

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 6800 A

Product name(s): DUKES

Chemical active substance(s):

Dithianon 700 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on DUKES *

Product name and code	DUKES
Formulation type	Water dispersible granules [WG]
Active substance(s) (incl. content)	Dithianon 700 g/kg
Function	Fungicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of DUKES can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for DUKES according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Acute Tox. 4, Eye Irrit. 2
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07
Signal word	Warning
Hazard statement(s)	H302, H319
Precautionary statement(s)	P264, P270, P280, P301+P312, P305+P351+P338, P501
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Contains dithianon and 1,2-benzisothiazolin-3(2H)-one (CAS 2634-33-5). May produce an allergic reaction [EUH208]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for DUKES

	Crops	Result	PPE / Risk mitigation measures
Operators	Pome fruits Vehicle mounted	Acceptable	Work wear M/L and A + gloves M/L and A
	Pome fruits and almond Manual (early)	Acceptable	Work wear (arms, body and legs covered) M/L and A
	Pome fruits and almond Manual (late)	Not acceptable	Do not apply with manual equipment
Workers	Pome fruits	Acceptable	Work wear and gloves – re-entry after 2 7 10 days or

	Crops	Result	PPE / Risk mitigation measures
			Work wear – re-entry after 7 12 17 days
Residents and bystanders	Pome fruits – early and late	Acceptable	None (when 5 m buffer zone is considered)

No unacceptable risk for bystanders and residents was identified when the product is used as intended. No specific PPE is necessary.

No unacceptable risk for operators and workers was identified when the product is used as intended and provided that the PPE stated in Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in the following table.

Table 6.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10
Use-No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application Method / Kind (incl. application technique ***)	Max. number (min. interval between applications) a) per use b) per crop/ season	Application rate Max. application rate kg as/ha a) a.s. 1	Water L/ha min / max	PHI (d)	Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, resident or bystander exposure based on [Exposure model]	Acceptability of exposure assessment
									Operator Worker Residents Bystander
1	Pome fruits (BBCH 51-79)	F	Spraying, HCTM	a) 4 (7) b) 4 (7)	a) 0.35 b) 1.4	1000-1500	21	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

*** e.g. LC: low crop, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 “Acceptability of exposure assessment”

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance

	Dithianon
Common Name	Dithianon
CAS-No.	3347-22-6
Classification and proposed labelling	

	Dithianon
Harmonized classification with regard to human health effects (ATP Inserted / Updated: CLP00) Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)	Hazard classes , categories: Acute Tox. 4 (oral) Code for hazard pictogram: GHS07 Signal word: Warning Hazard statement: H302
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	0.0135 mg/kg bw/d (corrected for 45% oral absorption)
Reference	EFSA Journal 2010;8(11):1904
Conditions to take into account/critical areas of concern with regard to toxicology	
According to EFSA Conclusion for Dithianon	The operator safety

6.3 Toxicological Evaluation of Plant Protection Product

The assessment of all acute toxicological properties of DUKES are derived from the classification of the active compound and co-formulants. When considering the properties of all co-formulants and toxicity study DUKES is classified as Acute Tox. 4, Eye Irrit. 2 Therefore the Signal Word “Warning” and the Hazard Statement “H302: Harmful by swallow” “H319: Causes serious eye irritation are proposed.

Table 6.3-1: Additional toxicological information relevant for classification/labelling of DUKES

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Dithianon (70% (w/w))	H302	Reg. 1272/2008	H302
Toxicological properties of non-active substance(s) (relevant for classification of product)	Coformulant 1 (≥ 1% (w/w))*	H318	Reg. 1272/2008	H319
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.

** Material safety data sheet by the applicant.

6.4 Toxicological Evaluation of Groundwater Metabolites

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in DUKES are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in DUKES

	Dithianon	
	Value	Reference
Concentrate	0.26%	EFSA Journal 2010;8(11):1904
Dilution	3.1%	EFSA Journal 2010;8(11):1904 (Addendum January 2010)

	Dithianon	
	Value	Reference
Concentrate	0.3%	New study reported in Appendix 2 - Raghu Patil J., 2021
Dilution	6.3%	New study reported in Appendix 2 - Raghu Patil J., 2021

6.5.1 Justification for proposed values – Dithianon

Proposed dermal absorption rates for Dithianon are based on dermal absorption studies on a formulation similar to DUKES: Statement comparability for dermal absorption prepared for DUKES

The study results are summarised in the following table.

Table 6.5-2: Summary of the results of submitted dermal absorption studies for Dithianon

Test	Concen- trate	Spray dilu- tion	Formula- tion in study	Accepta- bility of study	Justification provided on representati- ty of study formulation for current product	Acceptability of justification	Reference*
<i>In vivo</i> (rat)	-	0.26% (2.1 mg/cm ²)	Dithianon technical	Yes / No / Suppleme ntary	Identic active substance	Justification accepted. End point can be used for current product / Justifi- cation not ac- cepted. Endpoint cannot be used for current product.	“DAR of Dithi- anon Volume 3, Annex B-6: toxicology and Metabolism- October 2006”.
<i>In vivo</i> (rat)	-	6.4% (0.0035 mg/cm ²)	DELAN 70 WG	Yes / No / Suppleme ntary	Similar formulation	Justification accepted. End point can be used for current product / Justifi- cation not ac- cepted. Endpoint cannot be used for current product.	“DAR of Dithi- anon Volume 3, Annex B-6: toxicology and Metabolism- October 2006”.

Test	Concen- trate	Spray dilu- tion	Formula- tion in study	Accepta- bility of study	Justification provided on representati- vity of study formulation for current product	Acceptability of justification	Reference*
<i>In vitro</i> (human)	-	0.02% (3.713 mg/cm ²)	DELAN 70 WG	Yes / No / Suppleme ntary	Similar formulation	Justification accepted. End- point can be used for current product / Justifi- cation not ac- cepted. Endpoint cannot be used for current product.	“DAR of Dithi- anon Volume 3, Annex B 6: toxicology and Metabolism- October 2006”.
	-	0.28% (0.00335 mg/cm ²)	DELAN 70 WG		Similar formulation		
<i>In vitro</i> (rat)	-	0.02% (4.317 mg/cm ²)	DELAN 70 WG	Yes / No / Suppleme ntary	Similar formulation	Justification accepted. End- point can be used for current product / Justifi- cation not ac- cepted. Endpoint cannot be used for current product.	“DAR of Dithi- anon Volume 3, Annex B 6: toxicology and Metabolism- October 2006”.
	-	0.64% (0.00345 mg/cm ²)	DELAN 70 WG		Similar formulation		
<i>In vitro</i> Human/rat ratio	1 (0.02/0.0 2)	-	-	Yes / No / Suppleme ntary	Not required	Justification accepted. End- point can be used for current product / Justifi- cation not ac- cepted. Endpoint cannot be used for current product.	-
Absorption rate human /skin ratio	0.9 (0.1646/ 0.1740)	-	-		Not required		-
<i>In vitro</i> Human/rat ratio	-	0.44 (0.28/0.64)	-		Not required		-
Absorption rate human /skin ratio	-	0.49 (0.00062/0.00 126)	-		Not required		-
<i>In vivo</i> (human)	0.26%	3.1%	-	Yes / No / Suppleme ntary	Not required	Justification accepted. End- point can be used for current product / Justifi- cation not ac- cepted. Endpoint cannot be used for current product.	-

* indicates that a study was reviewed at EU level

Table 6.5-3: Summary of in vitro human dermal absorption

Test	Concen- trate	Spray dilu- tion (dilution concentra- tion)	Formula- tion in study	Acceptabil- ity of study	Justification provided on representativity of study formu- lation for cur- rent product	Acceptability of justification	Refer- ence*
In vitro (human)	0.3 %	6.3 %	SHA 6800 A / DUKES	Yes / No / Supplementar y	Yes (see Appendix A 2.10)	Justification accepted. Endpoint can be used for current product / Justification not accepted. Endpoint cannot be used for current product.	Raghu Patil J., 2021

* indicates that a study was reviewed at EU level

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	DUKES
Formulation type	WG
Category	Fungicide
Active substance(s) (incl. content)	Dithianon 700 g/kg
AOEL systemic	0.0135 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	45%
Dermal absorption	Concentrate: 0.26% 0.3% Dilution: 3.1% 6.3% (EU Agreed / Based on product DELAN 70 WG)

6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in No unacceptable risk for bystanders and residents was identified when the product is used as intended. No specific PPE is necessary.

No unacceptable risk for operators and workers was identified when the product is used as intended and provided that the PPE stated in Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in the following table.

Table 6.1-4. A list of all intended uses within the zone/ is given in Part B, Section 0.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of DUKES according to the critical use(s) is presented in

Table 6.6-2. The outcome of the estimation is presented in (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Pome fruits (max. 0.50 kg product/ha)
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-3: Estimated operator exposure (longer term exposure)

		Dithianon	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
<i>Tractor mounted application outdoors to pome fruits</i>			
Application rate		0.35 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Without RPE/PPE	0.0253295	188
	Work wear M/L and A	0.0094763	70
<i>Manual hand held application outdoors to pome fruits — late (dense foliage)</i>			
Application rate		0.35 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Without RPE/PPE	0.5355708	3967
	Work wear M/L and A	0.0293249	217
	Work wear M/L and A + gloves M/L and A + hood and visor A	0.0254186	188
<i>Manual hand held application outdoors to pome fruits — early (without leaves)</i>			
Application rate		0.35 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Without RPE/PPE	0.0380307	282
	Work wear M/L and A	0.0050249	37
<i>Manual knapsack application outdoors to pome fruits — late (dense foliage)</i>			
Application rate		0.35 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Without RPE/PPE	0.5359276	3970
	Work wear M/L and A	0.0296732	220
	Work wear M/L and A + gloves M/L and A + hood and visor A	0.0253813	188
<i>Manual knapsack application outdoors to pome fruits — early (without leaves)</i>			
Application rate		0.35 kg a.s./ha	

Model data	Level of PPE	Dithianon	
		Total ab-sorbed dose (mg/kg/day)	% of sys-temic AOEL
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Without RPE/PPE	0.0290093	215
	Work wear M/L and A	0.0025656	19

According to the AOEM model calculations, it can be concluded that:

The risk for the operator using vehicle-mounted application equipment is acceptable even not considering the use of PPE.

The risk for the operator using manual application equipment is acceptable for early season (without leaves) but is not acceptable for late season (dense foliage) even considering the use of PPE.

Implication for labelling:

Do not apply to pome fruits and almond with manual equipment for late season (dense foliage).

		Dithianon	
Model data	Level of PPE	Total ab-sorbed dose (mg/kg/day)	% of sys-temic AOEL
Tractor mounted application outdoors to pome fruits			
Application rate		0.35 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Without RPE/PPE	0.0480699	567
	Work wear M/L and A + gloves M/L and A	0.0078755	58
Manual-hand held application outdoors to pome fruits – late (dense foliage)			
Application rate		0.35 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Without RPE/PPE	1.0868432	8051
	Work wear M/L and A	0.0580431	430
	Work wear M/L and A + gloves M/L and A + hood and visor A	0.0487870	361
Manual-hand held application outdoors to pome fruits – early (without leaves)			
Application rate		0.35 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Without RPE/PPE	0.0746182	553
	Work wear M/L and A	0.0076006	56
Manual-knapsack application outdoors to pome fruits – late (dense foliage)			
Application rate		0.35 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Without RPE/PPE	1.0872608	8054
	Work wear M/L and A	0.0584510	433
	Work wear M/L and A + gloves M/L and A + hood and visor A	0.0487498	361
Manual-knapsack application outdoors to pome fruits – early (without leaves)			
Application rate		0.35 kg a.s./ha	
Spray application (AOEM; 75 th percentile)	Without RPE/PPE	0.0575520	426
	Work wear M/L and A	0.0038412	28

		Dithianon	
Model data	Level of PPE	Total ab-sorbed dose (mg/kg/day)	% of systemic AOEL
Body weight: 60 kg			

Conclusion

According to the AOEM model calculations, it can be concluded that:

The risk for the operator using vehicle-mounted application equipment is acceptable when work wear M/L and A + gloves M/L and A.

The risk for the operator using manual application equipment is acceptable for early season (without leaves) but is not acceptable for late season (dense foliage) even considering the use of PPE.

Implication for labelling:

Do not apply to pome fruits and almond with manual equipment for late season (dense foliage).

Conclusion is acceptable

6.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-3 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with DUKES according to the critical use(s). Outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.** (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-3: Exposure models for intended uses

Critical use(s)	Pome fruits (max. 4 x 0.50 kg product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-4: Estimated worker exposure

		Dithianon	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Pome fruits—early and late			
Searching, reaching, picking / Outdoor Work rate: 8 hours/day, DT ₅₀ : 5.29 days based on SGS data—residue trials (please refer to data presented in Appendix 5) DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm ² /person/h	0.1585020	1174
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0317004	235
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0158502	117

Proposal of Re-entry period of 2 days			
Searching, reaching, picking / Outdoor Work rate: 8 hours/day; DT ₅₀ : 5.29 days based on SGS data—residue trials (please refer to data presented in Appendix 5) DFR: 2.31 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm ² /person/h	0.1220465	904
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0244093	181
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0122047	90
Proposal of Re-entry period of 7 days			
Searching, reaching, picking / Outdoor Work rate: 8 hours/day; DT ₅₀ : 5.29 days based on SGS data—residue trials (please refer to data presented in Appendix 5) DFR: 1.20 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm ² /person/h	0.0634008	470
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0126802	94
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0063401	47

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves), for maintenance activities when for re-entering pome fruits treated with DUKES a time period of 2 days after application is respected or without gloves when a time period of 7 days after application is respected. 7 days is below PHI and therefore is acceptable.

		Dithianon	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Pome fruits – early and late			
Searching, reaching, picking / Outdoor Work rate: 8 hours/day, DT ₅₀ : 5.29 days based on SGS data – residue trials (please refer to data presented in Appendix 5) DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm ² /person/h	0.3221169	2386
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0644234	477
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0322117	239

Proposal of Re-entry period of 7 days Searching, reaching, picking / Outdoor Work rate: 8 hours/day, DT ₅₀ : 5.29 days based on SGS data – residue trials (please refer to data presented in Appendix 5) DFR: 1.20 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm ² /person/h	0.1288468	954
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0257694	191
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0128847	95
Proposal of Re-entry period of 12 days Searching, reaching, picking / Outdoor Work rate: 8 hours/day, DT ₅₀ : 5.29 days based on SGS data – residue trials (please refer to data presented in Appendix 5) DFR: 0.62 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm ² /person/h	0.0665708	493
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0133142	99
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0066571	49

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves), for maintenance activities when for re-entering pome fruits treated with DUKES a time period of 7 days after application is respected or without gloves when a time period of 12 days after application is respected. 7 days is below PHI and therefore is acceptable.

Conclusion is acceptable

		Dithianon	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Pome fruits – early and late			
Searching, reaching, picking / Outdoor Work rate: 8 hours/day, DT ₅₀ : 6.68 days based on SGS data – residue trials (please refer to data presented in Appendix 5) DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm ² /person/h	0.3633134	2691
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0726627	538
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0363313	269

Proposal of Re-entry period of 10 days Searching, reaching, picking / Outdoor Work rate: 8 hours/day, DT ₅₀ : 6.68 days based on SGS data – residue trials (please refer to data presented in Appendix 5) DFR: 1.08 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Body weight: 60 kg	Potential		
	TC: 22500 cm ² /person/h	0.1307928	969
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0261586	194
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0130793	97
Proposal of Re-entry period of 17 days Searching, reaching, picking / Outdoor Work rate: 8 hours/day, DT ₅₀ : 6.68 days based on SGS data – residue trials (please refer to data presented in Appendix 5) DFR: 0.52 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Body weight: 60 kg	Potential		
	TC: 22500 cm ² /person/h	0.0629743	466
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0125949	93
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0062974	47

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves), for maintenance activities when for re-entering pome fruits treated with DUKES a time period of 10 days after application is respected or without gloves when a time period of 17 days after application is respected. 10 days is below PHI and therefore is acceptable.

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm² per kg s.a/ha.

Refinement

Proposal of Re-entry period

The Applicant propose to consider as refinement a re-entry period. Therefore we propose to calculate DFR value at ~~2 and 7 days~~ 7 and 12 days 10 and 17 days for pome fruits.

Body weight 60 kg.

DT₅₀ calculation is based on SGS data – residue trials (please refer to data presented in Appendix 5). A DT₅₀ value = 5.29 days were obtained.

DFR_t is calculated according the following formula:

$$DFR_T = DFR_0 \times e^{-k, t}$$

Where:

DFR_T Dislodgeable foliar residue at the time of re-entry (µg/cm²)

DFR₀ Dislodgeable foliar residue just after application (µg/cm²)

- k Degradation constant (days⁻¹), calculated from the half life time:
 $k = \ln(2)/DT_{50}$,
 DT₅₀ Foliar half-life time (days)
 t Re-entry interval (days)

Dislodgeable foliar residue just after application is calculated as:

$$DFR_0 = DFR_{def} \times MAF$$

Where:

DFR_{def} default value (If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm² per kg s.a/ha)

MAF_m (multiple application factor for mean residue data for *n* application) is:

$$MAF = (1 - e^{-nki}) / (1 - e^{-ki})$$

where:

n is the number of applications

k is the rate constant for foliar dissipation $k = \ln(2)/DT_{50}$,

i is the interval between applications (days)

DFR factor was calculated for every crop based on above formula and according to the EFSA Journal 2014;12(10):3874¹, corresponding to a half-life_{foliar} of 5.29 days (please refer to data presented in Appendix 5).

Pome fruits:

For pome fruits, a number of 4 applications (*n*) and a 7 day interval (*i*) between applications is considered (worst case scenario) and MAF is 1.80. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.80 = 5.4 \mu\text{g}/\text{cm}^2 \quad (\text{where } DFR_{def} = 3 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha})$$

Therefore for 2 7 10 days of re-entry interval:

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 4.86 \mu\text{g}/\text{cm}^2 \times 0.772 = 3.75 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def \text{ ref}} \times MAF = 3.75 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def \text{ ref}} = 2.31 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 5.4 \mu\text{g}/\text{cm}^2 \times 0.401 = 1.95 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def \text{ ref}} \times MAF = 1.95 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def \text{ ref}} = 1.20 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 5.4 \mu\text{g}/\text{cm}^2 \times 0.361 = 1.95 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def \text{ ref}} \times MAF = 1.95 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def \text{ ref}} = 1.08 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

Therefore for 7 12 17 days of re-entry interval:

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 4.86 \mu\text{g}/\text{cm}^2 \times 0.401 = 1.95 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def \text{ ref}} \times MAF = 1.95 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def \text{ ref}} = 1.20 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 5.4 \mu\text{g}/\text{cm}^2 \times 0.208 = 1.01 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def \text{ ref}} \times MAF = 1.01 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def \text{ ref}} = 0.62 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 5.4 \mu\text{g}/\text{cm}^2 \times 0.174 = 0.94 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def \text{ ref}} \times MAF = 0.94 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def \text{ ref}} = 0.52 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

Acceptable

¹ Guidance of EFSA (EFSA Journal 2014;12(10):3874): "Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products"

6.6.3.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

Table 6.6-5 shows the exposure model(s) used for estimation of resident and bystander exposure to Dithianon. The outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.** (longer term resident exposure) and Table 6.6-6 (acute bystander exposure). Detailed calculations are in Appendix 3.

Table 6.6-5: Exposure models for intended uses

Critical use(s)	Pome fruits (max. 4 x 0.50 kg product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-6: Estimated resident exposure (longer term exposure)

		Dithianon	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Pome fruits — early and late			
Tractor mounted — application outdoors — early Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 5.29 days based on SGS data — residue trials (please refer to data presented in Appendix 5) DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0015602	11.56
	Vapour (75 th perc.)	0.0010700	7.93
	Deposits (75 th perc.)	0.0013083	9.69
	Re-entry (75 th perc.)	0.0029719	22.01
	Sum (mean)	0.0054424	40.31
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0008471	6.27
	Vapour (75 th perc.)	0.0002300	1.70

		Dithianon	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
	Deposits (75 th perc.)	0.0003383	2.51
	Re-entry (75 th perc.)	0.0016511	12.23
	Sum (mean)	0.0023525	17.43
Tractor mounted – application outdoors – late Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 5.29 days based on SGS data – residue trials (please refer to data presented in Appendix 5) DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0015602	11.56
	Vapour (75 th perc.)	0.0010700	7.93
	Deposits (75 th perc.)	0.0005005	3.71
	Re-entry (75 th perc.)	0.0029719	22.01
	Sum (mean)	0.0047828	35.43
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0008471	6.27
	Vapour (75 th perc.)	0.0002300	1.70
	Deposits (75 th perc.)	0.0001294	0.96
	Re-entry (75 th perc.)	0.0016511	12.23
	Sum (mean)	0.0021820	16.16

		Dithianon	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Pome fruits – early and late			
Tractor mounted - application outdoors – early Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 5.29 days based on SGS data – residue trials (please refer to data presented in Appendix 5) DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0031114	23.05
	Vapour (75 th perc.)	0.0010700	7.93
	Deposits (75 th perc.)	0.0020547	15.22
	Re-entry (75 th perc.)	0.0060397	44.74
	Sum (mean)	0.0099738	73.88
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0017089	12.66
	Vapour (75 th perc.)	0.0002300	1.70
	Deposits (75 th perc.)	0.0006876	5.09

		Dithianon	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
	Re-entry (75 th perc.)	0.0033554	24.85
	Sum (mean)	0.0048130	35.65
Tractor mounted - application outdoors – late Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 5.29 days based on SGS data – residue trials (please refer to data presented in Appendix 5) DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0031114	23.05
	Vapour (75 th perc.)	0.0010700	7.93
	Deposits (75 th perc.)	0.0007860	5.82
	Re-entry (75 th perc.)	0.0060397	44.74
	Sum (mean)	0.0089380	66.21
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0017089	12.66
	Vapour (75 th perc.)	0.0002300	1.70
	Deposits (75 th perc.)	0.0002630	1.95
	Re-entry (75 th perc.)	0.0033554	24.85
	Sum (mean)	0.0044664	33.08

No unacceptable risk for bystanders and residents was identified when the product is used as intended

		Dithianon	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Pome fruits – early and late			
Tractor mounted - application outdoors – early Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 6.68 days based on SGS data – residue trials (please refer to data presented in Appendix 5) DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0031114	23.05
	Vapour (75 th perc.)	0.0010700	7.93
	Deposits (75 th perc.)	0.0023175	17.17
	Re-entry (75 th perc.)	0.0068121	50.46
	Sum (mean)	0.0102708	76.08
Resident adult	Drift (75 th perc.)	0.0017089	12.66

		Dithianon	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Body weight: 60 kg	Vapour (75 th perc.)	0.0002300	1.70
	Deposits (75 th perc.)	0.0007755	5.74
	Re-entry (75 th perc.)	0.0037845	28.03
	Sum (mean)	0.0049406	36.60
Tractor mounted - application outdoors – late Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 6.68 days based on SGS data – residue trials (please refer to data presented in Appendix 5) DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.35 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0031114	23.05
	Vapour (75 th perc.)	0.0010700	7.93
	Deposits (75 th perc.)	0.0008865	6.57
	Re-entry (75 th perc.)	0.0068121	50.46
	Sum (mean)	0.0091025	67.43
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0017089	12.66
	Vapour (75 th perc.)	0.0002300	1.70
	Deposits (75 th perc.)	0.0002967	2.20
	Re-entry (75 th perc.)	0.0037845	28.03
	Sum (mean)	0.0045496	33.70

No unacceptable risk for bystanders and residents was identified when the product is used as intended Buffer zone: 5 (m)

6.6.4.2 Measurement of resident and/or bystander exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for dithianon will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and 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	Owner
KCP 7.6.2	Raghu Patil J.	2021	In vitro percutaneous dermal absorption study of Dithianon 70% WG, through human skin. Eurofins Advinus Limited, Study No. G20355 GLP, Unpublished	N	Sharda Cropchem Limited

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

No additional study submitted.

The following tables are to be completed by MS

List of data submitted by the applicant and not 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	Owner
KCP XX	Author	YYYY	Title Company Report N Source	Y/N	Owner

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	Owner
			GLP/non GLP/GEP/non GEP Published/Unpublished		

List of data relied on not submitted by the applicant but necessary for evaluation

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	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Comments of zRMS:	N/A
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A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	<p>The acute oral toxicity for Dithianon 70% WG (DUKES) has been estimated to be 685 mg/kg bw and therefore <2000 mg / kg bw</p> <p>According to the Regulation EC No. 1272/2008, from calculations, Dithianon 70% WG (DUKES) should be classified for oral toxicity: Acute Tox.4/H302: Harmful by swallow</p>
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Acute toxicity studies for Dithianon 70% WG were not evaluated as part of the EU review of Dithianon . Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Dithianon 70% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The acute oral toxicity of Dithianon 70% WG was calculated as follow:

$$ATE_{mix} = \frac{100}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100}{\frac{71.79}{500} + \frac{xxx}{500} + \frac{xxx}{500}} = 685 \text{ mg/kg bw}$$

The acute oral toxicity calculation for Dithianon 70% WG was estimated to be < 2000 mg/kg, DITH (Dithianon 70% WG therefore should be classified as harmful by swallow.

According to the Regulation EC No. 1272/2008, using worse results from calculations, Dithianon 70% WG should be classified for oral toxicity. Therefore the Signal Word “**Warning**” and the Hazard Statement “**H302: Harmful by swallow**” are proposed.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	There is no co-formulant in the Dithianon 70% WG (DUKES) recipe classified as danger through dermal contact. According to the Regulation EC No. 1272/2008, Dithianon 70% WG (DUKES) is not classified
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Acute toxicity studies for Dithianon 70% WG were not evaluated as part of the EU review of Dithianon . Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute dermal toxicity of Dithianon 70% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

There is no co-formulant in the Dithianon 70% WG recipe classified as danger through dermal contact.

According to the Regulation EC No. 1272/2008, Dithianon 70% WG is **not classified**. No signal word or hazard statement is required for this hazard

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	There is no co-formulant in the Dithianon 70% WG (DUKES) recipe classified as acute inhalation toxicity. According to the Regulation EC No. 1272/2008, Dithianon 70% WG (DUKES) is not classified.
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Acute toxicity studies for Dithianon 70% WG were **not** evaluated as part of the EU review of acrinathrin. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute inhalation toxicity of Dithianon 70% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

There is no co-formulant in the Dithianon 70% WG recipe classified as acute inhalation toxicity.

According to the Regulation EC No. 1272/2008, Dithianon 70% WG is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	The product contains < 10% of co-formulants considered as skin irritant (classified as: Skin Irrit. 2; H315). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008. According to the Regulation EC No. 1272/2008, Dithianon 70% WG (DUKES) is not classified.
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Acute toxicity studies for Dithianon 70% WG were **not** evaluated as part of the EU review of acrinathrin. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Dithianon 70% WG can be found in an appendix to the confidential dossier of this submission (Registra-

tion Report, Part C).

The product contains < 10% of co-formulants considered as skin irritant (classified as: Skin Irrit. 2; H315). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Dithianon 70% WG is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	<p>The product contains > 1% of co-formulants considered as eye damage (classified as: Eye Dam. 1; H318). Under the GHS classification system this component is gets the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.</p> <p>According to the Regulation EC No. 1272/2008, Dithianon 70% WG (DUKES) is classified as Eye Irrit.2/ H319</p>
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Acute toxicity studies for Dithianon 70% WG were **not** evaluated as part of the EU review of acrinathrin. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Dithianon 70% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The product contains > 1% of co-formulants considered as eye damage (classified as: Eye Dam. 1; H318). Under the GHS classification system this component is gets the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Dithianon 70% WG is classified as Eye irritant. Therefore hazard statement H319 with pictogram GHS07 and the signal word “Warning” is proposed

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	<p>According to the Regulation EC No. 1272/2008, Dithianon 70% WG (DUKES) is not classified. No signal word or hazard statement is required.</p> <p>However, the Dithianon 70% WG contains ≥ 0.0025 – < 0.025% of 1,2-benzisothiazol-3(2H)-one (CAS: 2634-33-5), which has specific limit concentration ($C \geq 0.05\%$).</p> <p>Therefore, the statement “EUH208: Contains 1,2-benzisothiazolin-3-one (2634-33-5). May produce an allergic reaction</p>
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The product contains < 1% of co-formulants considered as skin sensitiser (classified as: Skin Sens. 1; H317). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Dithianon 70% WG is **not classified**. No signal word or hazard statement is required.

However, the Dithianon 70% WG contains $\geq 0.0025 - < 0.025\%$ of 1,2-benzisothiazol-3(2H)-one (CAS: 2634-33-5), which has specific limit concentration ($C \geq 0.05\%$). Therefore, the statement “**EUH208:** Contains 1,2-benzisothiazolin-3-one (2634-33-5). May produce an allergic reaction.” is proposed.

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplementary studies are necessary.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

Comments of zRMS:	0.3 % of dose for undiluted Dithianon formulation (concentrate: 706 g/kg) Dithianon)
	6.3 % of dose for actual spray strength used in the field dilution (0.35 g/L Dithianon)

The dermal absorption value for granules formulations as stated in the List of endpoints of Dithianon is based on a WG formulation containing 700 g/kg Dithianon. The dermal absorption is 0.26% for a concentrate and 3.1% for a spray dilution.

According to "EFSA Journal 2012;10(4):2665, Guidance on Dermal Absorption, EFSA Panel on Plant Protection Products and their Residues (PPR)" data on another (reference) formulation can be used if the formulation to be assessed is closely related.

This is the case for the formulation Dithianon 70% WG.

EU agreed endpoint can be used as DELAN 70 WG and Dithianon 70% WG are similar formulations:

- Active substance content: Dithianon
- Formulation type: WG
- Active substance content: 700 g/kg
- Acute dermal toxicity: $> 2000 \text{ mg/kg bw}$
- Skin irritation : not a skin irritant

A 2.10.1

A 2.10.2 Study 1 – Dithianon in Dithianon 70% WG

A 2.10.3 Comparative dermal absorption, in vitro using rat and human skin

Reference	KCP 7.6.2
Report	In vitro percutaneous dermal absorption study of Dithianon 70% WG, through human skin, Raghu Patil J., 2021. Study No.: G20355
Guideline(s)	OECD Guideline 428 “Skin Absorption: in vitro Method” April 2004
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material	Name (Lot/Batch No.)	¹⁴ C-Dithianon (XXV/4/A/2)
	Test preparation	radioformulation
	Specific activity	6.853 MBq/mg
	Radiochemical purity	98.73 %
Product	Name (Lot/Batch No.)	Dithianon 70% WG (SCL-10231)
	Company code	Dithianon
	Concentration a.s.	701 g/kg
	Formulation type	Dithianon 70% WG
Blank product	Name (Lot/Batch No.)	Dithianon 70% WG blank formulation (SCL-61452)
	Concentration a.s.	0 g/kg

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1.8 mL/h
	Exposed skin area	0.64 cm ²
Membrane	Skin type	isolated epidermis
	Skin thickness range	0.2-0.4 mm
	Skin donors age	51, 45, 53, 47 years
	Skin donors sex	female
	Location	abdomen
	Source	post-mortem
	Integrity test	yes
Receptor	Receptor medium	Phosphate buffered saline (PBS) + 0.01% sodium azide +6% polyethylene glycol (PEG), pH ca. 7.2
	Solubility in receptor medium	Yes
Sample Time	Exposure time	8 h
	Observation time	16 h
Sampling	Sample intervals	At 0-1 h, 1-2 h, followed by 2-h intervals until 24 hours after

		application
Washing		At 8 h using water and a mild soap solution (3% Dove)
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	y

Tested doses	Concentrate	Spray dilution
Target concentration	700 g·kg ⁻¹	0.35 g·L ⁻¹
Area dose	3532 ± 6.24 µg/cm ²	3.61 ± 0.008 µL/cm ²
Specific activity	7.56 MBq.g ⁻¹	2.43 MBq.mL ⁻¹
No. of donors	4	4
No of cells used/valid cells*	8/8	8/8

Results and discussions - Dithianon

Dose group	High dose (Formulation concentrate)		Low dose (Spray dilution 1:2000)	
	Mean	S.D.	Mean	S.D.
Target concentration	700 g·kg ⁻¹		0.35 g·L ⁻¹	
Target dose	5000 µg/cm ²		10 µL/cm ²	
Mean actual applied dose	3532 ± 6.24 µg/cm ²		3.61 ± 0.008 µL/cm ²	
Number of replicates (n)	8		8	
Dislodgeable dose				
Skin wash	100.8158	3.7957	93.3358	5.1621
Donor chamber wash	0.6002	0.1826	1.7059	2.8357
Dose associated to skin				
Tape strips: 1 st sample, strips 1 + 2	0.8270	0.3678	3.7840	0.5515
Tape strips: 2 nd sample; strips 3 - n	0.2224	0.0509	3.4801	0.5546
Skin preparation	0.0207	0.0131	1.9253	0.2052
Absorbed dose				
Receptor fluid	0.0172	0.0055	0.2519	0.0398
Receptor chamber wash	0.0015	0.0010	0.0456	0.0152
Total recovery ¹	102.5048	3.6369	104.5285	4.2041
Absorption essentially complete at end of study (>75% absorption within half the study duration) [% Absorption at t _{0.5}]	No [46.85 ± 9.82]		No [57.2 ± 2.08]	
If no: Absorption estimates = absorbed dose + skin preparation + tape strips sample 2) ²	0.2618	0.0625	5.7028	0.6581
If yes: Absorption estimates = absorbed dose + skin preparation	N/A	N/A	N/A	N/A
Absorption estimate normalised ³	0.2618 ± 0.84 × 0.0625		5.7028 ± 0.84 × 0.6581	
Relevant absorption estimate	0.3143		6.2556	
Absorption estimates ⁴	0.3		6.3	

¹ Values may not calculate exactly due to rounding of figures

² In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study (see Table 7.6.2-1) Finally, the skin preparation is also considered potentially absorbable.

³ In accordance with the EFSA Guidance on Dermal Absorption (2017), dermal absorption should be calculated as follows: Absorption (mean value) + ks, where s is the sample standard deviation. The multiplication factor required depends on the number of replicates and is given in Table 1 of EFSA Guidance.

⁴ Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

Conclusion/endpoint: 0.3 % of dose for undiluted Dithianon formulation (concentrate: 706 g/kg) Dithianon)

6.3 % of dose for actual spray strength used in the field dilution (0.35 g/L Dithianon)

A 2.11 Other/Special Studies

No new additional other/special studies

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.2 Table A 1: Pome fruits with vehicle-mounted application equipment (No PPE) with PPE

Operator exposure for outdoor spray applications

Application rate of active substance	0,45 kg a. c./ha	$L_{AppRate}$
Assumed area treated	10 ha/day	$d_{AreaTreated}$
Amount of active substance applied	4,5 kg a. c./day	L_{Amount}
Dermal absorption of the product	0,25%	$L_{AbsorpProduct}$
Dermal absorption of in-use dilution	4,10%	$L_{AbsorInUse}$
Formulation type	Wettable granules, soluble granules	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
Mixing and loading	Hands	3539	16382	ADNM	
	Body	2979	23126	ADNM	
	Head	23	333	ADNM	
	Protected hands (gloves)	37	110	ADNM	
	Protected body (workwear or protective garment and sturdy footwear)	56	213	ADNM	
	Protected head (hood and face shield)	0	13	ADNM	
	Inhalation	54	267	ADNM	
	Protective equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in ADNM model	
Application	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	7665	21329	ADNM	No data available for a drift reduction scenario
	Body	30341	179957	ADNM	
	Head	4053	24373	ADNM	
	Protected hands (gloves)	123	3213	ADNM	
	Protected body (workwear or protective garment and sturdy footwear)	402	736	ADNM	
	Inhalation	110	239	ADNM	
	Protective equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in ADNM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer Term			
Total systemic exposure from mixing, loading and application (mg a. c./day)	1,5197716	0,5605756	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0254295	0,0094763	
% of RVNAS	137,63%	70,19%	

Operator exposure for Dithianon 70% WG outdoor spray applications

Application rate of active substance	0,35 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	10 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	3,5 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	0,30%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	6,30%	<i>i_AbsorInuse</i>
Formulation type	Wettable granules, soluble granules	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
Mixing and loading	Hands	3439	16582	AOEM	
	Body	2979	23126	AOEM	
	Head	23	313	AOEM	
	Protected hands (gloves)	37	110	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	56	218	AOEM	
	Protected head (hood and face shield)	0	18	AOEM	
	Inhalation	54	267	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Application	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	7664	21829	AOEM	No data available for a drift reduction scenario
	Body	30841	179957	AOEM	
	Head	4053	24875	AOEM	
	Protected hands (gloves)	123	3218	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	402	786	AOEM	
	Inhalation	130	289	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	2,8841966	0,4725320
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0480699	0,0078755
% of RVNAS	356,07%	58,34%

Table A 2: Pome fruits with manual-hand held application equipment– late (dense foliage)

Operator exposure for outdoor spray applications

Application rate of active substance	0,35 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	1 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0,35 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	0,26%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	3,10%	<i>i_AbsorInuse</i>
Formulation type	Wettable granules, soluble granules	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Hand held	
Season	late (dense foliage)	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	584	2761	AOEM	
	Body	590	11846	AOEM	
	Head	2	31	AOEM	
	Protected hands (gloves)	8	11	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	22	AOEM	
	Protected head (hood and face shield)	0	2	AOEM	
	Inhalation	27	253	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	Hood and visor		Incl. in AOEM model	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	7576	11626	AOEM	No data available for a drift reduction scenario
	Body	1024702	2167317	AOEM	
	Head	1343	2257	AOEM	
	Protected hands (gloves)	64	142	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	44920	188036	AOEM	
	Inhalation	62	179	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	32,1342489	1,5251143	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,5355708	0,0254186	
% of RVNAS	3967,19%	188,29%	

Operator exposure for Dithianon 70% WG outdoor spray applications

Application rate of active substance	0,35 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	1 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0,35 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	0,30%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	6,30%	<i>i_AbsorInuse</i>
Formulation type	Wettable granules, soluble granules	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Hand held	
Season	late (dense foliage)	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	584	2761	AOEM	
	Body	590	11846	AOEM	
	Head	2	31	AOEM	
	Protected hands (gloves)	8	11	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	22	AOEM	
	Protected head (hood and face shield)	0	2	AOEM	
	Inhalation	27	253	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	7576	11626	AOEM	No data available for a drift reduction scenario
	Body	1024702	2167317	AOEM	
	Head	1343	2257	AOEM	
	Protected hands (gloves)	64	142	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	44920	188036	AOEM	
	Inhalation	62	179	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	Hood and visor		0,05	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	65,2105935	2,9272209
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	1,0868432	0,0487870
% of RVNAS	8050,69%	361,39%

Table A 3: Pome fruits with manual-hand held application equipment (No PPE) – early (without leaves)

Operator exposure for outdoor spray applications

Application rate of active substance	0,35 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	4 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	1,4 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	0,26%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	3,10%	<i>i_AbsorInuse</i>
Formulation type	Wettable granules, soluble granules	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Hand held	
Season	early (without leaves)	
	OutdoorWettable granules, soluble granulesUpward sprayingManual-Hand held	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	1699	8124	AOEM	
	Body	1565	17721	AOEM	
	Head	9	125	AOEM	
	Protected hands (gloves)	21	44	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	87	AOEM	
	Protected head (hood and face shield)	0	7	AOEM	
	Inhalation	41	262	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	3605	11383	AOEM	No data available for a drift reduction scenario
	Body	64786	179311	AOEM	
	Head	170	918	AOEM	
	Protected hands (gloves)	33	174	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	107	223	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	2,2818401	0,3014928	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0380307	0,0050249	
% of RVNAS	281,71%	37,22%	

Operator exposure for Dithianon 70% WG outdoor spray applications

Application rate of active substance	0,35 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	4 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	1,4 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	0,30%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	6,30%	<i>i_AbsorInuse</i>
Formulation type	Wettable granules, soluble granules	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Hand held	
Season	early (without leaves)	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	1699	8124	AOEM	
	Body	1565	17721	AOEM	
	Head	9	125	AOEM	
	Protected hands (gloves)	21	44	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	87	AOEM	
	Protected head (hood and face shield)	0	7	AOEM	
	Inhalation	41	262	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	3605	11383	AOEM	No data available for a drift reduction scenario
	Body	64786	179311	AOEM	
	Head	170	918	AOEM	
	Protected hands (gloves)	33	174	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	107	223	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	4,4770946	0,4560339
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0746182	0,0076006
% of RVNAS	552,73%	56,30%

Table A 4: Pome fruits with manual-knapsack application equipment– late (dense foliage)

Operator exposure for outdoor spray applications

Application rate of active substance	0,35 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	1 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0,35 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	0,26%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	3,10%	<i>i_AbsorInuse</i>
Formulation type	Wettable granules, soluble granules	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Knapsack	
Season	late (dense foliage)	
	OutdoorWettable granules, soluble granulesUpward sprayingManual-Knapsack	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	Hood and visor		Incl. in AOEM model	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	7576	11626	AOEM	No data available for a drift reduction scenario
	Body	1024702	2167317	AOEM	
	Head	1343	2257	AOEM	
	Protected hands (gloves)	64	142	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	44920	188036	AOEM	
	Inhalation	62	179	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	32,1556550	1,5228767	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,5359276	0,0253813	
% of RVNAS	3969,83%	188,01%	

Operator exposure for Dithianon 70% WG outdoor spray applications

Application rate of active substance	0,35 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	1 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0,35 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	0,30%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	6,30%	<i>i_AbsorInuse</i>
Formulation type	Wettable granules, soluble granules	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Knapsack	
Season	late (dense foliage)	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	7576	11626	AOEM	No data available for a drift reduction scenario
	Body	1024702	2167317	AOEM	
	Head	1343	2257	AOEM	
	Protected hands (gloves)	64	142	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	44920	188036	AOEM	
	Inhalation	62	179	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	Hood and visor		0,05	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	65,2356500	2,9249896
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	1,0872608	0,0487498
% of RVNAS	8053,78%	361,11%

Table A 5: Pome fruits with manual-knapsack application equipment (No PPE) – early (without leaves)

Operator exposure for outdoor spray applications

Application rate of active substance	0,35 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	1 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0,35 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	0,26%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	3,10%	<i>i_AbsorInuse</i>
Formulation type	Wettable granules, soluble granules	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Knapsack	
Season	early (without leaves)	
	OutdoorWettable granules, soluble granulesUpward sprayingManual-Knapsack	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1131	3942	AOEM	No data available for a drift reduction scenario
	Body	52149	177000	AOEM	
	Head	109	583	AOEM	
	Protected hands (gloves)	8	43	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	34	98	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,7405570	0,1539347	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0290093	0,0025656	
% of RVNAS	214,88%	19,00%	

Operator exposure for Dithianon 70% WG outdoor spray applications

Application rate of active substance	0,35 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	1 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0,35 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	0,30%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	6,30%	<i>i_AbsorInuse</i>
Formulation type	Wettable granules, soluble granules	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Knapsack	
Season	early (without leaves)	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	9495	25482	AOEM	
	Body	803	2787	AOEM	
	Head	5	11	AOEM	
	Protected hands (gloves)	18	164	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	25	103	AOEM	
	Protected head (hood and face shield)	5	11	AOEM	
	Inhalation	25	26	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1131	3942	AOEM	No data available for a drift reduction scenario
	Body	52149	177000	AOEM	
	Head	109	583	AOEM	
	Protected hands (gloves)	8	43	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	34	98	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	3,4531190	0,2304697
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0575520	0,0038412
% of RVNAS	426,31%	28,45%

A 3.3 Worker exposure calculations (KCP 7.2.3.1)

A 3.3.1 Calculations for Dithianon

Table A 6: Pome fruit

Worker exposure from residues on foliage for				
Crop type	Pome fruit			
Indoor or outdoor	Outdoor			
Application method	Upward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Searching, reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0,35	kg a.s./ha		<i>i_AppRate</i>
Number of applications	4			<i>i_AppNo</i>
Interval between multiple applications	7	days		<i>i_AppInt</i>
Half-life of active substance	5,29	days		<i>d_HalfLifeAS</i>
Multiple application factor	1,6			<i>d_MAF</i>
Dermal absorption of the product	0,26%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	3,10%			<i>i_Absorplnuse</i>
Dislodgeable foliar residue ($i_AppRate \cdot i_DFR$)	1,05	$\mu\text{g a.s./cm}^2$		<i>d_DFR</i>
Working hours	8	hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	22500	cm^2/hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	4500	cm^2/hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm^2/hr		<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA	$\text{ha/hr} \cdot 10^{(-3)}$		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA	$\text{ha/hr} \cdot 10^{(-3)}$		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	$\text{ha/hr} \cdot 10^{(-3)}$		<i>d_InhalTcSort</i>
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	9,5101187	1,9020237	0,9510119	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1585020	0,0317004	0,0158502	
% of RVNAS	1174,09%	234,82%	117,41%	

Worker exposure from residues on foliage for Dithianon 70% WG				
Crop type	Pome fruit			
Indoor or outdoor	Outdoor			
Application method	Upward spraying			
Application equipment	Manual-Knapsack			
Worker's task	Searching, reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0,35	kg a.s./ha		
Number of applications	4			
Interval between multiple applications	7	days		
Half-life of active substance	5,29	days		
Multiple application factor	1,6			
Dermal absorption of the product	0,30%			
Dermal absorption of the in-use dilution	6,30%			
Dislodgeable foliar residue ($i_AppRate \cdot i_DFR$)	1,05	$\mu\text{g a.s./cm}^2$		
Working hours	8	hr		
Dermal transfer coefficient - Total potential exposure	22500	cm^2/hr		
Dermal transfer coefficient - arms, body and legs covered	4500	cm^2/hr		
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm^2/hr		
Inhalation transfer coefficient for automated applications	NA	$\text{ha/hr} \cdot 10^{(-3)}$		
Inhalation transfer coefficient for cutting ornamentals	NA	$\text{ha/hr} \cdot 10^{(-3)}$		
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	$\text{ha/hr} \cdot 10^{(-3)}$		
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	
Total systemic exposure (mg a.s./day)	19,3270154	3,8654031	1,9327015	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,3221169	0,0644234	0,0322117	
% of RVNAS	2386,05%	477,21%	238,61%	

Worker exposure from residues on foliage for	
Crop type	Pome fruit
Indoor or outdoor	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Worker's task	Searching, reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	0,35 kg a.s./ha
Number of applications	4
Interval between multiple applications	7 days
Half-life of active substance	6,68 days
Multiple application factor	1,8
Dermal absorption of the product	0,30%
Dermal absorption of the in-use dilution	6,30%
Dislodgeable foliar residue (i_AppRate*i_DFR)	1,05 µg a.s./cm ²
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	22500 cm ² /hr
Dermal transfer coefficient - arms, body and legs covered	4500 cm ² /hr
Dermal transfer coefficient - hands, arms, body and legs covered	2250 cm ² /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ^{^(-3)}
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ^{^(-3)}
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ^{^(-3)}

1. Total	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	21,7988066	4,3597613	2,1798807	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,3633134	0,0726627	0,0363313	
% of RVNAS	2691,21%	538,24%	269,12%	

Table A 7: Pome fruit re-entry period of ~~2 days~~ 7 days 10 days

Worker exposure from residues on foliage for			
Crop type	Pome fruit		
Indoor or outdoor	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Searching, reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,35 kg a.s./ha		i_AppRate
Number of applications	4		i_AppNo
Interval between multiple applications	7 days		i_AppInt
Half-life of active substance	5,29 days		d_HalfLifeAS
Multiple application factor	1,6		d_MAF
Dermal absorption of the product	0,26%		i_AbsorpProduct
Dermal absorption of the in-use dilution	3,10%		i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.8085 µg a.s./cm²		d_DFR
Working hours	8 hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	22500 cm²/hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	4500 cm²/hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	2250 cm²/hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA ha/hr*10^(-3)		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10^(-3)		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10^(-3)		d_InhalTcSort
1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	7,3227914	1,4645583	0,7322791
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1220465	0,0244093	0,0122047
% of RVNAS	904.05%	180.81%	90.40%

Worker exposure from residues on foliage for Dithianon 70% WG			
Crop type	Pome fruit		
Indoor or outdoor	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Searching, reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,35 kg a.s./ha		
Number of applications	4		
Interval between multiple applications	7 days		
Half-life of active substance	5,29 days		
Multiple application factor	1,6		
Dermal absorption of the product	0,30%		
Dermal absorption of the in-use dilution	6,30%		
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,42 µg a.s./cm²		
Working hours	8 hr		
Dermal transfer coefficient - Total potential exposure	22500 cm²/hr		
Dermal transfer coefficient - arms, body and legs covered	4500 cm²/hr		
Dermal transfer coefficient - hands, arms, body and legs covered	2250 cm²/hr		
Inhalation transfer coefficient for automated applications	NA ha/hr*10^(-3)		
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10^(-3)		
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10^(-3)		
1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	7,7308062	1,5461612	0,7730806
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1288468	0,0257694	0,0128847
% of RVNAS	954,42%	190,88%	95,44%

Worker exposure from residues on foliage for			
Crop type	Pome fruit		
Indoor or outdoor	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Searching, reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,35 kg a.s./ha		
Number of applications	4		
Interval between multiple applications	7 days		
Half-life of active substance	6,68 days		
Multiple application factor	1,8		
Dermal absorption of the product	0,30%		
Dermal absorption of the in-use dilution	6,30%		
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,378 µg a.s./cm ²		
Working hours	8 hr		
Dermal transfer coefficient - Total potential exposure	22500 cm ² /hr		
Dermal transfer coefficient - arms, body and legs covered	4500 cm ² /hr		
Dermal transfer coefficient - hands, arms, body and legs covered	2250 cm ² /hr		
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ^{^(-3)}		
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ^{^(-3)}		
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ^{^(-3)}		

1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	7,8475704	1,5695141	0,7847570	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1307928	0,0261586	0,0130793	
% of RVNAS	968,84%	193,77%	96,88%	

Table A 8: Pome fruit re-entry period of 7 days 12 days 17 days

Worker exposure from residues on foliage for				
Crop type	Pome fruit			
Indoor or outdoor	Outdoor			
Application method	Upward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Searching, reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0,35	kg a.s./ha		<i>i_AppRate</i>
Number of applications	4			<i>i_AppNo</i>
Interval between multiple applications	7	days		<i>i_AppInt</i>
Half-life of active substance	5,29	days		<i>d_HalfLifeAS</i>
Multiple application factor	1,6			<i>d_MAF</i>
Dermal absorption of the product	0,26%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	3,10%			<i>i_Absorplnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0,42	µg a.s./cm ²		<i>d_DFR</i>
Working hours	8	hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	22500	cm ² /hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	4500	cm ² /hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm ² /hr		<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		<i>d_InhalTcSort</i>
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	3,8040475	0,7608095	0,3804047	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0634008	0,0126802	0,0063401	
% of RVNAS	469,64%	93,93%	46,96%	

Worker exposure from residues on foliage for Dithianon 70% WG				
Crop type	Pome fruit			
Indoor or outdoor	Outdoor			
Application method	Upward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Searching, reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0,35	kg a.s./ha		
Number of applications	4			
Interval between multiple applications	7	days		
Half-life of active substance	5,29	days		
Multiple application factor	1,6			
Dermal absorption of the product	0,30%			
Dermal absorption of the in-use dilution	6,30%			
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0,217	µg a.s./cm ²		
Working hours	8	hr		
Dermal transfer coefficient - Total potential exposure	22500	cm ² /hr		
Dermal transfer coefficient - arms, body and legs covered	4500	cm ² /hr		
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm ² /hr		
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	
Total systemic exposure (mg a.s./day)	3,9942499	0,7988500	0,3994250	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0665708	0,0133142	0,0066571	
% of RVNAS	493,12%	98,62%	49,31%	

Worker exposure from residues on foliage for	
Crop type	Pome fruit
Indoor or outdoor	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Worker's task	Searching, reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	0,35 kg a.s./ha
Number of applications	4
Interval between multiple applications	7 days
Half-life of active substance	6,68 days
Multiple application factor	1,8
Dermal absorption of the product	0,30%
Dermal absorption of the in-use dilution	6,30%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,182 µg a.s./cm ²
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	22500 cm ² /hr
Dermal transfer coefficient - arms, body and legs covered	4500 cm ² /hr
Dermal transfer coefficient - hands, arms, body and legs covered	2250 cm ² /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ^{^(-3)}
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ^{^(-3)}
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ^{^(-3)}

1. Total	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	3,7784598	0,7556920	0,3778460	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0629743	0,0125949	0,0062974	
% of RVNAS	466,48%	93,30%	46,65%	

A 3.4 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.4.1 Calculations for Dithianon

Table A 9: Pome fruits - early

Resident exposure for					
Croptype	Pome fruit				
Application method	Upward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Wettable granules, soluble granules				i_FormVal
Buffer strip	5 m				i_Buffer
Application rate of the product	0,35 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,35 g a.s./l				d_ConcAS
Dermal absorption of product	0,26%				i_AbsorpProduct
Dermal absorption of in-use dilution	3,10%				i_AbsorpInuse
Oral absorption	45,00%				i_AbsorpOrallInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	1,05 µg a.s./cm²				d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa			i_Volat
Concentration in air	0,001 mg/m³				d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	5,63 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	1,689 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0,00210 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0,00164 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	3,68 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	1,11 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0,00170 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0,00133 ml spray dilution/person				
Exposure duration dermal	2 hours				d_ReExpDur
Exposure duration inhalation	24 hours				d_ReExpDurInhal
Exposure duration entry into treated crops	0,25 hours				d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%				d_ClothAF
Breathing rate adult	0,23 m³/day/kg				d_BreathRAD
Breathing rate child (1-3 year old)	1,07 m³/day/kg				d_BreathRCh
Drift percentage on surface (75th percentile)	15,79%				
Drift percentage on surface (mean)	11,69%				
Turf transferable residues percentage	5,00%				d_Turf
Transfer coeff. of surface deposits-adult	7300 cm²/hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				d_ReTCCh
Saliva extraction percentage	50,00%				d_SalExt
Surface area of hands mouthed	20 cm²				d_AreaHM
Frequency of hand to mouth activity	9,5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				d_TcEntryCh
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0156023	0,0107000	0,0130834	0,0297191	0,0544235
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0015602	0,0010700	0,0013083	0,0029719	0,0054424
% of RVNAS	11,56%	7,93%	9,69%	22,01%	40,31%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0508251	0,0138000	0,0203001	0,0990637	0,1411518
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0008471	0,0002300	0,0003383	0,0016511	0,0023525
% of RVNAS	6,27%	1,70%	2,51%	12,23%	17,43%

Resident exposure for Dithianon 70% WG					
Croptype	Pome fruit				
Application method	Upward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Wettable granules, soluble granules				i_FormVal
Buffer strip	5 m				i_Buffer
Application rate of the product	0,35 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,4375 g a.s./l				d_ConcAS
Dermal absorption of product	0,30%				i_AbsorpProduct
Dermal absorption of in-use dilution	6,30%				i_Absorplnuse
Oral absorption	45,00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	1,05 µg a.s./cm²				d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				i_Volat
Concentration in air	0,001 mg/m³				d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	5,63 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	1,689 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0,00210 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0,00164 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	3,68 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	1,11 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0,00170 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0,00133 ml spray dilution/person				
Exposure duration dermal	2 hours				d_ReExpDur
Exposure duration inhalation	24 hours				d_ReExpDurInhal
Exposure duration entry into treated crops	0,25 hours				d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%				d_ClothAF
Breathing rate adult	0,23 m³/day/kg				d_BreathRAD
Breathing rate child (1-3 year old)	1,07 m³/day/kg				d_BreathRCh
Drift percentage on surface (75th percentile)	15,79%				
Drift percentage on surface (mean)	11,69%				
Turf transferable residues percentage	5,00%				d_Turf
Transfer coeff. of surface deposits-adult	7300 cm²/hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				d_ReTCCh
Saliva extraction percentage	50,00%				d_SalExt
Surface area of hands mouthed	20 cm²				d_AreaHM
Frequency of hand to mouth activity	9,5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				d_TcEntryCh
1. Total					
1.1 1-3 year old child					

Resident exposure for					
Croptype	Pome fruit				
Application method	Upward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Wettable granules, soluble granules				
Buffer strip	5 m				
Application rate of the product	0,35 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0,35 g a.s./l				
Dermal absorption of product	0,30%				
Dermal absorption of in-use dilution	6,30%				
Oral absorption	45,00%				
Dislodgeable foliar residue (I_AppRate*I_DFR)	1,05 µg a.s./cm ²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa				
Concentration in air	0,001 mg/m ³				
Resident dermal spray drift exposure 75th percentile - adult	5,63 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	1,689 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0,00210 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0,00164 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	3,68 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	1,11 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0,00170 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0,00133 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0,25 hours				
Light clothing adjustment factor	18,0%				
Breathing rate adult	0,23 m ³ /day/kg				
Breathing rate child (1-3 year old)	1,07 m ³ /day/kg				
Drift percentage on surface (75th percentile)	15,79%				
Drift percentage on surface (mean)	11,69%				
Turf transferable residues percentage	5,00%				
Transfer coeff. of surface deposits-adult	7300 cm ² /hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour				
Saliva extraction percentage	50,00%				
Surface area of hands mouthed	20 cm ²				
Frequency of hand to mouth activity	9,5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm ²				
Dislodgeable residues percentage transferability for object to mouth	20,00%				
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h				
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h				
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)		Entry into treated crops (75th percentile)	
Total systemic exposure (mg a.s./day)		0,0311140		0,1027080	
Total systemic exposure per kg body weight (mg/kg a.s./day)		0,0031114		0,0102708	
% of RVNAS		23,05%		76,08%	
1.2 Adult					
Spray drift		Vapour		Entry into treated crops	
Total systemic exposure (mg a.s./day)		0,1025310		0,2964333	
Total systemic exposure per kg body weight (mg/kg a.s./day)		0,0017089		0,0049406	
% of RVNAS		12,66%		36,60%	

Table A 10: Pome fruits – late

Resident exposure for					
Croptype			Pome fruit		
Application method			Upward spraying		
Application equipment			Vehicle-mounted		i_AppEquip
Formulation type	Wettable granules, soluble granules				i_FormVal
Buffer strip			5 m		i_Buffer
Application rate of the product			0,35 kg a.s./ha		i_AppRate
Concentration of active substance (in-use dilution for liquid applications)			0,35 g a.s./l		d_ConcAS
Dermal absorption of product			0,26%		i_AbsorpProduct
Dermal absorption of in-use dilution			3,10%		i_AbsorpInuse
Oral absorption			45,00%		i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)			1,05 µg a.s./cm²		d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa		Pa		i_Volat
Concentration in air			0,001 mg/m³		d_AirCon
Resident dermal spray drift exposure 75th percentile - adult			5,63 ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child			1,689 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult			0,00210 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child			0,00164 ml spray dilution/person		
Resident dermal spray drift exposure mean - adult			3,68 ml spray dilution/person		
Resident dermal spray drift exposure mean - child			1,11 ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult			0,00170 ml spray dilution/person		
Resident inhal. spray drift exposure mean - child			0,00133 ml spray dilution/person		
Exposure duration dermal			2 hours		d_ReExpDur
Exposure duration inhalation			24 hours		d_ReExpDurInhal
Exposure duration entry into treated crops			0,25 hours		d_ExpDurTreatCrop
Light clothing adjustment factor			18,0%		d_ClothAF
Breathing rate adult			0,23 m³/day/kg		d_BreathRAD
Breathing rate child (1-3 year old)			1,07 m³/day/kg		d_BreathRCh
Drift percentage on surface (75th percentile)			6,04%		
Drift percentage on surface (mean)			3,73%		
Turf transferable residues percentage			5,00%		d_Turf
Transfer coeff. of surface deposits-adult			7300 cm²/hour		d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)			2600 cm²/hour		d_ReTCCCh
Saliva extraction percentage			50,00%		d_SalExt
Surface area of hands mouthed			20 cm²		d_AreaHM
Frequency of hand to mouth activity			9,5 events/hour		d_ReFreqHM
Ingestion rate for mouthing of grass per day			25 cm²		d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth			20,00%		d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult			7500 cm²/h		d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child			2250 cm²/h		d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult			5980 cm²/h		d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child			1794 cm²/h		d_TcEntryCh
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0156023	0,0107000	0,0050047	0,0297191	0,0478280
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0015602	0,0010700	0,0005005	0,0029719	0,0047828
% of RVNAS	11,56%	7,93%	3,71%	22,01%	35,43%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0508251	0,0138000	0,0077652	0,0990637	0,1309182
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0008471	0,0002300	0,0001294	0,0016511	0,0021820
% of RVNAS	6,27%	1,70%	0,96%	12,23%	16,16%

Resident exposure for Dithianon 70% WG					
Croptype	Pome fruit				
Application method	Upward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Wettable granules, soluble granules				i_FormVal
Buffer strip	5 m				i_Buffer
Application rate of the product	0,35 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,4375 g a.s./l				d_ConcAS
Dermal absorption of product	0,30%				i_AbsorpProduct
Dermal absorption of in-use dilution	6,30%				i_Absorplnuse
Oral absorption	45,00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	1,05 µg a.s./cm²				d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				i_Volat
Concentration in air	0,001 mg/m³				d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	5,63 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	1,689 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0,00210 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0,00164 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	3,68 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	1,11 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0,00170 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0,00133 ml spray dilution/person				
Exposure duration dermal	2 hours				d_ReExpDur
Exposure duration inhalation	24 hours				d_ReExpDurInhal
Exposure duration entry into treated crops	0,25 hours				d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%				d_ClothAF
Breathing rate adult	0,23 m³/day/kg				d_BreathRAD
Breathing rate child (1-3 year old)	1,07 m³/day/kg				d_BreathRCh
Drift percentage on surface (75th percentile)	6,04%				
Drift percentage on surface (mean)	3,73%				
Turf transferable residues percentage	5,00%				d_Turf
Transfer coeff. of surface deposits-adult	7300 cm²/hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				d_ReTCCh
Saliva extraction percentage	50,00%				d_SalExt
Surface area of hands mouthed	20 cm²				d_AreaHM
Frequency of hand to mouth activity	9,5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				d_TcEntryCh
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0388925	0,0107000	0,0078596	0,0603969	0,0893796
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0038893	0,0010700	0,0007860	0,0060397	0,0089380
% of RVNAS	28,81%	7,93%	5,82%	44,74%	66,21%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1281638	0,0138000	0,0157809	0,2013231	0,2679834
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0021361	0,0002300	0,0002630	0,0033554	0,0044664
% of RVNAS	15,82%	1,70%	1,95%	24,85%	33,08%

Resident exposure for					
Croptype	Pome fruit				
Application method	Upward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Wettable granules, soluble granules				
Buffer strip	5 m				
Application rate of the product	0,35 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0,35 g a.s./l				
Dermal absorption of product	0,30%				
Dermal absorption of in-use dilution	6,30%				
Oral absorption	45,00%				
Dislodgeable foliar residue (I_AppRate*I_DFR)	1,05 µg a.s./cm ²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa				
Concentration in air	0,001 mg/m ³				
Resident dermal spray drift exposure 75th percentile - adult	5,63 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	1,689 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0,00210 ml spray dilution/person				
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Resident dermal spray drift exposure mean - adult	3,68 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	1,11 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0,00170 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0,00133 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0,25 hours				
Light clothing adjustment factor	18,0%				
Breathing rate adult	0,23 m ³ /day/kg				
Breathing rate child (1-3 year old)	1,07 m ³ /day/kg				
Drift percentage on surface (75th percentile)	6,04%				
Drift percentage on surface (mean)	3,73%				
Turf transferable residues percentage	5,00%				
Transfer coeff. of surface deposits-adult	7300 cm ² /hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour				
Saliva extraction percentage	50,00%				
Surface area of hands mouthed	20 cm ²				
Frequency of hand to mouth activity	9,5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm ²				
Dislodgeable residues percentage transferability for object to mouth	20,00%				
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h				
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h				
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)		Surface deposits (75th percentile)	
Total systemic exposure (mg a.s./day)		0,0311140		0,0681213	
Total systemic exposure per kg body weight (mg/kg bw/day)		0,0031114		0,0068121	
% of RVNAS		23,05%		50,46%	
1.2 Adult					
Spray drift		Vapour		Surface deposits	
Total systemic exposure (mg a.s./day)		0,1025310		0,2270709	
Total systemic exposure per kg body weight (mg/kg bw/day)		0,0017089		0,0037845	
% of RVNAS		12,66%		28,03%	

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Not relevant.

Appendix 5 DT50 foliar calculation on Dithianon - data from SGS

DT₅₀ estimates based on the ratio of maximum and final measured residues - dithianon

A comparison was made between the highest residue levels in the 0-21 d interval (c_{max}) and the last measured value (c_{final}). Using the quotient c_{final}/c_{max} and the time interval *t* between the two corresponding sampling dates, an estimate DT₅₀ can be calculated according to the following equation.

$$DT_{50} = - \frac{t \times \ln 2}{\ln \frac{c_{final}}{c_{max}}}$$

Trial No	Rate	Crop	ANALYZED	RESIDUE (mg/kg)	TIME (day)		
S-18-01091 / S France / SEU Analytical phase DPL/77/2019	4 x 1050 g ai/ha	peas	Green peas (wi- hole plant)	3.89	0		
				2.33	1		
				2.11	3		
				1.99	5		
				1.81	7		
				0.44	14		
				0.44	21	DT50	6.68

Trial No	Rate	Crop	ANALYZED	RESIDUE (mg/kg)	TIME (day)		
BPL-18-033 / Spain / SEU Analytical phase DPL/67/2019	4 x 1050 g ai/ha	peas	Green peas (wi- hole plant)	23.6	0		
				13.2	1		
				5.54	3		
				5.46	5		
				5.16	7		
				2.42	14		
				0.57	21	DT50	3.91

mean DT₅₀ = 5.29