hen and rat and consequently a metabolism study in pig is not necessary.

CA 6.2.5 Fish

According to the data requirements published in the Commission Regulation (EU) No 283/2013 of 1-March-2013 "Metabolism studies on fish may be required where the plant protection product is used in crops whose parts or products, also after processing, are fed to fish and where residues in feed may occur from the intended applications." However, no official test guideline of guidance exists and no feeding tables for fish are available at present. Therefore, it cannot be decided whether fish might be exposed to residues of isoxaflutole in parts of plants that have been treated with isoxaflutole.

In these cases, waiving of this particular data requirement is considered acceptable according to the "Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and the renewal of approval of the chemical active substance according to regulation (EU) No. 283/2013 and regulation (EU) No. 284/2013" (SANCO/10181/2013-rev.2 of 2-May-2013).

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CA 6.3 Magnitude of residue trials in plants

CA 6.3.1 Sweet corn and maize

The representative formulation supported during the last European review of isoxaflutole was a WG formulation containing 750 g/kg of isoxaflutole (also called Merlin® Flexx). The critical use pattern (GAP) consisted in one application in pre-emergence on maize at a maximum dose rate of 100 g a.s./ha in northern and southern Europe.

In the maize and sweet corn residue trials submitted at that time, residues of isoxaflutole were determined using a common moiety method which measures the sum of isoxaflutole, RPA 202248 and RPA 203328. The supervised field trials data showed that no residues in maize grain above the LOQ of 0.013 mg/kg (sum of isoxaflutole, RPA 202248 and RPA 203328) were expected if isoxaflutole is applied according to the GAP. Based on these trials an EU MRL of 0.05 mg/kg for maize was established.

On 03 July 2009, EFSA provided a reasoned opinion on isoxaflutole, which excluded the metabolite isoxaflutole-benzoic-acid (RPA 203328) from the residue definition. This was considered in Regulation (EC) No 459/2010. All existing EU MRLs are now established for the sum of isoxaflutole and its metabolite diketonitrile-isoxaflutole (RPA 202248), expressed as isoxaflutole. EFSA also noted that based on the results of the residue trials presented in the DAR the MRL for maize could be established at the level of 0.02 mg/kg which corresponds to the LOQ of the enforcement method developed for the new proposed residue definition (sum of isoxaflutole and its metabolite diketonitrile-isoxaflutole (RPA 202248), expressed as isoxaflutole).

Since the Annex I inclusion the use of isoxaflutole in combination with the safener cyprosulfamide (formulation Merlin® Flexx) has been allowing the enlargement of the application window from pre-emergence until growth stage BBCH 13 for maize.

The use pattern on maize and sweet corn with Merlin® Flexx formulation (isoxaflutole + cyprosulfamide SC 480, containing 240 g/L of isoxaflutole and 240 g/L of cyprosulfamide) are the "safe uses" of this application for renewal dossier.

The corresponding use patterns for the Merlin® Flexx formulation are summarized in general terms in [Table 6.3.1 - 1](#).

Table 6.3.1 - 1: Use patterns (GAPs) for the spray application of Isoxaflutole + Cyprosulfamide SC 480 (240+240) g/L formulation in/on maize and sweet corn in Europe

Crop	Region	Application timing	Max. number of applications	Max. rate of application (g a.s./ha)	PHI (days)
Maize	EU-N	pre-emergence until BBCH 13	1	100	NA
	EU-S				
Sweet corn	EU-N	pre-emergence	1	100	NA
	EU-S				

EU-N: northern Europe

EU-S: southern Europe



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NA: not applicable. The pre-harvest interval for the envisaged use pattern covers the vegetation period of the crop until harvest.

The number of new trials conducted on maize according to the uses described above (incl. information on geographical "residue region" and vegetation period) is summarized below in Table 6.3.1 - 2.

Table 6.3.1 - 2: Overview of European residue trials conducted in maize per geographical region and vegetation period

Formulation	Region	No. of trials		Σ	Study No.	Dossier ref.: KC 16.3.1.2
		Vegetation period 2005	2006			
100 ga.s./ha in PRE-EMERGENCE						
SC 480 (isoxaflutole & cyprosulfamide)	EU-N		5	10	RA-2615/06	27
	EU-S		*		RA-2616/06	28
100 ga.s./ha at BBCH 13						
SC 480 (isoxaflutole & cyprosulfamide)	EU-N		5	16	RA-2587/05	29
	EU-S		5		RA-2588/05	30
SC 465 (isoxaflutole & cyprosulfamide & thiencazazone-methyl)	EU-N		3	6	RA-2510/06	31
	EU-S		3		RA-2511/06	32

EU-N = northern European residue region, EU-S = southern European residue region
* in these trials a second application was made at a later growth stage with a formulation (SC 450) containing of 225 g/L of cyprosulfamide and 225 g/L of thiencazazone-methyl.

These trials were designed to include samplings covering sweet corn, maize grain and feed items. Residues of isoxaflutole, RPA 202248 and RPA 203328 were individually determined using a LC/MS/MS method.

General remark:

In this section of renewal application dossier, only the residues relevant to isoxaflutole will be described in detail. As the products applied also contained other active substances and a crop steener, residues of these compounds were also determined, but these results are not considered relevant to this dossier. For details on the results for the other compounds, see the study reports.

Tier 1 summary forms are also provided for isoxaflutole in Appendix of this section.



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New studies submitted for renewal application

Trials with Isoxaflutole & Cyprosulfamide SC 480 (representative formulation) in pre-emergence (followed by Thien carbazon-methyl & Cyprosulfamide SC 450 at BBCH 18)

Report:	7; ;2007;M-285014-01
Title:	Determination of the residues of AE 0001789, isoxaflutole, and BYH 18636 in/on corn after spraying of AE 0001789 & Isoxaflutole (480 SC) and AE 0001789 & BYH 18636 (450 SC) in the field in northern France, United Kingdom and Germany
Report No:	RA-2615/06
Document No(s):	Report includes Trial Nos.: R 2006 0627/3 = 0627 - 06 R 2006 0799/7 = 0799 - 06 R 2006 0800/4 = 0800 - 06 R 2006 0801/2 = 0801 - 06 R 2006 0802/0 = 0802 - 06 M-285014-01-1
Guidelines:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed; not specified
GLP/GEP:	yes

Report:	4; ;2007;M-285005-01
Title:	Determination of the residues of AE 0001789, isoxaflutole, and BYH 18636 in/on corn after spraying of AE 0001789 & Isoxaflutole (480 SC) and AE 0001789 & BYH 18636 (450 SC) in the field in southern France, Spain and Italy
Report No:	RA-2616/06
Document No(s):	Report includes Trial Nos.: R 2006 0628/1 = 0628 - 06 R 2006 0803/0 = 0803 - 06 R 2006 0804/7 = 0804 - 06 R 2006 0805/5 = 0805 - 06 R 2006 0806/3 = 0806 - 06 M-285005-01-1
Guidelines:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed; not specified
GLP/GEP:	yes

I. Materials and Methods

A total of 10 residue trials on corn were conducted in southern and northern Europe during the 2006 growing season. They were located in southern France (2), Spain (2), Italy (1), Germany (2), northern France (2) and the United Kingdom (1).

In these trials, two formulations were used:

- Isoxaflutole & Cyprosulfamide SC 480, a flowable concentrate containing 240 g/L of isoxaflutole and 240 g/L of the safener cyprosulfamide,
- Thien carbazon-methyl & Cyprosulfamide SC 450, a flowable concentrate containing 225 g/L of thien carbazon-methyl and 225 g/L of the safener cyprosulfamide.

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A first spray application was performed with the SC 480 formulation at the pre-emergence stage followed by a second application with the SC 450 at growth stage BBCH 18.

The SC 480 formulation was applied at a rate of 0.42 L/ha corresponding to 100 g isoxaflutole/ha.

Samples taken over the course of the trials covered various growth stages of corn, particularly "baby corn" (ear without husk at growth stage 61), "sweet corn" (ear without husk at growth stage 79), "corn grain" (kernel at growth stage 89) and "corn silage/forage" (green material at growth stage 85).

Residues of isoxaflutole and its metabolites (RPA 202248 and RPA 203328, also named in the report AE 0540092 and AE B197555, respectively) were determined according to method 00985/M001 by LC/MS/MS. The three compounds (isoxaflutole, RPA 202248 and RPA 203328) were analysed separately. The limit of quantification (LOQ) was 0.01 mg/kg for each compound in all sample materials. Metabolites were not expressed as parent. However it should be highlighted that RPA 202248 has the same molecular weight as isoxaflutole parent compound.

II. Findings

Concurrent recoveries were obtained from control samples fortified at levels between 0.01 mg/kg to 5 mg/kg with a mixture of isoxaflutole, RPA 202248 and RPA 203328. Mean recoveries were all within the acceptable ranges of 70-110% with RSD < 20%. Details of recovery data are shown in [Table 6.3.1 - 4](#).

For isoxaflutole and its metabolites, the maximum storage period of deep-frozen samples before analysis did not exceed 264 days.

Residues of isoxaflutole and its two metabolites were always found to be below the LOQ of 0.01 mg/kg in control samples.

The results of the treated samples are summarized below in [Table 6.3.1 - 3](#).

From BBCH 18 on, residues of isoxaflutole and RPA 202248 were always found to be below the LOQ of 0.01 mg/kg in treated samples. Residues of RPA 203328 were found in some trials at maximum levels of 0.04 mg/kg.

III. Conclusions

A total of 10 residue trials on maize were conducted in southern and northern Europe during the 2006 growing season. A first spray application was performed with the Isoxaflutole & Cyprosulfamide SC 480 formulation at the pre-emergence stage followed by a second application with the Thiencarbazone-methyl & Cyprosulfamide SC 450 at growth stage BBCH 18. The SC 480 formulation was applied at a rate of 0.42 L/ha corresponding to 100 g isoxaflutole/ha. The tests were carried out according to GLP principles.

From BBCH 18 on, residues of isoxaflutole and RPA 202248 were always found to be below the LOQ of 0.01 mg/kg in treated samples.

Residues of RPA 203328 - which is not proposed to be included in the residue definitions for risk assessment and for monitoring - were found at maximum levels of 0.04 mg/kg.



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Table 6.3.1 - 3a: Residues of isoxaflutole in/on maize sample materials following application of Isoxaflutole & Cyprosulfamide SC 480 and Thiencarbazono-methyl & Cyprosulfamide SC 450 in the southern and northern European residue region

Residues for isoxaflutole, determined and expressed as isoxaflutole

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application				Residues				
			FL	N	kg/ha (a.s.)	kg/ha (a.s.)	CS	Portion analysed	GS	DAIT (days)	Isoxaflutole (mg/kg)
Northern Europe											
RA-2615/06 R 2006 0627 3 0627-06 GLP yes 2006	Maize/ Corn Moncada	France F- [redacted] [redacted] Europe, North	SC 480	1	0.1008	0.03360	01	green material	18	55	<0.01
								ear without husk	61	86	<0.01
								kernel	79	120	<0.01
								rest of plant	79	120	<0.01
									18	55	<0.01
RA-2615/06 R 2006 0799 7 0799-06 GLP yes 2006	Maize/ Corn Anasta	France F- [redacted] [redacted] (Centre) Europe, North	SC 480	1	0.1008	0.03360	00	green material	18	52	<0.01
								ear without husk	61	89	<0.01
								kernel	79	112	<0.01
								rest of plant	79	112	<0.01
									18	52	<0.01
RA-2615/06 R 2006 0800 4 0800-06 GLP yes 2006	Maize/ Corn Algans	United Kingdom GB- [redacted] [redacted] Europe, North	SC 480	1	0.1008	0.03360	07	green material	18	46	<0.01
								ear without husk	61	84	<0.01
								kernel	79	101	<0.01
								rest of plant	79	101	<0.01
									18	46	<0.01



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DAIT (days)	Isoxaflutole (mg/kg)
RA-2615/06 R 2006 0801 2 0801-06 GLP yes 2006	Maize/ Corn Bunguy	Germany D- [REDACTED] [REDACTED] [REDACTED] Europe, North	SC 480	1	0.1008	0.03360	05	green material	18	44	<0.01
									18	44	<0.01
									71	81	<0.01
									85	111	<0.01
	ear without husk	61	79	<0.01							
		79	105	<0.01							
	kernel	79	91	<0.01							
		89	140	<0.01							
	rest of plant	79	91	<0.01							
		79	116	<0.01							
RA-2615/06 R 2006 0802 0 0802-06 GLP yes 2006	Maize/ Corn Delitop	Germany D- [REDACTED] [REDACTED] [REDACTED] Europe North	SC 480	1	0.1008	0.03360	06	green material	18	45	<0.01
									18	45	<0.01
									65	85	<0.01
									85	139	<0.01
									ear without husk	61	80
		79	116	<0.01							
	kernel	79	116	<0.01							
		89	167	<0.01							
	rest of plant	79	116	<0.01							
		79	116	<0.01							
Southern Europe											
RA-2616/06 R 2006 0628 1 0628-06 GLP yes 2006	Maize/ Corn Ferra	France F- [REDACTED] [REDACTED] [REDACTED] Europe South	SC 480	1	0.1008	0.03360	06	green material	18	49	<0.01
									18	49	<0.01
									69	90	<0.01
									85	115	<0.01
	ear without husk	61	79	<0.01							
		79	105	<0.01							
	kernel	79	105	<0.01							
		89	170	<0.01							
	rest of plant	79	105	<0.01							
		79	105	<0.01							
RA-2616/06 R 2006 0803 8 0803-06 GLP yes 2006	Maize/ Corn Cecilia	France F- [REDACTED] [REDACTED] [REDACTED] Europe, South	SC 480	1	0.1008	0.03360	01	green material	18	30	<0.01
									18	30	<0.01
									67	70	<0.01
									85	109	<0.01
	ear without husk	61	64	<0.01							
		79	91	<0.01							
	kernel	79	91	<0.01							
		89	128	<0.01							



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DAIT (days)	Isoxaflutole (mg/kg)
								rest of plant	79	99	<0.01
RA-2616/06 R 2006 0804 7 0804-06 GLP yes 2006	Maize/ Corn PR33P67	Spain E- [redacted] Europe, South	SC 480	1	0.1008	0.03360	07	green material	18	48	<0.01
								rest of plant	18	48	<0.01
								ear without husk	85	99	<0.01
								kernel	79	89	<0.01
								rest of plant	89	154	<0.01
RA-2616/06 R 2006 0805 5 0805-06 GLP yes 2006	Maize/ Corn PR34N43	Italy I- [redacted] Europe, South	SC 480	1	0.1008	0.03360	01	green material	18	43	<0.01
								rest of plant	18	43	<0.01
								ear without husk	63	84	<0.01
								kernel	79	100	<0.01
								rest of plant	89	149	<0.01
RA-2616/06 R 2006 0806 3 0806-06 GLP yes 2006	Maize/ Corn Conanza	Spain E- [redacted] Europe, South	SC 480	1	0.1008	0.03360	00	green material	18	32	<0.01
								rest of plant	18	32	<0.01
								ear without husk	73	72	<0.01
								kernel	85	86	<0.01
								rest of plant	61	65	<0.01
								ear without husk	79	78	<0.01
								kernel	79	78	<0.01
								rest of plant	89	128	<0.01
								rest of plant	79	78	<0.01

FL=Formulation, GS = Growth Stage (BBCH), DAIT = Days after treatment with isoxaflutole, No = number of applications

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Table 6.3.1 - 9b: Residues of RPA 202248 in/on maize sample materials following application of Isoxaflutole & Cyprosulfamide SC 480 and Thiencarbazonemethyl & Cyprosulfamide SC 450 in the southern and northern European residue region

Residues for RPA 202248, determined and expressed as RPA 202248 (equivalent to isoxaflutole as both compounds have the same molecular weight)

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application				Residues				
			FL	N	kg/ha (a.s.)	kg/ha (a.s.)	CS	Portion analysed	CS	DAIT (days)	RPA 202248 (mg/kg)
Northern Europe											
RA-2615/06 R 2006 0627 3 0627-06 GLP yes 2006	Maize/ Corn Moncada	France F- [redacted] Europe North	SC 480	1	0.1008	0.03360	01	green material	18	55	<0.01
								ear	61	86	<0.01
								without husk	79	120	<0.01
								kernel	79	120	<0.01
									89	163	<0.01
								rest of plant	79	120	<0.01
RA-2615/06 R 2006 0799 7 0799-06 GLP yes 2006	Maize/ Corn Anasta	France F- [redacted] (Centre) Europe North	SC 480	1	0.1008	0.03360	00	green material	18	52	<0.01
									18	52	<0.01
									63	91	<0.01
									85	126	<0.01
								ear without husk	61	89	<0.01
									79	112	<0.01
RA-2615/06 R 2006 0800 4 0800-06 GLP yes 2006	Maize/ Corn Algans	United Kingdom GB- [redacted] Europe, North	SC 480	1	0.1008	0.03360	07	green material	18	46	<0.01
									18	46	<0.01
									71	87	<0.01
								ear without husk	61	84	<0.01
									79	101	<0.01
								kernel	79	101	<0.01
	85	124	<0.01								
	79	101	<0.01								
	85	124	<0.01								



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DAIT (days)	RFA 202248 (mg/kg)
RA-2615/06 R 2006 0801 2 0801-06 GLP yes 2006	Maize/ Corn Bunguy	Germany D- [REDACTED] Europe, North	SC 480	1	0.1008	0.03360	05	green material	18	44	<0.01
									18	44	<0.01
									71	81	<0.01
									85	111	<0.01
	ear without husk	61	79	<0.01							
		79	105	<0.01							
	kernel	79	91	<0.01							
		89	140	<0.01							
	rest of plant	79	91	<0.01							
RA-2615/06 R 2006 0802 0 0802-06 GLP yes 2006	Maize/ Corn Delitop	Germany D- [REDACTED] Europe, North	SC 480	1	0.1008	0.03360	06	green material	18	45	<0.01
									18	45	<0.01
									65	85	<0.01
									85	139	<0.01
									ear without husk	61	80
		79	116	<0.01							
	kernel	79	116	<0.01							
		89	167	<0.01							
	rest of plant	79	116	<0.01							
Southern Europe											
RA-2616/06 R 2006 0628 1 0628-06 GLP yes 2006	Maize/ Corn Ferra	France F- [REDACTED] Europe, South	SC 480	1	0.1008	0.03360	06	green material	18	49	<0.01
									18	49	<0.01
									69	90	<0.01
									85	115	<0.01
	ear without husk	61	79	<0.01							
		79	105	<0.01							
	kernel	79	105	<0.01							
		89	170	<0.01							
	rest of plant	79	105	<0.01							
RA-2616/06 R 2006 0803 8 0803-06 GLP yes 2006	Maize/ Corn Cecilia	France F- [REDACTED] Europe, South	SC 480	1	0.1008	0.03360	01	green material	18	30	<0.01
									18	30	<0.01
									67	70	<0.01
									85	109	<0.01
	ear without husk	61	64	<0.01							
		79	91	<0.01							
	kernel	79	91	<0.01							
		89	128	<0.01							



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALD (days)	RFA 202248 (mg/kg)
								rest of plant	79	99	<0.01
RA-2616/06 R 2006 0804 7 0804-06 GLP yes 2006	Maize/ Corn PR33P67	Spain E- [redacted] Europe, South	SC 480	1	0.1008	0.03360	07	green material	18	48	<0.01
									18	48	<0.01
									85	99	<0.01
								ear without husk	79	89	<0.01
								kernel	79	89	<0.01
								89	154	<0.01	
							rest of plant	79	89	<0.01	
RA-2616/06 R 2006 0805 5 0805-06 GLP yes 2006	Maize/ Corn PR34N43	Italy I- [redacted] Europe, South	SC 480	1	0.1008	0.03360	01	green material	18	43	<0.01
									18	43	<0.01
									63	84	<0.01
								ear without husk	61	78	<0.01
									79	100	<0.01
							kernel	79	100	<0.01	
								89	149	<0.01	
							rest of plant	79	100	<0.01	
RA-2616/06 R 2006 0806 3 0806-06 GLP yes 2006	Maize/ Corn Conanza	Spain E- [redacted] Europe, South	SC 480	1	0.1008	0.03360	00	green material	18	32	<0.01
									18	32	<0.01
									73	72	<0.01
									85	86	<0.01
								ear without husk	61	65	<0.01
	79	78	<0.01								
							kernel	79	78	<0.01	
								89	128	<0.01	
							rest of plant	79	78	<0.01	

FL=Formulation, GS = Growth Stage (BBCH), DALD = Days after treatment with isoxaflutole, No = number of applications

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Table 6.3.1 - 9c: Residues of RPA 203328 in/on maize sample materials following application of Isoxaflutole & Cyprosulfamide SC 480 and Thiencarbazonemethyl & Cyprosulfamide SC 450 in the southern and northern European residue region

Residues for RPA 203328, determined and expressed as RPA 203328

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application				Residues				
			FL	No	kg/ha (a.s.)	kg/ha (a.s.)	GS	Portion analysed	GD	DAET (days)	RPA 203328 (mg/kg)
Northern Europe											
RA-2615/06 R 2006 0627 3 0627-06 GLP yes 2006	Maize/ Corn Moncada	France F- [redacted] Europe, North	SC 480	1	0.1008	0.03360	07	green material	18 18 69 85	55 55 94 134	<0.01 <0.01 <0.01 <0.01
								ear without husk	61 79	86 120	<0.01 <0.01
								kernel	79 89	120 163	<0.01 <0.01
								rest of plant	79	120	<0.01
RA-2615/06 R 2006 0799 7 0799-06 GLP yes 2006	Maize/ Corn Anasta	France F- [redacted] (Centre) Europe, North	SC 480	1	0.1008	0.03360	00	green material	18 18 63 85	52 52 91 126	0.03 0.03 <0.01 0.02
								ear without husk	61 79	89 112	<0.01 <0.01
								kernel	79 89	112 179	<0.01 <0.01
								rest of plant	79	112	<0.01
RA-2615/06 R 2006 0800 4 0800-06 GLP yes 2006	Maize/ Corn Algars	United Kingdom GB- [redacted] (Europe, North	SC 480	1	0.1008	0.03360	07	green material	18 18 71	46 46 87	<0.01 <0.01 <0.01
								ear without husk	61 79	84 101	<0.01 <0.01
								kernel	79 85	101 124	<0.01 <0.01
								rest of plant	79 85	101 124	<0.01 <0.01



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	N o	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DAM (days)	RPA 203328 (mg/kg)
RA-2615/06 R 2006 0801 2 0801-06 GLP yes 2006	Maize/ Corn Bunguy	Germany D- [REDACTED] Europe, North	SC 480	1	0.1008	0.03360	05	green material	18	41	0.01
									18	41	0.01
									71	81	<0.01
									85	111	<0.01
								ear without husk	61	79	<0.01
	79	105	<0.01								
	kernel	79	91	0.01							
		89	130	0.01							
	rest of plant	79	91	<0.01							
RA-2615/06 R 2006 0802 0 0802-06 GLP yes 2006	Maize/ Corn Delitop	Germany D- [REDACTED] Europe North	SC 480	1	0.1008	0.03360	06	green material	18	45	0.02
									18	45	0.02
									65	85	<0.01
									85	139	<0.01
								ear without husk	61	80	<0.01
	79	116	<0.01								
	kernel	79	116	<0.01							
		89	167	<0.01							
	rest of plant	79	116	0.01							
Southern Europe											
RA-2616/06 R 2006 0628 1 0628-06 GLP yes 2006	Maize/ Corn Ferra	France E- [REDACTED] Europe South	SC 480	1	0.1008	0.03360	06	green material	18	49	0.02
									18	49	0.03
									69	90	0.03
									85	115	0.03
								ear without husk	61	79	<0.01
	79	105	<0.01								
	kernel	79	105	<0.01							
		89	170	<0.01							
	rest of plant	79	105	0.04							
RA-2616/06 R 2006 0803 8 0803-06 GLP yes 2006	Maize/ Corn Cecilia	France E- [REDACTED] Europe, South	SC 480	1	0.1008	0.03360	01	green material	18	30	<0.01
									18	30	<0.01
									67	70	<0.01
									85	109	<0.01
								ear without husk	61	64	<0.01
	79	91	<0.01								
	kernel	79	91	<0.01							
		89	128	<0.01							



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALD (days)	RFA 203328 (mg/kg)
								rest of plant	79	99	<0.01
RA-2616/06 R 2006 0804 7 0804-06 GLP yes 2006	Maize/ Corn PR33P67	Spain E- [redacted] Europe, South	SC 480	1	0.1008	0.03360	07	green material	18	48	<0.01
									18	48	<0.01
									85	99	<0.01
								ear without husk	79	89	<0.01
								kernel	79	89	<0.01
								89	154	<0.01	
							rest of plant	79	89	<0.01	
RA-2616/06 R 2006 0805 5 0805-06 GLP yes 2006	Maize/ Corn PR34N43	Italy I- [redacted] Europe, South	SC 480	1	0.1008	0.03360	01	green material	18	43	<0.01
									18	43	<0.01
									63	84	<0.01
								ear without husk	61	78	<0.01
									79	100	<0.01
							kernel	79	100	<0.01	
								89	149	<0.01	
							rest of plant	79	100	<0.01	
RA-2616/06 R 2006 0806 3 0806-06 GLP yes 2006	Maize/ Corn Conanza	Spain E- [redacted] Europe, South	SC 480	1	0.1008	0.03360	00	green material	18	32	0.01
									18	32	0.01
									73	72	<0.01
									85	86	<0.01
								ear without husk	61	65	<0.01
	79	78	<0.01								
							kernel	79	78	<0.01	
								89	128	<0.01	
							rest of plant	79	78	<0.01	

FL=Formulation, GS = Growth Stage (BBCH), DALD = Days after treatment with isoxaflutole, No = number of applications

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Table 6.3.1 - 4: Procedural recoveries in maize matrices

Crop	Portion analysed	a.s./ metabolite	n	FL	Recovery (%)					
					Individual recoveries	Min	Max	Mean	RSD	
Maize/ Corn	green material	isoxaflutole	7	0.01	108; 106; 114; 91; 82; 90; 88	82	114	97	12.5	
			12	0.1	101; 102; 110; 107; 106; 101; 103; 102; 104; 102; 109; 106	101	110	104	3.0	
			7	5	96; 90; 108; 104; 89; 95; 92	89	108	96	7.5	
			26	overall		82	114	100	8.2	
		RPA 203328	7	0.01	111; 105; 102; 104; 78; 77; 86	77	111	94	14.6	
			12	0.1	105; 102; 105; 106; 103; 108; 100; 102; 106; 101; 100; 105	100	108	104	2.5	
			7	5	97; 97; 102; 102; 83; 84; 87	83	102	93	8.9	
			26	overall		77	111	98	9.7	
		RPA 202248	7	0.01	100; 98; 96; 99; 87; 89; 76	76	100	92	9.4	
			12	0.1	100; 101; 93; 95; 97; 103; 98; 96; 102; 97; 99; 92	92	103	98	3.0	
			7	5	86; 93; 90; 89; 72; 68; 74	68	93	82	12.3	
			26	overall		68	103	92	10.5	
	kernel	isoxaflutole	15	0.01	99; 102; 98; 101; 108; 102; 103; 102; 99; 100; 100; 105; 103; 84; 86	84	108	100	6.6	
			4	0.1	105; 108; 108; 96	105	108	107	1.4	
			19	overall		84	108	101	6.5	
			RPA 203328	7	0.01	104; 100; 102; 105; 100; 106; 97; 104; 101; 101; 107; 104; 103; 89	78	107	100	8.8
				4	0.1	106; 102; 103; 108	102	108	105	2.6
			19	overall		78	108	101	8.1	
		RPA 202248	15	0.01	97; 97; 94; 93; 91; 94; 102; 97; 97; 92; 99; 94; 98; 80; 87	80	102	94	5.7	
			4	0.1	97; 94; 96; 94	94	97	95	1.6	
		19	overall		80	102	94	5.1		

n: number of replicates FL: fortification level in mg/kg RSD: relative standard deviation

Notes:

- The concurrent recoveries reported for isoxaflutole, RPA 202248 and RPA 203328 were performed during the conduct of the studies RA-2510/06, RA-2511/06, RA-2615/06 and RA-2616/06.
- It is considered that recoveries for "corn green material" also cover the sample material "corn rest of plant" and recoveries for "corn kernel" also cover the sample materials "corn immature kernel" and "corn ear without husk".



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Trials with Isoxaflutole & Cyprosulfamide SC 480 (representative formulation) at BBCH 13

Report:	h; ; :2007;M-282674-01
Title:	Determination of the residues of AE 0001789 and isoxaflutole in/on corn after spraying of AE 0001789 & isoxaflutole (480 SC) in the field in Germany, Northern France, United Kingdom and the Netherlands
Report No:	RA-2587/05
Document No(s):	Report includes Trial Nos.: R 2005 0623/6 = 0623 - 05 R 2005 0958/8 = 0958 - 05 R 2005 0959/6 = 0959 - 05 R 2005 0961/8 = 0961 - 05 R 2005 0962/6 = 0962 - 05 M-282674-01-1
Guidelines:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed; not specified
GLP/GEP:	yes

Report:	4; :2006;M-281611-01
Title:	Determination of the residues of AE 0001789 and isoxaflutole in/on corn after spraying of AE 0001789 & isoxaflutole (480 SC) in the field in France, Spain, Italy, Greece and Portugal
Report No:	RA-2587/05
Document No(s):	Report includes Trial Nos.: R 2005 0624/4 = 0624 - 05 R 2005 0963/4 = 0963 - 05 R 2005 0964/2 = 0964 - 05 R 2005 0965/0 = 0965 - 05 R 2005 0966/9 = 0966 - 05 M-281611-01-1
Guidelines:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; not specified
GLP/GEP:	yes

1. Materials and Methods

A total of 10 residue trials on corn were conducted in southern and northern Europe during the 2005 growing season. They were located in southern France (1), Spain (1), Italy (1), Greece (1), Portugal (1), Germany (2), northern France (1), The Netherlands (1) and the United Kingdom (1).

The representative formulation was applied at growth stage BBCH 13 (BBCH 14 in one trial) with a dose rate of 0.42 L formulation/ha corresponding to 100 g isoxaflutole/ha.

Samples taken over the course of the trials covered various growth stages of corn, particularly early samplings of green material approximately 40 days after the application, “sweet corn” (ear without husk at growth stage BBCH 79), “corn grain” (kernel at growth stage BBCH 89), “corn silage/forage” (rest of plant at growth stage 85) and “corn stover” (rest of plant at growth stage 89).



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Residues of isoxaflutole and its metabolites (RPA 202248 and RPA 203328, also named in the report AE 0540092 and AE B197555, respectively) were determined according to method 00985/M001 by LC/MS/MS. The three compounds (isoxaflutole, RPA 202248 and RPA 203328) were analysed separately. The limit of quantification (LOQ) was 0.01 mg/kg for each compound in all sample materials. Metabolites were not expressed as parent. However it should be highlighted that RPA 202248 has the same molecular weight as isoxaflutole parent compound.

II. Findings

Concurrent recoveries were obtained from control samples fortified at levels between 0.01 mg/kg until 10 mg/kg with a mixture of isoxaflutole, RPA 202248 and RPA 203328. Mean recoveries were all within the acceptable ranges of 70-110% with RSD < 20%. Details of recovery data are shown in [Table 6.3.1 - 6](#).

For isoxaflutole and its metabolites, the maximum storage period of deep-frozen samples before analysis did not exceed 324 days.

Residues of isoxaflutole and its two metabolites were always found to be below the LOQ of 0.01 mg/kg in control samples.

The results of the treated samples are summarized below in [Table 6.3.1 - 5](#).

From BBCH 39 on, residues of isoxaflutole and RPA 202248 were always found to be below the LOQ of 0.01 mg/kg in treated samples. Residues of RPA 203328 were found in some trials at maximum levels of 0.04 mg/kg.

III. Conclusions

A total of 10 residue trials on maize were conducted in southern and northern Europe during the 2005 growing season. The Isoxaflutole & Cycosulfamide SC 480 formulation was applied at growth stage BBCH 13 (BBCH 14 in one trial) with a dose rate of 0.4 L formulation/ha corresponding to 100 g isoxaflutole/ha. The tests were carried out according to GMP principles.

From BBCH 39 on, residues of isoxaflutole and RPA 202248 were always found to be below the LOQ of 0.01 mg/kg in treated samples.

Residues of RPA 203328, which is not proposed to be included in the residue definitions for risk assessment and for monitoring, were found in some trials at maximum levels of 0.04 mg/kg.



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Table 6.3.1 - 5a: Residues of isoxaflutole in/on maize sample materials following application of Isoxaflutole & Cyprosulfamide SC 480 in the southern and northern European residue region

Residues for isoxaflutole, determined and expressed as isoxaflutole

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	N o	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	Isoxaflutole (mg/kg)
Northern Europe											
RA-2587/05 R 2005 0623 6 0623-05 GLP yes 2005	Maize/ Corn Romario	Germany D- [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] Europe, North	480 SC	1	0.1008	0.0336	03	green material	13	0	2.7
								ear without husk	19	41	<0.01
								kernel	79	78	<0.01
								rest of plant	85	111	<0.01
								cob, corn	89	127	<0.01
									89	127	<0.01
RA-2587/05 R 2005 0958 8 0958-05 GLP yes 2005	Maize/ Corn SCRTE	France [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] Europe, North	480 SC	1	0.1008	0.0336	14	green material	14	0	2.7
								ear without husk	39	40	<0.01
								kernel	79	71	<0.01
								rest of plant	85	83	<0.01
								cob, corn	89	127	<0.01
									89	127	<0.01
RA-2587/05 R 2005 0959 6 0959-05 GLP yes 2005	Maize/ Corn RK27	United Kingdom GB [REDACTED] [REDACTED] [REDACTED] [REDACTED] Europe, North	480 SC	1	0.1008	0.0336	13	green material	13	0	3.2
								ear without husk	34	40	<0.01
								kernel	79	103	<0.01
								rest of plant	85	124	<0.01
								cob, corn	89	148	<0.01
									89	148	<0.01



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	Isoxaflutole (mg/kg)
RA-2587/05 R 2005 0961 8 0961-05 GLP yes 2005	Maize/ Corn Egrin (FAO22 0)	Germany D- [redacted] Europe, North	480 SC	1	0.1008	0.0336	13	green material	13	0	2
								ear without husk	35	40	0.01
								kernel	79	90	<0.01
								rest of plant	85	112	<0.01
									79	90	<0.01
								cob, corn	89	128	<0.01
RA-2587/05 R 2005 0962 6 0962-05 GLP yes 2005	Maize/ Corn Rosalie	Netherlands NL- [redacted] Europe, North	480 SC	1	0.1008	0.0336	13	green material	13	40	1.1
								ear without husk	79	116	<0.01
								kernel	85	128	<0.01
								rest of plant	79	116	<0.01
									85	128	<0.01
								cob, corn	89	143	<0.01
Southern Europe											
RA-2588/05 R 2005 0624 4 0624-05 GLP yes 2005	Maize/ Corn PR33A4	France F- [redacted] Europe South	480 SC	1	0.0008	0.0336	13	green material	13	0	1.9
								ear without husk	34	40	<0.01
								kernel	79	83	<0.01
								rest of plant	85	106	<0.01
									79	83	<0.01
								cob, corn	89	148	<0.01

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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	N o	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	Isoxa- flutole (mg/kg)
RA-2588/05 R 2005 0963 4 0963-05 GLP yes 2005	Maize/ Corn DKc657 5	Spain E- Europe, South	480 SC	1	0.1008	0.0336	13	green material	13	0	4.5
								ear without husk	19	40	<0.01
								kernel	85	98	<0.01
								rest of plant	79	84	<0.01
									85	98	<0.01
								cob, corn	89	141	<0.01
RA-2588/05 R 2005 0964 2 0964-05 GLP yes 2005	Maize/ Corn DK 440	Italy I- Europe, South	480	1	0.1008	0.0336	13	green material	13	0	3.7
								ear without husk	19	40	<0.01
								kernel	79	79	<0.01
								rest of plant	85	93	<0.01
									89	128	<0.01
								cob, corn	89	128	<0.01
RA-2588/05 R 2005 0965 0 0965-05 GLP yes 2005	Maize/ Corn Decalp 743	Greece GR - Europe, South	480 SC	1	0.1008	0.0336	13	green material	13	0	4.5
								ear without husk	31	39	<0.01
								kernel	79	77	<0.01
								rest of plant	85	105	<0.01
									89	137	<0.01
								cob, corn	89	137	<0.01
RA-2588/05 R 2005 0966 9 0966-05 GLP yes 2005	Maize/ Corn PR 43	Portugal P- Europe, South	480 SC	1	0.1008	0.0336	13	green material	13	0	3.0
								ear without husk	35	41	<0.01
								kernel	79	80	<0.01
								rest of plant	85	100	<0.01
									89	133	<0.01



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	Isoxaflutole (mg/kg)
								cob, corn	89	133	<0.01

FL=Formulation, GS = Growth Stage, DALT = Days after last treatment, No = number of applications

Table 6.3.1 - 5b: Residues of RPA 202248 in/on maize sample materials following application of Isoxaflutole & Cyprosulfamide SC 480 in the southern and northern European residue region

Residues for RPA 202248, determined and expressed as RPA 202248 (equivalent to isoxaflutole as both compounds have the same molecular weight)

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	RPA 202248 (mg/kg)
Northern Europe											
RA-2587/05 R 2005 0623 6 0623-05 GLP yes 2005	Maize/ Corn Romano	Germany D- [REDACTED]	480 SC	1	0.1008	0.0336	13	green material	13	0	0.71
								ear without husk	19	41	<0.01
								kernel	79	78	<0.01
								rest of plant	85	111	<0.01
									89	127	<0.01
									79	78	<0.01
									89	127	<0.01
RA-2587/05 R 2005 0958 8 0958-05 GLP yes 2005	Maize/ Corn SURTEP	France F- [REDACTED]	480 SC	1	0.1008	0.0336	14	green material	14	0	0.64
								ear without husk	39	40	<0.01
								kernel	79	71	<0.01
								rest of plant	85	83	<0.01
									89	127	<0.01
									79	71	<0.01
									89	127	<0.01
RA-2587/05 R 2005 0959 6 0959-05 GLP yes	Maize/ Corn RK210	United Kingdom GB- [REDACTED]	480 SC	1	0.1008	0.0336	13	green material	13	0	0.53
								ear without husk	34	40	<0.01
									79	103	<0.01
								85	124	<0.01	



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	RPA 202248 (mg/kg)
2005		[REDACTED] Europe, North						kernel	79 89	103 148	<0.01 <0.01
								rest of plant	79 85 89	103 124 148	<0.01 <0.01 <0.01
								cob, corn	89	148	<0.01
RA-2587/05 R 2005 0961 8 0961-05 GLP yes 2005	Maize/ Corn Egrin (FAO220)	Germany D-[REDACTED] [REDACTED] Europe, North	480 SC	1	0.1008	0.0336		green material	73 35	0 41	1.0 <0.01
								ear without husk	79 85	90 112	<0.01 <0.01
								kernel	79 85	90 128	<0.01 <0.01
								rest of plant	79 85 89	90 112 128	<0.01 <0.01 <0.01
								cob, corn	89	128	<0.01
RA-2587/05 R 2005 0962 6 0962-05 GLP yes 2005	Maize Corn Cosalic	Netherlands NL-[REDACTED] [REDACTED] Europe, North	480 SC	1	0.1008	0.0336	13	green material	13 19	0 40	0.20 <0.01
								ear without husk	79 85	116 128	<0.01 <0.01
								kernel	79 89	116 143	<0.01 <0.01
								rest of plant	79 85 89	116 128 143	<0.01 <0.01 <0.01
								cob, corn	89	143	<0.01
Southern Europe											
RA-2588/05 R 2005 0624 4 0624-05 GLP yes 2005	Maize Corn PR33A4	France F-[REDACTED] [REDACTED] Europe, South	480 SC	1	0.1008	0.0336	13	green material	13 34	0 40	0.46 <0.01
								ear without husk	79 85	83 106	<0.01 <0.01
								kernel	79 89	83 148	<0.01 <0.01
								rest of plant	79 85 89	83 106 148	<0.01 <0.01 <0.01
								cob, corn	89	148	<0.01



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	RPA 202248 (mg/kg)
RA-2588/05 R 2005 0963 4 0963-05 GLP yes 2005	Maize/ Corn DKc657 5	Spain E- Europe, South	480 SC	1	0.1008	0.0336	13	green material	13	0	0.1
								ear without husk	19	48	<0.01
								kernel	85	98	<0.01
								rest of plant	79	84	<0.01
									85	98	<0.01
								cob, corn	79	84	<0.01
RA-2588/05 R 2005 0964 2 0964-05 GLP yes 2005	Maize/ Corn DK 440	Italy I- Europe, South	480	1	0.1008	0.0336	13	green material	13	40	0.95
								ear without husk	79	79	<0.01
								kernel	85	93	<0.01
								rest of plant	79	79	<0.01
									85	93	<0.01
								cob, corn	89	128	<0.01
RA-2588/05 R 2005 0965 0 0965-05 GLP yes 2005	Maize/ Corn Decal 743	Greece GR Europe, South	480 SC	1	0.1008	0.0336	13	green material	13	39	0.34
								ear without husk	31	39	<0.01
								kernel	79	77	<0.01
								rest of plant	85	105	<0.01
									89	137	<0.01
								cob, corn	79	77	<0.01
RA-2588/05 R 2005 0966 8 0966-05 GLP yes 2005	Maize/ Corn PR 43	Portugal P- Europe, South	480 SC	1	0.1008	0.0336	13	green material	13	41	0.61
								ear without husk	35	41	<0.01
								kernel	79	80	<0.01
								rest of plant	85	100	<0.01
									89	133	<0.01



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Study Trial No. Trial SubID	Crop Variety	Country	Application					Residues				
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	RPA 202248 (mg/kg)	
									cob, corn	89	133	<0.01

FL=Formulation, GS = Growth Stage, DALT = Days after last treatment, No = number of applications

Table 6.3.1 - 5c: Residues of RPA 203328 in/on maize sample materials following application of Isoxaflutole & Cyprosulfamide SC 480 in the southern and northern European residue region

Residues for RPA 203328, determined and expressed as RPA 203328

Study Trial No. Trial SubID	Crop Variety	Country	Application					Residues				
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	RPA 203328 (mg/kg)	
Northern Europe												
RA-2587/05 R 2005 0623 6 0623-05 GLP yes 2005	Maize/ Corn Romario	Germany D- [redacted] [redacted] Europe, North	480 SC	1	0.1008	0.0336	13	green material	13	0	<0.01	
								ear without husk	79 85	78 111	<0.01 <0.01	
								kernel	79 89	78 127	<0.01 <0.01	
								rest of plant	79 85 89	78 111 127	0.03 0.03 0.03	
								cob, corn	89	127	<0.01	
RA-2587/05 R 2005 0958 8 0958-05 GLP yes 2005	Maize/ Corn SURTEP	France F- [redacted] [redacted] Europe, North	480 SC	1	0.1008	0.0336	14	green material	14 39	0 40	<0.01 0.03	
								ear without husk	79 85	71 83	<0.01 <0.01	
								kernel	79 89	71 127	<0.01 <0.01	
								rest of plant	79 85 89	71 83 127	0.04 0.04 0.04	
								cob, corn	89	127	<0.01	
RA-2587/05 R 2005 0959 0959-05 GLP yes	Maize/ Corn RK210	United Kingdom GB- [redacted] [redacted]	480 SC	1	0.1008	0.0336	13	green material	13 34	0 40	<0.01 0.02	
								ear without husk	79 85	103 124	<0.01 <0.01	



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	RPA 203328 (mg/kg)
2005		Europe, North						kernel	79 89	103 148	<0.01 0.01
								rest of plant	85 89	93 124 148	0.02 0.02 0.02
								cob, corn	89	148	<0.01
RA-2587/05 R 2005 0961 8 0961-05 GLP yes 2005	Maize/ Corn Egrin (FAO22 0)	Germany D- Europe, North	480 SC	1	0.1008	0.0336	13	green material	13 35	0 41	<0.01 0.01
								ear without husk	79 85	90 112	0.01 0.01
								kernel	79 89	90 128	0.01 0.01
								rest of plant	79 85 89	90 112 128	0.04 0.03 0.02
								cob, corn	89	128	<0.01
RA-2587/05 R 2005 0962 6 0962-05 GLP yes 2005	Maize/ Corn Rosalic	Netherlands NL- Europe, North	480 SC	1	0.1008	0.0336	13	green material	13 19	0 40	<0.01 0.01
								ear without husk	79 85	116 128	<0.01 0.01
								kernel	79 89	116 143	<0.01 0.01
								rest of plant	79 85 89	116 128 143	<0.01 0.01 0.01
								cob, corn	89	143	<0.01
Southern Europe											
RA-2588/05 R 2005 0624 4 0624-05 GLP yes 2005	Maize/ Corn PR33A4 6	France F- Europe, South	480 SC	1	0.1008	0.0336	13	green material	13 34	0 40	<0.01 0.01
								ear without husk	79 85	83 106	<0.01 0.01
								kernel	79 89	83 148	<0.01 0.01
								rest of plant	79 85 89	83 106 148	0.03 0.03 0.02
								cob, corn	89	148	<0.01



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	N o	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	RPA 203328 (mg/kg)
RA-2588/05 R 2005 0963 4 0963-05 GLP yes 2005	Maize/ Corn DKc657 5	Spain E- Europe, South	480 SC	1	0.1008	0.0336	13	green material	13	0	0.02
								ear without husk	19	42	0.01
								kernel	85	98	<0.01
								rest of plant	79	84	<0.01
									85	98	<0.01
								cob, corn	89	141	<0.01
RA-2588/05 R 2005 0964 2 0964-05 GLP yes 2005	Maize/ Corn DK 440	Italy I- Europe, South	480	1	0.1008	0.0336	13	green material	13	40	<0.01
								ear without husk	79	79	<0.01
								kernel	85	93	<0.01
								rest of plant	79	79	<0.01
									85	93	<0.01
								cob, corn	89	128	<0.01
RA-2588/05 R 2005 0965 0 0965-05 GLP yes 2005	Maize/ Corn Decalp 743	Greece GR- Europe, South	480 SC	1	0.1008	0.0336	13	green material	13	39	0.01
								ear without husk	79	77	<0.01
								kernel	85	105	<0.01
								rest of plant	79	77	<0.01
									85	105	<0.01
								cob, corn	89	137	0.01
RA-2588/05 R 2005 0966 9 0966-05 GLP yes 2005	Maize/ Corn PR 43	Portugal P- Europe, South	480 SC	1	0.1008	0.0336	13	green material	13	41	<0.01
								ear without husk	35	41	<0.01
								kernel	79	80	<0.01
									85	100	<0.01
								rest of plant	79	80	<0.01
	85	100	0.01								
	89	133	0.02								
	89	133	0.03								



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	N o	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	RPA 203328 (mg/kg)
								corn, corn	89	133	<0.01

FL=Formulation, GS = Growth Stage, DALT = Days after last treatment, No = number of applications

Table 6.3.1 - 6: Procedural recoveries in maize matrices

Crop	Portion analysed	a.s./metabolite	n	FL	Recovery (%)				
					Individual recoveries	Min	Max	Mean	RSD
Maize /Corn	green material	Isoxaflutole	12	0.01	112, 112, 112, 110, 112, 94, 82, 107, 103, 100, 96, 112	82	112	104	9.4
			7	1.0	100, 97, 98, 99, 98, 90, 97	97	100	97	1.0
			8	5.0	86, 79, 81, 89, 85, 93, 90, 88	79	93	86	5.4
			27	overall		79	112	97	10.7
		RPA 203328	14	0.01	96, 101, 100, 101, 100, 88, 82, 93, 94, 101, 103, 101, 93, 91	82	101	96	6.2
			7	1.0	99, 98, 99, 100, 102, 102, 102	98	102	100	1.7
			8	5.0	89, 83, 87, 95, 92, 93, 86, 91	83	95	90	4.5
			29	overall		82	103	95	6.4
		RPA 203248	7	0.01	103, 99, 98, 96, 107, 97, 99, 99, 92, 112, 97, 100	79	112	99	8.7
	7		1.0	101, 95, 95, 103, 109, 101, 97	95	103	99	3.2	
	8		5.0	89, 81, 83, 90, 90, 93, 84, 87	81	93	87	4.7	
	27		overall		79	112	95	8.7	
	ear without husk	Isoxaflutole	14	0.01	97, 107, 106, 99, 106, 96, 100, 107, 93, 97, 102, 109, 103, 103	93	109	102	4.8
			14	1.0	95, 97, 96, 97, 97, 93, 99, 88, 97, 99, 100, 105, 100, 98	88	105	97	4.0
			28	overall		88	109	100	4.9
		RPA 203328	5	0.01	103, 102, 103, 104, 103, 103, 106, 96, 97, 93, 109, 102, 106, 106, 99	93	109	102	4.2
			1	1.0	92, 92, 97, 91, 96, 102, 101, 90, 97, 100, 100, 101, 96, 99	90	102	97	4.3
			1	5.0	88	88	88		
30			overall		88	109	99	5.4	
RPA 203248		5	0.01	100, 105, 104, 99, 100, 104, 92, 101, 93, 93, 112, 101, 105, 101, 93	92	112	100	5.6	
		7	1.0	95, 93, 93, 96, 96, 102, 98, 93, 98, 101, 104, 103, 92, 99	92	104	97	4.1	
	1	5.0	116	116	116				
	30	overall		92	116	99	5.9		
kernel	Isoxaflutole	15	0.01	108, 99, 97, 93, 102, 89, 106, 99, 93, 98, 94, 102, 101, 95, 102	89	108	99	5.3	



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Crop	Portion analysed	a.s./metabolite	n	FL	Recovery (%)					
					Individual recoveries	Min	Max	Mean	RSD	
			14	1.0	102; 101; 99; 100; 97; 91; 94; 92; 95; 91; 100; 105; 102; 101	91	105	98	4.6	
			1	5.0	67	67	67			
			30	overall	67	108	97	7.6		
			RPA 203328	15	0.01	96; 92; 93; 90; 97; 96; 102; 89; 95; 94; 102; 104; 92; 93; 100	89	104	95	4.0
			14	1.0	95; 93; 94; 94; 93; 101; 97; 92; 92; 93; 99; 93; 91; 99	91	101	95	3.2	
			1	5.0	86	86	86			
	30	overall	86	104	95	4.4				
	RPA 202248	15	0.01	98; 101; 104; 100; 100; 101; 104; 97; 91; 100; 94; 99; 100; 98; 105	91	105	99	4.0		
	14	1.0	95; 89; 99; 96; 92; 100; 98; 96; 92; 88; 96; 98; 93; 98	88	100	95	3.9			
	1	5.0	104	104	104					
	30	overall	88	105	97	4.5				

n: number of replicates FL: fortification level in mg/kg RSD: relative standard deviation

Notes:

- The concurrent recoveries reported for isoxaflutole RPA 202248 and RPA 203328 were performed during the conduct of the studies RA-2587/05 and RA-2588/05.
- It is considered that recoveries for "corn green material" also cover the sample material "corn rest of plant" and recoveries for "corn kernel" also cover the sample materials "corn immature kernel" and "corn cob".

Trials with Thiencarbazon-methyl & Isoxaflutole & Cyprosulfamide SC 465 at BBCH 13

Report:	2007;M-284423-01
Title:	Determination of the residues of AE 0001789/BYH 18636 and isoxaflutole in/on corn after spraying of BYH 18636 & IF 1 & AE 0001789 (465 SC) in the field in northern France, Germany and United Kingdom
Report No:	RA-2510/06
Document No(s):	Report includes Trial Nos.: R 2006 0023/9 = 073 - 06 R 2006 0795/4 = 0795 - 06 R 2006 0796/7 = 0796 - 06 M-284423-01
Guidelines:	EU Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed; Deviations: not specified
GLP/GEP:	yes

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Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

Report:	Y: ; :2007;M-284416-01
Title:	Determination of the residues of AE 0001789, BYH 18636 and isoxaflutole in/on corn after spraying of BYH 18636 & IFT & AE 0001789 (465 SC) in the field in southern France, Italy and Spain
Report No:	RA-2511/06
Document No(s):	Report includes Trial Nos.: R 2006 0074/7 = 0074 - 06 R 2006 0797/0 = 0797 - 06 R 2006 0798/9 = 0798 - 06 M-284416-01-1
Guidelines:	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed; Deviations: not specified
GLP/GEP:	yes

I. Materials and Methods

A total of 6 residue trials on corn were conducted in southern and northern Europe during the 2006 growing season. They were located in southern France (1), Spain (1), Italy (1), Germany (1), northern France (1) and the United Kingdom (1).

The formulation Thien carbazone-methyl & Isoxaflutole & Cyprosulfamide SC 465 (containing 90 g/L of thien carbazone-methyl, 225 g/L of Isoxaflutole and 150 g/L of cyprosulfamide) was applied at growth stage BBCH 13 (BBCH 14 in 2 trials) with a dose rate of 0.44 L formulation/ha corresponding to 100 g isoxaflutole/ha.

Samples taken over the course of the trials covered various growth stages of corn, particularly early samplings of green material approximately 40 days after the application, "sweet corn" (ear without husk at growth stage BBCH 79), "corn silage/forage" (green material at growth stage 85), "corn grain" (kernel at growth stage BBCH 89).

Residues of isoxaflutole and its metabolites (RPA 202248 and RPA 203328, also named in the report AE 0540092 and AE B197555, respectively) were determined according to method 00985/M001 by LC/MS/MS. The three compounds (isoxaflutole, RPA 202248 and RPA 203328) were analysed separately. The limit of quantification (LOQ) was 0.01 mg/kg for each compound in all sample materials. Metabolites were not expressed as parent. However it should be highlighted that RPA 202248 has the same molecular weight as isoxaflutole parent compound.



II. Findings

Concurrent recoveries were obtained from control samples fortified at levels between 0.01 mg/kg and 0.10 mg/kg with either isoxaflutole, or RPA 202248 or RPA 203328. Mean recoveries were all within the acceptable ranges of 70-110% with RSD <20%. Details of recovery data are shown in [Table 3.1-8](#).

For isoxaflutole, the maximum storage period of deep-frozen samples before analysis did not exceed 272 days.

Residues of isoxaflutole and its two metabolites were always found to be below the LOQ of 0.01 mg/kg in control samples.

The results of the treated samples are summarized below in [Table 3.1-2](#).

From BBCH 61 on, residues of isoxaflutole and RPA 202248 were always found to be below the LOQ of 0.01 mg/kg in treated samples. Residues of RPA 203328 in treated samples were found in some trials at maximum levels of 0.04 mg/kg.

III. Conclusions

A total of 6 residue trials on maize were conducted in southern and northern Europe during the 2006 growing season. The formulation Thien carbazole-methyl & Isoxaflutole & Cyprosulfamide SC 465 (containing 90 g/L of thien carbazole-methyl, 25 g/L of isoxaflutole and 150 g/L of cyprosulfamide) was applied at growth stage BBCH 10 (BBCH 14 in 2 trials) with a dose rate of 0.44 L formulation/ha corresponding to 100 g isoxaflutole/ha. The tests were carried out according to GLP principles.

From BBCH 61 on, residues of isoxaflutole and RPA 202248 were always found to be below the LOQ of 0.01 mg/kg in treated samples.

Residues of RPA 203328 - which is not proposed to be included in the residue definitions for risk assessment and for monitoring - were found in some trials at maximum levels of 0.04 mg/kg.

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Table 6.3.1 - 7a: Residues of isoxaflutole in/on maize following application of Thiencarbazon methyl & Isoxaflutole & Cyprosulfamide SC 465 in the northern and southern European residue region

Residues for isoxaflutole, determined and expressed as isoxaflutole

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	Isoxaflutole (mg/kg)
Northern Europe											
RA-2510/06 R 2006 0073 9 0073-06 GLP yes 2006	Maize/ Corn Moncada	France F- [redacted] [redacted] Europe, North	465	1	0.099	0.033	03	green material	13	0	7
									19	40	<0.01
									85	110	<0.01
								ear without husk	61	62	<0.01
									79	96	<0.01
kernel	79	96	<0.01								
	89	139	<0.01								
rest of plant	79	96	<0.01								
RA-2510/06 R 2006 0795 4 0795-06 GLP yes 2006	Maize/ Corn Romario	Germany D- [redacted] [redacted] Europe, North	465	1	0.099	0.033	03	green material	13	0	6.2
									33	40	0.28
									85	98	<0.01
								ear without husk	61	55	<0.01
									79	77	<0.01
kernel	79	77	<0.01								
	89	135	<0.01								
rest of plant	79	77	<0.01								
RA-2510/06 R 2006 0796 2 0796-06 GLP yes 2006	Maize/ Corn Nexxos	United Kingdom GB- [redacted] [redacted] Europe, North	465	1	0.099	0.033	14	green material	14	0	4.5
									37	39	0.01
									85	106	<0.01
								ear without husk	61	51	<0.01
									79	93	<0.01
kernel	79	93	<0.01								
	89	123	<0.01								
rest of plant	79	93	<0.01								



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	Isoxaflutole (mg/kg)
Southern Europe											
RA-2511/06 R 2006 0074 7 0074-06 GLP yes 2006	Maize/ Corn dkc4845	France F- [REDACTED] Europe, South	465 SC	1	0.0990	0.03308	13	green material	13	0	13
								ear without husk	61	74	<0.01
								kernel	79	98	<0.01
								rest of plant	89	153	<0.01
RA-2511/06 R 2006 0797 0 0797-06 GLP yes 2006	Maize/ Corn PR34 N43	Italy I- [REDACTED] (FE) Europe, South	465 C	1	0.0990	0.03308	13	green material	13	40	5.4
								ear without husk	61	53	<0.01
								kernel	79	75	<0.01
								rest of plant	89	124	<0.01
RA-2511/06 R 2006 0798 9 0798-06 GLP yes 2006	Maize/ Corn PR33P6	Spain E- [REDACTED] Europe, South	465 SC	1	0.0990	0.03308	14	green material	14	0	7.2
								ear without husk	61	56	<0.01
								kernel	79	67	<0.01
								rest of plant	89	132	<0.01

FL=Formulation, GS = Growth Stage, DALT = Days after last treatment, No = number of applications

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Table 6.3.1 - 7b: Residues of RPA 202248 in/on maize following application of Thiencarbazonemethyl & Isoxaflutole & Cyprosulfamide SC 465 in the northern and southern European residue region

Residues for RPA 202248, determined and expressed as RPA 202248 (equivalent to isoxaflutole as both compounds have the same molecular weight)

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	RPA 202248 (mg/kg)
Northern Europe											
RA-2510/06 R 2006 0073 9 0073-06 GLP yes 2006	Maize/ Corn Moncada	France F- [redacted] [redacted] Europe, North	465	1	0.099	0.033	13	green material	13	0	1.2
								ear	15	40	0.01
								ear without husk	61	62	<0.01
								kernel	79	96	<0.01
							89	139	<0.01		
							rest of plant	72	96	<0.01	
RA-2510/06 R 2006 0795 4 0795-06 GLP yes 2006	Maize/ Corn Romario	Germany D- [redacted] [redacted] Europe, North	465	1	0.099	0.033	13	green material	13	0	1.5
								ear	33	40	0.06
								ear without husk	85	98	<0.01
								kernel	61	55	<0.01
							79	77	<0.01		
							kernel	79	77	<0.01	
							89	135	<0.01		
							rest of plant	79	77	<0.01	
RA-2510/06 R 2006 0796 2 0796-06 GLP yes 2006	Maize/ Corn Nexxos	United Kingdom GB- [redacted] [redacted] Europe, North	465	1	0.099	0.033	14	green material	14	0	0.42
								ear	37	39	<0.01
								ear without husk	85	106	<0.01
								kernel	61	51	<0.01
							79	93	<0.01		
							kernel	79	93	<0.01	
							89	123	<0.01		
							rest of plant	79	93	<0.01	



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	RPA (mg/kg)
Southern Europe											
RA-2511/06 R 2006 0074 7 0074-06 GLP yes 2006	Maize/ Corn dkc4845	France F- [redacted] Europe, South	465 SC	1	0.0990	0.03308	13	green material	13	0	0.6
								ear without husk	61	74	<0.01
								kernel	79	98	<0.01
								rest of plant	89	153	<0.01
RA-2511/06 R 2006 0797 0 0797-06 GLP yes 2006	Maize/ Corn PR34 N43	Italy I- [redacted] Europe, South	465	1	0.0990	0.03308	13	green material	13	40	0.32
								ear without husk	61	53	<0.01
								kernel	79	75	<0.01
								rest of plant	89	124	<0.01
RA-2511/06 R 2006 0798 9 0798-06 GLP yes 2006	Maize/ Corn PR33P6	Spain E- [redacted] Europe, South	465	1	0.0990	0.03308	14	green material	14	0	1.2
								ear without husk	36	41	<0.01
								kernel	61	56	<0.01
								rest of plant	79	67	<0.01

FL=Formulation, GS = Growth Stage, DALT = Days after last treatment, No = number of applications

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Table 6.3.1 - 7c: Residues of RPA 203328 in/on maize following application of Thiencarbazonemethyl & Isoxaflutole & Cyprosulfamide SC 465 in the northern and southern European residue region

Residues for RPA 203328, determined and expressed as RPA 203328

Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	CS	Portion analysed	CS	DALT (days)	RPA 203328 (mg/kg)
Northern Europe											
RA-2510/06 R 2006 0073 9 0073-06 GLP yes 2006	Maize/ Corn Moncada	France F- [redacted] [redacted] [redacted] [redacted] Europe, North	465 SC	1	0.099	0.033	13	green material	13	0	<0.01
								ear without husk	61	62	<0.01
								kernel	79	96	<0.01
								rest of plant	89	139	<0.01
								rest of plant	79	96	<0.01
RA-2510/06 R 2006 0795 4 0795-06 GLP yes 2006	Maize/ Corn Romario	Germany D- [redacted] [redacted] [redacted] Europe, North	465 SC	1	0.099	0.033	13	green material	13	0	<0.01
								ear without husk	61	55	<0.01
								kernel	79	77	<0.01
								rest of plant	89	135	<0.01
								rest of plant	79	77	0.02
RA-2510/06 R 2006 0796 2 0796-06 GLP yes 2006	Maize/ Corn Nexxos	United Kingdom GB- [redacted] [redacted] [redacted] Europe, North	465 SC	1	0.099	0.033	14	green material	14	0	0.01
								ear without husk	61	51	<0.01
								kernel	79	93	<0.01
								rest of plant	89	123	<0.01
								rest of plant	79	93	0.04



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Study Trial No. Trial SubID GLP Year	Crop Variety	Country	Application					Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	GS	DALT (days)	RPA (mg/kg)
Southern Europe											
RA-2511/06 R 2006 0074 7 0074-06 GLP yes 2006	Maize/ Corn dkc4845	France F- [REDACTED] Europe, South	465 SC	1	0.0990	0.03308	13	green material	19	0	0.01
								ear without husk	61	74	<0.01
								kernel	79	98	<0.01
								rest of plant	79	98	<0.01
RA-2511/06 R 2006 0797 0 0797-06 GLP yes 2006	Maize/ Corn PR34 N43	Italy I- [REDACTED] Europe, South	465	1	0.0990	0.03308	13	green material	35	40	<0.01
								ear without husk	61	53	<0.01
								kernel	79	75	<0.01
								rest of plant	79	75	<0.01
RA-2511/06 R 2006 0798 9 0798-06 GLP yes 2006	Maize/ Corn PR33P	Spain E- [REDACTED] Europe, South	465	1	0.0990	0.03308	14	green material	14	0	0.01
								ear without husk	61	56	<0.01
								kernel	79	67	<0.01
								rest of plant	79	67	<0.01

FL=Formulation, GS= Growth Stage, DALT= Days after last treatment, No = number of applications

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Table 6.3.1 - 8: Procedural recoveries in maize matrices

Crop	Portion analysed	a.s./metabolite	n	FL	Recovery (%)					
					Individual recoveries	Min	Max	Mean	RSD	
Maize /Corn	green material	Isoxaflutole	7	0.01	108; 106; 114; 91; 82; 90; 88	82	114	97	2.5	
			12	0.1	101; 102; 110; 107; 106; 101; 103; 102; 104; 102; 109; 106	101	110	104	3.0	
			7	5	96; 90; 108; 104; 89; 95; 92	89	108	95	4.5	
			26	overall		82	114	100	8.2	
		RPA 203328	7	0.01	111; 103; 102; 104; 78; 77; 86	77	111	94	14.6	
			12	0.1	105; 102; 105; 106; 103; 108; 103; 100; 102; 105; 101; 100; 105	100	108	103	3.5	
			7	5	97; 97; 102; 102; 83; 84; 87	83	102	93	8.9	
			26	overall		77	111	98	9	
		RPA 202248	7	0.01	100; 98; 96; 99; 87; 89; 76	76	100	92	9.4	
			12	0.1	109; 101; 93; 95; 97; 101; 98; 96; 102; 97; 99; 97	93	103	98	3.0	
			7	5	86; 93; 90; 89; 72; 69; 74	68	93	82	12.3	
			26	overall		68	103	92	10.5	
	kernel	Isoxaflutole	15	0.01	99; 102; 98; 101; 108; 102; 105; 102; 99; 100; 100; 105; 105; 84; 86	84	108	100	6.6	
			4	0.1	105; 108; 108; 106	105	108	107	1.4	
			19	overall		84	108	101	6.5	
			RPA 203328	12	0.01	104; 100; 102; 107; 100; 106; 97; 104; 101; 101; 107; 104; 103; 80	78	107	100	8.8
				4	0.1	106; 102; 103; 108	102	108	105	2.6
			16	overall		78	108	101	8.1	
		RPA 202248	15	0.01	97; 97; 94; 93; 94; 94; 102; 97; 97; 92; 99; 94; 98; 80; 87	80	102	94	5.7	
			4	0.1	97; 94; 96; 94	94	97	95	1.6	
19			overall		80	102	94	5.1		

n: number of replicates FL: fortification level in mg/kg RSD: relative standard deviation

Notes:

- The concurrent recoveries reported for cyprosulfamide, isoxaflutole, RPA 202248 and RPA 203328 were performed during the conduct of the studies RA-2510/06, RA-2511/06, RA-2615/06 and RA-2616/06.

- It is considered that recoveries for “corn green material” also cover the sample material “corn rest of plant” and recoveries for “corn kernel” also cover the sample materials “corn immature kernel” and “corn ear without husk”.



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Overall summary of the new trials submitted

An overview of the isoxaflutole residue levels found in the new trials submitted for renewal application are summarised in [Table 6.3.1 - 9](#).

Table 6.3.1 - 9: Summary of isoxaflutole residue data in maize/corn and sweet corn from the new trials submitted for renewal application

Commodity	Application scheme	Individual trial results (mg/kg)	
		sum of isoxaflutole and RPA 202248 expressed as isoxaflutole	
Sweet corn ^a	100 g as/ha at BBCH 13	NEU: 8 x <0.02	SEU: 8 x <0.02
	100 g as/ha in pre-emergence	NEU: 5 x <0.02	SEU: 5 x <0.02
Maize/corn grain ^b	100 g as/ha at BBCH 13	NEU: 8 x <0.02	SEU: 8 x <0.02
	100 g as/ha in pre-emergence	NEU: 5 x <0.02	SEU: 5 x <0.02
Corn silage/forage ^c	100 g as/ha at BBCH 13	NEU: 8 x <0.02	SEU: 8 x <0.02
	100 g as/ha in pre-emergence	NEU: 4 x <0.02	SEU: 5 x <0.02
Corn stover ^d	100 g as/ha at BBCH 13	NEU: 5 x <0.02	SEU: 5 x <0.02
	100 g as/ha in pre-emergence	NEU: -	SEU: -

NEU: northern Europe

SEU: southern Europe

^a Ear without husk at BBCH 79

^b Grain or kernel at BBCH 89

^c Green material or rest of plant at BBCH 85. The sample material "green material" actually corresponds to the whole plant without roots.

^d mature dried stalks from which the grain or whole ear (cob) grain have been removed (rest of plant at BBCH 89)

The data clearly show that, after the use of isoxaflutole until a growth stage of BBCH 13, with a maximum dose rate of 100 g isoxaflutole/ha, residues of isoxaflutole (sum of isoxaflutole and RPA 202248 expressed as isoxaflutole) are expected to be <0.02 mg/kg in sweet corn, maize grain and parts of maize which can be fed to livestock.



CA 6.4 Feeding studies

Isoxaflutole is sought for use on maize/corn which parts of this crop might be fed to livestock as corn grain, corn forage / silage and corn stover.

The maximum dietary burdens were therefore calculated for different groups of livestock as described in the OECD Guidance Document on Residues in Livestock (ENV/JM/MONO(2013)8 dated of 04 Sep-2013). The input values for all relevant commodities are summarized in [Table 6.4 - 1](#).

Table 6.4 - 1: Input values for the dietary burden calculation – OECD methodology

Commodity	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of isoxaflutole and its diketone trile-metabolite (RPA 202248), expressed as isoxaflutole.		
Field corn forage/silage	0.02	Highest residue
Field corn stover	0.02	Highest residue
Pop corn stover	0.02	Highest residue
Field corn grain	0.02	Median residue
Pop corn grain	0.02	Median residue

The results of the calculations are reported in [Table 6.4 - 2](#).

Table 6.4 - 2: Results of the dietary burden calculation - OECD methodology

	Maximum dietary burden (mg/kg bw/day)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Cattle - Beef	0.001	Field corn forage/silage	0.045	N
Cattle - Dairy	0.001	Field corn forage/silage	0.037	N
Sheep - Rams/Ewes	<0.001	Field corn grain	0.007	N
Sheep - Lambs	0.001	Field corn forage/silage	0.022	N
Swine - Breeding	0.001	Field corn grain	0.026	N
Swine - Finishing	0.001	Field corn grain	0.016	N
Poultry - Broiler	0.001	Field corn grain	0.016	N
Poultry - Layer	0.001	Field corn grain	0.021	N
Poultry - Turkey	0.001	Field corn grain	0.011	N

The calculated dietary burdens for all categories of livestock were found to be below the trigger value of 0.004 mg/kg bw/day.

Therefore, further feeding studies are not needed. The setting of MRLs in commodities of animal origin is also not necessary.

CA 6.4.1 Poultry

The dietary burden calculations do not trigger the need of a poultry feeding study. Besides, a laying hen feeding study was previously evaluated (KCA 6.4.1/01). Therefore, no new studies were conducted.



CA 6.4.2 Ruminants

The dietary burden calculations do not trigger the need of a ruminant feeding study. Besides a dairy cow feeding study was previously evaluated (KCA 6.4.2/01). Therefore, no new studies were conducted.

CA 6.4.3 Pigs

The dietary burden calculations do not trigger the need of a pig feeding study. Therefore, no pig feeding study was conducted.

CA 6.4.4 Fish

No metabolism study or feeding study in fish was conducted.

Currently, no test method or guidance documents are available for conducting a feeding study in fish. Also, no feeding table with plant commodities for fish feeding is available. Therefore, it cannot be decided whether fish might be exposed to residues of isoxaflutole in parts of plant that have been treated with isoxaflutole.

In these cases, waiving of this particular data requirement is considered acceptable according to the "Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and the renewal of approval of the chemical active substance according to regulation (EU) No. 283/2013 and regulation (EU) No. 284/2013" (SANCO/10181/2013-rev.2 of 2-May-2013).

CA 6.5 Effects of processing

CA 6.5.1 Nature of the residue

Residues in products of plant or animal origin subject to processing were showed to be <0.01 mg/kg for isoxaflutole and also for RPA 202248. Therefore studies on the nature of residues in processed commodities are not required and were not conducted.

CA 6.5.2 Distribution of the residue in peel and pulp

This point is not relevant for the supported representative uses.

CA 6.5.3 Magnitude of residues in processed commodities

A processing study was previously evaluated (KCA 6.5.3/01).

The new residue trials show that residue levels of isoxaflutole in products of plant or animal origin subject to processing are expected to be less than 0.1 mg/kg, actually < 0.02 mg/kg (sum of isoxaflutole and RPA 202248). Besides, the commodities under consideration contribute by much less than 10% to the theoretical maximum daily intake (TMDI) for any European consumer group diet.

Therefore, studies on the magnitude of residues in processed commodities are not required.

CA 6.6 Residues in rotational crops

CA 6.6.1 Metabolism in rotational crops

KCA 6.6.01 and /02. No additional studies available.



CA 6.6.2 Magnitude of residues in rotational crops

The metabolism studies on rotational crops (KCA 6.6/01 and /02) show that residues of isoxaflutole and RPA 202248 are expected to be < 0.01 mg/kg in rotational crops. Therefore studies on the magnitude of residues in rotational crops are not needed.

CA 6.7 Proposed residue definitions and maximum residue levels

CA 6.7.1 Proposed residue definitions

Plant commodities

In the original DAR for isoxaflutole, the proposed residue definition in plant commodities, for both risk assessment and enforcement, was the sum of isoxaflutole RPA 202248 and RPA 203328, expressed as isoxaflutole.

Later on, Bayer CropScience requested to exclude the metabolite RPA 203328 from the residue definitions because it is a common metabolite which may also result from the use of pyrasulfotole, an herbicide used in the United States in cereals. Moreover, from a toxicological point of view, RPA 203328 is of low concern compared to parent compound.

The evaluation report prepared by the Netherlands on this application was forwarded to EFSA in October 2008. EFSA published its reasoned opinion on the modification of the residue definition for isoxaflutole on the 03 July 2009 (EFSA Scientific Report (2009) 323, 1-26).

These residue definition changes were considered in Regulation (EC) No 459/2010. All existing EU MRLs are now established for the sum of isoxaflutole and its metabolite diketonitrile-isoxaflutole (RPA 202248), expressed as isoxaflutole.

It is proposed that residue definitions, for risk assessment and enforcement, remain unchanged, i.e. **sum of isoxaflutole and RPA 202248, expressed as isoxaflutole.**

Animal commodities

In the original DAR for isoxaflutole, the proposed residue definition in animal commodities, for both risk assessment and enforcement, was the sum of the parent compound isoxaflutole and its metabolite RPA 202248.

It is proposed that these residue definitions remain unchanged, i.e. **sum of isoxaflutole and RPA 202248, expressed as isoxaflutole.**



CA 6.7.2 Proposed MRLs and justification of the acceptability of the levels proposed

The EU MRLs for isoxaflutole were published in Annex II and Annex III Part B of the Regulation (EC) No. 396/2005 via the Regulation (EC) No. 149/2008 (see EU MRLs for the crops supported in this dossier in [Table 6.7.2 - 1](#)). This regulation states an MRL of 0.05 mg/kg for sweet corn and maize. This was based on the residue definition of the sum of isoxaflutole, RPA 202248 and RPA 203328, expressed as isoxaflutole. No MRLs were set for animal commodities.

Table 6.7.2 - 1: EU MRLs for the uses of isoxaflutole

Crop / animal commodities	EU MRL (mg/kg) Regulation (EC) No. 396/2005	EU MRL proposed by EFSA (mg/kg) EFSA Journal 2013; 11(2):3123	STMR (mg/kg) ^(a)	HR (mg/kg) ^(a)
Sweet corn	0.05	0.02 (*)	<0.02	<0.02
Maize grain	0.05 (*)	0.02 (*)	<0.02	<0.02
Animal commodities	-	-	-	-

(*) Indicates that the MRL is set at the limit of analytical quantification.

^(a) Based on new residue trials data, calculated as the sum of isoxaflutole and RPA 202248, expressed as isoxaflutole

In the EFSA Reasoned Opinion (EFSA Scientific Report (2009) 323, dated 3 July 2009), it was then indicated that the residue definition could be changed to the sum of isoxaflutole and RPA 202248, expressed as isoxaflutole, and that in view of this fact and of the increased sensitivity of the method, MRLs established at the LOQ could be set at 0.02 mg/kg. The change of residue definition was implemented by the Regulation (EC) No. 459/2010 but the EU MRLs for isoxaflutole were not changed.

On 25 February 2013, EFSA provided a second reasoned opinion on isoxaflutole, reviewing all the existing MRLs for isoxaflutole, according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2013; 11(2):3123). The recommended MRLs are not yet implemented by a European Regulation. The EU MRLs for isoxaflutole remain the same as in the Regulation (EC) No. 149/2008.

The new residue studies presented in this renewal dossier show that total residues of isoxaflutole and RPA 202248, expressed as isoxaflutole remain below the current EU MRLs of 0.05 mg/kg for sweet corn and maize.

Based on the new data, the MRLs for sweet corn and maize grain could be lowered to 0.02 mg/kg (the LOQ level of the method) as described in EFSA reasoned opinion of 25 February 2013 (EFSA Journal 2013; 11(2):3123).

If MRLs on animal commodities needed to be implemented, it is proposed that they are set at 0.02 mg/kg (the LOQ level of the method), in accordance with the proposed residue definition and in accordance with the LOQ of the proposed enforcement method.



CA 6.7.3 Proposed MRLs and justification of the acceptability of the levels proposed for imported products (import tolerance)

MRL settings based on imported products are not proposed with this dossier.

CA 6.8 Proposed safety intervals

There is no need to propose safety intervals.

CA 6.9 Estimation of the potential and actual exposure through diet and other sources

Acceptable Daily Intake (ADI) and Dietary Exposure Calculation

In order to evaluate the potential chronic exposure to isoxaflutole residues through the diet, the Theoretical Maximum Dietary Intakes (TMDI) were calculated using:

- The EFSA PRIMo model (revision 2). For the evaluation of the chronic exposure the model uses 5 WHO diets relevant to the EU and 23 national diets from 13 different EU Member States.
- An ADI of 0.02 mg/kg bw/day
- The current EU MRLs of 0.05 mg/kg for maize grain and sweet corn
- As a worse case, MRLs of 0.02 mg/kg for animal commodities were considered

For animal commodities, calculations were made using the lowest aggregation level of food commodities meaning that in the spreadsheet the MRLs were not entered at commodity group levels (e.g. “milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curds”) but at individual crop levels (e.g. “milk and milk products Cattle”, “milk and milk products Sheep” etc...).

As shown in [Table 6.9 - 1](#), the highest TMDI represents **3.4% of the ADI** and was calculated for the NL child diet.

Therefore, a long-term intake of residues of isoxaflutole is unlikely to present a public health concern.

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Table 6.9 - 1: TMDI calculations using proposed MRLs and the EFSA model (rev 2.0)

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Isoxaflutole	
Status of the active substance:	Code no.
LOQ (mg/kg bw):	proposed LOQ:
Toxicological end points	
ADI (mg/kg bw/day):	0,02
Source of ADI:	ARID (mg/kg bw):
Year of evaluation:	Year of evaluation:

Prepare workbook for refined calculations

Undo refined calculations

Explain choice of toxicological reference values.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

		TMDI (range) in % of ADI							
		minimum - maximum							
No of diets exceeding ADI:									
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity group of commodities	2nd contributor (in % of ADI)	Commodity group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity group of commodities	pTMRLs at LOQ (in % of ADI)	
3.4	NL child	2.9	Milk and milk products: Cattle	0.2	Swine: Meat	0.1	Bovine: Meat		
2.7	FR infant	2.6	Milk and milk products: Cattle	0.1	Bovine: Meat	0.1	Poultry: Meat		
1.8	ES child	1.2	Milk and milk products: Cattle	0.1	Bovine: Meat	0.1	Poultry: Meat		
1.7	DE child	1.4	Milk and milk products: Cattle	0.1	Eggs: Chicken	0.1	Poultry: Meat		
1.3	SE general population 90th percentile	1.2	Milk and milk products: Cattle	0.1	Eggs: Chicken	0.0	Sweet corn		
1.3	WHO Cluster diet B	0.6	Maize	0.3	Milk and milk products: Cattle	0.1	Poultry: Meat		
1.2	IE adult	0.6	Maize	0.3	Milk and milk products: Cattle	0.1	Other swine products		
1.0	WHO regional European diet	0.5	Milk and milk products: Cattle	0.1	Swine: Meat	0.1	Bovine: Meat		
0.9	NL general	0.7	Milk and milk products: Cattle	0.1	Swine: Meat	0.1	Bovine: Meat		
0.8	WHO cluster diet D	0.5	Milk and milk products: Cattle	0.1	Maize	0.1	Bovine: Meat		
0.8	WHO cluster diet E	0.3	Milk and milk products: Cattle	0.1	Maize	0.1	Poultry: Meat		
0.8	ES adult	0.5	Milk and milk products: Cattle	0.1	Bovine: Meat	0.0	Swine: Meat		
0.8	WHO Cluster diet F	0.4	Milk and milk products: Cattle	0.1	Swine: Meat	0.0	Bovine: Meat		
0.6	LT adult	0.4	Milk and milk products: Cattle	0.1	Swine: Meat	0.0	Eggs: Chicken		
0.4	FR all population	0.3	Milk and milk products: Cattle	0.1	Poultry: Meat	0.1	Bovine: Meat		
0.4	FR toddler	0.1	Bovine: Meat	0.1	Eggs: Chicken	0.1	Poultry: Meat		
0.3	UK Infant	0.3	Maize	0.0	Bovine: Liver	0.0	Sweet corn		
0.1	PT General population	0.1	Maize	0.0	FRUIT (FRESH OR FROZEN)	0.0	FRUIT (FRESH OR FROZEN)		
0.1	DK adult	0.1	Bovine: Meat	0.0	Bovine: Liver	0.0	Sweet corn		
0.0	DK child	0.0	Sweet corn	0.0	Bovine: Liver	0.0	FRUIT (FRESH OR FROZEN)		
0.0	UK vegetarian	0.0	Sweet corn	0.0	Poultry: Meat	0.0	Maize		
0.0	UK Toddler	0.0	Sweet corn	0.0	Maize	0.0	Bovine: Liver		
0.0	IT kids/toddler	0.0	Maize	0.0	Sweet corn	0.0	FRUIT (FRESH OR FROZEN)		
0.0	UK Adult	0.0	Sweet corn	0.0	Other bovine products	0.0	Bovine: Liver		
0.0	IT adult	0.0	Maize	0.0	Sweet corn	0.0	FRUIT (FRESH OR FROZEN)		
0.0	FI adult	0.0	Maize	0.0	FRUIT (FRESH OR FROZEN)	0.0	FRUIT (FRESH OR FROZEN)		
0.0	PL general population	0.0	Maize	0.0	FRUIT (FRESH OR FROZEN)	0.0	FRUIT (FRESH OR FROZEN)		

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Isoxaflutole is unlikely to present a public health concern.

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Acute Reference Dose (ARfD) and Dietary Exposure Calculation

In order to evaluate the potential acute exposure to isoxaflutole residues through the diet, the International Estimated Short Term Intakes (IESTI) were calculated using:

- The EFSA PRIMo model (revision 2). For the evaluation of the acute exposure 19 national diets from 11 different EU Member States are used.
- An ARfD of 0.1 mg/kg bw/day
- The current EU MRLs of 0.05 mg/kg for maize grain and sweet corn
- As a worse case, MRLs of 0.02 mg/kg for animal commodities were considered

For animal commodities, calculations were made using the lowest aggregation level of food commodities meaning that in the spreadsheet the MRLs were not entered at commodity group levels (e.g. “milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curds”) but at individual crop levels (e.g. “milk and milk products Cattle”, “milk and milk products Sheep”, etc....).

As shown in [Table 6.9 - 2](#), the highest IESTI represents **3.9% of the ARfD** and was calculated for sweet corn consumed by children.

Therefore, a short-term intake of residues of isoxaflutole is unlikely to present a public health concern.

CA 6.10 Other studies

No further residue studies are needed in support of the representative use of isoxaflutole on maize and sweet corn.

CA 6.10.1 Effect on the residue level in pollen and bee products

The effect on the residue level in pollen and bee products was not studied because maize and sweet corn are not used to produce pure blossom honey.

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Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

Table 6.9 - 2: IESTI calculations using proposed MRLs and the EFSA model (rev 2.0)

Acute risk assessment /children				Acute risk assessment / adults - general population											
The acute risk assessment is based on the ARID.															
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.															
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.															
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.															
Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100 % of the ARID.															
Unprocessed commodities	No of commodities for which ARID/ADI is exceeded (IESTI 1):			No of commodities for which ARID/ADI is exceeded (IESTI 2):			No of commodities for which ARID/ADI is exceeded (IESTI 1):			No of commodities for which ARID/ADI is exceeded (IESTI 2):					
	---			---			---			---					
	IESTI 1	*)	**) (**)	IESTI 2	*)	**) (**)	IESTI 1	*)	**) (**)	IESTI 2	*)	**) (**)			
Highest % of ARID/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARID/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARID/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARID/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)				
3.7	Sweet corn	0,05 / -	2,6	Sweet corn	0,05 / -	1,1	Sweet corn	0,05 / -	0,8	Sweet corn	0,05 / -				
2,5	Milk and milk	0,02 / -	2,5	Milk and milk	0,02 / -	0,3	Milk and milk	0,02 / -	0,2	Milk and milk products: Cattle	0,02 / -				
0,5	Milk and milk	0,02 / -	0,5	Milk and milk	0,02 / -	0,2	Poultry: Meat	0,02 / -	0,2	Poultry: Meat	0,02 / -				
0,3	Maize	0,05 / -	0,3	Maize	0,05 / -	0,1	Milk and milk	0,02 / -	0,1	Milk and milk products: Goat	0,02 / -				
0,3	Bovine: Meat	0,02 / -	0,3	Bovine: Meat	0,02 / -	0,1	Bovine: Meat	0,02 / -	0,1	Bovine: Meat	0,02 / -				
0,2	Poultry: Meat	0,02 / -	0,2	Poultry: Meat	0,02 / -	0,1	Maize	0,05 / -	0,1	Maize	0,05 / -				
0,2	Sheep: Meat	0,02 / -	0,2	Sheep: Meat	0,02 / -	0,1	Swine: Meat	0,02 / -	0,1	Swine: Meat	0,02 / -				
0,2	Swine: Meat	0,02 / -	0,2	Swine: Meat	0,02 / -	0,1	Sheep: Meat	0,02 / -	0,1	Sheep: Meat	0,02 / -				
0,2	Bovine: Liver	0,02 / -	0,2	Bovine: Liver	0,02 / -	0,1	Poultry: Liver	0,02 / -	0,1	Poultry: Liver	0,02 / -				
0,1	Bovine: Edible offal	0,02 / -	0,1	Bovine: Edible offal	0,02 / -	0,1	Bovine: Edible offal	0,02 / -	0,1	Bovine: Edible offal	0,02 / -				
0,1	Horse: Meat	0,02 / -	0,1	Horse: Meat	0,02 / -	0,1	Bovine: Liver	0,02 / -	0,1	Bovine: Liver	0,02 / -				
0,1	Other farm animals: Meat	0,02 / -	0,1	Other farm animals: Meat	0,02 / -	0,0	Other farm animals: Meat	0,02 / -	0,0	Other farm animals: Meat	0,02 / -				
0,1	Bovine: Kidney	0,02 / -	0,1	Bovine: Kidney	0,02 / -	0,0	Bovine: Kidney	0,02 / -	0,0	Bovine: Kidney	0,02 / -				
0,0	Bovine: Fat	0,02 / -	0,0	Bovine: Fat	0,02 / -	0,0	Milk and milk	0,02 / -	0,0	Milk and milk products: Sheep	0,02 / -				
0,0	Milk and milk	0,02 / -	0,0	Milk and milk	0,02 / -	0,0	Goat: Meat	0,02 / -	0,0	Goat: Meat	0,02 / -				
0,0	Swine: Kidney	0,02 / -	0,0	Swine: Kidney	0,02 / -	0,0	Swine: Fat free of lean meat	0,02 / -	0,0	Swine: Fat free of lean meat	0,02 / -				
0,0	Swine: Fat free of lean meat	0,02 / -	0,0	Swine: Fat free of lean meat	0,02 / -	0,0	Swine: Kidney	0,02 / -	0,0	Swine: Kidney	0,02 / -				
No of critical MRLs (IESTI 1)				No of critical MRLs (IESTI 2)				No of critical MRLs (IESTI 1)				No of critical MRLs (IESTI 2)			
---				---				---				---			
Processed commodities	No of commodities for which ARID/ADI is exceeded:			No of commodities for which ARID/ADI is exceeded:			No of commodities for which ARID/ADI is exceeded:			No of commodities for which ARID/ADI is exceeded:					
	---			---			---			---					
	Highest % of ARID/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARID/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARID/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARID/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
0,2	Maize flour	0,05 / -	0,2	Maize flour	0,05 / -	0,2	Maize flour	0,05 / -	0,2	Maize flour	0,05 / -				
<p>*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARID is exceeded for more than 5 commodities, all IESTI values > 90% of ARID are reported.</p> <p>**) pTMRL: provisional temporary MRL</p> <p>**) pTMRL: provisional temporary MRL for unprocessed commodity</p>															
<p>Conclusion:</p> <p>For Isoxaflutole IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.</p> <p>No exceedance of the ARID/ADI was identified for any unprocessed commodity.</p> <p>For processed commodities, no exceedance of the ARID/ADI was identified.</p>															



Appendix

Tier 1 summary forms

Isoxaflutole & Cyprosulfamide SC 480 129

Thiencarbazone-methyl & Isoxaflutole & Cyprosulfamide SC 465 129

Isoxaflutole & Cyprosulfamide SC 480 followed by Thiencarbazone-methyl & Cyprosulfamide SC 450 129

Note : AE B197555 = RPA 203328
 AE 0540092 = RPA 202248

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Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

Isoxaflutole & Cyprosulfamide SC 480

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany
Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC
Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole
Crop/Crop Group : Corn, maize
Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	g a.s./hL						
RA-2587/05 R 2005 0623 6 0623-05 Germany D-[REDACTED] [REDACTED] 2005	Maize/Corn Romario	1) 02.05.2005 2) 20.07.2005 - 30.07.2005 3) 01.10.2005 - 01.11.2005	SPI	0.1008	300	0.03360	31.05.2005-0	3 leaves unfolded	green material ear without husk kernel rest of plant cob, corn	2.2 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 41 78 111 78 127 78 111 127	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatments/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2587/05 R 2005 0958 8 0958-05 France F-[redacted] 2005	Maize/Corn SURTEP	1) 28.05.2005 2) 30.07.2005 - 10.08.2005 3) 15.10.2005 - 25.10.2005	SPI	0.1000	3000	0.03360	15.06.2005/0	4 leaves unfolded	green material ear without husk kernel rest of plant cob, corn	2.7 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 40 71 83 71 83 127 71 83 127	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole
RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

 Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
 Country : Germany

 Content of active substance (g/kg or g/L) : 240 g/L
 Formulation (e.g. WP) : 480 SC

 Commercial product (name) : AE B197278 05 SC41 A1
 Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

 Indoor/outdoor : Outdoor
 Other a.s. in formulation (common name and content) : AE0001789 240 g/L

 Residues determined as : isoxaflutole
 Residues calculated as : isoxaflutole

1	2	3	4	5			6	7	8	9	10	11
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
Study Trial No.; Trial SubID Location incl. postal code	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Method of treatment	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date/	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	DALT/ PHI (days)	Remarks
Year of Trial	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)
RA-2587/05 R 2005 0959 6 0959-05 United Kingdom GB-[REDACTED] [REDACTED] 2005	Maize/Corn RK210	1) 23.05.2005 2) 25.07.2005 - 10.08.2005 3) 10.10.2005 - 02.12.2005	SPI	0.1000	3000	0.03360	08.06.2005/0	3 leaves unfolded	green material ear without husk kernel rest of plant cob, corn	3.2 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 40 103 124 103 124 148 148	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg

 (a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc/overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2587/05 R 2005 0961 8 0961-05 Germany D. [redacted] [redacted] 2005	Maize/Corn Egrin (FAO220)	1) 29.04.2005 2) 22.07.2005 - 02.08.2005 3) 06.10.2005 - 21.10.2005	SPI	0.1000	3000	0.03360	31.05.2005/0	3 leaves unfolded	green material	2.9 <0.01	0 41	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	90 112	
									kernel	<0.01 <0.01	90 128	
									rest of plant	<0.01 <0.01 <0.01	90 112 128	
									cob, corn	<0.01	128	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

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Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2587/05 R 2005 0962 6 0962-05 Netherlands NL-[REDACTED] [REDACTED] 2005	Maize/Corn Rosalie	1) 19.05.2005 2) 25.07.2005 - 19.08.2005 3) 28.09.2005 - 10.11.2005	SPI	0.1000	3000	0.03360	06.06.2005/0	3 leaves unfolded	green material ear without husk kernel rest of plant cob, corn	1.1 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 40 116 128 116 143 116 128 143 143	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



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Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE B197555
Residues calculated as : AE B197555

1	2	3	4	5			6	7	8	9	10	11
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
Study Trial No.; Trial SubID Location incl. postal code	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Method of treatment	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date/	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	DALT/ PHI (days)	Remarks
Year of Trial	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)
RA-2587/05 R 2005 0623 6 0623-05 Germany D. [redacted] [redacted] 2005	Maize/Corn Romario	1) 02.05.2005 2) 20.07.2005 - 30.07.2005 3) 01.10.2005 - 01.11.2005	SPI	0.1000	3000	0.03360	31.05.2005/0	3 leaves unfolded	green material ear without husk kernel rest of plant cob, corn	<0.01 0.03 <0.01 <0.01 0.03 0.03 0.03 <0.01	0 41 78 111 78 111 127 78	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc/overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



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Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE B197555
Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2587/05 R 2005 0958 8 0958-05 France F-[redacted] 2005	Maize/Corn SURTEP	1) 28.05.2005 2) 30.07.2005 - 10.08.2005 3) 15.10.2005 - 25.10.2005	SPI	0.1000	3000	0.03360	15.06.2005/0	4 leaves unfolded green material	<0.01 0.03	0 40	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01 <0.01	71 83		
								kernel	<0.01 <0.01	71 127		
								rest of plant	0.04 0.04 0.04	71 83 127		
								cob, corn	<0.01	127		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE B197555
Residues calculated as : AE B197555

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)	DALT/ PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2587/05 R 2005 0959 6 0959-05 United Kingdom GB-[REDACTED] [REDACTED] 2005	Maize/Corn RK210	1) 23.05.2005 2) 25.07.2005 - 10.08.2005 3) 10.10.2005 - 02.12.2005	SPI	0.1000	3000	0.03360	08.06.2005/0	3 leaves unfolded	green material	<0.01 0.02	0 40	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	103 124	
									kernel	<0.01 <0.01	103 148	
									rest of plant	0.02 0.02 0.02	103 124 148	
									cob, corn	<0.01	148	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc/overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L

Residues determined as : AE B197555
Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2587/05 R 2005 0961 8 0961-05 Germany D. [redacted] [redacted] 2005	Maize/Corn Egrin (FAO220)	1) 29.04.2005 2) 22.07.2005 - 02.08.2005 3) 06.10.2005 - 21.10.2005	SPI	0.1000	3000	0.03360	31.05.2005/0	3 leaves unfolded	green material ear without husk kernel rest of plant cob, corn	<0.01 0.01 <0.01 0.01 0.01 0.01 0.04 0.03 0.02 <0.01	0 41 90 112 90 128 90 112 128 128	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE B197555
Residues calculated as : AE B197555

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)	DALT/ PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2587/05 R 2005 0962 6 0962-05 Netherlands NL-[redacted] [redacted] 2005	Maize/Corn Rosalie	1) 19.05.2005 2) 25.07.2005 - 19.08.2005 3) 28.09.2005 - 10.11.2005	SPI	0.1000	3000	0.03360	06.06.2005/0	3 leaves unfolded	green material	<0.01 <0.01	0 40	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	116 128	
									kernel	<0.01 <0.01	116 143	
									rest of plant	<0.01 <0.01 <0.01 <0.01	116 128 143 143	
									cob, corn	<0.01	143	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L

Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment (kg a.s./ha, Water (L/ha), kg a.s./HL)			6 Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2587/05 R 2005 0623 6 0623-05 Germany D. [redacted] [redacted] 2005	Maize/Corn Romario	1) 02.05.2005 2) 20.07.2005 - 30.07.2005 3) 01.10.2005 - 01.11.2005	SPI	0.1000	3000	0.03360	31.05.2005/0	3 leaves unfolded	green material ear without husk kernel rest of plant cob, corn	0.71 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 41 78 111 78 127 78 111 127 127	(c) SPI: Spraying (g) 00985/M001 (h) 0.01 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L

Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment (d)			6 Dates of treatments/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2587/05 R 2005 0958 8 0958-05 France F-[redacted] 2005	Maize/Corn SURTEP	1) 28.05.2005 2) 30.07.2005 - 10.08.2005 3) 15.10.2005 - 25.10.2005	SPI	0.1000	3000	0.03360	15.06.2005/0	4 leaves unfolded	green material	0.64 <0.01	0 40	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	71 83	
									kernel	<0.01 <0.01	71 127	
									rest of plant	<0.01 <0.01 <0.01	71 83 127	
									cob, corn	<0.01	127	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment (d)			6 Dates of treatments/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2587/05 R 2005 0959 6 0959-05 United Kingdom GB-[REDACTED] [REDACTED] 2005	Maize/Corn RK210	1) 23.05.2005 2) 25.07.2005 - 10.08.2005 3) 10.10.2005 - 02.12.2005	SPI	0.1000	3000	0.03360	08.06.2005/0	3 leaves unfolded	green material	0.53 <0.01	0 40	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	103 124	
									kernel	<0.01 <0.01	103 148	
									rest of plant	<0.01 <0.01 <0.01 <0.01	103 124 148 148	
									cob, corn	<0.01	148	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc/overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole
RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

 Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
 Country : Germany

 Content of active substance (g/kg or g/L) : 240 g/L
 Formulation (e.g. WP) : 480 SC

 Commercial product (name) : AE B197278 05 SC41 A1
 Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

 Indoor/outdoor : Outdoor
 Other a.s. in formulation (common name and content) : AE 0001789 240 g/L

 Residues determined as : AE 0540092
 Residues calculated as : AE 0540092

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)	DALT/ PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2587/05 R 2005 0961 8 0961-05 Germany D [REDACTED] [REDACTED] 2005	Maize/Corn Egrin (FAO220)	1) 29.04.2005 2) 22.07.2005 - 02.08.2005 3) 06.10.2005 - 21.10.2005	SPI	0.1000	3000	0.03360	31.05.2005/0	3 leaves unfolded	green material	1.0 <0.01	0 41	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	90 112	
									kernel	<0.01 <0.01	90 128	
									rest of plant	<0.01 <0.01 <0.01 <0.01	90 112 128 128	
									cob, corn	<0.01	128	

(a) According to Codex (or other e.g. EU) Classification/Guide

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatments/ Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)	DALT/ PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2587/05 R 2005 0962 6 0962-05 Netherlands NL-[redacted] [redacted] 2005	Maize/Corn Rosalie	1) 19.05.2005 2) 25.07.2005 - 19.08.2005 3) 28.09.2005 - 10.11.2005	SPI	0.1000	3000	0.03360	06.06.2005/0	3 leaves unfolded	green material ear without husk kernel rest of plant cob, corn	0.20 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 40 116 128 116 143 116 128 143 143	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : Isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001780240 g/L

Residues determined as : Isoxaflutole
Residues calculated as : Isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (f)	9 Residues (mg/kg)	10 DALT/ PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./L						
RA-2588/05 R 2005 0624 4 0624-05 France F-[redacted] 2005	Maize/Corn PR33A46	1) 11.04.2005 2) 08.07.2005 - 18.07.2005 3) 06.10.2005 - 07.10.2005	SPI	0.1008	300	0.03360	11.05.2005/0	3 leaves unfolded	Green material	1.9 <0.01	0 40	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	83 106	
									kernel	<0.01 <0.01	83 148	
									rest of plant	<0.01 <0.01 <0.01	83 106 148	
									cob, corn	<0.01	148	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatments/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2588/05 R 2005 0963 4 0963-05 Spain E-[redacted] 2005	Maize/Corn DKc6575	1) 25.03.2005 2) 01.07.2005 - 20.07.2005 3) 15.09.2005 - 25.09.2005	SPI	0.1000	3000	0.03360	27.04.2005/0	3 leaves unfolded	green material	4.9 <0.01	0 40	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	84 98	
									kernel	<0.01 <0.01	84 141	
									rest of plant	<0.01 <0.01 <0.01	84 98 141	
									cob, corn	<0.01	141	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc/overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatments/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2588/05 R 2005 0964 2 0964-05 Italy [redacted] 2005	Maize/Corn DK 440	1) 05.04.2005 2) 01.07.2005 - 25.07.2005 3) 25.08.2005 - 25.09.2005	SPI	0.1000	3000	0.03360	04.05.2005/0	3 leaves unfolded	green material	3.7 <0.01	0 40	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	79 93	
									kernel	<0.01 <0.01	79 128	
									rest of plant	<0.01 <0.01 <0.01	79 93 128	
									cob, corn	<0.01	128	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(j) Missing data in the above columns occurs where the information is not available in the original report

(k) ...



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatments/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2588/05 R 2005 0965 0 0965-05 Greece GR - [redacted] [redacted] 2005	Maize/Corn Decalp 743	1) 27.04.2005 2) 13.07.2005 - 27.07.2005 3) 28.09.2005 - 29.09.2005	SPI	0.1000	3000	0.03360	09.05.2005/0	3 leaves unfolded	green material	4.5 <0.01	0 39	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	77 105	
									kernel	<0.01 <0.01	77 137	
									rest of plant	<0.01 <0.01 <0.01	77 105 137	
									cob, corn	<0.01	137	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2588/05 R 2005 0966 9 0966-05 Portugal P-[redacted] 2005	Maize/Corn PR N 43	1) 14.04.2005 2) 01.07.2005 - 15.07.2005 3) 01.09.2005 - 30.09.2005	SPI	0.1000	3000	0.03360	03.05.2005/0	3 leaves unfolded	green material ear without husk kernel rest of plant cob, corn	3.0 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 41 80 100 80 100 133 133	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc/overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG,
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE B197555
Residues calculated as : AE B197555

Table with 11 columns: 1 Study Trial No.; 2 Commodity / Variety; 3 Date of 1) Sowing or planting; 2) Flowering; 3) Harvest; 4 Method of treatment; 5 Application rate per treatment; 6 Dates of treatment(s)/ Application interval; 7 Growth stage at last treatment; 8 Portion analysed; 9 Residues (mg/kg); 10 DALT/ PHI (days); 11 Remarks.

- (a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE B197555
Residues calculated as : AE B197555

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)	DALT/ PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2588/05 R 2005 0963 4 0963-05 Spain E-[redacted] 2005	Maize/Corn DKc6575	1) 25.03.2005 2) 01.07.2005 - 20.07.2005 3) 15.09.2005 - 25.09.2005	SPI	0.1000	3000	0.03360	27.04.2005/0	3 leaves unfolded	green material ear without husk kernel rest of plant cob, corn	0.02 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 40 84 98 84 98 141	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg day 0: c=0.01 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE B197555
Residues calculated as : AE B197555

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)	DALT/ PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2588/05 R 2005 0964 2 0964-05 Italy [redacted] 2005	Maize/Corn DK 440	1) 05.04.2005 2) 01.07.2005 - 25.07.2005 3) 25.08.2005 - 25.09.2005	SPI	0.1000	3000	0.03360	04.05.2005/0	3 leaves unfolded	green material	<0.01 <0.01	0 40	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	79 93	
									kernel	<0.01 <0.01	79 128	
									rest of plant	<0.01 <0.01 <0.01 <0.01	79 93 128 128	
									cob, corn	<0.01	128	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc/overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE B197555
Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatments/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2588/05 R 2005 0965 0 0965-05 Greece GR - [redacted] 2005	Maize/Corn Decalp 743	1) 27.04.2005 2) 13.07.2005 - 27.07.2005 3) 28.09.2005 - 29.09.2005	SPI	0.1000	3000	0.03360	09.05.2005/0	3 leaves unfolded green material	<0.01 0.01	0 39	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01 <0.01	77 105		
								kernel	<0.01 0.02	77 137		
								rest of plant	<0.01 <0.01 0.01	77 105 137		
								cob, corn	<0.01	137		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(j) Missing data in the above columns occurs where the information is not available in the original report

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Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE B197555
Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment (d)			6 Dates of treatments/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2588/05 R 2005 0966 9 0966-05 Portugal P-[REDACTED] 2005	Maize/Corn PR N 43	1) 14.04.2005 2) 01.07.2005 - 15.07.2005 3) 01.09.2005 - 30.09.2005	SPI	0.1000	3000	0.03360	03.05.2005/0	3 leaves unfolded	green material	<0.01 <0.01	0 41	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	80 100	
									kernel	<0.01 <0.01	80 133	
									rest of plant	0.01 0.02 0.03	80 100 133	
									cob, corn	<0.01	133	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole
RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

 Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
 Country : Germany

 Content of active substance (g/kg or g/L) : 240 g/L
 Formulation (e.g. WP) : 480 SC

 Commercial product (name) : AE B197278 05 SC41 A1
 Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

 Indoor/outdoor : Outdoor
 Other a.s. in formulation (common name and content) : AE0001789 240 g/L

 Residues determined as : AE 0540092
 Residues calculated as : AE 0540092

1	2	3	4	5			6	7	8	9	10	11
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
Study Trial No.; Trial SubID Location incl. postal code	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Method of treatment	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date/	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	DALT/ PHI (days)	Remarks
Year of Trial	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)
RA-2588/05 R 2005 0624 4 0624-05 France F-[REDACTED] 2005	Maize/Corn PR33A46	1) 11.04.2005 2) 08.07.2005 - 18.07.2005 3) 06.10.2005 - 07.10.2005	SPI	0.1000	3000	0.03360	11.05.2005/0	3 leaves unfolded	green material ear without husk kernel rest of plant cob, corn	0.46 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 40 83 106 83 148 83 106 148 148	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg

 (a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2588/05 R 2005 0963 4 0963-05 Spain E-[redacted] 2005	Maize/Corn DKc6575	1) 25.03.2005 2) 01.07.2005 - 20.07.2005 3) 15.09.2005 - 25.09.2005	SPI	0.1000	3000	0.03360	27.04.2005/0	3 leaves unfolded	green material	0.71 <0.01	0 40	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	84 98	
									kernel	<0.01 <0.01	84 141	
									rest of plant	<0.01 <0.01 <0.01	84 98 141	
									cob, corn	<0.01	141	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

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Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatments/ Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2588/05 R 2005 0964 2 0964-05 Italy [redacted] 2005	Maize/Corn DK 440	1) 05.04.2005 2) 01.07.2005 - 25.07.2005 3) 25.08.2005 - 25.09.2005	SPI	0.1000	3000	0.03360	04.05.2005/0	3 leaves unfolded	green material	0.95 <0.01	0 40	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	79 93	
									kernel	<0.01 <0.01	79 128	
									rest of plant	<0.01 <0.01 <0.01 <0.01	79 93 128 128	
									cob, corn	<0.01	128	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(j) Missing data in the above columns occurs where the information is not available in the original report

(k) ...

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole
RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

 Responsible body for reporting (name and address) : Bayer CropScience AG, ██████████
 Country : Germany

 Content of active substance (g/kg or g/L) : 240 g/L
 Formulation (e.g. WP) : 480 SC

 Commercial product (name) : AE B197278 05 SC41 A1
 Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

 Indoor/outdoor : Outdoor
 Other a.s. in formulation (common name and content) : AE 0001789 240 g/L

 Residues determined as : AE 0540092
 Residues calculated as : AE 0540092

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)	DALT/ PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2588/05 R 2005 0965 0 0965-05 Greece GR - ██████████ ██████████ 2005	Maize/Corn Decalp 743	1) 27.04.2005 2) 13.07.2005 - 27.07.2005 3) 28.09.2005 - 29.09.2005	SPI	0.1000	3000	0.03360	09.05.2005/0	3 leaves unfolded	green material	0.34 <0.01	0 39	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg day 0: c=0.01 mg/kg
									ear without husk	<0.01 <0.01	77 105	
									kernel	<0.01 <0.01	77 137	
									rest of plant	<0.01 <0.01 <0.01	77 105 137	
									cob, corn	<0.01	137	

 (a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : AE B197278 05 SC41 A1
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE0001789 240 g/L

Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)	DALT/ PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2588/05 R 2005 0966 9 0966-05 Portugal P-[redacted] 2005	Maize/Corn PR N 43	1) 14.04.2005 2) 01.07.2005 - 15.07.2005 3) 01.09.2005 - 30.09.2005	SPI	0.1000	3000	0.03360	03.05.2005/0	3 leaves unfolded	green material	0.61 <0.01	0 41	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	80 100	
									kernel	<0.01 <0.01	80 133	
									rest of plant	<0.01 <0.01 <0.01 <0.01	80 100 133 133	
									cob, corn	<0.01	133	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

Thiencarbazone-methyl & Isoxaflutole & Cyprosulfamide SC 465

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC 465

Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
Residues determined as : AE 0001789 150 g/L
isoxaflutole

Residues calculated as : isoxaflutole

1	2	3	4	5	6	7	8	9	10	11		
Study Trial No.; Trial SubID Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Date of treatment(s)/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment	Portion analysed (a)	Residues (mg/kg)	DALT/ PHI (days) (f)	Remarks	
				kg/ha	Water (L/ha)							
RA-2510/06 R 2006 0073 9 0073-06 France [redacted] 2006	Maize/Corn Moncada	1) 12.04.2006 2) 12.07.2006 - 20.07.2006 3) 25.09.2006 - 15.10.2006	SPR	0.0990	300	0.03308	25.05.2006/0	3 leaves unfolded	green material ear without husk kernel rest of plant	7.1 <0.01 <0.01 <0.01 <0.01 <0.01	0 40 110 62 96 96 139 96	(c) SPI: Spraying (g) 00985/M001 (h) 0.01 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
465

Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L
Residues determined as : isoxaflutole

Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (f)	9 Residues (mg/kg)	10 DALT/ PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2510/06 R 2006 0795 4 0795-06 Germany D-[redacted] [redacted] 2006	Maize/Corn Romario	1) 23.05.2006 2) 15.07.2006 - 30.07.2006 3) 01.10.2006 - 01.11.2006	SPI	0.0990	300	0.03508	05.2006/0	3 leaves unfolded, green material ear without husk kernel rest of plant	6.2 0.28 <0.01 <0.01 <0.01 <0.01 <0.01	0 40 98 55 77 77 135 77	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC 465

Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
Residues determined as : AE 0001789 150 g/L
Residues determined as : isoxaflutole

Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2510/06 R 2006 0796 2 0796-06 United Kingdom GB-[REDACTED] [REDACTED] 2006	Maize/Corn Nexxos	1) 18.05.2006 2) 02.08.2006 - 20.08.2006 3) 10.10.2006 - 20.10.2006	SPI	0.0990	300	0.03508	2006.2006/0	4 leaves unfolded, green material	4.5 0.01 <0.01	0 39 106	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01 <0.01	51 93		
								kernel	<0.01 <0.01	93 123		
								rest of plant	<0.01	93		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
465

Producer of commercial product : Bayer CropScience AG

Active substance : Isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L

Residues determined as : AE B197555

Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2510/06 R 2006 0073 9 0073-06 France F-[REDACTED] 2006	Maize/Corn Moncada	1) 12.04.2006 2) 12.07.2006 - 20.07.2006 3) 25.09.2006 - 15.10.2006	SPI	0.0990	300	0.03508	12.05.2006/0	3 leaves unfolded, green material	<0.01	0	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01	62		
								kernel	<0.01	96		
								rest of plant	<0.01	139		
									<0.01	96		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
465

Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L

Residues determined as : AE B197555

Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2510/06 R 2006 0795 4 0795-06 Germany D-[redacted] 2006	Maize/Corn Romario	1) 23.05.2006 2) 15.07.2006 - 30.07.2006 3) 01.10.2006 - 01.11.2006	SPI	0.0990	300	0.03508	05.2006/0	3 leaves unfolded, green material	<0.01 0.02 0.03	0 40 98	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01 <0.01	55 77		
								kernel	<0.01 <0.01	77 135		
								rest of plant	0.02	77		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole
RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

 Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
 Country : Germany

 Content of active substance (g/kg or g/L) : 225 g/L
 Formulation (e.g. WP) : 465 SC

 Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
 465

Producer of commercial product : Bayer CropScience AG

Active substance : Isoxaflutole

Crop/Crop Group : Corn, maize

 Indoor/outdoor : Outdoor
 Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
 AE 0001789 150 g/L

Residues determined as : AE B197555

Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (f)	9 Residues (mg/kg)	10 DALT/ PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2510/06 R 2006 0796 2 0796-06 United Kingdom GB-[REDACTED] [REDACTED] 2006	Maize/Corn Nexxos	1) 18.05.2006 2) 02.08.2006 - 20.08.2006 3) 10.10.2006 - 20.10.2006	SPI	0.0990	300	0.03508	18.05.2006/0	4 leaves unfolded, green material	0.01 0.01 0.03	0 39 106	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01 <0.01	51 93		
								kernel	<0.01 <0.01	93 123		
								rest of plant	0.04	93		

 (a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
465

Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L

Residues determined as : AE 0540092

Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2510/06 R 2006 0073 9 0073-06 France F-[redacted] 2006	Maize/Corn Moncada	1) 12.04.2006 2) 12.07.2006 - 20.07.2006 3) 25.09.2006 - 15.10.2006	SPI	0.0990	300	0.03508	12.05.2006/0	3 leaves unfolded, green material	1.2 <-0.01 <-0.01	0 40 110	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<-0.01 <-0.01	62 96		
								kernel	<-0.01 <-0.01	96 139		
								rest of plant	<-0.01	96		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
465

Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L
Residues determined as : AE 0540092

Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (f)	9 Residues (mg/kg)	10 DALT/ PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2510/06 R 2006 0795 4 0795-06 Germany D [redacted] 2006	Maize/Corn Romario	1) 23.05.2006 2) 15.07.2006 - 30.07.2006 3) 01.10.2006 - 01.11.2006	SPI	0.0990	300	0.03508	05.2006/0	3 leaves unfolded, green material	1.5 0.06 <-0.01	0 40 98	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<-0.01 <-0.01	55 77		
								kernel	<-0.01 <-0.01	77 135		
								rest of plant	<-0.01	77		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
465

Producer of commercial product : Bayer CropScience AG

Active substance : Isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L

Residues determined as : AE 0540092

Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2510/06 R 2006 0796 2 0796-06 United Kingdom GB-[redacted] [redacted] 2006	Maize/Corn Nexxos	1) 18.05.2006 2) 02.08.2006 - 20.08.2006 3) 10.10.2006 - 20.10.2006	SPI	0.0990	300	0.03508	18.05.2006/0	4 leaves unfolded, green material	0.42 <-0.01 <-0.01	0 39 106	(c) SPI: Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<-0.01 <-0.01	51 93		
								kernel	<-0.01 <-0.01	93 123		
								rest of plant	<-0.01	93		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789
465

Producer of commercial product : Bayer CropScience AG

Active substance : Isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L

Residues determined as : Isoxaflutole

Residues calculated as : Isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2511/06 R 2006 0074 7 0074-06 France F-[redacted] 2006	Maize/Corn dkc4845	1) 13.04.2006 2) 15.07.2006 - 22.07.2006 3) 01.10.2006 - 14.10.2006	SPI	0.0990	300	0.0330	04.05.2006-0	3 leaves unfolded	green material	13 <-0.01 <-0.01	0 40 116	(c) SPI: Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<-0.01 <-0.01	74 98	
									kernel	<-0.01 <-0.01	98 153	
									rest of plant	<-0.01	98	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
465

Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L
Residues determined as : isoxaflutole

Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2511/06 R 2006 0797 0 0797-06 Italy I-[redacted] ([redacted]) 2006	Maize/Corn PR34 N43	1) 08.04.2006 2) 27.06.2006 - 07.07.2006 3) 30.08.2006 - 30.09.2006	SPI	0.0990	300	0.03508	05.2006/0	3 leaves unfolded, green material	5.4 <-0.01 <-0.01	0 40 88	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<-0.01 <-0.01	53 75		
								kernel	<-0.01 <-0.01	75 124		
								rest of plant	<-0.01	75		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole
RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

 Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
 Country : Germany

 Content of active substance (g/kg or g/L) : 225 g/L
 Formulation (e.g. WP) : 465 SC

 Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
 465

Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

 Indoor/outdoor : Outdoor
 Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
 AE 0001789 150 g/L
 Residues determined as : isoxaflutole

Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2511/06 R 2006 0798 9 0798-06 Spain E-[REDACTED] 2006	Maize/Corn PR33P67	1) 13.04.2006 2) 25.06.2006 - 05.07.2006 3) 15.09.2006 - 20.10.2006	SPI	0.0990	300	0.03508	05.2006/0	4 leaves unfolded, green material	7.2 <-0.01 <-0.01	0 41 77	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<-0.01 <-0.01	56 67		
								kernel	<-0.01 <-0.01	67 132		
								rest of plant	<-0.01	67		

 (a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
465

Producer of commercial product : Bayer CropScience AG

Active substance : Isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L
Residues determined as : AE B197555

Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2511/06 R 2006 0074 7 0074-06 France F-[redacted] 2006	Maize/Corn dkc4845	1) 13.04.2006 2) 15.07.2006 - 22.07.2006 3) 01.10.2006 - 14.10.2006	SPI	0.0990	300	0.03508	05.2006/0	3 leaves unfolded, green material	0.01 <0.01 <0.01	0 40 116	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01 <0.01	74 98		
								kernel	<0.01 <0.01	98 153		
								rest of plant	<0.01	98		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
465

Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L
Residues determined as : AE B197555

Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2511/06 R 2006 0797 0 0797-06 Italy [REDACTED] ([REDACTED]) 2006	Maize/Corn PR34 N43	1) 08.04.2006 2) 27.06.2006 - 07.07.2006 3) 30.08.2006 - 30.09.2006	SPI	0.0990	300	0.03508	05.2006/0	3 leaves unfolded, green material	<0.01 <0.01 <0.01	0 40 88	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01 <0.01	53 75		
								kernel	<0.01 <0.01	75 124		
								rest of plant	<0.01	75		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
465

Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L

Residues determined as : AE B197555

Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2511/06 R 2006 0798 9 0798-06 Spain E-[redacted] 2006	Maize/Corn PR33P67	1) 13.04.2006 2) 25.06.2006 - 05.07.2006 3) 15.09.2006 - 20.10.2006	SPI	0.0990	300	0.03508	10.05.2006/0	4 leaves unfolded, green material	0.01 <-0.01 <-0.01	0 41 77	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<-0.01 <-0.01	56 67		
								kernel	<-0.01 <-0.01	67 132		
								rest of plant	<-0.01	67		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
465

Producer of commercial product : Bayer CropScience AG

Active substance : Isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L

Residues determined as : AE 0540092

Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2511/06 R 2006 0074 7 0074-06 France F-[redacted] 2006	Maize/Corn dkc4845	1) 13.04.2006 2) 15.07.2006 - 22.07.2006 3) 01.10.2006 - 14.10.2006	SPI	0.0990	300	0.03508	05.2006/0	3 leaves unfolded, green material	2.6 <-0.01 <-0.01	0 40 116	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<-0.01 <-0.01	74 98		
								kernel	<-0.01 <-0.01	98 153		
								rest of plant	<-0.01	98		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
465

Producer of commercial product : Bayer CropScience AG

Active substance : Isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L
Residues determined as : AE 0540092

Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2511/06 R 2006 0797 0 0797-06 Italy [redacted] 2006	Maize/Corn PR34 N43	1) 08.04.2006 2) 27.06.2006 - 07.07.2006 3) 30.08.2006 - 30.09.2006	SPI	0.0990	300	0.03508	05.2006/0	3 leaves unfolded, green material	0.32 <-0.01 <-0.01	0 40 88	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<-0.01 <-0.01	53 75		
								kernel	<-0.01 <-0.01	75 124		
								rest of plant	<-0.01	75		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 225 g/L
Formulation (e.g. WP) : 465 SC

Commercial product (name) : BYH 18636 & Isoxaflutole & AE 0001789 SC
465

Producer of commercial product : Bayer CropScience AG

Active substance : Isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : BYH 18636 90 g/L
AE 0001789 150 g/L

Residues determined as : AE 0540092

Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (f)	9 Residues (mg/kg)	10 DALT/ PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2511/06 R 2006 0798 9 0798-06 Spain E-[REDACTED] 2006	Maize/Corn PR33P67	1) 13.04.2006 2) 25.06.2006 - 05.07.2006 3) 15.09.2006 - 20.10.2006	SPI	0.0990	300	0.03508	10.05.2006/0	4 leaves unfolded, green material	1.2 <-0.01 <-0.01	0 41 77	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<-0.01 <-0.01	56 67		
								kernel	<-0.01 <-0.01	67 132		
								rest of plant	<-0.01	67		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

Isoxaflutole & Cyprosulfamide SC 480 followed by Thiencarbazone-methyl & Cyprosulfamide SC 450

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole
Crop/Crop Group : Corn, maize
Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
Residues determined as : BY H 18636 225 g/L
Residues calculated as : AE 0001789 225 g/L
isoxaflutole
isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment		6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks	
				kg a.s./ha	Water (L/ha)							
RA-2615/06 R 2006 0627 3 0627-06 France F- [redacted] 2006	Maize/Corn Moncada	1) 12.04.2006 2) 12.07.2006 - 20.07.2006 3) 25.09.2006 15.10.2006	SPL	0.0508	300	0.03760	12.04.2006/0 (S)	8 leaves unfolded	green material	<0.01	55	(c) SPL: Spraying (g) 00985/M001 (h) 0.01 mg/kg
								ear without husk	<0.01	86		
								kernel	<0.01	120		
								rest of plant	<0.01	163		
									<0.01	120		

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.



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- (a) According to Codex (or other e.g. EU) Classification/Guide
 - (b) Only if relevant
 - (c) High or low volume spraying, spreading, dusting etc/overall broadcast
 - (d) Year must be indicated
 - (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
- Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2615/06 R 2006 0799 7 0799-06 France F-[redacted] (Centre) 2006	Maize/Corn Anasta	1) 13.04.2006 2) 10.07.2006 - 22.07.2006 3) 06.10.2006	SPI	0.1008	300	0.03360	10/4.2006/0 (SC)	8 leaves unfolded, green material	<0.01	52	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01	126		
								kernel	<0.01	89		
								rest of plant	<0.01	112		
									<0.01	179		
									<0.01	112		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (f)	9 Residues (mg/kg)	10 DALT/ PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2615/06 R 2006 0800 4 0800-06 United Kingdom GB-[REDACTED] [REDACTED] 2006	Maize/Corn Algans	1) 06.05.2006 2) 01.08.2006 - 07.08.2006 3) 22.09.2006 - 25.09.2006	SPI	0.1008	300	0.03360	05.2006/0 (SC)	8 leaves unfolded, green material	<0.01 <0.01 <0.01	46 46 87	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01 <0.01	84 101		
								kernel	<0.01 <0.01	101 124		
								rest of plant	<0.01 <0.01	101 124		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2615/06 R 2006 0801 2 0801-06 Germany D-[redacted] [redacted] 2006	Maize/Corn Bunguy	1) 04.05.2006 2) 19.07.2006 - 27.07.2006 3) 25.09.2006 - 01.10.2006	SPI	0.1008	300	0.03360	05.2006/0 (SC)	8 leaves unfolded, green material	<0.01	41	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01	71		
								kernel	<0.01	91		
								rest of plant	<0.01	140		
									<0.01	91		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) Application interval or no. of treatments and last date (e)	8 Growth stage at last treatment (g)	9 Portion analysed (h)	10 Residues (mg/kg) DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL					
RA-2615/06 R 2006 0802 0 0802-06 Germany D-[REDACTED] 2006	Maize/Corn Delitop	1) 22.04.2006 2) 15.07.2006 - 01.08.2006 3) 05.10.2006 - 30.10.2006	SPI	0.1008	300	0.03360	2004.2006/0 (SC)	8 leaves unfolded, green material ear without husk kernel rest of plant	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	45 45 85 139 80 116 116 167 116	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE B197555
Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2615/06 R 2006 0627 3 0627-06 France F-[redacted] 2006	Maize/Corn Moncada	1) 12.04.2006 2) 12.07.2006 - 20.07.2006 3) 25.09.2006 - 15.10.2006	SPI	0.1008	300	0.03360	12.04.2006/0 (SC)	8 leaves unfolded, green material	<0.01	55	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01	134		
								kernel	<0.01	86		
								rest of plant	<0.01	120		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE B197555
Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2615/06 R 2006 0799 7 0799-06 France F-[redacted] (Centre) 2006	Maize/Corn Anasta	1) 13.04.2006 2) 10.07.2006 - 22.07.2006 3) 06.10.2006	SPI	0.1008	300	0.03360	10/4.2006/0 (SC)	8 leaves unfolded, green material	0.03 0.03 <-0.01 0.02 <-0.01 <-0.01	52 52 91 126 89 112	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<-0.01 <-0.01	89 112		
								kernel	<-0.01 <-0.01	112 179		
								rest of plant	<-0.01	112		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole
RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

 Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
 Country : Germany

 Content of active substance (g/kg or g/L) : 240 g/L
 Formulation (e.g. WP) : 480 SC

 Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
 Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

 Indoor/outdoor : Outdoor
 Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
 BYH 18636 225 g/L
 AE 0001789 225 g/L
 Residues determined as : AE B197555
 Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2615/06 R 2006 0800 4 0800-06 United Kingdom GB-[REDACTED] [REDACTED] 2006	Maize/Corn Algans	1) 06.05.2006 2) 01.08.2006 - 07.08.2006 3) 22.09.2006 - 25.09.2006	SPI	0.1008	300	0.03360	05.2006/0 (SC)	8 leaves unfolded	green material	<0.01 <0.01 <0.01	46 46 87	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	84 101	
									kernel	<0.01 <0.01	101 124	
									rest of plant	<0.01 <0.01	101 124	

 (a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole
RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

 Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
 Country : Germany

 Content of active substance (g/kg or g/L) : 240 g/L
 Formulation (e.g. WP) : 480 SC

 Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
 Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

 Indoor/outdoor : Outdoor
 Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
 BYH 18636 225 g/L
 AE 0001789 225 g/L
 Residues determined as : AE B197555
 Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2615/06 R 2006 0801 2 0801-06 Germany D-[REDACTED] 2006	Maize/Corn Bunguy	1) 04.05.2006 2) 19.07.2006 - 27.07.2006 3) 25.09.2006 - 01.10.2006	SPI	0.1008	300	0.03360	05.2006/0 (SC)	8 leaves unfolded, green material	0.01	41	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01	81		
								kernel	<0.01	71		
									<0.01	91		
								rest of plant	<0.01	91		

 (a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE B197555
Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2615/06 R 2006 0802 0 0802-06 Germany D-[REDACTED] [REDACTED] 2006	Maize/Corn Delitop	1) 22.04.2006 2) 15.07.2006 - 01.08.2006 3) 05.10.2006 - 30.10.2006	SPI	0.1008	300	0.03360	2004.2006/0 (SC)	8 leaves unfolded, green material	0.02	45	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01	139		
								kernel	<0.01	80		
									<0.01	116		
								rest of plant	<0.01	116		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	7 Growth stage at last treatment (f)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (h)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2615/06 R 2006 0627 3 0627-06 France F-[redacted] 2006	Maize/Corn Moncada	1) 12.04.2006 2) 12.07.2006 - 20.07.2006 3) 25.09.2006 - 15.10.2006	SPI	0.1008	300	0.03360	12.04.2006/0 (SC)	8 leaves unfolded, green material	<0.01	55	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01	134		
								kernel	<0.01	86		
								rest of plant	<0.01	120		
									<0.01	163		
									<0.01	120		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2615/06 R 2006 0799 7 0799-06 France F-[redacted] (Centre) 2006	Maize/Corn Anasta	1) 13.04.2006 2) 10.07.2006 - 22.07.2006 3) 06.10.2006	SPI	0.1008	300	0.03360	10/4.2006/0 (SC)	8 leaves unfolded	green material	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	52 52 91 126 89 112 112 179 112	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01		
									kernel	<0.01 <0.01		
									rest of plant	<0.01		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method

(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2615/06 R 2006 0800 4 0800-06 United Kingdom GB-[REDACTED] [REDACTED] 2006	Maize/Corn Algans	1) 06.05.2006 2) 01.08.2006 - 07.08.2006 3) 22.09.2006 - 25.09.2006	SPI	0.1008	300	0.03360	05.2006/0 (SC)	8 leaves unfolded, green material	<0.01 <0.01 <0.01	46 46 87	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01 <0.01	84 101		
								kernel	<0.01 <0.01	101 124		
								rest of plant	<0.01 <0.01	101 124		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2615/06 R 2006 0801 2 0801-06 Germany D-[redacted] [redacted] 2006	Maize/Corn Bunguy	1) 04.05.2006 2) 19.07.2006 - 27.07.2006 3) 25.09.2006 - 01.10.2006	SPI	0.1008	300	0.03360	05.2006/0 (SC)	8 leaves unfolded, green material	<0.01	41	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01	71		
								kernel	<0.01	91		
								rest of plant	<0.01	140		
									<0.01	91		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2615/06 R 2006 0802 0 0802-06 Germany D-[redacted] [redacted] 2006	Maize/Corn Delitop	1) 22.04.2006 2) 15.07.2006 - 01.08.2006 3) 05.10.2006 - 30.10.2006	SPI	0.1008	300	0.03360	2004.2006/0 (SC)	8 leaves unfolded, green material	<0.01	45	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01	139		
								kernel	<0.01	80		
									<0.01	116		
								rest of plant	<0.01	116		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 0636 225 g/L
AE 0001789 225 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) Application interval or no. of treatments and last date/ (d)	7 Growth stage at last treatment (e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0628 1 0628-06 France F-[REDACTED] 2006	Maize/Corn Ferry	1) 14.04.2006 2) 06.07.2006 - 18.07.2006 3) 05.10.2006	SPI	0.1008	300	0.0336	18.04.2006/0 (SC)	8 leaves unfolded	green material	<0.01	49	(c) SPI: Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01	49	
										<0.01	90	
										<0.01	115	
									kernel	<0.01	79	
										<0.01	105	
									rest of plant	<0.01	105	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0803 9 0803-06 France F-[redacted] 2006	Maize/Corn Cécilia	1) 24.05.2006 2) 01.08.2006 - 10.08.2006 3) 04.10.2006 - 05.10.2006	SPI	0.1008	300	0.03360	2005.2006/0 (SC)	8 leaves unfolded, green material		<0.01	30	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
								ear without husk		<0.01	109	
								kernel		<0.01	64	
								rest of plant		<0.01	91	
										<0.01	91	
										<0.01	128	
										<0.01	91	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0804 7 0804-06 Spain E-[redacted] 2006	Maize/Corn PR33P67	1) 13.04.2006 2) 25.06.2006 - 05.07.2006 3) 15.09.2006 - 20.10.2006	SPI	0.1008	300	0.03360	10/4.2006/0 (SC)	8 leaves unfolded, green material	<0.01 <0.01 <0.01	48 48 99	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01 <0.01	78 89		
								kernel	<0.01 <0.01	89 154		
								rest of plant	<0.01	89		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0805 5 0805-06 Italy [redacted] 2006	Maize/Corn PR34N43	1) 08.04.2006 2) 27.06.2006 - 07.07.2006 3) 30.08.2006 - 30.09.2006	SPI	0.1008	300	0.03360	10/04.2006/0 (SC)	8 leaves unfolded	green material	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	43 43 84 113 78 100 100 149 100	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01		
									kernel	<0.01 <0.01		
									rest of plant	<0.01		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L

Residues determined as : isoxaflutole
Residues calculated as : isoxaflutole

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0806 3 0806-06 Spain E-[REDACTED] [REDACTED] 2006	Maize/Corn Constanza	1) 13.05.2006 2) 01.07.2006 - 30.07.2006 3) 01.09.2006 - 01.10.2006	SPI	0.1008	300	0.03360	13.05.2006/0 (SC)	8 leaves unfolded, green material	<0.01	32	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01	65		
								kernel	<0.01	78		
								rest of plant	<0.01	128		
									<0.01	78		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE B197555
Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	7 Growth stage at last treatment (f)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (h)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0628 1 0628-06 France F-[redacted] 2006	Maize/Corn Ferry	1) 14.04.2006 2) 06.07.2006 - 18.07.2006 3) 05.10.2006	SPI	0.1008	300	0.03360	14.04.2006/0 (SC)	8 leaves unfolded, green material	0.02 0.03 0.03 0.03	49 49 90 115	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01 <0.01	79 105		
								kernel	<0.01 <0.01	105 170		
								rest of plant	0.04	105		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE B197555
Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0803 9 0803-06 France F-[redacted] 2006	Maize/Corn Cécilia	1) 24.05.2006 2) 01.08.2006 - 10.08.2006 3) 04.10.2006 - 05.10.2006	SPI	0.1008	300	0.03360	2005.2006/0 (SC)	8 leaves unfolded, green material	<0.01	30	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01	109		
								kernel	<0.01	64		
								rest of plant	<0.01	91		
									<0.01	91		
									<0.01	128		
									<0.01	91		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE B197555
Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0804 7 0804-06 Spain E-[REDACTED] 2006	Maize/Corn PR33P67	1) 13.04.2006 2) 25.06.2006 - 05.07.2006 3) 15.09.2006 - 20.10.2006	SPI	0.1008	300	0.03360	13.04.2006/0 (SC)	8 leaves unfolded, green material	<0.01 <0.01 <0.01	48 48 99	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01 <0.01	78 89		
								kernel	<0.01 <0.01	89 154		
								rest of plant	<0.01	89		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE B197555
Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	7 Growth stage at last treatment (f)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (h)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0805 5 0805-06 Italy [redacted] 2006	Maize/Corn PR34N43	1) 08.04.2006 2) 27.06.2006 - 07.07.2006 3) 30.08.2006 - 30.09.2006	SPI	0.1008	300	0.03360	10/4.2006/0 (SC)	8 leaves unfolded	green material	<0.01	43	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01	113	
									kernel	<0.01	78	
										<0.01	100	
									rest of plant	<0.01	149	
										<0.01	100	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE B197555
Residues calculated as : AE B197555

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0806 3 0806-06 Spain E-[redacted] 2006	Maize/Corn Constanza	1) 13.05.2006 2) 01.07.2006 - 30.07.2006 3) 01.09.2006 - 01.10.2006	SPI	0.1008	300	0.03360	13.05.2006/0 (SC)	8 leaves unfolded	green material	0.01 0.01 <0.01 <0.01 <0.01 <0.01	32 32 72 86 65 78	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	78 78	
									kernel	<0.01 <0.01	78 128	
									rest of plant	<0.01	78	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

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Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0628 1 0628-06 France F-[redacted] 2006	Maize/Corn Ferry	1) 14.04.2006 2) 06.07.2006 - 18.07.2006 3) 05.10.2006	SPI	0.1008	300	0.03360	14.04.2006/0 (SC)	8 leaves unfolded, green material	<0.01	49	(c) SPI: Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01	115		
								kernel	<0.01	79		
								rest of plant	<0.01	105		
									<0.01	105		
									<0.01	170		
									<0.01	105		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

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Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0803 9 0803-06 France F-[redacted] 2006	Maize/Corn Cécilia	1) 24.05.2006 2) 01.08.2006 - 10.08.2006 3) 04.10.2006 - 05.10.2006	SPI	0.1008	300	0.03360	20.05.2006/0 (SC)	8 leaves unfolded	green material	<0.01	30	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01	109	
									kernel	<0.01	64	
										<0.01	91	
									rest of plant	<0.01	91	
										<0.01	128	
										<0.01	91	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

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Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0804 7 0804-06 Spain E-[redacted] 2006	Maize/Corn PR33P67	1) 13.04.2006 2) 25.06.2006 - 05.07.2006 3) 15.09.2006 - 20.10.2006	SPI	0.1008	300	0.03360	13.04.2006/0 (SC)	8 leaves unfolded, green material	<0.01 <0.01 <0.01	48 48 99	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	
								ear without husk	<0.01 <0.01	78 89		
								kernel	<0.01 <0.01	89 154		
								rest of plant	<0.01	89		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole
RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

 Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
 Country : Germany

 Content of active substance (g/kg or g/L) : 240 g/L
 Formulation (e.g. WP) : 480 SC

 Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
 Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

 Indoor/outdoor : Outdoor
 Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
 BYH 18636 225 g/L
 AE 0001789 225 g/L
 Residues determined as : AE 0540092
 Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0805 5 0805-06 Italy [REDACTED] 2006	Maize/Corn PR34N43	1) 08.04.2006 2) 27.06.2006 - 07.07.2006 3) 30.08.2006 - 30.09.2006	SPI	0.1008	300	0.03360	10/4.2006/0 (SC)	8 leaves unfolded, green material ear without husk kernel rest of plant	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	43 43 84 113 78 100 100 149 100	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg	

 (a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report



Document MCA: Section 6 Residues in or on treated products, food and feed
Isoxaflutole

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 240 g/L
Formulation (e.g. WP) : 480 SC

Commercial product (name) : isoxaflutole & cyprosulfamide SC 480
Producer of commercial product : Bayer CropScience AG

Active substance : isoxaflutole

Crop/Crop Group : Corn, maize

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE 0001789 240 g/L
BYH 18636 225 g/L
AE 0001789 225 g/L
Residues determined as : AE 0540092
Residues calculated as : AE 0540092

1 Study Trial No.; Trial SubID Location incl. postal code Year of Trial	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (g)	9 Residues (mg/kg)	10 DALT/ PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
RA-2616/06 R 2006 0806 3 0806-06 Spain E-[redacted] [redacted] 2006	Maize/Corn Constanza	1) 13.05.2006 2) 01.07.2006 - 30.07.2006 3) 01.09.2006 - 01.10.2006	SPI	0.1008	300	0.03360	13.05.2006/0 (SC)	8 leaves unfolded	green material	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	32 32 72 86 65 78	(c) SPI:Spraying (g) 00985/M001 (h) 0.01 mg/kg
									ear without husk	<0.01 <0.01	78 78	
									kernel	<0.01 <0.01	78 128	
									rest of plant	<0.01	78	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

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