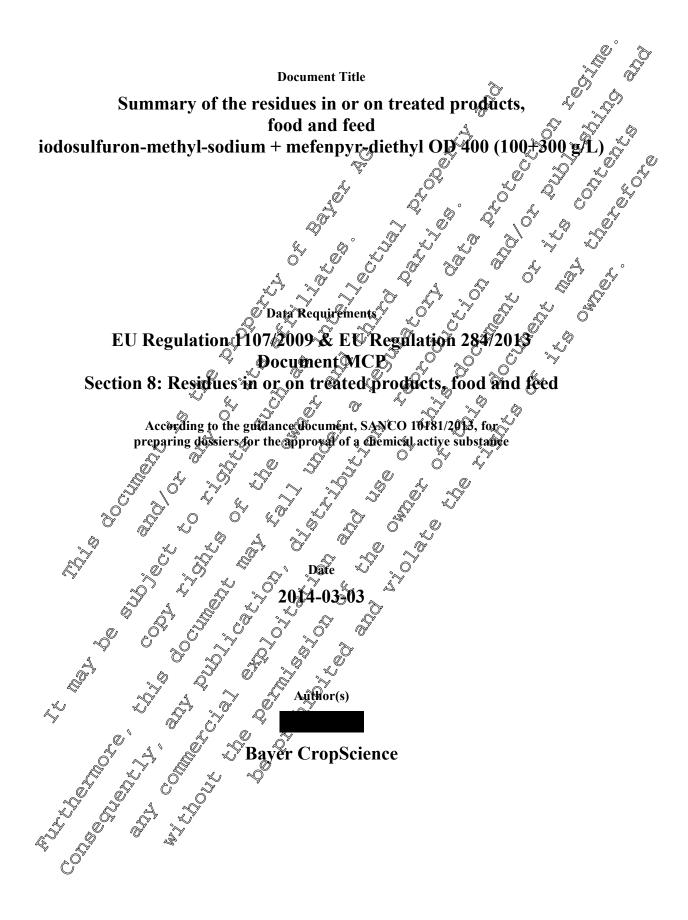


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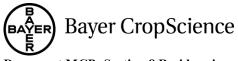
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Document MCP: Section 8 Residues in or on treated products, food and feed iodosulfuron-methyl-sodium + mefenpyr-diethyl OD 400 (100+300 g/L)

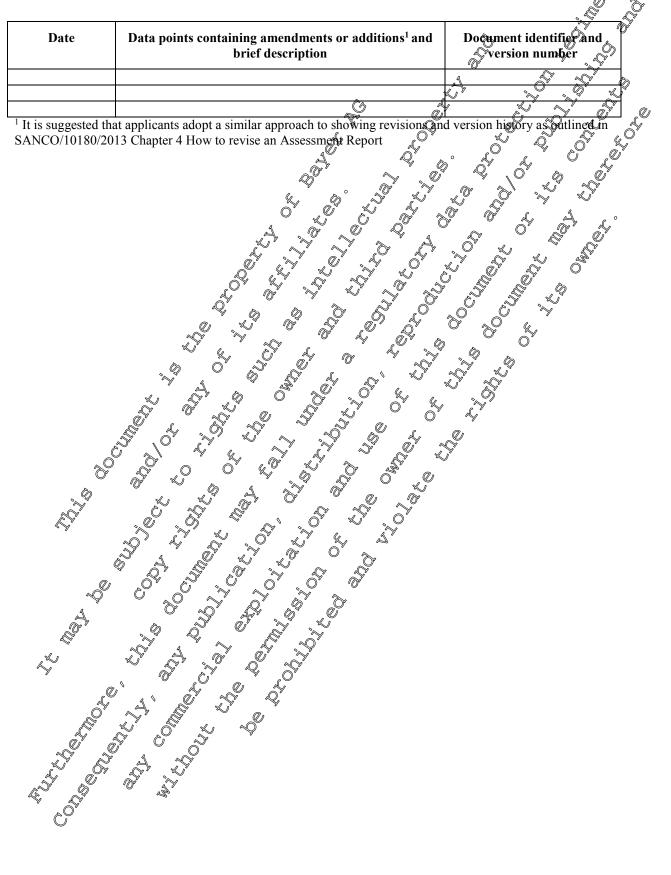
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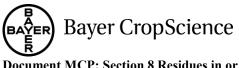
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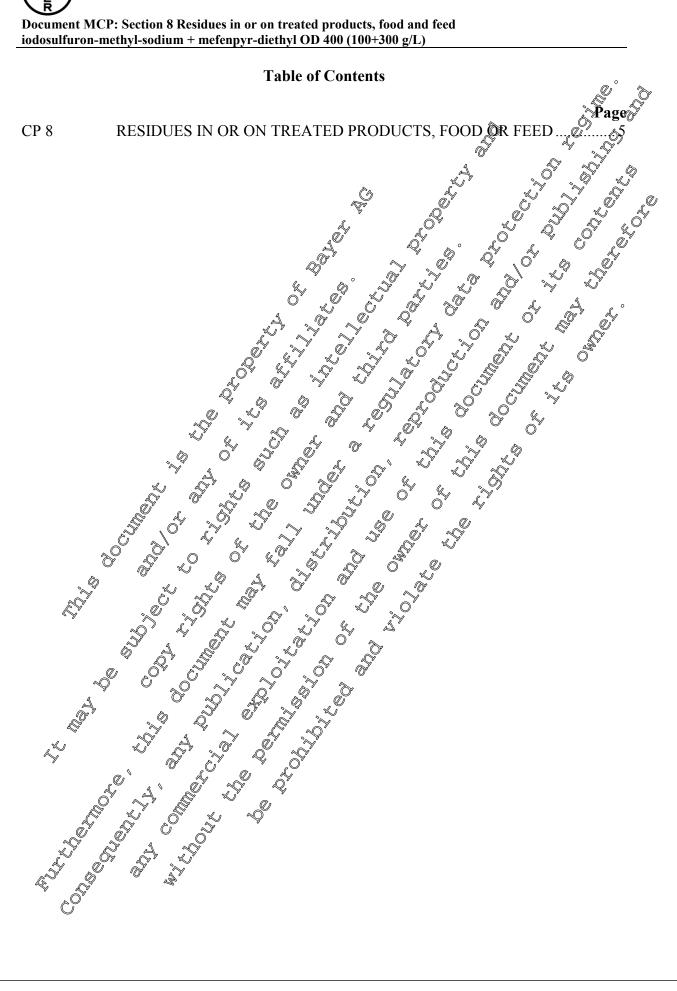
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Version history









CP 8 RESIDUES IN OR ON TREATED PRODUCTS, FOOD OR FEED

In this summary no new studies/information is provided that is not already included in the active \ll substance dossier. A brief summary of the key data has been provided below for completeness

Stability of residues

Stability of residues during storage of samples

In the original Annex II dossier, the storage stability of jodosulfuron Bethyl-sodiun was described for cereal matrices (shoot, straw and grain). The results of the respective studies indicated that the compound is stable in deep-frozen samples over periods of 24 months in wheat rain and 18 months in wheat shoot and wheat straw. The analytes were found to be stable upon deep-freeze storage for the durations studied.

Since Annex I inclusion, two new studies have been generated with longer storage periods govered 26 months in wheat shoot and 28 months in wheat straw) Table CP 8-1 shows the maximum storage stability periods as

Table CP 8-1: Summary of storage stability of iodosulfuron-meth F113008) in cereal matrices

Active substance	Plant matrix	Stability 🔗	Keference
Iodosulfuron-methyl-	Wheat Shoot	Up to 26 months	M-192961-017 / C005930
sodium	🖉 Wheat Straw 🖓		₩ M _c 192550-99-1 / C005716
	Wheat Grain	bp to 24 months	₩ 181689-01-1 / C001041

Stability of residues on samples extracts

During the development of the enforcement method 0/060 (Report MR-13/007) for the determination of amidosulfuron, metsulfuron methy iodosulfuron methy sodium, mesosulfuron-methyl and foramsulfuron in samples from plant origin by HPLC-MS/MS, the stability in final plant extracts was checked for the tested sample materials over a period of 16 to 43 days. The results suggest that samples should be analysed as soon appossible after preparation, because not all analytes are stable in final plant extracts. This is not surprising when considering the hydrolytical data of sulfonylureas. During the development of the Helependent Lab Validation, the stability was tested after storage of the final samples in the dark at a temperature between $2 - 8^{\circ}$ C over three to thirteen days. Calibration was conducted with fresh prepared matrix standards at initial analysis and for analysis after storage. Significant deviations between initial and re-analysis were observed especially for the matrices lemon Therefore the analysis of the samples has to be conducted within 1 day. fruit and oilsee drape.

Studies on metabolismun plants or livestock

Metabolism in plants

In the original Annex II dossier, the behavior and metabolism of iodosulfuron-methyl-sodium was investigated in cereals only.

Group	Crop	Label	Ар	Application and sampling details							
		position	Method F	Rate (kg	No	Sampling (DAT)	Reference				
			or G (a)	as/ha)		ĺ [™]					
Cereals	Wheat	2- ¹⁴ C-	Foliar, F	20 g/ha +	1	Forage: 3, 7, 22	M482772+				
		triazinyl		safener (b)		Hay: 35 🔬	Q1-1 ~ ~				
						Maturez 🛱 🦻 🐁					
				Č.	7	Harvest: 77 🔬					
		U- ¹⁴ C-	Foliar, G	20 g/ha 🎬	1	Forage: 0, 20, 23, 28	1-1 × 4				
		phenyl		safener (b)		Hay: 43	Q1-1 8 K				
				A		Aarvest: 87 🔬 🔬					
(a): Outdoo	r/field appli	cation (F) or g	glasshouse/protect	ed/indoor applicat	ion (G		ġ Ű				

Table CP 8-2: Summary of available metabolism studies in plants

(b): The safener used is metenpyr diethyl at ratio 3/1

The data from the original submission are regarded as being sufficien developed subsequent to the first submission, and as cereals AIRS -the already been tested, no new studies are presented for the Annex I Renewa

Metabolism in animals

The calculated dietary burdens for different groups of poultry do that exceed the Figger value of 0.004 mg/kg bw/day. Therefore, no poulky metabolismstudies are required However, a poultry metabolism study was nevertheless conducted to satisfy formal requirements in the course of an anticipated registration of the active substance odosulfuron-methy sodium in the USA.

The calculated dietary buddens do not exceed the trigger value of 0.004 mg/kg bw/day for poultry, cattle and swine It is slightly exceeded for speep lambs only. Therefore a livestock metabolism study could be required.

A dairy covernetabolism study was conducted to satisfy formal requirements in the course of an anticipated registration of iodesulfurer-methyl-sodium in the USA.

Both studies are presented in the active substance dossier.

A pig metabolism study was not conducted, since metabolism followed comparable pathways in all Ľ, other tested species (rat, dog, her and erw). Since not residues above 0.01 mg/kg were found in vereal grain and no accumulation is to be expected

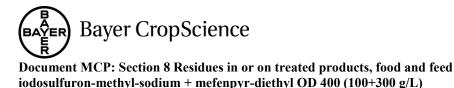
in tissues (log Pow 3), the fish metabolism study is not required.

Residue trials (supervised field trials)

Cereals

Iodosulfution-manyl-sodium of a herbicide from the substance class of sulfonylureas developed for the use in Sereals Eike other sulfonylureas it acts systemically by inhibition of acetohydroxy acid synthase (AHAS). Todosulfuron-methyl-sodium was included in Annex I to Directive 91/414/EEC by Commission Directive 2003/84/EC of 25 September 2003.

Application takes place once per season in spring or autumn. The residue trials were made in spring in order to cover the shortest pre-harvest interval (PHI). The critical GAP for iodosulfuron-methyl-



sodium consists of one treatment in cereal, in spring at a maximum rate of 10 g a.i./ha and at growth stages up to BBCH 32 (end of tillering, node 2 at least 2 cm above node 1). To increase its selectively, the product contains the safener mefenpyr-diethyl (maximum rate of 30 g/L). The safener has power herbicidal activity; it decreases the sensitivity of the treated crop to the sulfory brea active substances allowing efficient weed control without phytotoxicity to the treated crop.

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	e. 1 41e	
Table CP 8-3: Use pattern (GAPs) for the spray application	of lodosulturon-me	thyl-sodium
containing formulations on cereals in Europe (Northern and	d Southern regions)	

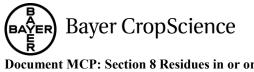
Crop	Member	F	Formulation	Pests or	Growth	Numbe	Water	Application	
	state or	/		group of 🖉	stage		(L/ha)		
	country	G	Conc. of as	pests		i N			e d'
		or I		controlled			A 1		d Start
Winter	Europe	F	OD	Grass 🕺	J BBCH	Q ^q per (¥100-	75410 g	Covered by
cereals	North /			weed	12-32	season	400	iodosulfuror-	the normal
(Barley,	South		100 g/kg	species and	End winter,	ô ^y '		iodošulfurovi- 	regetation
wheat,			iodosulfuron methyl-0	dicor weed	beginning of spring	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		sodorm (period
durum, rye,			sodium					+32.5-36 g	between
spelt,			~			AO -	Š	mefenpyr-	last
triticale)			+ 300 g/kg	, '0'	ð L			diethyl	application
Spring			ngofenpyr- ′ diethyl∕	lar lar	® ×			Č.	and harvest
cereals		0	alende					4.J	
(Barley,		,				4		S .	
wheat,	Â	2		\sim		Ď 🌾	, A	<i>*</i>	
triticale)		ľ	L. O. 1	S .			<i>a</i> .		
	, N	1				Ő, í	C.		

A total of 14 supplementary trials were performed since Annex Enclusion.

Northern Europe: six residue trials were conducted with a 4000D formulation. The formulations were applied once at growth stage 92 to 43. Residues of iodosulfuron-methyl-sodium in shoot ranged from 0.08 to 0.31 mg/kg at the day of the application. Residues of iodosulfuron-methyl-sodium at harvest were always lower than the respective LOQ at harvest (LOQ grain: 0.01 mg/kg and LOQ straw: 0.05 mg/kg).

Southern Europe: eight residue trials were conducted with two different formulation types (20WG with addition of the adjuvant Biopower and 4000D). The formulations were applied once at growth stage BBCH 32 to 33 Residues of iodosulfuron methyl-sodium in shoot ranged from < 0.05 to 0.58 mg/kg at the day of the application and were always lower than the LOQ (LOQ shoot: 0.05 mg/kg) at intermediate growth stage (13 trays after the upplication). Residues of iodosulfuron-methyl-sodium at harvest were dways lower than the respective LOQ at harvest (LOQ grain: 0.01 mg/kg and LOQ straw: 0.05 mg/kg).

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EESA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the perficide active substance iodosulfuron-methyl-sodium. A reasoned Opinion on the review of the existing maximum residue levels (MRLs) for iodosulfuron-methyl-sodium was published in EFSA Journal 2012; 10(11):2974.



Livestock Feeding Studies

The cereal commodities likely to be fed to livestock consist of grain (which is fed to poultry, pigsand cattle) and straw (which is fed to cattle only). Use of iodosulfuron-methyl-sodium in cereals according to the recommended GAP is not likely to result in significant residues in any othese commedities. Furthermore, livestock metabolism studies showed that iodosulfuron-methyl-sodium do not accumulate in eggs, milk or edible tissues. The calculated dietary burdens do not exceed the trigger value of 0.004 mg/kg bw/day for poultry, cattle and swine It is slightly exceeded for sheep lambs only. Therefore, no livestock feeding studies to investigate the residuo levels of iodosulfuron-methy sodium in food of animal origin are required.

Effects of processing

Metabolism studies conducted with iodosul furon-meth l-sodiumon an abb rate of 20 a a in cereals showed residues of 0.006 - 0.014 mg/kg TRR otal adioactive eŴďu in the edible agricultural commodity grain.

In the field residue trials, no residues of jodosulfuron-methyl sodium above 0.01 mg/kg (15mit of quantification) were found in grain at the exaggerated application rate of 19 g a. That Consequently, no residues of the active substance or metabolites are to be expected at levels above the trigger value of 0.1 mg/kg under normal field conditions.

Furthermore iodosulf@ron-methyl-sedium is of low

estigate there Therefore, no processing study is required to in idues of jodosulfuron-methyl-sodium in processed cereal commodities

Nature of residues A confined rotational crop study was submitted in the original EU dossier. Studies for Residues in Repossentative Succeeding Crops

			Application and sampling details						
Crop group	Сгор	Label position	Method F or G (a)	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest intervals (DAT)	Reptarks		
Leafy vegetables	Spinach				A A	408	₹- <u>6</u> 4 €		
Root and tuber vegetables	Carrot	¹⁴ C- triazinyl	Soil, F ^(b)	0.02×	29, 120 4 365 0	252, 454			
Cereals	Wheat					99, 239, 464 0			

Table CP-4: Summary of available metabolism studies in rotational c	rops
Table C1 -4. Summary of available includionshi studies in rotationare	Tops

(a): outdoor/field application (F) or glasshouse/protected/indogr application (G)

Magnitude of residues in rotational copps

A reasoned opinion on the review of the existing maximum residue levels (MRLS) for j dosulfuronmethyl-sodium was published in EFSA Journal 2012; 10(11):2974. Based on the rotational field crop study, the individual metabolite fractions are not expected to exceed 0.05 mg/kg (£OQ for cereal straw). Considering that it was carried out on a bare foil with twice the normal application rate and that the primary use of this active substance is authorised on cereal crops, it can be concluded that iodosulfuron residue levels in rotational commodities are not expected to exceed 0.01 mg/kg. Specific plant back restrictions related to the ase of odosulfuron methyl-sodium are therefore not required.

A second experiment (single study) was performed later and consequently used lower application rates (5.4 – 8.1 g/ha) This test included plantback intervals of 7 days and 14 days for soybean (emergency plantback scenario), 60 days for sugarbeet, and 63 days for wheat (re-cropping scenario), to specifically support an envisaged registration of iodosulfuron-methyl-sodium in the USA. Extremely low residues of AE F115008 were transferred into rotated crops in all three tested crop rotation scenarios (emergency plantback of soybean 7 at 14 days after application of 5.4 g/ha AE F115008, plantback of sugarbeet 60 days after application of 5.4 g/ha AE F115008, plantback of wheat 65 days after application of 8(1 g/ha) AE F115008). The agricultural use of AE F115008 will therefore not lead to a significant carryover of sol residues into rotated crops.

Proposed Residue Definition and Maximum Residue Levels

Proposed residue definition

According to Article 12 of Regulation (ECONo 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active robstance iodosulfuron-methyl-sodium. A reasoned opinion on the review of the existing maximum residue levels (MRLs) for iodosulfuron-methyl-sodium was published in EFSA Journal 2012/10(1).2974

C

Table CP-5 : Current proposed residue definitions

Matrices		Reference	
Food of plant origin	Risk assessment and Monitoring	sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron- methyl	EFSA Journal 2012;
Food of animal origin	Risk assessment and Monitoring	None, as no residue anticipated	H0(11):2994

Proposed maximum residue levels (MRLs)

According to the EFSA review, MRLs for the mimal commodities are not required because animals are not expected to be exposed to significant levels of residues.

Table CP 8-6 : Current MRLs established by EFS

Commodity		- A	MI	RL (mg/kg	e) 🖓	<i>w</i>		Re	ference 🔊	<u> </u>
Maize grain		S.	°O″	0.01*	ж <u>у</u> :	S.	ð	Ô.	<u>Ş</u> , 4	,
Barley grain	a	¥ .¢		Q0.01*O	Ĉ		D EF		2012.10(1)	1).2074
Rye grain		Z°	"Or	0.0	s.	, Q	Er		2012; 10(1	1).29/4
Wheat grain	N.	la		0.01*	- %	Å,	S.	- 100	0	

* indicates that the MRL is set at the limit of analytical quantification

Proposed Pre-Harvest Intervals Re-Entry or Withholding Period

It is not necessary to define a pre-harvest interval. Instead, the pre-harvest interval is given by the growing period between the growth stage at treatment and harvest and h

The product is not incended for use in areas where lives to k animals may be grazed. Therefore no reentry period needs to be proposed? Δ

The product is applied carly post-emergence on very young plants. Thus, dermal exposure to persons entering a treated field is negligible. No use in bindings is intended. Therefore no re-entry period needs to be proposed for man.

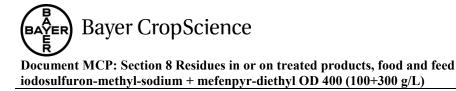
Handling of treated cereals is generally not required before harvest, which is always done mechanically. Therefore there is no need to define a waiting period between application and handling of treated products.

The use of iodosulfuron methol-sodium in cereals is not likely to result in significant uptake of residues by succeeding crops. Thus, it is not necessary to set a waiting period between last application and sowing or planting succeeding crops.

Estimation of Exposure Through Dier and Other Means

TMDI calculations

In order to evaluate the potential chronic exposure to iodosulfuron-methyl-sodium residues through the order, the Theoretical Maximum Dietary Intakes (TMDI) was estimated using the EFSA PRIMo model prevision 2). For the evaluation of the chronic exposure the model uses 5 WHO diets relevant to the EU and 22 national diets from 13 different EU Member States.



Multiple of the stand of the st indesufferenerettylsadium + metenyr-diethyl OD 400 (100-300 gr). attool the selection of the selection of