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VOLUME 3 – Annex B (A14111B)

Chlorothalonil

B.6 Toxicology and metabolism

Rapporteur Member State: The Netherlands

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Renewal Assessment Report and Proposed decision of the Netherlands prepared in the context of the possible approval of chlorothalonil under Regulation (EC) 1107/2009

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B.6 Toxicology and metabolism data

This document supports the application for renewal of the regulatory approval of chlorothalonil under Commission Implementing Regulation (EU) 844/2012 of 18 September 2012. This document reviews the toxicological studies for the product A14111B containing:

- 400 g/L chlorothalonil
- 80 g/L azoxystrobin

A14111B is a suspension concentrate (SC) containing 400 g/L chlorothalonil and 80 g/L azoxystrobin for use as a fungicide in cereals and other speciality crops. A14111B was not the representative formulation in the EU review of chlorothalonil.

B.6.1 Acute toxicity

A14111B, containing 80 g/L azoxystrobin and 400 g/L chlorothalonil, is of low toxicity by the oral and dermal route of administration and is considered harmful if inhaled. It is non-irritating to the skin but a severe irritant to the rabbit eye. No skin sensitisation study was conducted for this formulation as there is adequate information from animal studies and human experience to conclude that technical chlorothalonil has skin sensitisation potential in humans and the formulation should therefore be labelled accordingly.

The classification according to Regulation (EC) No 1272/2008, as amended, is given in the table below.

Table 6.1-1: Summary of acute toxicological data obtained with A14111B

Parameter [Reference]	Species	Result	Classification according to Regulation (EC) No 1272/2008 as amended
Acute oral LD50 (Kuhn J, 2004)	Rat	>3045 mg/kg	None
Acute dermal LD50 (Kuhn J, 2004a)	Rat	5050mg/kg	None
Acute inhalation (Rattray NJ, 2004)	Rat	> 1.06mg/l	H332
Acute skin irritation (Kuhn J, 2004b)	Rabbit	Non-irritating	None
Acute eye irritation (Kuhn J, 2004c)	Rabbit	Severe irritant	H318
Skin sensitisation*	Guinea Pigs	May cause skin sensitization	H317

* No skin sensitisation was conducted because for this formulation as there is adequate information from animal studies and human experience to conclude that technical chlorothalonil has skin sensitisation potential in humans.

B.6.1.1 Oral

Previous evaluation:	*Submitted for the purpose of renewal, new data*
RMS remarks	*Acceptable. The RMS agrees with the conclusions drawn by the applicant.*

Report:	K-CP 7.1.1/01, Kuhn J. (2004). Azoxystrobin (80 g/l) and chlorothalonil (400 g/l) SC formulation (A14111B): Acute Oral Toxicity Study In Rats. Stillmeadow Inc, Sugar Land, TX 77478, US. Laboratory Report No. 8065-04. Issue date 15 April 2004. Unpublished. (Syngenta File No. ICI5504/2243)

GUIDELINES: OECD 425 (2008): OPPTS 870.1100 (2002).

GLP: Signed and dated GLP and Quality Assurance statements were provided.

Acceptability: There were no deviations from the current regulatory guideline considered to compromise the scientific validity of the study.

Study design

Young adult female Sprague-Dawley albino rats were given a single oral dose of azoxystrobin/chlorothalonil SC formulation (A14111B). An initial limit test at 5000 mg/kg resulted in the death of the dosed animal and a full test was initiated at doses of 175, 550, 1750 and 5000 mg/kg. The test substance was dosed as supplied, the dose volume ranged from 0.14 ml/kg at the 175 mg/kg level to 4.15 ml/kg at the 5000 mg/kg level. The rats were fasted overnight prior to dosing. They were assessed daily for the following 14 days for any signs of systemic toxicity and their bodyweights were recorded at intervals throughout the study. Animals found dead and those killed at the end of the study were subjected to a macroscopic examination *post mortem*.

Test Material: Azoxystrobin/chlorothalonil 80/400 g/l SC formulation (A14111B)
Description: Formulation, cream coloured aqueous suspension
Lot/Batch number: J7518/024
Purity: 6.6% w/w azoxystrobin, 34.6% w/w chlorothalonil
Stability of test compound: Stable (stored at room temperature)
Vehicle and/or positive control: None

Results

Mortality: Mortality is given in Table 1. Animals dosed with 175 and 550 mg/kg survived. One of three rats dosed at 1750 mg/kg died and two of three rats dosed at 5000 mg/kg died.

Table 7.1.1-1 : Doses, mortality/animals treated

Step	Dose Regime/Mortality		
	Animal numbers	Dose level (mg/kg)	Comment
1	2	175	Survived
2	3	550	Survived
3	4	1750	Survived
4	5	5000	Survived
5	6	5000	Died
6	7	1750	Survived
7	8	5000	Died
8	9	1750	Died

Clinical observations: Clinical signs included decreased activity, crusted fur, diarrhoea, polyuria and sensitivity to touch. There was complete recovery by day 5.

Body Weight: Bodyweight gain in surviving animals was unaffected by the administration of azoxystrobin/chlorothalonil SC formulation (A14111B), with the exception of one animal that lost weight between days 0 and 7.

Necropsy: Macroscopic examination *post mortem* of the animals that were found dead revealed stained fur, fluid in the chest cavity, discoloured lungs, liver, spleen and contents of the gastrointestinal tract. There were no abnormalities seen in animals killed at study termination.

Conclusion
The acute oral LD_{50} of azoxystrobin/chlorothalonil SC formulation (A14111B) was estimated to be 3045 mg/kg in female rats.
The acute oral toxicity was greater than 2000 mg/kg therefore no classification is required for acute oral toxicity of A14111B according to Regulation (EC) No 1272/2008 as amended.

The conclusion is not yet agreed with; the study design needs to be clarified first, see RMS remark in box above study.

B.6.1.2 Dermal

Previous evaluation:	*Submitted for the purpose of renewal, new data*
RMS remarks	*Acceptable. The RMS agrees with the conclusions drawn by the applicant.*

Report:	K-CP 7.1.2/01, Kuhn J. (2004a). Azoxystrobin (80 g/l) and Chlorothalonil (400 g/l) SC (A14111B): Acute Dermal Toxicity Study In Rats. Stillmeadow Inc, Sugar Land, TX 77478, US. Laboratory Report No. 8066-04. Issue date 15 April 2004. Unpublished. (Syngenta File No. ICI5504/2244)

GUIDELINES: OECD 402 (1987): OPPTS 870.1200 (1998): EC 440/2008 (2008).

GLP: Signed and dated GLP and Quality Assurance statements were provided.

Acceptability: There were no deviations from the current regulatory guideline considered to compromise the scientific validity of the study.

Study design
A group of five male and five female Sprague-Dawley rats were dermally exposed to 5050 mg (4.19 ml/kg) azoxystrobin/chlorothalonil 80/400 g/l SC formulation (A14111B)/kg bodyweight. The test substance was tested as supplied. Test sites (not less than 10% of total body surface) were covered with an occlusive dressing for approximately 24 hours, after which the dressing was removed and the skin cleansed using clean warm water. The animals were assessed daily for the following 14 days for any signs of systemic toxicity and their bodyweights were recorded at intervals throughout the study. At the end of the study the animals were killed and subjected to a macroscopic examination *post mortem*.

Test Material:	Azoxystrobin/chlorothalonil 80/400 g/l SC formulation (A14111B)
Description:	Formulation, cream coloured aqueous suspension
Lot/Batch number:	J7518/024
Purity:	6.6% w/w azoxystrobin, 34.6% w/w chlorothalonil
Stability of test compound:	Stable (stored at room temperature)

Vehicle and/or positive control: None

Results
Mortality: There were no mortalities.
The acute dermal LD_{50} for males and females is in excess of 5050 mg/kg bodyweight (limit test, no mortalities).

Clinical observations: There were no signs of systemic toxicity. Four males and four females showed signs of slight skin irritation (very slight to well-defined erythema and desquamation), which was still present in one male on day 11, but had disappeared by day 14.

Body Weight: One male and two females lost bodyweight, and one male failed to gain bodyweight, between days 7 and 14.

Necropsy: There were no macroscopic abnormalities at examination *post mortem*.

Conclusion
The acute dermal LD_{50} of azoxystrobin/chlorothalonil 80/400 g/l SC formulation (A14111B) is in excess of 5050 mg/kg.
The acute dermal toxicity was greater than 2000 mg/kg therefore no classification is required for acute dermal toxicity of A14111B according to Regulation (EC) No 1272/2008 as amended.

B.6.1.3 Inhalation

Previous evaluation:	*Submitted for the purpose of renewal, new data*
RMS remarks	*Acceptable. The RMS agrees with the conclusions drawn by the applicant.*

Report:	K-CP 7.1.3/01, Rattray NJ. (2004). Azoxystrobin/Chlorothalonil 80/400 g/l SC Formulation (A14111B) 4-Hour Acute Inhalation Toxicity Study In Rats. Syngenta Central Toxicology Laboratory, Alderley Park, Macclesfield, Cheshire, UK. Laboratory Report No. CTL/HR2464/REGULATORY/REPORT. Issue date 25 March 2004. Unpublished. (Syngenta File No. ICI5504/2229)

GUIDELINES: Acute Inhalation (rat) OECD 403 (1981): OPPTS 870.1300 (1998): 92/69/EEC (1992) + amendment 93/21/EEC (1993).

GLP: Signed and dated GLP and Quality Assurance statements were provided.

Acceptability: There were no deviations from the current regulatory guideline considered to compromise the scientific validity of the study.
The MMAD is exceeding the recommended MMAD of 1-4 µm. The applicant indicated that, because of the inherently high viscosity of chlorothalonil liquid formulations, they will not form respirable aerosols in their neat (undiluted) state. It is only possible to generate respirable aerosols using the SC formulations of chlorothalonil when the formulations are diluted with water, and even then, it was not possible to generate aerosols with an MMAD in the range 1-4µm as required by current test guidelines.

Study design
A group of five male and five female Alpk:AP_fSD (Wistar-derived) rats was exposed nose-only for a single four-hour period to azoxystrobin/chlorothalonil 80/400 g/l SC formulation (A14111B) at a target formulation concentration of 1 mg/l. Test atmospheres were analysed for total particulate concentration and chlorothalonil. The particle size distribution of the test atmosphere was analysed twice during the exposure period. Following exposure, the animals were retained without treatment for 14 days. Clinical observations and bodyweights were recorded throughout the study and at the end of the scheduled period, the animals were killed and subjected to a gross examination *post mortem*.

The achieved test atmosphere had the following characteristics:

Target Total Formulation Concentration mg/l	Achieved Total Formulation Concentration mg/l	MMAD* µm	GSD+
1	1.06±0.1	5.52 6.56	1.85 1.78

* Mass Median Aerodynamic Diameter (µm)

+ Geometric Standard Deviation

Test Material:	Azoxystrobin/chlorothalonil 80/400 g/l SC formulation (A14111B)
Description:	Formulation, cream opaque liquid
Lot/Batch number:	J7518/024
Purity:	6.6% w/w, 80 g/l azoxystrobin, 34.6% w/w, 419 g/l chlorothalonil
Stability of test compound:	Stable (stored at ambient temperature in the dark)

Vehicle and/or positive control: None

Results

Mortality: One male was found dead on day 2.

Clinical observations: Abnormalities generally associated with restraint (wet fur and salivation all animals, and chromodacryorrhoea, some animals) were observed during exposure. All animals had test substance around the snout.
Immediately following exposure, abnormalities generally associated with restraint (wet fur and salivation, all animals, and chromodacryorrhoea, some animals) were observed and all animals had test substance around the snout. Changes indicative of mild toxicity (decreased activity was seen in 1 female) and irritation of the respiratory tract (reduced breathing rate, increased breathing depth, abnormal respiratory noise and stains around the nose) were observed in all animals.
The clinical condition of the surviving animals had greatly improved by day 5 of the study and all animals had fully recovered by day 11 of the study.

Body Weight: Of the surviving animals, 2 males and 2 females had gained weight by day 8 of the study and all surviving animals had gained weight by the end of the study.

Necropsy: Stained nares were observed in the male rat, found dead, on day 2 of the study. This finding is considered to be related to treatment.

Conclusion

Nose-only exposure for 4 hours to a total formulation concentration of 1.06 mg/l resulted in 1 death. Evidence of transitory mild respiratory irritation was seen in the surviving animals. It is concluded that the acute LC_{50} of this azoxystrobin/chlorothalonil 80/400 g/l SC formulation (A14111B) exceeds 1.06 mg/l.
The inhalation toxicity was less than 5 mg/L threshold defined in Regulation (EC) No 1272/2008 as amended. Therefore, H332 classification is required for inhalation properties of A14111B. Not yet agreed upon by RMS…

B.6.1.4 Skin irritation

Previous evaluation:	*Submitted for the purpose of renewal, new data*
RMS remarks	*Acceptable. The RMS agrees with the conclusions drawn by the applicant.*

Report:	K-CP 7.1.4/01, Kuhn J. (2004b). Azoxystrobin (80g/l) and Chlorothalonil (400g/l) SC (A14111B): Acute Dermal Irritation Study In Rabbits. Stillmeadow Inc, Sugar Land, TX 77478, US. Laboratory Report No. 8068-04. Issue date 15 April 2004. Unpublished. (Syngenta File No. ICI5504/2245)

GUIDELINES: Primary Dermal Irritation (rabbit) OECD 404 (2002): OPPTS 870.2500 (1998): 2004/73/EC B.4 (2004).

GLP: Signed and dated GLP and Quality Assurance statements were provided.

Acceptability: There were no deviations from the current regulatory guideline considered to compromise the scientific validity of the study.

Study design
In a primary irritation study, three young adult New Zealand White albino rabbits (one male and two females) were dermally exposed to 0.5 ml of undiluted azoxystrobin/chlorothalonil 80/400 g/l SC formulation (A14111B) for 4 hours to an area (approximate size 2.5 cm x 2.5 cm) on the shorn flank under an occlusive dressing. The Draize scale was used to assess any irritation approximately 1 hour, 1, 2, 3 and 7 days after removal of the dressings. Mean erythema and oedema scores were calculated. Bodyweights were recorded at the start of the study.

Test Material:	Azoxystrobin/chlorothalonil 80/400 g/l SC formulation (A14111B)
Description:	Formulation, cream coloured aqueous suspension
Lot/Batch number:	J7518/024
Purity:	6.6% w/w azoxystrobin, 34.6% w/w chlorothalonil
Stability of test compound:	Stable (stored at room temperature)

Vehicle and/or positive control: None

Results
Very slight to well-defined erythema was present up to and including day 3. Oedema was not observed. Desquamation was seen in one animal at the 48 hour reading.

Table 7.1.4-1: Individual and mean skin irritation scores of azoxystrobin (80g/l) and chlorothalonil (400 g/l) SC (A14111B) **according to the Draize scheme**

Time	Erythema			Oedema		
Animal number	**6892**	**6847**	**6899**	**6892**	**6847**	**6899**
after 1 hour	1	2	2	0	0	0
after 24 hours	1	1	1	0	0	0
after 48 hours	0	1	1	0	0	0
after 72 hours	0	1	0	0	0	0
mean score 24-72 h	0.3	1.0	0.7	0	0	0
after 7 days	0	0	0	0	0	0

Conclusion
The primary irritation index of 0.9 out of a possible 8.0 was used to give azoxystrobin (80g/l) and chlorothalonil (400 g/l) SC (A14111B) a descriptive rating of slightly irritating.

The mean irritation scores 24 to 72 hours after application were less than the thresholds defined in Regulation (EC) No 1272/2008 as amended. Therefore, no classification is required for skin irritating properties of A14111B.

B.6.1.5 Eye irritation

Previous evaluation:	*Submitted for the purpose of renewal, new data*
RMS remarks	*Acceptable. The RMS agrees with the conclusions drawn by the applicant.*

Report:	K-CP 7.1.5/01, Kuhn J. (2004c). Azoxystrobin (80g/l) and Chlorothalonil (400g/l) SC (A14111B): Acute Eye Irritation Study In Rabbits. Stillmeadow Inc, Sugar Land, TX 77478, US. Laboratory Report No. 8067-04. Issue date 15 April 2004. Unpublished. (Syngenta File No. ICI5504/2242)

GUIDELINES: Primary Eye Irritation (rabbit) OECD 405 (2002): OPPTS 870.2400 (1998): 2004/73/EC B.5 (2004).

GLP: Signed and dated GLP and Quality Assurance statements were provided.

Acceptability: There were no deviations from the current regulatory guideline considered to compromise the scientific validity of the study.

Study design

In a primary eye irritation study, 0.1 ml of azoxystrobin (80g/l) and chlorothalonil (400 g/l) SC formulation (A14111B) was instilled into the conjunctival sac of the right eye of a group of three young adult (two male and one female) New Zealand White albino rabbits. The eyes were examined and the grade of ocular reaction was assessed approximately 1 hour and 1, 2, 3, 4, 7, 10, 14, 17, 21, 24 and 28 days after instillation. All treated eyes were rinsed for 1 minute with deionised water immediately following the 24 hour reading. A modified form of the Kay and Calandra system (***Kay and Calandra,1962***) was used to interpret and classify the numerical scores.

Test Material:	Azoxystrobin/chlorothalonil 80/400 g/l SC formulation (A14111B)
Description:	Formulation, cream coloured aqueous suspension
Lot/Batch number:	J7518/024
Purity:	6.6% w/w azoxystrobin, 34.6% w/w chlorothalonil
Stability of test compound:	Stable (stored at room temperature)

Vehicle and/or positive control: None

Results

Signs of severe eye irritation were seen following application of azoxystrobin (80g/l) and chlorothalonil (400 g/l) SC formulation (A14111B) into the rabbit eye. Fluorescein staining was observed in all animals after treatment and evidence of irritation persisted in all animals up to day 28 (study termination) and included: corneal opacity (scores of 1-2 on a 0-4 scale) covering more than 75% of the cornea after one hour and 25% or less at all other readings; conjunctival redness (scores of 1-3 on a 0-3 scale); conjunctival chemosis (scores of 1-4 on a 0-4 scale) and conjunctival discharge (scores of 1-3 on a 0-3 scale). In addition, constricted pupils were seen in all 3 rabbits, necrosis of the conjunctivae was seen in all three rabbits, blisters on the nictitating membrane/eyelid were seen in 3 rabbits and invasion of the cornea by blood vessels was seen in one animal.

Table 7.1.5-1: Eye irritation scores

Time	Cornea			Iris			Conjunctiva								
							Redness			Chemosis			Discharge		
Animal number	6864	6868	6865	6864	6868	6865	6864	6868	6865	6864	6868	6865	6864	6868	6865
1 hour	1	1	1	0	0	0	1	1	1	1 d	1 d	1 d	3	2	3
24 hours	2	a	2	0 c	a	0 c	3N	3N	3N	3	4	3	3	3	3
48 hours	2	a	2	0 c	a	0	3N	3N	3N	3	4	3 d	3	3	3
72 hours	2	2	2	0 c	0 c	0 c	3N	3N	3N	3	3	3	3	3	3
Mean: 24-72h	2	a	2	0	a	0	3	3	3	3	3.7	3	3	3	3
4 days	2	2	2	0 c	0 c	0 c	3N	3N	3N	3	3	3	3	3	3
7 days	2	2	2	0 c	0 c	0 c	3N	3N	3N	2	3	2	2	3	2
10 days	2	1	2	0 c	0	0 c	3N	2	3	2	1	1	3	1	2
14 days	2	1	1	0	0	0	3	1	1	1	0	1	1	0	0
17 days	2	1	2 b	0	0	0	2	2	3	1	0	2	0	0	2
21 days	2	1	2 b	0	0	0	0	0	3	0	0	2	0	0	2

a – unable to score due to severity of chemosis b – invasion of cornea by blood vessels c – constricted pupil
d – blister on nictating membrane/eyelid
N – Necrosis of the conjunctivae

Conclusion

Under the conditions of this study, azoxystrobin (80 g/l) and chlorothalonil (400 g/l) SC formulation (A14111B) is considered to be severely irritating to the rabbit eye according to a modified form of the Kay and Calandra system.

The mean irritation scores 24 to 72 hours after application were greater the thresholds defined in Regulation (EC) No 1272/2008 as amended. Therefore, H318 classification is required for eye irritating properties of A14111B.

B.6.1.6 Skin sensitisation

No skin sensitisation study was conducted for this formulation as there is adequate information from animal studies and human experience to conclude that technical chlorothalonil has skin sensitisation potential in humans. A default classification of H317 'may cause sensitisation following skin contact' should be applied to the formulation.

B.6.1.7 Supplementary studies on the plant protection product

No additional studies have been conducted. A14111B is an azoxystrobin/chlorothalonil solo formulation and its potential acute toxicity has been fully addressed as presented in Sections CP 6.1.1-6.1.6. No additional studies to address potential health effects are considered to be unnecessary.

B.6.1.8 Supplementary studies for the combination of plant protection products

This product does not contain recommendations for combinations of plant protection products.

B.6.2 Dermal absorption

Azoxystrobin

No *in vitro* data has been generated to determine the dermal absorption potential of azoxystrobin from formulation A14111B.

For azoxystrobin, dermal absorption default values can be used as described in the EFSA guidance document (EFSA Journal 2012; 10(4):2665). Therefore, all relevant data are provided and are considered adequate.

The percentage absorptions used in the operator exposure assessment are given in Table 7.3-1.

Table 6.2-1: Dermal absorption end-points for the risk assessment of azoxystrobin

End-Point	Azoxystrobin	
Dermal penetration	Concentrate:	25%
	Spray dilutions:	75%

Chlorothalonil

The dermal absorption of chlorothalonil from A14111B has been investigated in an *in vitro* study using human dermatomed skin. For chlorothalonil the dermal absorption values have been derived according to the EFSA guidance on Dermal Absorption.

Dermal absorption was therefore calculated as follows:

Table 6.2-2: Summary of dermal absorption study for chlorothalonil in formulation A14111B

Test	% of applied dose				Reference
	Concentrate (400 g/L)	Spray dilution 1 (1/40; 10 g/L)	Spray dilution 2 (1/213; 1.88 g/L)	Spray dilution 3 (1/600; 0.67 g/L)	
***In vitro* (human)**	0.05	0.7	3	7	Noakes J, 2013

Study 1 In vitro dermal absorption

Previous evaluation:	*Submitted for the purpose of renewal, new data*
RMS remarks	*Acceptable. The RMS agrees with the conclusion drawn by the applicant.*

Report:	K-CP 7.3/01, Noakes J. (2013). Chlorothalonil/Azoxystrobin SC (A14111B) - In Vitro Absorption through Dermatomed Human Skin Using [^{14}C]-Chlorothalonil. Dermal Technology Laboratory Ltd., Med IC4, Keele University Science and Business Park, Keele, Staffordshire, ST5 5NL, United Kingdom. Report No. JV2271/REG, 12 September 2013. Unpublished. (Syngenta File No. A14111B_10828)

GUIDELINES: OECD 428; *In Vitro* Dermal Absorption (Human)

GLP: Signed and dated GLP and Quality Assurance statements were provided.

Acceptability: There were no deviations from the current regulatory guideline considered to compromise the scientific validity of the study.

Study design

The absorption and distribution of chlorothalonil from a chlorothalonil/azoxystrobin suspension concentrate (SC) formulation (A14111B) was measured *in vitro* through human dermatomed skin conforming to the Regulatory Guidelines.

The doses were applied to the dermatomed human skin as the chlorothalonil/azoxystrobin SC (A14111B) formulation concentrate containing 400 g chlorothalonil/L and three aqueous spray strength dilutions: nominally containing 10 g, 1.875 g and 0.667 g chlorothalonil/L: equivalent to 1/40, 1/213.3 and 1/600 w/v, respectively. The formulation and the aqueous spray strength dilutions were applied at rates of 10 µL/cm^2 and left unoccluded for an exposure period of six hours and a total run time of 24 hours.

The absorption process was followed by taking samples of the receptor fluid (50% ethanol in water) at recorded intervals throughout the exposure period. The surface of the dermatomed skin was decontaminated after a six hour exposure period to investigate the amount of chlorothalonil absorbed by the end of a typical 'working day' period. After decontamination, the absorption of chlorothalonil was monitored for the remainder of the 24 hour observation period. At the end of the experiment, the distribution of chlorothalonil in the test system was assessed, which included a tape stripping technique to determine its distribution in the *stratum corneum* and in the remaining skin.

Test Material:	Azoxystrobin
Description:	Technical, yellow solid (powder)
Lot/Batch number:	GRA9J1084
Purity:	99.2% w/w a.i
Stability of test compound:	Confirmed

Test Material:	Chlorothalonil
Description:	Technical, grey/brown solid (powder)
Lot/Batch number:	P5
Purity:	98.6% w/w a.i
Stability of test compound:	Confirmed
Radiolabelled Test Material:	[^{14}C]-Chlorothalonil
Radiochemical number:	RDR-XVI-66
Purity:	98.3% (chemical), 98.9% (radiochemical)
Stability of test compound:	Confirmed
Blank Formulation:	Blank of A14111B
Batch number:	JHU001-026-005

Receptor fluid: The receptor fluid (50% ethanol in water) was chosen to ensure that the chlorothalonil would freely partition into this from the skin membrane and never reach a concentration that would limit its diffusion.

Duration of exposure and sampling: The skin was exposed to the test preparations for six hours after which an interim decontamination of the application site was performed by gently swabbing the application site with natural sponges pre-wetted with 3% Teepol® and with further sponges pre-wetted with water. During the experimental run time samples of receptor fluid were taken at suitable intervals (pre, 1, 2, 3, 4, 6, 8, 10, 12, 16, 20 and 24 hours) to allow adequate characterisation of the absorption profile.

Terminal procedures: The donor chamber was carefully removed and washed with acetone. The epidermal surface of the skin was decontaminated by gently swabbing the application site with natural sponges pre-wetted with 3% Teepol® and with further sponges pre-wetted with water. Decontamination was shown to be complete following assessment of residual radioactivity levels on the skin surface with a Geiger counter. The sponges were digested in Soluene 350® and made up to a recorded volume. The surface of the skin was allowed to dry naturally and to assess penetration through the *stratum corneum*, successive layers of the *stratum corneum* were removed by the repeated application of adhesive tape (e.g. Scotch 3M Magic Tape) to a maximum of 5 strips. Each individual adhesive strip was sequentially numbered and digested with Soluene 350®. The remaining epidermal tissue was carefully removed from the receptor chamber and digested in Soluene 350® and analysed.

Analysis: All components of the test system (e.g. receptor fluid, skin wash, donor chamber, tape strips and epidermis) were analysed by LSC and the recovery determined.

Data: Results of the analysis of the samples of receptor fluid collected in the study were expressed as amounts of chlorothalonil in the receptor solution in terms of µg/cm^2, 'percentage of dose absorbed' and rates of absorption (µg/cm^2/h) (see Tables below).

Results

Analysis of the [^{14}C]-Dose Preparations

Dose levels achieved and homogeneity of the dose preparations

LSC analysis of the dose preparations confirmed that the dose levels achieved were 397 g chlorothalonil/L, 10.1 g chlorothalonil/L, 1.95 g chlorothalonil/L and 0.705 g chlorothalonil/L.

The dose preparations were considered to be homogeneous and acceptable for use in these experiments, with percentage relative standard deviations of < 2.1 between replicates.

Stability of chlorothalonil in the Formulations

Radiochemical purities of greater than 98% were seen in all dose preparations both prior to application and post dose preparation at 24 hours.

Absorption, mass balance and distribution of chlorothalonil

400 g Chlorothalonil/L formulation concentrate
The potentially absorbed amount of chlorothalonil from the formulation concentrate through human dermatomed skin was 0.41% of the applied dose. The mean absorption rate of chlorothalonil was 0.008 µg/cm²/h over 24 hours.

The vast majority of the applied chlorothalonil (mean 105%) was washed off the skin at six hours, and an additional 0.238% was removed in the skin wash after 24 hours. A small proportion of the dose applied was recovered from the donor chamber (0.039%), and tape strips 1-2 (0.009%). The mean total recovery was 105% of the dose applied.

10 g chlorothalonil/L aqueous spray dilution 1 (1/40 w/v)
The potentially absorbed amount of chlorothalonil from the formulation concentrate through human dermatomed skin was 8.17% of the applied dose. The mean absorption rate of chlorothalonil was 0.005 µg/cm²/h over 24 hours.

The majority of the applied chlorothalonil (mean 90.6%) was washed off the skin at six hours, and an additional 4.39% was removed in the skin wash after 24 hours. A small proportion of the dose applied was recovered from the donor chamber (0.299%), and tape strips 1-2 (0.181%). The mean total recovery was 104% of the dose applied.

1.875 g chlorothalonil/L aqueous spray dilution 2 (1/213.3 w/v)
The potentially absorbed amount of chlorothalonil from the formulation concentrate through human dermatomed skin was 6.79% of the applied dose. The mean absorption rate of chlorothalonil was 0.002 µg/cm²/h over 24 hours.

A mean of 99.7% of the applied chlorothalonil was washed off the skin after 6 hours, with a further 1.61% removed at 24 hours. A small proportion of the dose applied was recovered from the donor chamber (0.076%), and tape strips 1-2 (0.119%). The mean total recovery was 108% of the dose applied.

0.667 g chlorothalonil/L aqueous spray dilution 3 (1/600 w/v)
The potentially absorbed amount of chlorothalonil from the formulation concentrate through human dermatomed skin was 11.98% of the applied dose. The mean absorption rate of chlorothalonil was 0.002 µg/cm²/h over 24 hours.

A mean of 85.1% of the applied chlorothalonil was washed off the skin after 6 hours, with a further 4.69% removed at 24 hours. A small proportion of the dose applied was recovered from the donor chamber (0.322%), and tape strips 1-2 (0.145%). The mean total recovery was 102% of the dose applied.

Table 6.2-3: Summary of chlorothalonil distribution from the 400 g/L concentrate formulation

Test Compartment	Percentage of Dose Recovered (%):								Mean % Recovered	SD
	Cell 36	Cell 49	Cell 51	Cell 56	Cell 58	Cell 62	Cell 67	Cell 69		
Donor chamber	0.032	0.012	0.067	0.022	0.007	0.015	0.137	0.018	0.039	0.044
Skin wash at 6 hours	108	105	105	103	102	106	106	103	105	1.79
Skin wash at 24 hours	0.104	0.127	0.452	0.149	0.118	0.097	0.501	0.361	0.238	0.170
Tape strips 1-2	0.007	0.016	0.020	0.002	0.001	0.001	0.019	0.005	0.009	0.008
Tape strips 3-5	0.004	0.015	0.007	0.002	0.001	0.002	0.013	0.014	0.007	0.006
Remaining skin	0.142	0.280	0.717	0.528	0.299	0.347	0.677	0.216	0.401	0.214
Receptor fluid	0.007	0.006	0.004	0.005	0.004	0.006	0.014	0.004	0.006	0.003
Total recovered	108	105	107	104	103	107	107	104	105	1.851
Potentially absorbed	0.153	0.301	0.728	0.535	0.304	0.355	0.704	0.234	0.414	0.202
Absorbed	0.007	0.006	0.004	0.005	0.004	0.006	0.014	0.004	0.006	0.003

Remaining skin = skin tissue remaining after tape stripping; Absorbed = amount in receptor fluid; Potentially absorbed = amount in receptor fluid, tape strips 3-5, and remaining skin.

Table 6.2-4: Summary of chlorothalonil distribution from the 10 g/L (1/40 w/v) aqueous spray dilution 1

Test Compartment	Percentage of Dose Recovered (%):								Mean % Recovered	SD
	Cell 41	Cell 50	Cell 53	Cell 57	Cell 60	Cell 66	Cell 68	Cell 71		
Donor chamber	0.026	0.098	0.802	0.177	0.252	0.527	0.245	0.267	0.299	0.251
Skin wash at 6 hours	92.6	97.1	83.1	85.4	91.1	86.8	93.8	94.8	90.6	4.96
Skin wash at 24 hours	1.95	1.76	4.18	10.46	6.62	4.91	2.49	2.76	4.39	2.96
Tape strips 1-2	0.109	0.183	0.442	0.017	0.075	0.126	0.288	0.204	0.181	0.134
Tape strips 3-5	0.076	0.145	0.314	0.016	0.064	0.169	0.322	0.211	0.165	0.113
Remaining skin	6.26	3.46	15.14	7.36	5.15	10.27	7.54	7.93	7.89	3.55
Receptor fluid	0.286	0.047	0.079	0.062	0.228	0.150	0.047	0.050	0.119	0.093
Total recovered	101	103	104	103	103	103	105	106	104	1.43
Potentially absorbed	6.622	3.652	15.533	7.438	5.442	10.589	7.909	8.191	8.174	3.37
Absorbed	0.286	0.047	0.079	0.062	0.228	0.15	0.047	0.05	0.119	0.093

Remaining skin = skin tissue remaining after tape stripping; Absorbed = amount in receptor fluid; Potentially absorbed = amount in receptor fluid, tape strips 3-5, and remaining skin.

Table 6.2-5: Summary of chlorothalonil distribution from the 1.875 g/L (1/213.3 w/v) aqueous spray dilution 2

Test Compartment	Percentage of Dose Recovered (%):								Mean % Recovered	SD
	Cell 29	Cell 36A	Cell 41A	Cell 46A	*Cell 48A*	Cell 51A	Cell 54A	Cell 63A		
Donor chamber	0.023	0.050	0.082	0.135	*0.328*	0.059	0.075	0.106	0.076	0.037
Skin wash at 6 hours	97.5	82.1	95.4	102	*140*	106	114	101	99.7	9.86
Skin wash at 24 hours	0.827	3.62	2.06	2.25	*1.33*	0.364	0.928	1.19	1.61	1.116
Tape strips 1-2	0.073	0.116	0.375	0.175	*0.112*	0.029	0.050	0.016	0.119	0.125
Tape strips 3-5	0.169	0.058	0.796	0.142	*0.053*	0.025	0.061	0.025	0.182	0.276
Remaining skin	4.50	15.9	10.7	2.67	*2.73*	2.78	4.36	3.20	6.31	5.07
Receptor fluid	0.099	0.624	0.460	0.217	*0.230*	0.199	0.232	0.218	0.293	0.182
Total recovered	103	102	110	108	*144*	109	120	106	108	5.75
Potentially absorbed	4.768	16.582	11.956	3.029	*3.013*	3.004	4.653	3.443	6.785	4.94
Absorbed	0.099	0.624	0.46	0.217	*0.23*	0.199	0.232	0.218	0.293	0.182

Cell 48A excluded from mean due to anomalous mass balance result.

Remaining skin = skin tissue remaining after tape stripping; Absorbed = amount in receptor fluid; Potentially absorbed = amount in receptor fluid, tape strips 3-5, and remaining skin.

Table 6.2-6: Summary of chlorothalonil distribution from the 0.667 g/L (1/600 w/v) aqueous spray dilution 3

Test Compartment	Percentage of Dose Recovered (%):								Mean % Recovered	SD
	Cell 33	Cell 40A	Cell 45A	Cell 47A	Cell 50A	Cell 53A	Cell 58A	Cell 67A		
Donor chamber	0.023	0.307	1.535	0.190	0.072	0.072	0.194	0.179	0.322	0.499
Skin wash at 6 hours	82.2	65.2	84.2	92.3	82.9	93.0	89.3	91.4	85.1	9.10
Skin wash at 24 hours	3.21	14.1	7.66	2.31	2.89	1.81	2.35	3.11	4.69	4.24
Tape strips 1-2	0.146	0.038	0.071	0.452	0.321	0.026	0.065	0.038	0.145	0.158
Tape strips 3-5	0.119	0.095	0.360	0.092	0.353	0.138	0.950	1.187	0.412	0.424
Remaining skin	10.3	18.1	6.76	4.17	14.9	9.07	11.5	11.7	10.8	4.38
Receptor fluid	0.696	0.988	1.319	0.499	0.989	0.575	0.552	0.503	0.765	0.301
Total recovered	96.7	98.8	102	100	102	105	105	108	102	3.66
Potentially absorbed	11.115	19.183	8.439	4.761	16.242	9.783	13.002	13.39	11.977	4.23
Absorbed	0.696	0.988	1.319	0.499	0.989	0.575	0.552	0.503	0.765	0.301

Remaining skin = skin tissue remaining after tape stripping; Absorbed = amount in receptor fluid; Potentially absorbed = amount in receptor fluid, tape strips 3-5, and remaining skin.

CONCLUSION: The results obtained in this study demonstrate that the absorption of chlorothalonil through human dermatomed skin following the application of chlorothalonil/azoxystrobin SC (A14111B) is slow. The continued absorption into the receptor fluid after the wash off at 6 hours, indicates that the remaining skin serves as a depot, hence tape strips 3-5 and remaining skin should be included as potentially absorbed.

The standard deviation is >25% of the potentially absorbed dose for each concentration, and needs to be added to the mean of the absorption.

For the risk assessment the following values will be used:

	Potentially absorbed (mean)	SD	Mean + SD	Dermal absorption used for risk assessment
Concentrate	0.414%	0.202	0.616%	0.6%
10 g/L (1/40 w/v)	8.174%	3.37	11.544%	12%
1.875 g/L (1/213.3 w/v)	6.785%	4.94	11.725%	12%
0.667 g/L (1/600 w/v)	11.977%	4.23	16.207%	16%

The applicant submitted the following argumentation for lower dermal absorption values. The RMS agrees with this refinement:

Syngenta has performed an EFSA compliant human in vitro dermal absorption study to understand the rate and dermal penetration potential of chlorothalonil from formulation A14111B. Using the EFSA guidance document to interpret the results from this study, highly conservative dermal absorption values (including the standard deviation) of 0.6, 12, 12 and 17% can be derived for the formulation concentrate and the 1/40, 1/213, 1/400 dilutions, respectively.

A review of the dermal absorption data for formulation A14111B indicates that only a very small proportion of chlorothalonil is absorbed across the skin membrane into the receptor fluid by the end of the study, <1% at all dilutions. By contrast, the vast majority of chlorothalonil present in skin (that would be regarded as potentially absorbable according to EFSA guidance) resides in the stratum corneum and remaining skin (Table 6.2-7).

Table 6.2-7*: Chlorothalonil dermal absorption profile from formulation A14111B in a human in vitro dermal absorption study*

	Compartment	***% of Applied Dose***			
		Concentrate (400 g/L)	***Dilution 1 (10 g/L)***	***Dilution 2 (1.88 g/L)***	***Dilution 3 (0.67 g/L)***
A14111B – 400 g/L Chlorothalonil SC formulation; Study Number: DTL JV2271 (IIIA, 7.6.2 - Noakes, 2013) (dermatoned skin, 6 hour wash)	***Stratum corneum Tape strips 3-5 (±SD)***	*0.007 (±0.006)*	*0.165 (±0.113)*	*0.182 (±0.276)*	*0.412 (±0.424)*
	Remaining Skin (±SD)	*0.401 (±0.214)*	*7.89 (±3.55)*	*6.31 (±5.07)*	*10.80 (±4.38)*
	Receptor Fluid + Wash (±SD)	*0.006 (±0.003)*	*0.119 (±0.093)*	*0.293 (±0.182)*	*0.765 (±0.301)*
	Total 'Absorbed' *	***0.6***	***12***	***12***	***17***
	No. of cells	*8*	*8*	*7*	*8*

** - According to EFSA 'Guidance on Dermal Absorption' this is the % of applied dose considered absorbed with the specified rounding and SD included where it is >25% of the mean.*

The flux rate data for each concentration tested in this study show that the rate of penetration into the receptor fluid is slow and relatively constant with time (Fig 6.2-1) throughout the 24 hour exposure

period (Remark RMS: 6 hours exposure, 24h observation period). *These data suggest that, with the constant flux rate, a significant proportion of chlorothalonil residue residing in skin at the end of the study will not become systemically bioavailable and will be lost through desquamation before it is absorbed. Given the large number of sulphydryl groups present in the skin (Ogawa et al., 1979) and chlorothalonil' s high affinity for binding free sulphydryl groups (Long and Siegel, 1975) it is likely that the slow rate of absorption is due to chlorothalonil readily binding to the available protein sulfhydryl groups present in skin. On this basis, the rate of absorption through the skin (i.e. flux rate) is considered to be a more appropriate and realistic measure of potential systemic exposure.*

Figure 6.2-1: The profile of chlorothalonil absorption into receptor fluid over time for the concentrate and all 3 dilutions

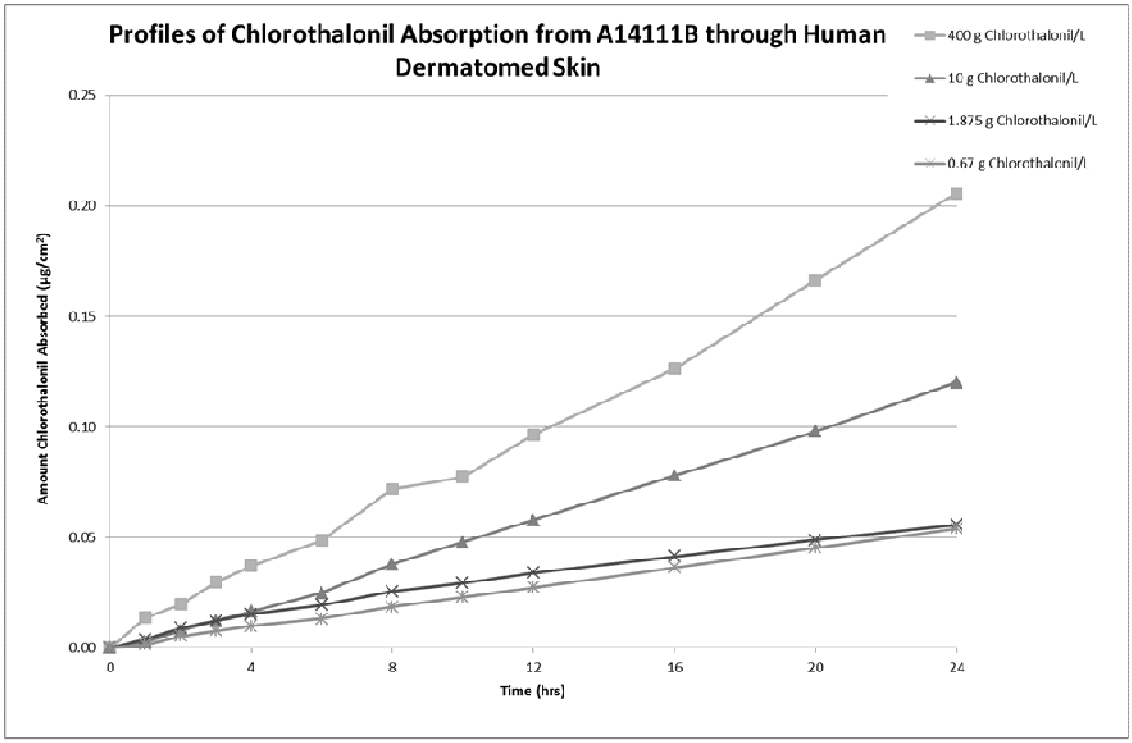

Table 6.2-8: The mean absorption profile of chlorothalonil from A14111B and corresponding flux rate through human skin in vitro

Time (h)	Concentrate (400 g/L)		Dilution 1 (10 g/L)		Dilution 2 (1.88 g/L)		Dilution 3 (0.67 g/L)	
	Amount Absorbed (µg/cm²)	Flux Rate (µg/cm²/hr)	Amount Absorbed (µg/cm²)	Flux Rate (µg/cm²/hr)	Amount Absorbed (µg/cm²)	Flux Rate (µg/cm²/hr)	Amount Absorbed (µg/cm²)	Flux Rate (µg/cm²/hr)
0	0.000	-	0.000	-	0.000	-	0.000	-
1	0.014	**0.0136**#	0.003	0.0027	0.004	0.0039	0.001	0.0014
2	0.020	0.0060	0.008	0.0052	0.009	**0.0051**#	0.005	**0.0040**#
3	0.030	0.0101	0.012	0.0044	0.012	0.0031	0.008	0.0024
4	0.037	0.0073	0.016	0.0041	0.015	0.0030	0.010	0.0021
6	0.049	0.0058	0.025	0.0043	0.019	0.0021	0.013	0.0017
8	0.072	0.0116	0.038	**0.0065**#	0.026	0.0031	0.019	0.0026
10	0.077	0.0028	0.048	0.0049	0.029	0.0019	0.023	0.0023
12	0.097	0.0096	0.058	0.0051	0.034	0.0023	0.027	0.0022
16	0.126	0.0074	0.078	0.0050	0.041	0.0018	0.036	0.0023
20	0.166	0.0100	0.098	0.0050	0.049	0.0018	0.045	0.0022
24	0.206	0.0098	0.120	0.0055	0.056	0.0017	0.054	0.0022
Mean		0.0085	-	0.0048	-	0.0027	-	0.0023
SD	-	0.0031	-	0.0010	-	0.0011	-	0.0007

 # - maximum flux rate

As shown in table 6.2-8, mean flux rates have been calculated for each sampling interval for the concentrate and each dilution as well as the overall mean flux rate across 24 hours. The EFSA guidance states that where the flux rate is to be considered, the maximum flux rate should be used. The maximum flux rate is calculated based on the slope of the linear portion of the absorption:time curve. Given the absorption profiles for the concentrate and dilutions shown in Fig. 6.2-1 showing the flux rates to be relatively constant, with no lag phase or plateau, it can be argued that the use of the average flux rate over the 24hr period rather than the maximum flux rate is appropriate. However, Syngenta has used the maximum flux rate as a conservative estimate for subsequent calculations.

The flux rate can also be used to make a conservative refinement of the % dermal absorption value from the data generated as shown in table 6.2-9. When considering this approach, two additional factors need to be taken into account; firstly, the turnover rate for human epidermis (as an indicator of potential residence time of skin protein bound chlorothalonil residue) and secondly, the rate of excretion of absorbed chlorothalonil from systemic circulation. The turnover rate for the human epidermis is reported to be approximately 39 days (Weinstein et al., 1984[1]). The flux rate can be used to determine the percentage of chlorothalonil that might become systemically bioavailable over a 39 day period. However, the systemic AOEL is a measure of an acceptable exposure within a 24 hour

[1] Weinstein, G.D., McCullough, J.L., Ross, P. (1984). Cell Proliferation in normal Epidermis. *J Invest Dermatol* (1984) 82:623-628.

period; therefore, the rate of excretion of chlorothalonil from systemic circulation also needs to be taken into consideration.

Analysis of the excretion profile following a low dose of chlorothalonil in a number of species shows that it does not accumulate and appears to be fully excreted within 72 hours.

In rats, a modern chlorothalonil biotransformation study has been completed (Punler, 2013). The low dose (5 mg/kg [^{14}C]-chlorothalonil) is considered here to be most representative of operator exposure. The majority (>94%) of the administered radioactivity was excreted by 48 h post dose with excretion essentially complete by 72 h post dose as less than 1% remained in the carcass and gastrointestinal tract. The total mean recovery of administered radioactivity including excreta, cage wash, gastrointestinal tract and residual carcass was 99% in both males and females. This was supported by data from previous studies where male and female rats were administered a single oral dose of 5 mg/kg [^{14}C]-chlorothalonil and groups of 4 animals were terminated at 2, 9, 24, 96 and 168 hours post dose (Marciniszyn, 1984[2], 1985[3]). In males excretion appeared complete by the 96 hour time point, 90% of the dose had been excreted and 0.62% was found remaining in the carcass at termination. Total recovery was 90.62%. In females excretion was complete at 96 hours post dose, 93.4% of the dose had been excreted and 0.73% was found remaining in the carcass at termination. The total recovery was 94.2%.

Additionally, 6 male bile duct cannulated rats were dosed 1.5 mg/kg [^{14}C]-chlorothalonil and terminated 48 hours post dose (Savides, 1986[4]). At 48 hours, biliary excretion accounted for 22.5% of the dose, and 7.9% and 53.0% was excreted in the urine and faeces respectively. Only 1.2% of the dose was found in the remaining carcass and 5.5% remained in the gastro-intestinal tract. The total recovery was 90.2%. To demonstrate that there is no accumulation of chlorothalonil, male rats were administered a repeat oral dose of 5 mg/kg [^{14}C]-chlorothalonil for 5 days. The results from this study showed no progressive increase in blood concentration (Savides, 1985[5]). The studies in rats show that oral doses of chlorothalonil are excreted quickly and there is no evidence of accumulation.

In mice, the lowest dose (1.5 mg/kg) was considered most representative of systemic exposure following operator exposure. Groups of four mice were administered a single oral dose of 1.5 mg/kg [^{14}C]-chlorothalonil and were terminated at 9, 24, 96 and 168 hours post dose (Ribovich, 1983[6]). Excretion in the mouse appeared complete by 96 hours. The excreta data shows that 90% was excreted in the faeces and 6.4% in the urine, and only 0.72% was remaining in the carcass. The overall recovery was 97.5%.

Three male dogs were administered a single oral dose of 50 mg/kg [^{14}C]-chlorothalonil. The majority of the dose was excreted in the faeces. Excretion was essentially complete within 48 hours; 1.4% was excreted in the urine and 93.2% was excreted in the faeces within 48 hours (Magee, 1991[7]). Only a further 0.7% of the dose was excreted between 48 and 72 hours. The

[2] EU review of chlorothalonil please refer to DAR
[3] EU review of chlorothalonil please refer to DAR
[4] EU review of chlorothalonil please refer to DAR
[5] EU review of chlorothalonil please refer to DAR
[6] EU review of chlorothalonil please refer to DAR
[7] EU review of chlorothalonil please refer to DAR

overall recovery mean recovery was 95%. In another study bile cannulated dogs were administered a single oral dose of 50 mg/kg [^{14}C]-chlorothalonil (Savides et al., 1995[8]). Again, excretion appeared complete at 48 hours; 5.1%, 1.4%, 81.3% was excreted in the bile, urine and faeces respectively. Biliary excretion was >90% complete by 26 hours post dose. Only 1.2% of the administered dose was retained in the carcass at 48 hours.

Based on the data available across three species, excretion appears to be complete within 3 days (72 hours) following a single oral dose chlorothalonil. There was no evidence of accumulation in any species; therefore, the flux rate can be used to refine the % dermal absorption value so that it reflects the amount of chlorothalonil that can be absorbed through the skin over 3 days before it is lost through excretion. This is considered a conservative approach as it assumes that no excretion will occur until 3 days after the initial exposure, when in reality excretion will occur steadily throughout this period. This approach is also considered protective for potential repeat exposures, as after 3 days, a steady state will be achieved as the rate of excretion will equal the rate of absorption based on the evidence that no accumulation has been observed in any species. However, as an additional level of conservatism Syngenta have used a 5 day period in subsequent calculations to determine refined % dermal absorption values as presented in Table 7.3-3.

Daily flux rate = Maximum flux rate (µg/cm^2/hr x 24 hr)

Amount of chlorothalonil absorbed in 5 days = Daily flux rate x 5 days

% refined dermal absorption = (Amount of chlorothalonil absorbed in 5 days / Total amount of chlorothalonil recovered) x 100

Table 6.2-9: Refined % dermal absorption values for chlorothalonil based on the flux rate.

	Compartment	**% of Applied Dose**			
		Concentrate (400 g/L)	**Dilution 1 (10 g/L)**	**Dilution 2 (1.88 g/L)**	**Dilution 3 (0.67 g/L)**
A14111B – 400 g/L Chlorothalonil SC formulation; Study Number: DTL JV2271 (Noakes, 2013) (dermatoned skin, 6 hour wash)	**Maximum flux rate (µg/cm^2/hr)**	*0.0136*	*0.0065*	*0.0051*	*0.004*
	Daily flux rate (µg/cm^2/day)	*0.3264*	*0.156*	*0.1224*	*0.096*
	Amount of Chlorothalonil absorbed in 5 days (µg/cm^2)	*1.632*	*0.780*	*0.612*	*0.480*
	Total amount of Chlorothalonil recovered (µg/cm^2)	*3433*	*105*	*21.1*	*7.21*
	Refined % 'Absorbed'#	***0.05***	***0.7***	***3***	***7***

 # - Dermal absorption rounding applied based on EFSA guidance.

Based on the overall weight of evidence, it is proposed that the flux rate of chlorothalonil is a more relevant representation of systemic exposure because:

[8] EU review of chlorothalonil please refer to DAR

- *Evidence from a number of human in vitro dermal absorption studies indicates that only very low levels of chlorothalonil penetrate to the receptor fluid.*
- *The flux rate across of chlorothalonil from A14111B in the human in vitro study shows that the rate of absorption is relatively constant and slow, limiting potential systemic exposure for the formulation concentrate and all the dilutions.*
- *The sensitive endpoint on which the chlorothalonil AOEL is set (kidney toxicity) is not evident in the repeat dose dermal toxicity study in rats following a repeat application of >600 mg/kg bw/day.*

Therefore, for formulation A14111B, refined % dermal absorption values of 0.05%, 0.7%, 3% and 7% are proposed for chlorothalonil for the formulation concentrate and the 1/40, 1/213, 1/400 dilutions respectively. This data is considered to be more representative of potential human systemic exposure.

B.6.3 Available toxicological data relating to co-formulants

B.6.4 Exposure data

Product information

Product: A14111B
Purpose: Fungicide
Active substance (a.s.): Chlorothalonil
Product type: Suspension Concentrate (SC)
Package size: 250 ml (45 mm neck)
1L (45 mm neck)
5L (63 mm neck)
10L (63 mm neck)

Table 6.4-1 describes the critical use patterns that has been defined following of the individual GAPs for each crop.

Table 6.4-1 Summary of critical use (i.e. worst case)

Application equipment	Crop	Max Application rate (kg product/ha)	Max Application rate (kg a.s./ha)	Spray dilution (L/ha)	Spray dilution (g/l)	Number applica-tions	Critical use
Tractor mounted, low crop	Wheat, barley	1.875	0.75	100-400	1.9-7.5	2	
Tractor mounted, low crop	Tomato	2.5	1.00	500-1500	0.67-2.0	1	Bystander, resident
Handheld, low crop	Tomato	2.5	1.00	500-1500	0.67-2.0	1	Operator, worker

B.6.4.1 Operator exposure

Estimations of potential operator exposure for the formulation A14111B are made for the intended critical uses described in table 6.4-1 and the following predictive models:

- Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection); Mitteilungen aus der Biologischen Bundesanstalt, Heft 277, Berlin 1992 ("German model")
- Revised UK POE Model, UK Predictive Operator Exposure Model (POEM): Estimation of Exposure and Absorption of Pesticides by Spray Operators, Scientific subcommittee on Pesticides and British Agrochemical association Joint Medical Panel Report (UK MAFF), 1986 and the Predictive Operator Exposure Model (POEM) V 7 of 2008 ("UK POEM")

The exposure estimations were compared to the Acceptable Operator Exposure Level of 0.009 mg/kg bw/day (see Volume 1, level 2, point 2.6.13). The following dermal absorption values are used (see Volume 3, B.6.2) :

Test	**% of applied dose**			
	Concentrate (400 g/L)	**Spray dilution 1 (1/40; 10 g/L)**	**Spray dilution 2 (1/213; 1.88 g/L)**	**Spray dilution 3 (1/600; 0.67 g/L)**
***In vitro* (human)**	0.05	0.7	3	7

In cereals, the in-use dilution is 7.5 g/L. This is closer to the tested 10 g/L than to the tested 1.9 g/L. An approximate dermal absorption of 1% is assumed for the 7.5 g/L dilution.

B.6.4.1.1 Estimation of operator exposure without personal protective equipment

The input parameters that were applied in the models for the operator exposure estimation are described in Table B.6.4.1.1-1 to B.6.4.1.1-3.

Table B.6.4.1.1-1 Input parameter in the German model

Application method	Input parameter
Tractor-mounted sprayer, field crops (wheat, barley)	Treated area: 20 ha/day Max. dose rate: 0.75 kg chlorothalonil/ha Operator body weight: 70 kg Dermal absorption spray dilution: 3%
Tractor-mounted sprayer, field crops (tomato)	Treated area: 20 ha/day Max. dose rate: 1.0 kg chlorothalonil/ha Operator body weight: 70 kg Dermal absorption spray dilution: 7%

Hand-held application, high crops (tomato, low crop)	Treated area: 1 ha/day Max. dose rate: 1.0 kg chlorothalonil/ha Operator body weight: 70 kg Dermal absorption spray dilution: 7%

Application method	Input parameter
Tractor-mounted sprayer, field crops (wheat, barley)	Treated area/duration: 50 ha/day, 6 hours Max. dose rate: 0.75 kg chlorothalonil /ha Spray volume: 100 L/ha Operator body weight: 60 kg Packaging: 5L* (54 mm neck) Dermal absorption spray dilution: 1%**
Tractor-mounted sprayer, field crops (tomato)	Treated area/duration: 50 ha/day, 6 hours Max. dose rate: 1.0 kg chlorothalonil /ha Spray volume: 500 L/ha Operator body weight: 60 kg Dermal absorption spray dilution: 3%
Hand-held application, field crops (tomato)	Treated area/duration: 1 ha/day, 6 hours Max. dose rate: 1.0 kg chlorothalonil /ha Spray volume: 500 L/ha Operator body weight: 60 kg Dermal absorption spray dilution: 3%

* The use of 1L bottles is considered too worst case for 50 ha/day, as this will involve 94 mixing and loading operations. A 5L bottle is a realistic worst case, with 19 handling operations.

** An approximate dermal absorption of 1% is assumed for the 7.5 g/L dilution.

The operator exposure estimates are summarized in Table B.6.4.1.1-3. The detailed calculator spreadsheet are included in Appendix 1.

Table B.6.4.1.1-3 Exposure prediction and risk assessment without PPE

Application method	**Model**	**Without PPE (mg/kg bw/day)**	**% of AOEL**	**With PPE (mg/kg bw/day)**	**% of AOEL**
Tractor-mounted sprayer, field crop **cereals**	German model	0.0137	152	0.0015[a]	17
	UK POEM	0.0601	668	0.0156[b]	173
Tractor-mounted sprayer, field crop **tomato**	German model	0.0416	462	0.0037[a]	41
	UK POEM	0.0444	493	0.0085[b]	94
Hand-held application, field crops **tomato**	German model	0.0469	521	0.0088[c]	98
	UK POEM	0.1069	1188	0.0228[d]	253

[a] Protective gloves and protective garment and sturdy footwear during application

[b] Protective gloves during mixing, loading and application

[c] Protective gloves during mixing, loading and application, and protective garment, sturdy footwear and broad-brimmed headgear during application

[d] Protective gloves during mixing and loading, and gloves and impermeable coverall during application

Conclusion

According to the German BBA model, it can be concluded that the risk for the operator using A14111B on cereals and tomatoes is acceptable with PPE.

According to the UK POEM calculations, it can be concluded that the risk for the operator using A14111B on tomatoes is acceptable with PPE only for tractor mounted spraying.

According to the UK POEM calculations, it can be concluded that no safe use is calculated for the operator using A14111B on cereals (tractor mounted) or tomatoes (handheld) even with the use of PPE during mixing/loading and application.

B.6.4.1.2 Estimation of operator exposure with personal protective equipment

The operator exposure estimates assuming that protective clothing is worn are summarized in Table B.6.4.1.1-3 in B.6.4.1.1. The detailed calculator spreadsheet are included in Appendix 1.

B.6.4.1.3 Measurement of operator exposure with personal protective equipment

An operator exposure study was performed to refine the risk assessment (Wilson, 2012). The study is evaluated below the table. Cabin equipped tractors were used in this study and all the windows were kept closed during the crop treatment.

In the study, Reglone® was applied at a target rate of 4.0 L/ha (800 g diquat cation/ha). The actual application rate was 706 to 803 g diquat cation/ha. The application volume was in the range of 250 to 483 L/ha, depending on crop canopy and the typical practices of each operator.

These values are similar to the application rate for A14111B in cereals, being 750 g chlorothalonil/ha in a volume of 100-400 L/ha. A justification for the use of the study to refine the exposure assessment for chlorothalonil is given below.

Table 6.4.1.3-1: Comparison of proposed use of A14111B with diquat exposure study

	Proposed use of A14111B chlorothalonil	**Application parameters for Diquat exposure study**
Application method	Field crop boom sprayer	Field crop boom sprayer
Formulation	400 g/L SC	200 g/L SC
Application rate (g a.s./ha)	750	706 - 803
Water volume (L/ha)	100 - 400	250 - 483
Area treated (ha)	Cereals, so assume full working day – German model assumes 20 ha, UK POEM 50 ha	21.6 to 63.3
Duration of spraying	Cereals, so assume full working day – UK POEM assumes 6 hours for application of spray solution plus 2 hours for mix/loading and travelling to field(s)	5.38 to 8.82

The exposure assessment is performed using the diquat exposure study values for (actual) dermal and inhalation exposure as reported in the study, i.e. these values have not been adjusted for differences in the application rate between chlorothalonil (750 g a.s./ha) and diquat (706 g a.s./ha to 803 g a.s./ha).

Table B.6.4.1.3-1 Exposure measurements and risk assessment in cereal (tractor mounted) with the use of PPE

	Arith mean	75th percentile	95th percentile	Maximum value
Actual dermal exposure (ug diquat/kg bw/d)	4.6003	4.4506	13.4832	17.1089
Inhalation exposure (ug diquat/kg bw/d)	0.0129	0.0129	0.039	0.0541
Total exposure (ug diquat/kg bw/d)	4.6132	4.4635	13.5222	17.163
Total systemic exposure (mg/kg bw/d)	0.000151	0.000146	0.000443	0.000567
% of AOEL (0.009 mg/kg bw/d)	2	2	5	6

The application rate in tomato is slightly higher (1 kg as/ha, instead of the 0.75 kg as/ha in the study); this will increase the exposure, but considering the measured exposure in the study and the corresponding risk assessment, the slightly higher application rate in tomato is expected to result in a safe use as well, even with an increased dermal absorption of 7% instead of 3% used in cereals. The study is considered to be applicable for tomato as well as cereals.

Table B.6.4.1.3-2 Exposure measurements and risk assessment handheld low crops with the use of PPE

		75th percentile	95th percentile	Maximum value
Actual dermal exposure (ug diquat /kg bw/d)		36.15	43.18	46.3
Inhalation exposure (ug diquat/kg bw/d)		4	4	4

Total exposure (ug diquat/kg bw/d)		0	0	0
Total systemic exposure (mg/kg bw/d)		0.009784	0.010909	0.011408
% of AOEL (0.009 mg/kg bw/d)		109	121	127

Previous evaluation:	*Submitted for the purpose of renewal, new data*
RMS remarks	*Acceptable. The RMS agrees with the conclusions drawn by the applicant. This study was submitted for the renewal of diquat, discussed in the expert meeting, and considered acceptable for diquat by the experts.*

Report:	K-CP 7.2.1.2/01, Wilson A. (2012). Diquat - Determination of Operator Exposure (Passive Dosimetry) during Typical Activities Associated with Mixing/Loading and Application of Reglone® (Soluble Concentrate Containing 200 g/L Diquat cation) as a Desiccant to Ware Potatoes in The Netherlands, 2011. AgroChemex International Ltd, Aldhams Farm Research Station, Lawford, Essex, UK. Report No. ACI11-003, Issue date 12 February 2012. Unpublished. (Syngenta File No. A1412A_10300)

Guidelines: OECD/GD (97)148 Series on Testing and Assessment No. 9, Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application, Organisation for Economic Cooperation and Development, Paris.

Deviations: None

GLP: Yes

Executive Summary
In 2011, a Good Laboratory Practice (GLP) operator exposure study was conducted with thirteen operators in The Netherlands. The study was performed to determine the dermal and inhalation exposure to diquat during typical activities associated with a ground boom application of Reglone® as a desiccant to ware potatoes.

Reglone® was mixed and sprayed as closely as possible to normal practices using commercial tractor mounted (self-propelled) or trailed boom sprayers. Cabin equipped tractors were used in this study and all the windows were kept closed during the crop treatment.

Reglone® was applied at a target rate of 4.0 L/ha (800 g diquat cation/ha). The actual application rate was 706 to 803 g diquat cation/ha. The application volume was in the range of 250 to 483 L/ha, depending on crop canopy and the typical practices of each operator.

The duration of each application was 5.38 to 8.82 hours (from the start of mixing/loading to completion of spraying, excluding scheduled breaks). The area actually treated was 21.6 to 63.3 ha. The total amount of formulated product and corresponding active substance handled by each operator was between 81 and 252 L of formulation and 16.2 to 50.4 kg of corresponding diquat cation.

Materials

Test Material:	Reglone®
Description:	Soluble concentrate (SL)
Lot/Batch Number:	BSN1G1438, BSN1F1050, BSN1H0432, BSN1G1429, BSN1G0437, BSN1H0827
Purity:	Nominal 200 g/L diquat cation
Stability of test compound:	Stable for the duration of the study

Study Design and Methods
Field Phase dates: 23rd August 2011 to 15th September 2011

Experimental dates: 29th September 2011 to 20th December 2011

Study Description:

13 operators were monitored between 23rd August 2011 and 15th September 2011.

The purpose of the study was to determine the dermal and inhalation exposure to diquat during typical activities associated with the mixing and loading and ground boom application of Reglone® as a desiccant to ware potatoes.

Dermal exposure to diquat cation was measured by operators wearing standardised whole-body outer and inner dosimeters. The outer dosimeter consisted of a 35/65% cotton/polyester coverall. The inner dosimeter, representing the skin, consisted of a full-length cotton undergarment covering arms, legs and torso.

Head exposure was measured by face/neck wipes.

Actual hand exposure was measured by the handwash procedure. Protective gloves, worn in accordance with label recommendations (one pair for mixing and loading tasks and one pair for maintenance tasks), were analysed for the determination of potential hand exposure.

Inhalation exposure was measured by means of personal air sampling pumps connected to an IOM sampling cassette with cellulose ester fibre filter located in the operator's breathing zone.

All samples collected were analysed for residues of diquat cation.

Inner and outer dosimeters, face/neck wipes and nitrile gloves were extracted with ammonium formate/acetonitrile by shaking. Extracts were analysed by high performance liquid chromatography using triple quadrupole mass spectrometry LC-MS/MS.

Hand wash solutions were directly analysed by LC-MS/MS.

Air sampling filters were extracted with ammonium formate/acetonitrile in an ultrasonic bath and aliquots analysed by GC-MS.

Results

Since all mean field fortification recoveries were greater than 91% operator exposure results have not been corrected. Where a residue below the limit of quantification (LOQ) or limit of detection (LOD) has been found a value of 0.5 x LOQ has been reported and used in summary calculations.

The following table gives a summary of the residues of test item on each dosimeter for each operator.

Potential dermal exposure is calculated by summing all dermal exposure residues. Actual dermal exposure is calculated by summing residues from inner dosimeters, hand wash and face/neck wipe specimens. Potential inhalation exposure is the residues measured in the breathing zone based upon a ventilation rate of 16.7 L/min for tasks.

Table 7.2.1.2-1: Determined Residues of diquat cation (all values in µg/sample)

Operator Number	1	2	3	4	5	6	7	8	9	10	11	12	13
Body Weight (kg)	134.0	90.4	89.4	95.8	83.2	71.0	81.1	101.0	74.5	115.1	80.9	93.0	102.5
Work Duration (mins)	451.0	504.0	406.0	475.0	510.0	494.0	406.0	370.0	323.0	323.0	391.0	529.0	380.0
Diquat cation mixed (kg)	34.0	36.8	26.8	24.5	38.4	16.2	26.8	36.0	32.4	39.2	43.2	50.4	28.0
Area Sprayed (ha)	42.4	48.8	34.8	34.3	47.8	21.6	35.0	46.0	41.0	54.0	55.8	63.3	35.0
Volume of air samples (L)	856.9	982.8	812.0	950.0	1020	963.3	791.7	721.5	646.0	646.0	782.0	1058	760.0
Outer Dosimeter – cotton/polyester coverall													
lower arms	26.25	379.88	523.13	61.38	1267.89	394.54	436.95	245.93	650.02	3251.03	453.25	122.41	527.41
upper arms	3.13	109.69	212.23	17.73	113.92	80.10	44.60	20.14	96.29	121.35	135.44	50.20	129.03
lower legs	944.46	8273.99	1479.36	203.32	1000.75	1731.92	473.46	107.52	126.60	5106.59	296.07	153.86	419.58
upper legs	440.30	144.55	151.57	38.47	265.95	543.27	1611.44	419.96	492.36	2611.38	241.99	369.29	211.03
front torso	725.24	240.54	328.07	88.91	590.90	243.75	4469.49	22.01	108.89	4515.13	700.38	91.86	1946.83
rear torso	5.01	150.68	77.17	11.65	106.28	151.44	73.12	25.28	57.77	226.20	67.89	51.02	174.10
TOTAL	2144.39	9299.33	2771.53	421.45	3345.69	3145.03	7109.06	840.84	1531.93	15831.67	1895.02	838.63	3407.98
Inner dosimeter (representing the skin)													
lower arms	2.261	14.768	7.421	1.446	31.889	87.928	17.001	6.502	7.847	12.551	21.849	4.948	14.753
upper arms	*0.050*	1.954	5.100	*0.500*	16.892	*0.500*	1.113	1.189	1.044	2.117	4.219	*0.500*	1.440
lower legs	1.512	2.455	2.235	*0.500*	1.351	3.081	1.467	4.282	1.087	2.519	4.755	2.294	*0.500*
upper legs	1.407	2.025	2.483	1.081	1.575	1.662	7.073	2.022	*0.500*	5.704	5.653	9.410	*0.500*
torso	2.458	9.702	11.971	1.564	5.493	1.546	4.922	5.111	2.044	18.901	15.241	3.480	4.050
TOTAL	7.688	30.903	29.210	5.092	57.200	94.716	31.575	19.106	12.521	41.792	51.717	20.632	21.243
Handwash													
Measured	*10.0*	547.2	239.4	109.4	842.0	25.9	1350.6	427.0	218.9	429.4	159.5	366.1	13.0
TOTAL	*10.0*	547.2	239.4	109.4	842.0	25.9	1350.6	427.0	218.9	429.4	159.5	366.1	13.0
Face/neck wipes													
Measured	*0.500*	5.698	2.455	*0.500*	21.440	1.921	5.384	3.453	1.505	11.220	9.998	5.940	1.453
TOTAL	*0.500*	5.698	2.455	*0.500*	21.440	1.921	5.384	3.453	1.505	11.220	9.998	5.940	1.453
Nitrile Gloves													
mixing	2218.6	7668.1	10642.7	187.0	1457.3	3964.9	3745.6	229.0	1322.7	8396.8	1389.6	1101.2	201.0
application		12.4	107.8	27.3	3833.1	1121.0	8091.5			17685.4	2830.3		243.3
TOTAL	2218.6	7680.5	10750.5	214.4	5290.4	5085.9	11837.0	229.0	1322.7	26082.2	4219.8	1101.2	444.2
Residues in air sampling tubes													
Measured	*0.003*	0.084	0.077	*0.003*	0.289	0.448	0.116	*0.003*	*0.003*	0.159	0.095	0.144	0.273
TOTAL	*0.003*	0.084	0.077	*0.003*	0.289	0.448	0.116	*0.003*	*0.003*	0.159	0.095	0.144	0.273

Values in italics are <LOQ. Half the LOQ is taken for the calculations

Table 7.2.1.2-2: Summary of Field Results in µg/operator

Operator Number	1	2	3	4	5	6	7	8	9	10	11	12	13
PDE	4381	17564	13793	751	9557	8353	20334	1519	3088	42396	6336	2333	3888
ADE	18.2	584	27	115	921	122	1388	450	233	482	221	393	36
PIE	0.022	0.715	0.645	0.021	2.416	3.838	0.990	0.021	0.021	1.324	0.795	1.198	2.280

PDE: Potential Dermal Exposure = Sum of residues on outer clothing (coverall), inner dosimeter representing the skin, face/neck wipes, protective gloves (nitrile – if worn) and handwash solutions.
ADE: Actual Dermal Exposure = Sum of residues on inner dosimeter representing the skin, face/neck wipes and hand wash solutions.
PIE: Potential Inhalation Exposure = Residues measured in the breathing zone expressed as µg diquat cation/operator based on an inhalation rate of 16.7 L/min.

B.6.4.2 Bystander and resident exposure

Bystander and resident exposure was estimated according to S. Martin (2008). The model covers the bystander and the residents in a comprehensive way. It differentiates between adults (body weight 60 kg) and 2 to 5 year old children (body weight 16.15 kg) and takes into account the following parameters:

For bystanders

- Dermal exposure through drift at a distance of 10 m from the edge of the field and considering an uncovered body area of 1 m2 for adults and 0.21 m2 for children.
- Exposure through inhalation assuming a conservative specific inhalation exposure of 1 µg (adult) and 0.575 µg (child), respectively per kg a.s. handled per day for a field crop application (20 ha/day) and an exposure period of 5 minutes.

For residents

- Contaminations of the resident area (turf) through spray drift at a distance of 10 m from the edge of the field.
- 5% transfer of residues from contaminated turf to wet hands
- Transfer coefficients = 7300 cm2/hour for adults and 2600 cm2/hour for children
- 2 hours of exposure
- Airborne concentration of 15 µg/m3 for volatile substances (vapour pressure ≥5 x 10-3 Pa), 1 µg/m3 for semivolatile substances (vapour pressure 1 x 10-5Pa to 5 x 10-3 Pa) and none for non-volatile substances. Inhalation exposure during 24 hours/day at an inhalation rate of 16.57 and 8.31 m3/day adults and children, respectively. Chlorothalonil vapor pressure: 7.62 x 10 –5 Pa at 25°C
- Saliva extraction factor of 50% for hand-to-mouth transfer
- 20 hand to mouth operations per hour for a child; 20 cm2 of skin area is contacted each time a child puts a hand in her or his mouth

- For ingestion of grass through a child a 20% transferability factor (grass to mouth) from 25 cm2 of grass is assumed
- Oral absorption 32%

For cereals, as a conservative approach for repeated applications, the 82nd percentile drift value for twice the single maximum application rate corresponding to an overall 90th percentile was used in order to account for potential residues that may originate from preceding applications on top of the terminal application.

The bystander and resident exposure estimation was compared to the AOEL systemic value of 0.009 mg/kg bw/d.

The following worst case dermal absorption values were used:
Cereals (1.88 g/L): 3%
Tomatoes (0.67 g/L): 7%

Summary results are provided in the following tables. The detailed calculation is given in Appendix 1.

Table 6.4.2-1 Estimated bystander exposure to chlorothalonil and % of AOEL (0.009 mg/kg bw/d)

Exposure (mg/kg bw/d)	Bystander		Resident	
	Adult	Child	Adult	Child
Cereals				
Total systemic exposure	0.00011	0.00009	0.00029	0.00055
% of AOEL	1	1	3	6
Tomato, tractor				
Total systemic exposure	0.00034	0.00027	0.00030	0.00056
% of AOEL	4	3	3	6
Tomato, handheld				
Total systemic exposure	0.00007	0.00015	0.00028	0.00051
% of AOEL	1	2	3	6

It is concluded that there is no undue risk to any bystander or residents after exposure to A14111B during or after downward spraying in cereals or tomatoes.

B.6.4.3 Worker exposure

B.6.5 Exposure and risk assessment

Worker exposure was estimated by the German re-entry model, according to Hoernicke E et al. (1998):.

- Hoernicke E et al. (1998): Details in the instructions for use on the protection of persons carrying out successive work with crops which have been treated with plant protection products. Nachrichtenbl. Deut. Pflanzenschutzd. 50, 267-268; in conjunction with: Krebs et al. (2000): Uniform principals for ensuring health protection for workers when re-entering treated crops following the application of plant protection products. Nachrichtenbl. Deut. Pflanzenschutzd. 52, 5-9 (both in German).

  This paper also has been converted into a computer-supported mathematical model which is available on the BfR homepage:
  Schutz von Personen bei Nachfolgearbeiten (Safeguarding the Health of Workers - Re-Entry Exposure) (xls)

For the DFR value, the German re-entry model recommends a default value of 1 µg/cm2 per kg a.s./ha. This is confirmed to be a worst case estimation, based on the DFR study in cereals (see B.6.4.3.2).
For manual harvesting of tomatoes an indicative TC value for vegetables of 2500 cm2/hr is used and a worst case working day of 8 hours which however does not represent the most common practice. All the crops considered in the present dossier are highly mechanized, hence re-entry operations are reduced and working day of 2 hours is assumed for inspection activities, and a TC of 1400 cm2/hr is used, according to the EFSA exposure guidance.
A worst case body weight of 60 kg is assumed.

The following worst case dermal absorption values were used:
Cereals (1.88 g/L): 3%
Tomatoes (0.67g/L): 7%

The worker exposure estimation was compared to the AOEL systemic value of 0.009 mg/kg bw/d. Results are provided in the following Table.

Table B.6.4.3.1-1 Systemic worker exposure prediction and risk assessment without and with PPE

Application method	Without PPE (mg/kg bw/day)	% of AOEL	With PPE (mg/kg bw/day)	% of AOEL
Crop inspection **cereal**	0.0021	23	0.0001	1
Crop inspection **tomato**	0.0014	16	<0.0001	1
Manual harvesting **tomato**	0.0233	259	0.0012	13

B.6.4.3.2 Refinement by DFR study

The notifier submitted a DFR study in cereals, to refine the worker risk assessment. From the study, a DT50 = 16.3 days is obtained and a DFR of 0.8405 µg/cm²/kg is calculated on wheat for chlorothalonil. In cereals, where 2 applications are foreseen, after 14 days at the time of the second application only around 60% of the rate of the first application is left.

In Table B.6.4.3.2-1, the worker exposure in cereals is refined by using a DRF of 0.8405 µg/cm²/kg, as calculated from the results of the DRF study, which is evaluated below the table.

Table B.6.4.3.2-1 Refined systemic worker exposure prediction and risk assessment without and with PPE

Application method	Without PPE (mg/kg bw/day)	% of AOEL	With PPE (mg/kg bw/day)	% of AOEL
Crop inspection **cereal** **Refined using DFR study**	0.0018	20	<0.0001	1
Crop inspection **tomato**	0.0014	16	<0.0001	1
Manual harvesting **tomato**	0.0233	259	0.0012	13

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing (but no PPE), when crop-inspection activities in cereals and tomato treated with A14111B. For hand harvesting tomato it is concluded that there is no unacceptable risk anticipated for the worker wearing adequate PPE, when hand harvesting tomatoes treated with A14111B.

Previous evaluation	*Submitted for the purpose of renewal, new data*
Evaluation RMS	*Acceptable. The RMS agrees with the conclusions drawn by the applicant.*

Report:	Roussel, C. (2015). Chlorothalonil and Azoxystrobin - Determination of Dislodgeable Foliar Residues of Chlorothalonil and Azoxystrobin on wheat leaves after one application of A14111B in Northern Europe (UK and Northern France), 2014. Staphyt, 23 rue de Moeuvres, F-62860 Inchy en Artois, France Study Dates: 22 May 2014 – 02 September 2015. Report Number ChR-14-19410 (Syngenta Regulatory Document No. A14111B_11228)

Guidelines

OECD Series on Testing and Assessment No. 9 ”Guidance document on the conduct of studies of occupational exposure to pesticides during agricultural application ”, Paris 1997. OCDE/GD(97)148.
European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000).
Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 (for residue studies), specifically OECD Test Guideline 509, (Crop field trials) and OECD (2011) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66).

This study was conducted in broad compliance with the U.S. EPA Series 875.2100 Occupational and Residential Exposure Test Guidelines. Foliar Dislodgeable Residue Dissipation (February 1996)

GLP
Fully GLP compliant study.

I. MATERIALS AND METHODS

A MATERIALS

A1 Test System, Test Item and Reference Item

Test system	The following test system is representative of the crop group required for product registration: Wheat (Triticum aestivum) EPPO - Code: TRZAW	
Test Item(s)	Formulation – Company Code	A14111B
	Formulation Content and Type	080/400 SC
	Batch No.	GRA1A063B/1
	Valid until:	End of Dec 2014 (re-analysis date)
	Active ingredients	Azoxystrobin Chlorothalonil
	Nominal Content in Formulation (nominal)	80 g/L azoxystrobin 400 g/L chlorothalonil
	Actual Content in Formulation (actual)	74.7 g/L azoxystrobin 384 g/L chlorothalonil
	Stability	The test item is assumed to be stable for the period of use in the study, pending concurrent batch re-analysis since it was stored below 30°C

A2 Test Facilities

The Field Phase was conducted at four sites in Northern France and the United Kingdom between 10 June 2014 and 16 July 2014.
The Analytical Phase was conducted at The Analytical Phase was conducted at Eurofins Agroscience Services Chem SAS, Vergèze, France between 25 November 2014 – 29 July 2015.

B FIELD PHASE

Four dislodgeable foliar residue field trials on wheat were conducted in the United Kingdom and Northern France during 2014.
Details of the application of chlorothalonil and azoxystrobin to wheat in trials ChR-14-19410 UK01, ChR-14-19410 FR02, ChR-14-19410 FR03 and ChR-14-19410 FR04 are summarised in Table IB-1.

Table IB-1: Treatment details for Trials ChR-14-19410 UK01, ChR-14-19410 FR02, ChR-14-19410 FR03 and ChR-14-19410 FR0

Trial. ChR-19410-	Applications	Application date	Formulation Code	Product rate (L/ha)	Actual spray volume (L/ha)	Growth stage at application (BBCH)	AI application rate (g ai/ha)		
							AI Name	Actual	Target
UK01	1	24 Jun 2014	A14111B	2.615	208	69	Azoxystrobin	209	200
							Chlorothalonil	1046	1000
FR02	1	12 Jun 2014	A14111B	2.445	194	69	Azoxystrobin	196	200
							Chlorothalonil	978	1000
FR03	1	11 Jun 2014	A14111B	2.487	297	69	Azoxystrobin	199	200
							Chlorothalonil	995	1000
FR04	1	10 Jun 2014	A14111B	2.487	198	69	Azoxystrobin	199	200
							Chlorothalonil	995	1000

B5 Sampling

Following the application, wheat leaves samples were collected in triplicate at 0 DAA1 as soon as spray deposit had dried and 8 hours (+/-1) after application; then 1, 2, 3, 5, 7, 14-15, 21-22 and 28-29 days after application. In trial UK01, sampling at 28 DAA1 was not performed because the leaves were already too dry. Each specimen was made of 20 wheat leaves and represented 2 upper leaves taken on 10 shoots randomly chosen.

On each sampling date, the leaves were taken in places kept untouched since application. Three replicates were sampled on each sampling date. 20 leaves were sampled from sub sampling area: each sample was made of 2 upper leaves on 10 shoots randomly selected in order to represent the upper part of foliage susceptible to be in contact with a worker entering the wheat field.

The leaves specimens were transferred to the test site under 'cool' conditions using blue ice.

B6 Leaf washing

All specimens of 20 leaves underwent a dislodging process at the test site within 4 hours of sampling. This procedure consists of mechanically shaking the foliage for 10 minutes with two sequential 400ml washes with an aqueous solution of 0.01% w/v Aerosol OT100 (dislodging solution).

Half the final solution was transferred into a bottle identified for chlorothalonil analysis. This bottle was acidified with 3 vials of HCl 1M (1.2 ml each) and wrapped in aluminium foil. The remaining 400 ml bottle was identified for azoxystrobin analysis. Both bottles were stored in freezers until shipment.

On two sampling events (1DBA and 22DAA) one extra field specimen of 20 leaves was taken in C1 plot to produce blank leaf wash solution. After the leaf washing procedure, 50 mL of control leaf wash specimens were added to 6 labelled bottles (125 ml). For azoxystrobin: 3 leaf wash specimens were each spiked with 100 µL of a solution containing 0.125 µg/mL (low rate fortification). In addition, 3 leaf wash specimens were each spiked with 100 µL of a solution containing 150 µg/mL. For chlorothalonil: 3 vial filled with 0.9 ml of acetonitrile were each spiked with 100 µL of a solution containing 0.125 µg/mL (low rate fortification). In addition, 3 other vials were each spiked with 100 µL of a solution containing 750 µg/mL. The fortified vial spiking were done with a micro pipet or Hamilton syringe. The leaf wash solution spiking were done by emptying the fortified vials in the leaf wash specimens and adding them (without the lid) into the solution. Then, the final solution was acidified with 500 µL of HCl 1M. Leaf wash specimens were kept deep frozen at or below -18°C during transport and storage prior to analysis.

C ANALYTICAL PHASE

Samples of wash solutions were analysed by Method GRM057/05A. The analytical method has been validated for analysis of chlorothalonil and azoxystrobin in leaf wash solutions. Determination of azoxystrobin was by LC-MS/MS. Determination of chlorothalonil was by GC-MS/MS. Field fortifications were analysed alongside the field specimens to demonstrate the stability of azoxystrobin and chlorothalonil in the leaf wash solutions.

II RESULTS AND DISCUSSION
A RESULTS OF ANALYSIS OF FIELD TRIAL SAMPLES
A1 Results of Trial Number ChR-14-19410 UK01

Residues of azoxystrobin and chlorothalonil in total leaf wash specimens from wheat leaves taken from Trial ChR-14-19410 UK01 are shown in Table IIA-1 and Table IIA-2.

Table IIA-2: Chlorothalonil residues in/on leaf washes from wheat treated at 1000 g AI/ha

Sample No. ChR-14-19410 UK01-	Number and Nominal Rate of Application	Sampling Interval	Sampling Interval	Area	Matrix	Chlorothalonil		
						Total Residue† (µg/L)	Residue (µg/cm^2)	Residue (µg/cm^2)
	(kg ai/ha)	(days)	(hours)	(cm^2)		Uncorrected	Uncorrected	Uncorrected Mean*
7-CTN	1 x 1	0DAA	-	966	Total washings 1	708.23	0.586526	0.566384
8-CTN	1 x 1	0DAA	-	841	Total washings 2	694.41	0.660553	
9-CTN	1 x 1	0DAA	-	950	Total washings 3	536.84	0.452074	
10-CTN	1 x 1	0DAA	8HAA	963	Total washings 1	518.70	0.430907	0.446222
11-CTN	1 x 1	0DAA	8HAA	988	Total washings 2	592.85	0.480042	
12-CTN	1 x 1	0DAA	8HAA	1116	Total washings 3	596.67	0.427718	
13-CTN	1 x 1	1DAA	-	818	Total washings 1	700.39	0.684982	0.706845
14-CTN	1 x 1	1DAA	-	1032	Total washings 2	887.95	0.688332	
15-CTN	1 x 1	1DAA	-	977	Total washings 3	912.54	0.747221	
16-CTN	1 x 1	2DAA	-	870	Total washings 1	882.79	0.811763	0.644190
17-CTN	1 x 1	2DAA	-	870	Total washings 2	664.91	0.611409	
18-CTN	1 x 1	2DAA	-	1006	Total washings 3	640.57	0.509399	
19-CTN	1 x 1	3DAA	-	951	Total washings 1	598.52	0.503487	0.492122
20-CTN	1 x 1	3DAA	-	973	Total washings 2	586.21	0.481984	
21-CTN	1 x 1	3DAA	-	933	Total washings 3	572.51	0.490895	
22-CTN	1 x 1	5DAA	-	1478	Total washings 1	895.31	0.484607	0.383307
23-CTN	1 x 1	5DAA	-	1351	Total washings 2	471.04	0.278927	
24-CTN	1 x 1	5DAA	-	1385	Total washings 3	668.93	0.386385	
25-CTN	1 x 1	7DAA	-	1068	Total washings 1	714.43	0.535152	0.498692
26-CTN	1 x 1	7DAA	-	1104	Total washings 2	454.84	0.329592	
27-CTN	1 x 1	7DAA	-	1186	Total washings 3	935.95	0.631333	
28-CTN	1 x 1	15DAA	-	844	Total washings 1	270.06	0.255982	0.192450
29-CTN	1 x 1	15DAA	-	863	Total washings 2	199.87	0.185279	
30-CTN	1 x 1	15DAA	-	1069	Total washings 3	181.85	0.136090	
31-CTN	1 x 1	21DAA	-	729	Total washings 1	132.57	0.145483	0.134716
32-CTN	1 x 1	21DAA	-	778	Total washings 2	111.81	0.114971	
33-CTN	1 x 1	21DAA	-	715	Total washings 3	128.43	0.143695	
1-CTN	Control	1DBA	-	1034	Total washings 1	<0.05	<0.00005	-
2-CTN	Control	1DBA	-	1038	Total washings 2	<0.05	<0.00005	-
3-CTN	Control	1DBA	-	1074	Total washings 3	<0.05	<0.00005	-
4-CTN	Control	0DAA	-	976	Total washings 1	<0.05	<0.00005	-
5-CTN	Control	0DAA	-	995	Total washings 2	0.77	0.000619	-
6-CTN	Control	0DAA	-	977	Total washings 3	<0.05	<0.00005	-
34-CTN	Control	22DAA	-	914	Total washings 1	<0.05	<0.00005	-
35-CTN	Control	22DAA	-	704	Total washings 2	<0.05	<0.00005	-
36-CTN	Control	22DAA	-	782	Total washings 3	<0.05	<0.00005	-

DBA: Days before application; DAA: Days after application; HAA: Hours after application

The application rate refers to chlorothalonil

No correction of results for control residues has been performed.

For residues <LOQ, the LOQ was used for the calculation of the mean except where all values were <LOQ in which case the mean is reported as <LOQ.

*Mean values calculated on unrounded values.

† Total extraction residue = Sample extraction residue + flask extraction residue

Note: The contamination of the controls being at maximum 0.8% of the residues found in the treated samples, there is no impact on the study.

Residues of azoxystrobin and chlorothalonil in total leaf wash specimens from wheat leaves taken from Trial ChR-14-19410 FR02 are shown in Table IIA-3 and Table IIA-4.

Table IIA-4: Chlorothalonil residues in/on leaf washes from wheat treated at 1000 g AI/ha

Sample No. ChR-14-19410 FR02-	Number and Nominal Rate of Application	Sampling Interval	Sampling Interval	Area	Matrix	Chlorothalonil		
						Total Residue† (µg/L)	Residue (µg/cm^2)	Residue (µg/cm^2)
	(kg ai/ha)	(days)	(hours)	(cm^2)		Uncorrected	Uncorrected	Uncorrected Mean*
46-CTN	1 x 1	0DAA	-	795	Total washings 1	778.49	0.783387	0.545575
47-CTN	1 x 1	0DAA	-	941	Total washings 2	498.95	0.424190	
48-CTN	1 x 1	0DAA	-	704	Total washings 3	377.65	0.429148	
49-CTN	1 x 1	0DAA	8HAA	820	Total washings 1	314.44	0.306773	0.334114
50-CTN	1 x 1	0DAA	8HAA	910	Total washings 2	373.74	0.328562	
51-CTN	1 x 1	0DAA	8HAA	724	Total washings 3	332.14	0.367006	
52-CTN	1 x 1	1DAA	-	893	Total washings 1	372.96	0.334116	0.344812
53-CTN	1 x 1	1DAA	-	769	Total washings 2	335.35	0.348872	
54-CTN	1 x 1	1DAA	-	688	Total washings 3	302.25	0.351449	
55-CTN	1 x 1	2DAA	-	1074	Total washings 1	552.93	0.411863	0.315881
56-CTN	1 x 1	2DAA	-	896	Total washings 2	236.39	0.211067	
57-CTN	1 x 1	2DAA	-	726	Total washings 3	294.68	0.324714	
58-CTN	1 x 1	3DAA	-	1069	Total washings 1	806.16	0.603302	0.694877
59-CTN	1 x 1	3DAA	-	868	Total washings 2	890.99	0.821193	
60-CTN	1 x 1	3DAA	-	751	Total washings 3	619.70	0.660135	
61-CTN	1 x 1	5DAA	-	836	Total washings 1	591.65	0.566169	0.553259
62-CTN	1 x 1	5DAA	-	836	Total washings 2	469.49	0.449272	
63-CTN	1 x 1	5DAA	-	729	Total washings 3	587.15	0.644335	
64-CTN	1 x 1	7DAA	-	956	Total washings 1	495.72	0.414825	0.436754
65-CTN	1 x 1	7DAA	-	964	Total washings 2	723.94	0.600776	
66-CTN	1 x 1	7DAA	-	872	Total washings 3	321.18	0.294660	
67-CTN	1 x 1	15DAA	-	1008	Total washings 1	312.89	0.248323	0.213949
68-CTN	1 x 1	15DAA	-	874	Total washings 2	307.87	0.281807	
69-CTN	1 x 1	15DAA	-	998	Total washings 3	139.37	0.111716	
70-CTN	1 x 1	21DAA	-	674	Total washings 1	351.39	0.417085	0.405253
71-CTN	1 x 1	21DAA	-	524	Total washings 2	261.15	0.398704	
72-CTN	1 x 1	21DAA	-	661	Total washings 3	330.47	0.399969	
40-CTN	Control	1DBA	-	863	Total washings 1	0.19	0.000181	-
41-CTN	Control	1DBA	-	745	Total washings 2	0.12	0.000134	-
42-CTN	Control	1DBA	-	919	Total washings 3	0.18	0.000156	-
43-CTN	Control	0DAA	-	919	Total washings 1	0.08	0.000067	-
44-CTN	Control	0DAA	-	848	Total washings 2	0.07	0.000071	-
45-CTN	Control	0DAA	-	963	Total washings 3	0.07	0.000054	-

DBA: Days before application; DAA: Days after application; HAA: Hours after application

The application rate refers to chlorothalonil

No correction of results for control residues has been performed.

For residues <LOQ, the LOQ was used for the calculation of the mean except where all values were <LOQ in which case the mean is reported as <LOQ.

*Mean values calculated on unrounded values.

† Total extraction residue = Sample extraction residue + flask extraction residue

Note: The samples at 28 DAA were not presented in this table because the area could not be determined. The leaf weight was too low to calculate leaf surface with average ratio.
Note: The contamination of the controls being at maximum 0.1% of the residues found in the treated samples, there is no impact on the study.

Residues of azoxystrobin and chlorothalonil in total leaf wash specimens from wheat leaves taken from Trial ChR-14-19410 FR03 are shown in Table IIA-5 and Table IIA-6.

Table IIA-6: Chlorothalonil residues in/on leaf washes from wheat treated at 1000 g AI/ha

Sample No. ChR-14-19410 FR03-	Number and Nominal Rate of Application	Sampling Interval	Sampling Interval	Area	Matrix	Chlorothalonil		
						Total Residue† (µg/L)	Residue (µg/cm^2)	Residue (µg/cm^2)
	(kg ai/ha)	(days)	(hours)	(cm^2)		Uncorrected	Uncorrected	Uncorrected Mean*
85-CTN	1 x 1	0DAA	-	694	Total washings 1	442.14	0.509667	0.527439
86-CTN	1 x 1	0DAA	-	593	Total washings 2	419.22	0.565559	
87-CTN	1 x 1	0DAA	-	668	Total washings 3	423.42	0.507092	
88-CTN	1 x 1	0DAA	8HAA	749	Total washings 1	404.40	0.431939	0.447930
89-CTN	1 x 1	0DAA	8HAA	777	Total washings 2	457.99	0.471543	
90-CTN	1 x 1	0DAA	8HAA	807	Total washings 3	444.16	0.440307	
91-CTN	1 x 1	1DAA	-	783	Total washings 1	437.94	0.447452	0.397389
92-CTN	1 x 1	1DAA	-	765	Total washings 2	363.77	0.380409	
93-CTN	1 x 1	1DAA	-	757	Total washings 3	344.72	0.364305	
94-CTN	1 x 1	2DAA	-	725	Total washings 1	368.85	0.407007	0.466705
95-CTN	1 x 1	2DAA	-	746	Total washings 2	384.53	0.412368	
96-CTN	1 x 1	2DAA	-	665	Total washings 3	482.74	0.580742	
97-CTN	1 x 1	3DAA	-	861	Total washings 1	284.12	0.263990	0.348478
98-CTN	1 x 1	3DAA	-	907	Total washings 2	245.80	0.216804	
99-CTN	1 x 1	3DAA	-	1007	Total washings 3	710.74	0.564639	
100-CTN	1 x 1	5DAA	-	846	Total washings 1	378.05	0.357497	0.333197
101-CTN	1 x 1	5DAA	-	877	Total washings 2	385.10	0.351285	
102-CTN	1 x 1	5DAA	-	883	Total washings 3	320.98	0.290808	
103-CTN	1 x 1	7DAA	-	997	Total washings 1	270.67	0.217190	0.277854
104-CTN	1 x 1	7DAA	-	924	Total washings 2	343.45	0.297359	
105-CTN	1 x 1	7DAA	-	849	Total washings 3	338.55	0.319012	
106-CTN	1 x 1	14DAA	-	865	Total washings 1	316.49	0.292707	0.368633
107-CTN	1 x 1	14DAA	-	726	Total washings 2	403.08	0.444164	
108-CTN	1 x 1	14DAA	-	786	Total washings 3	362.57	0.369027	
109-CTN	1 x 1	21DAA	-	559	Total washings 1	127.38	0.182300	0.192508
110-CTN	1 x 1	21DAA	-	573	Total washings 2	149.97	0.209378	
111-CTN	1 x 1	21DAA	-	546	Total washings 3	126.84	0.185848	
79-CTN	Control	0DBA	-	934	Total washings 1	<0.05	<0.00005	-
80-CTN	Control	0DBA	-	917	Total washings 2	<0.05	<0.00005	-
81-CTN	Control	0DBA	-	919	Total washings 3	<0.05	<0.00005	-
82-CTN	Control	0DAA	-	665	Total washings 1	<0.05	<0.00005	-
83-CTN	Control	0DAA	-	852	Total washings 2	<0.05	<0.00005	-
84-CTN	Control	0DAA	-	801	Total washings 3	-	-	-

DBA: Days before application; DAA: Days after application; HAA: Hours after application

The application rate refers to chlorothalonil

No correction of results for control residues has been performed.

For residues <LOQ, the LOQ was used for the calculation of the mean except where all values were <LOQ in which case the mean is reported as <LOQ.

*Mean values calculated on unrounded values.

† Total extraction residue = Sample extraction residue + flask extraction residue

**Not enough samples was remained for analysis after use for tests

Note: The samples of 28 DAA were not presented in this table because the area could not be determined. The leaf weight was too low to calculate leaf surface with average ratio.

Residues of azoxystrobin and chlorothalonil in total leaf wash specimens from wheat leaves taken from Trial ChR-14-19410 FR04 are shown in Table IIA-7 and Table IIA-8.

Table IIA-8: Chlorothalonil residues in/on leaf washes from wheat treated at 1000 g AI/ha

Sample No. ChR-14-19410 FR04-	Number and Nominal Rate of Application	Sampling Interval	Sampling Interval	Area	Matrix	Chlorothalonil		
						Total Residue† (µg/L)	Residue (µg/cm^2)	Residue (µg/cm^2)
	(kg ai/ha)	(days)	(hours)	(cm^2)		Uncorrected	Uncorrected	Uncorrected Mean*
124-CTN	1 x 1	0DAA	-	797	Total washings 1	624.37	0.626717	0.653522
125-CTN	1 x 1	0DAA	-	815	Total washings 2	659.69	0.647545	
126-CTN	1 x 1	0DAA	-	769	Total washings 3	659.71	0.686303	
127-CTN	1 x 1	0DAA	8HAA	831	Total washings 1	621.14	0.597966	0.711402
128-CTN	1 x 1	0DAA	8HAA	753	Total washings 2	703.90	0.747839	
129-CTN	1 x 1	0DAA	8HAA	657	Total washings 3	647.47	0.788400	
130-CTN	1 x 1	1DAA	-	775	Total washings 1	459.13	0.473943	0.382758
131-CTN	1 x 1	1DAA	-	809	Total washings 2	371.39	0.367259	
132-CTN	1 x 1	1DAA	-	732	Total washings 3	280.97	0.307072	
133-CTN	1 x 1	2DAA	-	740	Total washings 1	269.28	0.291109	0.354731
134-CTN	1 x 1	2DAA	-	764	Total washings 2	389.90	0.408274	
135-CTN	1 x 1	2DAA	-	824	Total washings 3	375.76	0.364811	
136-CTN	1 x 1	3DAA	-	819	Total washings 1	380.16	0.371343	0.357628
137-CTN	1 x 1	3DAA	-	773	Total washings 2	342.20	0.354155	
138-CTN	1 x 1	3DAA	-	907	Total washings 3	393.85	0.347386	
139-CTN	1 x 1	5DAA	-	800	Total washings 1	364.66	0.364662	0.413468
140-CTN	1 x 1	5DAA	-	732	Total washings 2	401.93	0.439264	
141-CTN	1 x 1	5DAA	-	857	Total washings 3	467.58	0.436479	
142-CTN	1 x 1	7DAA	-	748	Total washings 1	333.56	0.356744	0.384168
143-CTN	1 x 1	7DAA	-	700	Total washings 2	342.66	0.391608	
144-CTN	1 x 1	7DAA	-	785	Total washings 3	396.57	0.404151	
145-CTN	1 x 1	14DAA	-	734	Total washings 1	253.06	0.275813	0.294651
146-CTN	1 x 1	14DAA	-	663	Total washings 2	217.99	0.263037	
147-CTN	1 x 1	14DAA	-	821	Total washings 3	354.16	0.345104	
148-CTN	1 x 1	21DAA	-	655	Total washings 1	122.10	0.149126	0.141877
149-CTN	1 x 1	21DAA	-	570	Total washings 2	93.48	0.131197	
150-CTN	1 x 1	21DAA	-	692	Total washings 3	125.69	0.145310	
118-CTN	Control	1DBA	-	831	Total washings 1	<0.05	<0.00005	-
119-CTN	Control	1DBA	-	824	Total washings 2	0.06	0.000057	-
120-CTN	Control	1DBA	-	819	Total washings 3	<0.05	<0.00005	-
121-CTN	Control	0DAA	-	855	Total washings 1	0.07	0.000068	-
122-CTN	Control	0DAA	-	813	Total washings 2	<0.05	<0.00005	-
123-CTN	Control	0DAA	-	793	Total washings 3	<0.05	<0.00005	-

DBA: Days before application; DAA: Days after application; HAA: Hours after application

The application rate refers to chlorothalonil

No correction of results for control residues has been performed.

For residues <LOQ, the LOQ was used for the calculation of the mean except where all values were <LOQ in which case the mean is reported as <LOQ.

*Mean values calculated on unrounded values.

† Total extraction residue = Sample extraction residue + flask extraction residue

Note: The samples of 28 DAA were not presented in this table because the area could not be determined. The leaf weight was too low to calculate leaf surface with average ratio.

III CONCLUSIONS

Uncorrected residues of chlorothalonil in total leaf washing specimens from wheat leaves treated at 200 and 1000 g per hectare respectively for chlorothalonil at BBCH 69 are summarised in Table III.

Some untreated samples appear to have small contaminations. Most of them were outliers: In trial UK01, one value above LOQ for chlorothalonil. In trial FR04: 2 values out of 6 just above LOQ (0.06 and 0.07 respectively for chlorothalonil One trial was clearly contaminated at a very low level. The

contamination observed at 0 DAA1 was representing 0.03% of the residue level. It was assumed that this contamination was originated by an insufficient cleaning process after the previous trial (FR04) had been processed with the same equipment. These contaminations have been considered without impact on the study results.

Table III: Summary of chlorothalonil residues from wheat leaves following application at 1000 g AI/ha

Sampling interval (days)	Chlorothalonil residue (µg/cm^2) Mean Uncorrected			
	Trial 1	Trial 2	Trial 3	Trial 4
0 DAA (<1 HAA)	0.566384	0.467546	0.527439	0.653522
0 DAA (8 HAA)	0.446222	0.286406	0.447930	0.711402
1 DAA	0.706845	0.295515	0.397389	0.382758
2 DAA	0.644190	0.270775	0.466705	0.354731
3 DAA	0.492122	0.595452	0.348478	0.357628
5 DAA	0.383307	0.474213	0.333197	0.413468
7 DAA	0.498692	0.374266	0.277854	0.384168
14 DAA	0.192450	0.213949	0.368633	0.294651
21-22 DAA	0.134716	0.405253	0.192508	0.141877

(C Roussel, 2015)

Derivation of DT50 value

Four DFR trials were provided to derive the DT50 value. A log-linear model (base e) was fitted to the data and the 1st half-life/DT50 value was calculated using the mean values of replicates of all trials. All calculations were performed in the statistical programming language R (R Core Team, 2015, version 3.2.1).

The DT50 value was calculated according to the following formula $DT50 = \frac{\ln(2)}{\lambda}$; where λ is the exponential decay constant, i.e. here the slope of the linear regression line.

Together, the assessment of all four trials with a log-linear model (base e) gives a DT50 of 16.3 days for chlorothalonil.

Derivation of DFR value

The intended use for A14111B on cereals includes two applications with 1.875 L product/ha (0.15 kg azoxystrobin/ha; 0.75 kg chlorothalonil/ha). The interval between applications is at least 14 days. The results of the GLP study were generated after single application of A14111B on cereals. This is not fully in compliance with the intended number of applications. Using DT50 value of 16.3 days for chlorothalonil, the predicted DFR value after two applications is 0.8405 µg/cm²/kg a.s.

B.6.6 Exposure and risk assessment

Conclusions on risk assessments for operators, bystanders, resident and workers (A14111B)

Operator

- Using the German model, a safe use was identified for operators, with PPE, for:
  - Mechanical downward spraying on cereals and tomato.
  - Manual spraying on tomato.
- Using UK-POEM, a safe use was identified for operators, with PPE, for:
  - Mechanical downward spraying on tomato.
- Using UK-POEM, no safe use was identified for operators, with PPE, for:
  - Mechanical downward spraying on cereals , or
  - Manual spraying on tomato.

Bystander and residents

It is concluded that there is no undue risk to any bystander or residents after accidental short-term exposure to A14111B during or after downward spraying in cereals or tomatoes, using the German model.

Worker

Using the German re-entry model it is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing (but no PPE), when performing crop-inspection activities in cereals or tomato treated with A14111B. For hand-harvesting tomato treated with A14111B it is concluded that there is no unacceptable risk anticipated for the worker wearing adequate PPE.

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B.6.7 References relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.1 / 01	Kuhn J.	2004	Amended Final Report: Acute Oral Toxicity in Rats Syngenta Crop Protection AG, Basel, Switzerland Stillmeadow Inc., Sugarland TX, USA, 8065-04 8321-03 GLP not published Syngenta File No ICI5504/2243	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
KCP 7.1.2 / 01	Kuhn J.	2004a	Amended Final Report: Acute Dermal Toxicity Study in Rats Syngenta Crop Protection AG, Basel, Switzerland Stillmeadow Inc., Sugarland TX, USA, 8066-04 8322-03 GLP not published Syngenta File No ICI5504/2244	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
KCP 7.1.3 / 01	Rattray N.J.	2004	A14111B: 4-Hour Acute Inhalation Toxicity Study in Rats Syngenta Limited, Cheshire, United Kingdom Central Toxicology Laboratory (CTL), Cheshire, United Kingdom, HR2464 GLP not published Syngenta File No ICI5504/2229	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
KCP 7.1.4 / 01	Kuhn J.	2004b	Amended Final Report: Acute Dermal Irritation Study in Rabbits Syngenta Crop Protection AG, Basel, Switzerland Stillmeadow Inc., Sugarland TX, USA, 8068-04 8319-03 GLP not published Syngenta File No ICI5504/2245	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
KCP 7.1.5 / 01	Kuhn J.	2004c	Amended Final Report: Acute Eye Irritation Study in Rabbits Syngenta Crop Protection AG, Basel, Switzerland Stillmeadow Inc., Sugarland TX, USA, 8067-04 0000-03 GLP not published Syngenta File No ICI5504/2242	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN

KCP 7.2.1.2 / 01	Wilson A.	2012	Diquat - Determination of Operator Exposure (Passive Dosimetry) during Typical Activities Associated with Mixing/Loading and Application of Reglone® (Soluble Concentrate Containing 200 g/L Diquat cation) as a Desiccant to Ware Potatoes in The Netherlands, 2011 Syngenta Agrochemex, Lawford, United Kingdom, ACI11-003 GLP not published Syngenta File No A1412A_10300	Y	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN
KCP 7.3 / 01	Noakes J.	2013	Chlorothalonil/Azoxystrobin SC (A14111B) - In Vitro Absorption through Dermatomed Human Skin Using [14C]-Chlorothalonil Syngenta Dermal Technology Laboratory Ltd., Staffordshire, UK, JV2271-REG GLP not published Syngenta File No A14111B_10828	N	Y	Eligible for data protection according to SANCO/12576/2012; dependent on national product registration status	SYN

Appendix 1-1: Detailed exposure models

Estimation of operator exposure (acc. to the German model)

Active substance (a.s.)	**Chlorothalonil**	
Product	**A14111B**	
Intended use(s)	**cereal**	
	Field Crops, Tractor Mounted (FCTM)	
Type of preparation	**Liquid**	
Application rate (AR)	**0.75**	**kg a.s./ha**
Treated area per day (A)	**20**	**ha/d**
Systemic AOEL	**0.009**	**mg/kg bw/d**
Dermal absorption (DA)	**0.05**	**% for mixing/loading (m/l)**
	3	**% for application (appl.)**
Inhalation absorption (IA)	**100**	**%**
Body weight (BW)	**70**	**kg**

Personal protective equipment:	BVL code	Reduction factor	to lower:	
Particle filtering half mask (m/l) [1]	ST1102	0.08	I_M	☐
Half mask with combined filter (m/l) [1]	ST2102	0.02	I_M	☐
Particle filtering half mask (appl.) [1]	ST1203	0.08	I_A	☐
		0.8	$D_{A(C)}$	
Half mask with combined filter (appl.) [1]	ST2202	0.02	I_A	☐
		0.8	$D_{A(C)}$	
Protective gloves (m/l) [2]	SS110	0.01	$D_{M(H)}$	☐
Protective gloves (appl.) [2]	SS120	0.01	$D_{A(H)}$	☑
Protective garment + sturdy footwear (appl.) [2]	SS2202	0.05	$D_{A(B)}$	☑
Broad-brimmed headgear (appl.) [2]	SS420	0.5	$D_{A(C)}$	☐
Hood and visor (appl.) [2]	SS520	0.05	$D_{A(C)}$	☐

[1] DIN EN 149 (2001), [2] BVL (2006) Guidelines for requirements concerning personal protective equipment in plant protection

Estimation of operator exposure: German model

Input parameters considered for the estimation of operator exposure:

Formulation type:	Liquid		**Application technique:**	Field Crops, Tractor Mounted (FCTM)	
Application rate (AR):	0.75	kg			
Area treated per day (A):	20	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg a.s.
Dermal absorption (DA):	0.05	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	3	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg a.s.
AOEL	0.009	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Operator exposure towards Chlorothalonil					
Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in cereal					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(2.4 x 0.75 x 20 x 0.05%) / 70			(2.4 x 0.75 x 20 x 1 x 0.05%) / 70		
External dermal exposure	36	mg/person	External dermal exposure	36	mg/person
External dermal exposure	0.5142857	mg/kg bw/d	External dermal exposure	0.5142857	mg/kg bw/d
Systemic dermal exposure	**0.000257**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000257**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(0.38 x 0.75 x 20 x 3%) / 70			(0.38 x 0.75 x 20 x 0.01 x 3%) / 70		
External dermal exposure	5.7	mg/person	External dermal exposure	0.057	mg/person
External dermal exposure	0.0814286	mg/kg bw/d	External dermal exposure	0.0008143	mg/kg bw/d
Systemic dermal exposure	**0.002443**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000024**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE^{2)} \times DA) / BW$		
(1.6 x 0.75 x 20 x 3%) / 70			(1.6 x 0.75 x 20 x 0.05 x 3%) / 70		
External dermal exposure	24	mg/person	External dermal exposure	1.2	mg/person
External dermal exposure	0.3428571	mg/kg bw/d	External dermal exposure	0.0171429	mg/kg bw/d
Systemic dermal exposure	**0.010286**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000514**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE^{3)} \times DA) / BW$		
(0.06 x 0.75 x 20 x 3%) / 70			(0.06 x 0.75 x 20 x 1 x 3%) / 70		
External dermal exposure	0.9	mg/person	External dermal exposure	0.9	mg/person
External dermal exposure	0.0128571	mg/kg bw/d	External dermal exposure	0.0128571	mg/kg bw/d
Systemic dermal exposure	**0.000386**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000386**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	66.6	mg/person	Total external dermal exposure	38.157	mg/person
Total external dermal exposure	0.9514286	mg/kg bw/d	Total external dermal exposure	0.5451	mg/kg bw/d
Total systemic dermal exposure	**0.01337**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.00118**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in cereal					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE^{4)} \times IA) / BW$		
(0.0006 x 0.75 x 20 x 100%) / 70			(0.0006 x 0.75 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.009	mg/person	External inhalation exposure	0.009	mg/person
External inhalation exposure	0.0001286	mg/kg bw/d	External inhalation exposure	0.0001286	mg/kg bw/d
Systemic inhalation exposure	**0.000129**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000129**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE^{4)} \times IA) / BW$		
(0.001 x 0.75 x 20 x 100%) / 70			(0.001 x 0.75 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.015	mg/person	External inhalation exposure	0.015	mg/person
External inhalation exposure	0.0002143	mg/kg bw/d	External inhalation exposure	0.0002143	mg/kg bw/d
Systemic inhalation exposure	**0.000214**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000214**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.024000	mg/person	Total external inhalation exposure	0.024000	mg/person
Total external inhalation exposure	0.000343	mg/kg bw/d	Total external inhalation exposure	0.000343	mg/kg bw/d
Total systemic inhalation exposure	**0.000343**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000343**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	0.96000	mg/person	Total systemic exposure	0.10671	mg/person
Total systemic exposure	**0.013714**	**mg/kg bw/d**	**Total systemic exposure**	**0.001524**	**mg/kg bw/d**
% of AOEL	**152.4**	**%**	**% of AOEL**	**16.9**	**%**

[1)] reduction factor for gloves is 0.01 (professional applications) and 0.5 (home/allotment garden applications), resp.

[2)] reduction factor for protective garment is 0.05 (prof. appl.) and 0.5 (workwear, home/allotment garden appl.), resp.

[3)] reduction factor for broad brimmed headgear and hood and visor is 0.5 and 0.05, respectively (professional appl.)

[4)] reduction factor for RPE is 0.08 (particle filter) and 0.02 (combined vapour and particle filter), resp. (prof. appl.)

Estimation of operator exposure (acc. to the German model)

Active substance (a.s.)	**Chlorothalonil**	
Product	**A14111B**	
Intended use(s)	**tomato**	
	Field Crops, Tractor Mounted (FCTM)	
Type of preparation	**Liquid**	
Application rate (AR)	**1**	**kg a.s./ha**
Treated area per day (A)	**20**	**ha/d**
Systemic AOEL	**0.009**	**mg/kg bw/d**
Dermal absorption (DA)	**0.05**	**% for mixing/loading (m/l)**
	7	**% for application (appl.)**
Inhalation absorption (IA)	**100**	**%**
Body weight (BW)	**70**	**kg**

Personal protective equipment:	**BVL code**	**Reduction factor**	**to lower:**	
Particle filtering half mask (m/l) [1]	ST1102	0.08	I_M	☐
Half mask with combined filter (m/l) [1]	ST2102	0.02	I_M	☐
Particle filtering half mask (appl.) [1]	ST1203	0.08	I_A	☐
		0.8	$D_{A(C)}$	
Half mask with combined filter (appl.) [1]	ST2202	0.02	I_A	☐
		0.8	$D_{A(C)}$	
Protective gloves (m/l) [2]	SS110	0.01	$D_{M(H)}$	☐
Protective gloves (appl.) [2]	SS120	0.01	$D_{A(H)}$	☑
Protective garment + sturdy footwear (appl.) [2]	SS2202	0.05	$D_{A(B)}$	☑
Broad-brimmed headgear (appl.) [2]	SS420	0.5	$D_{A(C)}$	☐
Hood and visor (appl.) [2]	SS520	0.05	$D_{A(C)}$	☐

[1] DIN EN 149 (2001), [2] BVL (2006) Guidelines for requirements concerning personal protective equipment in plant protection

Estimation of operator exposure: German model

Input parameters considered for the estimation of operator exposure:

Formulation type:	Liquid		**Application technique:**	Field Crops, Tractor Mounted (FCTM)	
Application rate (AR):	1	kg			
Area treated per day (A):	20	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg a.s.
Dermal absorption (DA):	0.05	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	7	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg a.s.
AOEL	0.009	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Operator exposure towards Chlorothalonil					
Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in tomato					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(2.4 x 1 x 20 x 0.05%) / 70			(2.4 x 1 x 20 x 1 x 0.05%) / 70		
External dermal exposure	48	mg/person	External dermal exposure	48	mg/person
External dermal exposure	0.6857143	mg/kg bw/d	External dermal exposure	0.6857143	mg/kg bw/d
Systemic dermal exposure	**0.000343**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000343**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(0.38 x 1 x 20 x 7%) / 70			(0.38 x 1 x 20 x 0.01 x 7%) / 70		
External dermal exposure	7.6	mg/person	External dermal exposure	0.076	mg/person
External dermal exposure	0.1085714	mg/kg bw/d	External dermal exposure	0.0010857	mg/kg bw/d
Systemic dermal exposure	**0.007600**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000076**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE^{2)} \times DA) / BW$		
(1.6 x 1 x 20 x 7%) / 70			(1.6 x 1 x 20 x 0.05 x 7%) / 70		
External dermal exposure	32	mg/person	External dermal exposure	1.6	mg/person
External dermal exposure	0.4571429	mg/kg bw/d	External dermal exposure	0.0228571	mg/kg bw/d
Systemic dermal exposure	**0.032000**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001600**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE^{3)} \times DA) / BW$		
(0.06 x 1 x 20 x 7%) / 70			(0.06 x 1 x 20 x 1 x 7%) / 70		
External dermal exposure	1.2	mg/person	External dermal exposure	1.2	mg/person
External dermal exposure	0.0171429	mg/kg bw/d	External dermal exposure	0.0171429	mg/kg bw/d
Systemic dermal exposure	**0.001200**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001200**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	88.8	mg/person	Total external dermal exposure	50.876	mg/person
Total external dermal exposure	1.2685714	mg/kg bw/d	Total external dermal exposure	0.7268	mg/kg bw/d
Total systemic dermal exposure	**0.04114**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.00322**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in tomato					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE^{4)} \times IA) / BW$		
(0.0006 x 1 x 20 x 100%) / 70			(0.0006 x 1 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.012	mg/person	External inhalation exposure	0.012	mg/person
External inhalation exposure	0.0001714	mg/kg bw/d	External inhalation exposure	0.0001714	mg/kg bw/d
Systemic inhalation exposure	**0.000171**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000171**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE^{4)} \times IA) / BW$		
(0.001 x 1 x 20 x 100%) / 70			(0.001 x 1 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.02	mg/person	External inhalation exposure	0.02	mg/person
External inhalation exposure	0.0002857	mg/kg bw/d	External inhalation exposure	0.0002857	mg/kg bw/d
Systemic inhalation exposure	**0.000286**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000286**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.032000	mg/person	Total external inhalation exposure	0.032000	mg/person
Total external inhalation exposure	0.000457	mg/kg bw/d	Total external inhalation exposure	0.000457	mg/kg bw/d
Total systemic inhalation exposure	**0.000457**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000457**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	2.91200	mg/person	Total systemic exposure	0.25732	mg/person
Total systemic exposure	**0.041600**	**mg/kg bw/d**	**Total systemic exposure**	**0.003676**	**mg/kg bw/d**
% of AOEL	**462.2**	**%**	**% of AOEL**	**40.8**	**%**

[1)] reduction factor for gloves is 0.01 (professional applications) and 0.5 (home/allotment garden applications), resp.

[2)] reduction factor for protective garment is 0.05 (prof. appl.) and 0.5 (workwear, home/allotment garden appl.), resp.

[3)] reduction factor for broad brimmed headgear and hood and visor is 0.5 and 0.05, respectively (professional appl.)

[4)] reduction factor for RPE is 0.08 (particle filter) and 0.02 (combined vapour and particle filter), resp. (prof. appl.)

Estimation of operator exposure (acc. to the German model)

Active substance (a.s.)	**Chlorothalonil**	
Product	**A14111B**	
Intended use(s)	**tomato**	
	High Crops, Hand Held (HCHH)	
Type of preparation	**Liquid**	
Application rate (AR)	**1**	**kg a.s./ha**
Treated area per day (A)	**1**	**ha/d**
Systemic AOEL	**0.009**	**mg/kg bw/d**
Dermal absorption (DA)	**0.05**	**% for mixing/loading (m/l)**
	7	**% for application (appl.)**
Inhalation absorption (IA)	**100**	**%**
Body weight (BW)	**70**	**kg**

Personal protective equipment:	**BVL code**	**Reduction factor**	**to lower:**	
Particle filtering half mask (m/l) [1]	ST1102	0.08	I_M	☐
Half mask with combined filter (m/l) [1]	ST2102	0.02	I_M	☐
Particle filtering half mask (appl.) [1]	ST1203	0.08	I_A	☐
		0.8	$D_{A(C)}$	
Half mask with combined filter (appl.) [1]	ST2202	0.02	I_A	☐
		0.8	$D_{A(C)}$	
Protective gloves (m/l) [2]	SS110	0.01	$D_{M(H)}$	☑
Protective gloves (appl.) [2]	SS120	0.01	$D_{A(H)}$	☑
Protective garment + sturdy footwear (appl.) [2]	SS2202	0.05	$D_{A(B)}$	☑
Broad-brimmed headgear (appl.) [2]	SS420	0.5	$D_{A(C)}$	☑
Hood and visor (appl.) [2]	SS520	0.05	$D_{A(C)}$	☐

[1] DIN EN 149 (2001), [2] BVL (2006) Guidelines for requirements concerning personal protective equipment in plant protection

Estimation of operator exposure: German model

Input parameters considered for the estimation of operator exposure:

Formulation type:	Liquid		**Application technique:**	High Crops, Hand Held (HCHH)	
Application rate (AR):	1	kg			
Area treated per day (A):	1	ha	**Dermal hands m/l ($D_{M(H)}$):**	205	mg/person/kg a.s.
Dermal absorption (DA):	0.05	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	10.6	mg/person/kg a.s.
	7	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	25	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	4.8	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.05	mg/person/kg a.s.
AOEL	0.009	mg/kg bw/d	**Inhalation appl. (I_A):**	0.3	mg/person/kg a.s.

Operator exposure towards Chlorothalonil					
Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in tomato					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(205 x 1 x 1 x 0.05%) / 70			(205 x 1 x 1 x 0.01 x 0.05%) / 70		
External dermal exposure	205	mg/person	External dermal exposure	2.05	mg/person
External dermal exposure	2.9285714	mg/kg bw/d	External dermal exposure	0.0292857	mg/kg bw/d
Systemic dermal exposure	**0.001464**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000015**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(10.6 x 1 x 1 x 7%) / 70			(10.6 x 1 x 1 x 0.01 x 7%) / 70		
External dermal exposure	10.6	mg/person	External dermal exposure	0.106	mg/person
External dermal exposure	0.1514286	mg/kg bw/d	External dermal exposure	0.0015143	mg/kg bw/d
Systemic dermal exposure	**0.010600**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000106**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE^{2)} \times DA) / BW$		
(25 x 1 x 1 x 7%) / 70			(25 x 1 x 1 x 0.05 x 7%) / 70		
External dermal exposure	25	mg/person	External dermal exposure	1.25	mg/person
External dermal exposure	0.3571429	mg/kg bw/d	External dermal exposure	0.0178571	mg/kg bw/d
Systemic dermal exposure	**0.025000**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001250**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE^{3)} \times DA) / BW$		
(4.8 x 1 x 1 x 7%) / 70			(4.8 x 1 x 1 x 0.5 x 7%) / 70		
External dermal exposure	4.8	mg/person	External dermal exposure	2.4	mg/person
External dermal exposure	0.0685714	mg/kg bw/d	External dermal exposure	0.0342857	mg/kg bw/d
Systemic dermal exposure	**0.004800**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.002400**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	245.4	mg/person	Total external dermal exposure	5.806	mg/person
Total external dermal exposure	3.5057143	mg/kg bw/d	Total external dermal exposure	0.0829429	mg/kg bw/d
Total systemic dermal exposure	**0.04186**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.00377**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in tomato					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE^{4)} \times IA) / BW$		
(0.05 x 1 x 1 x 100%) / 70			(0.05 x 1 x 1 x 1 x 100%) / 70		
External inhalation exposure	0.05	mg/person	External inhalation exposure	0.05	mg/person
External inhalation exposure	0.0007143	mg/kg bw/d	External inhalation exposure	0.0007143	mg/kg bw/d
Systemic inhalation exposure	**0.000714**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000714**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE^{4)} \times IA) / BW$		
(0.3 x 1 x 1 x 100%) / 70			(0.3 x 1 x 1 x 1 x 100%) / 70		
External inhalation exposure	0.3	mg/person	External inhalation exposure	0.3	mg/person
External inhalation exposure	0.0042857	mg/kg bw/d	External inhalation exposure	0.0042857	mg/kg bw/d
Systemic inhalation exposure	**0.004286**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.004286**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.350000	mg/person	Total external inhalation exposure	0.350000	mg/person
Total external inhalation exposure	0.005000	mg/kg bw/d	Total external inhalation exposure	0.005000	mg/kg bw/d
Total systemic inhalation exposure	**0.005000**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.005000**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	3.28050	mg/person	Total systemic exposure	0.61395	mg/person
Total systemic exposure	**0.046864**	**mg/kg bw/d**	**Total systemic exposure**	**0.008771**	**mg/kg bw/d**
% of AOEL	**520.7**	**%**	**% of AOEL**	**97.5**	**%**

[1)] reduction factor for gloves is 0.01 (professional applications) and 0.5 (home/allotment garden applications), resp.

[2)] reduction factor for protective garment is 0.05 (prof. appl.) and 0.5 (workwear, home/allotment garden appl.), resp.

[3)] reduction factor for broad brimmed headgear and hood and visor is 0.5 and 0.05, respectively (professional appl.)

[4)] reduction factor for RPE is 0.08 (particle filter) and 0.02 (combined vapour and particle filter), resp. (prof. appl.)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Product	**A14111B**	Active substance	**chlorothalonil**
Formulation type	water-based	a.s. concentration	**400** mg/ml
Dermal absorption from product	**0.05** %	Dermal absorption from spray	**1** %
Container	5 litres 45 or 63 mm closure		
PPE during mix/loading	None	PPE during application	None
Dose	**1.875** l/ha	Work rate/day	**50** ha
Application volume	**100** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	5	litres
Hand contamination/operation	0.01	ml
Application dose	1.875	litres product/ha
Work rate	50	ha/day
Number of operations	19	/day
Hand contamination	0.19	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	0.19	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	spray/ha		
Volume of surface contamination	10	ml/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.19	ml/day	41.55	ml/day
Concen. of a.s. product or spray	400	mg/ml	7.5	mg/ml
Dermal exposure to a.s.	76	mg/day	311.625	mg/day
Percent absorbed	0.05	%	1	%
Absorbed dose	0.038	mg/day	3.11625	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	7.5	mg/ml
Inhalation exposure to a.s.	0.45	mg/day
Percent absorbed	100	%
Absorbed dose	0.45	mg/day

PREDICTED EXPOSURE

Total absorbed dose	3.60425	mg/day
Operator body weight	60	kg
Operator exposure	0.060070833	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Product	**A14111B**	Active substance	**chlorothalonil**
Formulation type	water-based	a.s. concentration	**400** mg/ml
Dermal absorption from product	**0.05** %	Dermal absorption from spray	**3** %
Container	5 litres 45 or 63 mm closure		
PPE during mix/loading	None	PPE during application	None
Dose	**2.5** l/ha	Work rate/day	**50** ha
Application volume	**500** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	5	litres
Hand contamination/operation	0.01	ml
Application dose	2.5	litres product/ha
Work rate	50	ha/day
Number of operations	25	/day
Hand contamination	0.25	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	0.25	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	500	spray/ha		
Volume of surface contamination	10	ml/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.25	ml/day	41.55	ml/day
Concen. of a.s. product or spray	400	mg/ml	2	mg/ml
Dermal exposure to a.s.	100	mg/day	83.1	mg/day
Percent absorbed	0.05	%	3	%
Absorbed dose	0.05	mg/day	2.493	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	2	mg/ml
Inhalation exposure to a.s.	0.12	mg/day
Percent absorbed	100	%
Absorbed dose	0.12	mg/day

PREDICTED EXPOSURE

Total absorbed dose	2.663	mg/day
Operator body weight	60	kg
Operator exposure	0.044383333	mg/kg bw/day

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Product	**A14111B**	Active substance	**chlorothalonil**
Formulation type	water-based	a.s. concentration	**400** mg/ml
Dermal absorption from product	**0.05** %	Dermal absorption from spray	**3** %
Container	5 litres 45 or 63 mm closure		
PPE during mix/loading	Gloves	PPE during application	Gloves and impermeable coveral
Dose	**2.5** l/ha	Work rate/day	**0.8** ha
Application volume	**500** l/ha	Duration of spraying	**6** h

EXPOSURE DURING MIXING AND LOADING

Container size	5	litres
Hand contamination/operation	0.01	ml
Application dose	2.5	litres product/ha
Work rate	0.8	ha/day
Number of operations	27	/day
Hand contamination	0.27	ml/day
Protective clothing	Gloves	
Transmission to skin	5	%
Dermal exposure to formulation	0.0135	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target			
Application volume	500	spray/ha		
Volume of surface contamination	50	ml/h		
Distribution	Hands	Trunk	Legs	
	25%	25%	50%	
Clothing	Gloves	Impermeable	Impermeable	
Penetration	10%	5%	5%	
Dermal exposure	1.25	0.625	1.25	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	18.75	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0.0135	ml/day	18.75	ml/day
Concen. of a.s. product or spray	400	mg/ml	2	mg/ml
Dermal exposure to a.s.	5.4	mg/day	37.5	mg/day
Percent absorbed	0.05	%	3	%
Absorbed dose	0.0027	mg/day	1.125	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	2	mg/ml
Inhalation exposure to a.s.	0.24	mg/day
Percent absorbed	100	%
Absorbed dose	0.24	mg/day

PREDICTED EXPOSURE

Total absorbed dose	1.3677	mg/day
Operator body weight	60	kg
Operator exposure	0.022795	mg/kg bw/day

Estimation of bystander and resident exposure (adults and children)		
Active substance (a.s.)		Chlorothalonil
Product		A14111B
Intended uses	cereals	Field Crops, Tractor Mounted (FCTM)
Treated area per day (A)	20	ha/d
Application rate (AR)	0.75	kg a.s./ha
Number of applications (NA)	2	1)

1) Consideration of more than two applications are not necessary if degradation of the active substance on foliage of at least 50 % can be assumed between two applications (otherwise use multiple application factor).

Dermal absorption (DA)	3	% (worst case, e.g. during application)
Inhalation absorption (IA)	100	%
Oral absorption (OA)	32	%
Systemic AOEL	0.009	mg/kg bw/d
Body weight (BW)	60	kg/person (adults)
	16.15	kg/person (children)

Distance between application and bystander or resident:

FCTM:	10	m
High crops not selected		
		m
Home & garden not selected		
		m

Drift deposit (D) for 1 appl. based on appl. technique and distance:	0.29 % (FCTM, 10 m)
Drift deposit (D) for 2 appl. based on appl. technique and distance:	0.24 % (FCTM, 10 m)
Airborne vapour concentration (ACv)	0.001 mg/m³ 2)

2) 1 µg/m³ for semivolatile substances, i.e. vapour pressure (20 °C): ≥ $1x10^{-5}$ - < $5x10^{-3}$ Pa; 15 µg/m³ for volatile substances, i.e. vapour pressure (20 °C): ≥ $5x10^{-3}$ Pa

Estimation of bystander exposure during/after application in Field Crops, Tractor Mounted

Input parameters considered for the estimation of bystander exposure:

Intended use(s):	cereals		**Drift (D):**	0.29	% (FCTM, 10 m)
Application rate (AR):	0.75	kg a.s./ha	**Exposed Body Surface Area (BSA):**	1	m² (adults)
				0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I*A):**	0.001	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.00057	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	3.00	% ('worst case')	**Area Treated (A):**	20	ha/d (based on Field Crops, Tractor Mounted (FCTM))
Inhalation absorption (IA):	100	%	**Exposure duration (T):**	5	min
AOEL:	0.009	mg/kg bw/d			

Bystander exposure towards Chlorothalonil					
Adults			**Children**		
Bystander: Dermal exposure after application in cereals (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(75 x 0.29% x 1 x 3%) / 60			(75 x 0.29% x 0.21 x 3%) / 16.15		
External exposure	0.2175	mg/person	External exposure	0.045675	mg/person
External exposure	0.003625	mg/kg bw/d	External exposure	0.00282817	mg/kg bw/d
Absorbed dose:	**0.0001088**	**mg/kg bw/d**	**Absorbed dose:**	**0.0000848**	**mg/kg bw/d**
Bystander: Inhalation exposure after application in cereals					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0,000 / 360 x 0.75 x 20 x 5 x 100%) / 60			(0,000 / 360 x 0.75 x 20 x 5 x 100%) / 16.15		
External exposure	0.00020833	mg/person	External exposure	0.00011973	mg/person
External exposure	3.4722E-06	mg/kg bw/d	External exposure	7.4137E-06	mg/kg bw/d
Absorbed dose:	**0.0000035**	**mg/kg bw/d**	**Absorbed dose:**	**0.0000074**	**mg/kg bw/d**
Total systemic exposure: SE_B = SDE_B + SIE_B			Total systemic exposure: SE_B = SDE_B + SIE_B		
Total systemic exposure (absorbed dose)	0.00673333	mg/person	Total systemic exposure (absorbed dose)	0.00148998	mg/person
Total systemic exposure (absorbed dose)	**0.0001122**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0.0000923**	**mg/kg bw/d**
% of AOEL:	**1.25**	**%**	**% of AOEL:**	**1.03**	**%**

Estimation of resident exposure after application in Field Crops, Tractor Mounted (FCTM)

Input parameters considered for the estimation of resident exposure:

Intended use(s):	cereals		**Drift (D):**	0.24	% (FCTM, 10 m)
Application rate (AR):	0.75	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
				2600	cm^2/h (children)
Number of applications (NA):	2		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0.001	mg/m3
Dermal absorption (DA):	3.00	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults),
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA)	32	%	**Saliva Extraction Factor (SE):**	50	%
AOEL	0.009	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Resident exposure towards Chlorothalonil					
Adults			**Children**		
Residents: Dermal exposure after application in cereals (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.0075 x 2 x 0.24% x 5% x 7300 x 2 x 3%) / 60			(0.0075 x 2 x 0.24% x 5% x 2600 x 2 x 3%) / 16.15		
External exposure	0.02628	mg/person	External exposure	0.00936	mg/person
External exposure	0.000438	mg/kg bw/d	External exposure	0.00057957	mg/kg bw/d
Absorbed dose:	**0.0000131**	**mg/kg bw/d**	**Absorbed dose:**	**0.0000174**	**mg/kg bw/d**
Residents: Inhalation exposure to vapour					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0.001 x 16.57 x 100%) / 60			(0.001 x 8.31 x 100%) / 16.15		
External exposure	0.01657	mg/person	External exposure	0.00831	mg/person
External exposure	0.00027617	mg/kg bw/d	External exposure	0.00051455	mg/kg bw/d
Absorbed dose:	**0.0002762**	**mg/kg bw/d**	**Absorbed dose:**	**0.0005146**	**mg/kg bw/d**
			Residents: Oral exposure (hand-to-mouth transfer)		
			SOE_H = (AR x NA x D x TTR x SE x SA x Freq x H x OA) /		
			(0.0075 x 2 x 0.24% x 5% x 50% x 20 x 20 x 2 x 32%) / 16.15		
			External exposure	0.00072	mg/person
			External exposure	4.4582E-05	mg/kg bw/d
			Absorbed dose	**0.0000143**	**mg/kg bw/d**
			Residents: Oral exposure (object-to-mouth transfer)		
			SOE_O = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.0075 x 2 x 0.24% x 20% x 25 x 32%) / 16.15		
			External exposure	0.00018	mg/person
			External exposure	1.1146E-05	mg/kg bw/d
			Absorbed dose	**0.0000036**	**mg/kg bw/d**
Total systemic exposure: SE_R = SDE_R + SIE_R			Total systemic exposure: SE_R = SDE_R + SIE_R + SOE_H + SOE_O		
Total systemic exposure (absorbed dose)	0.0173584	mg/person	Total systemic exposure (absorbed dose)	0.0088788	mg/person
Total systemic exposure (absorbed dose)	**0.0002893**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0.0005498**	**mg/kg bw/d**
% of AOEL:	**3.21**	**%**	**% of AOEL:**	**6.11**	**%**

Estimation of bystander and resident exposure (adults and children)		
Active substance (a.s.)		Chlorothalonil
Product		A14111B
Intended uses	tomato	Field Crops, Tractor Mounted (FCTM)
Treated area per day (A)	20	ha/d
Application rate (AR)	1	kg a.s./ha
Number of applications (NA)	1	1)

1) Consideration of more than two applications are not necessary if degradation of the active substance on foliage of at least 50 % can be assumed between two applications (otherwise use multiple application factor).

Dermal absorption (DA)	7	% (worst case, e.g. during application)
Inhalation absorption (IA)	100	%
Oral absorption (OA)	32	%
Systemic AOEL	0.009	mg/kg bw/d
Body weight (BW)	60	kg/person (adults)
	16.15	kg/person (children)

Distance between application and bystander or resident:

FCTM:	10	m
High crops not selected		
		m
Home & garden not selected		
		m

Drift deposit (D) for 1 appl. based on appl. technique and distance: **0.29 % (FCTM, 10 m)**

Airborne vapour concentration (ACv): **0.001** mg/m³ 2)

2) 1 µg/m³ for semivolatile substances, i.e. vapour pressure (20 °C): ≥ $1x10^{-5}$ - < $5x10^{-3}$ Pa; 15 µg/m³ for volatile substances, i.e. vapour pressure (20 °C): ≥ $5x10^{-3}$ Pa

Estimation of bystander exposure during/after application in Field Crops, Tractor Mounted

Input parameters considered for the estimation of bystander exposure:

Intended use(s):	tomato		**Drift (D):**	0.29	% (FCTM, 10 m)
Application rate (AR):	1	kg a.s./ha	**Exposed Body Surface Area (BSA):**	1	m² (adults)
				0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I*A):**	0.001	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.00057	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	7.00	% ('worst case')	**Area Treated (A):**	20	ha/d (based on Field Crops, Tractor Mounted (FCTM))
Inhalation absorption (IA):	100	%	**Exposure duration (T):**	5	min
AOEL:	0.009	mg/kg bw/d			

Bystander exposure towards Chlorothalonil					
Adults			**Children**		
Bystander: Dermal exposure after application in tomato (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(100 x 0.29% x 1 x 7%) / 60			(100 x 0.29% x 0.21 x 7%) / 16.15		
External exposure	0.29	mg/person	External exposure	0.0609	mg/person
External exposure	0.00483333	mg/kg bw/d	External exposure	0.0037709	mg/kg bw/d
Absorbed dose:	**0.0003383**	**mg/kg bw/d**	**Absorbed dose:**	**0.0002640**	**mg/kg bw/d**
Bystander: Inhalation exposure after application in tomato					
SIE_B = (I*A x AR x A x T x IA) / BW			SIE_B = (I*A x AR x A x T x IA) / BW		
(0,000 / 360 x 1 x 20 x 5 x 100%) / 60			(0,000 / 360 x 1 x 20 x 5 x 100%) / 16.15		
External exposure	0.00027778	mg/person	External exposure	0.00015964	mg/person
External exposure	4.6296E-06	mg/kg bw/d	External exposure	9.885E-06	mg/kg bw/d
Absorbed dose:	**0.0000046**	**mg/kg bw/d**	**Absorbed dose:**	**0.0000099**	**mg/kg bw/d**
Total systemic exposure: SE_B = SDE_B + SIE_B			Total systemic exposure: SE_B = SDE_B + SIE_B		
Total systemic exposure (absorbed dose)	0.02057778	mg/person	Total systemic exposure (absorbed dose)	0.00442264	mg/person
Total systemic exposure (absorbed dose)	**0.0003430**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0.0002738**	**mg/kg bw/d**
% of AOEL:	**3.81**	**%**	**% of AOEL:**	**3.04**	**%**

Estimation of resident exposure after application in Field Crops, Tractor Mounted (FCTM)

Input parameters considered for the estimation of resident exposure:

Intended use(s):	tomato		**Drift (D):**	0.29	% (FCTM, 10 m)
Application rate (AR):	1	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
				2600	cm^2/h (children)
Number of applications (NA):	1		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0.001	mg/m3
Dermal absorption (DA):	7.00	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults),
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA)	32	%	**Saliva Extraction Factor (SE):**	50	%
AOEL	0.009	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Resident exposure towards Chlorothalonil					
Adults			**Children**		
Residents: Dermal exposure after application in tomato (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.01 x 1 x 0.29% x 5% x 7300 x 2 x 7%) / 60			(0.01 x 1 x 0.29% x 5% x 2600 x 2 x 7%) / 16.15		
External exposure	0.02117	mg/person	External exposure	0.00754	mg/person
External exposure	0.00035283	mg/kg bw/d	External exposure	0.00046687	mg/kg bw/d
Absorbed dose:	**0.0000247**	**mg/kg bw/d**	**Absorbed dose:**	**0.0000327**	**mg/kg bw/d**
Residents: Inhalation exposure to vapour					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0.001 x 16.57 x 100%) / 60			(0.001 x 8.31 x 100%) / 16.15		
External exposure	0.01657	mg/person	External exposure	0.00831	mg/person
External exposure	0.00027617	mg/kg bw/d	External exposure	0.00051455	mg/kg bw/d
Absorbed dose:	**0.0002762**	**mg/kg bw/d**	**Absorbed dose:**	**0.0005146**	**mg/kg bw/d**
			Residents: Oral exposure (hand-to-mouth transfer)		
			SOE_H = (AR x NA x D x TTR x SE x SA x Freq x H x OA) /		
			(0.01 x 1 x 0.29% x 5% x 50% x 20 x 20 x 2 x 32%) / 16.15		
			External exposure	0.00058	mg/person
			External exposure	3.5913E-05	mg/kg bw/d
			Absorbed dose	**0.0000115**	**mg/kg bw/d**
			Residents: Oral exposure (object-to-mouth transfer)		
			SOE_O = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.01 x 1 x 0.29% x 20% x 25 x 32%) / 16.15		
			External exposure	0.000145	mg/person
			External exposure	8.9783E-06	mg/kg bw/d
			Absorbed dose	**0.0000029**	**mg/kg bw/d**
Total systemic exposure: SE_R = SDE_R + SIE_R			Total systemic exposure: SE_R = SDE_R + SIE_R + SOE_H + SOE_O		
Total systemic exposure (absorbed dose)	0.0180519	mg/person	Total systemic exposure (absorbed dose)	0.0090698	mg/person
Total systemic exposure (absorbed dose)	**0.0003009**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0.0005616**	**mg/kg bw/d**
% of AOEL:	**3.34**	**%**	**% of AOEL:**	**6.24**	**%**

Estimation of bystander and resident exposure (adults and children)

Active substance (a.s.)		**Chlorothalonil**
Product		**A14111B**
Intended uses	**tomato**	**High crops, hand held (HCHH)**
Treated area per day (A)	**1**	**ha/d**
Application rate (AR)	**1**	kg a.s./ha
Number of applications (NA)	**1**	[1]

[1] Consideration of more than two applications are not necessary if degradation of the active substance on foliage of at least 50 % can be assumed between two applications (otherwise use multiple application factor).

Dermal absorption (DA)	**7**	% (worst case, e.g. during application)
Inhalation absorption (IA)	**100**	%
Oral absorption (OA)	**32**	%
Systemic AOEL	**0.009**	mg/kg bw/d
Body weight (BW)	**60**	kg/person (adults)
	16.15	kg/person (children)

Distance between application and bystander or resident:

Field crops not selected	**10**	m
HCTM/HCHH:		
		m
Home & garden not selected		
		m

Drift deposit (D) for 1 appl. based on appl. technique and distance: **% (HCHH, 0 m)**

Airborne vapour concentration (ACv) **0.001** mg/m³ [2]

[2] 1 µg/m³ for semivolatile substances, i.e. vapour pressure (20 °C): ≥ $1x10^{-5}$ - < $5x10^{-3}$ Pa; 15 µg/m³ for volatile substances, i.e. vapour pressure (20 °C): ≥ $5x10^{-3}$ Pa

Estimation of bystander exposure during/after application in High crops, hand held (HCHH)

Input parameters considered for the estimation of bystander exposure:

Intended use(s):	tomato		**Drift (D):**		% (HCHH, 0 m)
Application rate (AR):	1	kg a.s./ha	**Exposed Body Surface Area (BSA):**	1	m² (adults)
				0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I*A):**	0.3	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.17241	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	7.00	% ('worst case')	**Area Treated (A):**	1	ha/d (based on High crops, hand held (HCHH))
Inhalation absorption (IA):	100	%	**Exposure duration (T):**	5	min
AOEL:	0.009	mg/kg bw/d			

Bystander exposure towards Chlorothalonil					
Adults			**Children**		
Bystander: Dermal exposure after application in tomato (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(100 x 0% x 1 x 7%) / 60			(100 x 0% x 0.21 x 7%) / 16.15		
External exposure		mg/person	External exposure		mg/person
External exposure		mg/kg bw/d	External exposure		mg/kg bw/d
Absorbed dose:		**mg/kg bw/d**	**Absorbed dose:**		**mg/kg bw/d**
Bystander: Inhalation exposure after application in tomato					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0,000 / 360 x 1 x 1 x 5 x 100%) / 60			(0,000 / 360 x 1 x 1 x 5 x 100%) / 16.15		
External exposure	0.00416667	mg/person	External exposure	0.00239464	mg/person
External exposure	6.9444E-05	mg/kg bw/d	External exposure	0.00014827	mg/kg bw/d
Absorbed dose:	**0.0000694**	**mg/kg bw/d**	**Absorbed dose:**	**0.0001483**	**mg/kg bw/d**
Total systemic exposure: SE_B = SDE_B + SIE_B			Total systemic exposure: SE_B = SDE_B + SIE_B		
Total systemic exposure (absorbed dose)	0.00416667	mg/person	Total systemic exposure (absorbed dose)	0.00239464	mg/person
Total systemic exposure (absorbed dose)	**0.0000694**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0.0001483**	**mg/kg bw/d**
% of AOEL:	**0.77**	**%**	**% of AOEL:**	**1.65**	**%**

Estimation of resident exposure after application in High crops, hand held (HCHH)

Input parameters considered for the estimation of resident exposure:

Intended use(s):	tomato		**Drift (D):**		% (HCHH, 0 m)
Application rate (AR):	1	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
				2600	cm^2/h (children)
Number of applications (NA):	1		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0.001	mg/m3
Dermal absorption (DA):	7.00	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults),
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA)	32	%	**Saliva Extraction Factor (SE):**	50	%
AOEL	0.009	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Resident exposure towards Chlorothalonil					
Adults			**Children**		
Residents: Dermal exposure after application in tomato (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.01 x 1 x 0% x 5% x 7300 x 2 x 7%) / 60			(0.01 x 1 x 0% x 5% x 2600 x 2 x 7%) / 16.15		
External exposure		mg/person	External exposure		mg/person
External exposure		mg/kg bw/d	External exposure		mg/kg bw/d
Absorbed dose:		**mg/kg bw/d**	**Absorbed dose:**		**mg/kg bw/d**
Residents: Inhalation exposure to vapour					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0.001 x 16.57 x 100%) / 60			(0.001 x 8.31 x 100%) / 16.15		
External exposure	0.01657	mg/person	External exposure	0.00831	mg/person
External exposure	0.00027617	mg/kg bw/d	External exposure	0.00051455	mg/kg bw/d
Absorbed dose:	**0.0002762**	**mg/kg bw/d**	**Absorbed dose:**	**0.0005146**	**mg/kg bw/d**
			Residents: Oral exposure (hand-to-mouth transfer)		
			SOE_H = (AR x NA x D x TTR x SE x SA x Freq x H x OA) /		
			(0.01 x 1 x 0% x 5% x 50% x 20 x 20 x 2 x 32%) / 16.15		
			External exposure		mg/person
			External exposure		mg/kg bw/d
			Absorbed dose		**mg/kg bw/d**
			Residents: Oral exposure (object-to-mouth transfer)		
			SOE_O = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.01 x 1 x 0% x 20% x 25 x 32%) / 16.15		
			External exposure		mg/person
			External exposure		mg/kg bw/d
			Absorbed dose		**mg/kg bw/d**
Total systemic exposure: SE_R = SDE_R + SIE_R			Total systemic exposure: SE_R = SDE_R + SIE_R + SOE_H + SOE_O		
Total systemic exposure (absorbed dose)	0.01657	mg/person	Total systemic exposure (absorbed dose)	0.00831	mg/person
Total systemic exposure (absorbed dose)	**0.0002762**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0.0005146**	**mg/kg bw/d**
% of AOEL:	**3.07**	**%**	**% of AOEL:**	**5.72**	**%**

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

Active substance (a.s.)	**Chlorothalonil**		
Product	**A14111B**		
Intended use(s)	**cereals**		
Application rate (AR)	**0.75**	**kg a.s./ha**	
Number of applications (NA)	**2**		1)
Dislodgeable foliar residues (DFR)	**0.8405**	**µg/cm²/kg a.s.**	2)
Transfer coefficient (TC)	**1400**	**cm²/person/h**	3)
Work rate per day (WR)	**2**	**h/d**	4)
Penetration through clothing (P)	**0.05**	**(5 %)**	5)
Systemic AOEL	**0.009**	**mg/kg bw/d**	
Dermal absorption DA)	**3**	**% (worst case, e.g. for dilution)**	
Body weight (BW)	**60**	**kg**	

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

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

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

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

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

Estimation of worker (re-entry) exposure

Input parameters considered for the estimation of worker exposure:

Intended use(s):	cereals		**Dislodgeable foliar residues (DFR):**	0.8405	µg/cm²/kg a.s.
Application rate (AR):	0.75	kg a.s./ha	**Transfer coefficient (TC):**	1400	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	3	% ('worst case')			
AOEL	0.009	mg/kg bw/d			

Worker exposure towards Chlorothalonil					
Without PPE 1)			**With PPE** 2)		
Worker (re-entry): Systemic dermal exposure after application in cereals					
SDEw = (DFR x TC x WR x AR x NA x DA) / BW			SDEw = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(0.8405 x 1400 x 2 x 0.75 x 2 x 3%) / 60			(0.8405 x 1400 x 2 x 0.75 x 2 x 5% x 3%) / 60		
External dermal exposure	3.53	mg/person	External dermal exposure	0.18	mg/person
External dermal exposure	0.06	mg/kg bw/d	External dermal exposure	0.00	mg/kg bw/d
Total systemic exposure	0.11	mg/person	Total systemic exposure	0.01	mg/person
Total systemic exposure	**0.001765**	**mg/kg bw/d**	**Total systemic exposure**	**0.000088**	**mg/kg bw/d**
% of AOEL	**19.6**	**%**	**% of AOEL**	**1.0**	**%**

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)

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

Active substance (a.s.)	**Chlorothalonil**		
Product	**A14111B**		
Intended use(s)	**tomato**		
Application rate (AR)	**1**	**kg a.s./ha**	
Number of applications (NA)	**1**		1)
Dislodgeable foliar residues (DFR)	**1**	**µg/cm²/kg a.s.**	2)
Transfer coefficient (TC)	**1400**	**cm²/person/h**	3)
Work rate per day (WR)	**2**	**h/d**	4)
Penetration through clothing (P)	**0.05**	**(5 %)**	5)
Systemic AOEL	**0.009**	**mg/kg bw/d**	
Dermal absorption DA)	**7**	**% (worst case, e.g. for dilution)**	
Body weight (BW)	**60**	**kg**	

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

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

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

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

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

Estimation of worker (re-entry) exposure

Input parameters considered for the estimation of worker exposure:

Intended use(s):	tomato		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	1	kg a.s./ha	**Transfer coefficient (TC):**	1400	cm²/person/h
Number of applications (NA):	1		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	7	% ('worst case')			
AOEL	0.009	mg/kg bw/d			

Worker exposure towards Chlorothalonil					
Without PPE 1)			**With PPE** 2)		
Worker (re-entry): Systemic dermal exposure after application in tomato					
SDEw = (DFR x TC x WR x AR x NA x DA) / BW			SDEw = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 1400 x 2 x 1 x 1 x 7%) / 60			(1 x 1400 x 2 x 1 x 1 x 5% x 7%) / 60		
External dermal exposure	2.80	mg/person	External dermal exposure	0.14	mg/person
External dermal exposure	0.05	mg/kg bw/d	External dermal exposure	0.00	mg/kg bw/d
Total systemic exposure	0.20	mg/person	Total systemic exposure	0.01	mg/person
Total systemic exposure	**0.003267**	**mg/kg bw/d**	**Total systemic exposure**	**0.000163**	**mg/kg bw/d**
% of AOEL	**36.3**	**%**	**% of AOEL**	**1.8**	**%**

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

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

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

Active substance (a.s.)	**Chlorothalonil**		
Product	**A14111B**		
Intended use(s)	**tomato**		
Application rate (AR)	**1**	**kg a.s./ha**	
Number of applications (NA)	**1**		1)
Dislodgeable foliar residues (DFR)	**1**	**µg/cm²/kg a.s.**	2)
Transfer coefficient (TC)	**2500**	**cm²/person/h**	3)
Work rate per day (WR)	**8**	**h/d**	4)
Penetration through clothing (P)	**0.05**	**(5 %)**	5)
Systemic AOEL	**0.009**	**mg/kg bw/d**	
Dermal absorption DA)	**7**	**% (worst case, e.g. for dilution)**	
Body weight (BW)	**60**	**kg**	

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

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

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

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

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

Estimation of worker (re-entry) exposure

Input parameters considered for the estimation of worker exposure:

Intended use(s):	tomato		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	1	kg a.s./ha	**Transfer coefficient (TC):**	2500	cm²/person/h
Number of applications (NA):	1		**Work rate per day (WR):**	8	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	7	% ('worst case')			
AOEL	0.009	mg/kg bw/d			

Worker exposure towards Chlorothalonil					
Without PPE 1)			**With PPE** 2)		
Worker (re-entry): Systemic dermal exposure after application in tomato					
SDEw = (DFR x TC x WR x AR x NA x DA) / BW			SDEw = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 2500 x 8 x 1 x 1 x 7%) / 60			(1 x 2500 x 8 x 1 x 1 x 5% x 7%) / 60		
External dermal exposure	20.00	mg/person	External dermal exposure	1.00	mg/person
External dermal exposure	0.33	mg/kg bw/d	External dermal exposure	0.02	mg/kg bw/d
Total systemic exposure	1.40	mg/person	Total systemic exposure	0.07	mg/person
Total systemic exposure	**0.023333**	**mg/kg bw/d**	**Total systemic exposure**	**0.001167**	**mg/kg bw/d**
% of AOEL	**259.3**	**%**	**% of AOEL**	**13.0**	**%**

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)