Bayer CropScience

Document Title

Summary of the toxicological studies Propineb WG 70 (700g/kg)

Data Requirements

EU Regulation 1107/2009 & EU Regulation 284/2013

Document MCP

Section 7: Toxicological studies

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

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[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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CP 7 TOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

INTRODUCTION

CP 7.1 Acute toxicity

The formulation 'Propineb WG 70' alias 'Antracol WG 70' (also coded Specification number 102000006516-02) is a water dispersible granulate formulation (WG) containing 700 g/kg of propineb. The product was developed as a fungicide to be used on various crops.
Hereafter is presented a summary of the results of the acute toxicity studies performed with the formulation 'Propineb WG 70' previously named 'LH 30/Z 70 WG (c.n.: Propineb)'.

Study	Species (sex)	Results	Reference
Acute oral	Rat (F)	LD_{50} > 2000 mg/kg bw	M-030439-01-1
Acute dermal	Rat (M + F)	LD_{50} > 2000 mg/kg bw	M-030435-01-1
Acute inhalation	Rat (M + F)	LC50 = 2.838 mg/L Not relevant because of low dust formation	M-013839-01-1
Acute skin irritation	Rabbit (M)	Not irritating	M-030650-01-1
Acute eye irritation	Rabbit (M)	Not irritating	M-030653-0 1-1

Propineb WG 70 (alias Antracol WG 70) is of low toxicity to rats after oral administration and non-toxic after acute dermal and inhalative application. It is not irritating to the skin or eyes of rabbits. It was not tested for sensitization with regard to the dermal allergenic potential of Propineb.

The study results trigger the following classification/labelling:
- EU directive 1999/45/EC: Xi, R43 (may cause sensitization by skin contact)
- Regulation (EC) No 1272/2008 (CLP): Skin sensitization Cat. 1 (H317 May cause allergic skin reaction)

CP 7.1.1 Oral toxicity

Report:	[redacted]_;[redacted];2000;M-030439-01
Title:	LH 30/Z 70 WG (c.n.: Propineb) - Study for acute oral toxicity in rats
Report No:	30527
Document No:	M-030439-01-1
Guidelines:	**OECD 423; Directive 96/54/EEC, Annex IV B, Part B, B.1 tris; US-EPA 712-C-98-190, OPPTS 870.1100** Deviations: The test substance is a commercial product known to be stable and homogenous in both undiluted and in ready-to-use dilution with water. The test substance was formulated in water. Therefore, analytical determinations of stability and homogeneity of the aqueous formulations were not performed.
GLP/GEP:	**yes**

Material and methods:

A study for acute oral toxicity in fasted male and female rats was performed with LH 30/Z 70 WG.

Test compound:	LH 30/Z 70 WG
Batch no.:	233013270
Development no.:	3000252002
Content:	68.4%
Vehicle:	demineralized water
Application route:	oral by gavage to fasted rats
Fasting time:	17 hours ± 1 hour
Dose:	2000 mg/kg bw
Application volume:	10 mL/kg bw
Test system / strain:	Wistar rat (SPF-bred) / HsdCpb:WU
Group size:	3 rats/sex/group
Post-treatment observation period:	2000-11-08 – 2000-11-24
Experimental phase:	14 days
Observations:	clinical signs, body weight, gross necropsy

Findings:

Table 7.1.1-1 Doses, mortality / animals treated

Dose [mg/kg bw]	Toxicological results*	Duration of signs	Time of death	Mortality [%]
Male rats				
2000	0/0/3	--	--	0
Female rats				
2000	1/3/3	5d – 10d	6d	33

$LD_{50\ cut\ off}$: = 2500 mg/kg bw

1st number	=	number of dead animals
2nd number	=	number of animals with signs
3rd number	=	number of animals in the group

** according to the OECD Guideline 423

Clinical signs: A dose of 2000 mg/kg body weight was tolerated by male rats without mortalities and clinical signs.
One female of the 2000 mg/kg dose group died on day 6.
In females the reactivity was decreased, and uncoordinated gait and hypostenia of the hind limbs were detected. In one animal each, also decreased motility and red incrusted orbital margins and labored breathing occurred.
The signs observed started on day 5 of the study and lasted up to day 10.

Body weights: Body weight and body weight gain of male rats was not affected by treatment.
A decrease in body weight was observed on day 6 of the study in one female.

Gross pathology: In the animal that died during the observation period the following changes were detected:
Kidneys: discoloration, spotted, both
No gross pathologic changes were observed in animals sacrificed at the end of the study period.

Conclusion: **LH 30/Z 70 WG was of low toxicity after acute oral administration to fasted rats.**

The study result triggers the following classification/labelling:
- EU directive 1999/45/EC: None
- Regulation (EC) No 1272/2008 (CLP): None

CP 7.1.2 Dermal toxicity

Report:	[redacted]; [redacted];2000;M-030435-01
Title:	LH 30/Z 70 WG (c.n.: Propineb) - Study for acute dermal toxicity in rats
Report No:	30528
Document No:	M-030435-01-1
Guidelines:	**OECD 402; Directive 67/548/EEC, Annex V, Part B.3.; US-EPA 712-C-98-192, OPPTS 870.1200**
GLP/GEP:	**yes**

Material and methods: A study for acute dermal toxicity under 24-hour occlusion conditions in male and female rats was performed with LH 30/Z 70 WG.

Test compound: LH 30/Z 70 WG
Batch no.: 233013270
Development no.: 3000252002
Content: 68.4%
Application route: dermal (occlusive dressing)
Duration: 24 hours
Dose: 2000 mg/kg bw
Test system, strain: Wistar rat (SPF-bred) / HsdCpb:WU
Group size: 5 rats/sex/dose
Post-treatment observation period: 14 days
Experimental phase: 2000-11-08 – 2000-11-22
Observations: clinical signs, local skin effects, body weight, gross necropsy

Application dose

Sex	Dose [mg/kg bw]	Range of doses [mg/cm²]
Male	2000	26.9 – 28.0
Female	2000	26.8 – 28.5

Table 7.1.2-1 Doses, mortality / animals treated

Findings:

Dose [mg/kg bw]	Toxicological results*	Duration of signs	Time of death	Mortality [%]
Male rats				
2000	0/5#/5	2d – 14d	--	0
Female rats				
2000	0/5#/5	2d – 14d	--	0
LD_{50}: > 2000 mg/kg bw				

* 1st number = number of dead animals
2nd number = number of animals with signs
3rd number = number of animals in the group
\# animals showed local skin findings only

Clinical signs: A dermal dose of 2000 mg/kg body weight was tolerated by males and females without mortalities and clinical signs.

Local skin findings: In both genders the treatment area was yellow discolored and in females the treatment area was partly reddened and a formation of scale was observed. The signs observed started on day 2 of the study and lasted up to the end of the study.

Body weights: No treatment-related effects on body weight and body weight gain in males and females at 2000 mg/kg body weight were observed.

Gross pathology: No gross pathologic changes were observed in animals sacrificed at the end of the study period.

Conclusion: **LH 30/Z 70 WG was none toxic to male and female rats after acute dermal administration.**

The study result triggers the following classification/labelling:
- EU directive 1999/45/EC: None
- Regulation (EC) No 1272/2008 (CLP): None

CP 7.1.3 Inhalation toxicity

Report:	[redacted]p;[redacted];1999;M-013839-01
Title:	LH 30/Z 70 WG 03245/0170 (c.n. Propineb) - Study on acute inhalation toxicity in rats according to OECD no. 403
Report No:	29072
Document No:	M-013839-01-1
Guidelines:	**OECD 403; Directive 92/69/EEC, method B.2; US-EPA 712-C-98-193; OPPTS 870.1300**
GLP/GEP:	**yes**

Material and methods:

A study on the acute inhalation toxicity of LH 30/Z 70 WG 03245/0170 on male and female rats has been conducted.

Test compound:	LH 30/Z 70 WG 03245/0170
Batch no.:	299713013
Development Article no.:	00929999
Content:	70.1%
Vehicle:	deionized water
Application route:	inhalation (nose-only)
Dose:	(dust): 0 – 496 – 1028 – 5005 mg/m³ air (aerosol) 1440 mg/m³ air (gravimetric concentration)
Duration:	4 hours
Test system / strain:	Wistar rats (SPF-bred) / HsdCpb:WU
Group size:	5 rats/sex/group
Post-treatment observation period:	2 weeks
Experimental phase:	1999-06-16 – 1999-07-14
Observations:	clinical signs, reflexes, rectal temperature, body weight, gross pathology

Findings: **Table 7.1.3-1: Characteristics of the achieved atmosphere**

	Group 1	Group 1	Group 2	Group 3	Group 4	Group 5
Target concentration [mg/m³]	Control [Air]	Control [Water]	500 [dust]	1000 [dust]	5000 [dust]	5000 [aerosol]
Nominal concentration [mg/m³]	--	--	--	--	--	7359
Gravimetric concentration [mg/m³]	--		496	1028	5005	1440
Inlet air flow [L/min]	15	15	28	28	28	15
Exhaust air flow [L/min]	13	13	23	23	23	13
Temperature [mean, °C]	23	21	22	20	20	22
Relative humidity [mean, %]	35	> 93	8	3	5	> 95
MMAD [µm]	--	--	2.79	2.56	2.12	3.27
GSD	--	--	2.70	2.62	1.94	2.50
aerosol mass < 3 µm [%]	--	--	53.1	56.7	70	46.6
mass recovered [mg/m³]	--	--	611	1220	4125	1401

MMAD = Mass Median Aerodynamic Diameter, GSD = Geometric Standard Deviation
– not applicable

Table 7.1.3-2: Doses, mortality / animals treated
Summary of acute inhalation toxicity - 4 hour exposure to aerosolized test item

Group no.	Target concentration [mg/m3]	Toxicological result*	Onset and duration of signs	Onset of mortality	Rectal temperature [°C]
Male rats					
1	Air-control	0/0/5	--	--	37.8
1	Water-control	0/0/5	--	--	37.8
2	496 (dust)	0/5/5	0d – 5d	--	37.4
3	1028 (dust)	0/5/5	0d – 5d	--	34.5 [b]
4	5005 (dust)	5/5/5	0d – 5d	4d – 5d	32.7
5	1440 (aerosol)	0/5/5	0d – 3d	--	33.3 [b]
Female rats					
1	Air-control	0/0/5	--	--	38.2
1	Water-control	0/0/5	--	--	37.7
2	496 (dust)	0/5/5	0d – 9d	--	36.5 [a]
3	1028 (dust)	2/5/5	0d – 14d	4d	33.6 [b]
4	5005 (dust)	2/5/5	0d – 14d	1d – 4d	31.1 [b]
5	1440 (aerosol)	0/5/5	0d – 8d	--	31.9 [b]
LC_{50} = 2838 mg/m³ air Confidence interval (95%) = 1568 - 5137 mg/m³ air; Slope = 1.0					

[a] = $p < 0.05$; [b] = $p < 0.01$ 0d = exposure day

* 1st number = number of dead animals
2nd number = number of animals with signs after cessation of exposure
3rd number = number of animals exposed

Clinical signs: Air/Water Control
All rats tolerated the exposure without specific signs.
496 mg/m³ air
Bradypnea, motility reduced, limp, piloerection, ungroomed hair-coat, flaccid paralysis of hind limbs.
1028 mg/m³ air
Labored breathing pattern, bradypnea, motility reduced, high-legged gait, limp, flaccid paralysis of hind-limbs, paralysis, piloerection, ungroomed hair-coat, cyanosis, emaciation, periorbicular red encrustations, prostration (lying on belly), abnormal posture of head, nostrils: reddened.
5005 mg/m³ air
Labored and irregular breathing pattern, bradypnea, tachypnea, nostrils with red encrustations, motility reduced, high-legged gait, limp, flaccid paralysis of hind-limbs, nasal discharge (serous), piloerection, ungroomed hair-coat, cyanosis, emaciation.
1440 mg/m³ air
Bradypnea, motility reduced, limp, piloerection, ungroomed hair-coat, labored breathing pattern, high-legged gait, emaciation.

Body weights: Comparisons between the air control and groups exposed to the test substance revealed concentration-dependent, statistically significant effects on body weight gain.

Reflex measurements: None of the rats of the control groups or test item exposure groups 496 mg/m³ air and 1028 mg/m³ air experienced any abnormal reflexes whilst some rats in groups 5005 mg/m³ air and 1440 mg/m³ air displayed a change in grip strength or tonus.

Rectal temperatures: Statistical comparisons between air control animals with those in the groups exposed to the test substance revealed a concentration-dependent statistically significant decrease in body temperature in groups 1028, 5005 and 1440 mg/m³ air.

Gross pathology: Animals that succumbed during observation period: Lung less collapsed, gray to dark-red discolorations; trachea with serous mucoid content; stomach filled with bedding material, black mucoid content; intestine: reddish mucoid content, reddish discoloration of mucous; discolorations of parenchymatous organs (pale).

Animals sacrificed at the end of the observation period: In rats exposed to the test compound a conclusive, increased incidence of macroscopic findings could not be ascertained. Therefore, the discolorations of lungs observed are not considered to be causally related to the exposure to the test item. Findings such as mild discolorations of lung and other parenchymatous organs are often observed in control animals euthanized with pentobarbital.

Conclusion: Exposure concentrations equal to 1028 mg/m³ and above resulted in mortality when exposure was to the dust whilst the exposure to the liquid aerosol (1440 mg/m³ air) was tolerated without mortality. The clinical signs observed were governed by neuromuscular effects and changes considered to be causally related to respiratory tract irritation and, in some instances, were observed throughout the 2-week post-exposure observation period. Necropsy findings were unobtrusive in surviving rats whilst in succumbed rats evidence of lung edema existed.

With regard to the respirability of the aerosol generated internationally recognized recommendations such as of SOT (1992) were fulfilled, i.e. the MMAD was < 4 µm (MMAD 2.1-3.3 µm, GSD 1.9-2.7).

LH 30/Z 70 WG 03245/0170 (solid aerosol) shows a low toxicity after acute inhalation to male and female rats.

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Report:	[redacted]*; [redacted]; [redacted];2003;M-108620-04; Amended: 2003-07-28
Title:	Particle sizes of Antracol WG70
Report No:	A0304156/1
Document No:	M-108620-04-1
Guidelines:	**-/-, Deviations: not specified**
GLP/GEP:	**no**

Material and methods: Test compound: LH 30/Z 70 WG

Assignment/ objective: In order to obtain information on the particle sizes existing in the delivered state, various batches of the product Antracol in the commercial WG70 form were to be analyzed using the modern laser diffraction method. The mass distribution of the aerodynamic particle sizes of existing secondary particles was to be derived from the analytical data obtained in this manner. A comparison was to be made with classical sieve analysis.

Procedure: The product was measured in the dry state with the Sympatec Helos laser diffraction analyzer in conjunction with the Gradis gravity dispersion system.
The comparative sieve analyses were similarly performed on the dry material using a Retsch sieving machine.
One batch was additionally measured using an image analyzer.

Results: The present Antracol samples consist of spherical particles with a median particle size X_{50} of 235 µm.
Both the laser diffraction analyzer and sieve analyses afforded nearly identical results. The supplementary particle size distribution determined with the image analyzer was similarly nearly identical.
The requirements for conversion to the aerodynamic particle size distribution are closely approximated by the present product.
No fractions with a particle size smaller than 50 µm could be detected by any of the described analytical methods.

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Report:	[redacted], [redacted]; 2003; M-116448-01
Title:	Propineb (Lf30/Z) (Antracol WG 70) - Acute inhalation and particle-size
Report No:	MO-03-009038
Document No:	M-116448-01-1
Guidelines:	**-/-**
GLP/GEP:	**no**

Material and methods: Test compound: Antracol WG 70
For analyses of 5 different batches of Antracol WG70 the most conservative approach was taken, i.e. the lowest mean MMAD (~ 159 µm) and the largest GSD (1.45). This results in the highest fraction of respirable particles in the left-hand side of the distribution. The analyses utilized both laser diffraction and sieving with essentially identical results.
The proportion of the `thoracic fraction`, in relation to the Antracol WG 70 as it is handled and used, is converging against 0.0%. With respect to Directive 94/779EEC, the particle mass < 50 µm is 0.02% (assuming a log-normal distribution of particle mass). Thus, the particle-size analysis is not triggering the determination of the acute inhalation toxicity bioassay with Antracol WG 70. Therefore, the results obtained with the micronized test article under conditions which were utilizing additional technologies to maximize the concentration of respirable particles have limited relevance, if any, for classification.
However, it can be argued that Antracol WG 70 is applied as aqueous aerosol. This has been addressed in a study in which a 40% aqueous solution of Antracol WG 70 was aerosolized in a Collison nebulizer (high aerosol output device). Exposure of rats (1x4h) to this maximum technical attainable concentration of respirable particles (MMAD 3.3 µm, GSD 2.5) did not cause mortality.

Conclusion: **The proportion of the 'thoracic fraction', in relation to the Antracol WG 70 as it is handled and used, is 0.0%. With respect to the Commission Directive 94/779/EEC, the particle mass < 50 µm is 0.02%. Thus, the particle size analysis of Antracol WG 70 does not warrant classification with respect to inhalation. Testing of the 40% aqueous solution of Antracol WG 70, which did not result in mortality up to the maximum technically attainable concentration, substantiates this conclusion further.**

The LC_{50} is not relevant for the formulation because of low dust formation, therefore the classification is as followed:

- EU directive 1999/45/EC: None
- Regulation (EC) No 1272/2008 (CLP): None

CP 7.1.4 Skin irritation

Report:	[redacted]6; [redacted];2000;M-030650-01
Title:	Acute skin irritation test (patch test) of LH 30/Z 70 WG in rabbits
Report No:	R7919
Document No:	M-030650-01-1
Guidelines:	**EC guideline B.4.; OECD 404**
GLP/GEP:	**yes**

Material and methods:

The aim of this examination was to examine LH 30/Z 70 WG for acute skin irritation in male rabbits (patch-test).

Pulverized solid was moistened sufficiently with water to insure good contact with the skin.

Test compound:	LH 30/Z 70 WG
Batch no.:	233013270
Article/Development no.:	0005468906
Content:	68.4%
Vehicle:	aqua ad injectabilia
Application route:	dermal to the shaved intact dorsal skin (semi-occlusive procedure)
Duration:	4 hours
Dose:	500 mg/patch/animal
Test system / strain:	rabbit / Himalayan
Group size:	3 male rabbits
Post-treatment observation period:	3 days
Experimental phase:	2000-11-03 – 2000-11-06
Observations:	clinical signs, body weight.

Findings: Under the present test conditions none of the three rabbits exposed for 4 hours to 500 mg LH 30/Z 70 WG/patch and animal (semi-occlusive condition) showed any substance-related lesions at the examination time-points 60 min, 24, 48 and 72 hours after patch removal.

There were no systemic intolerance reactions.

Conclusion: **LH 30/Z 70 WG is not irritating to the skin of rabbits.**

The study result triggers the following classification/labelling:

- EU Directive 1999/45/EC (as amended): none
- Regulation (EC) No 1272/2008 (CLP): none

CP 7.1.5 Eye irritation

Report:	[redacted] <; [redacted];2000;M-030653-01
Title:	Acute eye irritation study of LH 30/Z 70 WG by instillation into the conjunctival sac of rabbits
Report No:	R7920
Document No:	M-030653-01-1
Guidelines:	**EC guideline B.5.; OECD 405**
GLP/GEP:	**yes**

Material and methods:

The aim of this experiment was to examine the influence of LH 30/Z 70WG on rabbit eyes (irritation/corrosion test).

Test compound:	LH 30/Z 70 WG
Batch no.:	233015270
Article/Development no::	000546890/3000252002
Content:	68.4%
Application route:	single instillation into the conjunctival sac
Dose:	0.1 g/animal
Test system / strain:	rabbit / Himalayan
Group size:	3 male rabbits
Post-treatment observation period:	4 days
Experimental phase:	2000-11-06 – 2000-11-10
Observations:	clinical signs, body weight.

Findings: Under the present test conditions a single application of 0.1 g LH 30/Z 70WG per animal into the conjunctival sac of the right eye of three rabbits did not cause any changes.

The cornea, the iris and the conjunctivae were not affected by instillation of the test compound.

There were no systemic intolerance reactions.

Conclusion: **LH 30/Z 70 WG is not irritating to the eyes of rabbits.**

The study result triggers the following classification/labelling:

- EU Directive 1999/45/EC (as amended): none
- Regulation (EC) No 1272/2008 (CLP): none

CP 7.1.6 Skin sensitisation

Report:	[redacted] ∃ ; [redacted] ;2012;M-428880-01
Title:	Propineb WG 70 - Evaluation of potential skin sensitization in the local lymph node assay in the mouse
Report No:	SA 11384
Document No:	M-428880-01-1
Guidelines:	**O.E.C.D. guideline 429 (2010); US-EPA OPPTS 870.2600 (2003); Deviations: not specified**
GLP/GEP:	**yes**

LH 30/Z 80 VM 00705/0790 was tested for its skin-sensitizing potential in the Magnusson-Kligman maximisation test (report no. 15897; [redacted], 1987). In this test evidence was found for a dermal allergenic potential of Propineb. For animal welfare reasons no sensitization study with Propineb WG 70 will be performed.

CP 7.1.7 Supplementary studies on the plant protection product

Not relevant: the formulation is not recommended to be combined with other plant protection products.

CP 7.1.8 Supplementary studies for combinations of plant protection products

Not relevant: the formulation is not recommended to be combined with other plant protection products.

CP 7.2 Data on exposure

Operator exposure to Antracol WG 70 was not evaluated as part of the EU review of propineb (this was done for the WP 70 formulation). Therefore, all relevant data and risk assessments are provided here and are considered adequate.

Antracol WG 70 is a water dispersible granule formulation containing 700 g a.s./kg propineb. The product is used as a fungicide in apple, grapes and greenhouse tomato. Non-dietary exposure is estimated and subsequent risk assessments are made for operators, bystanders/residents and workers. Exposure estimations are based on the respective critical GAP for each relevant scenario providing the highest exposure estimate. Dossier part D contains the detailed use information.

CP 7.2.1 Operator exposure

Operator exposure is estimated for the field applications (apple and grapes) using the UK-POEM and the German Model. Both the Dutch Model as well as the ECPA Greenhouse Model are used for the greenhouse applications (tomato). A summary of the critical GAP (cGAP) used for operator risk assessment is presented in Table 7.2.1-1.

Table 7.2.1-1 Summary of critical operator GAP

Crop	F/ G	Application method	Region	German Model	UK-POEM		Dutch and ECPA Greenhouse Model
				Dose rate kg product/ ha (kg a.s./ha)	Dose rate kg product/ ha (kg a.s./ha)	Water volume (L/ha)	Dose rate kg product/ha (kg a.s./ha)
Apple	F	Broadcast air-assisted sprayer, high crop	N-/S-EU	2.25 (1.575)	2.25 (1.575)	1500	-
Grapes	F	Boom sprayer: hydraulic nozzles, low crop	N-EU	1.6 (1.12)	1.6 (1.12)	800	-
			S-EU	2 (1.4)	2 (1.4)	1000	-
Tomato	G	Hand held lance/tank sprayer, low crop	N-EU	-	-	-	2.4 (1.68)
			S-EU	-	-	-	3 (2.1)

F = field, G = greenhouse

Apple:

The cGAP is evaluated for the application method using tractor-mounted/-trailed broadcast air-assisted sprayers ('airblast'). Differences in the application rate are accounted for by using the maximum application rate (1.575 kg a.s./ha) when using the German Model. The critical GAP when using the UK-POEM results from a combination of highest dose rate with lowest water volume. As the application concentration is constant the highest exposure is calculated with the highest dose rate (1.575 kg a.s./ha) and a water volume of 1500 L/ha.

Grapes:

The methods of application will be tractor-mounted/-trailed broadcast air-assisted spraying ('airblast'). Differences in the application rate are accounted for by using the maximum application rate (1.12 kg a.s./ha in N-EU and 1.4 kg a.s./ha in S-EU) when using the German Model. The critical GAP when using the UK-POEM results from a combination of highest dose rate with lowest water volume. As the application concentration is constant the highest exposure is calculated with the highest dose rate and a water volume of 800 L/ha in northern Europe and a water volume of 1000 L/ha in southern Europe.

Tomato:

The method of application in the greenhouse will be hand-held spraying. Differences in the application rate are accounted for by using the maximum application rate (1.68 kg a.s./ha in N-EU and 2.1 kg a.s./ha in S-EU) when using the Dutch and the ECPA Greenhouse models.

- Endpoints relevant for risk assessment

AOEL:

The original endpoint of 0.003 mg/kg bw/day in the Review Report for propineb (SANCO7574VI97-final, 26 February 2003) was based on a chronic dietary study because a sub-chronic study was not available. A new sub-chronic rat study (14-week oral rat) is now available. It provides the relevant scientific information for the review of the product. An AOEL of 0.046 mg/kg bw/day (NOAEL = 7.6 mg/kg bw/day, corrected by a 60% oral absorption and a safety factor of 100) is established from this study.

Dermal absorption:

A dermal absorption study was performed with the WG 70 formulation *in vitro* using human and rat skin. As a result of the study dermal absorption of 0.1% (for the concentrate) and 1% (for the spray dilution) is used in the following risk assessment (for details see CP 7.3).

Summary

A summary of the exposure estimates resulting from the cGAP and proportions of the systemic AOEL accounted for by the estimates are presented in the following.

Table 7.2.1-2: Predicted operator exposure

Crops	F/G	Application method	PPE	Systemic exposure * (mg/kg bw/day)			
				UK-POEM	German Model	Dutch Greenh. Model	ECPA Greenh. Model
Apple	F	Broadcast air-assisted sprayer, high crop	No[1]	0.0428	0.0257	-	-
			With[2]	0.0343	0.0077	-	-
Grapes (N-EU)	F	Broadcast air-assisted sprayer, high crop	No[1]	0.0469	0.0183	-	-
			With[2]	0.0369	0.0055	-	-
Grapes (S-EU)	F	Broadcast air-assisted sprayer, high crop	No[1]	0.0498	0.0229	-	-
			With[2]	0.0394	0.0069	-	-
Tomato (N-EU)	G	Hand held lance/tank sprayer, high crop	No		-	0.0720	0.0270
			With[2]	-	-	0.0072	0.0209
Tomato (S-EU)	G	Hand held lance/tank sprayer, high crop	No	-	-	0.0900	0.0337
			With[2]	-	-	0.0090	0.0261

[1] No PPE: UK-POEM: Coverall, no gloves; German Model: T-shirt and shorts, no gloves; Dutch Model: described as normal working clothes; ECPA Greenhouse Model: Coverall, no gloves

[2] With PPE: Coverall and gloves during mixing/loading and application;

[*] Dermal absorption of 0.1% (concentrate) and 1% (spray), 100% absorption *via* inhalation route

Table 7.2.1-3: Proportions of the systemic AOEL accounted for by the exposure estimates

Crops	F/ G	Application method	PPE	% of AOEL (0.046 mg/kg bw/day)			
				UK-POEM	German Model	Dutch Greenh. Model	ECPA Greenh. Model
Apple	F	Broadcast air-assisted sprayer, high crop	No	93	56	-	-
			With	75	17		
Grapes (N-EU)	F	Broadcast air-assisted sprayer, high crop	No	102	40	-	-
			With	80	12		
Grapes (S-EU)	F	Broadcast air-assisted sprayer, high crop	No	108	50	-	-
			With	87	15		
Tomato (N-EU)	G	Hand held lance/tank sprayer, high crop	No	-	-	157	58
			With			16	45
Tomato (S-EU)	G	Hand held lance/tank sprayer, high crop	No	-	-	196	73
			With			20	57

Assessment

Exposure estimates predict acceptable risks for all intended uses.

The UK-POEM demonstrates safe uses in apple and grapes. The product can be applied in apple without PPE. In grapes, exposure of unprotected operators only slightly exceeds the AOEL. However, when gloves are worn systemic exposure will be below the AOEL

The German Model demonstrates safe uses in apple and grapes without PPE.

The Duch Model used for the exposure evaluation of the greenhouse use predicts exposure below the AOEL for operators wearing a coverall and gloves. The main reason for the exposure of unprotected operators above the AOEL is that the model does not account for different dermal absorption values for the concentrate and the dilution (higher dermal absorption of the dilution is used).

This is demonstrated with the ECPA Greenhouse model. A safe use is predicted even for unprotected operators.

Conclusion

Overall, it is concluded that the use of Antracol WG 70 does not result in an unacceptable risk for operators.

CP 7.2.1.1 Estimation of operator exposure

Exposure estimates for the use in apple and grapes are made using the UK-POEM and the German model. The use in greenhouse tomato is evaluated using the Dutch and the ECPA Greenhouse models.

Exposure is calculated based on the critical GAP (see Table 7.2.1-1). Detailed calculations are presented in the following tables.

UK-POEM calculations

Table 7.2.1.1-1 : UK-POEM calculations - apple

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM) WITH GERMAN MODEL MIX/LOAD DATA (75th PERCENTILE)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Product	**Antracol WG 70**	Active substance	**Propineb**
Formulation type	WG or SG	a.s. concentration	**700** mg/g
Dermal absorption from product	**0.1** %	Dermal absorption from spray	**1** %
PPE during mix/loading	Gloves	PPE during application	Gloves
Dose	**2.25** kg product/ha	Work rate/day	**15** ha
Application volume	**1500** l/ha	Duration of spraying	**6** h

DERMAL EXPOSURE DURING MIXING AND LOADING		
Hand contamination/kg a.s.	5.72 mg/kg a.s.	
Hand contamination/day	135.135 mg/day	
Protective clothing	None	Gloves
Transmission to skin	100 %	1 %
Dermal exposure to a.s.	135.135 mg/day	1.351 mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING	
Inhalation exposure/kg a.s.	0.036 mg/kg a.s.
Inhalation exposure/day	0.846 mg/day
RPE	None
Transmission through RPE	100 %
Inhalation exposure to a.s.	0.846 mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION						
Application technique	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha					
Application volume	1500 spray/ha					
Volume of surface contamination	400 ml/h					
Distribution	Hands	Trunk	Legs			
	10 %	65 %	25 %			
Clothing	None	Permeable	Permeable	Gloves	Permeable	Permeable
Penetration	100 %	2 %	5 %	10	2	5 %
Dermal exposure	10	5.2	5 ml/h	4	5.2	5 ml/h
Duration of exposure	6 h			6 h		
Total dermal exposure to spray	121.2 ml/day			85.2 ml/day		
Conc. of a.s. in spray solution	1.05 mg/ml			1.05 mg/ml		
Dermal exposure to a.s.	127.260 mg/day			89.460 mg/day		

INHALATION EXPOSURE DURING SPRAYING	
Inhalation exposure to spray	0.05 ml/h
Duration of exposure	6 h
Concentration of a.s. in spray	1.05 mg/ml
Inhalation exposure to a.s.	0.315 mg/day
Percent absorbed	100 %
Absorbed dose	0.315 mg/day

ABSORBED DOSE	No PPE		With PPE	
	Mix/load	Application	Mix/load	Application
Dermal exposure to a.s.	135.135	127.260 mg/day	1.351	89.460 mg/day
Percent absorbed	0.1	1 %	0.1	1 %
Absorbed dose (dermal route)	0.135	1.273 mg/day	0.001	0.895 mg/day
Inhalation exposure to a.s.	0.846	0.315 mg/day	0.846	0.315 mg/day
Absorbed dose	0.981	1.588 mg/day	0.847	1.210 mg/day

PREDICTED EXPOSURE		
Total absorbed dose	2.5685 mg/day	2.0567 mg/day
Operator body weight	60 kg	60 kg
Operator exposure	0.0428 mg/kg bw/day	0.0343 mg/kg bw/day

Table 7.2.1.1-2: UK-POEM calculations – grapes (N-EU)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM) WITH GERMAN MODEL MIX/LOAD DATA (75th PERCENTILE)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Product	**Antracol WG 70**	Active substance	**Propineb**
Formulation type	WG or SG	a.s. concentration	**700** mg/g
Dermal absorption from product	**0.1** %	Dermal absorption from spray	**1** %
PPE during mix/loading	Gloves	PPE during application	Gloves
Dose	**1.6** kg product/ha	Work rate/day	**15** ha
Application volume	**800** l/ha	Duration of spraying	**6** h

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	5.72 mg/kg a.s.	
Hand contamination/day	96.096 mg/day	
Protective clothing	None	Gloves
Transmission to skin	100 %	1 %
Dermal exposure to a.s.	96.096 mg/day	0.961 mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.036 mg/kg a.s.	
Inhalation exposure/day	0.601 mg/day	
RPE	None	
Transmission through RPE	100 %	
Inhalation exposure to a.s.	0.601 mg/day	

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha					
Application volume	800 spray/ha			800.0	spray/ha	
Volume of surface contamination	400 ml/h			400.0	ml/h	
Distribution	Hands	Trunk	Legs	Hands	Trunk	Legs
	10 %	65 %	25 %	10.0 %	65.0 %	25.0 %
Clothing	None	Permeable	Permeable	Gloves	Permeable	Permeable
Penetration	100 %	2 %	5 %	10	2	5 %
Dermal exposure	16	5.2	5 ml/h	4	5.2	5 ml/h
Duration of exposure	6 h			6 h		
Total dermal exposure to spray	121.2 ml/day			85.2 ml/day		
Conc. of a.s. in spray solution	1.4 mg/ml			1.4 mg/ml		
Dermal exposure to a.s.	169.680 mg/day			119.280 mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure to spray	0.05 ml/h	
Duration of exposure	6 h	
Concentration of a.s. in spray	1.4 mg/ml	
Inhalation exposure to a.s.	0.42 mg/day	
Percent absorbed	100 %	
Absorbed dose	0.42 mg/day	

ABSORBED DOSE	No PPE		With PPE	
	Mix/load	Application	Mix/load	Application
Dermal exposure to a.s.	96.096	169.680 mg/day	0.961	119.280 mg/day
Percent absorbed	0.1	1 %	0.1	1 %
Absorbed dose (dermal route)	0.096	1.697 mg/day	0.001	1.193 mg/day
Inhalation exposure to a.s.	0.601	0.420 mg/day	0.601	0.420 mg/day
Absorbed dose	0.698	2.117 mg/day	0.602	1.613 mg/day

PREDICTED EXPOSURE

Total absorbed dose	2.8143 mg/day	2.2152 mg/day
Operator body weight	60 kg	60 kg
Operator exposure	0.0469 mg/kg bw/day	0.0369 mg/kg bw/day

Table 7.2.1.1-3: UK-POEM calculations – grapes (S-EU)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM) WITH GERMAN MODEL MIX/LOAD DATA (75th PERCENTILE)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Product	**Antracol WG 70**	Active substance	**Propineb**
Formulation type	WG or SG	a.s. concentration	**700** mg/g
Dermal absorption from product	**0.1** %	Dermal absorption from spray	**1** %
PPE during mix/loading	Gloves	PPE during application	Gloves
Dose	**2** kg product/ha	Work rate/day	**15** ha
Application volume	**1000** l/ha	Duration of spraying	**6** h

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	5.72 mg/kg a.s.	
Hand contamination/day	120.12 mg/day	
Protective clothing	None	Gloves
Transmission to skin	100 %	1 %
Dermal exposure to a.s.	120.120 mg/day	1.201 mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.036 mg/kg a.s.	
Inhalation exposure/day	0.752 mg/day	
RPE	None	
Transmission through RPE	100 %	
Inhalation exposure to a.s.	0.752 mg/day	

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha					
Application volume	1000 spray/ha			1000.0	spray/ha	
Volume of surface contamination	400 ml/h			400.0	ml/h	
Distribution	Hands	Trunk	Legs	Hands	Trunk	Legs
	10 %	65 %	25 %	10.0 %	65.0 %	25.0 %
Clothing	None	Permeable	Permeable	Gloves	Permeable	Permeable
Penetration	100 %	2 %	5 %	10	2	5 %
Dermal exposure	10	5.2	5 ml/h	4	5.2	5 ml/h
Duration of exposure	6 h			6 h		
Total dermal exposure to spray	121.2 ml/day			85.2 ml/day		
Conc. of a.s. in spray solution	1.4 mg/ml			1.4 mg/ml		
Dermal exposure to a.s.	169.680 mg/day			119.280 mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure to spray	0.05 ml/h	
Duration of exposure	6 h	
Concentration of a.s. in spray	1.4 mg/ml	
Inhalation exposure to a.s.	0.42 mg/day	
Percent absorbed	100 %	
Absorbed dose	0.42 mg/day	

ABSORBED DOSE	No PPE		With PPE	
	Mix/load	Application	Mix/load	Application
Dermal exposure to a.s.	120.120	169.680 mg/day	1.201	119.280 mg/day
Percent absorbed	0.1	1 %	0.1	1 %
Absorbed dose (dermal route)	0.12	1.697 mg/day	0.001	1.193 mg/day
Inhalation exposure to a.s.	0.752	0.420 mg/day	0.752	0.420 mg/day
Absorbed dose	0.872	2.117 mg/day	0.753	1.613 mg/day

PREDICTED EXPOSURE

Total absorbed dose	2.9857 mg/day	2.3658 mg/day
Operator body weight	60 kg	60 kg
Operator exposure	0.0498 mg/kg bw/day	0.0394 mg/kg bw/day

German Model calculations

Table 7.2.1.1-4: German Model calculations - apple

Operator exposure estimate: German model. Tractor-mounted/trailed broadcast air-assisted sprayer

Product:	Antracol WG 70				
Active substance:	Propineb		a.s. concentration:	700	[g/l or kg]
Formulation:	WG		PPE during mix/loading:	Respiration:	None
Dose [l or kg/ha]:	2.25			Hands:	Gloves
Work rate [ha/day]:	8		PPE during application:	Respiration:	None
Body weight [kg]:	70			Hands:	Gloves
Inhalation absorption [%]	100			Head:	None
Dermal absorption [%]	0.1	(concentrate)		Body:	Standard protective coverall
	1.0	(dilution)			

Calculation of route exposure:

Route	Specific exposure [mg/kg a.s.]	a.s. handled [kg/day]	Estimated exposure [mg/kg bw/day] No PPE	Reduction factor	with PPE	
I_M =	0.008	12.6	0.00144	1.0	0.00144	I = Inhalation
$D_{M(H)}$ =	2.0	12.6	0.36	0.01	0.0036	D = Dermal
I_A =	0.018	12.6	0.00324	1.0	0.00324	M = Mix/Loading
$D_{A(C)}$ =	1.2	12.6	0.216	1.0	0.216	A = Application
$D_{A(H)}$ =	0.7	12.6	0.126	0.01	0.00126	H = Hands
$D_{A(B)}$ =	9.6	12.6	1.728	0.05	0.0864	C = Head
						B = Body

Absorbed dose:

Route		Absorption [%]	No PPE: Estimated route exposure [mg/kg bw/day]	No PPE: Systemic exposure [mg/kg bw/day]	With PPE: Estimated route exposure [mg/kg bw/day]	With PPE: Systemic exposure [mg/kg bw/day]
Dermal:	Mix/Loading	0.1	0.36	0.00036	0.0036	0.000004
	Application	1.0	2.07	0.0207	0.30366	0.003037
Inhalation:	Mix/Loading	100	0.00144	0.00144	0.00144	0.00144
	Application	100	0.00324	0.00324	0.00324	0.00324
		Total =		**0.02574**		**0.00772**

Table 7.2.1.1-5: German Model calculations – grapes (N-EU)

Operator exposure estimate: German model. Tractor-mounted/trailed broadcast air-assisted sprayer

Product:	Antracol WG 70				
Active substance:	Propineb		a.s. concentration:	700	[g/l or kg]
Formulation:	WG		PPE during mix/loading:	Respiration:	None
Dose [l or kg/ha]:	1.6			Hands:	Gloves
Work rate [ha/day]:	8		PPE during application:	Respiration:	None
Body weight [kg]:	70			Hands:	Gloves
Inhalation absorption [%]	100			Head:	None
Dermal absorption [%]	0.1	(concentrate)		Body:	Standard protective coverall
	1.0	(dilution)			

Calculation of route exposure:

Route	Specific exposure [mg/kg a.s.]	a.s. handled [kg/day]	Estimated exposure [mg/kg bw/day]: No PPE	Reduction factor	with PPE	
I_M =	0.008	8.96	0.001024	1.0	0.001024	I = Inhalation
$D_{M(H)}$ =	2.0	8.96	0.256	0.01	0.00256	D = Dermal
I_A =	0.018	8.96	0.002304	1.0	0.002304	M = Mix/Loading
$D_{A(C)}$ =	1.2	8.96	0.1536	1.0	0.1536	A = Application
$D_{A(H)}$ =	0.7	8.96	0.0896	0.01	0.000896	H = Hands
$D_{A(B)}$ =	9.6	8.96	1.2288	0.05	0.06144	C = Head
						B = Body

Absorbed dose:

Route		Absorption [%]	No PPE: Estimated route exposure [mg/kg bw/day]	No PPE: Systemic exposure [mg/kg bw/day]	With PPE: Estimated route exposure [mg/kg bw/day]	With PPE: Systemic exposure [mg/kg bw/day]
Dermal:	Mix/Loading	0.1	0.256	0.000256	0.00256	0.000003
	Application	1.0	1.472	0.01472	0.215936	0.002159
Inhalation:	Mix/Loading	100	0.001024	0.001024	0.001024	0.001024
	Application	100	0.002304	0.002304	0.002304	0.002304
			Total=	**0.018304**		**0.00549**

Table 7.2.1.1-6: German Model calculations - grapes (S-EU)

Operator exposure estimate: German model. Tractor-mounted/trailed broadcast air-assisted sprayer

Product:	Antracol WG 70				
Active substance:	Propineb	a.s. concentration:	700	[g/l or kg]	
Formulation:	WG	PPE during mix/loading:	Respiration:	None	
Dose [l or kg/ha]:	2.0		Hands:	Gloves	
Work rate [ha/day]:	8	PPE during application:	Respiration:	None	
Body weight [kg]:	70		Hands:	Gloves	
Inhalation absorption [%]	100		Head:	None	
Dermal absorption [%]	0.1	(concentrate)	Body:	Standard protective coverall	
	1.0	(dilution)			

Calculation of route exposure:

Route	Specific exposure [mg/kg a.s.]	a.s. handled [kg/day]	Estimated exposure [mg/kg bw/day] No PPE	Reduction factor	with PPE	
I_M =	0.008	11.2	0.00128	1.0	0.00128	I = Inhalation
$D_{M(H)}$ =	2.0	11.2	0.32	0.01	0.0032	D = Dermal
I_A =	0.018	11.2	0.00288	1.0	0.00288	M = Mix/loading
$D_{A(C)}$ =	1.2	11.2	0.192	1.0	0.192	A = Application
$D_{A(H)}$ =	0.7	11.2	0.112	0.01	0.00112	H = Hands
$D_{A(B)}$ =	9.6	11.2	1.536	0.05	0.0768	B = Head
						B = Body

Absorbed dose:

Route		Absorption [%]	No PPE Estimated route exposure [mg/kg bw/day]	No PPE Systemic exposure [mg/kg bw/day]	With PPE Estimated route exposure [mg/kg bw/day]	With PPE Systemic exposure [mg/kg bw/day]
Dermal:	Mix/Loading	0.1	0.32	0.00032	0.0032	0.000003
	Application	1.0	1.84	0.0184	0.26992	0.002699
Inhalation:	Mix/Loading	100	0.00128	0.00128	0.00128	0.00128
	Application	100	0.00288	0.00288	0.00288	0.00288
			Total=	**0.02288**		**0.006862**

Dutch Model calculations:

Table 7.2.1.1-7: Dutch Model calculations - greenhouse tomato (N-EU)

OPERATOR EXPOSURE			DUTCH GREENHOUSE MODEL	
form	Antracol WG 70		Application including mixing and loading	
a.s.	Propineb			
Parameter	**Value**	**Unit**	**References, comments**	
MANUAL SPRAYING in greenhouses				
AR	Application rate	1.68	kg a.s./ha	summary of intended uses
A	Area treated	1	ha/ day	Dutch model
Inhalation Exposure			without PPE	
SV	Surrogate Exposure Value	1	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
	Inhalation Exposure (without PPE)	**1.68**	mg a.s./ day	IE = SV x AR x A
Inhalation Exposure (with PPE)			with PPE	
	PPE-factor	10		Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)
	Inhalation Exposure (with PPE)	**0.168**	mg a.s./ day	IE(PPE) = (1/PPE-factor) x IE
Dermal Exposure			without PPE	
SV	Surrogate Exposure Value	200	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
	Dermal Exposure	**336**	mg a.s./ day	DE = SV x AR x A
Dermal Exposure (with PPE)			with PPE	
	PPE-factor	10		Gloves + coverall: 10 (Dutch model)
	Dermal Exposure (with PPE)	**33.6**	mg a.s./ day	DE(PPE) = (1/PPE-factor) x DE
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	1	%	
	AOEL	3.22	mg a.s./ day	based on 70 kg bw

	Internal exposure	**Without PPE** [mg a.s. / day]	**With PPE** [mg a.s. / day]	
	Inhalation	1.6800	0.1680	IE(int) = IE x (IA/100)
	Dermal	3.3600	0.3360	DE(int) = DE x (DA/100)
	Total	**5.0400**	**0.5040**	**sum**
	%AOEL			
	Inhalation	52	5	%AOEL = 100 x IE(int) / AOEL
	Dermal	104	10	%AOEL = 100 x DE(int) / AOEL
	Total	**157**	**16**	**sum**

	Systemic exposure	
	(mg/person)	(mg/kg bw/day)
Without PPE	5.0400	0.0720
With PPE	0.5040	0.0072

Table 7.2.1.1-8: Dutch Model calculations - greenhouse tomato (S-EU)

Parameter		Value	Unit	References, comments
MANUAL SPRAYING in greenhouses				
AR	Application rate	2.1	kg a.s./ha	summary of intended uses
A	Area treated	1	ha/ day	Dutch model
Inhalation Exposure				without PPE
SV	Surrogate Exposure Value	1	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
	Inhalation Exposure (without PPE)	**2.1**	mg a.s./ day	IE = SV x AR x A
Inhalation Exposure (with PPE)				with PPE
	PPE-factor	10		Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)
	Inhalation Exposure (with PPE)	**0.21**	mg a.s./ day	IE(PPE) = (1/PPE-factor) x IE
Dermal Exposure				without PPE
SV	Surrogate Exposure Value	200	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
	Dermal Exposure	**420**	mg a.s./ day	DE = SV x AR x A
Dermal Exposure (with PPE)				with PPE
	PPE-factor	10		Gloves + coverall: 10 (Dutch model)
	Dermal Exposure (with PPE)	**42**	mg a.s./ day	DE(PPE) = (1/PPE-factor) x DE
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	1	%	
	AOEL	3.22	mg a.s./ day	based on 70 kg bw

Internal exposure	Without PPE [mg a.s. / day]	With PPE [mg a.s. / day]	
Inhalation	2.1000	0.2100	IE(int) = IE x (IA/100)
Dermal	4.2000	0.4200	DE(int) = DE x (DA/100)
Total	**6.3000**	**0.6300**	**sum**

% AOEL			
Inhalation	65	7	%AOEL = 100 x IE(int) / AOEL
Dermal	130	13	%AOEL = 100 x DE(int) / AOEL
Total	**196**	**20**	**sum**

	Systemic exposure	
	(mg/person)	(mg/kg bw/day)
Without PPE	6.3000	0.0900
With PPE	0.63000	0.0090

ECPA Greenhouse Model calculations

To address a data gap for hand-held applications in greenhouses, particularly in Southern Europe, ECPA conducted seven operator exposure studies during the period of 2002 to 2006. Details of the location and the crop are summarized in the following table.

Table 7.2.1.1-9: List of operator exposure studies in the ECPA Greenhouse Model

EOEM Study ID-	Country	Region	Crop	No of Operators	
				Mix/Load	Application
2	Spain	Almeria	Peppers	10	32
3	Spain	Almeria	Cucumber	10	10
10	Italy	Tuscany/Veneto	Pot Plants	10	10
12	Spain	Murcia/Alicante	Cucumber	10	10
13	Spain	Murcia/Alicante	Tomato	10	10
14	Italy	Sicily	Melon	10	20
15	Italy	Sicily	Melon	NA	10

NA: not applicable

The studies were conducted according to OECD Guidance[1] and were GLP compliant for the field, analytical and report phases, including assessment reports. The studies conducted by internationally recognized contract research organizations.

Briefly, the exposure was determined using standardized passive dosimetry methodology. This entailed the use of inner and outer dosimeters for body exposure, protective gloves and hand washes for hand exposure, face and neck washes for head exposure. Inhalation exposure was monitored using a suitable collection device located in the breathing zone to collect the inhalable fraction of airborne particles.

Analysis of the work practices and exposure data has identified four exposure scenarios:
High crop (>0.5m):

- Standard scenario – insignificant contact with treated foliage
- Intensive scenario – direct contact with treated foliage (dense crop, no or narrow rows)

Low crop (<0.5m):

- Standard scenario – insignificant contact with treated foliage
- Intensive scenario – direct contact with treated foliage (dense crop, no or narrow rows)

In the **'Standard'** scenario, operators wore polyester/cotton standard working coveralls.

In certain cropping scenarios, where contact to treated foliage could not be avoided rain suit coveralls/trousers were worn. Exposure of these operators was determined for an **'Intensive'** scenario.

Algorithms using the 75th percentile of the exposure distributions have been developed based on normalization for the amount of kg a.s. handled or applied. These have been generated for each of the

[1] OECD (1997) Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application OECD Environmental Health and Safety Publications Series on Testing and Assessment No. 9

four scenarios' data sets and incorporated into a Microsoft Excel-based model [Greenhouse model v_2.1 (20101223).xls].

The model has passed through a workshop with European experts from Member States and was further developed during several commenting periods according to the requirements of Member States authorities.

More details about the model and the underlying studies are given in:

Report:	[redacted]d; [redacted];2010;M-400719-01
Title:	Southern European greenhouse model overview
Report No:	M-400719-01-1
Document No:	M-400719-01-1
Guidelines:	**-/-**
GLP/GEP:	**n.a.**

n.a. = not applicable

Detailed calculations:
Exposure calculations for tomato are made for the high crop 'standard' scenario.

Table 7.2.1.1-10: ECPA Greenhouse Model calculations, tomato (N-EU, high crop – standard)

Operator exposure estimate: Greenhouse model, high crop, standard

Product:	Antracol WG 70				
Active substance:	Propineb	a.s. concentration:	700	[g/kg; kg]	
Formulation:	WG	PPE during mix/loading:	Respiration:	None	
Dose [l or kg/ha product]:	1.4		Hands:	Gloves	
Work rate [ha/day]:	1	PPE during application:	Respiration:	None	
Body weight [kg]:	70		Hands:	Gloves	
Inhalation absorption [%]	100		Head:	None	
Dermal absorption [%]	0.1 (concentrate)		Body:	Coverall	
	1.0 (dilution)				

Calculation of route exposure:

Route	Intermediate exposure figures [mg/kg a.s.] used to calculate "Estimated exposure" for		a.s. handled [kg/day]	Estimated exposure [mg/kg bw/day]			
	"Unprotected"	"Protected"		Unprotected	Reduction factor	Protected	
$I_{M/L}$ =	0.013344		1.680	0.00032025			I = Inhalation
$D_{M/L}$ =	2.295118	0.029689	1.680	0.05508282		0.00071253	D = Dermal
I_A =	0.676955		1.680	0.01624692			M = Mix/Loading
$D_{A(C)}$ =	0.806061		1.680	0.01934545			A = Application
$D_{A(H)}$ =	25.190286	0.021652	1.680	0.6045693		0.0005197	C = Head
$D_{A(B)}$ =	17.084126		1.680	0.410019			H = Hands
							B = Body

Absorbed dose:

Route		Absorption [%]	Unprotected		Protected	
			Estimated route exposure [mg/kg bw/day]	Systemic exposure [mg/kg bw/day]	Estimated route exposure [mg/kg bw/day]	Systemic exposure [mg/kg bw/day]
Dermal:	Mix/Loading	0.1	0.055083	0.0000551	0.000713	0.000001
	Application	1.0	1.033934	0.010339	0.429884	0.0042988
Inhalation:	Mix/Loading	100	0.00032025	0.00032025	0.00032025	0.00032025
	Application	100	0.016247	0.016247	0.016247	0.016247
		Total =		**0.026962**		**0.020867**

Table 7.2.1.1-11: ECPA Greenhouse Model calculations, tomato (S-EU, high crop – standard)

Operator exposure estimate: Greenhouse model, High crop, standard

Product:	Antracol WG70				
Active substance:	Propineb		a.s. concentration:	700	[g/l or kg]
Formulation:	WG		PPE during mix/loading:	Respiration:	None
Dose [l or kg/ha product] :	3.0			Hands:	Gloves
Work rate [ha/day]:	1		PPE during application:	Respiration:	None
Body weight [kg]:	70			Hands:	Gloves
Inhalation absorption [%]	100			Head:	None
Dermal absorption [%]	0.1	(concentrate)		Body:	Coverall
	1.0	(dilution)			

Calculation of route exposure:

Route	Intermediate exposure figures [mg/kg a.s.] used to calculate "Estimated exposure" for		a.s. handled [kg/day]	Estimated exposure [mg/kg bw/day]			
	"Unprotected"	"Protected"		Unprotected	Reduction factor	Protected	
I_M =	0.013344		2.100	0.00040031			I = Inhalation
$D_{M(H)}$ =	2.295118	0.029689	2.100	0.06885353		0.00089067	D = Dermal
I_A =	0.676955		2.100	0.02030865			M = Mix/Loading
$D_{A(C)}$ =	0.806061		2.100	0.02418182			A = Application
$D_{A(H)}$ =	25.190386	0.021652	2.100	0.7557116		0.0006496	C = Head
$D_{A(B)}$ =	17.084126		2.100	0.512524			H = Hands
							B = Body

Absorbed dose:

Route		Absorption [%]	Unprotected		Protected	
			Estimated route exposure [mg/kg bw/day]	Systemic exposure [mg/kg bw/day]	Estimated route exposure [mg/kg bw/day]	Systemic exposure [mg/kg bw/day]
Dermal:	Mix/Loading	0.1	0.068854	0.0000689	0.000891	0.000001
	Application	1.0	1.292417	0.012924	0.537355	0.0053736
Inhalation:	Mix/Loading	100	0.00040031	0.00040031	0.00040031	0.00040031
	Application	100	0.020309	0.020309	0.020309	0.020309
		Total =		**0.033702**		**0.026083**

CP 7.2.1.2 Measurement of operator exposure

Since the exposure estimate carried out indicated that the AOEL will not be exceeded under practical condition of use, a study to provide a measure of operator exposure was not necessary and was therefore not carried out.

CP 7.2.2 Bystander and resident exposure

A harmonized European guidance for the estimation of bystander and resident exposure is not available. However, national guidance exists in Germany and in the UK. The German guidance ([redacted]. et al., 2008)[2] is followed and the official calculation spreadsheet[3] is used in the following evaluation.

[2] [redacted] Guidance for Exposure and Risk Evaluation for Bystanders and Residents exposed to Plant Protection Products during and after Application, J. Verbr. Lebensm. 3, 272-28, 2008

[3] http://www.bfr.bund.de/cm/343/schutz_von_nebenstehenden_und_anwohnern_v1.xls

The cGAP for bystanders (acute exposure, 1 application) and residents (longer term exposure considering multiple applications) is presented in the following table. Bystanders and residents will be exposed during and after spray applications in the field by off-target drift.

Table 7.2.2-1: Summary of critical GAPs for bystanders and residents

Crop (grouping)	Application technique	Max. dose rate (kg a.s./ha)	Max no. of appl.	% Drift (1 appl., 90th perc., 3 m)	% Drift (1-2 applic., 82nd percentile, 3 m)
Apple	Broadcast air assisted sprayer	1.575	2	29.20	25.53
Grapes	Broadcast air assisted sprayer	1.4	2	2.70	2.53

- Justification of the selection of the critical GAP

The exposure scenario for high crop spray application in apple and grapes with off-target drift is to be considered with a maximum dose rate and single application for bystanders and repeated applications for residents. A minimum distance of 3 m in high crops is considered. Spraying apples constitutes a worst case for bystanders/residents (max. dose rate and max. drift). A risk assessment is therefore presented for this scenario and a separate estimate for spraying grapes is not made.

Bystander/resident exposure from greenhouse (indoor) applications is considered to be negligible and estimations are therefore not conducted.

Summary

A summary of the exposure estimates resulting from the cGAP is presented in the following table. Detailed calculations are presented in CP 7.2.2.1.

Table 7.2.2-2: Predicted systemic exposures as a proportion of the AOEL

Target group	Scenario	Total systemic exposure (mg/kg bw/day)*	AOEL (mg/kg bw/day)	% of AOEL
Bystander	Adult	0.0077	0.046	17
	Child	0.0061		13
Resident	Adult	0.0013		3
	Child	0.0093		20

* Assumes a 60 kg bodyweight for an adult and 16.15 kg for a child
* Absorption: 1% (spray) via the dermal route, 100 % via the inhalation route

Assessment

Exposure is calculated for the use of broadcast air assisted spray equipment using the maximum dose rate and highest drift. Persons are assumed to be positioned at a distance of 3 m to the application equipment. Estimates of adult and child bystander exposure are 17% and 13% of the AOEL, respectively. Estimates of adult and child resident exposure are 3% and 20% of the AOEL, respectively.

Conclusion

It is predicted that all exposures are within acceptable levels. Therefore, an unacceptable risk for bystanders and residents is not anticipated.

CP 7.2.2.1 - Estimation of bystander and resident exposure

The following definitions and assumptions for bystanders and residents may be applied.

Bystanders are persons:

- who are located within or directly adjacent to the area where pesticide application or treatment is in process or has taken place
- whose presence is quite incidental and unrelated to work involving pesticides but whose position may put them at risk of exposure
- who take no action to avoid or control exposure
- that are not wearing protective clothing and/or are wearing light clothing e.g. short sleeved shirt and short trousers

Residents may possibly live or work near areas of the application of plant protection products (e.g. standing, working or sitting in a garden in the vicinity of the application). They may be exposed to plant protection products mainly via the dermal route from spray drift deposits and by inhalation of vapour drift (depending on the vapour pressure of the active substance). For infants and toddlers exposure might also occur orally (e.g. through hand-to-mouth transfer and/or object-to-mouth transfer - the so-called mouthing and/or pica behaviour[4]).

Exposure is calculated for adult and child bystanders as well as adult and child residents. The German guidance for bystander/resident exposure is used.

a) Bystander exposure assessment

Dermal Exposure (Spray Drift):

$SDE_B = (AR \times D \times BSA \times DA) / BW$

Where: SDE_B = *Systemic Exposure of Bystanders via the Dermal Route (mg/kg bw/day)*

		Input parameters:
AR	= *Application Rate (mg/m²):*	*157.5 (= 1.575 kg a.s./ha)*
D	= *Drift (%):*	*29.2 (single application, 3 m distance)*
BSA	= *Exposed Body Surface Area (m²):*	*1 (adult), 0.21 (child)*
DA	= *Dermal Absorption (%):*	*1*
BW	= *Body Weight (kg/person):*	*60 (adult), 16.15 (child)*

Inhalation Exposure (Spray Drift):

$SIE_B = (I^*_A \times AR \times A \times T \times IA) / BW$

[4] Pica is typically defined as eating non-nutritive substances. Mouthing is typically defined as putting objects (e.g. hands) into the mouth. Pica and mouthing behaviour are normal parts of development for young children.

Where: SIE_B = Systemic Exposure of Bystanders via the Inhalation Route(mg/kg bw/day)

		Input parameters:
I^*_A	*= Specific Inhalation Exposure (mg/kg a.s. handled per day), field crop sprayer:*	*0.018 (adult), 0.018/1.74 (child)*
AR	*= Application Rate (kg a.s./ha):*	*1.0*
A	*= Area Treated (ha/day):*	*8*
T	*= Time [Duration] (min):*	*5 min. of 6 hours = 5/360*
IA	*= Inhalation Absorption (%):*	*100*
BW	*= Body Weight (kg/person):*	*60 (adult), 16.15 (child)*

Total Systemic Exposure of Bystanders

Adults and children: $SE_B = SDE_B + SIE_B$ (mg/kg bw/day)

Where:

SE_B = Systemic Exposure of Bystanders (mg/kg bw/day)
SDE_B = Systemic Dermal Exposure of Bystanders (mg/kg bw/day)
SIE_B = Systemic Inhalation Exposure of Bystanders (mg/kg bw/day)

Table 7.2.2.1-1: Calculation of bystander exposure and proportion of the AOEL

Input parameters considered for the estimation of bystander exposure:

Intended use(s):	Apple		**Drift (D):**	29.20	% (HC, 3 m)
Application rate (AR):	1.575	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	157.5	mg/m²		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.018	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.01034	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	1.00	% ('worst case')	**Area Treated (A):**	8	ha/d (based on HCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.046	mg/kg bw/d	**Exposure duration (T):**	5	min

Bystander exposure towards Propineb					
Adults			**Children**		
Bystander: Systemic dermal exposure during/after application in Apple (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(157.5 x 29.2% x 1 x 1%) / 60			(157.5 x 29.2% x 0.21 x 1%) / 16.15		
External dermal exposure	45.99	mg/person	External dermal exposure	9.6579	mg/person
External dermal exposure	0.7665	mg/kg bw/d	External dermal exposure	0.598012384	mg/kg bw/d
Systemic dermal exposure	**0.007665**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.005980**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application in Apple (via spray drift)					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0,000 / 360 x 1.575 x 8 x 5 x 100%) / 60			(0,000 / 360 x 1.575 x 8 x 5 x 100%) / 16.15		
External inhalation exposure	0.00315	mg/person	External inhalation exposure	0.001810345	mg/person
External inhalation exposure	0.0000525	mg/kg bw/d	External inhalation exposure	0.000112096	mg/kg bw/d
Systemic inhalation exposure	**0.000053**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000112**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure	0.46305	mg/person	Total systemic exposure	0.098389345	mg/person
Total systemic exposure	**0.007718**	**mg/kg bw/d**	**Total systemic exposure**	**0.006092**	**mg/kg bw/d**
% of AOEL	**16.78**	**%**	**% of AOEL**	**13.24**	**%**

b) Resident exposure assessment

Dermal Exposure (via deposits caused by spray drift):

$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$

Where: SDE_R = Systemic Exposure of Residents via the Dermal Route (mg/kg bw/day)

		Input parameters:
AR	*= Application Rate (mg/cm²):*	*0.01575 (= 1.575 kg a.s./ha)*
NA	*= Number of applications:*	*2*
D	*= Drift (%):*	*25.53% (≥ 2 applications,3 m distance)*
TTR	*= Turf Transferable Residues (%):*	*5*
TC	*= Transfer Coefficient (cm²/hour):*	*7300 (adult), 2600 (child)*
H	*= Exposure Duration (hours):*	*2*
DA	*= Dermal Absorption (%):*	*1*
BW	*= Body Weight (kg/person):*	*60 (adult), 16.15 (child)*

Inhalation Exposure (Vapour Drift):

$SIE_R = (AC_V \times IR \times IA) / BW$

Where: SIE_R = Systemic Exposure of Residents via the Inhalation Route (mg/kg bw/day)

		Input parameters:
AC_V	*= Airborne Concentration of Vapour (mg/m³):*	*0.001 (vapour pressure of propineb = 1.6 x 10⁻⁴ Pa at 20 °C = semi-volatile)*
IR	*= Inhalation Rate (m³/day):*	*16.52 (adult), 8.31 (child)*
IA	*= Inhalation Absorption (%):*	*100*
BW	*= Body Weight (kg/person):*	*60 (adult), 16.15 (child)*

Child Oral Exposure

Children's hand-to-mouth exposure

$SOE_H = (AR \times NA \times D \times TTR \times SE \times SA \times Freq \times H \times OA) / BW$

Where: SOE_H = Systemic Oral Exposure via the Hand to Mouth Route (mg/kg bw/day)

		Input parameters:
AR	*= Application Rate (mg/cm²):*	*0.01575 (= 1.575 kg a.s./ha)*
NA	*= Number of applications:*	*2*
D	*= Drift (%):*	*25.53 (≥ 2 applications, 3 m distance)*
TTR	*= Turf Transferable Residues (%):*	*5*
SE	*= Saliva Extraction Factor (%):*	*50*
SA	*= Surface Area of Hands (cm²):*	*20*
Freq	*= Frequency of Hand-to-Mouth (events/hour):*	*20*
H	*= Exposure Duration (hours):*	*2*
OA	*= Oral Absorption (%):*	*60*
BW	*= Body Weight (kg/person):*	*16.15*

Children's object-to-mouth exposure

SOE_O = (AR x D x DFR x IgR x OA) / BW

Where: SOE_O = Systemic Oral Exposure via the Object to Mouth Route (mg/kg bw/day)

		Input parameters:
AR	*= Application Rate (mg/cm²):*	*0.0152 (= 1.575 kg a.s./ha)*
NA	*= Number of applications:*	*2*
D	*= Drift (%):*	*25.53 (= 2 applications, 3 m distance)*
DFR	*= Dislodgeable Foliar Residues (%):*	*20*
IgR	*= Ingestion Rate for Mouthing of Grass/Day (cm²):*	*25*
OA	*= Oral Absorption (%):*	*60*
BW	*= Body Weight (kg/person):*	*16.15*

Total Systemic Exposure of Residents

Adults: $SER = SDE_R + SIE_R$ (mg/kg bw/day)

Children: $SER = SDE_R + SIE_R + SOE_H + SOE_O$ (mg/kg bw/day)

Where: SER = Systemic Exposure of Residents (mg/kg bw/day)
SDE_R = Systemic Dermal Exposure of Residents (mg/kg bw/day)
SIE_R = Systemic Inhalation Exposure of Residents (mg/kg bw/day)
SOE_H = Systemic Oral Exposure via the Hand to Mouth Route (mg/kg bw/day)
SOE_O = Systemic Oral Exposure via the Object to Mouth Route (mg/kg bw/day)

Table 7.2.2.1-2: Calculation of resident exposure, absorbed dose and % of AOEL

Input parameters considered for the estimation of resident exposure:

Intended use(s):	Apple		**Drift (D):**	25.53	% (HC, 3 m)
Application rate (AR):	1.575	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.01575	mg/cm^2		2600	cm^2/h (children)
Number of applications (NA):	2		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0.001	mg/m3
Dermal absorption (DA):	1.00	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults)
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA):	60	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.046	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Resident exposure towards Propineb					
Adults			**Children**		
Residents: Systemic dermal exposure after application in Apple (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.01575 x 2 x 25.53% x 5% x 7300 x 2 x 1%) / 60			(0.01575 x 2 x 25.53% x 5% x 2600 x 2 x 1%) / 16.15		
External dermal exposure	5.8706235	mg/person	External dermal exposure	2.090907	mg/person
External dermal exposure	0.0978437	mg/kg bw/d	External dermal exposure	0.129467926	mg/kg bw/d
Systemic dermal exposure	**0.000978**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001295**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application in Apple (via vapour)					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0,001 x 16.57 x 100%) / 60			(0,001 x 8.31 x 100%) / 16.15		
External inhalation exposure	0.01657	mg/person	External inhalation exposure	0.00831	mg/person
External inhalation exposure	0.0002762	mg/kg bw/d	External inhalation exposure	0.000514551	mg/kg bw/d
Systemic inhalation exposure	**0.000276**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000515**	**mg/kg bw/d**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)}$ = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.01575 x 2 x 25.53% x 5% x 50% x 20 x 20 x 2 x 60%) / 16.15		
			External oral exposure	0.160839	mg/person
			External oral exposure	0.009959071	mg/kg bw/d
			Systemic oral exposure	**0.005975**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)}$ = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.01575 x 2 x 25.53% x 20% x 25 x 60%) / 16.15		
			External oral exposure	0.04020975	mg/person
			External oral exposure	0.002489768	mg/kg bw/d
			Systemic oral exposure	**0.001494**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	0.0752762	mg/person	Total systemic exposure	0.14984832	mg/person
Total systemic exposure	**0.001255**	**mg/kg bw/d**	**Total systemic exposure**	**0.009279**	**mg/kg bw/d**
% of AOEL	**2.73**	**%**	**% of AOEL**	**20.17**	**%**

CP 7.2.2.2 Measurement of bystander and resident exposure

Since the exposure estimate carried out indicated that the AOEL will not be exceeded under practical conditions of use, a study to provide a measure of bystander or resident exposure was not necessary and was therefore not carried out.

CP 7.2.3 Worker exposure

The determination of the cGAP for worker re-entry is based on the recommendation provided in the EUROPOEM II report[5] for worker exposure for four different harvesting scenarios with bare hands:

Crop group	Transfer Coefficient (cm^2/h)
Fruits (from trees):	4500
Vegetables:	2500
Ornamentals:	5000
Strawberries:	3000

The cGAP for worker exposure includes re-entry in grapes. A Transfer Coefficient (TC) for re-entry activities in this crop is not provided in the EUROPOEM report. Therefore, the EPA policy 3[6] is adopted which presents transfer coefficients (TC) for agricultural or commercial activities for use in post-application exposure assessments for grapes. **Vine/trellis** is identified as the appropriate transfer coefficient group. The activity with the highest transfer coefficient is used as a "screening-level" post-application exposure and risk assessment to calculate exposure. The highest TC is **10100 cm^2/h** provided for hand harvesting considering high crop height and full foliage density.

The worker risk assessment is made for the intended uses of Propineb WG 70. A summary of proposed uses and selection of the cGAP used for worker risk assessment is presented in Table 7.2.3-1.

Table 7.2.3-1: Critical GAPs for worker exposure

Crop grouping	Re-entry task	Transfer coefficient [cm^2/h]	Region	Duration [h]	Max. dose rate		No.	Min. interval [days]	PHI [days]
					[kg/ha product]	[kg a.s./ha]			
Apple	Pruning/ thinning/ harvesting	4500	N- and S-EU	8	2.25	1.575	2	14	n.a.

[5] EUROPOEM II project FAIR3-CT96-1406; Post Application Exposure of Workers to Pesticides in Agriculture, Report of the Re-entry Working Group; December 2002

[6] Science Advisory Council for Exposure (ExpoSAC) Policy 3, US Environmental Protection Agency, Revised March 2012

Grapes	Binding/ tying/ harvesting	10100	N-EU	8	1.6	1.12	2	7	n.a.
			S-EU	8	2	1.40	2	7	56
Tomato	Binding/ tying/ harvesting	2500	N-EU	8	2.4	1.68	4	7	28
			S-EU	8	3	2.10	4	7	28

- Summary

Predicted exposures are calculated from a cumulative foliar deposit based on the maximum number of applications, the maximum dose rate and 8 hours/day contact with the foliage. Exposure is compared with the AOEL. Exposure estimates and proportions of the AOEL accounted for by the estimates are summarised in the following tables.

Table 7.2.3-2: Predicted worker exposure (no PPE)

Crop	Systemic exposure* (mg/kg bw/day)	% of AOEL (0.046 mg/kg bw/day)
Tier 1 (no PPE)		
Apple (N-/S-EU)	0.0482	105
Grapes (N-EU)	0.0860	187
Grapes (S-EU)	0.1075	234
Tomato (N-EU)	0.0538	117
Tomato (S-EU)	0.0672	146
Tier 2 (no PPE, refinement based on realistic LAI and interception)		
Apple (N-/S-EU)	0.0161	35
Grapes (N-EU)	0.0287	62
Grapes (S-EU)	0.0358	78
Tomato (N-EU)	0.0179	39
Tomato (S-EU)	0.0224	49
Tier 3 (with PPE)		
Apple (N-/S-EU)	0.0008	2
Grapes (N-EU)	0.0013	3
Grapes (S-EU)	0.0016	4
Tomato (N-EU)	0.0010	2
Tomato (S-EU)	0.0012	3
Tier 4 (no PPE, refinement based on experimental dislodgeable foliar residues)		
Apple (N-/S-EU)	0.0022	5
Grapes (N- and S-EU)	0.0096	21
Tomato (N- and S-EU)	0.0047	10

* 1% dermal absorption, 60 kg worker

Conclusions

Predicted exposures of unprotected workers slightly exceed the AOEL in the Tier 1 exposure assessment.

In a tiered approach, refinements are done for the evaluation of more realistic exposure. Refinements of the DFR_0 are made using realistic leaf area index (LAI) and crop interception. Predicted exposures of unprotected operators based on these refinements are below the AOEL (Tier 2).

Additional estimates are calculated for protected operators (Tier 3, protective clothing incl. gloves). Exposures are demonstrated to be far below the AOEL.

Finally, exposure is calculated for unprotected workers using experimentally determined dilodgeable foliar residues (DFR, Tier 4). All exposure estimates are below the AOEL.

An unacceptable risk is therefore not anticipated for re-entry workers following application of Antracol WG 70.

CP 7.2.3.1 Estimation of worker exposure

The exposure is calculated in a tiered approach. In Tier 1, exposure is estimated for unprotected operators based on default assumptions. In Tier 2, a refinement is made for the DFR_0 based on realistic LAI and crop interception. The exposure of protected operators is estimated in Tier 3. An additional evaluation is conducted for unprotected operators using experimentally determined dislodgeable foliar residue (DFR) data in Tier 4.

Tier 1 (no PPE):

The exposure is calculated according to the following equation:

$$S = DFR \times N \times TC \times WR \times AR \times P / BW \times DA$$

Where S: Systemic exposure
DFR: Dislodgeable foliar residues (3 µg as/cm²)
*N: Number of applications (considering MAF)**
apple = 1.7 (2 appl., 14 d interval)
grapes = 1.9 (2 appl., 7 d interval)
tomato = 3.2 (4 appl., 7 d interval)
TC : Transfer Coefficient (activity specific; cm²/h)
apple = 4500 cm²/h
grapes = 10100 cm²/h
tomato = 2500 cm²/h
WR: Work rate (8 hours/day)
AR: Application rate (crop specific; kg as/ha)
P: Protection factor for clothing/PPE (1, no PPE)
BW: Body weight (60 kg person)
DA: Dermal absorption (1%)

**based on Multiple Application Factor (MAF) when more than one application and assuming DT_{50} of 30 days*

Exposure is calculated with the maximum dose rate and 8 hours/day contact with the foliage. The higher of the dermal absorption values from concentrate or any dilution is applied (1%). Where sequential applications are performed a worst case is assumed considering re-entry directly after the final treatment and potential accumulation of DFR from successive treatments. If no data are available on the degree of dissipation (decay) over time, the worst-case approach would be to assume that no dissipation occurs. In this case DFR_0 would be used for calculations, i.e. the residue available directly after application. However, for active substances that are organic chemicals for which there is evidence of breakdown by photolysis or hydrolysis in soil or water, available data indicate that it would be reasonable to assume, as a default, that dissipation occurs exponentially, with a half-life of 30 days (USDA Natural Resources Conservation Service, 2006; Willis and McDowell, 1987[7]). Where sequential applications of an active substance were made on the same crop, the dissipation would then be taken into account by application of multiple application factors (MAFs[8]), calculated from the assumed half-life.

Re-entry in <u>apple</u>:

S	=	DFR x N x TC x WR x AR x P / BW x DA
	=	3 x 1.7 x 4500 x 8 x 1.575 x 1 / 60 x 1%
	=	0.0482 mg/kg bw/day
% of AOEL:		105

Re-entry in <u>grapes (N-EU)</u>:

S	=	DFR x N x TC x WR x AR x P / BW x DA
	=	3 x 1.9 x 10100 x 8 x 1.12 x 1 / 60 x 1%
	=	0.0860 mg/kg bw/day
% of AOEL:		187

Re-entry in <u>grapes (S-EU)</u>:

S	=	DFR x N x TC x WR x AR x P / BW x DA
	=	3 x 1.9 x 10100 x 8 x 1.4 x 1 / 60 x 1%
	=	0.1075 mg/kg bw/day
% of AOEL:		234

Re-entry in <u>tomato</u> (N-EU):

S	=	DFR x N x TC x WR x AR x P / BW x DA
	=	3 x 3.2 x 2500 x 8 x 1.68 x 1 / 60 x 1%
	=	0.0538 mg/kg bw/day
% of AOEL:		117

[7] Willis G H and McDowell L L, 1987. Pesticide persistence on foliage. Reviews of Environmental Contamination and Toxicology, 100, 23-73
[8] Scientific Opinion on Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents, EFSA Journal 2010;8(2):1501

Re-entry in tomato (S-EU):

S	=	DFR x N x TC x WR x AR x P / BW x DA
	=	3 x 3.2 x 2500 x 8 x 2.1 x 1 / 60 x 1%
	=	0.0672 mg/kg bw/day
% of AOEL:		146

Tier 2 (no PPE, refinement based on realistic LAI and interception)

The default DFR_0 value (3 µg/cm²) proposed by EUROPOEM is based on consideration of leaf area index (LAI) for which a worst case LAI = 2 is proposed for Tier 1 evaluation. The EUROPOEM II report on re-entry notes the following:

> *If no DFR data for the specific compound are available, DFR may be calculated from the application rate, divided by a reasonable estimate of the leaf area index (LAI, a possible default value for this is no larger than 2). In other cases, a highly conservative default value for the DFR may be taken as 3 µg/cm² for a standardized application rate of 1 kg/ha.*

The default value of 3 µg/cm² provided in the EUROPOEM report is calculated as follows:

- Assuming 100% interception by the crop the DFR_0 is 10 µg/cm² x kg a.s.(LAI = 1);
- Based on worst case assumption for LAI = 2: DFR_0 is 5 µg/cm² x kg a.s. (LAI = 2);
- Double-sided leaves DFR_0 is = 2.5 ug/cm² (LAI is one-sided)
- This is rounded to 3 ug/cm² in the EUROPOEM repot

The higher tier risk assessment may consider realistic LAI for the crop under evaluation. Also, realistic interception rates (crop capture efficiency) should be considered in order to account for loss of a.s. via drift or deposit on ground. Appropriate LAI as well as interception rates are presented in the FOCUS Groundwater Report[9] for apple, grapes and tomato. A summary of LAI, interception and a proposal for refined default DFR_0 is presented in the following table.

Table 7.2.3.1-1: DFR0 as a result of LAI and interception (FOCUS GW Report)

	LAI*	Interception*	Default DFR_0 (if LAI = 2) in EUROPOEM	Refined DFR_0 (if LAI = min. 4)	Refined DFR_0 (if LAI ≥ 4 and max. interception = 80%)
Apple	4-6	65%-80%	2.5 ~ 3	1.25	1
Grapes	5-6	60%-85%	2.5 ~ 3	1.25	1
Tomato	4-6	80%	2.5 ~ 3	1.25	1

* FOCUS Groundwater Report

A refined DFR_0 of 1 µg/cm² per kg a.s. handled is used in the higher tier risk assessment based on a realistic leaf area index (LAI, minimum of 4) and a realistic crop interception (maximum of 80%).

[9] FOCUS groundwater scenarios in the EU review of active substances, Sanco/321/2000 rev.2
Generic guidance for FOCUS groundwater scenarios, version 1.1, April 2002

Re-entry in apple:

S	=	DFR x N x TC x WR x AR x P / BW x DA
	=	1 x 1.7 x 4500 x 8 x 1.575 x 1 / 60 x 1%
	=	0.0161 mg/kg bw/day
% of AOEL:		35

Re-entry in grapes (N-EU):

S	=	DFR x N x TC x WR x AR x P / BW x DA
	=	1 x 1.9 x 10100 x 8 x 1.12 x 1 / 60 x 1%
	=	0.0287 mg/kg bw/day
% of AOEL:		62

Re-entry in grapes (S-EU):

S	=	DFR x N x TC x WR x AR x P / BW x DA
	=	1 x 1.9 x 10100 x 8 x 1.4 x 1 / 60 x 1%
	=	0.0358 mg/kg bw/day
% of AOEL:		78

Re-entry in tomato (N-EU):

S	=	DFR x N x TC x WR x AR x P / BW x DA
	=	1 x 3.2 x 2500 x 8 x 1.68 x 1 / 60 x 1%
	=	0.0179 mg/kg bw/day
% of AOEL:		39

Re-entry in tomato (S-EU):

	=	DFR x N x TC x WR x AR x P / BW x DA
	=	1 x 3.2 x 2500 x 8 x 2.1 x 1 / 60 x 1%
	=	0.0224 mg/kg bw/day
% of AOEL:		49

Tier 3 (with PPE)

Exposure calculations are provided in the following for a protected worker (based on German worker exposure guidance[10]). The BfR Excel spreadsheet[11] is used. The default DFR_0 in the German guidance is 1 ug/cm^2.

The exposure is calculated using a protection factor of 0.05 (5 % of external dermal exposure) corresponding to protective clothing incl. gloves for professionals

P Protection factor for protective clothing (0.05, with PPE)

[10] Uniform Principles for Safeguarding the Health of Workers Re-entering Crop growing Areas after Application of Plant Protection Products (Krebs. B.; Maasfeld, W.; Schrader, J.; Wolf, R.; Hoernicke, E.; Nolting, H. G.; Backhaus, G. F.; Westphal, D. (2000); Nachrichtenbl. Deut. Pflanzenschutzd., 52, S. 5 - 9) - Hinweise in der Gebrauchsanleitung zum Schutz von Personen bei Nachfolgearbeiten in mit Pflanzenschutzmitteln behandelten Kulturen (worker-re-entry) (Hoernicke, E., Nolting, H.-G., Westphal, D. (1998), Nachrichtenbl. Deut. Pflanzenschutzd. 50 (10), S. 267 - 269) Calculation spreadsheet: http://www.bfr.bund.de/cm/343/schutz_von_personen_bei_nachfolgearbeiten_v1.xls

[11] http://www.bfr.bund.de/cm/343/schutz_von_personen_bei_nachfolgearbeiten_v1.xls

Table 7.2.3.1-2: Calculation of worker re-entry in apple (with PPE)

Estimation of post-application exposure of workers (re-entry exposure)

Active substance (a.s.)	Propineb	
Product	Antracol WG 70	
Intended use(s)	Apple	
Application rate (AR)	1.575	kg a.s./ha
Number of applications (NA)	2	1)
Dislodgeable foliar residues (DFR)	1	µg/cm²/kg a.s. 2)
Transfer coefficient (TC)	4500	cm²/person/h 3)
Work rate per day (WR)	8	h/d 4)
Penetration through clothing (P)	0.05	(5 %) 5)
Systemic AOEL	0.046	mg/kg bw/d
Dermal absorption DA)	1	% (worst case, e.g. for dilution)
Body weight (BW)	70	kg

1) consideration of more than two applications will not be necessary if degradation on foliage of at least 50 % can be assumed between 2 applications (otherwise use multiple application factor)

2) default of 1 µg a.s./cm² per kg a.s./ha acc. to Krebs et al. (2000)

3) TC 30000 cm²/person/hour ('worst case', hand harvesting, both sides of leaves) acc. to Krebs et al. (2000),
acc. EUROPOEM II (2002): 2500 (vegetables), 3000 (strawberries), 4500 (fruits from trees), 5000 (ornamentals)
acc. US EPA Policy # 3.1 (2000): 1500 (cereals, e.g. crop inspection), 10000 (grapes)

4) 8 h/day for professional applications if re-entry tasks are intended, 2 h/day for professional applications if re-entry tasks are not intended (e.g. irrigation, maintenance) or for applications in the home and allotment garden area

5) 5 % of dermal exposure corresponding to protective clothing incl. gloves for professionals, 50 % reduction of dermal exposure corresponding to long sleeved shirt, long trousers and gloves for applications in the home and allotment garden area

Estimation of worker (re-entry) exposure

Input parameters considered for the estimation of worker exposure:

Intended use(s):	Apple		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	1.575	kg a.s./ha	**Transfer coefficient (TC):**	4500	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	8	h/d
Body weight (BW):	70	kg/person	**PPE**	5	%
Dermal absorption (DA):	1	% (worst case)			
AOEL	0.046	mg/kg bw/d			

Worker exposure towards Propineb					
Without PPE 1)			**With PPE** 2)		
Worker (re-entry): Systemic dermal exposure after application in Apple					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 4500 x 8 x 1.575 x 2 x 1%) / 70			(1 x 4500 x 8 x 1.575 x 2 x 5% x 1%) / 70		
External dermal exposure	113.40	mg/person	External dermal exposure	5.67	mg/person
External dermal exposure	1.62	mg/kg bw/d	External dermal exposure	0.08	mg/kg bw/d
Total systemic exposure	1.13	mg/person	Total systemic exposure	0.06	mg/person
Total systemic exposure	**0.016200**	**mg/kg bw/d**	**Total systemic exposure**	**0.000810**	**mg/kg bw/d**
% of AOEL	**35.2**	**%**	**% of AOEL**	**1.8**	**%**

1) acceptable without PPE: allocation of BVL code SF245-01 for spray applications
2) acceptable only with PPE: allocation of BVL code SF1891 and SF190 for professional and home and allotment garden applications, respectively (cf. Krebs et al., 2000)

Table 7.2.3.1-3: Calculation of worker re-entry in grapes (N-EU, with PPE)

Estimation of post-application exposure of workers (re-entry exposure)

Active substance (a.s.)	Propineb		
Product	Antracol WG 70		
Intended use(s)	Grapes (N-EU)		
Application rate (AR)	1.12	kg a.s./ha	
Number of applications (NA)	2		1)
Dislodgeable foliar residues (DFR)	1	µg/cm²/kg a.s.	2)
Transfer coefficient (TC)	10100	cm²/person/h	3)
Work rate per day (WR)	8	h/d	4)
Penetration through clothing (P)	0.05	(5 %)	5)
Systemic AOEL	0.046	mg/kg bw/d	
Dermal absorption DA)	1	% (worst case, e.g. for dilution)	
Body weight (BW)	70	kg	

1) consideration of more than two applications will not be necessary if degradation on foliage of at least 50 % can be assumed between 2 applications (otherwise use multiple application factor)

2) default of 1 µg a.s./cm² per kg a.s./ha acc. to Krebs et al. (2000)

3) TC 30000 cm²/person/hour ('worst case', hand harvesting, both sides of leaves) acc. to Krebs et al. (2000), acc. EUROPOEM II (2002): 2500 (vegetables), 3000 (strawberries), 4500 (fruits from trees), 5000 (ornamentals) acc. US EPA Policy # 3.1 (2000): 1500 (cereals, e.g. crop inspection), 10000 (grapes)

4) 8 h/day for professional applications if re-entry tasks are intended, 2 h/day for professional applications if re-entry tasks are not intended (e.g. irrigation, maintenance) or for applications in the home and allotment garden area

5) 5 % of dermal exposure corresponding to protective clothing incl. gloves for professionals, 50 % reduction of dermal exposure corresponding to long sleeved shirt, long trousers and gloves for applications in the home and allotment garden area

Estimation of worker (re-entry) exposure

Input parameters considered for the estimation of worker exposure:

Intended use(s):	Grapes (N-EU)		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	1.12	kg a.s./ha	**Transfer coefficient (TC):**	10100	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	8	h/d
Body weight (BW):	70	kg/person	**PPE**	5	%
Dermal absorption (DA):	1	% ('worst case')			
AOEL	0.046	mg/kg bw/d			

Worker exposure towards Propineb					
Without PPE 1)			**With PPE** 2)		
Worker (re-entry): Systemic dermal exposure after application in Grapes (N-EU)					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 10100 x 8 x 1.12 x 2 x 1%) / 70			(1 x 10100 x 8 x 1.12 x 2 x 5% x 1%) / 70		
External dermal exposure	180.99	mg/person	External dermal exposure	9.05	mg/person
External dermal exposure	2.59	mg/kg bw/d	External dermal exposure	0.13	mg/kg bw/d
Total systemic exposure	1.81	mg/person	Total systemic exposure	0.09	mg/person
Total systemic exposure	**0.025856**	**mg/kg bw/d**	**Total systemic exposure**	**0.001293**	**mg/kg bw/d**
% of AOEL	**56.2**	**%**	**% of AOEL**	**2.8**	**%**

1) acceptable without PPE: allocation of BVL code SF245-01 for spray applications

2) acceptable only with PPE: allocation of BVL code SF1891 and SF190 for professional and home and allotment garden applications, respectively (cf. Krebs et al., 2000)

Table 7.2.3.1-4: Calculation of worker re-entry in grapes (S-EU, with PPE)

Estimation of post-application exposure of workers (re-entry exposure)			
Active substance (a.s.)	**Propineb**		
Product	**Antracol WG 70**		
Intended use(s)	**Grapes (S-EU)**		
Application rate (AR)	**1.4**	**kg a.s./ha**	
Number of applications (NA)	**2**		[1]
Dislodgeable foliar residues (DFR)	**1**	**µg/cm²/kg a.s.**	[2]
Transfer coefficient (TC)	**10100**	**cm²/person/h**	[3]
Work rate per day (WR)	**8**	**h/d**	[4]
Penetration through clothing (P)	**0.05**	**(5 %)**	[5]
Systemic AOEL	**0.046**	**mg/kg bw/d**	
Dermal absorption DA)	**1**	**% (worst case, e.g. for dilution)**	
Body weight (BW)	**70**	**kg**	

[1] consideration of more than two applications will not be necessary if degradation on foliage of at least 50 % can be assumed between 2 applications (otherwise use multiple application factor)

[2] default of 1 µg a.s./cm² per kg a.s./ha acc. to Krebs et al. (2000)

[3] TC 30000 cm²/person/hour ('worst case', hand harvesting, both sides of leaves) acc. to Krebs et al. (2000),
acc. EUROPOEM II (2002): 2500 (vegetables), 3000 (straw berries), 4500 (fruits from trees), 5000 (ornamentals)
acc. US EPA Policy # 3.1 (2000): 1500 (cereals, e.g. crop inspection), 10000 (grapes)

[4] 8 h/day for professional applications if re-entry tasks are intended, 2 h/day for professional applications if re-entry tasks are not intended (e.g. irrigation, maintenance) or for applications in the home and allotment garden area

[5] 5 % of dermal exposure corresponding to protective clothing incl. gloves for professionals, 50 % reduction of dermal exposure corresponding to long sleeved shirt, long trousers and gloves for applications in the home and allotment garden area

Estimation of worker (re-entry) exposure

Input parameters considered for the estimation of worker exposure:

Intended use(s):	Grapes (S-EU)		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	1.4	kg a.s./ha	**Transfer coefficient (TC):**	10100	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	8	h/d
Body weight (BW):	70	kg/person	**PPE**	5	%
Dermal absorption (DA):	1	% ('worst case')			
AOEL	0.046	mg/kg bw/d			

Worker exposure towards Propineb					
Without PPE [1]			**With PPE [2]**		
Worker (re-entry): Systemic dermal exposure after application in Grapes (S-EU)					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 10100 x 8 x 1.4 x 2 x 1%) / 70			(1 x 10100 x 8 x 1.4 x 2 x 5% x 1%) / 70		
External dermal exposure	226.24	mg/person	External dermal exposure	11.31	mg/person
External dermal exposure	3.23	mg/kg bw/d	External dermal exposure	0.16	mg/kg bw/d
Total systemic exposure	2.26	mg/person	Total systemic exposure	0.11	mg/person
Total systemic exposure	**0.032320**	**mg/kg bw/d**	**Total systemic exposure**	**0.001616**	**mg/kg bw/d**
% of AOEL	**70.3**	**%**	**% of AOEL**	**3.5**	**%**

[1] acceptable without PPE: allocation of BVL code SF245-01 for spray applications

[2] acceptable only with PPE: allocation of BVL code SF1891 and SF190 for professional and home and allotment garden applications, respectively (cf. Krebs et al., 2000)

Table 7.2.3.1-5: Calculation of worker re-entry in tomato (N-EU, with PPE)

Estimation of post-application exposure of workers (re-entry exposure)

Active substance (a.s.)	**Propineb**		
Product	**Antracol WG 70**		
Intended use(s)	**Tomato (N-EU)**		
Application rate (AR)	**1.68**	**kg a.s./ha**	
Number of applications (NA)	**4**		1)
Dislodgeable foliar residues (DFR)	**1**	**µg/cm²/kg a.s.**	2)
Transfer coefficient (TC)	**2500**	**cm²/person/h**	3)
Work rate per day (WR)	**8**	**h/d**	4)
Penetration through clothing (P)	**0.05**	**(5 %)**	5)
Systemic AOEL	**0.046**	**mg/kg bw/d**	
Dermal absorption DA)	**1**	**% (worst case, e.g. for dilution)**	
Body weight (BW)	**70**	**kg**	

1) consideration of more than two applications will not be necessary if degradation on foliage of at least 50 % can be assumed between 2 applications (otherwise use multiple application factor)

2) default of 1 µg a.s./cm² per kg a.s./ha acc. to Krebs et al. (2000)

3) TC 30000 cm²/person/hour ('worst case', hand harvesting, both sides of leaves) acc. to Krebs et al. (2000),
acc. EUROPOEM II (2002): 2500 (vegetables), 3000 (straw berries), 4500 (fruits from trees), 5000 (ornamentals)
acc. US EPA Policy # 3.1 (2000): 1500 (cereals, e.g. crop inspection), 10000 (grapes)

4) 8 h/day for professional applications if re-entry tasks are intended, 2 h/day for professional applications if re-entry tasks are not intended (e.g. irrigation, maintenance) or for applications in the home and allotment garden area

5) 5 % of dermal exposure corresponding to protective clothing incl. gloves for professionals, 50 % reduction of dermal exposure corresponding to long sleeved shirt, long trousers and gloves for applications in the home and allotment garden area

Estimation of worker (re-entry) exposure

Input parameters considered for the estimation of worker exposure:

Intended use(s):	Tomato (N-EU)		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	1.68	kg a.s./ha	**Transfer coefficient (TC):**	2500	cm²/person/h
Number of applications (NA):	4		**Work rate per day (WR):**	8	h/d
Body weight (BW):	70	kg/person	**PPE**	5	%
Dermal absorption (DA):	1	% ('worst case')			
AOEL	0.046	mg/kg bw/d			

Worker exposure towards Propineb					
Without PPE 1)			**With PPE 2)**		
Worker (re-entry): Systemic dermal exposure after application in Tomato (N-EU)					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 2500 x 8 x 1.68 x 4 x 1%) / 70			(1 x 2500 x 8 x 1.68 x 4 x 5% x 1%) / 70		
External dermal exposure	134.40	mg/person	External dermal exposure	6.72	mg/person
External dermal exposure	1.92	mg/kg bw/d	External dermal exposure	0.10	mg/kg bw/d
Total systemic exposure	1.34	mg/person	Total systemic exposure	0.07	mg/person
Total systemic exposure	**0.019200**	**mg/kg bw/d**	**Total systemic exposure**	**0.000960**	**mg/kg bw/d**
% of AOEL	**41.7**	**%**	**% of AOEL**	**2.1**	**%**

1) acceptable without PPE: allocation of BVL code SF245-01 for spray applications

2) acceptable only with PPE: allocation of BVL code SF1891 and SF190 for professional and home and allotment garden applications, respectively (cf. Krebs et al., 2000)

Table 7.2.3.1-6: Calculation of worker re-entry in tomato (S-EU, with PPE)

Estimation of post-application exposure of workers (re-entry exposure)

Active substance (a.s.)	**Propineb**		
Product	**Antracol WG 70**		
Intended use(s)	**Tomato (S-EU)**		
Application rate (AR)	**2.1**	**kg a.s./ha**	
Number of applications (NA)	**4**		[1]
Dislodgeable foliar residues (DFR)	**1**	**µg/cm²/kg a.s.**	[2]
Transfer coefficient (TC)	**2500**	**cm²/person/h**	[3]
Work rate per day (WR)	**8**	**h/d**	[4]
Penetration through clothing (P)	**0.05**	**(5 %)**	[5]
Systemic AOEL	**0.046**	**mg/kg bw/d**	
Dermal absorption DA)	**1**	**% (worst case, e.g. for dilution)**	
Body weight (BW)	**70**	**kg**	

[1] consideration of more than two applications will not be necessary if degradation on foliage of at least 50 % can be assumed between 2 applications (otherwise use multiple application factor)

[2] default of 1 µg a.s./cm² per kg a.s./ha acc. to Krebs et al. (2000)

[3] TC 30000 cm²/person/hour ('worst case', hand harvesting, both sides of leaves) acc. to Krebs et al. (2000),
acc. EUROPOEM II (2002): 2500 (vegetables), 3000 (straw berries), 4500 (fruits from trees), 5000 (ornamentals)
acc. US EPA Policy # 3.1 (2000): 1500 (cereals, e.g. crop inspection), 10000 (grapes)

[4] 8 h/day for professional applications if re-entry tasks are intended, 2 h/day for professional applications if re-entry tasks are not intended (e.g. irrigation, maintenance) or for applications in the home and allotment garden area

[5] 5 % of dermal exposure corresponding to protective clothing incl. gloves for professionals, 50 % reduction of dermal exposure corresponding to long sleeved shirt, long trousers and gloves for applications in the home and allotment garden area

Estimation of worker (re-entry) exposure

Input parameters considered for the estimation of worker exposure:

Intended use(s):	Tomato (S-EU)		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	2.1	kg a.s./ha	**Transfer coefficient (TC):**	2500	cm²/person/h
Number of applications (NA):	4		**Work rate per day (WR):**	8	h/d
Body weight (BW):	70	kg/person	**PPE**	5	%
Dermal absorption (DA):	1	% ('worst case')			
AOEL	0.046	mg/kg bw/d			

Worker exposure towards Propineb					
Without PPE [1]			**With PPE [2]**		
Worker (re-entry): Systemic dermal exposure after application in Tomato (S-EU)					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 2500 x 8 x 2.1 x 4 x 1%) / 70			(1 x 2500 x 8 x 2.1 x 4 x 5% x 1%) / 70		
External dermal exposure	168.00	mg/person	External dermal exposure	8.40	mg/person
External dermal exposure	2.40	mg/kg bw/d	External dermal exposure	0.12	mg/kg bw/d
Total systemic exposure	1.68	mg/person	Total systemic exposure	0.08	mg/person
Total systemic exposure	**0.024000**	**mg/kg bw/d**	**Total systemic exposure**	**0.001200**	**mg/kg bw/d**
% of AOEL	**52.2**	**%**	**% of AOEL**	**2.6**	**%**

[1] acceptable without PPE: allocation of BVL code SF245-01 for spray applications

[2] acceptable only with PPE: allocation of BVL code SF1891 and SF190 for professional and home and allotment garden applications, respectively (cf. Krebs et al., 2000)

Tier 4 (no PPE, refinement based on experimental DFR data):

Measured Dislodgeable Foliar Residues (DFR_M) are available for propineb. The above mentioned equation changes to:

$$S = (DFR_M \times TC \times WR \times P)/BW \times DA$$

Where: DFR_M =Measured dislodgeable foliar residues (µg as/cm²)

Dislodgeable foliar residues were experimentally determined under actual use conditions (maximum dose rate and maximum no. of applications, therefore no correction for the application rate is necessary). Work rates in the equation are considered with a maximum of 8 hours. A calculation for protective equipment is not made (PPE, P = 1). Summaries of the DFR trials and results are reported below. The highest DFR values observed in the course of the experiments were considered in the exposure assessment (see following table).

Table 7.2.3.1-7: Experimentally derived maximum DFRM values

Crop	Max. DFR_M (µg/cm²)	Observed on	Study conditions (no. of appl.) / appl. rate (kg a.s./ha)	cGAP (no. of appl.) / appl. rate (kg a.s./ha)	Report no., document no.
Apple (N-EU)	0.2130	0 days after 3rd appl., DAFT 14	3 / 1.575 - 1.687	2 / 1.575	10-2902, M-405621-01-1
Apple (S-EU)	0.3696	3 days after 2nd appl., DAFT 10	3 / 1.49 – 1.58	2 / 1.575	10-2900, M-405614-01-1
Grapes (S-EU)	1.593	0 days after 3rd appl., DAFT 38	4 / 1.0486 - 1.1228	2 / 1.4	10-2901, M-405617-01-1
Tomato indoor (S-EU)	1.411	3 days after 4th appl., DAFT 24	4 / 2.1	4 / 2.1	10-2904, M-405638-01-1

It is noted that the DFR trials in apple were conducted with three applications using the maximum dose rate whereas the cGAP under evaluation considers only two applications. Also, four applications were conducted in grapes whereas the cGAP under evaluation considers two applications only. Although the four applications in grapes were performed with a somewhat lower dose rate than indicated by the cGAP the higher no. of applications results in a higher seasonal dose rate compared to the cGAP. The maximum DFR values (max. DFR_M) from these trials therefore constitute highly conservative estimates for the worker exposure evaluation.

Calculation of worker exposure during re-entry in apple:

The highest DFR_M in apple was observed in the southern European trial (apple S-EU, 10-2900). This value is taken for the exposure calculation and will cover the worker scenario in N-EU.

S = (DFR_M x TC x WR x P)/BW x DA
= (0.3696 µg/cm^2 x 4500 cm^2/h x 8 h x 1)/60 kg x 1%
= 0.0022 mg/kg bw/day
= 5% of AOEL

Calculation of worker exposure during re-entry in grapes:

The DFR_M is taken from trials conducted in southern Europe. Although the application rate was lower than the cGAP the value is not extrapolated because it is the maximum from 4 applications compared to 2 applications in the cGAP. It is therefore considered to be the worst case for the N-EU and the S-EU scenario.

S = (DFR_M x TC x WR x P)/BW x DA
= (1.593 µg/cm^2 x 4500 cm^2/h x 8 h x 1)/60 kg x 1%
= 0.0096 mg/kg bw/day
= 21% of AOEL

Calculation of worker exposure during re-entry in tomato:

The DFR_M is taken from trials conducted in southern European greenhouse. As the trials were conducted with the maximum dose rate of 2.1 kg a.s./ha it is considered to cover also the northern European GAP with 1.68 kg a.s./ha.

S = (DFR_M x TC x WR x P)/BW x DA
= (1.411 µg/cm^2 x 2500 cm^2/h x 8 h x 1)/60 kg x 1%
= 0.0047 mg/kg bw/day
= 10% of AOEL

Summary of DFR studies

Propineb dislodgeable foliar residues were determined following foliar spray treatment in the field on apple (southern and northern/central zone), grapes (southern zone) as well as in greenhouses on tomato (southern zone). Summaries of the studies and results are presented in the following.

DFR study apple (N-EU):

Report:	[redacted]u; [redacted]; [redacted];2011;M-405621-01
Title:	Determination of dislodgeable foliar residues of propineb after spraying of Antracol on apple in the field in Germany
Report No:	10-2902
Document No(s):	Report includes Trial Nos.: 10-2902-01 M-405621-01-1
Guidelines:	**US EPA OPPTS 875.2100; Deviations: not specified**
GLP/GEP:	**yes**

I Material and methods

The purpose of the study 10-2902 was to determine the magnitude of the dislogeable foliar residues of propineb on apple leaf foliage in northern Europe after three spraying applications with Antracol WG 70. The study included one supervised residue trial conducted in Northern Europe (Germany) during the 2010 season.

Table 7.2.3.1-8: Application parameters

Country	Application				
	Type	No	Growth stage (BBCH)	Interval (days)	Rate (kg a.s./ha)
Germany	Spraying	3	57 / 59 / 63	7 / 7	1.58 / 1.58 / 1.69

Samples were collected in a manner designed to obtain representative samples. They were taken, prepared in the field where necessary, transported and stored according to US EPA OPPTS 875.2100 Foliar Dislodgeable Residue Dissipation. Leaf punches were collected directly into a pre-labelled poly-propylene jar using a leaf punch sampler (Birkestrand Co; El Monte, CA). Each sample consisted of 40 discs cut with a leaf puncher with 2.523 cm diameter and a disk area of 5 cm^2. The leaf punches represented a total double-sided leaf surface area of 400 cm^2. A sample was collected from each of the three subplots to provide three replicate samplings at each sampling interval. Leaf punches were taken from the potential worker contact zone including upper, middle, and lower portions of the crop foliage and interior and exterior portions of the crop foliage. Control leaf punch samples were collected prior to the first application. Treated samples collected on the day of application were taken after the spray had dried. After each sample was collected, the sampling jar was capped and kept cool for transport to the field site laboratory. Leaf punch samplers were cleaned after each sampling interval. The dislodging of the leaf samples was performed as soon as possible, but not later than 4 hours after collection.

II Results and discussion

The results are summarised in the following table.

Table 7.2.3.1-9: Amounts of dislodgeable foliar residues of propineb on apple leaves in Germany [µg a.s./cm2], two sided, figures in bold indicate day of treatment

DAFT[#]	Sampling interval (DAT)	Propineb* DFR (µg/cm²)
0	**0**	**n.a.**
3	3	n.a.
6	6	0.0221
7	**0**	**0.0809**
10	3	0.0706
13	6	0.0412
14	**0**	**0.2130**
17	3	0.1667
19	5	0.1259
21	7	0.0235
24	10	0.0544
28	14	0.0118
35	21	0.0044
42	28	0.0059
54	40	0.0009
74	61	0.0009

[#]:DAFT: day after first treatment; DAT: day after treatment
* corrected for recoveries < 70%
n.a.: not applicable (no sample collection conducted)

The 1st treatment started at BBCH 57 (pink bud stage: flower petals elongating; sepals slightly open) with intervals of 7 days each for consecutive treatments. The 2nd treatment was performed at BBCH 59 (most flowers with petals forming a hollow ball) followed by the 3rd treatment at BBCH 63 (about 30% of flowers open). There was no rain after the treatments. Where field recoveries were < 70% sample results were corrected to 100%.

A first-order single-exponential dissipation equation was fitted to the set of experimental data. Overall mean dissipation half-life for propineb was 7.2 days (see Appendix).

III Conclusion

The maximum DFR value is 0.2130 µg/cm² observed at day 0 after the 3rd application. Thereafter, a constant residue decline is observed with residues < LOQ from day 40 onwards. First application starts at BBCH <40 'bud swelling') at which leaf foliage is small, thus interception is low. Last application will be performed until BBCH 73 'second fruit fall' at which leaf foliage is fully developed and interception is high. Dislodgeable foliar residues from first treatment are 'diluted' due to considerable increment of leaf growth thereafter. Therefore, the total amount of DFR is low and accumulation due to repeated applications is limited.

Appendix

Propineb DFR on apple leaves

Report: 10-2902

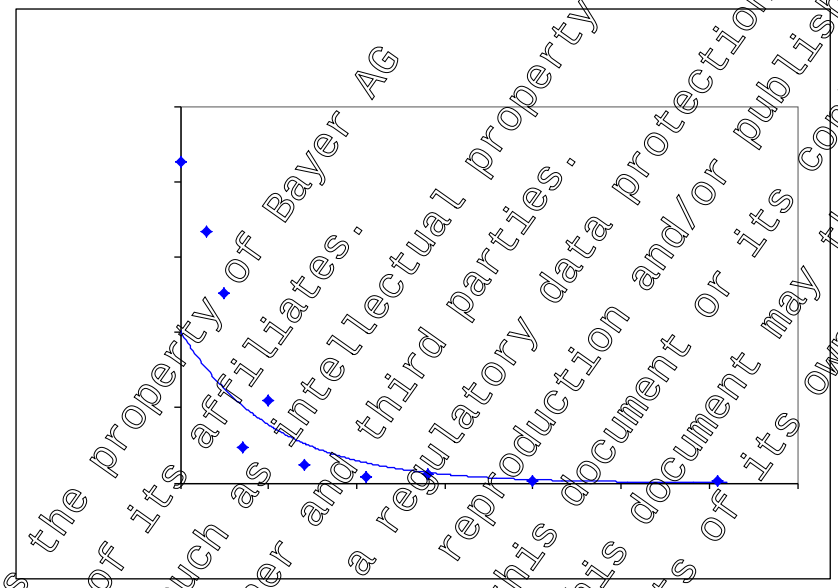
Calculation of DT_{50} assuming first order kinetics

DALT (Days)	Residues (µg/cm²)
0	0.21296
3	0.16667
5	0.12593
7	0.02353
10	0.05441
14	0.01176
21	0.00441
28	0.00588
40	0.00092
61	0.00092

$$C = C_0 \times e^{-k t} = C_0 \times e^{-\frac{\ln 2}{t_{1/2}} t}$$

C_0	0.100749654
k	0.095799443
$t_{1/2}$	**7.235398826**
R^2	0.827936269

DT_{50}(days): 7.2



DFR study apple (S-EU):

Report:	[redacted]o; [redacted]; [redacted];2011;M-405614-01
Title:	Determination of dislodgeable foliar residues of propineb on apple after spraying of Antracol in the field in Spain
Report No:	10-2900
Document No(s):	Report includes Trial Nos.: 10-2900-01 M-405614-01-1
Guidelines:	**US EPA OPPTS 875.2100; Deviations: not specified**
GLP/GEP:	**yes**

I Material and methods

The purpose of the study 10-2900 was to determine the magnitude of the dislogable foliar residues of propineb on apple leaf foliage in southern Europe after three spraying applications with Antracol WG 70. The study included one supervised residue trial conducted in Southern Europe (Spain) during the 2010 season.

Table 7.2.3.1-10: Application parameters

Country	Application				
	Type	No	Growth stage (BBCH)	Interval (days)	Rate (kg a.s./ha)
Spain	Spraying	3	n.n. / 61 / 65	7 / 7	1.58 / 1.49 / 1.58

n.d. = not determined

Samples were collected in a manner designed to obtain representative samples. They were taken, prepared in the field where necessary, transported and stored according to US EPA OPPTS 875.2100 Foliar Dislodgeable Residue Dissipation. Leaf punches were collected directly into a pre-labelled poly-propylene jar using a leaf punch sampler (Birkestrand Co; El Monte, CA). Each sample consisted of 40 disks cut with a leaf puncher with 2.523 cm diameter and a disk area of 5 cm^2. The leaf punches represented a total double-sided leaf surface area of 400 cm^2. A sample was collected from each of the three subplots to provide three replicate samplings at each sampling interval. Leaf punches were taken from the potential worker contact zone including upper, middle, and lower portions of the crop foliage and interior and exterior portions of the crop foliage. Control leaf punch samples were collected prior to the first application. Treated samples collected on the day of application were taken after the spray had dried. After each sample was collected, the sampling jar was capped and kept cool for transport to the field site laboratory. Leaf punch samplers were cleaned after each sampling interval. The dislodging of the leaf samples was performed as soon as possible, but not later than 4 hours after collection.

II Results and discussion

The results are summarised in the following table.

Table 7.2.3.1-11 Amounts of dislodgeable foliar residues of propineb on apple leaves in Spain [µg a.s./cm2], two sided, figures in bold indicate day of treatment

DAFT[#]	Sampling interval (DAT)	Propineb* DFR (µg/cm²)
0	**0**	**n.a.**
3	3	n.a.
7	7	n.a.
7	**0**	**0.2870**
10	3	0.3696
14	7	0.1609
14	**0**	**0.2500**
17	3	0.2391
20	6	0.0794
21	7	0.0618
23	9	0.0471
28	14	0.0088
35	21	0.0059
42	28	0.0018
56	42	0.0018
73	59	0.0018

[#]:DAFT: day after first treatment; DAT: day after treatment
* Corrected for recoveries < 70%
n.a.: not applicable (no sample collection conducted)

The 1st treatment started before flowering (< BBCH 60, not determined) with intervals of 7 days each to the following treatments i.e. the 2nd treatment was performed at BBCH 61 (beginning of flowering: about 10% of flowers open) followed by the 3rd treatment at BBCH 65 (full flowering: at least 50% of flowers open, first petals falling). There was no rain after the treatments (1 mm of precipitation after 2nd treatment). Where field recoveries were < 70% sample results were corrected to 100%.

A first-order single-exponential dissipation equation was fitted to the set of experimental data. Overall mean dissipation half-life for propineb was 7.6 days (see Appendix).

III Conclusion

The maximum DFR value is 0.3696 µg/cm² observed at day 3 after the 2nd application. The max residue level is followed by a rapid decline between the day 3 and 6/7 with residues < LOQ after day 35. First application starts at BBCH >40 ('bud swelling'). At this growth stage leaf foliage is small and interception is low. Last application will be performed until BBCH 73 'second fruit fall' at which leaf foliage is fully developed and interception is high. Dislodgeable foliar residues from first treatment are 'diluted' due to considerable increment of leaf growth thereafter. Therefore, the total amount of DFR is low and accumulation due to repeated applications is limited.

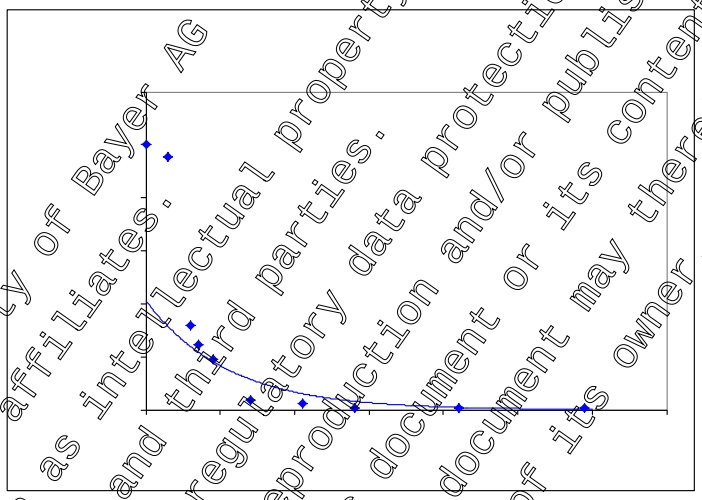
Appendix

Propineb DFR on apple leaves

Report: 10-2900

DALT (Days)	Residues (µg/cm²)
0	0.25
3	0.23913
6	0.07941
7	0.06176
9	0.04706
14	0.00882
21	0.00588
28	0.00184
42	0.00184
59	0.00184

Calculation of DT_{50} assuming first order kinetics



$$C = C_0 \times e^{-k\,t} = C_0 \times e^{-\frac{\ln 2}{t_{1/2}}t}$$

C_0	0.103062492
k	0.091162494
$t_{1/2}$	**7.603424979**
R^2	0.762438521

DT_{50}(days):	7.6

DFR study grapes (S-EU):

Report:	[redacted]y;[redacted];[redacted];2011;M-405617-01
Title:	Determination of dislodgeable foliar residues of propineb after spraying of Antracol on grape in the field in Spain
Report No:	10-2901
Document No(s):	Report includes Trial Nos.: 10-2901-01 M-405617-01-1
Guidelines:	**US EPA OPPTS 875.2100; Deviations: not specified**
GLP/GEP:	**yes**

I Material and methods

The purpose of the study 10-2901 was to determine the magnitude of the dislogable foliar residues of propineb on grape leaf foliage after four spraying applications with Antracol WG 70. The study included one supervised residue trial conducted in Southern Europe (Spain) during the 2010 season.

Table 7.2.3.1-12: Application parameters

Country	Application				
	Type	No	Growth stage (BBCH)	Interval (days)	Rate (kg a.s./ha)
Spain	Spraying	4	53 / 55 / 75 / 76	7 / 31 / 7	1.60 / 1.55 / 1.50 / 1.60

Samples were collected in a manner designed to obtain representative samples. They were taken, prepared in the field where necessary, transported and stored according to US EPA OPPTS 875.2100 Foliar Dislodgeable Residue Dissipation. Leaf punches were collected directly into a pre-labelled poly-propylene jar using a leaf punch sampler (Birkestrand Co; El Monte, CA). Each sample consisted of 40 disks cut with a leaf puncher with 2.523 cm diameter and a disk area of 5 cm^2. The leaf punches represented a total double-sided leaf surface area of 400 cm^2. A sample was collected from each of the three subplots to provide three replicate samplings at each sampling interval. Leaf punches were taken from the potential worker contact zone including upper, middle, and lower portions of the crop foliage and interior and exterior portions of the crop foliage. Control leaf punch samples were collected prior to the first application. Treated samples collected on the day of application were taken after the spray had dried. After each sample was collected, the sampling jar was capped and kept cool for transport to the field site laboratory. Leaf punch samplers were cleaned after each sampling interval. The dislodging of the leaf samples was performed as soon as possible, but not later than 4 hours after collection.

II Results and discussion

The results are summarised in the following table.

Table 7.2.3.1-13: Amounts of dislodgeable foliar residues of propineb on grape leaves in Spain [µg a.s./cm2], two sided, figures in bold indicate day of treatment

DAFT#	Sampling interval (DAT)	Propineb* DFR (µg/cm²)
0	**0**	**0.173**
3	3	0.255
7	7	0.300
7	**0**	**0.300**
10	3	1.049
14	7	0.334
21	14	0.293
28	21	0.200
38	31	0.145
38	**0**	**1.593**
41	3	0.822
45	7	0.629
45	**0**	**1.444**
48	3	1.041
50	5	0.459
52	7	0.398
55	10	0.564
59	14	0.327
66	21	0.127
73	28	0.191
85	40	0.082
105	60	0.027

#:DAFT: day after first treatment; DAT: day after treatment
* Corrected for recoveries < 70%

The 1st treatment started at emergence of inflorescence at BBCH 53 (inflorescences clearly visible) with an interval of 7 days until the 2nd treatment at BBCH 55 (inflorescences swelling, flowers closely pressed together), 3rd treatment was performed with interval of 31 days at BBCH 75 (berries pea-sized, bunches hang) followed by the 4th treatment at BBCH 76 (some berries beginning to touch). There was no rain after the treatments. Where field recoveries were < 70% sample results were corrected to 100%.

A first-order single-exponential dissipation equation was fitted to the set of experimental data. Overall mean dissipation half-life for propineb was 11.5 days (see Appendix).

III Conclusion

The maximum DFR value is 1.593 µg/cm² observed at day 0 after the 3rd application similar to the residue level at day 0 after the 4th application (1.444 µg/cm²). Dislodgeable foliar residues after the first 2 applications are low compared to treatments 3 and 4. The first 2 applications were performed at early growth stages when leaves were still small whereas leaves were fully expanded at the last 2 applications. The effect of low DFR during early growth stages was seen in other DFR studies with propineb (apple). The 'dilution' effect due to considerable leave growth after early applications is noted. The values demonstrate that accumulation of DFR after repeated applications does not occur or is limited.

The risk assessment is done with the highest DFR value found after the 3rd application although the cGAP is based on 2 treatments only. In addition, no correction is made for the higer dose rate of up to 1.6 kg a.s./ha exceeding the cGAP maximum dose rate of 1.4 kg a.s./ha by about 15%.

Appendix

Propineb DFR on grape leaves

Report: 10-2901

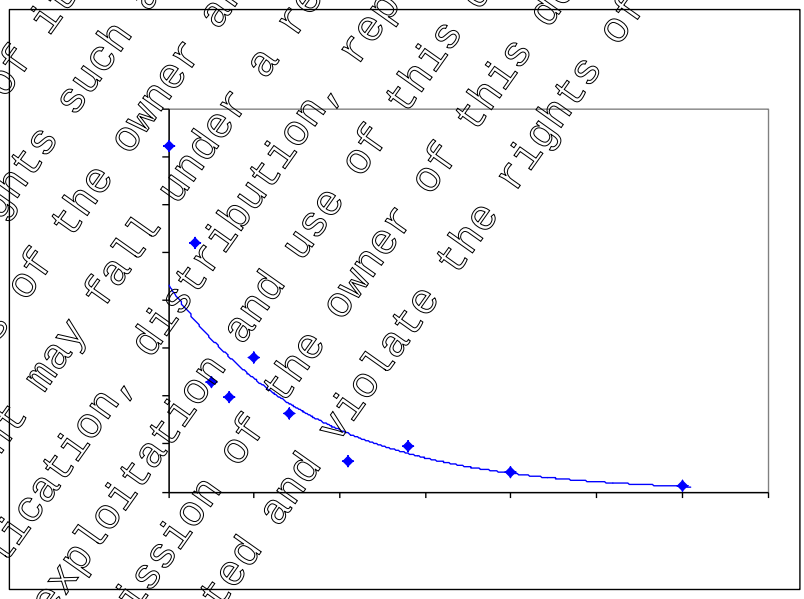
Calculation of DT_{50} assuming first order kinetics

DALT (Days)	Residues (µg/cm²)
0	1.4439
3	1.04146
5	0.45854
7	0.39756
10	0.56384
14	0.32727
21	0.12727
28	0.19091
40	0.08182
60	0.02727

$$C = C_0 \times e^{-kt} = C_0 \times e^{-\frac{\ln 2}{t_{1/2}} t}$$

C_0	0.861142775
k	0.060170258
$t_{1/2}$	**11.51976422**
R^2	0.910482305

DT_{50} (days): 11.5



DFR study grapes (S-EU):

Report:	[redacted]3;[redacted];[redacted];2011;M-404866-01
Title:	Determination of the dislodgeable foliar residues (DFR) of propineb and tebuconazole in/on grape after spraying of Antracol and Folicur EW 250 in the field after dislodging with various concentrations of Aerosol OT
Report No:	10-2920
Document No:	M-404866-01-1
Guidelines:	**US EPA OPPTS 875.2100;Deviations: not specified**
GLP/GEP:	**yes**

I Material and methods

Some of the 2011 DFR studies in grapes using propineb and tebuconazole were conducted with an Aerosol OT concentration of 0.001% instead of using the guideline concentration of 0.01%. The purpose of the study 10-2919 was therefore to determine the magnitude of the dislogable foliar residues depending of the Aerosol OT concentration in the dislodging solution. Two concentrations of the Aerosol OT, 0.01% and 0.001%, were applied to different leaf punches from the treated plots. The analytical results of propineb and tebuconazole after dislodging with the two different solutions were compared to show the extraction efficiency of both dislodging solutions (cross-validation of extraction efficiency).

Table 7.2.3.1-14: Application parameters

Country	Formulation	Application				
		Type	No	Growth stage (BBCH)	Interval (days)	Rate (kg a.s./ha)
Germany	Antracol WG 70	Spraying	1	91	-	0.98
	Folicur WG 25		1	87	-	0.15

Samples were collected in a manner designed to obtain representative samples. They were taken, prepared in the field where necessary, transported and stored according to US EPA OPPTS 875.2100 Foliar Dislodgeable Residue Dissipation. Leaf punches were collected directly into a pre-labelled poly-propylene jar using a leaf punch sampler (Birkestrand Co; El Monte, CA). Each sample consisted of 40 disks cut with a leaf puncher with 2.523 cm diameter and a disk area of 5 cm^2. The leaf punches represented a total double-sided leaf surface area of 400 cm^2. Leaf punches were taken from the potential worker contact zone including upper, middle, and lower portions of the crop foliage and interior and exterior portions of the crop foliage. Control leaf punch samples were collected prior to the first application. Treated samples collected on the day of application were taken after the spray had dried. After each sample was collected, the sampling jar was capped and kept cool for transport to the field site laboratory. Leaf punch samplers were cleaned after each sampling interval. The samples were dislodged by adding 100 mL of a 0.01 % or 0.001 % Aerosol OT solution (i.e. docusate sodium salt), respectively, which corresponds to a surfactant (stored at < 6°C). The dislodging of the leaf samples was performed as soon as possible, but not later than 4 hours after collection.

II Results and discussion

The results are summarised in the following table.

Table 7.2.3.1-15: Comparison of dislodgeable foliar residues depending on the Aerosol OT concentration.

Aerosol OT concentration (%)	Sampling interval (DAT)	DFR (µg/cm²)	
		Propineb	Tebuconazole
0.01	0	0.14	0.17
	2	0.07	0.12
0.001	0	0.22	0.17
	2	0.11	0.12

DAT: day after treatment

III Conclusion

The dislodgeable foliar residues of propineb on grape leaves obtained with a 0.001% Aerosol OT solution are by a factor of 1.6 higher than obtained with the guideline concentration of 0.01%.

The dislodgeable foliar residues of tebuconazole on grape leaves obtained with a 0.001% Aerosol OT solution are in the same magnitude as obtained with the guideline concentration of 0.01 %.

DFR study greenhouse tomato (S-EU):

Report:	[redacted]_[redacted];[redacted];[redacted];2011;M-405638-01
Title:	Determination of dislodgeable foliar residues of propineb on tomato after spraying of antracol in the greenhouse in Spain
Report No:	10-2904
Document No(s):	Report includes Trial Nos.: 10-2904-01 M-405638-01-1
Guidelines:	**US EPA OPPTS 875.2100; Deviations: not specified**
GLP/GEP:	**yes**

I Material and methods

The purpose of the study 10-2904 was to determine the magnitude of the dislogable foliar residues of propineb on tomato leaf foliage after four spraying applications in the greenhouse with Antracol WG 70. The study included one supervised residue trial conducted in Southern Europe (Spain) during the 2010 season.

Table 7.2.3.1-16: Application parameters

Country	Application				
	Type	No	Growth stage (BBCH)	Interval (days)	Rate (kg a.s./ha)
Spain	Spraying	4	72 / 73 / 74 / 75	7 / 7 / 7	2.1 / 2.1 / 2.1 / 2.1

Samples were collected in a manner designed to obtain representative samples. They were taken, prepared in the field where necessary, transported and stored according to US EPA OPPTS 875.2100 Foliar Dislodgeable Residue Dissipation. Leaf punches were collected directly into a pre-labelled poly-propylene jar using a leaf punch sampler (Birkestrand Co; El Monte, CA). Each sample consisted of 40 disks cut with a leaf puncher with 2.523 cm diameter and a disk area of 5 cm^2. The leaf punches represented a total double-sided leaf surface area of 400 cm^2. A sample was collected from each of the three subplots to provide three replicate samplings at each sampling interval. Leaf punches were taken from the potential worker contact zone including upper, middle, and lower portions of the crop foliage and interior and exterior portions of the crop foliage. Control leaf punch samples were collected prior to the first application. Treated samples collected on the day of application were taken after the spray had dried. After each sample was collected, the sampling jar was capped and kept cool for transport to the field site laboratory. Leaf punch samplers were cleaned after each sampling interval. The dislodging of the leaf samples was performed as soon as possible, but not later than 4 hours after collection.

II Results and discussion

The results are summarised in the following table.

Table 7.2.3.1-17: Amounts of dislodgeable foliar residues of propineb on greenhouse tomato leaves in Spain [µg a.s./cm²], two sided, figures in bold indicate day of treatment

DAFT#	Sampifferentling interval (DAT)	Propineb* DFR (µg/cm²)
0	**0**	**0.195**
1	1	0.192
3	3	0.248
7	7	0.219
7	**0**	**0.453**
8	1	0.283
10	3	0.467
14	7	0.636
14	**0**	**0.728**
15	1	0.791
17	3	0.692
21	7	0.439
21	**0**	**1.000**
22	1	1.011
24	3	1.411
26	5	1.281
28	7	0.844
31	10	0.961
35	14	0.600
42	21	0.547
49	28	0.442

#DAFT: day after first treatment; DAT: day after treatment
* Corrected for recoveries < 70%

The 4 treatments were performed during development of fruit stages (BBCH 72 – 75, development of 2nd to 5th fruit cluster) with intervals of 7 days each. Where field recoveries were < 70% sample results were corrected to 100%.

A first-order single-exponential dissipation equation was fitted to the set of experimental data. Overall mean dissipation half-life for propineb was 18.8 days (see Appendix).

III Conclusion

An accumulation of dislodgeable foliar residues is observed from the 1st to the 4th application. The maximum DFR value is 1.411 µg/cm² observed at day 3 after the 4th application followed by a slow residue decline.

Appendix

Propineb DFR on greenhouse tomato leaves

Report: 10-2904

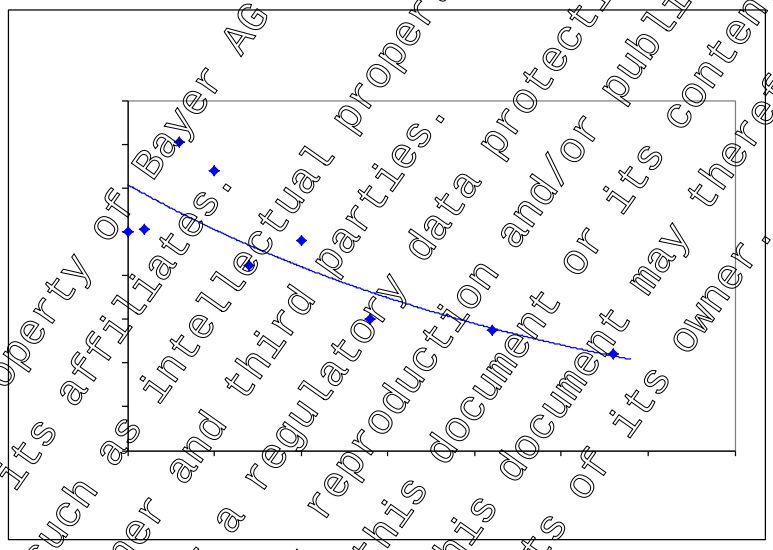
Calculation of DT_{50} assuming first order kinetics

DALT (Days)	Residues (µg/cm²)
0	1.0000
1	1.0111
3	1.4111
5	1.2806
7	0.8444
10	0.9611
14	0.6000
21	0.5472
28	0.4417

$$C = C_0 \times e^{-k\,t} = C_0 \times e^{-\frac{\ln 2}{t_{1/2}} t}$$

C_0	1.215022562
k	0.036964156
$t_{1/2}$	**18.75187354**
R^2	0.798871678

DT_{50}(days):	18.8



DFR study greenhouse tomato (S-EU):

Report:	[redacted]t;[redacted];[redacted];2011;M-404858-01
Title:	Determination of the dislodgeable foliar residues (DFR) of propineb and tebuconazole in/on tomato after spraying of Antracol and Folicur WG 25 in the greenhouse after dislodging with various concentrations of Aerosol OT
Report No:	10-2919
Document No:	M-404858-01-1
Guidelines:	**US EPA OPPTS 875.2100; Deviations: not specified**
GLP/GEP:	**yes**

I Material and methods

Some of the 2011 DFR studies in greenhouse tomato using propineb and tebuconazole were conducted with an Aerosol OT concentration of 0.001% instead of using the guideline concentration of 0.01%. The purpose of the study 10-2919 was therefore to determine the magnitude of the dislodgable foliar residues depending of the Aerosol OT concentration in the dislodging solution. Two concentrations of the Aerosol OT, 0.01% and 0.001%, were applied to different leaf punches from the treated plots. The analytical results of propineb and tebuconazole after dislodging with the two differently concentrated solutions were compared to show the extraction efficiency of both dislodging solutions (cross-validation of extraction efficiency).

Table 7.2.3.1-18: Application parameters

Country	Formulation	Application				
		Type	No	Growth stage (BBCH)	Interval (days)	Rate (kg a.s./ha)
Germany	Antracol WG 70	Spraying	1	87	-	2.1
	Folicur WG 25		1	87	-	0.2

Samples were collected in a manner designed to obtain representative samples. They were taken, prepared in the field where necessary, transported and stored according to US EPA OPPTS 875.2100 Foliar Dislodgeable Residue Dissipation. Leaf punches were collected directly into a pre-labelled poly-propylene jar using a leaf punch sampler (Birkestrand Co; El Monte, CA). Each sample consisted of 40 disks cut with a leaf puncher with 2.523 cm diameter and a disk area of 5 cm^2. The leaf punches represented a total double-sided leaf surface area of 400 cm^2. Leaf punches were taken from the potential worker contact zone including upper, middle, and lower portions of the crop foliage and interior and exterior portions of the crop foliage. Control leaf punch samples were collected prior to the first application. Treated samples collected on the day of application were taken after the spray had dried. After each sample was collected, the sampling jar was capped and kept cool for transport to the field site laboratory. Leaf punch samplers were cleaned after each sampling interval. The samples were dislodged by adding 100 mL of a 0.01 % or 0.001 % Aerosol OT solution (i.e. docusate sodium salt), respectively, which corresponds to a surfactant (stored at < 6°C). The dislodging of the leaf samples was performed as soon as possible, but not later than 4 hours after collection.

II Results and discussion

The results are summarised in the following table.

Table 7.2.3.1-19: Comparison of dislodgeable foliar residues depending on the Aerosol OT concentration.

Aerosol OT concentration (%)	Sampling interval (DAT)	DFR (µg/cm²)	
		Propineb	Tebuconazole
0.01	0	0.013	0.21
	2	0.012	0.14
0.001	0	0.011	0.18
	2	0.011	0.13

DAT: day after treatment

III Conclusion

The dislodgeable foliar residues of propineb and tebuconazole on tomato leaves obtained with a 0.001% Aerosol OT solution are in the same magnitude as obtained with the guideline concentration of 0.01 %.

CP 7.2.3.2 Measurement of worker exposure

Since the exposure estimate carried out indicated that the AOEL will not be exceeded under practical conditions of use, a study to provide a measure of worker exposure was not necessary and was therefore not carried out.

CP 7.3 Dermal absorption

Summary and conclusion on dermal absorption

The extent of dermal absorption of propineb formulated as a WG 70 formulation (PPB WG 70) was investigated *in vitro* using human and rat skin. A summary of the study is given in the following sections along with the mean values based on the study results and following application of the new EFSA[12] guidance rules. A conclusion and recommendation regarding the dermal absorption of propineb formulated as a WG 70 is given below.

The mean percentage of propineb in the WG 70 formulation that was considered to be potentially absorbable *(directly absorbed plus total remaining at dose site & stratum corneum)* over a period of 24 hours for the neat formulation was 0.05% and 0.39% for the human and rat skin, respectively. Applying the new EFSA guidance these values adjust to 0.1% and 0.7% for human and rat skin respectively.

The mean percentage of propineb in the WG 70 formulation that was considered to be potentially absorbable *(directly absorbed plus total remaining at dose site & stratum*

[12] EFSA Panel on Plant Protection Products and their Residues (PPR); Guidance on Dermal Absorption. EFSA Journal 2012;10(4):2665. [30 pp.] doi:10.2903/j.efsa.2012.2665.

corneum) over a period of 24 hours for the intermediate dose formulation was 0.33% and 2.39% for the human and rat skin, respectively. Applying the new EFSA guidance these values adjust to 0.6% and 3.3% for human and rat skin respectively.

The mean percentage of propineb in the WG 70 formulation that was considered to be potentially absorbable *(directly absorbed plus total remaining at dose site &stratum corneum)* over a period of 24 hours for the low dose formulation was 0.44% and 3.49% for the human and rat skin, respectively. Applying the new EFSA guidance these values adjust to 1% and 5% for the human and rat skin respectively.

According to the new EFSA guidance there is the provision that when the sampling period is 24 hours (which is the case for this study) and over 75% of the total absorption (material in the receptor fluid at the end of the study) occurred within half of the duration (12 hours) of the total sampling period that the absorption will be taken as the sum of receptor fluid, receptor chamber washes and the skin sample excluding all tape strips. These criteria were only met by the high dose human skin set of samples in this study. There is also the provision that a standard deviation equal to or larger than 25% of the mean of the absorption requires the use of an alternative value or rejection of the study. The guidance prefers the approach of adding the standard deviation to the mean to cover the upper 84th percentile value of the results. Additionally where an overall recovery of less than 95% occurs, a normalisation procedure is to be used by preference. Albeit that the notifier considers that both the value of 25% for the standard deviation limit and the 95% recovery limit to be too conservative, the application of the guidance results in the following values for [^{14}C]-propineb in the PPB WG 70 formulation:

Human skin

- 0.1% for the neat formulation (700 g/kg)
- 0.6% for the intermediate dose spray dilution (3.5 g/L)
- 1% for the low dose spray dilution (1 g/L)

Rat skin

- 0.7% for the neat formulation (700 g/kg)
- 3% for the spray dilution (3.5 g/L)
- 5% for the neat formulation (1 g/L)

Report:	[redacted]0;Hxq.t れ,;2014;M-483806-01
Title:	Propineb-WG 70: [14C]-propineb - Comparative in vitro dermal absorption study using human and rat skin
Report No:	SA 13078
Document No:	M-483806-01-1
Guidelines:	**OECD Guideline for the testing of Chemicals; Skin Absorption In Vitro Method Guideline 428 (April 2004); OECD Environmental Health and Safety Publication Series on testing and Assessment No 28, Guidance Document for the Conduct of Skin Absorption Studies (March 2004); EFSA Panel on Plant Protection Products and their Residues (PPR): Guidance on Dermal Absorption, EFSA Journal 2012; 10(4): 2665; Deviations: not specified**
GLP/GEP:	**yes**

Material and methods

Rat skin:

Species, strain:	Rat, Wistar Rj: WI (IOPS HAN).
Source:	R. Janvier (France).
Sex:	Male (8).
Anatomical site:	Dorsal.
Rat Skin Preparation:	Each animal was killed by cervical dislocation. After sacrifice the skin was clipped and removed for use in the study. The dorsal skin was dermatomed by use of a mini-dermatome to obtain samples of *ca* 450 to 550 µm in thickness.

Human skin: Source: [redacted] or [redacted] France.
Number and sex: 11 donors, female.
Anatomical region: Abdomen.
Thickness: 316.4 to 505 µm.

Test Material:

Radiolabelled: [propane-1-^{14}C]-propineb
Batch: MXM 7250-1-2 & MXM 7104-1-2.
Specific activity: 14.8 kBq/mg & 3.56 MBq/mg.

Formulation: The formulation used in this experiment was the propinebWG70 formulation (specification N° 1020000006516) containing propineb (700 g/Kg). It was used at three nominal concentrations of propineb: neat, 700 g/kg, 3.5 g/L and 1 g/L.

Test system: A flow-through diffusion cell system (Franz's cell modified, Gallas, France) was used to study the absorption of the test substance (exposure area of 1 cm^2 skin). A diffusion cell consisted of a donor chamber and a receptor chamber between which the skin was positioned. The receptor fluid was Eagle's medium supplemented with 5% bovine serum albumin and gentamycin (50 mg/L) at a pH of 7.4. The receptor chamber was warmed by a constant circulation of warm water which maintained the receptor fluid at 32 ± 2°C (close to the normal skin temperature). The receptor fluid was pumped through the receptor chamber at a rate of 1.5 mL/h and stirred continuously whilst in the receptor chamber by means of a magnetic bar.

Skin integrity: Before dose application, the integrity of the skin samples was assessed by measuring the trans-epidermal water loss (TEWL) from the stratum corneum. An evaporimeter probe ([redacted] Technology, Denmark) was placed securely on the top of the donor chamber and the amount of water diffusing through the skin was measured. Human and rat skin with a TEWL of greater than 40 g/hm² were considered potentially damaged and were not used. These samples were replaced by new skin fragments which were also tested for integrity before use in the study.

Treatment: The dose preparation was applied to the split-thickness skin sample with a pipette at the rate of approximately either 5 mg/cm² or 10 µL/cm² exposed skin. The dose preparations were assayed for radioactivity content (by LSC) by using dose checks (surrogate dose) taken before, during and after the dosing process.

Sampling: The receptor fluid passing through the receptor chamber was collected in glass vials held in a fraction collector. The fraction collector was started after dose application. Samples were then collected hourly for the duration of the experiment (24 hours). At 8 hours post-application, the skin was swabbed with freshly prepared 1% v/v Tween 80 in PBS (phosphate buffer saline) using natural sponge swabs, in order to remove and retain the non-absorbed dose, until no radioactivity was detected with a Geiger-Müller monitor. At the end of the study (24 hours after application), the treated skin and the skin adjacent to the treatment site (surrounding swabs) were swabbed. Each skin sample was tape-stripped to remove the stratum corneum. This involved the application of [redacted] adhesive tape ([redacted], Monaco) for 5 seconds before the tape was carefully removed against the direction of hair growth. This procedure was continued until a 'shiny' appearance of the epidermis was evident, which indicated that the stratum corneum had been removed. The tape-strips were collected into scintillation vials for analysis. The skin surrounding the application site (surrounding skin) was separated from the treated skin. Both surrounding skin and tape-stripped treated skin were retained for analysis.

Radioassay: The amounts of radioactivity in the various samples were determined by liquid scintillation counting (LSC). Samples were counted for 10 minutes or for 2 sigma % in an appropriate scintillation cocktail using a Packard 1900 TR counter with on-line computing facilities. Quenching effects were determined using an external standard and spectral quench parameter (tSIE) method. Efficiency correlation curves were prepared for each scintillation cocktail and were regularly checked by the use of [^{14}C-n-hexadecane standards. The scintillation counter was recalibrated when a deviation of greater than 2% was observed when counting quality control standards. The limit of detection was taken to be twice the background values for blank samples in appropriate scintillation cocktails.

Findings:

Propineb was demonstrated to be sufficiently soluble in the receptor fluid to avoid any risk of back diffusion. Measurements of the homogeneity of the three concentrations of formulation applied indicated that it was acceptable. The study results are presented in Table 7.6.2-1.

Table 7.6.2-1: Mean distribution of radioactivity at 24 hours after dose application of [14C]- propineb in an WG 70 formulation at the rates of 700 g/kg, 3.5 g/L and 1 g/L to human and rat skin samples.

Results expressed in terms of percentage of applied radioactivity.

	Distribution of radioactivity (% dose)											
Dose Levels	Neat formulation: High dose (700 g/kg)				Dilution: Intermediate dose (3.5 g/L)				Dilution: Low dose (1 g/L)			
Species	Human (n=5)		Rat (n=5)		Human (n=5)		Rat (n=5)		Human (n=6)		Rat (n=6)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
SURFACE COMPARTMENT												
Skin swabs (8h)	100.6	4.37	102.1	1.97	101.9	4.13	97.14	4.23	102.4	2.78	95.43	3.54
Skin swabs (24h)[a]	0.10	0.12	0.06	0.07	1.91	4.12	0.73	0.45	0.09	0.06	1.02	0.99
Surface Dose (tape-strips 1&2)	0.09	0.06	0.07	0.10	0.05	0.05	0.14	0.05	0.08	0.05	0.59	0.42
Donor chamber	0.06	0.03	0.07	0.06	0.06	0.12	0.05	0.05	0.02	0.03	0.15	0.18
Total % non-absorbed	***100.8***	***4.45***	***102.3***	***2.02***	***103.9***	***1.11***	***98.06***	***4.19***	***102.6***	***2.84***	***97.19***	***3.17***
SKIN COMPARTMENT												
Skin [b]	***0.01***	***0.01***	0.11	0.12	0.05	0.03	0.74	0.53	0.04	0.04	0.77	0.32
Stratum corneum [c]	0.02	0.01	0.13	0.19	0.03	0.02	0.49	0.40	0.05	0.04	1.29	1.47
Total % at dose site	**0.03**	**0.01**	***0.24***	***0.31***	***0.08***	***0.04***	***1.23***	***0.70***	***0.09***	***0.06***	***2.05***	***1.68***
RECEPTOR COMPARTMENT												
Receptor fluid (0-24h)	0.02	0.02	0.12	0.05	0.24	0.21	1.10	0.50	0.34	0.13	1.29	0.44
Receptor fluid terminal	0.001	0.002	0.001	0.002	0.01	0.01	0.04	0.03	0.01	0.005	0.06	0.04
Receptor chamber	n.d.	n.a.	0.04	0.05	n.d.	n.a.	0.02	0.05	n.d.	n.a.	0.09	0.22
Total % directly absorbed [d]	**0.02**	**0.02**	**0.16**	**0.09**	**0.25**	**0.21**	**1.16**	**0.54**	**0.35**	**0.14**	**1.43**	**0.58**
Total % Potentially Absorbable [e]	**0.05**	**0.03**	**0.39**	**0.31**	**0.33**	**0.23**	**2.39**	**0.93**	**0.44**	**0.18**	**3.49**	**1.61**
TOTAL % RECOVERY	**100.9**	**4.46**	**102.7**	**2.18**	**104.2**	**1.21**	**100.5**	**4.54**	**103.0**	**2.95**	**100.7**	**2.63**
Evaluation according to EFSA Guidance												
Absorption <75% by 12hrs?	Yes		No		No		No		No		No	
SD >25% ?	Yes		Yes		Yes		Yes		Yes		Yes	
Recovery <95% ?	No		No		No		No		No		No	
adjusted: Total % Potentially Absorbable [f]	**0.1**		**0.7**		**0.6**		**3**		**1**		**5**	

[a]: sum of radioactivity found in swabs at termination and in surrounding swabs.
[b]: sum of radioactivity found in skin after tape-stripping procedure and in surrounding skin.
[c]: tape-strips excluding numbers 1 & 2 which are considered to be non-absorbed dose.
[d]: sum of radioactivity found in receptor fluid (0-24h), receptor fluid terminal and receptor chamber.
[e]: total % directly absorbed + total % at dose site
[f]: values considered for the adjusted Total % Potentially Absorbable according to EFSA are in ***bold Italics***
SD: standard deviation
n.d.: not detected (below the limit of detection)
n.a. : not applicable
n: number of skin cells used for calculation
In the above table, the presented means do not always calculate exactly from the presented individual data. This is due to rounding-up differences resulting from the use of the spreadsheet program.

Conclusion:

The extent of dermal absorption of propineb formulated as a WG 70 formulation (PPB WG 70) was investigated *in vitro* using human and rat skin. A summary of the study is given in the following sections along with the mean values based on the study results and following application of the new EFSA[13] guidance rules. A conclusion and recommendation regarding the dermal absorption of propineb formulated as a WG 70 is given below.

The mean percentage of propineb in the WG 70 formulation that was considered to be potentially absorbable *(directly absorbed plus total remaining at dose site & stratum corneum)* over a period of 24 hours for the neat formulation was 0.05% and 0.39% for the human and rat skin, respectively. Applying the new EFSA guidance these values adjust to 0.1% and 0.7% for human and rat skin respectively.

The mean percentage of propineb in the WG 70 formulation that was considered to be potentially absorbable *(directly absorbed plus total remaining at dose site & stratum corneum)* over a period of 24 hours for the intermediate dose formulation was 0.33% and 2.39% for the human and rat skin, respectively. Applying the new EFSA guidance these values adjust to 0.6% and 3.3% for human and rat skin respectively.

The mean percentage of propineb in the WG 70 formulation that was considered to be potentially absorbable *(directly absorbed plus total remaining at dose site &stratum* corneum*)* over a period of 24 hours for the low dose formulation was 0.44% and 3.49% for the human and rat skin, respectively. Applying the new EFSA guidance these values adjust to 1% and 5% for the human and rat skin respectively.

According to the new EFSA guidance there is the provision that when the sampling period is 24 hours (which is the case for this study) and over 75% of the total absorption (material in the receptor fluid at the end of the study) occurred within half of the duration (12 hours) of the total sampling period that the absorption will be taken as the sum of receptor fluid, receptor chamber washes and the skin sample excluding all tape strips. These criteria were only met by the high dose human skin set of samples in this study. There is also the provision that a standard deviation equal to or larger than 25% of the mean of the absorption requires the use of an alternative value or rejection of the study. The guidance prefers the approach of adding the standard deviation to the mean to cover the upper 84th percentile value of the results. Additionally where an overall recovery of less than 95% occurs, a normalisation procedure is to be used by preference. Albeit that the notifier considers that both the value of 25% for the standard deviation limit and the 95% recovery limit to be too conservative, the application of the guidance results in the following values for [^{14}C]-propineb in the PPB WG 70 formulation:

[13] EFSA Panel on Plant Protection Products and their Residues (PPR); Guidance on Dermal Absorption. EFSA Journal 2012;10(4):2665. [30 pp.] doi:10.2903/j.efsa.2012.2665.

Human skin

- 0.1% for the neat formulation (700 g/kg)
- 0.6% for the intermediate dose spray dilution (3.5 g/L)
- 1% for the low dose spray dilution (1 g/L)

Rat skin

- 0.7% for the neat formulation (700 g/kg)
- 3% for the spray dilution (3.5 g/L)
- 5% for the neat formulation (1 g/L)

CP 7.4 Available toxicological data relating to co-formulants

CONFIDENTIAL information - data provided separately (Document J)