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Version history

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Date	Data points containing amendments or additions ¹ and brief description	Avorsion number
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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' talso coded Specification number 102000006516-02) is a water dispersible grandle formulation (1000) 102000006516-02) is a water dispersible grant at 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 "AH 30/470 WG (c.n. Propineb)'.

Study	Species (sex) _∅	Reference
Acute oral	Rat (F)	LD ₅₀ > 2000 mg/kg bw M-030439-01-1
Acute dermal	Rat (M) + F) &	LD 2000 mg/kg bw M ₂ 030435-01-1
Acute inhalation	Rat (M OF)	LC50 = 2.838 mg/L M-013839-01-1 Nowrelevant because of the dust M-013839-01-1
Acute skin irritation	Rabbit (M)	Not irritating M-030650-01-1
Acute eye irritation	Rabby (M)	Not ioritating M-030653-0 1-1

Propineb W 70 (alias Antracol WG 10) is W low toxicity to rate after oral administration and nontoxic after acute derma Cand Malatine application at is not irritating to the skin or eyes of rabbits. It The study resulte trigger the fedrowing classification/labelling:
- EU directive 1999/45/EC:
- Regulation (EC) No 127/22008 (CLP)
- Regulation (EC) No 127/22008 (CLP)
- Resulting the fedrowing classification/labelling:
- Kin sensitization Cat. 1 (H317 May cause allergic skin reaction) was not rested for semistization with regard to the dermal allergenic potential of Propineb.

CP 7.1.1 Oral toxicity

Report: ;2000;M-030439-01

LH 30/Z 70 WG (c.n.: Propineb) - Study for acute of all toxicity in cat Title:

Report No: 30527

Document No: M-030439-01-1

Guidelines: OECD 423; Directive 96/54/EEC, Annex IVB, Part B, B

712-C-98-190, OPPTS 870.1 P00

Deviations: The test substance a commercial production be stable and nomogenous in both undiluted and in ready to use abution with water. The sest substance was formulated in water Therefore, analytical determinations of stability and homogeneity of the aqueous formulations were set to the stability and homogeneity of the aqueous formulations were set to the stability and homogeneity of the aqueous formulations were set to the stability and homogeneity of the aqueous formulations were set to the stability and homogeneity of the aqueous formulations were set to the stability and homogeneity of the aqueous formulations were set to the stability and homogeneity of the aqueous formulations were set to the stability and homogeneity of the aqueous formulations were set to the stability and homogeneity of the stability and

GLP/GEP:

Material and methods:

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

Test compound:

EH 30/Z 70 WG

Batch rio.:

233013270

Development no.:

3000252002 Content: 4

demineralized water **V**øhicle:∜

demineralized water oral or gated of asted of the control or the control or the control of the c Application oute

Fasting time 17 hour<u>©</u> 1 hour 2000 mg/kg bw Application volume 10 ml/kg bw

Wistar ran (SPF-bred) / HsdCpb:WU Test system strain:

Prats/sex/grows Group size

Post-treatment observation poriod: « 2000-11-08 - 2000-11-24

Experimental phase 14 days &

mical Signs, body weight, gross necropsy

Findings:

"Dable A.1.1-1 Poses Phortality / alimals treated

Findings: 🧢 🤍	Pose N	Toxicological	Duration of	Time of death	Mortality
	[mg/kg [ww]	resulte*	y signs		[%]
	~ Q		Male rats		
4,,	2000	@0/0/3×			0
		Q Ş'	Female rats		
	2000	7 143/3	5d – 10d	6d	33
	$LD_{50 \text{ cut}} = 250$	mg/kg/bw			
Q" ~	T 1st numb	_(U)	number of dead anir		
	2 nd numb	perQ =	number of animals v	•	
	% humb	er =	number of animals i	n the group	
	according	g to the OECD Guid	ieiine 423		
		er = g to the OECD Guid			



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 hypogenia of the hind limbs were detected. In one animal each, also decreased mobility and

red incrusted orbital margins and labored breathing occurred.

The signs observed started on day 5 of the study and tasted up to day 10.

Body weight and body weight gain of male rats was not affected by treatment s **Body weights:**

A decrease in body weight was observed on day of the study in one male

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 animal sacrificed at the end

CP 7.1.2

the study period.
the study period. Conclusion: LH 30/Z 70 WG was of low toxicity after acute oral administration to fasted rats.
fasted rats.
The study result triggers the following classification Habelling:
fasted rats. The study result triggers the following classification babelling: - EU directive 1999/45/EC: - Regulation (EC) No 1272/2008 (CLP): None
- Regulation (EC) No 1272/2008 (QLP): None None
CD 7 1 2 Down all to whater with the control of the
CP 7.1.2 Dermal toxicity
CP 7.1.2 Dermal toxicity
Report: Title: Report No: Document No: Chidolines: DECD 102: Proceedings 67/5%/FEC. Applie V. Part R 3: US. FPA 712 C.
Title: LH 300Z 70 VG (cp.: Propineb) Study for acute dermal toxicity in rats
Report No: \$\infty 305\text{Q8} \infty \qquad \qq \qua
Report No: 30528 Document No: M 03043 7-01-1 Guidelines: OECD 402; Directive 67/548/EEC, Annex V, Part B.3.; US-EPA 712-C-
98-192, OPPTS 870.1200
GLP/GEP? yes, yes, yes, yes, yes, yes, yes, yes,

Material and methods:

nuty for acute dermal toxicity under 24-hour occlusion conditions in male and female rats was performed with LPI 30/Z 70 WG.

Fest compound ″LH ∰″Z 70∰ G BatchOno.: 233013270 **3**00025**2**002 Development no Contento

demal (occlusive dressing) Application foute

24 hours Duration: 2000 mg/kg bw

Wistar rat (SPF-bred) / HsdCpb:WU Test sy@em /strain: 🍳

5 rats/sex/dose Group šize:

Post treatment observation period: 14 days Experimental phase: 2000-11-08-2000-11-22Observations: clinical signs, local skin effects, body weight, gross necropsy

Application dose

Sex Dose [mg/kg bw]	Range of doses [mg/cm ²]
Male 2000	26.9 - 28.0
Female 2000	26.8 - 28.5

Table 7.1.2-1 Doses, mortality / animals treated

Findings:

				n // //
Dose	Toxicological	Duration of	Time of death	Mortality [%]
[mg/kg bw]	results*	signs	Ŝ	4 2
		Male rats	4	Q A
2000	0/5#/5	2d – 14d	₩	
		Female rats		
2000	0/5#/5	2d – 14d	₽ ©	\$ 0 \$
	LD	$9 > 2000 \mathrm{mgAkg}$	g bw	Q O
4 1 ct 1	4	1 (1 (1))	1 0	a CI VA

1st number number of dead nimals number of animals with signs 2nd number 3^{rd} number number of @mimals he the group

animals showed local skin findings only

Clinical signs:

A dermal dose of 2000 mg/kg body weight was tolerated by mates and temals without mortalities and clinical signs.

Local skin findings:

In both genders the treatment area was yellow discolored and in comales the treatment area was partly reddened and a formation of scale was observed. The signs observed started on da 2 of the study and lasted us 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:

were observed in animals sacrificed at the end of No gross pathologic@hanges the study period.

Conclusion:

Administration. Conclusion:

Administration.

The study result triggers the following classification/labelling:

None

None The study result triggers the following classification/labelling:

- EU directive 1999/45/EC:

- Regulation (EC) No 1272/2008 (CLP):

None

- Regulation (EC) No 1272/2008 (CLP):

- Regulation (EC) No 1272/2008 (CL

CP 7.1.3 Inhalation toxicity

Report: :1999;M-013839-01

LH 30/Z 70 WG 03245/0170 (c.n. Propineb) - Study on acute inhalation toxicity in rats according to OFCD no. 402 Title:

29072 Report No:

Document No: M-013839-01-1

, method **Guidelines:** OECD 403; Directive 92/69/EEC

OPPTS 870.1300

GLP/GEP: yes

Material and methods:

A study on the acute inhalation toxicity

and female rats has been conducted

Test compound:

Batch no.: Batch no.: Development Article no.:

Content: Vehicle: _@

deion Zed wate Application rout inhalation (nose-oaly)

inhalation (nose-only) (dust): 0 – 496 – 1028 – 5005 @ng/m³ air Dose

1440 mg/m²air (aerosol) (gravimetric concentration)

Wistar Pats (SPF-bred) / HsdCpb:WU

Rost-treatment observation portiod:

1**99**9-06**0**6 – 1**99**9-07-14

Clinica signs reflexes, rectal temperature, body weight, gross pathology

Findings:

haracteristics of the achieved atmosphere

	Group	Group 1	Group 2	Group 3	Group 4	Group 5
Target concentration [mg/m³]	Control 🔩	Control	500	1000	5000	5000
	[Air]	[Water]	[dust]	[dust]	[dust]	[aerosol]
Nominal concentration [mg/m³]			-	ł	ł	7359
Gravimetric concentration	7 Q		496	1028	5005	1440
[mg/m³]	@ 4	9				
Inlet air flow //min	j\$' - 4	15	28	28	28	15
Exhaust air flow [L/min] Temperative [mean, °C]	13	13	23	23	23	13
Temperature [mean, °C]	23	21	22	20	20	22
Relative Trumidity Imean. %	35	> 93	8	3	5	> 95
$ MMAD [\mu m_0] ^{\gamma}$			2.79	2.56	2.12	3.27
GSΦ aerosol mass < 3 μm [%]			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 ex	posure to	aerosolized	test item
---------	----------	------------	------------	-----------	-----------	-------------	-----------

Group	Target concentration	Toxicological	Onset and	Onset of	Rectal temperature
no.	[mg/m3]	result*	duration of	mortality	
			signs	Ö	
Male rats				A.	
1	Air-control	0/0/5	» _n	, , , , ,	37.8
1	Water-control	0/0/5			278
2	496 (dust)	0/5/5	0d − 5d 🦠	Q	304 S
3	1028 (dust)	0/5/5	0d – 50	L	\$34.5 Q bob \$
4	5005 (dust)	5/5/5	0d ⊉ \$d	40 5d ° S	32.7g & & g
5	1440 (aerosol)	0/5/5	0 d © 3d ∧	- · · · · · · · · · · · · · · · · · · ·	330° 6 b 0°
Female rat	ts	//-	~ <u>,</u> 0		
1	Air-control	0/0/5	1 03 X		38.2
1	Water-control	0/0/5	 		37.7\$\frac{1}{2}
2	496 (dust)	0/5/5	Qd 9d		36.5 & a V
3	1028 (dust)	2/5/5	9d – 14d Ö	4d 🗸	33.6 , b
4	5005 (dust)	2/5/5 Ø «Ž	0d √ 4 d	ld [©] '4d &'	31.7 36.5 31.1 5 5
5	1440 (aerosol)	0/5/50	Qd\\$\\\8d\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\		131.90° & b
$LC_{50} = 283$	38 mg/m³ air			y S	S V
Confidenc	e interval $(95\%) = 1568$	- 5137 m@m³ air	ØSlope ♥1.0 💍		

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

1st number

number of dad animals

 2^{nd} number 3rd number

number of shimals with signs after cessation of ex

number of animals exposed

Clinical signs:

without specific signs. All rats colerated the exposure

 $496 \, \text{mg/m}^3 \, \text{cm}^2$

Bradypnea/motility reduced, hopp, piloerection, ungroomed hair-coat, flaccid paralysis of hind limbs

Labored breathing pattern, brady nea, motility reduced, high-legged gait, limp, flaccid paralysis of hind-limbs paralysis, pilverection, ungroomed hair-coat, Vanosis, emaciation perior ocular red encrustations, prostration (lying on belly abnormal posture of head nostrils. reddened.

5005 mg/s air &

Expored and irregular breathing pattern, bradypnea, tachypnea, nostrils with red Cencrustations, motifity redired, high-legged gait, limp, flaccid paralysis of hindlimbs, nasa discharge (serous), piloerection, ungroomed hair-coat, cyanosis, emaciation.

1440 mg/m³ air

Bradypnea motility reduced, limp, piloerection, ungroomed hair-coat, labored breathing pattern, high Paged gait, emaciation.

Company ons between the air control and groups exposed to the test substance revealed concentration-dependent, statistically significant effects on body weight gain.

Body weights;

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: feddish mucoid content, reddish discoloration of mucous; discolorations of parenchymatous or gans

(pale).

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

observed in control animals cuthanized with pentobarbital.

Conclusion: Exposure concederations equal to 1028 mg/m and above resulted in mortality

when exposure was to the dust whilst the exposure to the fiquid aerosof (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 to me instances, were observed throughout the 2-week post exposure observation period. Necropsy findings were unobtrusive in surviving rats whilst in succumbal rats widence of lung

edema existed. 💍

With regards the espirability of the agosol generated internationally recognized recommendations such as of SOT 1992 were fulfilled, i.e. the MAD was <4 µm (MMAD 2.1-3.3 µm, OSD 1.9-2.7).

LH 30/Z 70 WG 03245/0120 (solar aerosol) shows a low toxicity after acute inhalation to make and female pats.

Report: ; 2003;M-108620-04; Amended:

Title: Particle sizes of Antracol WG76
Report No: A09041561

Document No: M-108620-04-V

Guidelines: A/-, Deviations: not specified of the control of the c

Material and methods:

resocompound.

LH 30/Z 70 WG

Assignment/

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 an week.

The present Antracol samples consist of spherical particles with a median

particle size X_{50} of 235 μ m.

Both the laser diffraction analyzer and sieve analyses afforded nearly identical results. The supplementary particle size distribution determined with the image

The requirements for conversion to the aerodynamic particle size distribution are closely approximated by the present product.

are closely approximated by the present product.

No fractions with a particle size smaller than 30 μm could be detected by any of the described aparytical methods.

Report:

Propineb (I/M30/Z) (Antracol MO-03-099038. Title:

Report No: M-116498-01-1 Document No: **Guidelines: GLP/GEP:** no.

Material and methods:

Results:

Test compound:

For maly ses of 5 different batches of Antracg WG7 the most conservative approach was taken, i.e. the lowest mean MMAD (\$159 \mu m) and the largest SSD (Q45). This results in the highest fraction of respirable particles in the lefthand side of the distribution. The analyses utilized both laser diffraction and sieving with essentially identical results.

The proportion of the thorage fraction, in relation to the Antracol WG 70 as it is handled and used is converging against 0.0%. With respect to Directive 94/779ΕΕ, the particle mass < 90 μm is 0.02% (assuming a log-normal duribution of particle mass) Thus, the particle-size analysis is not triggering The defermination of the acute inhalation toxicity bioassay with Antracol WG 70. Therefore, the sisults obtained with the micronized test article under conditions which were willizing additional technologies to maximize the concentration of respirable particles have limited relevance, if any, for ¿ classification

However at 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 zerosolized in a Collison nebulizer (high aerosol output device). Exposure of rats (0x4h) 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 $< 50 \mu m$ 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 Antragol WG 70, which did not result in mortality up to the maximum technically attainable concentration, substantiates this conclusion further.

The LC₅₀ is not relevant for the formulation because of low dust formation, therefore the classification is as followed:
- EU directive 1999/45/EC:
- Regulation (EC) No 1272/2008 (CLP):

CP 7.1.4 Skin irritation

Report:

Acute skin irritation test (patch test) of LH 30/Z 90 Title: Report No: R7919

M-0306500-01-1% Document No:

EC guideline B.4.; QEC **Guidelines:**

GLP/GEP:

Material and methods:

The air 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: **2**3301*3*270 Batch no. Acticle/Development no. 0005468906

qua ad injectabilia

dermato to the shaved intact dorsal skin Apolicatio

(semi-occlusive procedure)

Duration

500 mg/patch/animal rabbit / Himalayan 3 male rabbits

vation period: Posterreatment obser 3 days

2000-11-03 - 2000-11-06Experimental phase: clinical signs, body weight. Observations:

Findings:

Under the present lest conditions none of the three rabbits exposed for 4 hours to 300 ng 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.

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:

Acute eye irritation study of LH 30/Z 70 WG by instillation into the conjunctival sac of rabbits Title:

R7920 Report No:

Document No: M-030653-01-1

Guidelines: EC guideline B.5.; OECD 405

GLP/GEP:

Material and methods:

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

Test compound:

Batch no: Batch no .:

Article/Development to.

Content:

Application route:

Dose: Test system / strain: Group size:

200091-06 2000-11-10° Experimental phase:

Øbservations.

Findings:

the influence of LH 30/Z 70WG on

3013270

00054689063000252002
68.4%

single instillation into the conjunctival sac

1 granimal

boit / Himalayan

tale rabbits

4 days

11-06—2000-11-10

1 signs, body weight.

application of 0
sight eye of Under the present test conditions a single application of 0.1 g LH 30/Z 70WG per animal into the conjunctival sac of the pight eye of three rabbits did not &cause any changes.

cause any changes.

The cornea the internal the conjunctive were not affected by instillation of the test combound

There were no systemic into Jerance reactions.

Conclusion: LH 30/Z 76 WG is not irritating to the eyes of rabbits. The study result taggers the following classification/labelling:

- EU Directive 1999/45 EC (as amended):

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

CP 7.1.6 Skin sensitisation

Report: ;2012;M-428880-01

Title: Propineb WG 70 - Evaluation of potential skin sensifization in the focal winph

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 on the Magnus on-Kligman, maximisation test (report no. 15897; 1987). In this test evidence was found for a derival allergenic potential of Propineb. For an inal 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 Antraco WG to 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 Dicontains the detailed use information.

CP 7.2.1 O Operator exposure

Operator prosure 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

							<u> </u>
Crop	F/	Application	Region	German Model	UK-PO	EM	Dutel and
	G	method				Ď	ECPA 🚕
					l a	Ş	Greenhouse
					, "@	y .	Model .
						l 6	
				Dose rate	Dose rate	Water	Dose rate
				kg product ha	kg product/	volume	kg product ha
				(kg a.s./ha)	ban (kg	(L/Ba)	kg a.s. Ha)
				a y	(a.s./ha)		
				4	Q' ~~	L L	
		Broadcast air-	N-/S-EU	2.25	2 2005 "	₽ <u>,</u> 0"	& Ü
Apple	F	assisted sprayer,		(1,575)	(1.575),	1500	
		high crop			(J.575)		~ *
		mgn crop	C			8 L	4 .
			N-EU	1,60	Q 1.6 2	800	
		Boom sprayer:	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	(1)2) »	(1)12) 0	1 800	
Grapes	F	hydraulic nozzles,		y" . O" . L"			
1	1	low crop	&-EU	2 2	₹ 20		<i>*</i>
		low crop		(1.44)	(° 624) .4	1000	_& -
							~~
		a.	NEU (4	8- %	2.4
		Hand held	S LO	~ ~ ~	<u> </u>	O - N	(1.68)
Tomata		Trand neid 💨		٨. ٥ ٨			(1.00)
Tomato	G	lance/tank				<u> </u>	2
		sprayer, low crop	S		W - ZZ	~~ ~	3
					(k, ,) .	63	(2.1)
			KŠ		b ^y 🖔 🦫	7"	

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 as./ha) when using the German Model. The critical GAP when using the UK-POEM esults 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 (1.775 kg s.s./ha) and a vater 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 (12 kg a.s./ha in NEU 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 one 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.

Ton Cato:

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 propried (SANCO7574VI97-final, 26 February 2003) was based on a chronic dietary study because as 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

	F /	Application S	Pře	5	(mg/kg	expostere * bw/day)	
Crops	G	method 4	PPE © «	POEMY	German Model	Dutch Greenh. Mødel	ECPA Greenh. Model
Apple	, Sy Y F	Broadcas Cair- assisted prayers high prop	With ²	©.0428 0.03©	0.0 2 57 0.0077	~ - } -	-
Grapes (N-EU)	F ~	Broadcast air- assisted sprayer. Chigh cop	Nov With ²	.~>/	0.61.83	-	-
Grapes (S-EU)		Broadcast air of assisted sprayers high crop	No.	0.0394	0.0229	-	-
Tomato (N-EU)	G	Fland ford lance/tanksprayer, high crop		\$ -	-	0.0720 0.0072	0.0270
Tomato (S-EU)		Mand ledd lance/tan sprayer, high crop	Now With ²	-	-	0.0900 0.0090	0.0337 0.0261

No PPE: UK-ROEM; 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 Psorption 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

	F/	Application				AOEL kg bw/day)	A .	
Crops	G	method	PPE	UK- POEM	German Model	Dutch Greenh. Model	CPA Greenh. Model	
Apple	F	Broadcast air- assisted sprayer, high crop	No With	93 75	⊘ 56 , 17		- 2	
Grapes (N-EU)	F	Broadcast air- assisted sprayer, high crop	No With	102	40 · 12 · · · · · · · · · · · · · · · · ·			
Grapes (S-EU)	F	Broadcast air- assisted sprayer, high crop	No With	0 108 V	15		7 - 4 5 - 4	
Tomato (N-EU)	G	Hand held lance/tank sprayer, high crop	With (A. 6	Ž - Ž		\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	
Tomato (S-EU)	G	Hand held @ lance/tank sprayer, high crop	With	7 - F	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	196	\$\frac{\tilde{0}^3}{57} \tilde{\tilde{0}}	<i>,</i>

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. An grape, exposure of unprojected operators only lightly 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 Saluation of the greenhouse use predicts exposure below the AOEL for operator's wearing a coverall and gloves. The main reason for the exposure of unprotected Conclusion

Overall, it is concluded that the use of Antracol WG 70 does not result in an unacceptable risk for pperators operators above the AQEL is that the model does not account for different dermal absorption values for the concedurate and the dilution (higher derman absorption of the dilution is used).

This is demonstrated operators.

Conclusion

Overall, it

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 Exposure estimates for the use in apple and grapes are made using the UK-POEM and the Oreman 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)4. Detailed calculations are presented in the following tables. A STANT OF S model. The use in greenhouse tomato is evaluated using the Dutch and the ECPA Greenhouse models.

UK-POEM calculations

Table 7.2.1.1-1 : UK-	-POEM calculations - app	le 🔊 .
		POEM) WITH GERMAN MODEL MIX/LOAD DATA (75th PERVENTILE)
**	ctor-mounted/trailed broadcast air-assisted spr	
Formulation type WG	tracol WG 70 Gor SG ▼	Active substance Propineb a.s. concentration 700 page
Dermal absorption from product	0.1 %	Dermal absorption from solvay
PPE during mix/loading Glo		
Dose	2.25 kg product/ha	Works te/day
Application volume	1500 l/ha	Duration of spraying 6 h

		Groves of the state of the stat
	NG MIXING AND LOADING	
Hand contamination/kg a.s. Hand contamination/day	5.72 mg/kg a.s. 135.135 mg/day	
Protective clothing	None None	A A A A A A A A A A A A A A A A A A A
Transmission to skin	100 %	
Dermal exposure to a.s.	135.135 mg/day	1.35 Lm//day (7) (7)
•		Aroles (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)
INHALATION EXPOSURE D	DURING MIXING AND LOADING	
Inhalation exposure/kg a.s.	0.036 mg/kg a.s. 💍	
Inhalation exposure/day	0.846 mg @ yy 🛴	
RPE	None S	
Transmission through RPE	100% &	
Inhalation exposure to a.s.	0.846 mg/day\(\text{mg/day}\)	
	NG SPRAY APPLICATION	
DERMAL EXPOSURE DURIN	NG SPRAY APPLICATION	ssisted strayer: 500 tha
Application technique Tra	nctor mountes grailed by ordeast air-as	sisted sprayer: 500 Ma O
Application volume Volume of surface contamination	400 ml/h	
Distribution Distribution	Pands Trunk	Vers 2 S S S
Distribution	10 %	725 % L
Clothing	Non© Perforable Permea	ible Gloves Permeable Permeable
Penetration @	100% 2%	\$\text{10} \text{2} 5\text{\text{\text{6}}}
Dermal exposure	√, 10 √, 5, 2	5 ml/h
Duration of expensure	O 6 140 0	€ 6 h
Total dermatesposure to spray		85.2 ml/day
Conc. of a.s. in spray solution	1,05 mg/ml ~ 0	1.05 mg/ml
Dermal exposure to a.s.	127.260 mg/day	89.460 mg/day
INHALATION EXPOSURE D	DURRING SPRAYING	
Inhalation exposure to spray	0.09m/h	
Duration of exposure Concentration of s. in spray	005 m 0 10	
Inhalation expudure to a.s.	T.05 mg/m	Y . V
Percent absorbed	100 %	<i>'</i>
Absorbed dose	0.34 mg/day	With PPE Mix/load Application
The second secon		
ABSORBED DOSE 🐧	No PPE	With PPE
<i>\O</i>	Mix/load Application	Mix/load Application
Dermal exposure to	135.126 121.260 mg/day	1.351 89.460 mg/day
Percent absorbed		0.1 1 %
Absorbed dose (deemal route)	0.135 1.273 mg/day	
Inhalation exposure to a 🛭	0.846 0 0.315 mg/day	
Absorbed/dose		0.847 1.210 mg/day
d ,ď á	,	
PREDICTED EXPOSURE O	2605/.	
Total absorbed dose	2.3083 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)

_			GERMAN MODEL MIX	8	
		ssisted sprayer: 500 l/ha			
	Antracol WG 70		Active substance Pr	ropineb	
Formulation type	WG or SG ▼		a.s. concentration		
Dermal absorption from product	0.1 %	De	rmal absorption from spray👟	· // /	
PPE during mix/loading			PE during application Gl	oves 🗸	
Dose	1.6 kg product/ha		Work rate day	15 4	9' ~~
Application volume	800 l/ha	L	Duration of sporying		
			<u></u>		
DWYL EADORIDE DIU	RING MIXING AND LOADI	vic.	Duration of specifying Gloves Other Store Duration of specifying Gloves Other Store S		
and contamination/kg a.s.	5.72 mg/kg a.s.				Q
and contamination/day	96.096 mg/day	(, (° 'O' '\	
otective clothing	None		W AGIOVER M		4
	100 %			"O" 🛵	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
ansmission to skin ermal exposure to a.s.	96.096 mg/day	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	04061	olds O	
лиш сърозше ю а.з.	96.096 mg/day 96.096 mg/day E DURING MIXING AND LO 0.036 mg/kg a.s. 0.601 mg/day None 100 % 0.601 mg/day RING SPRAY APPLIC ATION Fractor-mounted/trailed broadce 800 sprawha 400 mg/day Hand 10 % 65 % Sone Permeable 100 % 2 % 10 5.2 11 mg/d 14 mg/d 14 mg/d 14 mg/d 14 mg/d 169.680 mg/day	ADING Y		To the second se	
HALATION EXPOSURE	E DURING MIXING AND L	Äding 😽 . @			
halation exposure/kg a.s.	0.036 mg/kg a s				
nalation exposure/day	0.601 mg/day 1			. ŠČ	. Ö
PE	None None	· · · · · · · · · · · · · · · · · · ·			
ansmission through RPE	100 % -) D 1, 8		•
nalation exposure to a.s.	0.601 mas day) "O" "Š			
1	A The state of the		500 1ha 800.0 4 miles		
ERMAL EXPOSURE DU	RING SPRAY APPLICATION	1 °C, °A			
oplication technique	Fractor-mounted/traileOproadc	est air-assisted spraver:	500 1/ha \		
oplication volume	800 spráw/ha		\$,800.0 K	Paylaa 💢	
lume of surface contamination	400 m 6	o »			
stribution	A Hands Hunl	: @, Legs		Less	
	Ø 10 % \$ 65 %	25%	10.0 % Gloves 10.0 % 4	65.0 % 25.0	%
othing ,	None Permeable	Permeable, . 9	& Gloves	Permeable Permea	able
netration Ö	√ 100 % √ C2 %	5 % s	J' Q' 184	2	5 %
ermal exposure	D 16 35.2	. Co 5√mµh		5.2	5 ml/h
ration of exposure	\$ 46 h		Ø 0 .006h		
tal dermal exposympto spray	121.2 ml/da		85.2 ml	l/day	
nc. of a.s. in spray solution	2 1.4 mam 0	,» O	1.4 m	g/ml	
ermal expossare to a.s.	69.680 day		(119.280 m	g/day	
T.		Legs 25 % Fermeable, 5 % With	4 6 h 85.2 mi 1.4 m 119.280 m		
HALATION EXPOSUR	QURING SPRAYING				
halation exposure to spray	y 4 0.05 ml/yQ √		>		
ration of exposure	6 k 0		A		
ncentration of a.s. in@pray	6 k 7 0 1.4 mg/ml . 0		"		
halation exposure a.s.	O O mg/day		₩		
rcent absorbed	000 % ~0" 3),		
osorbed do	0.42 mg day 0/j				
	Q 0.42 mesany				
BSORBED DOSE	No PPE	# X	With PPE		
**************************************	Mix Gad Application		Mix/load	Application	
ermal exposure to a.s.	90.096 (169.680	mg/day.O	0.961	119.280 mg/day	
rcent absorbed	0.1 4 201	% 👋	0.1	1 %	
sorbed dose (dermat soute)	△ 0.09€	mg/day	0.001	1.193 mg/day	
nalation exposure a.s.	0.420	@g/day	0.601	0.420 mg/day	
osorbed dose		9mg/day	0.602	1.613 mg/day	
Ű ÁS					
REDICTED EXPOSTRE					
otal absorbed dose	2.8143 mg/day		2.2152 m	g/dav	
perator body weight	60 kg		60 kg		
perator exposure	0.0469 mg/kg bw/day		-	g/kg bw/day	
negator exhibitative	U.UTUJ IIIE/KE UW/UUV				

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

THE LIV DDENIGTRIE OF	EDATOD EVBORIDE 35	ODEL (BOEM) WEE	H CEDMAN MODEL AS	IVII OAN NATA /754	L DEDCENANTE V
THE UK PREDICTIVE OPP	EKATUK EXPOSUKE MO	ODEL (POEM) WIT	H GERMAN MODEL M	LALUAD DATA (75t	h PERCENTLE)
Application method Tra	actor-mounted/trailed broadcast air-	assisted sprayer: 500 l/ha		Ş	
	ntracol WG 70		Active substance	Propineb	
Formulation type W			a.s. concentration	700 mg/g	
Dermal absorption from product	0.1 %	I	Dermal absorption from spray	1%%	
PPE during mix/loading Glo			DPE during application	Gloves	
Dose	2 kg product/ha		Work rate day	15 6	9 V
Application volume	1000 l/ha	Ô	Duration of smoothing Glovas		
DERMAL EXPOSURE DURI	NC: MIVINC: AND LOAD	NG.	, Q		
Hand contamination/kg a.s.					
Hand contamination/day	5.72 mg/kg a.s. 120.12 mg/day	()		~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	
Protective clothing	None		Y J James		γ
Protective clouding Transmission to skin	100 %				· 🛋
Pransmission to skin Dermal exposure to a.s.	100 % 120.120 mg/day	,A 0	Q Q 14001	mg/da	
Jermai exposure to a.s.	120.120 mg/day	JADING Y	Glove 1801		
NHALATION EXPOSURE I	OURING MIXING AND L	Bading, 😽 🏒	<i>"</i> "		
nhalation exposure/kg a.s.	0.036 mg/kg a.s. 🖇				* ~
Inhalation exposure/day	0.752 mg/day			', jj' ,£	, Q
RPE	NT - 1	, ,			
Fransmission through RPE	100 %				. **
nhalation avecours to a s	0.752 ms day	j "O" 🥋			1
•			Y "O" , Ø) , " ()	
DERMAL EXPOSURE DURI	NG SPRAY APPLICATIO				
Application technique Tra	NG SPRAY APPLICATION actor-spotsted/trailed broadc 1000 spray/ha 400 #Qn	abst air-assisteed sprayer	r: 500 1/ha 🐧		
Application volume	1000 správ/ha		Y Q 1000.0		
olume of surface contamination		o »	° 0, 0 ° 0 ° 0		
Distribution	S Hands Trunk	No air-assisted sprayer Leggy Fermeable, 5 % John Marines	r. 500 lha 1000.0 Hamiles		Legs
	16% \$ 65%	25%	D 0, 10.0 %	(03.U % A	5.0 %
Clothing	_ (Done _ Permeab}	Permeable,	TO 100 %	Permeable Pe	ermeable
Penetration 💍	100 %	6 ~ 5% L, X	i v z z	2	5 %
Dermal exposure	Q 10 05.	2 vo 5√malh		5.2	5 ml/h
Ouration of exposure	S LOTA	~ . Q	~ 0 , W 6	h	
cotta dermai emposito spray	121.2 ml/da	<u> </u>	\$\frac{1}{6}\tag{85.2}	ml/day	
Conc. of a.s. in spray solution	2 1.4 man 0		1.4	mg/ml	
Dermal expressive to a.s.	69.680 mg day		119.280	mg/day	
			/. AY		
NHALATION EXPOSUR E	URING SPRAYING				
nhalation exposure to spray	4 0.05 ml/hQ ×		J &		
Ouration of exposure	6 k . 0°		Ž		
oncentration of a.s. in Oprav	O 1.# mg/ml . O	5 % July 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	4 6 85.2 85.2 1.4 119.280		
nhalation exposure a.s.	OD mg/day		*		
Percent absorbed	000 % ~ 0	R' &			
Absorbed dos	0.42 me day	F' % &	J.		
ABSORBED DOSE ~	No PPE	\$.~Q'	With PPE		
A V	Mix Cad Application		Mix/load		
Dermal exposure to a.s.		0 mg/day.0	1.201	119.280 mg/d	av
Percent absorbed	0.1 & 0.00	1 %	0.1	_	-,
Absorbed dose (dermat soute)	1 0 120 × 560	7 mg/da/y	0.001		av
nhalation exposure a.s.	0.42	O @ #/day	0.752	~	
Absorbed dose	7 0.421 0.421 72	Ong/day Ong/day	0.753	_	
TOSOIDER ROSEN		Wink/ day	0./53	1.013 tilg/di	цу
REDICTES EXPOSORE					
otal absorbed dos	20007		2 2450	ma/dass	
	2.9885 mg/day 60 kg			mg/day	
Operator body weight O	0.0498 mg/kg bw/day			kg malka buulday	
Operator exposure	U.U+30 ing/kg DW/day		0.0394	mg/kg bw/day	
\sim					

German Model calculations

Table 7.2.1.1-4: German Model calculations - apple

	A
Operator exposure estimate: German model. Tractor-mounted/tra	ailed broadcast air-assisted spray@

Product:	Antracol WG 70)			.1	\$ 40
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		₄ ©"	Hands;	Gloves, O	
Inhalation absorption [%]	100			Head:	None	4
Dermal absorption [%]	0.1	(concentrate)		Body:	Standard p	rotective coverall a
	1.0	(dilution)	<i>"</i>	~10° ~ 7° 7°	.0 ?	

Calculation of route exposure:

Cureumeron or route e	1 postare v	
Route	Specific exposure	a.s. handled Estimated exposure [ing/kg bw/day]
Route	[mg/kg a.s.]	[kg/day] No PDE Reduction factor with PE
		I = Inh@tion
$I_M =$	0.008	
$D_{M(H)} =$	2.0	12.6 0 0.36 0.01 0.0036 M/Mix/Loading
$I_A =$	0.018	12.6 0.00024 110 0.00324 X Application
$D_{A(C)} =$	1.2	NA OF ON ON AND OF AND OF HE Hands
$D_{A(H)} =$	0.7	
$D_{A(B)} =$	9.6	12.6 0 1.728 0.05 0.0864 B=Body

. ,			V (~ 29 ×		
Al J. J. J		Specifical [%]		, J , Ž PPE & , ,	With	DDE
Absorbed dose:	Mic Ecoading O		Ø	PPE	With	PPE
Route		Macounting [9/1	Estimated route exposure	Systemic	Estimated route exposure	Systemic
Route	\$ 5 \ \display \text{2}	Ostosoibeon [20]	route exposure	exposure [mg/kg b/w/day]	[mg/kg bw/day]	exposure [mg/kg bw/day]
 			route exposure [mg/kg pw/day]	Ing kg w/day	[IIIg/kg 0w/day]	[IIIg/kg bw/day]
Darmal:	Mickonding	(V) (V)	₩036 %	0.00036	0.0036	0.000004
Demai.	Moblication V	\$ 1.0 °	2.07	0.020	0.30366	0.003037
Inhalation:	Miv/Lostding	\$ 4\hat{1.0}	2.00 7 0.00144 @	0.000144	0.00144	0.003037
ministron.	Application	2100	@00324 [©]	0.00324	0.00324	0.00324
	7 Application (7)	Toral =	\$\\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	° 0.02574	0.00321	0.00772
Dermal: Similar in the state of						

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

Operator exposure estin	nate: German mo	del. Tractor-r	nounted/trailed broadc	ast air-assis	ted sprayer	
Product:	Antracol WG 70				Ö	
Active substance:	Propineb		a.s. concentration:	700	[g/lowkg]	4 8
Formulation:	WG		PPE during mix/loading:	Respiration:	None	
Dose [l or kg/ha]:	1.6			Hands:	_ ∕a loves	
Work rate [ha/day]:	8		PPE during application:	Respiration:	None	
Body weight [kg]:	70			Hands:	Gloves	
Inhalation absorption [%]	100		y	Head:	None ,	
Dermal absorption [%]	0.1	(concentrate)	, Ö	Body:	Standard	rotective coverall
	1.0	(dilution)	4	$\mathbb{Q}^{"}$	~ ~	(

~ · · · ·		
Calculation	of route	evnocure.
Caiculation	or route	CAPOSUIC.

Route	Specific exposure	a.s. handled Estimated exposure [mg/kg/bw/day]
	[mg/kg a.s.]	[kg/day] No PPE Reduction factor with PPE []
		8.95
$I_{M} =$	0.008	
$D_{M(H)} =$	2.0	8-276 \ 0.2756 \ 0.401 \ \ 0.4002.56 \ M = Mix Boading
$I_A =$	0.018	0.96 A = Application
$D_{A(C)} =$	1.2	$\sim 8.96 \text{ m/s} \sim 10.1536 \text{ m/s} \sim 1.0 \text{ m/s} \sim 10.1536 \text{ m/s} \sim 1.0 \text{ m/s} \sim 1.0$
$D_{A(H)} =$	0.7	0.0896 0.0896 0.019 0.000896 0.000896
$D_{A(B)} =$	9.6	8.96 12.88 0 005 0.06.144 B=Body

IA =	0.018	3 9.90 (**)	09002304		25023040 y	A = Application
$D_{A(C)} =$	1.2	√ 8.96 ×	0.1536	1.0	№ 0.1536	H © Jands
$D_{A(H)} =$	0.7	8.96	0.0896	0.01	O 0.000896	€ Head
$D_{A(B)} =$	9.6	8.96 8.96 8.96	0.0896	PPE Systemic exposure	0.1536 0.000896 0.00144	Head B = Body
	9.6) 		O. T. C.		,
		v	-0 ~	e v	0"	
	***	&, O	\$ m.			DDE
Absorbed dose:			No No	PPE *	© With	
	~~~ 4	- Q	Estimated	Systemic 🧷	Estimated	Systemic
Route		, Absorption [%	rout exposure	exposure ~	route xposure	exposure
		Absorption [%]	Estimated rout Exposure [makg bw/day]	[mg/kg bw/kky]	[mgkg bw/day]	[mg/kg bw/day]
				_ 0.	4	
Dermal:	A ix/Loadine	0 291	0.200	. <b>©</b> 0.000256 ∉	7, 0.00256	0.000003
J. J	Application	y' 100		9 00 1472 ×	0.215936	0.002159
I.1.1.4	Application	\$\langle 1.00	W 001024	• A 00102	0.213730	
Innaiation:	Mix/Coading	0" 100 "0"	0.001824	80.001024	0.001024	0.001024
<u> </u>	Application	100%	© 0.002\$#04	0.002304	0.002304	0.002304
		Total		0.018304		0.00549
		,				
E.A.				, O'		
* *				4		
	\$\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\tin}\ext{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\texi{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\texi{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\ti}}\\ \tittt{\text{\text{\text{\text{\text{\text{\text{\text{\text{\texi}\text{\text{\texi}\text{\text{\text{\texi}\tinz{\text{\texi}\text{\texi}\text{\texi}\\\ \tittt{\texitit}\\ \tittt{\texitit{\text{\texi{\texi{\texi{\texi{\texi}\tint{\texit{\texi{\texi}					
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Q' Q						
	The same of the sa					
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Ö						
Route Dermal: Inhalation:						

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

Operator exposure estin	nate: German mo	del. Tractor-n	nounted/trailed broadc	ast air-assist	ted sprayer	
Product:	Antracol WG 70			_	Ŏ,	.V A
Active substance:	Propineb		a.s. concentration:	700	[g/ kg /kg]	4 , 4
Formulation:	WG		PPE during mix/loading:	Respiration:	None	
Dose [l or kg/ha]:	2.0			Hands:	/ Sloves	
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	rotective coverall
1	1.0	(dilution)	4	Æ."		e O e

Calculation of route exposu

Calculation of foute e	xposure.		. 0 . 0	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	<u> </u>	s. 'S
Dourto	Specific exposure	a.s. handled	Estimated expo	osvare [mg/kg bw	/day](>	
Route	[mg/kg a.s.]	[kg/day]		on factor	with PPE 🎝	4
		1	6		<u>~</u> 0.	I — Whalation D = Derma
$I_{M} =$	0.008	11.2		1.0	0.00138	D Derma
$D_{M(H)} =$	2.0		0.00		0.4032	M = Mix Boading
$I_A =$	0.018	Q-2 4 1	_0 1 00288≈./	KVO P.	\$60288	A = Application
$D_{A(C)} =$	1.2	11.2 %	~ 0.192 ~ ~ C	1.0	0.00	H Plands
$D_{A(H)} =$	0.7		0.142	0.0	J 0.00 1 2	Ç = Head
$D_{A(B)} =$	9.6	V.Ž	1,636	0405	0.0568	B = Body
		**************************************				7
	₹ y				Q 2	
41 1 1 1			// /// br DDD	- // 6	× 200	DDD

La	$I_A =$	0.018	Q 2 (Y	0.00288	₩.0 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	() () () () () () () () () ()	A = Application
DA(H) = 0.7 11.2 0.10 0.00 0.00 192 E Head DA(B) = 9.6 11.4 0.10 0.00 0.00 0.00 0.00 0.00 0.00			J11.2	% 0.192 √ v	1.0	3 0.192 3	H Dands
No PPE With PPE Systemic rough Sposure Impere box (Absorbed dose; Absorbed dose;	$D_{A(H)} =$		Q" 11.2	0.142	S" 0.045"	O.004742	°C = Head
Route	$D_{A(B)} =$	9.6	, 'U.P @	\$ 1,6₹6 °C	D 0405 2	0.0568	B = Body
No PPE Systemic		~C		~ L			
Route		\swarrow'		4			
Route Absorption P Estingated Systemic route-keyosure Estingated route-keyosure	Absorbed dose:	<u> </u>		O' No P	PE v	With S	
Noute Absorption Toug Exposure Gegosure Toug Exposure		*** 4		Estimated	Systemic (Estimated	
Dermal: Strict Loading 1.0. 1.84 0.00032 0.0032 0.00003	Route		Absorption [%]	route exposure	exposure	route	•
Dermal:				[mg/kg bw/day]	[n@kg bw/day]	[mgkg bw/day]	[mg/kg bw/day]
Dermai: Strict Coages 0.1 1.0 1.84 0.26992 0.002699 Inhalation: Mix Coading Application 1.00 0.0028 0.00128 0.00128 0.00128 Application 1.00 0.0028 0.00288 0.00288 0.00288 Application 1.00 0.0028 0.00288 0.00288 0.00288 Application 1.00 0.0028 0.00288 0.00288 0.00288 Application 1.00 0.0028 Applicat	D 1				U 0 000020	» 0.0022	0.000002
Inhalation: Application 100 0 0.00128 0.00128 0.00128 0.00128 0.00128 0.00128 0.00128 0.00128 0.00128 0.00128 0.00128 0.00128 0.00288	Dermal:	Mix/Loading %		, , , , , ,	0.00032 (0.0032	
Infraiation: 0 Mist Sading 100 0 000288 0.00128 0.00128 0.0028 0.0028 0.		Application	1.0	(1.84 ×)*	00184	0.26992	
Application 100 0.00288 0.0028	Inhalation:	Mix/Loading	O" 100 "O"	0.00128,	\$0.00128	0.00128	
THE THE PARTY OF T		Application	100 %	9 0.00 08 8	0.00288	0.00288	
			I otal	* [']	0,92288		0.006862
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### **Dutch Model calculations:**

<b>Dutch Model calculations:</b>			e de la companya de
Table 7.2.1.1-7: Dutch Model calc	ulations - greenhouse tom	nato (N-EU)	
OPERATOR EXPOSURE		DUTCH	GREENHOUSE MODEL
form Antracol WG 70		Application in	cluding mixing and loading
a.s. Propineb			
Parameter	Value	Unit Unit	References, conments of Q
MANUAL SPRAYING in greenhouses		₩.	
AR Application rate	1.68	kg a.s./h	a summary dintende uses &
A Area treated	1	ha/ day	a summary of intended uses  Dutch model
Inhalation Exposure		. "	, "Y withhaut PPE, "♥ \"Y"
SV Surrogate Exposure Value	1 0	mg a.s./ kg	
Inhalation Exposure (without PPE)	1.68	mg a.s./d	ay J€≠ SV x AR x A €
Inhalation Exposure (with PPE)			
PPE-factor		mg a.s./di	Non-powered mask filtertype 2 (most conservative): 10 prore advanced FPE: see note** (Detch model)
Inhalation Exposure (with PPE)		mg a.s./9	ay JE(PPE) = (1/PPE actor) x IE
Dermal Exposure	200		
SV Surrogate Exposure Value	2005	moda.s./ kgg	a.s. For dustion see note* (Dutch
Dermal Exposure	36 S	y mg a _y s./ d	model) ay DE = SV x AR x A
Dermal Exposure with PRE			with PPE
PPE-factor P			Gloves + coverall: 10 (Dutch
Dermal Exposure (with PPE)	33.6	mg/a.s./ d	model)  DE(PPE) = (1/PPE-factor) x DE
Internal exposure			
IA Inhalation Absorption	\$\frac{100}{6} \times 0	%	
DA Dermal Absorption AOEL	1	©‴% Ömga.s./d	ay based on 70 kg bw
		y grig a.s., a	ay based on 70 kg bw
	Without PPE	With PP	
Internal exposure	[mg a.s. day ]	[mg a.s. / d	
	1,6800	0.1680	$IE(int) = IE \times (IA/100)$
Dermal	\$3600°	0.3360	$DE(int) = DE \times (DA/100)$
Total	5.0400	0.5040	sum
WAGEL JuftHalation Derma			
Lipe alation		5	%AOEL = 100 x IE(int) / AOEL
Derman	104	10	%AOEL = 100 x DE(int) / AOEL
Total	157	16	sum
		Systemic	exposure
	(mg/person		(mg/kg bw/day)
Wi4h and DDE	5 0400	,	0.0720

A G	Systemic	e 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)

Param e te r	Value	Unit	References, comments
MANUAL SPRAYING in greenhou	ISES		
AR Application rate	2.1	kg a.s./ha	sumary of intended uses.
A Area treated	1	ha/ day	A Dutch model A
Inhalation Exposure			w ith ord PPE
SV Surrogate Exposure Value	1	mg a.s./ kg a	For dusting see note (Dutch
	.0.7		modelQ
Inhalation Exposure (w ithout PPE)	2.1	mg a.s.∕Qay	° AE SV X AR X A
	Ø		
Inhalation Exposure (with PPE)			The PPE W
PPE-factor	100" 0"		Non-powered mask filtertype 2
		V Q .	O'(most conservative): 1/6√more
			(Ditth model)
Inhalation Exposure (with PPE)	0.21,	Ang a.s. Pay	ME(PPEQ + (1/PPE) actor) QIE
Derm al Exposure			WANDOUT RPE
SV Surrogate Exposure Value		mg D.s./kg Ga.s	. For dusting see note* (Dutch
6			(model)
Dermal Exposure	J & 320 &	mg als/ day,	DE = SV x AR x A
Derm al Exposure (with PPÉ)			with PPE
PPE-factor			Gloves 4 coverall: 10 (Dutch model)
Dermal Exposure (w PPE)	A2	pogra.s./ gray	)`
Definal Exposure (WEATTE)			() - () - () - () - () - () - () - () -
Internal expos _{tu} le			<u></u> & *
IA Inhalation Absorp@n	100	y 0% , 0	
DA Derma Absorption	10		
ACEC	3.22	mg a. S day	based on 70 kg bw
			· ·
	Northout/PPE	With PPE	
Internal Apposi	mg a s. day ]	mg a.s. / day	1
© ∑Ö [∀] Inha@	ion , 0 20000, 0	0.2100	$IE(int) = IE \times (IA/100)$
Q Q	mal 04.200.00 0	0.4200	DE(int) = DEx (DA/100)
Д то	otal 6.3900 V	0.6300	sum
A S WA			
Apprala:	tio _p 9 650	7	%AOEL = 100 x IE(int) / AOEL
O Der		13	%AOEL = 100 x DE(int) / AOEL
	mal 4.2000 6.3900 bital 6.5000 final 196	20	sum
		Systemic exp	oosure
J Ž A ,	(mg/person)		(mg/kg bw/day)
Without PPE	6.3000	,	0.0900
With PPE			0.0900
willier	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 C	Operators Application
2	Spain	Almeria	Peppers	,10	320
3	Spain	Almeria	Cucumber	0 10 Q ,	O 40 O
10	Italy	Tuscany/Venet	Bot Plans		10
12	Spain	Murcia/Alicante	Cuciumber	<b>6</b> 10	Sy 100
13	Spain	Murcia/Africante			, 10
14	Italy	Strily &	Meton (		200
15	Italy	Sicily	Melon	NAS	\$ \$90

NA: not applicable

The studies were conducted according to OECD Guidance¹ and were GLP compliant for the field, analytical and report phases, including assessment reports. The studies conducted by internationally recognized contract research againzations.

Briefly, the exposite was determined using standardized passive dometry methodology. This entailed the use of inner and outer dosimeters for body exposure proteorive gloves and hand washes for hand exposure, face and neck washes for head exposure. Infialation 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 scerario misignificant contact with treated foliage
- Intensive scenario direct contact with reated to liage (dense crop, no or narrow rows) Low crop (0.5m):
- Standard scenario in ignificant contact with treated foliage
- Intensive sconario directo contact with treated foliage (dense crop, no or narrow rows)

In the 'Standard' scenario, perates wore olyester/cotton standard working coveralls.

In certain copping scerarios, where contact to treated foliage could not be avoided rain suit coveralls fousers were corn. 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

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:		d; 2010;M-4007Q-01, · · · · · · · · · · · · · · · · · · ·
Title:	Southern Europe	can greenhouse model overview
Report No:	M-400719-01-1	
Document No:	M-400719-01-1	
<b>Guidelines:</b>	-/-	
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 tomate (N-EU, high crop - standard)

0 4		<i>©</i> ′			4)	0	
Operator exposure estima	- (2)	20.0	verop, standare			7/-	
Product:	Anacol Web	80 ~ O)			Ŏ ~	<i>(</i> )	a.
Active substance:	🄊 PropinD	.(~)		ncontration:		[g/lər,kg]	~(7)
Formulation:	Ny Ny	~	PPE during n	%ix/loading K	espiration:	None	4J
Dose [l or kg/ha produst].	<b>2</b> 4		)		ands	Noves	
Work rate [ha/day]:	ori ≪		PPE during a	pplicarion: R	espiration:	ONone @	<i>'</i> )
Body weight [kg]:	[©] 70		<u> </u>	<b>≫</b> Н	a@as: €.	Gloves	
Inhalation absorption [%]	100		O y	H	ead:	Nane	
Dermal absorbion [%]	$\mathcal{A}^{\mathcal{P}}$	concentra	ite <b>t</b>	Ŝ®.	ody: 🏑 🧗	@verall	
	%¥.0 ·	(dilution)		~~			

Calculatio	n ot route expo	sures a		2 1 10				_
		ntermediate exp	ospic figures					
Ι,	D 4	Intermediate exp	Lto calculate	a.s. Mandled	Estimate	ed exposure [mg/kg]	ow/day]	
1	Route 0	Estimated exp	sure" for	Rg/day]				
	**	"Unprotected"	"Protested"	a b'	protected	Reduction factor	Protected	
	4	0"	29		,Ø			I = Inhalation
	IMO y	0.018344		/ 1680 ·	0.00032025			D = Dermal
D	INO "	2. <b>295</b> 118	<b>3</b> .029689	A 680 ~ 7	0.05508282		0.00071253	M = Mix/Loading
	$I_A =$	^ <b>Q</b> 76955 <u></u>		Ø1.680 ×	0.01624692			A = Application
L X	6 _{A(C)} =	Ø.80606 <b>)</b>		(2) 1.08eV(39	0.01934545			C = Head
	$\mathbf{O}_{\mathrm{A(H)}} =$	25.190386	Q <del>2</del> 021652	1.600	0.6045693		0.0005197	H = Hands
Ι	$O_{A(B)} = O$	17.084126	L _ U	7 14.680	0.410019			B = Body

Absorbed dose:		A .	Unprot	ected	Prote	ected
		Absorption	Estimated route	Systemic	Estimated route	Systemic
Rould			exposure	exposure	exposure	exposure
		[70]	[mg/kg bw/day]	[mg/kg bw/day]	[mg/kg bw/day]	[mg/kg bw/day]
A, C						
Dermal:	Mo Loading Application	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
Ü	Application	100	0.016247	0.016247	0.016247	0.016247
		Total =		0.026962		0.020867

Table 7.2.1.1-11: ECPA Greenho	use Model calculations,	, tomato (S-EU, hig	gh crop – standard)

Operator exposure estima	ite: Greenhouse r	nodel. High c	rop, 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 O
Dermal absorption [%]	0.1	(concentrate	)	Body:	Covered
	1.0	(dilution)		Ů	4
			4		O' -

Table 7.2.1.1-11; E	CPA Greeni	nouse Mo	dei caiculations	, tomato (S-	-EU, nign cr	op – standard	,
Operator exposure estima	ite: Greenhouse n	nodel. High c	rop, standard				
Product:	Antracol WG70						
Active substance:	Propineb		a.s. concentration:	700	[g/l or kg]		
Formulation:	WG		PPE during mix/loading:	Respiration:	None	10	
Dose [l or kg/ha product]:	3.0			Hands:	Gloves	L	
Work rate [ha/day]:	1		PPE during application:	Respiration:	None 🖔	) ^p	
Body weight [kg]:	70			Hands:	Gloves		
Inhalation absorption [%]	100			Head ?	None O		
Dermal absorption [%]	0.1	(concentrate)	)	Body:	Covered		
1	1.0	(dilution)		a Y	4		
			2	<b>.</b>	Q, , , o		' Ö "Q"
Calculation of route expos	ure:		~	<i>y</i>	~~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~		
	Intermediate exp	osure figures		•			1,9 ~
Route	[mg/kg a.s.] used	d to calculate	a.s. handled	° Estant	ated exposure [mg/	kg <b>6</b> w/day]	
Route	"Estimated exp	osure" for	[kg/dav]	7, 4,			] " , "
	"Unprotected"	"Protected"		Unprotested	Reduction Pact		
			2.100	, <i>©</i>	Q , "	~ O.	I = Inhalation
$I_M =$	0.013344		2.100 ×	0.000040034	·A		D Dermal
$D_{M(H)} =$	2.295118	0.029689	2.100	006885365		0.00089067	M = Mix/Loading
$I_A =$	0.676955		Q 24100 X	0.02030865	70 %		A = Appl aion
$D_{A(C)} =$	0.806061	Ĉ	😽 (2.j\u00000	0.02408182		, Ç Q	C = Head
$D_{A(H)} =$	25.190386	0.021652	″ @ <b>2</b> .100 ° <b>&gt;</b> √″	0.02×008182 0.75257116 / 0.512524 ^		0.000\$9067 0.0006496	H = Hands
$D_{A(B)} =$	17.084126		2.100	0.512524	) o		B = Body

Absorbed dose:	•		Unprotecto	ed 🖑	_	ected O
Route	<b>&amp;</b>	Absorption	Estimated rouse Sexposur	exposure	Estimated route  Expessure  [mg//g bw/day]	Systemic  exposure
	**************************************		Q[mg/kg baday] A	ng/kg bw/daŷ]	[mgskg bw/day]ş	[mg/kg-hw/day]
Dermal:	Mix/Loading	9 0.1 J	0.068854	0.0000689	0.000	0000001
	Application	000	@.292417\\\	0.0/12924	0.53⑦\$55	<b>4</b> 0.0053736
Inhalation:	Max Loading L	(O)		<b>ॐ</b> 000400 <b>3</b> €	0,00040031	0.00040031
	Application 0"	~ <b>*</b> 700	0.020309	Ø 0.0203 <b>%</b>	020309	0.020309
	0 2	Total =	Y L	0.033702		0.026083
	, (i) (i) ₋			A	(A)	

# Measorement 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

# 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 ( at 2008) is to lowed and the official calculation spreadsheet³ is used in the following

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 o	of critical	GAPs for b	bystanders and residents

Crop (grouping)	Application technique	Max. dose rate (kg a.s./ha)	Max no. of appl	% <b>Drift</b> (1 appl, 90 th perc., 3 m)	Drift 2 applic., 82 percentile, 2 m)
Apple	Broadcast air assisted sprayer	1.575		<b>29</b> .20	25.53 O
Grapes	Broadcast air assisted sprayer	1.4		270 V	\$\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\f

• Justification of the selection of the critical GAP

The exposure scenario for high crop spray application in apple and grapes with off-parget 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 props 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 GP 7.2.2.1.

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

Target growp	Scenario Total system (mg/kg by/d	e (mg/kg bw/day)	% of AOEL
Bystander 2	6 Adult 0 2 0:9077		17
	Childy \$\int 0.0061		13
Pasident	Adult Q 0.0013	0.046	3
Resident	Child 0.0093		20

^{*} Assumes a 60 kg body weight for an adult and 16.15 kg for a child

#### 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.

^{*} Absorption 1% (spray) watthe dermal route, 100 % via the inhalation route

#### Conclusion

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

# CP 7.2.2.1 - Estimation of bystander and resident exposure

The following definitions and assumptions for bystarders 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 inrelated to work involving pesticides but whose position may put them at risk of exposite
- 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 of work mear areas of the application of plant projection products (e.g. standing, working of 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 vapous 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 drouthing and/or pica behaviour⁴).

Exposure is calculated for adult and child by standers as well as adult and child residents. The German guidance for by stander resident exposure is used.

#### a) Bystander exposure assessment

#### Dermal Exposure (Spray Drift):

 $SDE_B \# (AR_{\bullet} D \times B A \times D A) / B W$ 

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

Input parameters:

$$AR = Application Rate (mg/m^2)$$
:

 $BSA = Esposed Body Surface Area (m^2)$ :

 $BSA = Esposed Bo$ 

Inhalation Expospre (Spray Drift):

$$\mathbb{E}_{B} = (I_A \times AR \times A \times T \times IA) / BW$$

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.

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

Input parameters:

#### Total Systemic Exposure of Bystanders

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

		ınpui pare	imeiers:	
$I^*_{_A}$	= Specific Inhalation Ex (mg/kg a.s. handled p field crop sprayer: = Application Rate (kg a = Area Treated (ha/day) = Time [Duration] (min) = Inhalation Absorption = Body Weight (kg/personal Exposure of Bystanders    dren: SE _B = SDE _B   SIE _B   Sie   Systemic Dermal Exposure of Bystander exposure of Bystander exposure of Bystemic Inhalation (bystemic Inhalation of Bystander exposure of Bystander e	posure		
	(mg/kg a.s. handled p	er day),	O ^y	
	field crop sprayer:	0.018 (ad	u <u>k</u> t), 0.018/1.:	74% hild
AR	= Application Rate (kg a	ı.s./ha): 🔪 1.0 🤾		
A	= Area Treated (ha/day)	: 🔻 8 Q'	Ď	
T	= Time [Duration] (min)	): 5 mi@6f	6 hours Æ\$/3	600 0
IA	= Inhalation Absorption	(%). 100°		
BW	= Body Weight (kg/perso	of (adult)	, 16:Þ (chið	) & Ø
			, or >	
Total Systemic Expos	ure of Bystanders			~ ~ ~
Adults and chi	1dron: SE_ = SDE_ + SIE_	Mary Caron	, O	Y TY
Addits and on	Idicii. SEB – SDEB – SIEB	(uig/kg gw/day)	. 0 4,	
Where				
$SE_{B}$	= Systemic Doposyte of I	By Fanders (mg/kg bw/da		ý. O
$SDE_{B}$	= Systemi@Dermal Exp	sure of Bystanders (mg/k	g Kw/day	
$SIE_{B}$	= Systemic Inkatation Ex	xposwe of Bystanders (m	okg by Iday)	, %,
				)*
<b>Table 7.2.2.1-1: Calcula</b>	tion of bystander exposure	and proportion of the ADE	L _N	
Input parameters consid	tion of bystander exposure a	stander exposure:	J' J	
Intended use(s):	Apple	Derift (D)?	29.20	% (HC, 3 m)
Application rate (AD):	1.575 Q a.s./ha	Exposed body surface area	1	m² (adults)
Application rate (AR):	157×5 mg/m² ~	(BSAQ)	<b>2</b> 0.21	m² (children)
			0.018	mg/kg a.s. (6
Body weight (BW):	60 (aguits)	Specific Inhalation Exposure	0.010	hours, adults)
	1 10.190		0.01034	mg/kg a.s. (6
Dermal absorption (DA):	(child control of the	<u> </u>		hours, children) ha/d (based on
Inhalation absorption (LA)		Orea Treated (A):	8	HCTM)
AOEL:		Exposure duration (T):	5	min
	· //* · // //	- ()		

Bystander exposure towards	Propineb		S S		
Adults © C	~ () ~		Children		
Bystander: Şystemic dermal	exposure (1)	uring/after applica	tion i@Apple (via spray drift)		
$SDE_B = (A R D \times D \times BSA \times DA)$	BW S	o' 'y'	$SDE_B = (AR \times D \times BSA \times DA)$	/ BW	
(157.5 x 29 2% x 1 x 1%) / 60 /	, "%		©\$7.5 x 29.2% x 0.21 x 1%) / 16	5.15	
External/dermal exposure	45.99	@ig/pers@d 🌅	Æxternal dermal exposure	9.6579	mg/person
External dermal exposure	0.766\$	mg/kg bw/d	External dermal exposure	0.598012384	mg/kg bw/d
Systemic dermal exposure	0.007665	mgÆg bw/d√	Systemic dermal exposure	0.005980	mg/kg bw/d
Bystander: Systemic inhalati	on exposur	e/dirring/after appl	ication in Apple (via spray drif	ft)	
$SIE_B = (I*_A x A x A x I X IA)$	/ <b>JEON</b>		$SIE_B = (I*_A x AR x A x T x IA)$	/ BW	
(0,000 / 360 x 4.575 x 8 x 5 x 100	P) / 60 💝	, 9	(0,000 / 360 x 1.575 x 8 x 5 x 100	0%) / 16.15	
External inhalation exposure		mg/pers on	External inhalation exposure	0.001810345	mg/person
External inhalation expositive	0,0000525	mg/kg bw/d	External inhalation exposure	0.000112096	mg/kg bw/d
Systemic inhabition of exposure	n	mg/kg bw/d	Systemic inhalation exposure	0.000112	mg/kg bw/d
Total systemic exposure: SE _B	= SDE _B + S	IE _B	Total systemic exposure: SE _B	= SDE _B + SIE _B	•
Total systemic exposure	0.46305	mg/pers on	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	%

Н

OABW = Oral Absorption (%):

= Body Weight (kg/person):

60

16.15

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```
b) Resident exposure assessment
<u>Dermal Exposure (via deposits caused by spray drift):</u>
        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 Roule (mg/kg b)
                                                                 Input pgkameters:
                        = Application Rate (mg/cm^2).
                AR
                        = Number of applications:
                NA
                        = Drift (%):
                D
                        = Turf Transferable Residues (%):
                TTR
                TC
                        = Transfer Coefficient (cm²/h@ur)
                        = Exposure Duration (hours)
                H
                        = Dermal Absorption (%)
                DA
                        = Body Weight (kg/person
                BW
Inhalation Exposure (Vapour Drift
        SIE_R = (AC_V \times IR \times IA) \otimes BV
                                                 Kesidems via the Inhalation Route
        Where: SIE<sub>R</sub>
                            l6x 10⁴8a at QO°C =$&mi-v&stile)
                                                                 16.5% (adult), 8.31 (child)
                          Inhalation Rate (m³/dav)
                                                              (adult), 16.15 (child)
Child Oral Exposo
        Children's hand-to-mouth ex
                                                  x Fooq x H x OA) / BW
                                          Exposure via the Hand to Mouth Route (mg/kg bw/day)
        ₩here: SOEĤ
                                                                 Input parameters:
                           Approximation Rate Img/cm²):
                                                                 0.01575 (= 1.575 \text{ kg a.s./ha})
                           Mimber of applications:
                                                                 25.53 (\geq 2 applications, 3 m distance)
                          TuroTransferable Residues (%):
                        = Saliva Extraction Factor (%):
                                                                 50
                         Surface Area of Hands (cm^2):
                                                                 20
                        = Frequency of Hand-to-Mouth (events/hour): 20
                        = Exposure Duration (hours):
```

Children's object-to-mouth exposure

 $SOE_O = (AR \times D \times DFR \times IgR \times OA) / BW$ 

...oute (mg/kg by/day)

...oute (mg/kg by/day)

...oute (mg/kg by/day)

22533 ( & 2 applications, 3 m distance)

residues (%):

...osorption (%):

...osorption (%):

...outh present (mg/kg by/day)

SER = SDE_R + SIE_R (mg/kg by/day)

SER = SDE_R + SIE_R + SOE₀ (mg/kg by/day)

Systemic Exposure of Residents (mg/kg bw/day)

Systemic Dermal Exposure of Residents (mg/kg bw/day)

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

AR

NA

Ster (me ke perday)

Jen + Ster + SOEn + SOEn (me ke berday)

stemle Experime of Residents (mg/ke berday)

Systemic Inhalation Exposure of Residents (mg/ke bw/day)

Soei - Systemic Inhalation Exposure of Residents (mg/ke bw/day)

SOEi - Systemic Orad Exposure via the Object of Mouter (mg/kg bw/day)

SOEi - Systemic Orad Exposure via the Object of Mouter Route (mg/kg bw/day) D

% of AOEL

2.73 %

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	1 C 41	4. 4. C	11 4		6
Input parameters consider		estimation of re			
Intended us e(s):	Apple	I	Drift (D):		% (HC, 3 m)
Application rate (AR):	1.575	kg a.s./ha	Transfer coefficient (TC):		cm ² /h (adults)
r-ppricuron ruce (rare)	0.01575	mg/cm ²	, ,	© ⁷ 2600	cm ² /h (children)%
Number of applications	2		Turf Transferable Residues	4. 5	
(NA):			(TTR):		% O S
	60	kg/person	Exposure Duration (H):	7) 2	
Body weight (BW):	- 00	(adults)	' Q		
Body weight (BW).	16.15	kg/person	Airborne Concentration of	വക്	mg/mg/ O
	10.13	(children)	vapour (ACV).		mg/mby
Dermal absorption (DA):	1.00	% ('worst case')	Malation Rate (IR):	Q 6.57,	no d (adults)
Inhalation absorption (IA):	100	%	mayaration Rate (IR):	@ 8. <b>%</b>	m³/d (children)
		0/	Saliva Extraction Factor		
Oral absorption (OA):	60	%	(SEX D	\$50	% A
AOEL:	0.046	mg/kg bw/d	Surface Area of Hands (SA);	<b>₽</b> 20	
·	3.0.0		Erequency of Handto Mouth		
		\\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\	(Freg):	~/ ·	even#s/h
		Q (A)	Distorgeable foliar residues	Ŭ Ž	
			(ĎEŘ):	5 5 20	
			Ingestion Rate for Mouthing		P %.
			of Grass/Day (lgR):		cm ² /d
	- Q			Ča Or	Ô
Resident exposure towards P	ropineb	& .O			<u> </u>
Adults	, Ø		Children		<b>2</b>
	exposure af	ter application in	Apple ( deposits caused by sp	orașarift) 🎾	
$SDE_R = (AR \times NA \times D \times TTR \times$	JTC x HADD	A)/B@	SDO = (AR XNA x DX/TTR X		BW
(0.01575 x 2 x 25.53% x 5%)	300 x 2 \$\vec{\psi}{1\%}	) 460 Q1	(D) 1575 x 2/x 25.53% x 5% x	600 x 2 x (1 %) / 10	5.15
External dermal exposur	5&706235	(0g/person)	External exposure	2.090907	mg/person
External dermal exposition	90978437	mg/kg bw/d	External dermal exposure	<b>9.129467926</b>	mg/kg bw/d
Systemic dermal exposure 🎘	0.000978	mg/kg/bw/d	Systemic dermal exposure	0.001295	mg/kg bw/d
Residents: Systemic inhafst	on expesure	e after application	in Apple (vie vapour)	•	
$SIE_R = (AC_V x IR x IA) / BW$	***	<u>څ</u> ۸ ۶	$SIE_R = (AC_V \times IR \times IA) / BW$		
(0,001 x 16.57 × 100%) / 60			(0,001 x 8.31 x 190%) /A6,95		
External inhalation exposure	0.01637	mg/person 🐧	External inhalation exposure	0.00831	mg/person
External inhalation exposure	0.0002762	mag/jkg bw/jal	Exernal inhalation exposure	0.000514551	mg/kg bw/d
Systemic inhalation	0.00027	Salve Land	Systemic inhalation	0.000515	ma/ka had
exposure	V.000276	nig/kg/pyv/d	exposure 💸	0.000515	mg/kg bw/a
	4 "S		Dadonte Wateria and and	osuro (band ta -	nouth transfer
	. 0		Systemic oral exp	osure (nand-to-r	nouth transfer)
4	8 ~		SOF Q= (AB vNA vD vTTI	O v CE v CA v Eno	a v H v OA ) / DW
			SOLMIN (ARXIVAXDXIII	X X SE X SA XI TE	q xII xOA)/ bw
	7 Q		$(0.0375 \times 2 \times 25.53\% \times 5\% \times 50)$	0% x 20 x 20 x 2 x	60%) / 16.15
4, 29	A		External oral exposure	0.160839	mg/person
	\$ 2		External oral exposure	0.009959071	mg/kg bw/d
	'U' _C		Systemic oral exposure	0.005975	mg/kg bw/d
\$ .	\		Dogidanta Cymtamia angl	oguno (obiost t-	mouth two-sfars
joy 🖈		W an	Residents: Systemic oral exp	os ure (object-to-	-mouth transfer)
		'J Q	$SOE_{R(O)} = (AR \times NA \times D \times DFI$	$R \times IgR \times OA)/B$	3W
Ű "Ş	کر ک	, "	(0.01575 x 2 x 25.53% x 20% x 2	25 x 60%) / 16.15	
A. Ž. Ž.			External oral exposure	0.04020975	mg/person
	, W		External oral exposure	0.002489768	mg/kg bw/d
	Ž.		Systemic oral exposure	0.001494	mg/kg bw/d
T. A. J. A. S.	CDF + C	TE .	Total systemic exposure: SE _R	= SDE _R + SIE _R +	SOE _{R(H)} +
10tal systemic exposure: SE _R	= SDE _R + S	IE _R	SOE _{R(O)}		` /
(( Л					
Total systemic exposure	0.0752762	mg/person	Total systemic exposure	0.14984832	mg/person
External dermal exposure External dermal exposure External dermal exposure External dermal exposure Residents: Systemic inhabit SIE _R = (AC _V × R × IA) / BW (0,001 x 16.5 × 100%) / 60 External inhalation exposure External inhalation exposure External inhalation exposure  Total systemic exposure Total systemic exposure Total systemic exposure Total systemic exposure	0.0752762 <b>0.001255</b>	mg/person mg/kg bw/d	Total systemic exposure  Total systemic exposure	0.14984832 <b>0.009279</b>	mg/person mg/kg bw/d

% 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 commendation provided in the

Crop group	Transfer Coefficient
	$(cm^2/\overline{P})$ $\tilde{C}$ $\tilde{C}$ $\tilde{C}$ $\tilde{C}$ $\tilde{C}$
Fruits (from trees):	4500 4500 45 45 45 45 45 45 45 45 45 45 45 45 45
Vegetables:	
Ornamentals:	4500 5000 3000 3000
Strawberries:	Q 3000 3 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5

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 36 is adopted which presents transfer coefficients (TC) for agricultural or commercial activities for use in post-application exposure assessments for grapes Vine rellis is identified as the appropriate transfer coefficient group. The activity with the highest transfer coefficient is used as a "screening-level" postapplication exposure and risk assessment to calculate exposure. The highest TC is 10100 cm²/h provided for hand havesting considering high crop height and fall 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 cOAP used for worker risk assessment is presented in Table 7.2.3-

Table 7.2.3-1: Critical GAPs for worker exposure

Crop Re-entry grouping task	coefficient [cm ² / ₂ ]		Dara- Vion (		[kg a.s./ha]	No.	Min. interval [days]	PHI [days]
Apple thinning harvesting	045005	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

Granes	Binding/ tying/	10100	N-EU	8	1.6	1.12	2	7	n.a.	
Grapes	harvesting	10100	S-EU	8	2	1.40	2	7	56 S	
Tomato	Binding/ tying/	2500	N-EU	8	2.4	1.68	4 0	7	28	
			S-EU	8		2.10	\$\frac{1}{2}\text{9}{4}	7 💸	287	
• Sı	ımmary	re calculated mum dose ra			Ž	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~				
Predicted application	exposures arns, the maxim	e calculated mum dose ra	from a cu te and 8 l	mulativ Ours/da	e foliar de Y contact	posit base with the	ed of t foriage	he maxim	num num re is con	ther of npared

applications, the maximum dose rate and 8 hours/day contact with the forage. 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 of AOEL

		, , , O , Q
Crop Q	Systemic exposure	of AOEL
	ng/kg bw/day)	(0.046) mg/kg
		Jow/day)
Apple (N-/SŒU)	0, <b>®</b> ,≇82 √	0° 5/05 2°
Apple (N-/SŒU)  Gropes (N-EU)	$\sim$ $\sim$ $\sim$ $\sim$ $\sim$	187 _{@1}
Grapes (S-EU)	0.1075	<b>23</b>
Tomato (N-EU)	/.° 0.9538 ≥.	\$\int 1\frac{1}{7}
Tomato (SJEU)	Q.9672 Q	©146
	Tier 2 Cno PPE, On realistic SAI and int	
	on realistic AI and int	
Apple (N-/SEU)	9:9161	<b>≫</b> 35
Grapes (N-EU)	√ √ √ √ √ 0.02870° × ×	62
©rapes (S-ELS)	× % 0.0338	78
		39
Tomato (S-EU)	002240	49
	Vier 3 (with PPE)	
Apple (N-/S-BU)	0.0008	2
Grapes (X-EU) @	<b>©</b>	3
Grapes S-ELD	ॐ <b>ൃ</b> Ø.0016	4
Tomato (N-EU)	Ø 0.0010	2
Tomato (SEU)	0.0012	3
	Tier 4 (no PPE,	
Gefinement based on ex	xperimental dislodgeable	e foliar residues)
Appte (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 V exposure assessment.

In a tiered approach, refinements are done for the evaluation of more realistic exposure. Refinements of the DFR₀ are made using realistic leaf area index (LAT) 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, projective clothing incl. gloves) Exposures are demonstrated to be far below the ADEL.

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 recentry workers following application of Antracol WG 70.

# CP 7.2.3.1 Estimation of worker exposure

The exposure is calculated in a trered approach. In Ter 1, exposure is estimated for unprotected operators based on default assumptions. In Tier 2, a refinement is made for the DFR₀ 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:

```
x P BW x DA
       Systemic exposure
        Distodgeable foljar residues (3 µg as/cm²)
        Yumberof appdicatious (considering MAF)*
                          1 (2 appl., 14 d interval)
                           3.9 (2 appl., 7 d interval)
                @matoÇ≟ 3.2 (4 appl., 7 d interval)
         Transfer Coefficient (activity specific; cm²/h)
                        = 4500 \text{ cm}^2/h
                Solution = 10100 \text{ cm}^2/h
               fomato = 2500 \text{ cm}^2/h
        Work rate (8 hours/day)
        Application rate (crop specific; kg as/ha)
        Protection factor for clothing/PPE (1, no PPE)
        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. Theo 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 the 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 DFR₀ 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 vater, available data indicate that it would be reasonable to assume, as a default, that dissipation occurs appointfully, with a half-life of 30 days (USDA Natural Resources Conservation Service, 2006; Willis and McDovell, 1987). 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 (MAFs⁸), calculated from the assumed half-life.

```
Re-entry in apple:

S = DFR x N x TC x WR x AR x P BW x DA

= 3 x 1.7 x 4500 x 8 x 1.675 x 1/60 x 1%

= 0.0482 mg/kg bw/day

% of AOEL: 103

Re-entry in grapes (N.EU):

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%

% of AOEL: 487

Re-entry in grapes (S-EU):

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%

(1075 mg/kg bw/day)

% of AOEL: 234

Re-entry in tomato (N-EU):

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%

(1075 mg/kg bw/day)

% of AOEL: 234

Re-entry in tomato (N-EU):

S = DFR x N x TC x WR x AR x P/BW x DA

= 0.0538 mg/kg bw/day

% of AOEL: 117
```

⁷ Willis 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):

AR x P/BW x DA DFR x N x TC x WR x

3 x 3.2 x 2500 x 8 x 2.1 X

0.0672 mg/kg bw/day

% of AOEL: 146

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

The default DFR₀ value (3 µg/cm²) proposed by EVROPOEM 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 Leg/cm² for a standardized application rate of 1 kg/ha.

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

- Assuming 100% interception by the cop the DFR of \$10 ppcm² x kg a.s.(LAI = 1);
- Based on worst case assumption for LAI =Q: DFR is 5 µg/cm² Rkg as (LAI = 2);
- Double-sided leaves DFR is = 25 ug/gm² (LAV is one-sided)
- This is rounded to ug m² in the EUROPOEM report

The higher tier risk assessment may consider realistic PAI for the crop under evaluation. Also, realistic interception rates (crop conture officiency) should be considered in order to account for loss of a.s. via drift or deposit on ground. Appropriate LAQ as well as inforception rates are presented in the FOCUS Groundwater Report for sopple, grapes and tomato. A summary of LAI, interception and a proposal for refined default OFR0 is presented in the following table. Q

Table 7.2,3 x-1: DFR0 as a result of LAL and interception (FQCUS CW Report)

		×( )	
	LAI* Interception* Default DFR	Refined DFR ₀	Refined DFR ₀
	$\bigcirc$	if LAI =	(if LAI $\geq$ 4 and
	in Figure 20	min. 4)	max. interception =
	O O O O O O O O O O O O O O O O O O O		80%)
Apple	94-6 0 63%-80% 0 25×3 %	1.25	1
Grapes	5-6 60% 55% 4 25~3	1.25	1
Tomato	4-6 80% 2.5	1.25	1

FOCUS Grown water Report

A refined DFR of 1 µg/cm² per kg s. handled is used in the higher tier risk assessment based on a Ex (LA); m realistic leaf nea index (LAS, 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: 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 0.0161 mg/kg bw/day % of AOEL: Re-entry in grapes (N-EU): DFR x 1 x 1.9 x 10106 0.0287 mg/kg bw % of AOEL: Re-entry in grapes (S-EU): % of AOEL: Re-entry in tomato (N-EU): Re-entry in tomat P/BW x DA 2.1 @ x 1 / 60 x 1% Tier 3 (with PPE

Exposure calculations are provided in the following for a <u>protected</u> worker (based on German worker exposure peridance¹⁰). The BRE Excel spreadsheet is used. The default DFR₀ in the German guidance is 1 ug/cm².

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

Protection factor for protective clothing (0.05, with PPE)

Uniform Principles for Safeguarding the Health of Workers Re-entering Crop growing Areas after Application of Plant Protection Products (Grebs. R. 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 on 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)

table 7.2.5.1-2. Calculation of work	2 To entry in appre (With 11 E)
Estimation of post-application expos	sure 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)	
Dislodgeable foliar residues (DFR)	1 µg/cm²/kg a.s.
Transfer coefficient (TC)	4500 cm²/@erson/h
Work rate per day (WR)	Apple  1.575 2 1 1 4500 8 0.05 0.046 mg/kg pw/d
Penetration through clothing (P)	0.05 (\$\%)
Systemic AOEL	0.046 mg/kg/bw/d 5
Dermal absorption DA)	
Body weight (BW)	4 70 kg 0 Q 0 Q 0
1)	
can be assumed between 2 applications (oth	will not be necessary if degradation on foliage of at least 50 % nerwise use multiple application factor)  of Yebs et al. (2000)  of harvesting, both sides of seaves) asc to Kretos et al. (2000).
	ici was tase instance approximation action
²⁾ default of 1 µg a.s./cm² per kg a.s./ha acc. to	o Krebs et al. (2000) La Caracter de
TC 30000 cm²/person/hour ('w orst case', ha	of harvesting, both sides of leaves) acc to Krebs et al. (2000), ), 3000 (straw barries), 4500 (fruits from trees), 5000 (organization)
acc. EUROPOEM II (2002): 2500 (vegetables	), 3000 (straw bactes), 4500 (fruits from trees), 5000 (argamentas)
ass. 55 = 71 : 5115) 1/ 511 (2555). 1544 (\$515	
7/8 h/day for professional applications if re-ent	ty tasks are intended 2 h/day for professional applications of
6. 4	on, mainterance) Offer applications in the home and allotherit gardervarea
	otective clothing and gloves for professionals, 50 % reduction of Germal exposure
corresponding to long sleeved shirt, long from	use@and gloves for applications in the home and allotment garden area

# Estimation of worker (re-chtry) exposure

Input parameter Considered for the estimation of worker exposure:

Intended use(s);	Apple	Dislodgeable foliar residues (DFR):	$1 \mu g/cm^2/kg a.s.$
Application rate (AR):		Transfer coefficient (PC):	4500 cm ² /person/h
Number of applications (NA):	2, 5	Work rate per day (WR):	8 h/d
Body weight (BW):	y Q0 kg/person	₽PE ♥ □	5 %
Dermal absorption (DA):	1 % (Sworst carse)		
AOEL Q		G G	

Worker exposure towards Propo			
Without PP		With PPE ²⁾	
Worker ( e-entry): Systemic der	mat exposure after applica	ation in Apple	
SDE _W (DFR x TC x WR) AR x N		$SDE_W = (DFR \times TC \times WR \times AR \times N)$	VA x PPE x DA) / BW
$(1 \times 4500 \times 8 \times 1.575 \times 2 \times 1\%) / 76$		(1 x 4500 x 8 x 1.575 x 2 x 5% x 1%)	) / 70
External dermal exposure	143.40 mg/person	External dermal exposure	5.67 mg/person
External dermal exposure	1.62 mg/kg byOd	External dermal exposure	0.08 mg/kg bw/d
	1.13 mg/person	Total systemic exposure	0.06 mg/person
	0.016 <b>20</b> 0 mg⁄k <b>Q</b> bw/d	Total systemic exposure	0.000810 mg/kg bw/d
% of AOE	<b>3</b> 5.2 %	% of AOEL	1.8 %

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

²⁾ acceptable only with PME: allocation of BVL code SF1891 and SF190 for professional and tome 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)

	e enery in grapes (1, 20, with 112	
Estimation of post-application expos	sure of workers (re-entry exposure	<u>e)</u>
Active substance (a.s.)	Propineb	
Product	Antracol WG 70	
Intended use(s)	Grapes (N-EU)	
Application rate (AR)	1.12 kg a. <b>€</b> ⁄⁄⁄⁄⁄ha	
Number of applications (NA)	2	
Dislodgeable foliar residues (DFR)	1 µg/cm²/kg a.s.	
Transfer coefficient (TC)	10100 cm²/person/hQ	
Work rate per day (WR)		g. for dilution)
Penetration through clothing (P)	(5.%)	
Systemic AOEL	0.046 @g/kg 5w/d	
Dormal absorption DA)	1 % (worst case, e.c	ı. fer dilution)
Body weight (BW)	70 kg ~	
Body weight (BW)  1) consideration of more than two applications of can be assumed between 2 applications (oth 2) default of 1 µg a.s./cm² per kg a.s./ha acc. to 3) TC 30000 cm²/person/hour ('worst cace', hat acc. EUROPOEM II (2002): 2500 (vegetables)		
1) consideration of more than two applications y	www.not be necessary if degradation on oliv	age of at least 0 %
can be assumed betw een 2 applications (oth	erwise use multiple application factor	
2) default of 1 µg a.s./cm² per kg a.s./ha accepto	Kreebs et al. (2000)	
3) TC 30000 cm²/person/hour ('w orst case', hat	nd harvesting, both sides of legales) ago to	Krebet al. (2000), &
acc. EUROPOEM II (2002): 2500 (vegetables	, 3000 (etraw berries), 4500 (fruits form tre	ees), 5000 (ornamentas)
acc. US EPA Policy # 3.1 (2000): 1500 (cere	als, e Črop ipspection)@10000 (grapes)	
4) 8 h/day for professional applications if re-ent	ry tasks are hatended 2 h/day to profession	onal applications
if re-entry tasks are not intended (e trigati		
5) 5 % of dermal exposure corresponding to pre-		(n
corresponding to long seeved shirt, long you	sers and gloves for applications in the hon	ne and allotment garden area
		W)

		O . O	
Input parameters considered for the	estimation Fworker expo	sure:	
Intended use(s):	s (N-EU) Wislodg a (DFR):	ble fotiar residues	μg/cm ² /kg a.s.
Application rate (AR)	1.12 kg a.s./ha Transfer o	coefficient (TC): 10100	cm ² /person/h
Number of applications (NA)	Work rate	per day (WR):	h/d
Body weight (BW):	kg/poson PPE V	5	%
Dermal absorption (DA):	1 % (Worst gase')		
AOEL A S	0.046 kg kg byod "O		

Worker exposure towards Propineb	).					
Without PPE ¹⁾	With PPE ²⁾					
Worker (re-entry): Systemic dermal exposure after application in Grapes (N-EU)						
$SDE_W = (DFR \times T_C \times WR_X \times R \times N_C \times DA) \times DA$	$SDE_W = (DFR \times TC \times WR \times AR \times N)$	IA x PPE x DA) / BW				
(1 x 10100 x 8 x 0 12 x 2 x 1%) / 76 0 0	$(1 \times 10100 \times 8 \times 1.12 \times 2 \times 5\% \times 1\%)$	/ 70				
External derman expossure \( \times \) \( \t	External dermal exposure	9.05 mg/person				
External deginal exposure 2.59 mg/kg bw/d	External dermal exposure	0.13 mg/kg bw/d				
Total systemic corosure 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 9 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)

	e enery in grapes (S 225, with 11	
Estimation of post-application expo	<u>sure of workers (re-entry exposi</u>	ure)
Active substance (a.s.)	Propineb	
Product	Antracol WG 70	
Intended use(s)	Grapes (S-EU)	
Application rate (AR)	1.4 kg a. <b>€</b> ⁄⁄ha	
Number of applications (NA)	2	
Dislodgeable foliar residues (DFR)	1 μg/cm²/kg a.s.	
Transfer coefficient (TC)	10100 cm²/person/h	
Work rate per day (WR)	Ø8 h/d ∼	a.g. for dilution)
Penetration through clothing (P)	0.05 (5%)	
Systemic AOEL	0.046 @g/kg 5w/d	
Dormal absorption DA)	4 1 % (weest case, e	.a. for dilution)
Body weight (BW)	70 kg	
Body weight (BW)  1) consideration of more than two applications can be assumed between 2 applications (of default of 1 µg a.s./cm² per kg a.s./ha acc. TC 30000 cm²/person/hour ('w orst cacc', ha acc. EUROPOEM II (2002): 2500 (varietables)		
1) consideration of more than two applications	will not be necessary if degradation on to	bliage of at least 50 %
can be assumed between 2 applications (at	Perw ise use multiple application factor	
2) default of 1 ug a s /cm² per kg a s /ha acct	o Krebs et al #2000)	
3) TC 30000 cm²/person/hour ('w orst case', ha	nd warvesting both sizes of leaves) aco	To KrebOet al (SP00)
acc. EUROPOEM II (2002): 2500 (ve getables	3, 3000 (straw berries), 4500 fruits from	trees 5000 (ornamentals)
acc. US EPA Policy # 3.1 (2000): 1500 (ces	eals, e Crop in pection 7710000 (grapes	
4) 8 h/day for professional applications if re-en		~ · y , · 4
if re-entry tasks are not intended (e right		
5) 5 % of dermal exposure or responding to a		(1)
corresponding to long seeved shirt, long to	users and gloves for applications in the h	ome and allotment garden area
		2

Input pararreters considered for the estimation of worker exposure:	
Intended use(s):  One of the control	1 μg/cm²/kg a.s
Application rate (AR) 1.4 kg/a.s./ha Transfer coefficient (TC):	10100 cm ² /person/h
Number of applications (NAT) Work rate per day (WR):	8 h/d
Body weight (BW):	5 %
Dermal absorption (DA)? \(\sigma 1 \) \(\sigma \) \(\sigma 1 \) \(\sigma \) \(\sigma \)	
AOEL SO	

Worker exposure towards Propineb	) [*]				
	With PPE ²⁾				
	Worker (re-entry): Systemic dermal exposure after application in Grapes (S-EU)				
$SDE_W = (DFR \times TCX WRXAR \times NAX \times DAXBW Q)$	$SDE_W = (DFR \times TC \times WR \times AR \times NA \times PPE \times DA) / BW$				
	$(1 \times 10100 \times 8 \times 1.4 \times 2 \times 5\% \times 1\%) / 70$				
External derman expositure 226.24 in person	External dermal exposure 11.31 mg/person				
External deginal exposure 3.23 mg/kg bw/d	External dermal exposure 0.16 mg/kg bw/d				
Total systemic coordinates 2.26 mg/person	Total systemic exposure 0.11 mg/person				
Total systemi@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 expos	sure of workers (re-entry expos	sure)
Active substance (a.s.)	Propineb	
Product	Antracol WG 70	
Intended use(s)	Tomato (N-EU)	
Application rate (AR)	1.68 kg a. <b>€</b> ⁄⁄ha	
Number of applications (NA)	4	
Dislodgeable foliar residues (DFR)	1 µg⊮cm²/kg a.s.	
Transfer coefficient (TC)	2500 cm²/person/h	
Work rate per day (WR)	h/d	e.g. for dilution)
Penetration through clothing (P)	<b>20.05</b> (5%)	
Systemic AOEL	0.046 @g/kg bw/d	
Dormal absorption DA)	4 1 % (werst case)	e.a. fer dilution)
Body weight (BW)	70 kg	
Body weight (BW)  1) consideration of more than two applications of can be assumed between 2 applications (other can be assumed between 2 applications).		
1) consideration of more than two applications v	Mot be necessary if degradation on	oliage of at least 50 % a
can be assumed betw een 2 applications (or	erw ise use multiple application factor)	
2) default of 1 µg a.s./cm² per kg a.s./ha accett	o Krebs et al. (2000)	
3) TC 30000 cm²/person/hour ('w orst case', hat	nd varvesting both sides of leaves) and	To Krebe et al. (2000). «
acc. EUROPOEM II (2002): 2500 (vegetables	), 3000 (etraw berries), 4500 (fruits for	trees, 5000 (ornamentas)
acc. US EPA Policy # 3.1 (2000): 1500 (cere	als, e Crop in rection 7010000 (grape:	s) 👸 🛴 👸
4) 8 h/day for professional applications if re-ent	ry taks are forended 2 h/day for profe	seional applications
if re-entry tasks are not intended (e dirigati		
5) 5 % of dermal exposure corresponding to the		(1)
corresponding to long seeved shirt, long you	isers and gloves for applications in the l	nome and allotment garden area
		<u> </u>

# Estimation of workei@re-entry) exposure

Input parameters considered for the estimation of worker exposure:

	,	1		
Intender (s):		Dislodgeable fotjar residues (DER):	1	μg/cm ² /kg a.s.
Application rate (AR)	1.68 kg a.s./ha	Transfer coefficient (TC):	2500	cm ² /person/h
Number of applications (NA)		Work rate per day (WR):	8	h/d
Body weight (BW):	kg/penson C	PPE ®	5	%
Dermal absorption (DA)	1 % (Worst case'	) %		
AOEL A	90.046 pre/kg bwod			

Worker exposure towards Propineb	)		
	With PPE ²⁾		
Worker (re-entry): Systemic dermal exposure after applica	ation in Tomato (N-EU)		
$SDE_{W} = (DFR \times T_{Q} \times WR_{A} \times AR \times N_{Q} \times DAQ \otimes W )$	$SDE_W = (DFR \times TC \times WR \times AR \times N)$	IA x PPE x DA) / BW	
	$(1 \times 2500 \times 8 \times 1.68 \times 4 \times 5\% \times 1\%) / 70$		
External derman exposure 34.40 mg/person	External dermal exposure	6.72 mg/person	
External domal exposure U 1.92 mg/kg bw/d	External dermal exposure	0.10 mg/kg bw/d	
Total systemic corosure 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 2 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)

		- C
Estimation of post-application expo	sure of workers (re-entry exposi	ure)
Active substance (a.s.)	Propineb	
Product	Antracol WG 70	
Intended use(s)	Tomato (S-EU)	
Application rate (AR)	2.1 kg a. <b>€</b> ⁄⁄⁄ha	
Number of applications (NA)	4	
Dislodgeable foliar residues (DFR)	1 µg/cm²/kg a.s.	
Transfer coefficient (TC)	2500 cm²/person/hQ	
Work rate per day (WR)	b/d ~	e.g. for dilution)
Penetration through clothing (P)	0.05 (5%)	
Systemic AOEL	0.046 @g/kg bw/d	
Dames I also seeffer DA)	1 % (warst case of	a fer dilution)
Body weight (BW)	70 kg	
Dermai absorption DA)  Body weight (BW)  1) consideration of more than two applications can be assumed between 2 applications (of default of 1 µg a.s./cm² per kg a.s./ha		
1) consideration of more than two applications	will not be sees said degradation of	pliage of at least of %
can be assumed between 2 applications (of	rerwise suse multiple application factor	
²⁾ default of 1 µg a.s./cm² per kg a.s./ha acc, t	o Krabs et al. (2000)	
3) TC 30000 cm²/person/hour ('w orst case', ha	o Niggs et al. (2000)	% 1/2-1 (
acc. EUROPOEM II (2002): 2500 (ve yetables	1000 (etraw berries) 4500 (fruits from	trees 5000 (ornamentals)
acc. US EPA Policy # 3.1 (2000): 1500 (case	eals e Crop inspection 1/2000 (grapes	
4) 8 h/day for professional applications if re-en	& JF	
if re-entry tasks are not intended (e.d. rigat		
V 1		/
5 % of dermal exposure corresponding to of corresponding to long devel shirt, long to	otective clothing tool. gloves for professions the h	one and allotment garden area
corresponding to long seeved shirt, long to	asers and gloves for applications in the h	2 Pi

# Estimation of workei@re-entry) exposure

Input parameters considered for the estimation of worker exposure:

	,	1		
Intender (s):		Dislodgeable fotjar residues (DER):	1	μg/cm ² /kg a.s.
Application rate (AR)		Transfer coefficient (TC):	2500	cm ² /person/h
Number of applications (NA)		Work rate per day (WR):	8	h/d
Body weight (BW):	kg/penson C	PPE ®	5	%
Dermal absorption (DA)	1 % (Worst case'	) %		
AOEL A	90.046 pre/kg bwod			

Worker exposure towards Propineb	
Without PPE ¹⁾	With PPE ²⁾
Worker (re-entry): Systemic dermal exposure after application	ation in Tomato (S-EU)
$SDE_W = (DFR \times TCX WRXAR \times NAX \times DAX BW Q^*)$	$SDE_W = (DFR \times TC \times WR \times AR \times NA \times PPE \times DA) / BW$
(1 x 2500 x 8 x 20 x 4 x 45) / 70	$(1 \times 2500 \times 8 \times 2.1 \times 4 \times 5\% \times 1\%) / 70$
External derma expossure 5 468.00 mg/person	External dermal exposure 8.40 mg/person
External deginal exposure 2.40 mg/kg bw/d	External dermal exposure 0.12 mg/kg bw/d
Total systemic corosure 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 2 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 montioned equation changes to:

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

Where:  $DFR_M = Measured\ dislodgeable\ \mathcal{F}$  diar residues  $\mathcal{G}$  ug as/cm²)

Dislodgeable foliar residues were experimentally desermined 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 = \( \) 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

Crop	Max.	Observed on	Study	cGAP	Report no.,
	DFR _M ~	<b>*</b>	Conditions	no. of appl.	document no.
	(μg/cm ² )%	4	',(no. gi appi 🙏	/ appl. rage	
			/ appl. rate	(Cg a.s. (Ma)	
	***		(Ag a.s.Da)		*
Apple (N-EU)	0.2130	0 days after 3 rd	3 / <b>1</b> ,375 - 0	2 ×1.575	10-2902,
		appl., DOFT 14	D:687_@		M-405621-01-1
Apple (S-EU)	0.3896	3 days after 2 rd	3/1.49-	© 2 (5.575	10-2900,
		appo, DAF 10	(* <b>1</b> 58 2	_	M-405614-01-1
Grapes (Ş-KW)	1.593	Pdays After 3	4 % 1.0486 -	© 2 / 1.4	10-2901,
	څ ک	appl DAFT 38	© 1.12Q8	Ý	M-405617-01-1
Tomato indoor	D.411	3 days after 4th	(/ )	4 / 2.1	10-2904,
(S-EU)	F 4	appl., DAFT 24	O' >,		M-405638-01-1

It is noted that the DFR wals in apple were conducted with three applications using the maximum dose rate of hereas 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 ....ares for the wo conservative estimates for the worker exposure evaluation.

# <u>Calculation of worker exposure during re-entry in apple:</u>

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 EU.

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

= 
$$(0.3696 \mu g/cm^2 x 4500 cm^2/h x 8 h x 1)/60 kg x 1%$$

$$= 0.0022 \text{ mg/kg bw/day}$$

$$= 5\%$$
 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

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

= 
$$(1.593 \,\mu\text{g/cm}^2\text{x} \, 4500 \,\text{cm}^2/\text{h}^2\text{x} \, 8 \,\text{h}^2\text{h}^2)/60 \,\text{kg} \, \text{x} \, 10^{-3}$$

$$= 0.0096 \text{ mg/kg bw/day}$$

# Calculation of worker exposure during is centry in tomato:

The DFR_M is taken from trial's conducted in southern European greenhouse. As the trials were conducted with the maximum dose rate of 2.1 kg a.s./kg it is considered to cover also the northern European GAP with \$2.68 kg a.s. And.

= 
$$(3.411 \, \mu g/cm^2) (2500 \, cm^2/h \approx 8 \, h \, x) / 60 \, kg \, x \, 1\%$$

$$= 10\%$$
 of  $\triangle OEL$ 

Propineb dislodgeable follow 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 comato (southern zone). Summaries of the studies and results are presented in

DFR study apple (N-EU):

Determination of dislodgeable foliar residues of propines after spraying of Antracol on apple in the field in Germanv Report:

Title:

Report No: 10-2902

Report includes Trial Nos.: 10-2902901 Document No(s):

M-405621-01-1

**Guidelines:** US EPA OPPTS 875.2100; Deviations: not specified

**GLP/GEP:** 

# I Material and methods

I Material and methods

The purpose of the study 10-2902 was to determine the residues 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

Table 7.2.3.1-8: Application parameters 

≪

Country	Application Q	
	Type So Growth stage Interval Rate  (BBCHO (days) (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 Dissipation. Leaf punches were collected directly into a pre-labelled poly-propylene jar using a leaf purch 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 cm². The leaf punches represented a total double-sided leaf surface area of 400 cm. 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 ontage zone pecluding upper, middle, and lower portions of the crop foliage and interior and exterior portions of the cropyfoliage. 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 dired. 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 w 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

nd discussion	on	O) *
re summaris	sed in the follow:	ing table.    Color
9: Amounts two sided, fi	of dislodgeable fo gures in bold indi	liar residues of propineb on apple leaves in Germany (icate day of treatment)  Propineb* DFR (μg/cm²)  0.0221  0.0809  0.01667  0.1667  0.0239  0.0009  0.0009
DAFT#	Sampling	n.a.
	interval	DFR (μg/cm²)
	(DA1)	
0	0	
3	3	
6	6	0.0221 5 5 27 27 27 27
7	0	0.0809° 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
10	3	A 0.0706 P Q 3
13	6	0.08412 7
14	0	₩0.2136
17	3 4	0 0.1667 Y Z Z Z Z Z
19		\$\hat{9.259} \text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\exitt{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\exittit{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\exittit{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\exititt{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\exitit{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\exitin
21	~ 7 ° 7	0.0235
24	10	\$\tilde{\text{U}} 0 \text{1} \text{3} \text{44 } \text{D} \text{V} \text{2} \text{V} \text{2} \text{V} \text{Q} \text{D}
28	1 414	\$\int_{0118}\forall  \tau^{\tau} \tau
35	\$\times_21 \times_3	0.0044
42	28	0.0059
<i>5</i> 3) \		\(\sigma_0.000\text{g}\text{y}\)
\$74 \$°	0 61 0	\$\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\math
AFT: day@after	C WALL A DAT	T: day after treatment
orrected for real	overies \$ 70%	ion conducted
%		
nent Parted	sat BROP 574	ink bud stage: flower petals elongating; sepals slightly open)
s of 7 days	each for consecu	tive treatments. The 2 nd treatment was performed at BBCH 59
Swith Seta	ls forming a ho	Now ball) followed by the 3 rd treatment at BBCH 63 (about
		3 0 4 1 0 4 1 1 C 11

^{#:}DAFT: day@ifter first treatment; DAT: day wifer treatment

The 1st treatment started at BBOH 57 pink bod 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 betals forming a hollow ball) followed by the 3rd treatment at BBCH 63 (about 30% of flowers open). There was no fain after the creatments. Where field recoveries were < 70% sample results were corrected to 100%.

A first-order single-exponential dissipation was fitted to the set of experimental data. Overall mean dissipation half-lift for propineb was 7 D days (see Appendix).

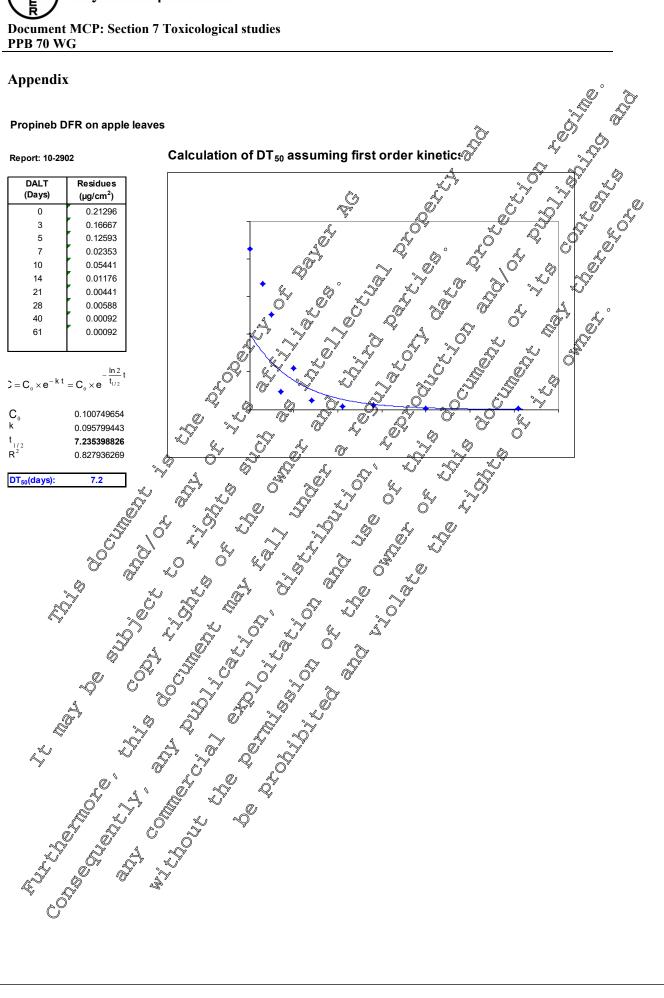
# III Conclusion

The maximum OFR value is 0.2130 μg/cm² observed at day 0 after the 3rd application. Thereafter, a constant residue decture is observed with residues < LOQ from day 40 onwards. First application starts at BPCH > 0 '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.

^{*} Corrected for recoveries ≤ 1/0%

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

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



DFR study apple (S-EU):

Report: ;2011;M-405614**9**01

Determination of dislodgeable foliar residues of propines on apple after spraying of Antracol in the field in Spain 10-2900 Title:

Report No: 10-2900

Document No(s): Report includes Trial Nos.:

> 10-2900-01 M-405614-01-1

US EPA OPPTS 875.2100; Deviations: not specified **Guidelines:** 

**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		Growth stage O'	Interval	Rate (kg a.s./ha)
Spain	Spraying	\$\tag{3}\$\tag{7}\$	n(n. / 61 / 65	P 7. F	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 recessary, transported and stored according to US EPA OPPTS 875.2100 Foliar Dislodgeable Residue Dissipation. Lease punches were collected directly into a pre-labelled poly-propylene jan using a leaf gunch samplet (Birkestrand Co; El Monte, CA). Each sample consisted of 40 disks cut with a caf puncher with 2.523 cm Tiameter and a disk area of 5 cm². The leaf punches represented a votal double-oded leaf surface area of 400 cm². 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 grop forage. Control leaf punch samples were collected prior to the first application. To eated 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. Feaf 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

The results are summarised in the following table.

DAFT#	Sampling interval (DAT)	Propineb* DFR (μg/cm²)	ropineb on apple leaves in Spain ment  A A A A A A A A A A A A A A A A A A A
0	0	n.a.	
3	3	n.a.	
7	7	n.a.	
7	0	0.2870	
10	3	0.362	
14	7	0.1609	
14	0	0.2500	
17	3	0.23	
20	6	0 <b>07</b> 94 ~	
21	7	& Ø.061&	
23	9 0	0.0471	
28	14 ^Q * 0	020088	
35	21	0.0059	
42	284	O.0618 0	
56 °	42	\$\$0018 ⊀√	
73 ≪∌	59	0.00	
	first treatment; DA	Today after treatmen	
* Corrected for rec	cokeries < 00% ~ One samble collecti	on conducted	
. O O			not determined) with intervals of 7 days expressed at BBCH 61 (beginning of floweri
ð Ş			

to the following treatments i.e. the 2nd reatment was performed at BBCH 61 (beginning of flowering: about 10% of flowers open). Followed by the 3rd treatment at BRCH 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%.

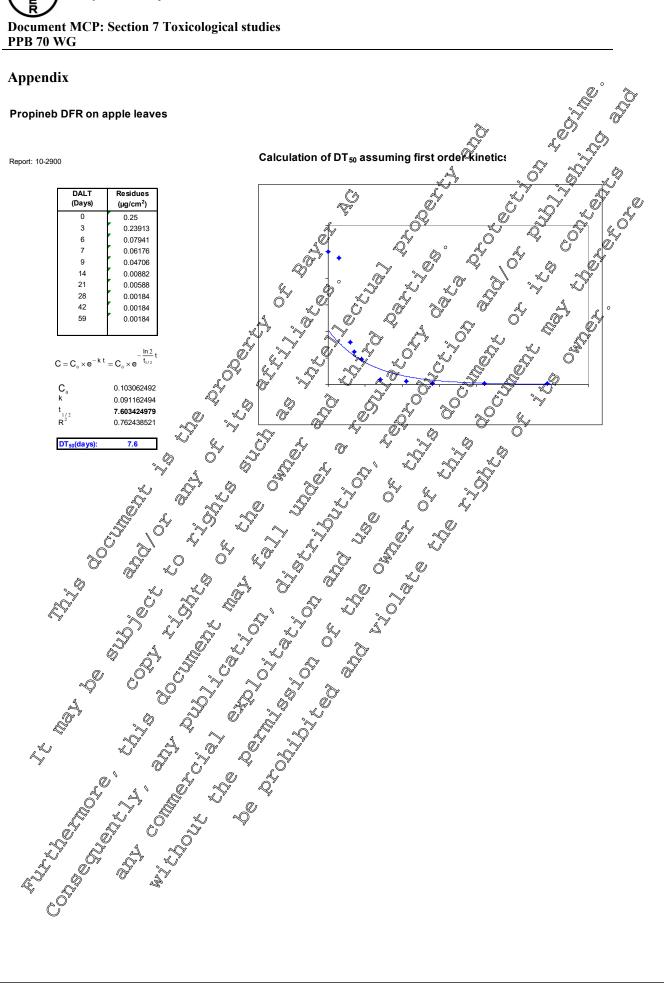
A first-order sugle-exponential dissipation equation was litted to the set of experimental data. Overall mean dissipation half-life for propineb was 7.6 days (see Appendix).

# **III Conclusion**

The maximum DFR value is 0.3696 µg/cm observed at day 3 after the 2nd application. The max residue level is followed by Crapid decline between the day 3 and 6/7 with residues < LOQ after day 35. First apprecation 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 for ge 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 ancount of FR is low and accumulation due to repeated applications is limited.

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	0.00404

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



DFR study grapes (S-EU):

Report:

Determination of dislodgeable foliar residues of propine after spraying of Antracol on grape in the field in Spain
10-2901
Report includes Trial Nos.:
10-2901-01
M-405617-01-1
US EPA OPPTS 875.2100; Deviations: not specified yes Title:

Report No:

Document No(s):

**Guidelines:** 

**GLP/GEP:** 

# 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 Antrace WG 70. The study included one supervised residue trial conducted in Southern Europe (Sprin) during the 2010 season.

Table 7.2.3.1-12: Application parameters

Country	Spplication of his
	Type No Growth stage Interval Rate  (kg a.s./ha)
Spain	Spraving 53 / 55 / 55 / 75 / 77 / 31 / 1.60 / 1.55 / 1.50 / 1.60

Samples were collected in a manner designed to obtain representative samples. They were taken, prepared on the field where necessary transported and stored according to US EPA OPPTS 875.2100 Foliar Dislodgeable Residue Discipation Leaf punches were collected directly into a pre-labelled poly-propylene jar using a leaf punch sampler Birke Pand Co; El Monte, CA). Each sample consisted of 40 disks cut with a leaf purcher with 2.523 cm diameter and a disk area of 5 cm². The leaf punches represented a total deviole-sided lead surface area of 400 cm². A sample was collected from each of the three subplots to provide oree 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 folioge. 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. Waf purch 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

esuits	and discussio	11					*/ &	
results	are summaris	ed in the follow:	oliar residues of particle day of treatm  Propineb* DFR (μg/cm²)  0.433  0.255  0.300  1.049  0.293  0.293  0.145  1.993  0.822  0.629  1.444  1.044  1.044  0.399  0.398  0.564  0.327  0.127				~~~	
					4	W'	_Q ~	
e 7.2.3. .s./cm2	.1-13: Amounts 21. two sided, fig	of dislodgeable f oures in bold indi	oliar residues of p cate day of treatn	ropineb or rent	grape te	aves in Sp	ainO' &	
Γ	DAFT#	Sampling	Propineh*					
	<b>D</b> 1	interval	DFR (μg/cm ² )		O _A			
		(DAT)		Q	' B	4	<u>,</u> ' ° '	L.
L	0	0	0.173			~ ~ \		~Q"
	3	3	<b>€0,255 €</b> 0°					Q*
	7	7	0.300			O'	4 4	L,°
	7	0	0:300		A			
	10	3	/	~ \ (				<b>2</b>
	14	7 8	<b>€</b> 0.33 <b>€</b>	9 0				
	21	140	0.293			Ĵ,		
	28	<b>2</b> ,1 \( \sqrt{2}	Ø.200 Ş		Y &		(4).	
	38	\$\int_31,	© 0.145	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		O ^y	O	
	38	\$ 00° 5	<b>1 2 9</b> 3			y _		
	41	A3 .	\$0.8220°					
	45	7 2	0.609		<b>W</b>			
F	45.8	4 6 4	1 444	_@	r a	<b>~</b>		
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	50		0.259		~> @n			
-	© 52 2		398		<b>V</b>			
	52 55 59 66	10	0.56					
	59	144	0.307 6					
-	660		Ø.127 O					
	73	28 0	0.127	Ž				
-	85 C	0 40	982	¥" 				
	" UJ	300	0.027	I				

The 1st treatment started at onergence of inflorescence at BBCH 53 (inflorescences clearly visible) with an interval of days with the 2nd treatment at BBCH 55 (inflorescences swelling, flowers closely pressed togother) and treatment was performed with interval of 31 days at BBCH 75 (berries pea-sized, bunches trang) 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**

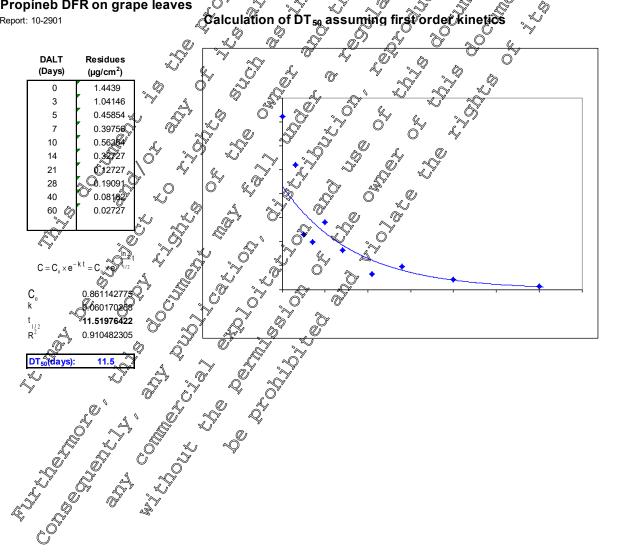
The maximum DFR value is 1.593 µg/cm² observed at day 0 after the 3rd application similar to the state of residue level at day 0 after the 4th application (1.444 µg/cm²). Dislodgeable foliar residues wier the first 2 applications are low compared to treatments 3 and 4. The first 2 applications were performed 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

The risk assessment is done with the highest DER value found after the 3rd application although the cGAP is based on 2 treatments only. In addition, no correction is made for the high dose rate of up to 1.6 kg a.s./ha exceeding the cGAP maximum dose rate of 1 4 kg a hha boabout 15%.

# **Appendix**

# Propineb DFR on grape leaves

Report: 10-2901



# DFR study grapes (S-EU):

Report: ;2011;M-404**\$**66-01

Determination of the dislodgeable foliar residues (DFR) of propined and Title:

tebuconazole in/on grape after spraying of Antracot and Folicur W 250 in the field after dislodging with various concentrations of Aerosol Of 10-2920
M-404866-01-1
US EPA OPPTS 875.2100; Deviations: not specified yes

Report No:

Document No:

**Guidelines:** 

**GLP/GEP:** 

# I Material and methods

Some of the 2011 DFR studies in grapes using propines and tebuconazolo were conducted with an Aerosol OT concentration of 0.001% instead of using the guide one 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 T concentration in the distodging solution. Two concentrations of the Aerosol OT, 0.01% and 0.001%, were applied to different leaf funches from the treated plots. The analytical results of propineb and tebuconazole after disloging with the two different solutions were compared to show the extraction excience of both dislosling solutions (cross-validation of extraction efficiency).

Table 7.2.3.1-14: Application parameters

		(C) . V		<i>U , a.</i>		
Country	Formulation					
		O' Aype	No	Growth	Interval	Rate
				<b>st</b> age	(days)	(kg a.s./ha)
				ВВСН)		
C	Antracol WG 70		1	91	-	0.98
Germany	Folicur WG 25	Spraying		87	-	0.15
Germany	Folicur WG 25	Spraying Spraying		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 leaf punch sample 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 cm². The leaf punches represented Total Touble Sided leaf surface area of 400 cm². Leaf punches were taken from the potential worker contact cone worluding 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 aboratory. Leaf punch samplers were cleaned after each sampling interval. The samples were disologed 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.

The resul	ts are summarised	d in the follow	ing table.		
l'able 7.2.	3.1-15: Compariso	n of dislodgeab	de foliar residues de	epending on the Ae	vosol OT concentration.
	Aerosol OT	Sampling	DFR (µg/cm²)	<del></del>	
	concentration (%)	interval (DAT)	Propineb	Tebucorazole	resol OT concentration.
	0.01	0	0.14	0.17	
	0.01	2	0.07	0.12	
	0.004	0	0.22 °	0,97	
	0.001	2	0.19"	0.12	
	DAT: day after treatr	nent		, Q A	
		Q)			
I Conc	lusion				th a 6.001% Aerosol OT
1. 1. 1	1 11 01				
he disk	odgeable foliar re	sidues of pro	pineb on grape le	avos obtained	th a 9.001% Aerosol O1 centration of 0.01%.
moniii	are by a factor of	1 to migner in	≈( ¥	the guideline con	icentration of 0.01%.
		<b>*</b>	). K	A. 0. 4	with 0.001% Aerosol

The dislodgeable foliar residues of tebuconazele on grape leaves obtained with a \$\tilde{0.01\%}\$. Aerosol OT solution are by a factor of 1 & higher than obtained with the guideline concentration of 0.01\%.

The dislodgeable foliar residues of tebuconazele on grape leaves obtained with \$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):

Determination of dislodgeable foliar residues of propineb on tomato after spraying of antracol in the greenhouse in Spain 10-2904
Report includes Trial Nos.: 10-2904-01
M-405638-01-1
US EPA OPPTS 875.2100; Deviations: not specified yes Report:

Title:

Report No:

Document No(s):

**Guidelines:** 

**GLP/GEP:** 

# I Material and methods

The purpose of the study 10-2904 was to determine the magnitude of the distogable foliar residues of propineb on tomato leaf foliage after four spraying applications in the greenhouse with Antracel 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			P. C.
	Type No	Growsh Grige (BRCH)	Anterval (	Kate
Spain	Spraying 4	72 / 73/94 / 75%	747/7	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 no essary, transported 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 winch compler Birkestrand Co; El Monte, CA). Each sample consisted of 40 disks cut with a leaf purcher with 2.523 cm Grameter and a disk area of 5 cm². The leaf punches represented a total double-saded lear surface area of 400 cm². A sample was collected from each of the three subplots to provide three replicate amplings at each sampling interval. Leaf punches were taken from the soliential worker concect zone including upper, middle, and lower portions of the crop foliage and interior and extenor portions of the copy 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 teaf 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 🔏	70.219	
7	0	0,453 _ C	
8	1 💍	6.283 F	
10	3	0.467	
14	7	0.696	
14	0 🗸 🐇	<b>9</b> .728	
15	7 4	0.79	
	3 7	0 <del>5</del> 92 V	
21	7 7	∑0.439\$	
21 21 22 24 27 24 27 28	3 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	0.79 0.392 0.4395 1.400 1.4110 1.281 0.844	
22 0 8		2011 / ×	
24 0		1.28	
Ž6		1.281	
28	7 5 4	0\844 O	
31	3 \$\infty\$ \\ \frac{5}{7} \\ \frac{5}{7} \\ \frac{10}{7} \\ \frac{1}{7} \\	0.964 🖔	
28 31 35	7 10 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	0.4600	
42 0 0	\$21 E	Ø.547 🔊 (	
49	280 % 0	0.442)	

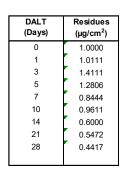
The 4 treatments were performed during development of fruit stages (BBCH 72 - 75, development of  $2^{nd}$  to  $5^{th}$  fruit effecter) with intervals of 7 days each. Where field recoveries were < 70% sample results were corrected to 100%.

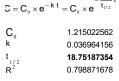
A first-order single-exponential dissipation equation was fitted to the set of experimental data. Overall mean dissipation half life for propine was 18.8 days (see Appendix).

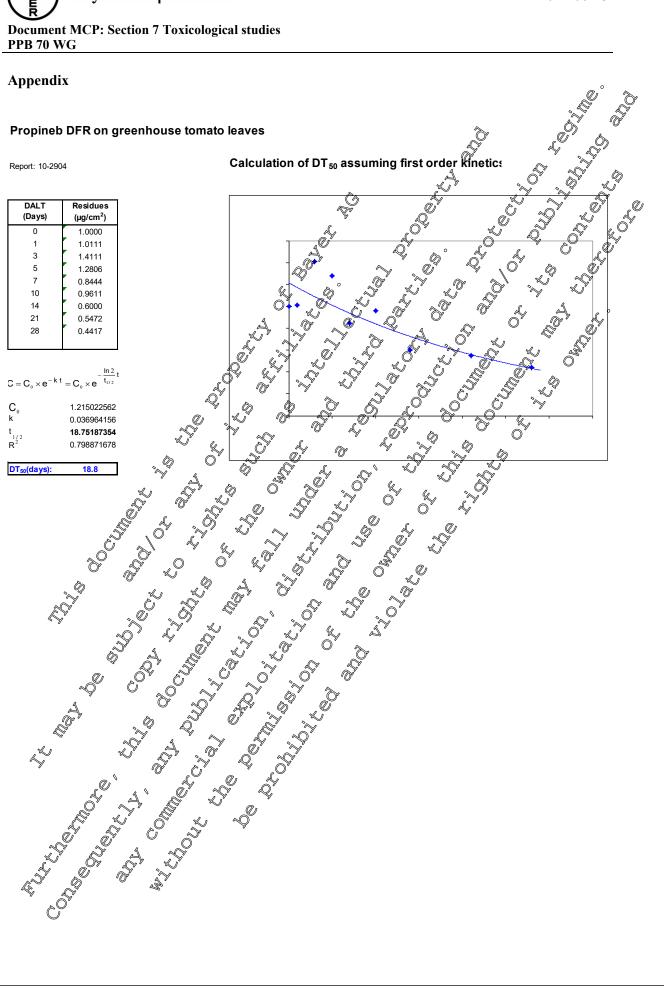
# III/Conclusion

An accumulation of dislodgeable foliar residues is observed from the  $1^{st}$  to the  $4^{th}$  application. The maximum DFR value is 1.411  $\mu g/cm^2$  observed at day 3 after the  $4^{th}$  application followed by a slow residue decline.

Calculation of DT ₅₀ assuming first order kinetics
---------------------------------------------------------------







DFR study greenhouse tomato (S-EU):

Title: Determination of the dislodgeable foliar residues (DER) of propine and

tebuconazole in/on tomato after spraying of Antraeol and Folicur WG 25 in

the greenhouse after dislodging with various concentrations of Aeroso 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 to nato using propine band tebuconagele were conducted with an Aerosol OT concentration of 0.01% 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 propinels and tebuconagole 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	<i>5</i> 2 29		
, Q	Type Type Type	No Growth stage BBCH)	Interval (days)	Rate (kg a.s./ha)
Germany	Antracol WG 70 Spraving 0	87	-	2.1
J	Forecur WG 25	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 cm². The leaf punches represented a total double sided leaf surface area of 400 cm². 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 related samples collected on the day of application were taken after the spray had dried. After each samples 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

	Aerosol OT	Sampling	DFR (µg/cm²)	
	(%)	(DAT)	Propineb	Tebuconazole
	0.01	0	0.013	0.21 \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$
	0.01	2	0.012	
	0.001	0	0.00)1	KO.18 & & &
	0.001	_	A	
		2	. <b>₽</b> ,011, Ø	0.132
Conc	DAT: day after treati	nent		Tebuconazole  0.21  0.18  0.18
Conc	clusion	esidades of pro	whine and the huce	onazole on tomato leaves obtained with a gnitude as obtained with the guideline

# Measurement of CP 7.2.3.2

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

# Degmal adsorption -**CP 7.3**

Summary and conclusion on dermal absorption

The extent of dermal absorption of propined formulated as a WG 70 formulation (PPB WG 70) was investigated in Vitro using human and rawskin. 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 guidance rules. A conclusion and recommendation regarding the dermal absorption of propine formulated as a WG 70 is given below.

The mean percentage of propries in the WG 70 formulation that was considered to be potentially Soorbable Sirectly 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 buman and rat skin, respectively. Applying the new EFSA guidance these values affect 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 7500. the receptor fluid at the end of the study) occurred within half of the doration (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 tage strips. These criteria wore 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 large 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. Abeit that the notifier considers that both the value of 25% for the standard deviation limit and the 95% Lecovery limit to be too conservative, the application of • 0.1% for the neat formulation (700 g/kg)
• 0.6% for the intermediate dose spray dilution (3.5 g/L)
• 1% for the neat formulation (700 g/kg)
• 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) the guidance results in the following values for Jt C]-propines in the PPB WG 70



Report: 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

SA 13078 Report No: M-483806-01-1 Document No:

**Guidelines:** OECD Guideline for the testing of Chemicals; Skin Absorption In Vitro

Method Guideline 428 (April 2004); OECD Favironmenta Health and Safety Publication Series on testing and Assessment No 28, Guidance Document for the Conduct & 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:

Source:

Sex:

Anatomical site: Dørsal.

Each animal was killed by corvical dislocation. After sacrifice the skin was Rat Skin Preparation:

clipped and removed for use in the study. The dorsal skin was dermatomed by use of a mini-derinatome to obtain samples of ca 450 to 550 μm in thickness.

Human skin:

Number and sex: (10 donors, female. Anatomical region: Abdomen S

Æhicknésss: 31∕6.4 to 505 um.

Test Material:

Radiolabelled: [propane-1-14C]-propinet

> Batch: XXM 7250-1-2& MXM 7104-1-2. specific activity: 14.8 kBg/mg & 356 MBq/mg.

The formulation dised in this experiment was the propinebWG70 formulation Formulation:

> (specification 102000006 16) containing propineb (700 g/Kg). It was used Pat three nominal concentrations of propineb: neat, 700 g/kg, 3.5 g/L and 1

Mow-through diffusion cell system (Franz's cell modified, Gallas, France) Test system:

was used to study the absorption of the test substance (exposure area of 1 cm² 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/LPat a pH of 7.4. The receptor chamber was warmed by a constant circulation of warm water which maintained the receptor fluid at  $32 \pm 2$ °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 (Technology, Denmark) has 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 though the receptor chamber was collected in glass vials held in a traction collector. The fraction collector was started after dose application. Samples were then collected fourly for the duration of the experiment (24 hours) At 8 hours post application the skin was swabbed with freshly prepared % v/ Twee 80 in PBS (Phosphere 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 and of the study (24 hours after application), the treated skin and the skin adjacent to the treatment site (surrounding swabs) were wabbed. Each skin sample was lape-stripped to remove the stratum cornei m. This involved the application of adresive dape ( , 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-stops were collected into scintillation vials for analysis. The sain surrounding the application site (surrounding skin) was separated from the treated skin. Both surrounding skin and tape-stripped treated skin were retained for analysis.

Radioassav:

The amounts of adioactivity in the various samples were determined by liquid scintillation counting (LSC). Samples were counted for 10 minutes or for 2 figma 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 [14C-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

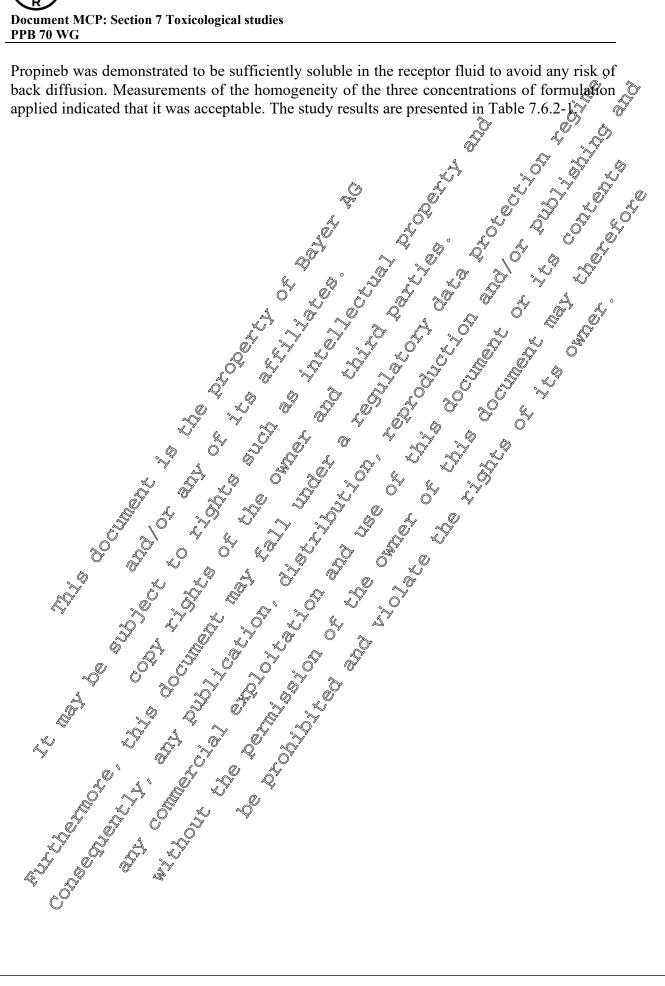


Table 7.6.2-1: Mean distribution of radioactivity at 24 hours after dose application of [14C]- propineb in an WG 70 formulation at the rates of 700 g/kg, 3.5 g/L and 1 g/L to human and rat skin samples.

Results expressed in terms of percentage of applied radioactivity.

	Distribution of radioa							(% dose	) <u> </u>		(W)	Ön	
	Neat formulation: High dose			Dilution: Intermediate dose				Dilution: I		I ow dose			
Dose Levels	11001		g/kg)				g/L)				LOW GOSA.		
Species	Human (n=5)		Rat (n=5)		Human (n=5)		Rat (n=5) 🖏		Human (n=6)		. Reft (n=6%)		
Species	Mean	SD	Mean	SD	Mean	SD)	Mean	S	Mean	SD	Mean	SD	
	SURFACE COMPARTMENT O O O												
Skin swabs (8h)	100.6	4.37	102.1	1.97	101.9 4		97.14	D4.23	102.4%	2.78	95.43	3.54O	
Skin swabs (24h) ^a	0.10	0.12	0.06	0.07	1.94	4.12	0.73	0.45	0.090	0.06	1,02	000	
Surface Dose							**	Ø		Ay .		4	
(tape-strips 1&2)	0.09	0.06	0.07	0.10	Ø005	0.05	0.14	<b>Ø</b> .05	0.08	0.05	©0.59 ~	$\mathbb{Q}_{0.42}^{y}$	
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-				Ô	. 0	\ \X	4	~~		e	4		
absorbed	100.8	4.45	102.3	2.02	103.9	1 H	98.06	4. 📆	102.6	2.84	97.19	B, 17	
SKIN COMPARTMENT A ST ST ST													
Skin ^b	0.01	0.01	0.11	\$0.12 °	≫0.05 <i>@</i>	₹0.03 _«	0.74	√ Ö.53 %	$\sqrt[8]{0.04}$	$9.04_{2}$	0.77	0.32	
Stratum corneum c	0.02	0.01	0.13	0.1%	0.02	0.02	$0.49^{\bigcirc}_{1}$	0.46	0.0 <b>5</b>	0.00	1.29	1.47	
Total % at dose			.04		. Q		. 6			Ŵ.	Ĉ		
site	0.03	0.01	0.24	<i>6</i> Ø1	0.08	0.04	₹23	<b>9</b> :70	Ø.09	Ø.06	Z.05	1.68	
PEGEDTOR COMPANIE O													
Receptor fluid			@ ,×	Į'	0.24	, W		O	0.34	4			
(0-24h)	0.02	0.02	0.12	0.05	0.24	0.24	1.000	050	0.34	<b>©</b> 13	1.29	0.44	
Receptor fluid		, ~	<b>%</b> /	$\mathcal{O}^{\circ}$		40	, A	~	Q	^ව ත			
terminal	0.001	0.0002	<b>©</b> 001	9.002	©0.01	0.01	0.04	√0.03 _×		°0.005	0.06	0.04	
Receptor chamber	n.d.	n.a.	₫ 0.04	0.05	n.d	n.aS	0.02	0.0%	n.đ.Ş	n.a.	0.09	0.22	
Total % directly	4	/ S				20.21		0.54	<b>40.35</b>				
absorbed d	0.02\$	0.02	0.08	<b>9</b> ,09	0.25	<b>20.21</b>	$\frac{1}{16}$	<b>6</b> .54	<b>40.35</b>	0.14	1.43	0.58	
Total %		Ó			- Č				<b>1</b>				
<b>Potentially</b>	Ö0.05.	0 02 *	, 2A	0.31		0.23				0.10	2.40	1.71	
Absorbable e	<b>₩0.05</b>	0.03	₹ 0.3 <b>0</b>	0.317	0.33	0.23	2,09	0:93	0.44	0.18	3.49	1.61	
TOTAL % & RECOVERY	10009	4.46	102.7	2.18	104.2	\$1.21	900.5	<b>2</b> 4.54	103.0	2.95	100.7	2.63	
RECOVERY	10009		((//)	tion acc	3/ //				103.0	2.95	100.7	2.03	
Absorption 75%	· ·		No - (()	7		N(V)		,	1				
by 12hrs?	Mes Ó		No No		No 🍪		、 [©] Nο		No		No		
SD >25% ?	Yes &		Yes ^O		V Yes		Yes		Yes		Yes		
Recovery <95%?	Noa Noa						No Yes		No		No		
adjusted: Total %	N			у 🛴	$\sim$		IN.	U	11	U	I N	10	
Potentially _@						6 🔊	3		1		5		
Absorbable f	\ \tilde{\pi}'	. 0	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		. U.U 9		J		1		S		
7103010401C													

a: sum of radioactivity found in swabs at termination and in surrounding swabs.

n.d.: not detected (Delow the himit of detection)

n: number of skin cells used for calculation

In the above table, the presented mean do not always calculate exactly from the presented individual data. This is due to rounding any differences resulting from the use of the spreadsheet program.

b: sum of radioactivity found in swass a summary than a more transfer 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 (0-24/0) receptor fluid terminal and receptor chamber.

e: total % directly absorbed + total % at dose site

f: values considered for the adjusted Total % Posentially Absorbable according to EFSA are in **bold Italics** 

SD: standard deviation

# **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 EFSA¹³ guidance rules. A conclusion and recommendation regarding the dermal absorption of propineb formulated as a WG 70 is given below.

The mean percentage of propine 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 mat formulation was 0.05% and 0.39% for the human and rat skin, respectively. Applying the new EKSA guidance these values adjust to 0.1% and 0.7% for human and rat skin respectively.

The mean percentage of propine in the WG 70 formulation that was considered to be potentially absorbable (directly absorbed plus total femaining 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 propiner in the WC 70 formulation that was considered to be potentially absorbable (directly absorbed plus total remaining at dose fare & 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 LFSA 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 fess than 95% occurs, a normalisation procedure is to be used by preference. Affect 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 [14C]-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.

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