

FINAL REGISTRATION REPORT

Part B

Section 5

Analytical Methods

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

Finalisation date: 12/2021; 01.2024

Version history

When	What
12.2021	Assessment
01.2024	The final Registration Report

Table of Contents

5	Analytical methods.....	5
5.1	Conclusion and summary of assessment.....	5
5.2	Methods used for the generation of pre-authorization data (KCP 5.1).....	5
5.2.1	Analysis of the plant protection product (KCP 5.1.1)	5
5.2.1.1	Determination of active substance and/or variant in the plant protection product (KCP 5.1.1).....	5
5.2.1.2	Description of analytical methods for the determination of relevant impurities (KCP 5.1.1).....	11
5.2.1.3	Description of analytical methods for the determination of formulants (KCP 5.1.1)	11
5.2.1.4	Applicability of existing CIPAC methods (KCP 5.1.1).....	11
5.2.2	Methods for the determination of residues (KCP 5.1.2).....	11
5.3	Methods for post-authorization control and monitoring purposes (KCP 5.2)	11
5.3.1	Analysis of the plant protection product (KCP 5.2)	11
5.3.2	Description of analytical methods for the determination of residues of Dimethomorph (KCP 5.2).....	12
5.3.2.1	Overview of residue definitions and levels for which compliance is required	12
5.3.2.2	Description of analytical methods for the determination of residues in plant matrices (KCP 5.2).....	13
5.3.2.3	Description of analytical methods for the determination of residues in animal matrices (KCP 5.2).....	14
5.3.2.4	Description of methods for the analysis of soil (KCP 5.2)	14
5.3.2.5	Description of methods for the analysis of water (KCP 5.2).....	15
5.3.2.6	Description of methods for the analysis of air (KCP 5.2).....	15
5.3.2.7	Description of methods for the analysis of body fluids and tissues (KCP 5.2)	16
5.3.2.8	Other studies/ information	16
5.3.3	Description of analytical methods for the determination of residues of Dithianon (KCP 5.2)	16
5.3.3.1	Overview of residue definitions and levels for which compliance is required	16
5.3.3.2	Description of analytical methods for the determination of residues in plant matrices (KCP 5.2).....	17
5.3.3.3	Description of analytical methods for the determination of residues in animal matrices (KCP 5.2).....	18
5.3.3.4	Description of methods for the analysis of soil (KCP 5.2)	18
5.3.3.5	Description of methods for the analysis of water (KCP 5.2).....	19
5.3.3.6	Description of methods for the analysis of air (KCP 5.2).....	19
5.3.3.7	Description of methods for the analysis of body fluids and tissues (KCP 5.2)	20
5.3.3.8	Other studies/ information	20
Appendix 1	Lists of data considered in support of the evaluation.....	21
Appendix 2	Detailed evaluation of submitted analytical methods	24

A 2.1	Analytical methods for Dimethomorph	24
A 2.1.1	Methods used for the generation of pre-authorization data (KCP 5.1).....	24
A 2.1.2	Methods for post-authorization control and monitoring purposes (KCP 5.2)	24
A 2.2	Analytical methods for Dithianon.....	24
A 2.2.1	Methods used for the generation of pre-authorization data (KCP 5.1).....	25
A 2.2.2	Methods for post-authorization control and monitoring purposes (KCP 5.2)	25

5 Analytical methods

5.1 Conclusion and summary of assessment

Sufficiently sensitive and selective analytical methods are available for the active substances in the plant protection product.

Noticed data gaps are:

- none

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Noticed data gaps are:

- none

MRLs for grapevine was set at 3.0 mg/kg for dimethomorph (Reg. (EU) 2020/1633) and for dithianon (Reg. (EC) 839/2008). Available analytical methods are sufficient to determine analytes for MRL compliance.

Commodity/crop	Supported/ Not supported
Grapevine	Supported

5.2 Methods used for the generation of pre-authorization data (KCP 5.1)

5.2.1 Analysis of the plant protection product (KCP 5.1.1)

5.2.1.1 Determination of active substance and/or variant in the plant protection product (KCP 5.1.1)

An overview on the acceptable methods and possible data gaps for analysis of dimethomorph and dithianon in plant protection product is provided as follows:

Reference:	KCP 5.1.1
Report	Dimethomorph 15% + Dithianon 35% WG: Method development and validation for the determination of active substances content in the formulation; Study code BA-21/17, Małgorzata Wołoszynowska, 2017.
Guideline(s):	Yes (SANCO/3030/99 rev.4.)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test item

- Trade name Dimethomorph 15% + Dithianon 35% WG

- Active substance 1: Dimethomorph

Chemical name: (E,Z)-4-[3-(4-Chlorphenyl)-3-(3,4-

- dimethoxyphenyl)acryloyl]morpholine
CAS No: [110488-70-5]
- Active substance 2: Dithianon
Chemical name: 2,3-Dicyano-9,10-dioxo-1,4-dithiaanthracene
CAS No: [3347-22-6]
 - Manufacturer: Sharda Cropchem. Limited, Sharda International, DMCC
Dominic Holm, 29th Road, Bandra (West), Mumbai –
400050, India
 - Batch No: SCL-20561
 - Code of examined item: 152/16/BA – 21/17

Reference item

- Dimethomorph, Sigma-Aldrich, batch no SZBE044XV, purity 98.9%
- Dithianon, IPO UCI 151, batch no 7A/15, purity 98.2%

Apparatus and materials

- Shimadzu liquid chromatograph equipped with UV/Vis detector, a thermostated column oven and autosampler
- Hypersil GOLD C18 column (5µm), 250 x 4.6 mm
- Mettler Toledo analytical balance, accuracy 0.01 mg

Reagents

- Water for HPLC, Millipore
- Acetonitrile for HPLC, POCh

Analytical method

The content of dimethomorph and dithianon in the examined specimen was determined by high performance liquid chromatography HPLC with UV/Vis detector using reversed phase column. External standard method was used.

Chromatographic conditions

- Column temperature: 30 °C
- Mobile phase: A: acetonitrile
- B: H₂O

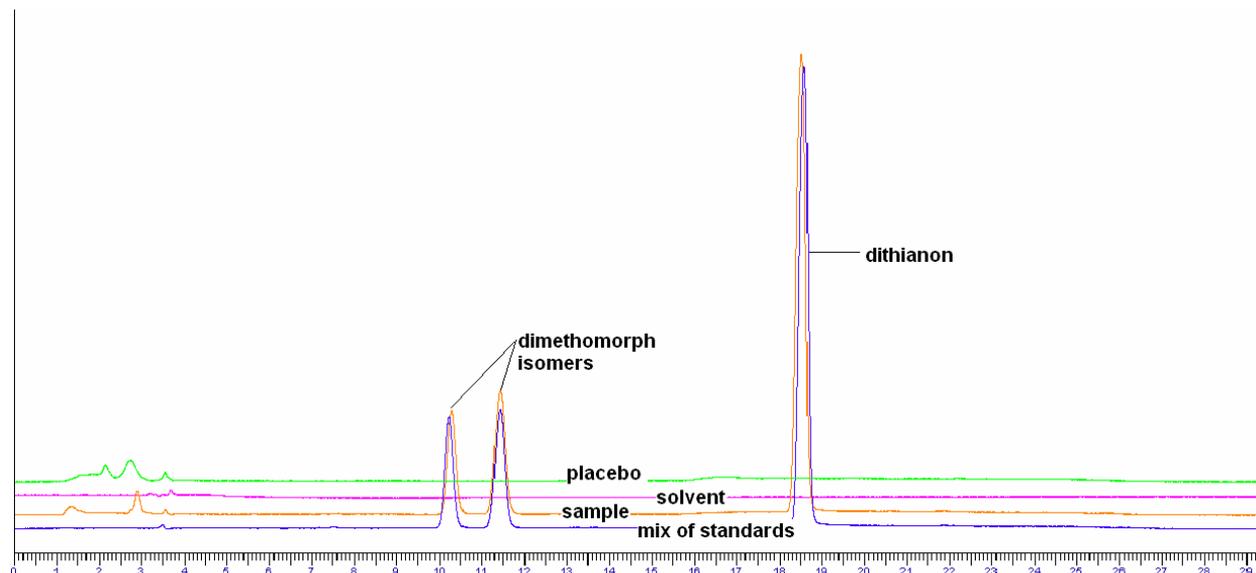
Time [min]	A [%]	B [%]
0.01-10.00	40	60
10.01-20.00	60	40
20.01-30.00	40	60

- Flow rate: 1.3 mL/min
- Wavelength $\lambda = 235$ nm
- Volume of sample solution injected: 5 µL

Validation - Results and discussions

Specificity

The chromatograms of placebo, solvent, solution of standards mixture and the examined specimen solution were performed and superimposed. The obtained results are presented in Fig. 1.



There are no interferences between the analytes and other components of the specimen.

Linearity

The linearity of the detector response was assessed using five mixtures of standard solutions at the concentration range of dimethomorph from 0.1625 mg/mL to 0.4225 mg/mL, which corresponds to the concentration range from 54% to 140% of dimethomorph content in the preparation and dithianon from 0.3928 mg/mL to 0.8681 mg/mL, which corresponds to the concentration range from 56% to 124% of dithianon content in the preparation. All solutions were analysed twice.

	Slope (Area/Concentration)	Intercept (Area)	R ²
Dimethomorph	18229377	-20341	0.9977
Dithianon	12167388	1701040	0.9966

Repeatability

The method repeatability was assessed on the basis of six independent determinations of active substances content in Dimethomorph 15% + Dithianon 35% WG preparation. RSD% for dimethomorph determination resulted equal to 0.86%, thus lower than modified Horwitz value of 1.78%. For Dithianon RSD% was equal to 0.53%, below modified Horwitz value of 1.57%.

Repeatability of dimethomorph determination

Chromatogram name	Specimen weight [mg]	Concentration C [mg/mL]	Peak area	Result [%]
pr1	19.68	1.968	5232925	14.64
pr2	20.61	2.061	5482114	14.64
pr3	19.63	1.963	5284712	14.82
pr4	20.29	2.029	5315938	14.42
pr5	19.85	1.985	5273672	14.62
pr6	20.64	2.064	5485397	14.63
Average				14.629
SD				0.126
RSD [%]				0.86

Repeatability of dithianon determination

Chromatogram name	Specimen weight [mg]	Concentration C [mg/mL]	Peak area	Result [%]
pr1	19.68	1.968	10530386	35.49
pr2	20.61	2.061	10995202	35.39
pr3	19.63	1.963	10599237	35.82
pr4	20.29	2.029	10849476	35.47
pr5	19.85	1.985	10650070	35.59
pr6	20.64	2.064	10971201	35.59
Average				35.503
SD				0.1895
RSD [%]				0.53

Precision of the system

Mixture of standard solution of active substances at concentration of dimethomorph 0.2925 mg/mL and dithianon 0.6432 mg/mL was injected six times into the chromatographic column and detector responses were recorded. Precision of the system and test of suitability – dimethomorph isomer 1

Injection No	Peak area	Retention time [min]	Tailing factor	Number of theoretical plates/meter
1	2328353	10.1	1.04	12221
2	2381142	10.23	1.04	12044
3	2397678	10.86	1	11542
4	2325698	12.6	1	11228
5	2304091	13.01	0.97	12293
6	2378927	12.55	1	11424
Average	2352648	11.557	1.01	11792
SD	37959	1.3079	0.026	
RSD [%]	1.61	11.32	2.58	

Precision of the system and test of suitability – dimethomorph isomer 2

Injection No	Peak area	Retention time [min]	Tailing factor	Number of theoretical plates/meter
1	2886572	11.2	1.02	10516
2	2895589	11.43	1	11770
3	2844269	12.22	1.02	10760
4	2889571	14.33	1	12234
5	2904259	14.66	1	12940

6	2900762	14.23	1.03	10451
Average	2886837	13.009	1.01	11445
SD	21880	1.5732	0.0135	
RSD [%]	0.76	12.09	1.33	

Precision of the system and test of suitability – dithianon

Injection No	Peak area	Retention time [min]	Tailing factor	Number of theoretical plates/meter
1	9370105	18.35	0.9	36618
2	9332763	18.58	0.9	38627
3	9391288	19.35	0.9	39195
4	9286523	20.74	0.9	48206
5	9263930	20.85	0.91	50329
6	9365830	20.68	0.91	45659
Average	9335073	19.759	0.9	43106
SD	50512	1.14	0.01	
RSD [%]	0.54	5.79	0.72	

Accuracy

Accuracy of active substance determination in Dimethomorph 15% + Dithianon 35% WG was assessed by recovery value at two levels of concentration. Each of twelve 5 mL volumetric flasks were charged with approximately 10 mg placebo and weighed. About 0.3 mL of dimethomorph standard solution at concentration of 3.2499 mg/mL and 1.2 mL of dithianon standard solution at concentration of 2.1555 mg/mL were added to the each of the first six flasks. To the each of remaining six flasks 1.0 mL of the dimethomorph standard solution at concentration of 1.4420 mg/mL and 1.5 mL of dithianon standard solution at concentration of 2.4579 mg/mL were added and acetonitrile was added up to the volume.

Accuracy of the method – dimethomorph

	Chromatogram name	Concentration of dimethomorph added [mg/mL]	Peak area	Peak area	Sum	Concentration of dimethomorph determined [mg/mL]	Recovery [%]	Average	SD	RSD [%]
Level I	odz1-1	0.195	1614059	1906290	3520349	0.1942	99.61	99.72	1.15	1.16
	odz1-2	0.195	1537637	1954611	3492248	0.1927	98.82			
	odz1-3	0.195	1611522	1963555	3575077	0.1972	101.15			
	odz1-4	0.195	1633766	1939441	3573207	0.1971	101.1			
	odz1-5	0.195	1544406	1959782	3504188	0.1933	99.15			
	odz1-6	0.195	1530529	1949054	3479583	0.192	99.15			
Level II	odz2-1	0.2884	2316185	2934489	5250674	0.2891	100.26	99.29	0.87	0.87
	odz2-2	0.2884	2294149	2923093	5217242	0.2873	99.63			

	odz2-3	0.2884	228749 7	285375 2	514124 9	0.2831	99.63			
	odz2-4	0.2884	227707 9	289048 9	516756 8	0.2846	98.68			
	odz2-5	0.2884	228237 3	289036 2	517273 5	0.2849	98.78			
	odz2-6	0.2884	228646 3	296111 0	524757 3	0.289	100.2			
						Average	99.5			

Accuracy of the method – dithianon

	Chromatogram name	Concentration of dithianon added [mg/mL]	Peak area	Concentration of dithianon determined [mg/mL]	Recovery [%]	Average	SD	RSD [%]
Level I	odz1-1	0.5173	8065249	0.5231	101.11	101.31	0.51	0.5
	odz1-2	0.5173	8093575	0.5254	101.56			
	odz1-3	0.5173	8101381	0.526	101.68			
	odz1-4	0.5173	8120044	0.5276	101.98			
	odz1-5	0.5173	8037096	0.5207	100.66			
	odz1-6	0.5173	8050837	0.5219	100.88			
Level II	odz2-1	0.7374	10596704	0.7311	99.15	100.75	1.24	1.23
	odz2-2	0.7374	10770616	0.7454	101.09			
	odz2-3	0.7374	10867504	0.7534	102.17			
	odz2-4	0.7374	10741798	0.743	100.77			
	odz2-5	0.7374	10624825	0.7334	99.46			
	odz2-6	0.7374	10843230	0.7514	101.9			
				Average	101.03			

Table 5.2-1: Methods suitable for the determination of active substances dimethomorph and dithianon in plant protection product Dimethomorph 15% + Dithianon 35% WG

	Dimethomorph	Dithianon
Author(s), year	Małgorzata Wołoszynowska, 2017.	Małgorzata Wołoszynowska, 2017.
Principle of method	HPLC with UV/Vis detector	HPLC with UV/Vis detector
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	0.1625 mg/mL to 0.4225 mg/mL	0.3928 mg/mL to 0.8681 mg/mL
Precision – Repeatability Mean n = 6 (%RSD)	0.86	0.53
Accuracy n = 6 (% Recovery)	99.50	101.03

Conclusion

The method for determination of active substances in Dimethomorph 15% + Dithianon 35% WG preparation is specific.

The validation parameters for linearity, instrument precision, repeatability and accuracy are within the acceptance range according to SANCO/3030/99 rev.4.

The determined average content of active substance in Dimethomorph 15% + Dithianon 35% WG is, respectively:

Dimethomorph: $14.63 \pm 0.13\%$,

Dithianon: $35.50 \pm 0.20\%$.

RMS Comment:

Presented method is accepted.

The validation parameters are within the acceptance range according to SANCO/3030/99 rev.4. because the test was started in 04.2017.

5.2.1.2 Description of analytical methods for the determination of relevant impurities (KCP 5.1.1)

Not relevant.

5.2.1.3 Description of analytical methods for the determination of formulants (KCP 5.1.1)

Not relevant.

5.2.1.4 Applicability of existing CIPAC methods (KCP 5.1.1)

A CIPAC method is available for Dimethomorph: 483.

A CIPAC method is available for Dithianon: 153.

5.2.2 Methods for the determination of residues (KCP 5.1.2)

Please refer to post registration methods.

5.3 Methods for post-authorization control and monitoring purposes (KCP 5.2)

5.3.1 Analysis of the plant protection product (KCP 5.2)

Please refer to the point 5.2.1.

5.3.2 Description of analytical methods for the determination of residues of Dimethomorph (KCP 5.2)

5.3.2.1 Overview of residue definitions and levels for which compliance is required

Compared to the residue definition proposed in the Draft Assessment Report (incl. its addenda) the current legal residue definition is identical.

Table 5.3-1: Relevant residue definitions for monitoring/enforcement and levels for which compliance is required

Matrix	Residue definition	MRL / limit	Reference for MRL/level Remarks
Plant, high water content	Dimethomorph	0.01 mg/kg	Reg. (EU) 2016/1902 Reg. (EU) 2020/1633
Plant, high acid content		0.01 mg/kg	Reg. (EU) 2016/1902 Reg. (EU) 2020/1633
Plant, high protein/high starch content (dry commodities)		0.01 mg/kg	Reg. (EU) 2016/1902 Reg. (EU) 2020/1633
Plant, high oil content		0.02 mg/kg	Reg. (EU) 2016/1902 Reg. (EU) 2020/1633
Plant, difficult matrices (hops, spices, tea)		0.05 mg/kg	Reg. (EU) 2016/1902 Reg. (EU) 2020/1633 Reg. (EU) 2020/1633
Muscle	Dimethomorph	0.01 mg/kg	Reg. (EU) 2016/1902 Reg. (EU) 2020/1633
Milk		0.01 mg/kg	Reg. (EU) 2016/1902 Reg. (EU) 2020/1633
Eggs		0.01 mg/kg	Reg. (EU) 2016/1902 Reg. (EU) 2020/1633
Fat		0.01 mg/kg	Reg. (EU) 2016/1902 Reg. (EU) 2020/1633
Liver, kidney		0.01 mg/kg	Reg. (EU) 2016/1902 Reg. (EU) 2020/1633
Soil (Ecotoxicology)	Dimethomorph	0.05 mg/kg	common limit
Drinking water (Human toxicology)	Dimethomorph	0.1 µg/L	General limit for drinking water
Surface water (Ecotoxicology)	Dimethomorph	56 µg/L	Lowest NOEC – <i>O. mykiss</i>
Air	Dimethomorph	45 µg/m ³	AOEL sys: 0.15 mg/kg bw/d
Tissue (meat or liver)	Nor required	Not required	Not classified as T / T+
Body fluids		Not required	Not classified as T / T+

5.3.2.2 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Dimethomorph in plant matrices is given in the following tables.

Table 5.3-2: Validated methods for food and feed of plant origin (required for all matrix types, “difficult” matrix only when indicated by intended GAP)

Component of residue definition: Dimethomorph				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
High water content	Primary	0.2 mg/kg	Multi method DFG S19 GC-PND	EU agreed
	ILV	-	-	-
	Confirmatory (if required)	-	-	-
High acid content	Primary	0.02 mg/kg	Multi method DFG S19 GC-PND	EU agreed
	ILV	-	-	-
	Confirmatory (if required)	0.05 mg/kg	GC-PND LC-MS/MS	EU agreed
High oil content	Primary	0.02 mg/kg	Multi method DFG S19 GC-PND	EU agreed
	ILV	-	-	-
	Confirmatory (if required)	-	-	-
High protein/high starch content (dry)	Primary	0.02 mg/kg	Multi method DFG S19 GC-PND	EU agreed
	ILV	-	-	-
	Confirmatory (if required)	0.05 mg/kg 0.01 mg/kg	GC-PND LC-MS/MS HPLC-UV	EU agreed
Difficult (if required, depends on intended use)	Primary	0.2 mg/kg	Multi method DFG S19 GC-PND	EU agreed
	ILV	-	-	-
	Confirmatory (if required)	-	-	-

Table 5.3-3: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	-
Not required, because:	Not provided during the EU review of Dimethomorph

5.3.2.3 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Dimethomorph in animal matrices is given in the following tables.

Table 5.3-4: Validated methods for food and feed of animal origin (if appropriate)

Component of residue definition: Dimethomorph				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Milk	Primary	0.01 mg/kg	Multi method DFG S19 GC-PND	EU agreed
	ILV	-	-	-
	Confirmatory (if required)	-	-	-
Eggs	Primary	0.01 mg/kg	Multi method DFG S19 GC-PND	EU agreed
	ILV	-	-	-
	Confirmatory (if required)	-	-	-
Muscle	Primary	0.01 mg/kg	Multi method DFG S19 GC-PND	EU agreed
	ILV	-	-	-
	Confirmatory (if required)	-	-	-
Fat	Primary	0.01 mg/kg	Multi method DFG S19 GC-PND	EU agreed
	ILV	-	-	-
	Confirmatory (if required)	-	-	-
Kidney, liver	Primary	-	-	-
	ILV	-	-	-
	Confirmatory (if required)	-	-	-

Table 5.3-5: Statement on extraction efficiency

	Method for products of animal origin
Required, available from:	-
Not required, because:	Not provided during the EU review of Dimethomorph

5.3.2.4 Description of methods for the analysis of soil (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Dimethomorph in soil is

given in the following tables.

Table 5.3-6: Validated methods for soil (if appropriate)

Component of residue definition: Dimethomorph			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	0.01 mg/kg	Multi method DFG S19 GC-PND GC-MS LC-MS/MS	EU agreed
Confirmatory	-	-	-

5.3.2.5 Description of methods for the analysis of water (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Dimethomorph in surface and drinking water is given in the following tables.

Table 5.3-7: Validated methods for water (if appropriate)

Component of residue definition: Dimethomorph				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Drinking water	Primary	0.05 µg/L	HPLC-UV	EU agreed
	ILV	-	-	According to SANCO/825/00 rev. 8.1, ILV is not required.
	Confirmatory	0.05 µg/L	LC-MS/MS	EU agreed
Surface water	Primary	0.05 µg/L	HPLC-UV	EU agreed
	Confirmatory	0.05 µg/L	LC-MS/MS	EU agreed

5.3.2.6 Description of methods for the analysis of air (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Dimethomorph in air is given in the following tables.

Table 5.3-8: Validated methods for air (if appropriate)

Component of residue definition: Dimethomorph			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	10 µg/m ³	GC-PND	EU agreed
Confirmatory	-	-	-

5.3.2.7 Description of methods for the analysis of body fluids and tissues (KCP 5.2)

No method was submitted during the EU review of Dimethomorph since the active substance is not classified as toxic or highly toxic.

5.3.2.8 Other studies/ information

Not relevant.

5.3.3 Description of analytical methods for the determination of residues of Dithianon (KCP 5.2)

5.3.3.1 Overview of residue definitions and levels for which compliance is required

Compared to the residue definition proposed in the Draft Assessment Report (incl. its addenda) the current legal residue definition is identical.

Table 5.3-9: Relevant residue definitions for monitoring/enforcement and levels for which compliance is required

Matrix	Residue definition	MRL / limit	Reference for MRL/level Remarks
Plant, high water content	Dithianon	0.01 mg/kg	Reg. (EC) No 839/2008
Plant, high acid content		0.01 mg/kg	Reg. (EC) No 839/2008
Plant, high protein/high starch content (dry commodities)		0.01 mg/kg	Reg. (EC) No 839/2008
Plant, high oil content		0.01 mg/kg	Reg. (EC) No 839/2008
Plant, difficult matrices (hops, spices, tea)		0.01 mg/kg	Reg. (EC) No 839/2008
Muscle		Dithianon	0.01 mg/kg
Milk	0.01 mg/kg		Reg. (EC) No 839/2008
Eggs	0.01 mg/kg		Reg. (EC) No 839/2008
Fat	0.01 mg/kg		Reg. (EC) No 839/2008
Liver, kidney	0.01 mg/kg		Reg. (EC) No 839/2008
Soil (Ecotoxicology)	Dithianon	0.05 mg/kg	Common limit
Drinking water (Human toxicology)	Dithianon	0.1 µg/L	General limit for drinking water
Surface water (Ecotoxicology)	Dithianon	0.46 µg/L	Lowest NOEC – <i>O. mykiss</i>
Air	Dithianon	4.05 µg/m ³	AOEL sys: 0.0135 mg/kg bw/d
Tissue (meat or liver)	Not required	Not required	Not classified as T / T+
Body fluids		Not required	Not classified as T / T+

5.3.3.2 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Dithianon in plant matrices is given in the following tables (please refer to the EFSA Journal 2010; 8 (11): 1904).

Table 5.3-10: Validated methods for food and feed of plant origin (required for all matrix types, “difficult” matrix only when indicated by intended GAP)

Component of residue definition: Dithianon				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
High water content	Primary	0.01 mg/kg	LC-MS/MS	EU agreed (The method is considered to be highly specific and therefore no confirmatory method is necessary)
	ILV	0.01 mg/kg	LC-MS/MS	EU agreed
	Confirmatory (if required)	-	-	-
High acid content	Primary	0.01 mg/kg	LC-MS/MS	EU agreed (The method is considered to be highly specific and therefore no confirmatory method is necessary)
	ILV	0.01 mg/kg	LC-MS/MS	EU agreed
	Confirmatory (if required)	-	-	-
High oil content	Primary	0.01 mg/kg	LC-MS/MS	EU agreed (The method is considered to be highly specific and therefore no confirmatory method is necessary)
	ILV	0.01 mg/kg	LC-MS/MS	EU agreed
	Confirmatory (if required)	-	-	-
High protein/high starch content (dry)	Primary	0.01 mg/kg	LC-MS/MS	EU agreed (The method is considered to be highly specific and therefore no confirmatory method is necessary)
	ILV	0.01 mg/kg	LC-MS/MS	EU agreed
	Confirmatory (if required)	-	-	-
Difficult (if required, depends on intended use)	Primary	1.0 mg/kg	LC-MS/MS	EU agreed (The method is considered to be highly specific and therefore no confirmatory method is necessary)
	ILV	1.0 mg/kg	LC-MS/MS	EU agreed
	Confirmatory (if required)	-	-	-

5.3.3.3 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Dithianon in animal matrices is given in the following tables (please refer to the EFSA Journal 2010; 8 (11): 1904).

Table 5.3-11: Validated methods for food and feed of animal origin (if appropriate)

Component of residue definition: Dithianon				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Milk	Primary	0.01 mg/kg	HPLC-ECD	EU agreed
		0.01 mg/kg	LC-MS/MS	EU agreed (The method is considered to be highly specific and therefore no confirmatory method is necessary)
	ILV	0.01 mg/kg	HPLC-ECD	EU agreed
	Confirmatory (if required)	0.01 mg/kg	LC-MS	EU agreed
Eggs	Primary	0.01 mg/kg	HPLC-ECD	EU agreed
	ILV	0.01 mg/kg	HPLC-ECD	EU agreed
	Confirmatory (if required)	0.01 mg/kg	LC-MS	EU agreed
Muscle	Primary	0.01 mg/kg	HPLC-ECD	EU agreed
	ILV	0.01 mg/kg	HPLC-ECD	EU agreed
	Confirmatory (if required)	0.01 mg/kg	LC-MS	EU agreed
Fat	Primary	0.01 mg/kg	HPLC-ECD	EU agreed
		0.01 mg/kg	LC-MS/MS	EU agreed (The method is considered to be highly specific and therefore no confirmatory method is necessary)
	ILV	0.01 mg/kg	HPLC-ECD	EU agreed
	Confirmatory (if required)	0.01 mg/kg	LC-MS	EU agreed
Kidney, liver	Primary	0.01 mg/kg	LC-MS/MS	EU agreed (The method is considered to be highly specific and therefore no confirmatory method is necessary)
	ILV	-	-	-
	Confirmatory (if required)	-	-	-

5.3.3.4 Description of methods for the analysis of soil (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Dithianon in soil is given

in the following tables (please refer to the EFSA Journal 2010; 8 (11): 1904).

Table 5.3-12: Validated methods for soil (if appropriate)

Component of residue definition: Dithianon			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	0.01 mg/kg	LC-MS	EU agreed (The method is considered to be highly specific and therefore no confirmatory method is necessary)
	0.01 mg/kg	LC-MS/MS	EU agreed (The method is considered to be highly specific and therefore no confirmatory method is necessary)
Confirmatory	-	-	-

5.3.3.5 Description of methods for the analysis of water (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Dithianon in surface and drinking water is given in the following tables (please refer to the EFSA Journal 2010; 8 (11): 1904).

Table 5.3-13: Validated methods for water (if appropriate)

Component of residue definition: Dithianon				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Drinking water	Primary	0.05 µg/L	LC-MS/MS	EU agreed (The method is considered to be highly specific and therefore no confirmatory method is necessary)
	ILV	-	-	According to SANCO/825/00 rev. 8.1, ILV is not required.
	Confirmatory	-	-	-
Surface water	Primary	0.05 µg/L	LC-MS/MS	EU agreed (The method is considered to be highly specific and therefore no confirmatory method is necessary)
	Confirmatory	-	-	-

5.3.3.6 Description of methods for the analysis of air (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Dithianon in air is given in the following tables (please refer to the EFSA Journal 2010; 8 (11): 1904).

Table 5.3-14: Validated methods for air (if appropriate)

Component of residue definition: Dithianon			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	0.001 mg/m ³	HPLC-UV	EU agreed
Confirmatory	-	-	According to SANCO/825/00 rev. 8.1, confirmatory is not required (sufficient confirmatory methods are available for the determination in soil and water).

5.3.3.7 Description of methods for the analysis of body fluids and tissues (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Dithianon in body fluids and tissues is given in the following table (please refer to the EFSA Journal 2010; 8 (11): 1904).

Table 5.3-15: Methods for body fluids and tissues (if appropriate)

Component of residue definition: Dithianon			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	0.05 mg/L for human urine and blood	LC-MS/MS	EU agreed (The method is considered to be highly specific and therefore no confirmatory method is necessary)
Confirmatory	-	-	-

5.3.3.8 Other studies/ information

Not relevant.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.
 MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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 5.1.1	Małgorzata Wołoszynowska	2017	Dimethomorph 15% + Dithianon 35% WG: Method development and validation for the determination of active substances content in the formulation Study code no. BA-21/17 Institute of Industrial Organic Chemistry GLP Unpublished	N	Sharda

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

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

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

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	Y/N	Owner

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished		

Appendix 2 Detailed evaluation of submitted analytical methods

A 2.1 Analytical methods for Dimethomorph

A 2.1.1 Methods used for the generation of pre-authorization data (KCP 5.1)

No new or additional studies have been submitted

A 2.1.2 Methods for post-authorization control and monitoring purposes (KCP 5.2)

A 2.1.2.1 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.2 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.3 Description of Methods for the Analysis of Soil (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.4 Description of Methods for the Analysis of Water (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.5 Description of Methods for the Analysis of Air (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.6 Description of Methods for the Analysis of Body Fluids and Tissues (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.7 A.2.A.9 Other Studies/ Information

No new or additional studies have been submitted

A 2.2 Analytical methods for Dithianon

A 2.2.1 Methods used for the generation of pre-authorization data (KCP 5.1)

No new or additional studies have been submitted

A 2.2.2 Methods for post-authorization control and monitoring purposes (KCP 5.2)

A 2.2.2.1 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)

No new or additional studies have been submitted

A 2.2.2.2 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)

No new or additional studies have been submitted

A 2.2.2.3 Description of Methods for the Analysis of Soil (KCP 5.2)

No new or additional studies have been submitted

A 2.2.2.4 Description of Methods for the Analysis of Water (KCP 5.2)

No new or additional studies have been submitted

A 2.2.2.5 Description of Methods for the Analysis of Air (KCP 5.2)

No new or additional studies have been submitted

A 2.2.2.6 Description of Methods for the Analysis of Body Fluids and Tissues (KCP 5.2)

No new or additional studies have been submitted

A 2.2.2.7 A.2.A.9 Other Studies/ Information

No new or additional studies have been submitted