FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 6821 A

Product name(s): PRIORITY

Chemical active substances:

Dimethomorph, 150 g/kg
Dithianon, 350 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: April 2019

Update: October 2019, February 2020

MS Finalisation date: December 2021; January 2024

Version history

When	What
October 2019	Updated by Applicant
February 2020	Updated by Applicant
December 2021	Evaluation by expert
January 2024	The final Registration Report

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on SHA 6821 A / Dimethomorph 15% + Dithianon 35% WG *

Product name and code	SHA 6821 A / PRIORITY
Formulation type	Watter dispersible granules [Code: WG]
Active substance(s) (incl. content)	Dithianon; 350 g/kg Dimethomorph; 150 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 SHA 6821 A / Dimethomorph 15% + Dithianon 35% WG 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 SHA 6821 A / Dimethomorph 15% + Dithianon 35% WG according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Acute Tox. 4, Eye Irrit. 1, Repr. 1B
Hazard pictograms or Code(s) for hazard pictogram(s)	~~GHS05,~~ GHS07,GHS08
Signal word	**Danger**
Hazard statement(s)	H302, H319 , H317, H360F
Precautionary statement(s)	P264, P280, P301+P312, P305+ P351+P338, P302+P352,P308+P313,~~P337+P313~~,P310, P391, P501
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for Dimethomorph 15% + Dithianon 35% WG

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) M/L and A + gloves M/L and A + hood - Applciation with tractor mounted Or Work wear (arms, body and legs covered) M/L and A + gloves M/L and A – Applciation with closed cab tractor Work wear (arms, body and legs covered) M/L and A + gloves M/L and A -

	Result	PPE / Risk mitigation measures
		Application with Manual-Hand held
Workers	Acceptable	Work wear (arms, body and legs covered) - time period of 26 days after application or Work wear (arms, body and legs covered) and gloves - time period of 17 days after application
Residents	Acceptable	None for addults, Entrence into treated crop prohibited for children.
Bystanders		

No unacceptable risk for adult bystanders and residents was identified when the product is used as intended. No specific PPE is necessary. **Entrence into treated crop prohibited for children**

NOTE: Entrence into treated crop prohibited for children.

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 residents/bystanders 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**		**Application rate**		**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**			
			Method / Kind **(incl. application technique *****| **Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**Max. application rate kg as/ha** **a) Dimethomorph** **b) Dithianon**	**Water L/ha** **min / max**				**Operator**	**Worker**	**Residents**	**Bystander**
1	Grapevine (BBCH 55-79)	F	Spraying, LCTM	a) 3 (10) b) 3 (10)	a) 0.225 b) 0.525	800 - 1000	-	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 crops, 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(s)

	Dithianon	**Dimethomorph**
Common Name	Dithianon	Dimethomorph
CAS-No.	3347-22-6	110488-70-5
Classification and proposed labelling		
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes, categories: Acute Tox. 4 Codes for hazard pictograms: GSH07, Signal word: Warning Hazard statements**:** H302,	~~Not classified~~ Repr. 1B/ H360F
Additional C&L proposal	-	-
Agreed EU endpoints		
AOEL systemic	0.0135 mg/kg bw/d (corrected for 45% oral absorption	0.15 mg/kg bw/d
Reference	EFSA Conclusion (EFSA Journal 2010;8(11):1904) Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation**)**	EFSA Conclusion (EFSA Scientific Report (2006) 82, 1-69) ECHA Committeee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of dimethomorph Adopted 20 September 2019 **COMMISSION DELEGATED REGULATION (EU) 2021/849 of 11 March 2021 Part 3 of Annex VI to Regulation (EC) No 1272/2008**
Conditions to take into account/critical areas of concern with regard to toxicology		
According to Review Report SANCO/10349/2011 final for Dithianon and Review Repot SANCO/10040/06 – rev. 3 for Dimethomorph	The operator safety and worker safety	The operator and worker safety

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for SHA 6821 A / Dimethomorph 15% + Dithianon 35% WG is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for SHA 6821 A / Dimethomorph 15% + Dithianon 35% WG

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (OECD 423)	500 mg/kg bw	Yes	Acute Tox.4 H302	C.S. Ghogale 2018
LD_{50} dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	C.S. Ghogale 2018
LC_{50} inhalation, rat (OECD 403)	Non	Yes	None	-
Skin irritation, rabbit (calculation)	Non-Irritant	Yes	None	Calculated
Eye irritation, rabbit (calculation)	Irritant	Yes	Eye Irrit. 2; H319	Calculated
Skin sensitisation, guinea pig (OECD 406)	Moderate	Yes	**Skin. Sens.1B**	C.S. Ghogale 2018
Supplementary studies for combinations of plant protection products	No data – not required			

Table 6.3-2: Additional toxicological information relevant for classification/labelling of SHA 6821 A / Dimethomorph 15% + Dithianon 35% WG

	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)	Dimethomorph (15.23% (w/w))	~~Not classified~~ H360F	ECHA Committeee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of dimethomorph Adopted 20 September 2019 **COMMISSION DELEGATED REGULATION (EU) 2021/849 of 11 March 2021 Part 3 of Annex VI to Regulation (EC) No 1272/2008**	~~H302, H319~~ H360F
Toxicological properties of active substance(s) (relevant for classification of product)	Dithianon (35.71% (w/w))	H302	Reg. 1272/2008 Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)	H302

	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 non-active substance(s) (relevant for classification of product)	Coformulant 2 (> 1% w/w) ***	H302, H315, H318	Reg. 1272/2008	H302, H318
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
*** Confidential information in Part C.

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 SHA 6821 A / Dimethomorph 15% + Dithianon 35% WG are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in SHA 6821 A / Dimethomorph 15% + Dithianon 35% WG

	~~Dimethomorph~~		~~Dithianon~~	
	~~Value~~	~~Reference~~	~~Value~~	~~Reference~~
~~Concentrate~~	~~10%~~	~~Default value according to guidance on dermal absorption (EFSA Journal 2017;15(6):4873)~~	~~0.26%~~	~~EFSA Journal 2010;8(11):1904~~
~~Dilution~~	~~50%~~	~~Default value according to guidance on dermal absorption (EFSA Journal 2017;15(6):4873)~~	~~3.1%~~	~~EFSA Journal 2010;8(11):1904 (Addendum January 2010)~~

	Dimethomorph		Dithianon	
	Value	Reference	Value	Reference
Concentrate	0.66%	New study reported in Appendix 2	0.67%	New study reported in Appendix 2
Dilution	20%		13%	

6.5.1 Justification for proposed values – Dimethomorph

No data on dermal absorption for Dimethomorph in SHA 6821 A / Dimethomorph 15% + Dithianon 35% WG is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA

Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for Dimethomorph

	~~Value~~	~~Justification for value~~	~~Acceptability of justification~~
~~Concentrate~~	~~10%~~	~~Product contains = 15% a.s. (>5%)~~	
~~Dilution~~	~~50%~~	~~Concentration of in use dilution ≤ 5 %~~	

Proposed dermal absorption rates for Dimethomorph are based on dermal absorption studies on a formulation Dimethomorph 15% + Dithianon 35% WG. The study results are summarised in the following table. Full summaries of studies on the dermal absorption Dimethomorph 15% + Dithianon 35% WG that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.
The dermal absorption of Dimethomorph is summarised in Table 6.5-3a.

Table 6.5-4a: Default dermal absorption rates for Dimethomorph

	Value	Justification for value	Acceptability of justification
Concentrate	0.66%	*In vitro* human skin	Acceptable
Dilution	20%	*In vitro* human skin	Acceptable

6.5.2 Justification for proposed values – Dithianon

No data on dermal absorption for Dithianon in SHA 6821 A / Dimethomorph 15% + Dithianon 35% WG is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-5: Default dermal absorption rates for Dithianon

	~~Value~~	~~Justification for value~~	~~Acceptability of justification~~
~~Concentrate~~	~~0.26%~~	~~Product contains = 35% a.s. (>5%)~~	
~~Dilution~~	~~3.1%~~	~~Concentration of in use dilution ≤ 5 %~~	

Proposed dermal absorption rates for Dithianon are based on dermal absorption studies on a formulation Dimethomorph 15% + Dithianon 35% WG. The study results are summarised in the following table. Full summaries of studies on the dermal absorption Dimethomorph 15% + Dithianon 35% WG that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.
The dermal absorption of Dithianon is summarised in Table 6.5-3a.

Table 6.5-6a: Default dermal absorption rates for Dithianon

	Value	Justification for value	Acceptability of justification
Concentrate	0.67%	*In vitro* human skin	Acceptable
Dilution	13%	*In vitro* human skin	Acceptable

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	SHA 6821 A / PRIORITY	
Formulation type	WG	
Category	Fungicide	
Active substance(s) (incl. content)	**Dithianon** 350 g/kg	**Dimethomorph** 150 g/kg
AOEL systemic	0.0135 mg/kg bw/d	0.15 mg/kg bw/d
Inhalation absorption	100%	100%
Oral absorption	100%	100%
Dermal absorption	Concentrate: 0.67% Dilution: 13%	Concentrate: 0.66% Dilution: 20%

6.6.1 Selection of critical use and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-4. A list of all intended uses within the zone is given in Part B, Section 0.

Justification

There is only one intended GAP.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure model used for estimation of operator exposure to the active substances during application of SHA 6821 A / Dimethomorph 15% + Dithianon 35% WG according to the critical use is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in 0.

Table 6.6-2: Exposure models for intended uses

Critical use	Grapevine (max. 1.5 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 6.6-3: Estimated operator exposure (longer term exposure)

		~~Dimethomorph~~		~~Dithianon~~	
~~Model data~~	~~Level of PPE~~	~~Total absorbed dose (mg/kg/day)~~	~~% of systemic AOEL~~	~~Total absorbed dose (mg/kg/day)~~	~~% of systemic AOEL~~
~~Grapevine - Tractor mounted boom spray application outdoors~~					

Application rate		0.225 kg a.s./ha		0.525 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.2403	160	0.0368	273
	Work wear (arms, body and legs covered) M/L and A + gloves M/L and A	0.0271	**18**	0.0073	**54**
Grapevine - Manual-Hand held - upward spraying outdoor					
Application rate		0.225 kg a.s./ha		0.525 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.5316	354	0.0418	310
	Work wear (arms, body and legs covered) M/L and A	0.0345	**23**	0.0066	**49**

		Dimethomorph		**Dithianon**	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Grapevine - Tractor mounted boom spray application outdoors					
Application rate		0.225 kg a.s./ha		0.525 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Without PPE	0.0950	**63**	0.1419	1051
	Work wear (arms, body and legs covered) M/L and A	0.0296	**20**	0.0425	315
	Work wear (arms, body and legs covered) M/L and A + gloves M/L and A + hood	0.0079	**5**	0.012	**89**
Grapevine - Tractor mounted boom spray application outdoors (closed cab)					
Application rate		0.225 kg a.s./ha		0.525 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Without PPE	0.0327	**22**	0.0484	359
	Work wear (arms, body and legs covered) M/L and A + closed cab	0.0110	**7**	0.0154	114
	Work wear (arms, body and legs covered) M/L and A + gloves M/L and A + closed cab	0.0019	**1**	0.0028	**21**
Grapevine - Manual-Hand held - upward spraying outdoor					
Application rate		0.225 kg a.s./ha		0.525 kg a.s./ha	
Spray applica-	Without PPE	0.2124	142	0.1647	1220

tion (AOEM**;** 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0142	**9**	0.0172	127
	Work wear (arms, body and legs covered) M/L and A + gloves M/L and A	0.0058	**4**	0.0060	**45**

Conclusion

Tractor mounted boom spray application outdoors:

According to the AOEM model calculations, it can be concluded that the risk for the operator using PRIORITY is acceptable with the use of gloves and working clothing (long sleeved shirt and trousers) during mixing/loading and application and hood during application.

and

with the use of gloves and working clothing (long sleeved shirt and trousers) during mixing/loading and application during closed cab tractor spraying.

Manual-Hand held - upward spraying outdoor

The risk for operator using PRIORITY is acceptable with the use of gloves and working clothing (long sleeved shirt and trousers) during mixing/loading and application.

~~According to the AOEM model, calculations, it can be concluded that the risk for the operator using PRIORITY is acceptable with the use of gloves and working clothing (long sleeved shirt and trousers) during mixing/loading and application.~~

Implication for labelling: P280: Wear protective gloves, protective clothing

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 consideration of the 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 6.6-4 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Dimethomorph 15% + Dithianon 35% WG according to the critical use. Outcome of the estimation is presented in Table 6.6-5 (longer term exposure). Detailed calculations are in 0.

Table 6.6-4: Exposure models for intended uses

Critical use	Grapevine (max. 1.5 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 6.6-5: Estimated worker exposure (longer term exposure)

		Dimethomorph		Dithianon	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Hand harvesting / Outdoor Work rate: 8 hours/day, DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 10 days					
		DT_{50}: 4.65 days		DT_{50}: 5.29 days	
Number of applications and application rate		3 x 0.225 kg a.s./ha		3 x 0.525 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000 cm²/person/h	0.6890	459	1.0995	8144
	Work wear (arms, body and legs covered) TC: 10100 cm²/person/h	0.2319	155	0.3702	2742
	~~Work wear (arms, body and legs covered) and gloves TC: 4861 µg/cm2*~~	~~0.27910913~~	~~186~~	~~0.0477686~~	~~354~~
Proposal of Re-entry period of 26 days Hand harvesting / Outdoor Work rate: 8 hours/day, DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 10 days					
		DT_{50}: 4.65 days DFR: 0.063 µg/cm2/kg a.s./ha		DT_{50}: 5.29 days DFR: 0.099 µg/cm2/kg a.s./ha	
Number of applications and application rate		3 x 0.225 kg a.s./ha		3 x 0.525 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000 cm²/person/h	0.0144	**10**	0.0363	269
	Work wear (arms, body and legs covered) TC: 10100 cm²/person/h	0.0049	**3**	0.0122	**90**
	~~Work wear (arms, body and legs covered) and gloves TC: 4861 µg/cm2*~~	~~0.27910913~~	~~**20**~~	~~0.0477686~~	~~**80**~~

According EFSA Journal 2014;12(10):3874 in exposure assessments for worker is proposed penetration factors with PPE: gloves – for workers a factor 10% can be considered for re-entry activities.
Therefore the TC = potential TC 30000 cm²/person/h × 10% = 3000 cm²/person/h

Proposal of Re-entry period of 17 days with gloves Hand harvesting / Outdoor Work rate: 8 hours/day, Interval between treatments: 10 days					
		DT_{50}: 4.65 days DFR: 0.237 µg/cm2/kg a.s./ha		DT_{50}: 5.29 days DFR: 0.323 µg/cm2/kg a.s./ha	
Number of applications and application rate		3 x 0.225 kg a.s./ha		3 x 0.525 kg a.s./ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves TC: 3000 µg/cm²	0.0054	**4**	0.01184	**88**

~~*In case of re-entry tasks in grapes the use of a lower than 10100 cm2/h TC value considering the use of gloves is considered acceptable. More specifically, as a Tier II the use of a refined TC of 4861 cm2/h is accepted considering the distribution of residues - Baugher (2005) - and the assumptions presented in detail in BROWSE WorkerDeliverable 2.4 (2014);~~

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 grapes treated with PRIORITY a time period of 17 day after application is respected or without gloves when a time period of 26 days after application is respected.

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 26 days

The Applicant propose to consider as refinement a re-entry period of 26 days. Therefore we propose to calculate DFR value 26 days grapevine.
Body weight 60 kg.
DT_{50}:

Dithianon:

~~For this calculation DT50 value of 7 days is considered according to "EFSA Journal 2014;12(10):3874[1],".~~

DT_{50} calculation is based on SGS data – residue trials (please refer to data presented in Appendix 5). A DT_{50} value = 5.29 days were obtained.

Dimethomorph:

Since not useful trials on DAR for Dimetomorph were available to calculate DT_{50} on foliage, DT_{50} calculation is based on JMPR data – residue trials (please refer to data presented in Appendix 4). A geomean DT_{50} value = 4.65 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)

[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"

DFR_0 Dislodgeable foliar residue just after application (µg/cm^2)
k Degradation constant (days $^{-1}$), calculated from the half life time:
$k = ln(2)/DT_{50}$,
DT_{50} 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/cm^2 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):3874[2], corresponding to a half-life $_{foliar}$ of 30 days.
Therefore for 26 days of re-entry interval:
Dithianon:

For grapevine, a number of 3 applications (n) and a 10 day interval (i) between applications is considered (worst case scenario) and MAF is 1.342. The following DFR value is calculated:
$DFR_0 = DFR_{def} \times 1.342 = 4.026$ µg/cm^2 (where DFR_{def} = 3 µg/cm^2 per kg s.a/ha)

$DFR_T = DFR_0 \times e^{-k, t} = 4.026$ µg/cm^2 × 0.033 = 0.133 µg/cm^2
Therefore for $DFR_T = DFR_{def\ ref} \times MAF$ = 0.133 µg/cm^2 the $DFR_{def\ ref}$ = 0.099 µg/cm^2 per kg s.a/ha

Dimethomorph:

For grapevine, a number of 3 applications (n) and a 10 day interval (i) between applications is considered (worst case scenario) and MAF is 1.28. The following DFR value is calculated:
$DFR_0 = DFR_{def} \times 1.28 = 3.84$ µg/cm^2 (where DFR_{def} = 3 µg/cm^2 per kg s.a/ha)

$DFR_T = DFR_0 \times e^{-k, t} = 3.84$ µg/cm^2 × 0.021 = 0.08 µg/cm^2
Therefore for $DFR_T = DFR_{def\ ref} \times MAF$ = 0.08 µg/cm^2 the $DFR_{def\ ref}$ = 0.063 µg/cm^2 per kg s.a/ha

Proposal of Re-entry period 17 days with gloves:

The Applicant would like to present also calculations when gloves are used.
In case the use of gloves the acceptable result is after 17 days of re-entery period.
Therefore we propose to calculate DFR value 17 days for grapevine:

[2] 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"

Dithianon:

For grapevine, a number of 3 applications (n) and a 10 day interval (i) between applications is considered (worst case scenario) and MAF is 1.342. The following DFR value is calculated:
$DFR_0 = DFR_{def} \times 1.342 = 4.026$ µg/cm² (where $DFR_{def} = 3$ µg/cm² per kg s.a/ha)

$DFR_T = DFR_0 \times e^{-k,t} = 4.026$ µg/cm² × 0.1077 = 0.434 µg/cm²
Therefore for $DFR_T = DFR_{def\ ref} \times MAF = 0.434$ µg/cm² the $DFR_{def\ ref} = 0.323$ µg/cm² per kg s.a/ha

Dimethomorph:

For grapevine, a number of 3 applications (n) and a 10 day interval (i) between applications is considered (worst case scenario) and MAF is 1.28. The following DFR value is calculated:
$DFR_0 = DFR_{def} \times 1.28 = 3.84$ µg/cm² (where $DFR_{def} = 3$ µg/cm² per kg s.a/ha)

$DFR_T = DFR_0 \times e^{-k,t} = 3.84$ µg/cm² × 0.079 = 0.303 µg/cm²
Therefore for $DFR_T = DFR_{def\ ref} \times MAF = 0.303$ µg/cm² the $DFR_{def\ ref} = 0.237$ µg/cm² per kg s.a/h

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 6.6-6 shows the exposure model used for estimation of resident and bystander exposure to Dimethomorph and Dithianon. The outcome of the estimation is presented in Table 6.6-7 (longer term resident exposure). Detailed calculations are in 0.

Table 6.6-6: Exposure models for intended uses

Critical use	Grapevine (max. 1.5 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 6.6-7: Estimated resident exposure (longer term exposure)

		Dimethomorph		Dithianon	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Grapevine - Tractor mounted boom spray application outdoors Buffer zone: 10 (m) Drift reduction technology: yes DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 10 days					
Number of applications and application rate		3 x 0.225 kg a.s./ha DT50: 4.65 days		3 x 0.525 kg a.s./ha DT_{50}: 5.29 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0078	5.22	0.0119	88.32
	Vapour (75th perc.)	0.0006	0.39	0.0010	7.74
	Deposits (75th perc.)	0.0097	6.46	0.0155	114.53
	Re-entry (75th perc.)	0.0144	9.6	0.0220	163.26
	Sum (mean)	0.0043	**2.89**	0.0065	**48.79**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0006	0.39	0.0010	7.74
	Vapour (75th perc.)	0.0002	0.15	0.0002	1.70
	Deposits (75th perc.)	0.0002	0.14	0.0003	2.54
	Re-entry (75th perc.)	0.0054	3.59	0.0086	63.63
	Sum (mean)	0.0075	**5.01**	0.0116	**86.27**

It is concluded that there is no unacceptable risk anticipated for the adult residents and bystanders.
However, for dithianone there is a risk for children during entry into treated crops.
The calculation in the table below shows that change buffer zone and drift reduction is not related as the risk for children is only when they enter into treated crop:

Table 6.6-8: Estimated resident exposure (longer term exposure) for dithianone

		Dithianon	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Grapevine - Tractor mounted boom spray application outdoors Buffer zone: 10 (m) Drift reduction technology: yes DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 × 0.525 kg a.s./ha DT_{50}: 5.29 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0059	44.16
	Vapour (75th perc.)	0.0011	7.93
	Deposits (75th perc.)	0.0002	1.29

	Re-entry (75th perc.)	0.0154	**115**
	Sum (mean)	0.0174	**129**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.1976	24.40
	Vapour (75th perc.)	0.0002	1.70
	Deposits (75th perc.)	0.0001	0.42
	Re-entry (75th perc.)	0.0086	63.63
	Sum (mean)	0.0093	68.72

Therefore the Applicant propose warning boards prohibiting the entrance to the treated area for children:

		Dimethomorph		**Dithianon**	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Grapevine - Tractor mounted boom spray application outdoors Buffer zone: 5 (m) Drift reduction technology: no DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 10 days					
Number of applications and application rate		3 × 0.225 kg a.s./ha DT_{50}: 4.65 days		3 × 0.525 kg a.s./ha DT_{50}: 5.29 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0078	5.22	0.0119	88.32
	Vapour (75th perc.)	0.0011	0.71	0.0011	7.93
	Deposits (75th perc.)	0.0006	0.39	0.0010	7.74
	Re-entry (75th perc.)	–	–	–	–
	Sum (mean)	0.0144	4.45	0.0097	71.94

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 Dimethomorph and 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

The product is a mixture of two active substances.

6.6.5.1 Exposure assessment of Dimethomorph and Dithianon in PRIORITY

Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from Table 6.6 9. converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-9: Risk assessment from combined exposure (longer term exposure)

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Grapevine – tractor application Operators – Work wear (arms, body and legs covered) M/L and A+gloves M/L and A + hood	Dithianon	0.89
	Dimethomorph	0.05
	Cumulative risk operators (HI)	**0.94**
Grapevine – closed cab application Operators – Work wear (arms, body and legs covered) M/L and A+gloves M/L and A + closed cab	Dithianon	0.21
	Dimethomorph	0.01
	Cumulative risk operators (HI)	**0.22**
Grapevine - Manual-Hand held Operators – Work wear (arms, body and legs covered) and gloves during M/L and A	Dithianon	0.45
	Dimethomorph	0.04
	Cumulative risk operators (HI)	**0.49**
Grapevine Workers – Work wear (arms, body and legs covered) - time period of 26 days after application	Dithianon	0.90
	Dimethomorph	0.03
	Cumulative risk workers (HI)	**0.93**
Grapevine Workers – Work wear (arms, body and legs covered) and gloves - time period of 17 days after application	Dithianon	0.88
	Dimethomorph	0.04
	Cumulative risk workers (HI)	**0.92**
Resident - child	Dithianon	
Buffer zone: 5 (m) Drift reduction technology: no **Entrence prohibited for children**	Drift	0.88
	Vapour	0.08
	Deposits	0.08
	Re-entry	–
	Sum of all pathways	0.72
	Dimethomorph	
	Drift	0.05
	Vapour	0.007
	Deposits	0.004
	Re-entry	–
	Sum of all pathways	0.04
	Cumulative risk resident – child (HI)	
	Drift	**0.93**
	Vapour	**0.09**

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Deposits	**0.08**
	Re-entry	**–**
	Sum of all pathways	**0.76**
Resident – adult Buffer zone: 5 (m) Drift reduction technology: no	***Dithianon***	
	Drift	0.49
	Vapour	0.02
	Deposits	0.03
	Re-entry	0.64
	Sum of all pathways	0.86
	Dimethomorph	
	Drift	0.03
	Vapour	0.002
	Deposits	0.001
	Re-entry	0.04
	Sum of all pathways	0.05
	Cumulative risk resident – adult (HI)	
	Drift	**0.52**
	Vapour	**0.02**
	Deposits	**0.03**
	Re-entry	**0.68**
	Sum of all pathways	**0.91**

The Hazard Index is < 1. Thus combined exposure to all active substances in product Dimethomorph 15% + Dithianon 35% WG is not expected to present a risk for operators, workers, bystanders and residents. No further refinement of the assessment is required.

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 7.1.1	xxxxxx	2018	Dimethomorph 15% + Dithianon 35% WG: Acute Oral Toxicity Study in Rat xxxxxx.,Report No. R/16776/AOR/18 GLP, Unpublished	Y	SHARDA Cropchem Ltd.
KCP 7.1.2	xxxxxx	2018	Dimethomorph 15% + Dithianon 35% WG: Acute Dermal Toxicity Study in Rat xxxxxx., Report No. R/16777/ADR/18 GLP, Unpublished	Y	SHARDA Cropchem Ltd.
KCP 7.1.6	xxxxxx	2018	Dimethomorph 15% + Dithianon 35% WG:Skin Sensitisation Study by Guinea Pig Maximitzation Test (GPMT) xxxxxxx., Report No. R/16781/SS-GPMT/18 GLP, Unpublished	Y	SHARDA Cropchem Ltd.
KCP 7.6.2	J. Bernal	2019	IN-VITRO HUMAN SKIN PENETRATION OF ^{14}C-DIMETHOMORPH AND ^{14}C-DITHIANON IN DIMETHOMORPH 15% + DITHIANON 35% WG TEST ITEM Eurofins Agroscience Services Chem SAS, Report No. S19-02246 GLP, Unpublished	N	SHARDA Cropchem Ltd.

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

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 GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	**Under the experimental conditions, the oral median LD50 of the PRIORITY is approximately 500 mg/kg bw in rats (GHS Classification – Category 4, > 300 – 2,000 mg/kg bodyweight).** **According to the Regulation (EC) No. 1272/2008, PRIORITY is classified in Category 4 with the signal word "Warning" and the hazard statement "H302: Harmful if swallowed**

Reference	KCP 7.1.1 - 01
Report	Dimethomorph 15% + Dithianon 35% WG: Acute Oral Toxicity Study in Rat (OECD guideline No. 423) C.S. xxxxxx 2018, report No. R/16776/AOR/18
Guideline(s):	Yes OECD 423
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	SHA 6821 A/PRIORITY (SCL-20561)
Species	Rat (Wistar)
No. of animals (group size)	3 per dose per step/female
Dose(s)	300 mg/kgbw, 2000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	Analytical grade water
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of SHA 6821 A/PRIORITY

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
Female rats				
2000	3/3/3	2 h, 4 h, 2 days	day 3	-
300	0/0/3	No signs	No deaths	500
300	0/0/3	No signs	No deaths	500 (cut-off)

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 2: Summary of findings of acute oral toxicity study in rats of SHA 6821 A/PRIORITY

Mortality	Yes mortality occurred. In step- 1 all treated rats died on day 3
Clinical signs	No clinical signs of toxicity were observed.
Body weight	The body weight change by treated rats was not adversely affected during 14 days observation period.
Macroscopic examination	No gross pathological alterations were encountered in any of the treated rats when sacrificed at termination of the study.

Conclusion

Under the experimental conditions, the oral median LD50 of the PRIORITY is approximately 500 mg/kg bw in rats (GHS Classification – Category 4, > 300 – 2,000 mg/kg bodyweight).

According to the Regulation (EC) No. 1272/2008, PRIORITY is classified in Category 4 with the signal word "**Warning**" and the hazard statement **"H302: Harmful if swallowed".**

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

Comments of zRMS:	**Under the experimental conditions, the dermal LD_{50} of SHA 6821 A/PRIORITY is higher than 2000 mg/kg bw in rats.** **No classification is required according to Regulation (EC) No. 1272/2008.**

A 2.3.1 Study 1

Reference	KCP 7.1.2 - 01
Report	Dimethomorph 15% + Dithianon 35% WG: Acute Dermal Toxicity Study in Rat (OECD Guideline No. 402), xxxxxx 2018, report No. R/16777/ADR/18
Guideline(s):	Yes, OECD 402
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	SHA 6821 A/PRIORITY (SCL-20561)
Species	Rat (Wistar)
No. of animals (group size)	5 male rats, 5 female rats
Dose(s)	2000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	Moistened with analytical grade water
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 3: Results of acute dermal toxicity study in rats of SHA 6821 A/PRIORITY

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
Male rats				
2000	0/0/5	-	-	> 2000
Female rats				
2000	0/0/5	-	-	> 2000

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 4: Summary of findings of acute dermal toxicity study in rats of SHA 6821 A/PRIORITY

Mortality	No mortality occurred.
Clinical signs	No clinical signs of toxicity were observed.
Body weight	Test item did not affect body weight gain of the treated rats during 14 days observation period.
Macroscopic examination	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the dermal LD_{50} of SHA 6821 A/PRIORITY is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	**See Part C, acceptable** **According to the Regulation EC No. 1272/2008, Dimethomorph 15% + Dithianon 35% WG is not classified.** **No signal word or hazard statement is required.**

There is no co-formulant in the Dimethomorph 15% + Dithianon 35% WG recipe classified as danger through inhalation

Details of the co-formulants and their classification and the calculation methodology that was used to assess the dermal irritation of Dimethomorph 15% + Dithianon 35% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Conclusion

According to the Regulation EC No. 1272/2008, Dimethomorph 15% + Dithianon 35% WG is **not classified**. No signal word or hazard statement is required.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	**According to the Regulation EC No. 1272/2008, Dimethomorph 15% + Dithianon 35% WG is not classified.** **No signal word or hazard statement is require**

Acute toxicity studies for Dimethomorph 15% + Dithianon 35% WG were **not** evaluated as part of the EU review of Dimethomorph and 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 Dimethomorph 15% + Dithianon 35% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

According to Regulation (EC) No 1272/2008 as amended the concentration limit ≥ 10 % is used to trigger classification of a mixture as a skin irritant. There is no co-formulant in the Dimethomorph 15% + Dithianon 35% WG recipe classified as skin irritant. Therefore no skin irritation is expected during using this product.

Conclusion

According to the Regulation EC No. 1272/2008, Dimethomorph 15% + Dithianon 35% WG is **not classified**. No signal word or hazard statement is required.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	**According to the Regulation EU No. 1272/2008, using worse results from calculations, Dimethomorph 15% + Dithianon 35% WG is classified as eye irritant.** **Signal word "Warning" with the hazard statement "H319: Causes serious eye irritation"**

Acute toxicity studies for Dimethomorph 15% + Dithianon 35% WG were **not** evaluated as part of the EU review of Dimethomorph and 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 Dimethomorph 15% + Dithianon 35% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The product contains ≥ 1% of formulants considered as eye damage (classified as: Eye Dam. 1; H318: Causes serious eye damage). Under the GHS classification system the severe irritant component is at the

value of ≥ 1% for formulants/co-formulants for the H319: Causes serious eye irritation. Therefore Dimethomorph 15% + Dithianon 35% WG will be considered as an eye irritant according to Regulation (EC) no. 1272/2008.

Conclusion

According to the Regulation EU No. 1272/2008, using worse results from calculations, Dimethomorph 15% + Dithianon 35% WG is classified as eye irritant. Signal word "**Warning**" with the hazard statement "**H319: Causes serious eye irritation**"

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	**Under the experimental conditions, SHA 6821 A/PRIORITY is classified as moderate sensitiser, based on the Magnusson and Kligman criteria of classification and Regulation (EC) No. 1272/2008.** **Under experimental conditions SHA 6821 A / PRIORITY, a positive response occurred in 40% of animals after administration of> 1% of an intradermal induction dose(, therefore SHA 6821 A / PRIORITY should be classified as sensitizing Skin Sens. 1 B / H317**.

A 2.7.1 Study 1

Report	Dimethomorph 15% + Dithianon 35% WG: Skin Sensitisation Study by Guinea Pig Maximitzation Test (GPMT). (OECD guideline No.406), xxxxxxxx, 2018, report No. R/16781/SS-GPMT/18
Guideline(s):	Yes (OECD 406)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	SHA 6821 A/PRIORITY (SCL-20561)
Species	Guinea pig, English (Hartley)
No. of animals (group size)	Test substance group: 20 male guinea pigs Vehicle control goup: 10 male guinea pigs
Range finding	Yes
Exposure (concentration(s), no. of applications)	Intradermal induction 5% w/v in sterile water Topical induction 33% w/v test item in analytical grade water Challenge 33% w/v test item in analytical grade water
Vehicle	Sterile water, analytical grade water

Pretreatment prior to topical application	Yes (sodium lauryl sulfate)
Reliability check	α-Hexylcinnamaldehyde ≥ 95% (intradermal injections at 5% v/v, topical application at 40% v/v, topical challenge application at 10% v/v)
Remarks	None

Results and discussions

Table A 5: Results of skin sensitisation study of SHA 6821 A/PRIORITY

	24 hours	**48 hours**	**Total number of animals affected**
	After challenge		
SHA 6821 A/PRIORITY	8/20*	8/20*	**40% of total animal**
Test vehicle control group	0/10*	0/10*	0% of total animal
Positive control	N/A*	N/A*	50% of total animal

* Number of animals with positive dermal response (scores of 1-3) /number of animals in dose group

Clinical signs:	No clinical signs of toxicity were observed.

Conclusion

Under the experimental conditions, SHA 6821 A/PRIORITY is classified as moderate sensitiser, based on the Magnusson and Kligman criteria of classification and Regulation (EC) No. 1272/2008.
Total number of animals affected; **40% of total animal. Skin. Sens.1B**

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:	**Study on dermal absorption for dimethomorph and dithianon are acceptable**

~~**Dimethomorph**~~

~~According to the new EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 adopted: 24 May 2017) a default dermal absorption value 10% (concentrate) and 50% (diluted) of may be applied for products that are water-based/dispersed [c] or solid formulated[d]~~

~~[c]: Formulation types: soluble concentrate (SL), suspension concentrate (SC), flowable concentrate for seed treatment (FS), flowable (FL) (SC).~~
~~[d]: Formulation types: wettable powder (WP), water dispersible granules (WG/WDG), water soluble granules (SG), water soluble powder (SP), powder for dry seed treatment (DS).~~

~~**Dithianon**~~

~~The dermal absorption value for granules formulations as stated in the List of endpoints of Dithianon is based on a WG formulation. 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 related.~~
~~This is the case for the formulation Dithianon 35% WG : Active substance content: Dithianon, Formulation type: WG, Acute dermal toxicity: > 2000 mg/kg bw, Skin irritation study: not a skin irritant~~

Dermal absorption to PRIORITY **was not** evaluated as part of the EU review of dimethomorph and dithianon. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

A 2.10.1 Study 1 – Dimethomorph in SHA 6821 A/ PRIORITY

Comparative dermal absorption, in vitro using rat and human skin

Comments of zRMS:	**The dermal absorption values for dimetnomorph in PRIORITY are: 0.66% for undiluted, 20% for spray dilution.**

Reference	KCP 7.6.2
Report	IN-VITRO HUMAN SKIN PENETRATION OF ^{14}C-DIMETHOMORPH AND ^{14}C-DITHIANON IN DIMETHOMORPH 15% + DITHIANON 35% WG TEST ITEM, J. Bernal, 2019, S19-02246
Guideline(s)	OECD Guideline 428 “Skin Absortion: 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.)	[veratrole ring-U-14C] dimethomorph (TJBIOS-NB72-228)
	Test preparation	radioformulation
	Specific activity	187.2 µCi/mg
	Radiochemical purity	98.9%
Product	Name (Lot/Batch No.)	Dimethomorph 15% + Dithianon 35% WG (SCL-22364)
	Company code	Dimethomorph 15% + Dithianon 35% WG (SHA 6821 A)
	Concentration a.s.	150 g/kg
	Formulation type	WG
Blank product	Name (Lot/Batch No.)	-
	Concentration a.s.	-

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1 ml/h
	Exposed skin area	1 cm²
Membrane	Skin type	isolated epidermis
	Skin thickness range	302-400 µm
	Skin donors age	48, 34, 32, 63, 56, 42, 50, 42 years
	Skin donors sex	f
	Location	abdomen
	Source	ex vivo (abdominal surgery)
	Integrity test	yes
Receptor	Receptor medium	PBS 0.01M + 6% polyoxyethylene 20 oleyl ether
	Solubility in receptor medium	y
Sample Time	Exposure time	8 h
	Observation time	16 h
Sampling	Sample intervals	24 h
Washing		post exposure
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	y
Remarks: -		

Tested doses	Concentrate	Spray dilution 1
Tested concentration [mg/ml]	84.2 mg/g	0.257
Area dose [mg/cm²]	5	10 µL/cm²
Specific activity [µCi/g]	32.18	6.08
No. of donors	4	4
No of cells used/valid cells	8/8	8/8

Results and discussions

Table A 6: In-vitro dermal penetration of active substance 1 formulated as product code/name through human skin - Recovery data

Dose group		High dose (Formulation concentrate)		Mid dose (Spray dilution)	
Target concentration	[mg/mL]	150 g/kg		0.225	
Target dose	[mg/cm²]	5 mg/cm²		10 µL/cm²	
Mean actual applied dose	[mg/cm²]	5.42 ± 0.36		10.16 ± 0.14	
		Recovery [%]		Recovery [%]	
		Mean	S.D.	Mean	S.D.
Skin washing		105.40	2.69	79.27	5.78
Donor chamber wash		BLQ	NC	0.000	0.001

Tape strips: 1st sample, strips 1 + 2	0.02	0.03	6.34	2.90
Tape strips: 2nd sample; strips 3 - n	0.01	0.02	4.44	1.98
Skin preparation	0.09	0.01	5.11	1.87
Absorbed dose	0.43	0.26	11.71	5.68
Receptor fluid	0.35	0.25	6.60	4.10
Receptor chamber wash	0.0001	0.0004	BLQ	NC
Total recovery[1]	105.87	2.68	101.76	0.71
Absorption essentially complete at end of study (>75% absorption within half the study duration) [%Absorption at $t_{0.5}$]	No [34.6%]		No [72.5%]	
If yes: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding all tape strips)	N/A	N/A	N/A	N/A
If no: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding tape strips 1 and 2) [2]	0.44	0.25	16.15	5.11
Absorption estimate normalised[3]	0.44 ± 0.84 × 0.25		16.15 ± 0.84 × 5.11	
Relevant absorption estimate[4]	0.44 ± 0.21		16.15 ± 4.29	
Absorption estimates used for risk assessment[5]	**0.657**		**20.4**	

SD= Standard Deviation ; BLQ : Below the Limit of Quantification; NC: Not Calculated; N/A: not applicable

[1] Values may not calculate exactly due to rounding of figures

[2] In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665 and 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. 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.

According to the Table 1 of EFSA Guidance for n = 8 the Multiplication factor (k) is 0.84.

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

Conclusion/endpoint:

The dermal absorption values for dimetnomorph in PRIORITY are:
0.66% for undiluted dimetnomorph,
20% for spray dilution.

A 2.10.2 Study 1 – Dithianon in SHA 6821 A/ PRIORITY

Comparative dermal absorption, in vitro using rat and human skin

Comments of zRMS:	**The dermal absorption values for dithianon in PRIORITY are:** **0.67% for undiluted,** **13% for spray dilution.**

Reference	KCP 7.6.2
Report	IN-VITRO HUMAN SKIN PENETRATION OF ^{14}C-DIMETHOMORPH AND ^{14}C-DITHIANON IN DIMETHOMORPH 15% + DITHIANON 35% WG TEST ITEM, J. Bernal, 2019, S19-02246

Guideline(s)	OECD Guideline 428 “Skin Absortion: 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.)	[CN-^{14}C] dithianon (TJBIOS-NB-72-244)
	Test preparation	radioformulation
	Specific activity	227.0 µCi/mg
	Radiochemical purity	99.9%
Product	Name (Lot/Batch No.)	Dimethomorph 15% + Dithianon 35% WG (SCL-22364)
	Company code	Dimethomorph 15% + Dithianon 35% WG (SHA 6821 A)
	Concentration a.s.	350 g/kg
	Formulation type	WG
Blank product	Name (Lot/Batch No.)	-
	Concentration a.s.	-

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1 ml/h
	Exposed skin area	1 cm²
Membrane	Skin type	isolated epidermis
	Skin thickness range	302-400 µm
	Skin donors age	48, 34, 32, 63, 56, 42, 50, 42 years
	Skin donors sex	f
	Location	abdomen
	Source	ex vivo (abdominal surgery)
	Integrity test	yes
Receptor	Receptor medium	PBS 0.01M + 6% polyoxyethylene 20 oleyl ether
	Solubility in receptor medium	y
Sample Time	Exposure time	8 h
	Observation time	16 h
Sampling	Sample intervals	24 h
Washing		post exposure
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	y
Remarks: -		

Tested doses	Concentrate	Spray dilution 1
Tested concentration [mg/ml]	196.2 mg/g	0.554
Area dose [mg/cm²]	5	10 µL/cm²
Specific activity [µCi/g]	24.57	6.07
No. of donors	4	4
No of cells used/valid cells	8/8	8/8

Results and discussions

Table A 7: In-vitro dermal penetration of active substance 1 formulated as product code/name through human skin - Recovery data

Dose group	High dose (Formulation concentrate)		Mid dose (Spray dilution)	
Target concentration [mg/mL]	350 g/kg		0.525	
Target dose [mg/cm²]	5 mg/cm²		10 µL/cm²	
Mean actual applied dose [mg/cm²]	5.12 ± 0.29		9.89 ± 0.10	
	Recovery [%]		Recovery [%]	
	Mean	S.D.	Mean	S.D.
Skin washing	102.02	5.42	77.44	11.45
Donor chamber wash	BLQ	NC	0.000	0.001
Tape strips: 1st sample, strips 1 + 2	0.04	0.05	9.59	5.73
Tape strips: 2nd sample; strips 3 - n	0.02	0.03	5.85	3.25
Skin preparation	0.01	0.03	6.72	3.52
Absorbed dose	0.55	0.12	7.86	3.77
Receptor fluid	0.54	0.11	1.14	0.36
Receptor chamber wash	0.0001	0.0004	BLQ	NC
Total recovery[1]	102.64	5.38	98.54	8.16
Absorption essentially complete at end of study (>75% absorption within half the study duration) [%Absorption at $t_{0.5}$]	No [3.0%]		No [12.2%]	
If yes: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding all tape strips)	N/A	N/A	N/A	N/A
If no: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding tape strips 1 and 2) [2]	0.57	0.11	11.52	2.28
Absorption estimate normalised[3]	0.57 ± 0.84 × 0.11		11.52 ± 0.84 × 2.28	
Relevant absorption estimate[4]	0.57 ± 0.092		11.52 ± 1.915	
Absorption estimates used for risk assessment[5]	**0.667**		**13.4**	

SD= Standard Deviation ; BLQ : Below the Limit of Quantification; NC: Not Calculated; N/A: not applicable

[1] Values may not calculate exactly due to rounding of figures

[2] In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665 and 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. 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.

According to the Table 1 of EFSA Guidance for n = 8 the Multiplication factor (k) is 0.84.

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

Conclusion/endpoint:

The dermal absorption values for dithianon in PRIORITY are:
0.67% for undiluted dithianon,
13% for spray dilution.

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 3.1.1 Calculations for Dimethomorph

Table A 10: Estimation of longer term operator exposure towards Dimethomorph according to EFSA guidance (tractor application)

Application rate of active substance	0.225	kg a.s./ha	*i_AppRate*
Assumed area treated	10	ha/day	*d_AreaTreated*
Amount of active substance applied	2.25	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0.66%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	20.00%		*i_AbsorInuse*
Formulation type	Wettable granules, soluble granules		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

OutdoorWettable granules, soluble granulesUpward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	2447	11755	AOEM	
	Body	2184	20340	AOEM	
	Head	15	201	AOEM	
	Protected hands (gloves)	28	71	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	38	140	AOEM	
	Protected head (hood and face shield)	0	11	AOEM	
	Inhalation	48	265	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	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	5179	14033	AOEM	No data available for a drift reduction scenario
	Body	19826	115686	AOEM	
	Head	2606	15991	AOEM	
	Protected hands (gloves)	79	2069	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	259	506	AOEM	
	Inhalation	101	186	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		0.5	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)	5.7013604	0.4770868
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0950227	0.0079514
% of RVNAS	63.35%	5.30%

Table A 8: Estimation of longer term operator exposure towards Dimethomorph according to EFSA guidance (closed cab tractor application)

Operator exposure for Dimethamorph 15% + Dithianone 35% WG outdoor spray applications

Application rate of active substance	0.225	kg a.s./ha	*i_AppRate*
Assumed area treated	10	ha/day	*d_AreaTreated*
Amount of active substance applied	2.25	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0.66%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	20.00%		*i_AbsorInuse*
Formulation type	Wettable granules, soluble granules		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

OutdoorWettable granules, soluble granulesUpward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	2447	11755	AOEM	
	Body	2184	20340	AOEM	
	Head	15	201	AOEM	
	Protected hands (gloves)	28	71	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	38	140	AOEM	
	Protected head (hood and face shield)	0	11	AOEM	
	Inhalation	48	265	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	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	2712	4670	AOEM	No data available for a drift reduction scenario
	Body	6607	18796	AOEM	
	Head	34	438	AOEM	
	Protected hands (gloves)	79	1716	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	153	362	AOEM	
	Inhalation	15	47	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	Yes		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)	1.9643545	0.1166801
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0327392	0.0019447
% of RVNAS	21.83%	1.30%

Table A 9: Estimation of longer term operator exposure towards Dimethomorph according to EFSA guidance (Manual-Hand held application)

Operator exposure for Dimethamorph 15% + Dithianone 35% WG outdoor spray applications

Application rate of active substance	0.225	kg a.s./ha	*i_AppRate*
Assumed area treated	4	ha/day	*d_AreaTreated*
Amount of active substance applied	0.9	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0.66%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	20.00%		*i_AbsorInuse*
Formulation type	Wettable granules, soluble granules		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Manual-Hand held		
Season	not relevant		

OutdoorWettable granules, soluble granulesUpward sprayingManual-Hand held

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	1209	5759	AOEM	
	Body	1147	15586	AOEM	
	Head	6	81	AOEM	
	Protected hands (gloves)	15	28	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	17	56	AOEM	
	Protected head (hood and face shield)	0	5	AOEM	
	Inhalation	36	259	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	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	2491	8118	AOEM	No data available for a drift reduction scenario
	Body	60457	178571	AOEM	
	Head	147	794	AOEM	
	Protected hands (gloves)	22	112	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	74	171	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)	12.7448317	0.3507044
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2124139	0.0058451
% of RVNAS	141.61%	3.90%

A 3.1.2 Calculations for Dithianon

Table A 10: Estimation of longer term operator exposure towards Dithianon according to EFSA guidance (tractor application)

Operator exposure for Dimethamorph 15% + Dithianone 35% WG outdoor spray applications

Application rate of active substance	0.525	kg a.s./ha	*i_AppRate*
Assumed area treated	10	ha/day	*d_AreaTreated*
Amount of active substance applied	5.25	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0.67%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	13.00%		*i_AbsorInuse*
Formulation type	Wettable granules, soluble granules		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

OutdoorWettable granules, soluble granulesUpward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	4699	22739	AOEM	
	Body	3962	26017	AOEM	
	Head	34	470	AOEM	
	Protected hands (gloves)	49	165	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	81	327	AOEM	
	Protected head (hood and face shield)	1	27	AOEM	
	Inhalation	61	270	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	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	10980	32743	AOEM	No data available for a drift reduction scenario
	Body	46261	269935	AOEM	
	Head	6080	37313	AOEM	
	Protected hands (gloves)	185	4827	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	604	1180	AOEM	
	Inhalation	163	434	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		0.5	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)	8.5140024	0.7227855
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1419000	0.0120464
% of RVNAS	1051.11%	89.23%

Table A 11: Estimation of longer term operator exposure towards Dithianon according to EFSA guidance (closed cab tractor application)

Operator exposure for Dimethamorph 15% + Dithianone 35% WG outdoor spray applications

Application rate of active substance	0.525	kg a.s./ha	*i_AppRate*
Assumed area treated	10	ha/day	*d_AreaTreated*
Amount of active substance applied	5.25	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0.67%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	13.00%		*i_AbsorInuse*
Formulation type	Wettable granules, soluble granules		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

OutdoorWettable granules, soluble granulesUpward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	4699	22739	AOEM	
	Body	3962	26017	AOEM	
	Head	34	470	AOEM	
	Protected hands (gloves)	49	165	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	81	327	AOEM	
	Protected head (hood and face shield)	1	27	AOEM	
	Inhalation	61	270	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	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	5750	10897	AOEM	No data available for a drift reduction scenario
	Body	15417	43857	AOEM	
	Head	79	1021	AOEM	
	Protected hands (gloves)	185	4004	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	357	844	AOEM	
	Inhalation	25	110	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	Yes		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)	2.9063312	0.1678325
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0484389	0.0027972
% of RVNAS	358.81%	20.72%

Table A 12: Estimation of longer term operator exposure towards Dithianon according to EFSA guidance (Manual-Hand held application)

Operator exposure for Dimethamorph 15% + Dithianone 35% WG outdoor spray applications

Application rate of active substance	0.525	kg a.s./ha	*i_AppRate*
Assumed area treated	4	ha/day	*d_AreaTreated*
Amount of active substance applied	2.1	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0.67%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	13.00%		*i_AbsorInuse*
Formulation type	Wettable granules, soluble granules		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Manual-Hand held		
Season	not relevant		

OutdoorWettable granules, soluble granules|Upward sprayingManual-Hand held

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	2321	11141	AOEM	
	Body	2081	19936	AOEM	
	Head	14	188	AOEM	
	Protected hands (gloves)	27	66	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	36	131	AOEM	
	Protected head (hood and face shield)	0	11	AOEM	
	Inhalation	47	264	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	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	5060	15523	AOEM	No data available for a drift reduction scenario
	Body	69031	179993	AOEM	
	Head	193	1048	AOEM	
	Protected hands (gloves)	50	261	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	149	284	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)	9.8825209	0.3624366
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1647087	0.0060406
% of RVNAS	1220.06%	44.75%

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Dimethomorph

Table A 13: Estimation of longer term worker exposure towards Dimethomorph according to EFSA guidance

Worker exposure from residues on foliage for Dimethamorph 15% + Dithianone 35% WG		
Crop type	Grapes	
Indoor or outdoor	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Hand harvesting	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0.225	kg a.s./ha
Number of applications	3	
Interval between multiple applications	10	days
Half-life of active substance	4.65	days
Multiple application factor	1.3	
Dermal absorption of the product	0.66%	
Dermal absorption of the in-use dilution	20.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.675	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	30000	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	10100	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	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)	41.3409944	13.9181348	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0.6890166	0.2319689	
% of RVNAS	459.34%	154.65%	

Table A 14: Estimation of longer term worker exposure towards Dimethomorph according to EFSA guidance for re-entry period of 26 days

Worker exposure from residues on foliage for Dimethamorph 15% + Dithianone 35% WG		
Crop type	Grapes	
Indoor or outdoor	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Hand harvesting	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0.225	kg a.s./ha
Number of applications	3	
Interval between multiple applications	10	days
Half-life of active substance	4.65	days
Multiple application factor	1.3	
Dermal absorption of the product	0.66%	
Dermal absorption of the in-use dilution	20.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.014175	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	30000	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	10100	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	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)	0.8681609	0.2922808	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0144693	0.0048713	
% of RVNAS	9.65%	3.25%	

Table A 15: Estimation of longer term worker exposure towards Dimethomorph according to EFSA guidance for re-entry period of 17 days with gloves

Worker exposure from residues on foliage for Dimethamorph 15% + Dithianone 35% WG		
Crop type	Grapes	
Indoor or outdoor	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Hand harvesting	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0.225	kg a.s./ha
Number of applications	3	
Interval between multiple applications	10	days
Half-life of active substance	4.65	days
Multiple application factor	1.3	
Dermal absorption of the product	0.66%	
Dermal absorption of the in-use dilution	20.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.053325	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	30000	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	10100	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	3000	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)	3.2659386	1.0995326	0.3265939
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0544323	0.0183255	0.0054432
% of RVNAS	36.29%	12.22%	3.63%

A 3.2.2 Calculations for Dithianon

Table A 16: Estimation of longer term worker exposure towards Dithianon according to EFSA guidance

Worker exposure from residues on foliage for Dimethamorph 15% + Dithianone 35% WG		
Crop type	Grapes	
Indoor or outdoor	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Hand harvesting	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0.525	kg a.s./ha
Number of applications	3	
Interval between multiple applications	10	days
Half-life of active substance	5.29	days
Multiple application factor	1.3	
Dermal absorption of the product	0.67%	
Dermal absorption of the in-use dilution	13.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	1.575	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	30000	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	10100	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	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)	65.9704259	22.2100434	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	1.0995071	0.3701674	
% of RVNAS	8144.50%	2741.98%	

Table A 17: Estimation of longer term worker exposure towards Dithianon according to EFSA guidance for re-entry period of 26 days

Worker exposure from residues on foliage for Dimethamorph 15% + Dithianone 35% WG		
Crop type	Grapes	
Indoor or outdoor	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Hand harvesting	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0.525	kg a.s./ha
Number of applications	3	
Interval between multiple applications	10	days
Half-life of active substance	5.29	days
Multiple application factor	1.3	
Dermal absorption of the product	0.67%	
Dermal absorption of the in-use dilution	13.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.051975	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	30000	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	10100	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	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)	2.1770241	0.7329314	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0362837	0.0122155	
% of RVNAS	268.77%	90.49%	

Table A 18: Estimation of longer term worker exposure towards Dithianon according to EFSA guidance for re-entry period of 17 days with gloves

Worker exposure from residues on foliage for Dimethamorph 15% + Dithianone 35% WG		
Crop type	Grapes	
Indoor or outdoor	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Hand harvesting	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0.525	kg a.s./ha
Number of applications	3	
Interval between multiple applications	10	days
Half-life of active substance	5.29	days
Multiple application factor	1.3	
Dermal absorption of the product	0.67%	
Dermal absorption of the in-use dilution	13.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.169575	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	30000	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	10100	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	3000	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)	7.1028159	2.3912813	0.7102816
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1183803	0.0398547	0.0118380
% of RVNAS	876.89%	295.22%	87.69%

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Dimethomorph

Table A 19: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for Dimethamorph 15% + Dithianone 35% WG		
Croptype	Grapes	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Wettable granules, soluble granules	
Buffer strip	5	m
Application rate of the product	0.225	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0.28125	g a.s./l
Dermal absorption of product	0.66%	
Dermal absorption of in-use dilution	20.00%	
Oral absorption	100.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.675	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	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)	3.07%	
Drift percentage on surface (mean)	2.32%	
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

Table A 20: Estimation of longer term resident exposure towards Dimethomorph according to EFSA guidance

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)	0.0783674	0.0107000	0.0058611	0.0968930	0.1439581
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0078367	0.0010700	0.0005861	0.0096893	0.0143958
% of RVNAS	5.22%	0.71%	0.39%	6.46%	9.60%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2602744	0.0138000	0.0128680	0.3229765	0.4512624
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0043379	0.0002300	0.0002145	0.0053829	0.0075210
% of RVNAS	2.89%	0.15%	0.14%	3.59%	5.01%

Table A 21: Input parameters considered for the estimation of longer term resident exposure for refinement for children

Resident exposure for Dimethamorph 15% + Dithianone 35% WG		
Croptype	Grapes	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Wettable granules, soluble granules	
Buffer strip	5	m
Application rate of the product	0.225	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0.28125	g a.s./l
Dermal absorption of product	0.66%	
Dermal absorption of in-use dilution	20.00%	
Oral absorption	100.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.675	µg a.s./cm²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0.001	mg/m³
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	m³/day/kg
Breathing rate child (1-3 year old)	1.07	m³/day/kg
Drift percentage on surface (75th percentile)	3.07%	
Drift percentage on surface (mean)	2.32%	
Turf transferable residues percentage	5.00%	
Transfer coeff. of surface deposits-adult	7300	cm²/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm²/hour
Saliva extraction percentage	50.00%	
Surface area of hands mouthed	20	cm²
Frequency of hand to mouth activity	9.5	events/hour
Ingestion rate for mouthing of grass per day	25	cm²
Dislodgeable residues percentage transferability for object to mouth	20.00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm²/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm²/h

Table A 22: Estimation of longer term resident exposure towards Dimethomorph according to EFSA guidance for refinement for children

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)	0.0783674	0.0107000	0.0058611	0.0000000	0.0667022
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0078367	0.0010700	0.0005861	0.0000000	0.0066702
% of RVNAS	5.22%	0.71%	0.39%	0.00%	4.45%

A 3.3.2 Calculations for Dithianon

Table A 23: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for Dimethamorph 15% + Dithianone 35% WG		
Croptype	Grapes	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Wettable granules, soluble granules	
Buffer strip	5	m
Application rate of the product	0.525	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0.65625	g a.s./l
Dermal absorption of product	0.67%	
Dermal absorption of in-use dilution	13.00%	
Oral absorption	100.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	1.575	µg a.s./cm²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0.001	mg/m³
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	m³/day/kg
Breathing rate child (1-3 year old)	1.07	m³/day/kg
Drift percentage on surface (75th percentile)	3.07%	
Drift percentage on surface (mean)	2.32%	
Turf transferable residues percentage	5.00%	
Transfer coeff. of surface deposits-adult	7300	cm²/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm²/hour
Saliva extraction percentage	50.00%	
Surface area of hands mouthed	20	cm²
Frequency of hand to mouth activity	9.5	events/hour
Ingestion rate for mouthing of grass per day	25	cm²
Dislodgeable residues percentage transferability for object to mouth	20.00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm²/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm²/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm²/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm²/h

Table A 24: Estimation of longer term resident exposure towards Dithianon according to EFSA guidance

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)	0.1192346	0.0107000	0.0104510	0.1546182	0.2204046
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0119235	0.0010700	0.0010451	0.0154618	0.0220405
% of RVNAS	88.32%	7.93%	7.74%	114.53%	163.26%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.3952318	0.0138000	0.0205342	0.5153940	0.6988131
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0065872	0.0002300	0.0003422	0.0085899	0.0116469
% of RVNAS	48.79%	1.70%	2.54%	63.63%	86.27%

Table A 25: Input parameters considered for the estimation of longer term resident exposure for 10m buffer strip and drift reduction

Resident exposure for Dimethamorph 15% + Dithianone 35% WG		
Croptype	Grapes	
Application method	Upward spraying	
Application equipment	Vehicle-mounted-Drift Reduction	
Formulation type	Wettable granules, soluble granules	
Buffer strip	10	m
Application rate of the product	0.525	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0.65625	g a.s./l
Dermal absorption of product	0.67%	
Dermal absorption of in-use dilution	13.00%	
Oral absorption	100.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	1.575	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	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)	1.02%	
Drift percentage on surface (mean)	0.77%	
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

Table A 26: Estimation of longer term resident exposure towards Dithianon according to EFSA guidance for 10m buffer strip and drift reduction

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)	0.0596173	0.0107000	0.0017362	0.1546182	0.1745551
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0059617	0.0010700	0.0001736	0.0154618	0.0174555
% of RVNAS	44.16%	7.93%	1.29%	114.53%	129.30%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1976159	0.0138000	0.0034112	0.5153940	0.5565932
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0032936	0.0002300	0.0000569	0.0085899	0.0092766
% of RVNAS	24.40%	1.70%	0.42%	63.63%	68.72%

Table A 27: Input parameters considered for the estimation of longer term resident exposure for refinement for children

Resident exposure for Dimethamorph 15% + Dithianone 35% WG		
Croptype	Grapes	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Wettable granules, soluble granules	
Buffer strip	5	m
Application rate of the product	0.525	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0.65625	g a.s./l
Dermal absorption of product	0.67%	
Dermal absorption of in-use dilution	13.00%	
Oral absorption	100.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	1.575	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	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)	3.07%	
Drift percentage on surface (mean)	2.32%	
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%	

Table A 28: Estimation of longer term resident exposure towards Dithianon according to EFSA guidance for refinement for children

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)	0.1192346	0.0107000	0.0104510	0.0000000	0.0971224
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0119235	0.0010700	0.0010451	0.0000000	0.0097122
% of RVNAS	88.32%	7.93%	7.74%	0.00%	71.94%

A 3.4 Combined exposure calculations for Dimethomorph and Dithianon

In tables below are presented calculations for combined exposure for Dimethomorph and Dithianon in Dimethomorph 15% + Dithianon 35% WG.

Operator exposure:

Model data	Level of PPE	Dimethomorph (AOEL = 0.15 mg/kg bw/d)		Dithianon (AOEL = 0.0135 mg/kg bw/d)		Cumulative risk Operators (HI)[3]
		Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	
Grapevine - Tractor mounted boom spray application outdoors						
Spray application (AOEM; 75th percentile) Body weight: 60 kg						
	Work wear (arms, body and legs covered) M/L and A	0.0296	**0.20**	0.0425	3.15	3.35
	Work wear (arms, body and legs covered) M/L and A + gloves M/L and A + hood	0.0079	**0.05**	0.012	**0.89**	**0.94**
Grapevine - Tractor mounted boom spray application outdoors (closed cab)						
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A + closed cab	0.0110	**0.07**	0.0154	1.14	1.21
	Work wear (arms, body and legs covered) M/L and A + gloves M/L and A + closed cab	0.0019	**0.01**	0.0028	**0.21**	**0.22**
Grapevine - Manual-Hand held - upward spraying outdoor						
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0142	**0.09**	0.0172	1.27	1.36
	Work wear (arms, body and legs covered) M/L and A	0.0058	**0.04**	0.0060	**0.45**	**0.49**

The Hazard Index is < 1 for the estimation with the use suitable gloves and working clothing (long sleeved shirt and trousers) and hood during mixing/loading and application for tractor application application or use suitable gloves and working clothing (long sleeved shirt and trousers) and during mixing/loading and application for closed cab tractor application.
The Hazard Index is < 1 for the estimation with the use suitable gloves and working clothing (long sleeved shirt and trousers) during mixing/loading and application for hand held application.

[3] The Hazard Index (HI) is the sum of the individual HQs for Dimethomorph and Dithianon

Worker exposure:

Model data	Level of PPE	Dimethomorph (AOEL = 0.15 mg/kg bw/d)		Dithianon (AOEL = 0.0135 mg/kg bw/d)		Cumulative risk Operators (HI)*
		Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	Total absorbed dose (mg/kg/day)	Estimated exposure / AOEL (HQ)	
Grapevine						
Body weight: 60 kg	Potential TC: 30000 cm^2/person/h	0.6890	4.59	1.0995	81.44	86.03
	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	0.2319	1.55	0.3702	27.42	28.97
Proposal of Re-entry period of 26 days						
Body weight: 60 kg	Potential TC: 30000 cm^2/person/h	0.0144	**0.10**	0.0363	2.69	2.79
	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	0.0049	**0.03**	0.0122	**0.90**	**0.93**
Proposal of Re-entry period of 17 days with gloves						
Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves TC: 3000 cm^2/person/h	0.0054	**0.04**	0.01184	**0.88**	**0.92**

The estimated exposure for workers present that the Hazard Index is < 1 for the worker wearing adequate work clothing and without gloves when a time period of 26 days after application is respected or with use gloves after 17 days after application.

Bystander and resident exposure:

		Dimethomorph (AOEL = 0.15 mg/kg bw/d)		Dithianon (AOEL = 0.0135 mg/kg bw/d)		Cumulative risk Operators (HI)*
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of system-ic AOEL**	**Total ab-sorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	
Grapevine						
Resident child Body weight:10 kg	Drift (75th perc.)	0.0078	0.05	0.0119	0.88	0.93
	Vapour (75th perc.)	0.0011	0.007	0.0011	0.08	0.09
	Deposits (75th perc.)	0.0006	0.004	0.0010	0.08	0.08
	Re-entry (75th perc.)	–	–	–	–	–
	Sum (mean)	0.0144	0.04	0.0097	0.72	**0.76**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0043	0.03	0.0065	0.49	0.52
	Vapour (75th perc.)	0.0002	0.002	0.0002	0.02	0.02
	Deposits (75th perc.)	0.0002	0.001	0.0003	0.03	0.03
	Re-entry (75th perc.)	0.0054	0.04	0.0086	0.64	0.68
	Sum (mean)	0.0075	0.05	0.0116	0.86	**0.91**

According to AOEM Model the Hazard Index is < 1. Thus combined exposure to all active substances in product Dimethomorph 15% + Dithianon 35% WG is not expected to present a risk for adult bystanders and residents.
The Hazard Index is < 1 when then entrance into treated crop is prohibited for children.

Appendix 4 DT50 foliar calculation on Dimethomorph-data from JMPR

JMPR – residue trials lettuce outdoor (N and S):

lettuce	**Report**	Rate	Analysed	Residues (mg/kg)	Time (day)		
	Germany, 1997	0,18 kg a.s./ha	head lettuce	8,3	0		
	DK-724-057 / DK-701-015			0,19	7		
	(RU-CY-0397 MZ)			0,07	10		
				0,02	14	DT50	**2,41**
				0,02	21		
	Spain, 1999	0,19-0,27 kg a.s./ha	head lettuce	0,19	0		
	DK-726-014			0,06	4		
	(99-214-21)			0,05	7		
				0,03	11	DT50	5,63
				0,03	15		
	Spain, 1998	0,2-0,22 kg a.s./ha	head lettuce	0,98	0		
	DK-726-009			0,4	4		
	(98-112-45)			0,16	7		
				0,08	11	DT50	4,06
				0,09	14		
	Spain, 1999	0,17-0,23 kg a.s./ha	head lettuce	1,5	0		
	DK-726-014			0,55	4		
	(99-214-22)			0,43	7		
				0,29	11	DT50	4,64
				0,09	13		
	Spain, 1998	0,21-0,25 kg a.s./ha	head lettuce	0,27	0		
	DK-726-009			0,08	4		
	(98-112-46)			0,1	7		
				0,04	11		
				0,03	14	DT50	4,42
						mean DT50	4,69
						90th percentile DT50	5,33
						geomean	4,65

Appendix 5 DT50 foliar calculation on Dithianon-data from SGS

DT_{50} 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 DT_{50} 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 (whole 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 (whole 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 DT_{50} = 5.29