

Document Title

Tier 2 Summary

of the Metabolism and Residues Data on the Plant Protection Product
Iprovalicarb & Folpet WG 65.3 (563+90 g/kg)
(Specification number 102000011659-04)

Substance(s)

IPROVALICARB (Annex I renewal)

Data Requirements

Regulation EC/1141/2010

on the renewal of the inclusion of ARL active substances

in conjunction with

Directive 91/414/EEC and Regulation EC/1107/2009

Annex IIIA

Section 4, Point 8

Document M

According to OECD format guidance for industry data submissions
on plant protection products and their active substances

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IIIA 8 Metabolism and residues data on the plant protection product

Preface and general remarks

This dossier supports the combination product Iprovalicarb & Folpet WG 65.3 for use in grapes grown in the southern and northern European residue regions. The wettable granulate formulation contains 56.25% folpet and 9% iprovalicarb.

This chapter on residues of Iprovalicarb & Folpet WG 65.3 in or on treated product, food, or feed is fully bridged from the Annex III dossier, point 8 for SZX 0722 & Folpet 43.5 WP (=Iprovalicarb & Folpet WP 43.5, "Melody Combi"), the full text of which is included below (with slight modifications to reflect the current dossier submission situation for both compounds). Both the ratio of actives in the new product as well as the use patterns of both formulations are the same, only the concentrations of the actives in the formulation have changed. No change in the residue behaviour is therefore to be expected when changing from the SZX 0722 & Folpet 43.5 WP to the Iprovalicarb & Folpet WG 65.3 formulation.

Re. folpet:

The representative formulation in the application for Annex I Renewal of Iprovalicarb is a combination with folpet, which – from a Bayer perspective – is a 3rd party substance, procured from [redacted]. Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Bayer CropScience's right to references extends to all EU countries. A separate Letter of Access is included in this supplementary dossier (M-428625-01-1).

Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

Introduction

Iprovalicarb (SZX 0722) is a fungicidal active substance. In March 1998, an Annex II dossier for this a.s. was submitted to the Irish PCS acting as rapporteur for the EU. In that dossier, the use of the compound was supported in grapes (data from studies conducted with the solo product, 50 WG) and potatoes (data from studies conducted with a combination product with mancozeb, 69 WP). Following EU evaluation, iprovalicarb was added to Annex I in 2002, with provisional MRLs — for which the grape MRLs were based on a supplementary evaluation of approx. 80 residue trials on grapes, with



approx. 7 different formulations — being published in Commission Directive 2003/60/EC, dated 18 June 2003. The provisional MRLs were for numerous crops and were based not only on the original submission mentioned above, but also on various Annex III dossiers submitted at later dates to individual EU member states. These values were then amended/corrected in Commission Directive 2004/115/EC, dated 15 December 2004; the most recent publication of EU MRLs in connection with Regulation (EC) no. 396/2005 also reflects the 2004 values. The MRL for iprovalicarb in grapes (wine and table grapes) is 2.0 mg/kg.

Iprovalicarb is on Annex I Renewal list 2, with the respective dossier being submitted in May 2012. This Annex III dossier is the "representative Annex III" document for the AIR2 submission.

Folpet is an established phthalimide contact fungicide which has been used and registered in many countries both in Europe and worldwide for many years. It is used in numerous crops — both horticultural and agricultural — primarily in those grown outdoors. [redacted] submitted an Annex II dossier to the EU (rapporteur: France) in April 2002. Prior to the EU Annex II submission, national registrations had been granted in various European countries for the use of folpet-containing products in grapes. In [redacted]'s Annex II dossier, an MRL for folpet was proposed in grapes at 5.0 mg/kg; the most recent publication of EU MRLs with regard to Regulation (EC) no. 396/2005 also reflects this value.

In this Annex III dossier, new data are presented to support the combination product Iprovalicarb & Folpet_WG 63.5 for use in grapes grown in the southern and northern European residue regions. With regard to chapter IIIA 8, the only "newer" studies relevant for submission to the EU or member states are the residue analytical data generated with the product presented below in chapter IIIA 8.3. Some basic information on residue definitions and MRLs is included in chapter IIIA 8.7 for clarity.

No entirely new uses of iprovalicarb or folpet are included in this Annex III dossier, and the results presented do not trigger any other new studies that would be reported in this chapter. Further details on the residues of iprovalicarb and folpet in or on treated products, food, or feed are presented in the respective Annex II dossiers (chapters 6) for both compounds.

IIIA 8.1 Stability of residues

IIIA 8.1.1 Stability of residues during storage of samples

No supplementary studies are required; all information is given in the relevant Annex II dossiers for each of the active substances (including AIR2 for iprovalicarb) and/or Annex III dossiers for the formulations thereof.

IIIA 8.1.2 Stability of residues in sample extracts

The stability of residues in sample extracts is routinely checked during analytical method development, and documented as part of the method.

IIIA 8.2 Supplementary studies on metabolism in plants or livestock

No supplementary studies are required; all information is given in the relevant Annex II dossiers for each of the active substances (including AIR2 for iprovalicarb) and/or Annex III dossiers for the formulations thereof.

IIIA 8.3.1 Grapes

The application pattern for the use of Iprovalicarb & Folpet WG 65.3 in/on grapes in Europe (northern and southern residue regions) is described in the table below.

Table 8.3.1-1: Use patterns (GAPs) for the spray application of Iprovalicarb & Folpet WG 65.3 in/on grapes in Europe

Formulation	Region	Application timing	Max. rate of application (kg/ha [prod.])		Max. a.s. rate of application (kg/ha)		Max. no. of apps.	PHI (days)
			43.5	65.3	iprovalicarb	folpet		
REGISTERED USE OF WG 65.3								
Iprovalicarb & Folpet WG 65.3 (9.0% iprovalicarb and 56.3% folpet)	EU-N	10-14 d int.	1.5*		0.135*	0.845	4	28
	EU-S	10-12 d int.			0.15	0.94	4	
AS TESTED								
SZX 0722 & Folpet 43.5 WP (6.0% iprovalicarb and 37.5% folpet)	EU-N	pre-flowering	1.5 (~1.0)		0.09	0.56	1	28
		post-flowering (10-14 d int.)	2.5** (~1.7*)		0.15**	0.94**	4	
	EU-S	pre-flowering	1.5 (~1.0)		0.09	0.56	1	28
		post-flowering (10-14 d int.)	2.5 (~1.0)		0.15	0.94	4	

EU-N = northern EU residue region, EU-S = southern EU residue region

* These rates are expressed as "kg/ha per meter foliage ('leaf wall' or leafy surface) height". The maximum absolute amounts to be applied refer to vines with 1.6 m "leafy surface", resulting in post-bloom a.s. rates of 0.216 kg/ha iprovalicarb and 1.35 kg/ha folpet.

** These rates are expressed as "kg/ha per meter foliage ('leaf wall' or leafy surface) height". The maximum absolute amounts applied refer to vines with 1.6 m "leafy surface", resulting in post-bloom a.s. rates of 0.24 kg/ha iprovalicarb and 1.5 kg/ha folpet.

The current registered use calls for a slightly lower application rate than originally tested and registered in the northern residue region, with maximum iprovalicarb and folpet applications rates in German grape vines of 216 g/ha and 1.35 kg/ha, respectively. (This reflects the following "core rates" per hectare and meter foliage height: 135 g/[ha×m] iprovalicarb and 845 g/[ha×m] folpet.) This is a 10% reduction, which is well within the EU acceptance criteria for use pattern comparability. The current uses in both regions also call for a maximum of 4 applications, instead of 5 as originally tested/registered. For iprovalicarb, it has been clearly shown with other, similar use patterns (e.g. with SZX 0722 & Azoxytobin, cf. AIR2 dossier, point 6.3.1) that additional applications well before harvest do not affect the residue levels in the harvested commodities. As stated previously, for folpet, the currently defended worst-case approved use in this crop in the EU is up to 10 applications of up to 1.6 kg/ha, thus the use in Iprovalicarb & Folpet WG 65.3 is far less critical than the worst-case European use.

Thus, the use pattern of SZX 0722 & Folpet 43.5 WP as tested is valid to support the use of Iprovalicarb & Folpet WG 65.3 as currently labelled.



New studies submitted for Annex I renewal:

Report: KIIIA 8.3.1/01, [redacted] 1998a

Title: Determination of residues of SZX 0722 & Folpet (43.5 WP) in/on grape following spray application in France and Germany

Report No. & Document No.: RA-2129/97
M-002068-01-1

Report: KIIIA 8.3.1/02, [redacted] 1998b

Title: Determination of residues of SZX 0722 & Folpet (43.5 WP) in/on grape following spray application in France, Portugal and Spain

Report No. & Document No.: RA-2130/97
M-002066-01-1

Guidelines (applies to both studies): Directive 91/414/EEC, residues in or on treated products, food and feed
GLP (applies to both studies): yes (certified laboratory); Deviations: none

Justification for including these studies in "AIR" dossier: Data required to establish MRLs and to support uses in grapes in the EU.

I. Materials and Methods

Northern European residue region

In northern Europe a total of 5 trials on grapes were conducted in 1997 (cf. KIIIA 8.3.1/01), using SZX 0722 & Folpet 43.5 WP, containing 6.0% iprovalicarb and 37.5% folpet. The trials were performed in Germany (2) and in northern France (3). The use pattern as defined for northern Europe was based on a set product concentration and water rates of approx. 600 L/ha prior to bloom (1 appl.) and then 1000 L/(ha x m leaf wall height) post-flowering (4 appl.); thus, vines were treated at a worst-case concentration (0.25% in high-volume sprays) and at water rates applicable to the practices common in the countries in which the trials were performed. In this system, while the post-flowering rate per hectare and meter vine height remains constant, the actual amount of product applied in a given trial can vary based on the height of the vines on the test plot, so that varying absolute amounts of product are directly comparable with one another.

Post-blossom sprays were at expected product rates of 4.0 kg/ha in Germany (1.6 m "leaf wall" height) and 2.0-2.5 kg/ha in France (0.8-1.0 m leaf wall) corresponding to 0.24 and 0.12-0.15 kg iprovalicarb/ha, respectively. Spray intervals were 10-14 days in post-blossom spraying. In all trials, vines were treated a total of 6 times (1 pre-5 post-blossom) instead of 5 (1/4), but this deviation from the nominal worst-case use pattern is within the EU's tolerances for residue trials. (Besides, the extra post-blossom spray was at a very early interval, thus having little effect on the final residue levels.) All applications in all trials were at the required rates.



Southern European residue region

In southern Europe, a total of 5 trials on grapes were conducted in 1997 (cf. KIIIA 8.3.1/02). The trials were conducted in Portugal (1), Spain (2), and southern France (2). SZX 0722 & Folpet 43.5 WP was applied 5 times (1 pre-bloom/4 post-bloom) at rates of 1.5 kg/ha prior to and 2.5 kg/ha subsequent to flowering, equivalent to 0.09 kg/ha (pre-fl.) or 0.15 kg/ha (post-fl.) iprovalicarb a.s. and approx. 0.56 kg/ha (pre-fl.) or 0.94 kg/ha (post-fl.) folpet. Spray intervals were generally 10-14 days in post-blossom spraying. Water rates were about 600 L/ha (pre-blossom) and 1000 L/ha (post-blossom sprays). All applications in all studies were at the required rates.

All trials

In all trials in the northern and southern European residue regions, bunches of grapes were sampled at days 0 and 28 (PHI) after the last application. At harvest time, additional samples of destemmed grapes (berries) were taken.

The samples were analyzed for iprovalicarb according to method 00442/M003, with a limit of quantitation of 0.05 mg/kg, and for folpet according to method 00086/M024, with a limit of quantitation of 0.01 mg/kg.

II Findings

Iprovalicarb

Concurrent recoveries of iprovalicarb were obtained from grapes (berries) fortified at levels between 0.05 mg/kg and 2 mg/kg. The sample material was chosen to represent all relevant sample materials collected in these trials. Mean recoveries were all within acceptable ranges (85-95%, RSDs 5.5-8.0%, n=2-8). Details of recovery data are shown in Table 8.3.1-5.

All trials are summarized below in Table 8.3.1-1 and Table 8.3.1-2 and in greater detail in the Tier 1 summary forms (cf. Tier I summary of report references KIIIA 6.3.1/07 and /08).

Northern Europe

Immediately following the final application, samples of grape bunches yielded iprovalicarb residues ranging from 0.26-1.6 mg/kg (median value 0.4 mg/kg). These residues declined to levels of 0.10-1.2 mg/kg (median 0.47 mg/kg) by day 28.

Samples of destemmed grapes (berries) were also taken in the trials. The residues were slightly lower in day-28 samples of grapes alone than those in bunches (0.07-1.1 mg/kg in destemmed grapes [median 0.38 mg/kg]).

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Southern Europe

Immediately following the final application, samples of grape bunches yielded iprovalicarb residues ranging from 0.13-1.3 mg/kg (median value 0.33 mg/kg). These residues declined to levels of <0.05-0.76 mg/kg (median 0.17 mg/kg) by day 28.

Samples of grapes themselves (destemmed berries) were also taken in the trials. The residues were slightly lower in day-28 samples of grapes alone than in bunches (<0.05-0.66 mg/kg in grapes alone [median 0.13 mg/kg]).

Folpet

Recoveries of folpet were obtained from grape samples (bunches) fortified at levels between 0.01 mg/kg and 3.2 mg/kg. The sample material was chosen to represent all relevant commodities (bunches and grapes themselves) collected in these trials. Mean recoveries at each fortification level were all within acceptable ranges (94-99%, RSDs 2.0-4.0%, n=2-4). Details of recovery data are shown in Table 8.3.1-5.

All trials are summarised below in Table 8.3.1-2 and Table 8.3.1-4 and in greater detail in the Tier 1 summary forms (cf. Tier I summary of report references KIIA.6.3.1-07 and -08).

Northern Europe

Immediately following the final application, samples of grape bunches yielded folpet residues ranging from 0.51-5.1 mg/kg (median value 4.5 mg/kg). These residues declined to levels of 0.15-3.5 mg/kg (median 2.6 mg/kg) by day 28.

Samples of grapes themselves (destemmed berries) were also taken in the trials. The residues were slightly lower in day-28 samples of grapes alone than in bunches (0.11-2.6 mg/kg in grapes alone [median 0.4 mg/kg]).

Southern Europe

Immediately following the final application, samples of grape bunches yielded folpet residues ranging from 0.84-6.1 mg/kg (median value 1.2 mg/kg). These residues declined to levels of 0.22-2.8 mg/kg (median 0.34 mg/kg) by day 28.

Samples of destemmed grapes (berries) were also taken in the trials. The residues were slightly lower in day-28 samples of grapes alone than those in bunches (0.19-2.5 mg/kg in destemmed grapes [median 0.31 mg/kg]).

III. Conclusions

Ten residue trials were conducted with SZX 0722 & Folpet 43.5 WP, containing 6.0% iprovalicarb and 37.5% folpet on grapes, five each in the northern and southern European residue regions. The product was applied in accordance with the proposed use patterns (slight deviations in the northern trials were within EU tolerances), and the tests were carried out according to GLP principles.



The results of trials presented above demonstrate that:

- residue levels of iprovalicarb in grape bunches decline with time, from values of 0.26-1.6 mg/kg (north) or 0.13-1.3 mg/kg (south) on day 0 to 0.10-1.2 mg/kg (north) or <0.05-0.76 mg/kg (south) on day 28. The respective median values were 1.4 and 0.33 mg/kg on day 0 and 0.47 and 0.17 mg/kg on day 28.
- residue values of iprovalicarb in destemmed grapes (berries) on day 28 were slightly lower than those in bunches, with median values of 0.38 and 0.13 mg/kg in the samples from the northern and southern European trials, respectively.
- all residue values for iprovalicarb on day 28 were well below the EU MRL for iprovalicarb in grapes (2 mg/kg).
- residue levels of folpet in grape bunches decline with time from values of 0.51-5.1 mg/kg (north) or 0.84-6.1 mg/kg (south) on day 0 to 0.15-3.5 mg/kg (north) or 0.22-2.8 mg/kg (south) on day 28. The respective median values were 4.5 and 1.2 mg/kg on day 0, and 2.6 and 0.34 mg/kg on day 28.
- residue values of folpet in destemmed grapes (berries) were slightly lower than those in bunches, ranging from 0.11-2.6 mg/kg (north) and 0.19-2.5 mg/kg (south). The median values were 2.4 and 0.31 mg/kg, respectively.
- all residue values for folpet in grapes (destemmed berries) on day 28 are well below the established European MRL of 5 mg/kg in grapes.

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Document M-III /Tier 2, Sec. 4, Point 8 - Metabolism and Residues Data on Iprovalicarb + Folpet WG 65.3
 (Submission for Annex I renewal)

Table 8.3.1-1: Residues of *iprovalicarb* in/on grapes following applications of SZX 0722 & Folpet (43.5 WP) in the field in the northern European residue region

Study No. Trial No. Plot No GLP Year	Crop Variety	Country	Application					Portion analyzed	Residues	
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS		DALT (days)	<i>iprovalicarb</i> (µg/kg)
RA-2129/97 70238/2 0238-97 GLP: yes 1997	Grape Sauvignon	France F- [REDACTED] EU-N	43.5 WP ¹	6	0.090- 0.20	0.015	85	bunch	0	0.25
								berry	28	0.10
RA-2129/97 70701/5 0701-97 GLP: yes 1997	Grape Müller- Thurgau	Germany D- [REDACTED] EU-N	43.5 WP ¹	6	0.090- 0.24	0.015	80	bunch	0	1.6
								berry	28	1.2
RA-2129/97 70702/3 0702-97 GLP: yes 1997	Grape Chardonnay	France F- [REDACTED] EU-N	43.5 WP ¹	6	0.090- 0.30	0.015	85	bunch	0	1.4
								berry	28	0.47
RA-2129/97 70703/1 0703-97 GLP: yes 1997	Grape Portugieser	Germany D- [REDACTED] EU-N	43.5 WP ¹	6	0.090- 0.24	0.015	80	bunch	0	1.4
								berry	28	0.92
RA-2129/97 70705/8 0705-97 GLP: yes 1997	Grape Gamay	France F- [REDACTED] EU-N	43.5 WP ¹	6	0.090- 0.150	0.015	85	bunch	0	1.3
								berry	29	0.45
									29	0.38

FL = formulation

GS = growth stage at last application

DALT = days after last treatment

Formulations used in trials:

 1 = SZX 0722 & Folpet (43.5 WP), containing 6.0% *iprovalicarb* and 37.5% folpet

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(Submission for Annex I renewal)

Table 8.3.1-2: Residues of folpet in/on grapes following applications of SZX 0722 & Folpet (43.5 WP) in the field in the northern European residue region

Study No. Trial No. Plot No GLP Year	Crop Variety	Country	Application					Residues		
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analyzed	DALT (days)	folpet (mg/kg)
RA-2129/97 70238/2 0238-97 GLP: yes 1997	Grape Sauvignon	France F- EU-N	43.5 WP ¹	6	0.5625- 0.7500	0.09375	83	bunch	0	0.51
								berry	28	0.17
RA-2129/97 70701/5 0701-97 GLP: yes 1997	Grape Müller-Thurgau	Germany D- EU-N	43.5 WP ¹	6	0.5625- 1.5000	0.09375	80	bunch	0	4.5
								berry	28	2.6
RA-2129/97 70702/3 0702-97 GLP: yes 1997	Grape Chardonnay	France F- EU-N	43.5 WP ¹	6	0.5625- 0.9375	0.09375	81	bunch	0	4.9
								berry	28	2.6
RA-2129/97 70703/1 0703-97 GLP: yes 1997	Grape Portugieser	Germany D- EU-N	43.5 WP ¹	6	0.5625- 1.5000	0.09375	80	bunch	0	5.1
								berry	28	2.4
RA-2129/97 70705/8 0705-97 GLP: yes 1997	Grape Gamay	France F- EU-N	43.5 WP ¹	6	0.5625- 0.9375	0.09375	85	bunch	0	4.1
								berry	29	1.6

FL = formulation

GS = growth stage at last application

DALT = days after last treatment

Formulations used in trials:

1 = SZX 0722 & Folpet (43.5 WP), containing 6.0% iprovalicarb and 3.5% folpet

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(Submission for Annex I renewal)

Table 8.3.1-3: Residues of iprovalicarb in/on grapes following applications of SZX 0722 & Folpet (43.5 WP) in the field in the southern European residue region

Study No. Trial No. Plot No GLP Year	Crop Variety	Country	Application					Residues		
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analyzed	DAIT (days)	iprovalicarb (mg/kg)
RA- 2130/97 70237/4 0237-97 GLP: yes 1997	Grape Periquita	Portugal P- [redacted] EU-S	43.5 WP ¹	5	0.090- 0.150	0.015	89	bunch berry	0 28 28	1.3 0.76 0.66
RA- 2130/97 70644/2 0644-97 GLP: yes 1997	Grape Grenache	France F- [redacted] EU-S	43.5 WP ¹	5	0.090- 0.150	0.015	85	bunch berry	0 28 28	0.13 0.05 0.05
RA- 2130/97 70645/0 0645-97 GLP: yes 1997	Grape Cabernet Sauvignon	Spain E- [redacted] EU-S	43.5 WP ¹	5	0.090- 0.150	0.015	85	bunch berry	0 28 28	0.33 0.17 0.13
RA- 2130/97 70646/9 0646-97 GLP: yes 1997	Grape Grenache blanc	France F- [redacted] EU-S	43.5 WP ¹	5	0.090- 0.150	0.015	85	bunch berry	0 28 28	0.17 <0.05 0.05
RA- 2130/97 70647/7 0647-97 GLP: yes 1997	Grape Macabeo	Spain E- [redacted] EU-S	43.5 WP ¹	5	0.090- 0.150	0.015	84	bunch berry	0 28 28	0.37 0.23 0.16

FL = formulation

GS = growth stage at last application

DAIT = days after last treatment

Formulations used in trials:

1 = SZX 0722 & Folpet (43.5 WP), containing 6.0% iprovalicarb and 37.5% folpet

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Document M-III /Tier 2, Sec. 4, Point 8 - Metabolism and Residues Data on Iprovalicarb + Folpet WG 65.3
(Submission for Annex I renewal)

Table 8.3.1-4 Residues of folpet in/on grapes following applications of SZX 0722 & Folpet (43.5 WP) in the field in the southern European residue region

Study No. Trial No. Plot No GLP Year	Crop Variety	Country	FL	Application				Portion analyzed	Residues	
				No	kg/ha (a.s.)	kg/hL (a.s.)	GS		DAIT (days)	folpet (mg/kg)
RA-2130/97 70237/4 0237-97 GLP: yes 1997	Grape Periquita	Portugal P- EU-S	43.5 WP ¹	5	0.5625- 0.9375	0.09375	89	bunch	0	6.1
								berry	28	2.5
RA-2130/97 70644/2 0644-97 GLP: yes 1997	Grape Grenache	France F- EU-S	43.5 WP ¹	5	0.5625- 0.9375	0.09375	85	bunch	0	1.1
								berry	28	0.22
RA-2130/97 70645/0 0645-97 GLP: yes 1997	Grape Cabernet Sauvignon	Spain E- EU-S	43.5 WP ¹	5	0.5625- 0.9375	0.09375	85	bunch	0	1.2
								berry	28	0.34
RA-2130/97 70646/9 0646-97 GLP: yes 1997	Grape Grenache blanc	France F- EU-S	43.5 WP ¹	5	0.5625- 0.9375	0.09375	85	bunch	0	0.84
								berry	28	0.34
RA-2130/97 70647/7 0647-97 GLP: yes 1997	Grape Macabeo	Spain E- EU-S	43.5 WP ¹	5	0.5625- 0.9375	0.09375	84	bunch	0	1.6
								berry	28	0.61

FL = formulation

GS = growth stage at last application

DAIT = days after last treatment

Formulations used in trials:

1 = SZX 0722 & Folpet (43.5 WP), containing 6.0% iprovalicarb and 37.5% folpet

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Table 8.3.1-5: Procedural recoveries for *iprovalicarb* and *folpet* in grape matrices

Study No., Trial No. (Trial SubID) GLP, Year	Crop	Portion analyzed	a.s./ metabolite	n	Fortification level (mg/kg)	Recovery (%)			RSD
						min	max	mean	
RA-2129/97	Grape	berry*	iprovalicarb	5	0.05	76	95	85	8.0
70238/2 (0238-97)				8	1.0	85	99	95	5.1
70701/5 (0701-97)				2	2.0	89	95	92	3.1
70702/3 (0702-97)				15	overall	76	99	91	7.6
70703/1 (0703-97)				15	overall	76	99	91	7.6
70705/8 (0705-97)		bunch**	folpet	3	0.1	96	100	98	2.0
RA-2130/97				4	1.0	90	99	94	3.0
70237/4 (0237-97)				2	3.2	92	106	99	1.1
70644/2 (0644-97)				9	overall	90	106	96	5.2
70645/0 (0645-97)				9	overall	90	106	96	5.2
70646/9 (0646-97)									
70647/7 (0647-97)									
GLP: yes									
1997									

* berry recoveries also valid for sample material bunch of grapes.

** bunch recoveries also valid for sample material berry

IIIA 8.4 Supplementary livestock feeding studies

No supplementary studies are required; all information is given in the relevant Annex II dossiers for each of the active substances (including AR2 for iprovalicarb) and/or Annex III dossiers for the formulations thereof.

IIIA 8.4.1 Poultry

All relevant data are presented in the respective Annex II dossiers, chapter 6.

IIIA 8.4.2 Lactating ruminants (goat or cow)

All relevant data are presented in the respective Annex II dossiers, chapter 6.

IIIA 8.4.3 Pigs

All relevant data are presented in the respective Annex II dossiers, chapter 6.

IIIA 8.4.4 Nature of residue in fish

Not required by Directive 91/414/EEC.



IIIA 8.5 Suppl. studies on the effects of industrial processing and/or household preparation on residue levels

No supplementary studies are required; all information is given in the relevant Annex II dossiers for each of the active substances (including AIR2 for iprovalicarb) and/or Annex III dossiers for the formulations thereof.

IIIA 8.5.1 Effects of industrial processing and/or household preparation (representative processing situations) on the nature of residue

All relevant data are presented in the respective Annex II dossiers, chapter 6.

IIIA 8.5.2 Distribution of the residue in peel/pulp

Not relevant for wine grapes.

IIIA 8.5.3 Balance studies on a core set of representative processes

All relevant data are presented in the respective Annex II dossiers, chapter 6.

IIIA 8.5.4 Follow-up studies: potable waters; irrigated crops

IIIA 8.5.4.1 Follow-up studies to determine concentration or dilution factors

All relevant data are presented in the respective Annex II dossiers, chapter 6.

IIIA 8.5.4.2 Potable waters

Not required by Directive 91/414/EEC.

IIIA 8.5.4.3 Irrigated crops

Not required by Directive 91/414/EEC.

IIIA 8.6 Supplementary studies for residues in representative succeeding crops

No supplementary studies are required; all information is given in the relevant Annex II dossiers for each of the active substances (including AIR2 for iprovalicarb) and/or Annex III dossiers for the formulations thereof.

IIIA 8.7 Proposed residue definition and maximum residue levels

IIIA 8.7.1 Proposed residue definition

As presented in the Annex II dossiers for each of the active substances, the proposed residue definitions in plants and animals for each of the active substances are the unchanged parent compounds, iprovalicarb and Folpet.



IIIA 8.7.2 Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed, including details of statistical analyses used

Iprovalicarb:

An MRL of 2.0 mg/kg for iprovalicarb (SZX 0722) in grapes was proposed in the original Annex II dossier, chapter 6. This MRL has been published (first in Commission Directives 2003/60/EC and 2004/115/EC, later in connection with Regulation [EC] no. 396/2005), and the value is confirmed in the AIR2 dossier.

The trials presented in this Annex III dossier yielded residue values below this MRL – and, as presented in the AIR2 dossier, play a role in "driving" it – thus supporting the use of Iprovalicarb & Folpet 43.5 WP (and, with it, the new formulation Iprovalicarb & Folpet WG 65.3) as described above.

Folpet:

A grape MRL of 5.0 mg/kg for folpet was proposed in the Annex II dossier, chapter 6. The most recent publication of EU MRLs with regard to Regulation (EC) no. 396/2005 also reflects this value. The trials presented in this Annex III dossier yielded residue values below the MRL level, thus supporting the use of Iprovalicarb & Folpet 43.5 WP (and, with it, the new formulation Iprovalicarb & Folpet WG 65.3) as described above.

IIIA 8.8 Proposed pre-harvest intervals, re-entry or withholding periods

IIIA 8.8.1 Pre-harvest interval (in days) for each relevant crop

Grapevine:

A minimum PHI of 28 days

IIIA 8.8.2 Re-entry period (in days) for livestock, to areas to be grazed

Iprovalicarb & Folpet WG 65.3 is not intended for use in areas where livestock animals may be grazed. A re-entry period does not need to be proposed.

IIIA 8.8.3 Re-entry period for man to crops, buildings or spaces treated

A comparison of the estimated exposure with the NOAELs shows sufficient margins of exposure/safety for all active substances. Thus, no risk is to be seen for workers performing activities like leaf pulling in vineyards treated with Iprovalicarb & Folpet WG 65.3. Therefore, a specific re-entry period is not needed.

IIIA 8.8.4 Withholding period (in days) for animal feedingstuffs

Not relevant, no use as a feeding stuff before harvest.

IIIA 8.8.5 Waiting period before sowing or planting crop to be protected

Not relevant.



IIIA 8.8.6 Waiting period between application and handling treated products

Not relevant, because crops are not handled before harvest.

IIIA 8.8.7 Waiting period (in days) before sowing or planting succeeding crops

Not needed, no phytotoxicity and no residues in succeeding crops.

IIIA 8.9 Other/special studies

None

IIIA 8.10 Estimation of exposure through diet and other means

IIIA 8.10.1 TMDI calculations

Iprovalicarb:

As stated above, the results for Iprovalicarb & Folpet WG 65.3 "fit" the MRLs as established previously and confirmed in the AIRO dossier. All information relevant to dietary risk assessment is given in the Annex II dossiers (original and the new AIR2 dossier). The use of iprovalicarb in grapes does not represent a risk to consumers.

Folpet:

As stated previously, the GAP supported for Iprovalicarb & Folpet WG 65.3 is much less critical than the critical GAP [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb..

IIIA 8.10.2 NEDI calculations

Please refer to the respective Annex II dossiers.

IIIA 8.10.3 NESTI calculations

Iprovalicarb:

No Acute Reference Dose (ARD) has been set for iprovalicarb. A calculation of the National Estimated Short-Term Intake (NESTI/ESTI) is therefore not required.

Folpet:

As stated previously, the GAP supported for Iprovalicarb & Folpet WG 65.3 is much less critical than the critical GAP [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb..



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IIIA 8.11 Summary and evaluation of residue behaviour

This Annex III dossier is the "representative Annex III" for the Annex I Renewal (AIR2) submission of iprovalicarb. The formulation supported is Iprovalicarb & Folpet WG 65.3, containing 9% iprovalicarb and 56.3% folpet. As originally tested, the product was a 43.5 WP containing 6% iprovalicarb and 37.5% folpet. However, the use of each of the two products is such that the same amounts of the two active substances are applied, using the corresponding lower amounts of the WG 65.3 formulation. The slight changes in the use patterns since the original 43.5 WP submission are of no consequence when evaluating the residue behaviour; the original trials support the current use.

To evaluate the residue behaviour of SZX 0722 & Folpet 43.5 WP in grapes, data from 10 trials on grapes (northern and southern European residue regions) are presented. The objective of the trials was to provide a data "bridge" to the individual national and EU submissions for each of the active substances, thus supporting the use of the new co-formulation. The product was applied in accordance with GLP and in accordance with — or in cases of slight deviations within acceptable tolerances of — intended use patterns.

The LOQs of the analytical methods employed in these studies were 0.05 mg/kg for iprovalicarb and 0.01 mg/kg for folpet, as described in chapter 2.3 of this AIN dossier.

Iprovalicarb

In grape bunches, residue levels of <0.03-0.76 mg/kg (median 0.17 mg/kg) and 0.10-1.2 mg/kg (median 0.47 mg/kg) were determined in day-28 samples in the southern and northern European residue regions, respectively. Residue values on day 28 in the grapes alone (destemmed) were slightly lower than those in bunches, with median values of 0.13 and 0.38 mg/kg in southern and northern trials, respectively. All residue values were well below the EU MRL of 2.0 mg/kg.

None of the data garnered from the uses and/or trials presented in this Annex III dossier would trigger additional metabolism, animal feeding, rotational crop or additional processing studies. Basic data on all aspects mentioned as well as processing data and data on the potential dietary exposure to iprovalicarb were presented in the original Annex II dossier as well as the AIR2 dossier for the compound.

Folpet

In destemmed grapes (fruit alone), residue levels of 0.19-2.5 mg/kg (median 0.31 mg/kg) and 0.11-2.6 mg/kg (median 2.4 mg/kg) were determined in day-28 samples in the southern and northern European residue regions, respectively. All residue levels were below the established EU MRLs (5 mg/kg). Residue values in the grape bunches were slightly higher than those in the grapes alone, with median residue levels of 0.34 and 2.6 mg/kg in southern and northern trials, respectively.

Basic data on all aspects mentioned as well as processing data and data on the potential dietary exposure to folpet were presented in [redacted]'s Annex II dossier for the compound.