FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 6800 A

Product name(s): DUKES

Chemical active substance(s):

Dithianon, 700 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: September 2020

MS Finalisation date: May 2021; December 2021; May 2022

Version history

When	What
May 2021	As requested *"List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review"* was updated by Applicant.
May 2021	Assessment
December 2021	Final registration report after commenting period
May 2022	Revision with regard to consumer risk assessment

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Storage stability

According to the EU agreed data (EFSA, 2011 and 2015) the available stability of residues data can cover the uses on pome fruits (matrix with high water content). This data were confirmed in EFSA Journal 2020;18(9):6189.

EFSA Journal 2020;18(9):6189: *The submitted data demonstrated stability of dithianon residues under frozen conditions in apples for up to 24 months*.

No additional information is required.

Metabolism in plants and animals

The metabolism of dithianon has been investigated in fruit crops (apple and orange), leafy vegetables (spinach) and cereals (wheat).

Plant residue definition for monitoring and risk assessment: Dithianon (open for processed commodities – data gap (EFSA, 2015, EFSA Journal 2020;18(9):6189)

This data gap can be completed only at the stage of evaluating an active substance.

Magnitude of residues in plants

Proposed GAP:

4 x 0.35 kg as/ha, interval: 7-12 days, BBCH 51 – 79, PHI: 21.

EU GAP (EFSA Journal 2020;18(9):6189, SANCO/10349/2011 final 11 March 2011)

1-12 x 0.525 kg as/ha, interval: 7-12 days, BBCH 10 – 79, PHI: 21.

Proposed GAP is less critical than EU GAP (application rate).

Applicant refers to the unprotected EU data*:

RMS, 2006 Apple	N-EU	GAP on which EU a.s. assessment is based: 12 x 0.525 kg as/ha, PHI 21-22d, outdoor ~~<0.03, <0.05,~~ 0.36, ~~0.38~~, 2 x 0.48, 0.62, 0.76, ~~1.03~~, 1.5, 1.7, 1.89 mg/kg
RMS, 2006 Pear	N-EU	GAP on which EU a.s. assessment is based: 12 x 0.525 kg as/ha, PHI 21-22d, outdoor 0.19, 0.37, 0.39, ~~0.69~~ 0,87 mg/kg

* *Conclusion on the peer review of the pesticide risk assessment of the active substance dithianon. EFSA Journal 2010;8(11):1904*
Updated peer review of the pesticide risk assessment for the active substance dithianon in light of confirmatory data submitted. EFSA Journal 2020;18(9):6189

Overall supporting data for cGAP (NEU): 0.19, 0.36, 0.37, 0.39, 2x0.48, 0.62, 0.76, 0.87, 1.5, 1.7, 1.89

STMR 0.55 (NEU); HR 1.89 (NEU)

According to the SANTE/2019/12752 extrapolation from apples to pears is possible.

The residues arising from the proposed uses will not exceed the MRLs established for apples and pears (3.0 mg/kg, Regulation (EC) No 839/2008).

~~Available data can cover the proposed use~~.

Magnitude of residues in livestock

EFSA Journal 2020;18(9):6189:

Ruminant:

No cow feeding study conducted - metabolism results indicate that the residues will be far below the LOQ (milk, tissues 0.01 mg/kg)

Poultry:

No hen feeding study conducted - metabolism results indicate that the residues will be far below the LOQ (eggs, tissues: 0.01 mg/kg)

Pig

No hen feeding study conducted – metabolism in rat and ruminant similar, residues will be below 0.01 mg/kg (LOQ).

No additional studies or calculations are required.

Note

according to the *Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009, (2019/C 229/01)** above data are not protected.

* *Official Journal of the European Union, C 229, 8 July 2019*

Processing studies

Applicant refer's to the unprotected EU studies

According to the EFSA Journal 2020;18(9):6189:

Dithianon was the predominant compound of the total applied radioactivity (TAR) for pasteurisation (up to 47.3% TAR) while it was extensively degraded at baking/brewing/boiling and sterilisation into Reg. No 4107273 (up to 12.7 % TAR), Reg. No 4110904 (up to 9.4% TAR), Reg. No 31062 (up to 10.5% TAR) and to a lesser extension to Reg. No 4005234 (Phthalic acid) and Reg. No 4110933 (up to 2.2% and 4.1% TAR, respectively).

Data gap: The general toxicity of metabolites Reg. No. 4107273 and Reg. No. 4005234 (Phthalic acid) recovered at significant levels in apples and grapes processed commodities is required.

This data gap can be completed only at the stage of evaluating an active substance.

According to the *Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009, (2019/C 229/01)** above data are not protected.

* *Official Journal of the European Union, C 229, 8 July 2019*

Processing factors were established for apples

Apple/washed apples, 10 trials, transfer factors: 0.23–1.8

Apple/juice, 13 trials , transfer factors: 0.0045–0.1

Apple/wet pomace, 13 trials , transfer factors: 0.49–3.5

Apple/dry pomace, 9 trials , transfer factors: 0.43–1.35

Apple/sauce 11 trials , transfer factors: 0.006–0.125

Apple/dried apples, 5 trials , transfer factors: 0.029, 2.18

Apple/canned apples, 7 trials, transfer factors: 0.033–0.125

Magnitude of residues in representative succeeding crops

No new data submitted in the framework of this application. Since the intended uses on pome fruits con-

cern permanent crops, further investigation of residues in rotational crops is therefore not required..

No risk mitigation measure are considered necessary.

Estimation of exposure through diet and other means

~~The proposed uses of Dithianon in the formulation Dithianon 70% WG do not represent unacceptable acute and chronic risks for the consumer.~~ Acute risk for children was identified in relation to pears. Use on apples is acceptable

Input Values for pome fruits: STMR 0.55 (NEU); HR 1.89 (NEU); VF: 3.8

IEDI (% ADI) according to EFSA PRIMo rev.3.1	83 % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo rev.3.1	Unprocessed commodities Results for children **118% Pears** 96% Apples Results for adults 32% Pears 29% Apples Processed commodities Results for children 25% Apples / juice 15% Pears / juice Results for adults 15% Apples / juice

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation DITH (SHA 6800 A) are presented in Table 7.1-1. They have been selected from the individual GAPs in the CEU for pome fruits. A list of all intended uses within the CEU is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for dithianon as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of dithianon residues are unlikely to present a public health concern (in relation to apples). Acute risk for children was identified in relation to pears.
As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use(s) on apple. Use on pears is not acceptable

According to available data, no specific mitigation measures should apply.

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:
none

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
1	**Pome fruits (apples)**	CEU	SHA 6800 A	F	Scab (*Venturia* sp.)	WG	700 g/L	Foliar Spray	BBCH 51 - 79	4	7-12	0.023 - 0.035	1000-1500	0.35	21	A Not acceptable for pears

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** 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

Explanation for Column 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation SHA 6800 A is composed of dithianon.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of dithianon

Reference value	Source	Year	Value	Study relied upon	Safety factor
dithianon					
ADI	11/41/EU		0.01	long-term rat study	100
ARfD	11/41/EU		0.12	7-day and 28-day oral rat studies (mechanistic studies)	100

7.1.2.1 Summary for dithianon

Table 7.1-3: Summary for dithianon

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	**Pome fruits (apples)**	Yes	Yes	Yes	Yes	Yes	No	No

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

The effects of processing on the nature of dithianon residues have been investigated. Data on effects of processing on the amount of residue have been submitted.
These data were considered for risk assessment.

7.1.2.2 Summary for SHA 6800 A

Table 7.1-4: Information on SHA 6800 A (KCA 6.8)

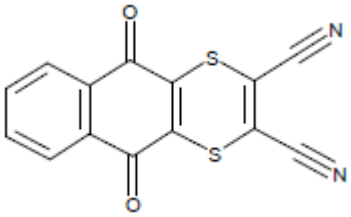
Crop	PHI for SHA 6800 A proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for SHA 6800 A proposed by zRMS	zRMS Comments (if different PHI proposed)
		dithianon		
Pome fruits (apples)	21	Yes		

Assessment

7.2 Dithianon

General data on Dithianon are summarized in the table below (last updated 2016/11/30)

Table 7.2-1: General information on Dithianon

Active substance (ISO Common Name)	Dithianon
IUPAC	5,10-dihydro-5,10-dioxonaphtho[2,3-*b*]-1,4-dithiine-2,3-dicarbonitrile
Chemical structure	
Molecular formula	$C_{14}H_4N_2O_2S_2$
Molar mass	296.3
Chemical group	Quinones (anthraquinones)
Mode of action (if available)	Multi-site contact activity
Systemic	No
Company (ies)	BASF SE*
Rapporteur Member State (RMS)	EL
Approval status	Approved Date of (01/06/2011) and reference to decision (COMMISSION IMPLEMENTING DIRECTIVE 2011/41/EU - COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011) active hyperlinks: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0540 http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011L0041
Restriction	Only uses as fungicide may be authorised
Review Report	SANCO/10349/2011 – 11/03/2011
Current MRL regulation	Regulation (EC) No 839/2008
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No
EFSA Journal : Conclusion on the peer review	Yes: EFSA, 2011 and EFSA, 2015 (confirmatory data)
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	EFSA-Q-2009-00044 Status: Evaluation ongoing

* Notifier in the EU process to whom the a.s. belong(s)

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Pome fruit	High water content	24 months	EFSA, 2015
Grape	High acid content	14 months	EFSA, 2011
Grape juice	High acid content	18 months	EFSA, 2011
Grape pomace	High acid content	6 months	EFSA, 2011
Apple sauce	-	24 months	EFSA, 2011

Conclusion on stability of residues during storage

According to the EU agreed data (EFSA, 2011 and 2015) the available stability of residues data can cover the uses on pome fruits, peach and tomato (matrix with high water content).

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

No data was submitted and required at EU level during the EU Review of Dithianon.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruit-	Orange	[^{14}C] BAS	foliar	390 g as/ha	2	14 DALT,	-	RMS, 2006

ing vegetable		216 F	treatment, F			28 DALT		
Leafy vegetables	Spinach	[^{14}C] BAS 216 F	foliar treatment, G	1000 g as/ha	3	0DAT1, 0 DAT2, 0DAT3, 20 DAT3	-	RMS, 2006
Cereals	Wheat	[^{14}C] BAS 216 F	foliar treatment, F	1500 g as/ha	2	0DAT2, 20 DAT2, 35DAT2		RMS, 2006

Summary of plant metabolism studies reported in the EU

Citrus: a small amount of Dithianon penetrated the orange fruits and was metabolized extensively to a large number of more or less mostly polar compounds, none that can be considered major. [^{14}C] Dithianon was identified as the major component of the residue and was found to be metabolized to polar compounds, none of which were identified.

Spinach: the major residue component in the Spinach from different growth stages and treatment timing was identified as the parent compound Dithianon. No parent was detected in the radioactivity released from the post rinse residues. Besides multiple minor polar unknown components, a dicarboxylic acid diamide derivative, 2-hydroxynapthoquinone and phthalic acid were found, indicating that the absorbed Dithianon was completely metabolized by spinach plants. All of the individual components of the extractable residues in spinach were between 0.1 and 0.5 of the total radioactive residues.

Wheat: [^{14}C] Dithianon was identified as the major component of the residue and was found to be metabolized to polar compounds, none of which were identified.

Conclusion on metabolism in primary crops

Based on the available data, the same EU conclusions can be used for the intendent uses (pome fruits): [^{14}C] Dithianon was identified as the major component of the residue and was found to be metabolized to polar compounds, none of which were identified.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application. No data was submitted during the EU review of Dithianon: *not required since intended to be used in permanent crops (pome fruits and grapes)*.

Conclusion on metabolism in rotational crops

Since the intended used in pome fruits and almond concern permanent crops, study is not required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-4: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (47.3)	EFSA, 2015
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Reg. No 4107273 (12.7), Reg. No 4110904 (9.4), Reg. No 31062 (10.5), Reg. No 4005234 (Phthalic acid – 2.2), Reg. No 4110933 (4.1)	EFSA, 2015
Sterilisation (20 minutes, 120°C, pH 6)		

Conclusion on nature of residues in processed commodities

The same EU agreed data can be used in the framework of this application.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Fruits (apples, oranges), leafy crop (spinach), wheat (cereals) via foliar treatment
Rotational crops covered	Not required since intended to be used in permanent crops (pome fruits and grapes)
Metabolism in rotational crops similar to metabolism in primary crops?	Not required since intended to be used in permanent crops (pome fruits and grapes)
Processed commodities	Dithianon was the predominant compound of the total applied radioactivity (TAR) for pasteurization (up to 47.3 % TAR) whilst it was extensively degraded at baking/brewing/boiling and sterilisation into Reg. No 4107273 (up to 12.7 % TAR), Reg. No 4110904 (up to 9.4 % TAR), Reg. No 31062 (up to 10.5 % TAR) and to a lesser extent into Reg. No 4005234 (Phthalic acid) and Reg. No 4110933 (up to 2.2 % and 4.1 % TAR, respectively).
Residue pattern in processed commodities similar to pattern in raw commodities?	No
Plant residue definition for monitoring	Dithianon (EFSA, 2015)
Plant residue definition for risk assessment	Dithianon (EFSA, 2015)
Conversion factor from enforcement to RA	Not applicable

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[^{14}C] BAS 216 F	-	3 mg/kg 30 mg/kg	-	Milk	twice daily	RMS, 2006
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[^{14}C] BAS 216 F	10	3 mg/kg 30 mg/kg	-	Eggs	twice daily	RMS, 2006
						Excreta	daily	
						Tissues	sacrifice	

Summary of plant metabolism studies reported in the EU

Lactating ruminants: Since there were very low levels of unchanged Dithianon detected in the tissues and urines and no metabolites were identified, it can be concluded that Dithianon was an unstable molecule, and was metabolized by a number of degradation processes.

Laying poultry: About 90% of the total radioactivity administered was eliminated in excreta by 6 hours after the last dose. Minor amount of the total dose applied were found in the GI tract contents (3.4% to 4.8%), GI tract (0.6%), liver (0.03%), and kidneys (0.02%); all of the eggs together contained <0.01% of the dose administered, most of which was retained in the yolk. There was no indication of accumulation of [^{14}C] BAS 216 F in poultry tissues and eggs.

Conclusion on metabolism in livestock

The same EU agreed data can be used in the framework of this application.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	Goat: 1 - 2 days
	Hen: > 4 days (not relevant, since the target crops are not fed to poultry)
Animal residue definition for monitoring	Dithianon (EFSA, 2015)
Animal residue definition for risk assessment	Dithianon (EFSA, 2015)

Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes (log P_{ow} > 3)

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)
** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.
*** If metabolism in rat and ruminant are not similar

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

No new data are submitted in the framework of this application.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of Dithianon 70% WG and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Pome fruits Apple and Pear	RMS, 2006 Apple	N-EU	GAP on which EU a.s. assessment is based: 12 x 0.525 kg as/ha, PHI 21-22d, outdoor ~~<0.03, <0.05~~, 0.36, ~~0.38~~, 2 x 0.48, 0.62, 0.76, ~~1.03~~, 1.5, 1.7, 1.89 mg/kg	N/A				
	RMS, 2006 Pear	N-EU	GAP on which EU a.s. assessment is based: 12 x 0.525 kg as/ha, PHI 21-22d, outdoor 0.19, 0.37, 0.39, ~~0.69~~ 0,87 mg/kg					
	~~RMS, 2006 Apple~~	~~S-EU~~	~~GAP on which EU a.s. assessment is based: 12 x 0.525 kg as/ha, PHI 21-22d, outdoor~~ ~~0.12, 0.13, 0.24, 0.30, 0.37, 0.85, 1.69, 1.73 mg/kg~~					
	Overall supporting data for cGAP	N-EU ~~S-EU~~	~~<0.03, <0.05~~, 0.19, 0.36, 0.37, ~~0.38~~, 0.39, 2 x 0.48, 0.62, , 0.76, ~~0.69~~ 0,87, ~~1.03~~, 1.5, 1.7, 1.89 mg/kg	~~0.48~~ 0,55	1.89	~~3~~ 2,72	3	Yes

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on apples are considered acceptable, for outdoor uses.

According to appendix D of EU guidelines, extrapolation to pears is possible with trials on apples, which is the case here.
The data submitted show that no exceedance of the MRL will occur.
The uses on apples are considered acceptable. Use on pears is not acceptable (acute risk for children).

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-9: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS/authorized within the zone/evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Apple pomace	1.12	STMR x PF (RMS, 2014)*	1.12	STMR x PF (RMS, 2014)*

Table 7.2-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Beef cattle*	0.013	0.013	Apple wet pomace	0.56	Y
Dairy cattle*	0.011	0.011	Apple wet pomace	0.28	Y
Ram/ewe	0.009	0.009	Apple wet pomace	0.3	Y
Lamb	0.012	0.012	Apple wet pomace	0.28	Y

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.

Conclusion on feeding studies

The conclusions of the EU review of Dithianon can be used (Addendum, RMS, 2014):
Based on this potential residue intake of 0.487 and 1.461 mg/kg of total diet for ruminants calculated

above, the magnitude of residues to be expected in ruminant tissues and milk was extrapolated from the goat metabolism studies. The metabolism studies in lactating goat were performed at actual dose levels of 25 and 28 mg/kg feed (high dose groups). This corresponds to an approximately 17.1 or 19.2-fold overdosing factor (…) Based on these overdosing factors, the expected total residues in milk and edible tissues from cattle can be extrapolated from the total radioactive residues found in the goat metabolism studies (…) extrapolated total residues are below the LOQ of the residue analytical method (<0.01 mg/kg) in muscle, milk, liver and fat but above the LOQ for kidney. The results from metabolism studies in the goat and hen showed that dithianon is effectively metabolized to multiple metabolites. In the goat metabolism study, parent was detected at low levels (≤0.01 mg/kg) and no single metabolite in the extracts was greater than 0.05 mg/kg. Therefore, it is not expected that parent or any single dithianon-related component would account for 100% of the residue in any edible tissue or milk, and thus the concentration of any metabolite in these matrices should be well below 0.01 mg/kg resulting from exposure at the 1 x dose rate.
For these reasons, the second criterion is not triggered, and therefore, no livestock feeding study with dithianon in lactating ruminants is required.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

No new data were submitted in the framework of this application.

Table 7.2-11: Overview of the available processing studies

Processed commodity	Number of studies	PF	Comments	Reference
EU data				
Apple/washed apples	7	0.23-1.8	-	EFSA, 2015
Apple/juice	10	0.0045-0.1	-	EFSA, 2015
Apple/wet pomace	10	0.49-3.5	-	EFSA, 2015
Apple/dry pomace	6	0.43-0.77	-	EFSA, 2015
Apple/sauce	8	0.006-0.125	-	EFSA, 2015
Apple/dried apples	2	0.029-0.033	-	EFSA, 2015
Apple/canned apples	4	0.033-0.125	-	EFSA, 2015
Grapes/must	13	0.01-0.33	-	EFSA, 2015
Grapes/wine	13	0.002-0.08	-	EFSA, 2015
Grapes/juice	4	0.002-0.003	-	EFSA, 2015
Grapes/wet pomace	4	0.19-2.18	-	EFSA, 2015
Grapes/dry pomace	4	0.08-0.28	-	EFSA, 2015
Grapes/young wine	4	0.002-0.003	-	EFSA, 2015
Grapes/must deposit	1	1.2	-	EFSA, 2015
Grapes/lees	2	0.02-0.01	-	EFSA, 2015

7.2.6 Magnitude of residues in representative succeeding crops

Since the intended use in pome fruits concern permanent crops, further investigation of residues in rota-

tional crops is therefore not required.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of Dithianon 70% WG. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-12: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
The refinement of the chronic risk assessments includes only intended uses.				
Apple	0.62	STMR (pome fruits)	1.89 3.8	HR VF (IESTI 2; EFSA 2010)
Pear	0.39	STMR (pome fruits)	0.69	HR (pear) (EFSA 2010)

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-13: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev.3.1	585 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo rev.3.1	84 % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo* rev.3.1	Unprocessed commodities Results for children 346.23% Pears 269.46% Apples Results for adults 76.36% Pears 70.18% Apples Processed commodities Results for children 135.4% Apples / juice 81.5% Pears / juice Results for adults 83.3% Apples / juice
IESTI (% ARfD) according to EFSA PRIMo* rev.3.1	Unprocessed commodities

	Results for children 96.46% Apples 54.51% Pears Results for adults 29.03% Apples 14.93% Pears Processed commodities Results for children 28.0% Apples / juice 10.6% Pears / juice Results for adults 17.2% Apples / juice

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of Dithianon in the formulation Dithianon 70% WG do not represent unacceptable acute and chronic risks for the consumer.

zRMS:
Input Values for pome fruits: STMR 0.55 (NEU); HR 1.89 (NEU); VF: 3.8

IEDI (% ADI) according to EFSA PRIMo rev.3.1	83 % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo rev.3.1	Unprocessed commodities Results for children **118% Pears** 96% Apples Results for adults 32% Pears 29% Apples Processed commodities Results for children 25% Apples / juice 15% Pears / juice Results for adults 15% Apples / juice

EFSA PRIMo revision 3.1; 2021/01/06

Dithianon

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0,01**	ARfD (mg/kg bw):	**0,12**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	83%	NL toddler	8,32	59%	Apples	24%	Pears				
	72%	DE child	7,22	69%	Apples	4%	Pears				
	38%	NL child	3,84	32%	Apples	7%	Pears				
	19%	FR toddler 2 3 yr	1,92	17%	Apples	2%	Pears				
	17%	DK child	1,65	13%	Apples	4%	Pears				
	15%	DE women 14-50 yr	1,50	14%	Apples	0,8%	Pears				
	14%	DE general	1,40	13%	Apples	0,7%	Pears				
	13%	PL general	1,28	11%	Apples	2%	Pears				
	11%	LT adult	1,11	10%	Apples	0,9%	Pears				
	11%	FR child 3 15 yr	1,07	9%	Apples	2%	Pears				
	10%	UK toddler	1,04	9%	Apples	1,0%	Pears				
	10%	FR infant	1,02	9%	Apples	1,0%	Pears				
	10%	UK infant	1,00	9%	Apples	1%	Pears				
	9%	GEMS/Food G11	0,95	9%	Apples	0,9%	Pears				
	9%	NL general	0,90	8%	Apples	1%	Pears				
	9%	ES child	0,87	6%	Apples	2%	Pears				
	8%	RO general	0,84	8%	Apples	0,6%	Pears				
	8%	SE general	0,77	6%	Apples	2%	Pears				
	8%	PT general	0,76	6%	Apples	2%	Pears				
	7%	GEMS/Food G08	0,74	7%	Apples	0,8%	Pears				
	7%	DK adult	0,70	5%	Apples	2%	Pears				
	7%	GEMS/Food G15	0,69	6%	Apples	0,9%	Pears				
	7%	IT toddler	0,68	5%	Apples	2%	Pears				
	6%	GEMS/Food G07	0,64	6%	Apples	0,8%	Pears				
	6%	IE adult	0,63	4%	Apples	2%	Pears				
	6%	FI 3 yr	0,61	5%	Apples	1,0%	Pears				
	6%	ES adult	0,60	4%	Apples	2%	Pears				
	6%	IT adult	0,57	4%	Apples	1%	Pears				
	6%	GEMS/Food G06	0,56	5%	Apples	0,5%	Pears				
	5%	FR adult	0,50	4%	Apples	0,8%	Pears				
	5%	GEMS/Food G10	0,50	4%	Apples	0,9%	Pears				
	4%	FI 6 yr	0,42	3%	Apples	1,0%	Pears				
	4%	UK vegetarian	0,37	3%	Apples	0,4%	Pears				
	3%	FI adult	0,35	3%	Apples	0,3%	Pears				
	3%	UK adult	0,26	2%	Apples	0,3%	Pears				
	2%	IE child	0,20	2%	Apples	0,2%	Pears				

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Dithianon is unlikely to present a public health concern.

DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Acute risk assessment /children	Acute risk assessment / adults / general population		
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
118%	Pears	0 / 1,89	142
96%	Apples	0 / 1,89	116

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
32%	Pears	0 / 1,89	39
29%	Apples	0 / 1,89	35

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 1

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
25%	Apples / juice	0 / 0,55	30
15%	Pears / juice	0 / 0,55	18

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
15%	Apples / juice	0 / 0,55	18

Conclusion:
The estimated short term intake (IESTI) exceeded the toxicological reference value for 1 commodities.

For processed commodities, no exceedance of the ARfD/ADI was identified.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

- EFSA Journal 2010;8(11):1904: Conclusion on the peer review of the pesticide risk assess-ment of the active substance dithianon
- EFSA Journal 2015;13(11):4278: Peer review of the pesticide risk assessment for the active substance dithianon in light of confirmatory data submitted
- Dithianon Volume 3, Annex B-7: Residue data October 2006
- Dithianon Volume 3, Annex B-7: Residue data January 2010
- Final addendum to the Draft Assessment Report (DAR) and Additional Report October 2010
- Final addendum to the Draft Assessment Report (DAR) and Additional Report November 2014

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

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
	Hawkins D.R. et al.	1991	The metabolism of 14C-Dithianon after application to apples Huntingdon Research Centre; Huntingdon; United Kingdom DT-640-013 (1990/7000532) Yes unpublishe	N	BASF
	Mayo B.C.	1993	Amendment no. 1: The metabolism of 14CDithianon after application to apples Huntingdon Research Centre; Huntingdon; United Kingdom DT-640-013 (Amendment 1) (1993/7002105) Yes unpublished	N	BASF
	Mayo B.C.	1994	14C-Dithianon: The metabolism in oranges Huntingdon Research Centre; Huntingdon; United Kingdom DT-640-018 Yes unpublished	N	BASF

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
	Schlueter H., Memmeshei mer H.	1994	14C-Dithianon: Investigation on the nature of metabolites occurring in oranges Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. DT-640-020 Yes unpublished	N	BASF
	Schlueter H.	1996	Amendment no. 1 to report CFS 1994-059: 14C-Dithianon: Investigation on the nature of metabolites occurring in oranges - Supplemental data Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. DT-123-045 (Amendment 1 to report DT640-020) Yes unpublished	N	BASF
	Schlueter H.	1998	14C-Dithianon (CL 37114): Further investigation on the nature of metabolites occurring in oranges Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. DT-123-066 Yes unpublished	N	BASF
	Hubert T.D.	1991	14C-Dithianon: Nature of the residue in citrus Hazleton Laboratories America Inc.; Kensington MD 20895; United States of America DT-640-015 Yes unpublished	N	BASF
	Hubert T.D.	1992	Amendment No. 1 to the final report 14CDithianon: Nature of the residue in citrus Hazleton Laboratories America Inc.; Kensington MD 20895; United States of America DT-640-016 (Amendment 1 to report DT640-015) Yes unpublished	N	BASF
	Dijk van A.	2000	Dithianon (CL 37114): Metabolism of 14CDithianon in spinach RCC Ltd. Environmental Chemistry & Pharmanalytics Division; Itingen; Switzerland DT-640-023 Yes unpublished	N	BASF
	Schlueter H., Grahl U.	1994	14C-Dithianon: Investigation on the nature of metabolites occuring in wheat Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. 1994/7001689 Yes unpublished	N	BASF
	Schlueter H.	1996	14C-Dithianon: Investigation on the nature of metabolites occurring in wheat - Supplemental data Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. DT-640-021 (Amendment 1 to report 1994/7001689) Yes unpublished	N	BASF
	Schlueter H., Varga J.	1998	14C-Dithianon (CL 37114): Further investigation on the nature of metabolites occurring in wheat Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. DT-640-017 Yes unpublished	N	BASF
	Hawkins D.R. et al.	1991	The metabolism of 14C-Dithianon in wheat Huntingdon Research Centre; Huntingdon; United Kingdom DT-640-014 Yes unpublished	N	BASF
	Mayo B.C.	1994	The metabolism of 14C-Dithianon in wheat Huntingdon Research Centre; Huntingdon; United Kingdom DT-640-019 Yes unpublished	N	BASF

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
		1994	Dithianon (WL 049890): Fate of [5,6,9,10- 13C/14C] Dithianon in the lactating goat following 5 consecutive daily doses (60 mg/day) … Yes unpublished	Y	BASF
	..	1990	Five-day repeated dose of 14C-Dithianon in lactating goats DT-440-006 Yes unpublished	Y	BASF
	…	1992	Supplement No. 1 to final report: Five-day repeated dose of 14C-Dithianon in lactating goats DT-440-008 Yes unpublishe	Y	BASF
	…	1990	Five-day repeated dose of 14C-Dithianon in laying hens DT-440-005 Yes unpublished	Y	BASF
	…	1992	Supplement No. 1 to final report: Five-day repeated dose of 14C-Dithianon in laying hens DT-440-007 Yes unpublished	Y	BASF
	Heupt W.	1976	Pflanzenschutzmittel - Rueckstaende: Dithianon - Aepfel Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT-711-005 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Heupt W.	1976	Pflanzenschutzmittel - Rueckstaende: Dithianon - Aepfel Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT-711-006 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Schenk W., Eichler D.	1986	Report on residue trials with Dithianon in apples Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT-711-009 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Schenk W., Eichler D.	1986	Report on residue trials with Dithianon in apples Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT-711-013 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Schenk W., Eichler D.	1986	Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln: Dithianon - Aepfel Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT-711-019 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Schenk W., Eichler D.	1986	Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln: Dithianon - Aepfel Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT-711-020 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF

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
	Todd M.A.	1992	Dithianon: The determination of residues in apples from France Hazleton UK; Harrogate North Yorkshire; United Kingdom DT-711-085 Yes unpublished	N	BASF
	Schilt H.G.	1990	Collection of samples of apples treated with Dithianon for residue analysis in normal French agricultural conditions Agrishell Research and Development Center; Fargues Saint Hilaire; France DT-711-085 (Protocol 1 - Translation) No unpublished	N	BASF
	Schilt H.G.	1990	Collection of samples of apples treated with Dithianon for residue analysis in normal French agricultural conditions Agrishell Research and Development Center; Fargues Saint Hilaire; France DT-711-085 (Protocol 2 - Translation) No unpublished	N	BASF
	Schilt H.G., Teyras G.	1990	Collection of samples of apples treated with Dithianon for residue analysis in normal French agricultural conditions Agrishell Research and Development Center; Fargues Saint Hilaire; France DT-923-008 (Translation) Yes, study was conducted prior to the implementation of GLP certificates unpublished	N	BASF
	Schilt H.G., Teyras G.	1990	Residue determination in apples Agrishell Research and Development Center; Fargues Saint Hilaire; France DT-923-007 (Translation) Yes, study was conducted prior to the implementation of GLP certificates unpublished	N	BASF
	Anonymous	1994	Rueckstandsuntersuchungen mit Pflanzenschutzmitteln - Rueckstaende Aepfel Dr. Specht & Partner, Chemische Laboratorien GmbH; Hamburg; Germany Fed.Rep. DT-711-094 No unpublished	N	BASF
	Anonymous	1994	Rueckstandsuntersuchungen mit Pflanzenschuttmitteln - Rueckstaende Aepfel Dr. Specht & Partner, Chemische Laboratorien GmbH; Hamburg; Germany Fed.Rep. DT-711-095 No unpublished	N	BASF
	Bitz K.	1996	Dithianon (CL 37114) 700 g ai/kg WG (SF 09321): Decline curve residue study in apples - (Germany, 1995) Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. DT-711-098 Yes unpublished	N	BASF
	Smalley R.	2001	BAS 216 03 F (Dithianon) 700 g as/kg WG (SF 09321): At harvest residue study on Dithianon in apples - South France, 2000 BASF Agro Research Gosport; Gosport; United Kingdom DT-711-104 Yes unpublished	N	BASF
	Smalley R.	2001	BAS 216 03 F (Dithianon) 700g as/kg WG (SF 09321): Decline curve residue study on Dithianon	N	BASF

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
			in apples - South France, 2000 BASF Agro Research Gosport; Gosport; United Kingdom DT-711-105 Yes unpublished		
	Smalley R.	2002	BAS 216 03 F (Dithianon) 700 g as/kg WG (SF 09321): At harvest residue study on Dithianon in apples - Italy, 2000 BASF Agro Research Gosport; Gosport; United Kingdom 2002/1011502 Yes unpublished	N	BASF
	Smalley R.	2002	BAS 216 03 F (Dithianon) 700 g as/kg WG (SF 09321): Decline curve residue study on Dithianon in apples - Italy, 2000 BASF Agro Research Gosport; Gosport; United Kingdom 2002/1011501 Yes unpublished	N	BASF
	Jones S.	2002	Study on the residue behaviour of BAS 216 F in apples after application of BAS 216 03 F under field conditions in Spain, Italy, Greece, 2001 BASF Agro Research Gosport; Gosport; United Kingdom 2002/1011505 Yes unpublished	N	BASF
	Anonymous	1987	~~Rueckstandsuntersuchungen mit Pflanzenschutzmitteln - Rueckstaende Trauben Shell Forschung Ingelheim; Ingelheim; Germany Fed.Rep. DT 713 031 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished~~	N	BASF
	~~Eichler D.~~	~~1987~~	~~Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln: Dithianon - Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT 713 032 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished~~	~~N~~	~~BASF~~
	~~Eichler D.~~	~~1987~~	~~Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln: Dithianon - Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT 713 033 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished~~	~~N~~	~~BASF~~
	~~Anonymous~~	~~1988~~	~~Plan und Versuchsbericht Rueckstandsversuche - Rueckstaende Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT 713 034 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished~~	~~N~~	~~BASF~~
	~~Anonymous~~	~~1988~~	~~Plan und Versuchsbericht Rueckstandsversuche - Rueckstaende Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT 713 035 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished~~	~~N~~	~~BASF~~
	~~Eichler D.~~	~~1988~~	~~Plan und Versuchsbericht Rueckstandsversuche: Dithianon - Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT 713 036 No, studies were conducted prior to the~~	~~N~~	~~BASF~~

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
			implementation of GLP but are scientifically valid unpublished		
	Eichler D.	1988	Plan und Versuchsbericht Rueckstandsversuche: Dithianon - Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT 713 037 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Eichler D.	1988	Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln: Dithianon - Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT 713 038 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Anonymous	1987	Rueckstandsuntersuchungen mit Pflanzenschutzmitteln - Rueckstaende Weintrauben Shell Forschung Ingelheim; Ingelheim; Germany Fed.Rep. DT 713 039 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Bitz K.	1996	Dithianon (CL 37114) - 700 g ai/kg WG (SF 09321): Decline curve residue study in vine (Germany, 1995) Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. DT 713 058 Yes unpublished	N	BASF
	Jones S.	2003	Study on the residue behaviour of BAS 216 F in grapes after application of BAS 216 03 F under field conditions in Germany, Spain, France (N), Italy, Greece, 2001 BASF Agro Research Gosport; Gosport; United Kingdom 2002/1008746 Yes unpublished	N	BASF
	Smalley R.	2003	Study on the residue behaviour of BAS 216 F in grape vines after application of BAS 216 03 F under field conditions in Italy, France South and Spain, 2002 BASF Agro Research Gosport; Gosport; United Kingdom 2003/1004349 Yes unpublished	N	BASF
	Schulz H.	2005	Study on the residue behaviour of Dithianon in pears after treatment with BAS 216 03 F under field conditions in Denmark, Germany, Northern France and the Netherlands, 2004 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed. Rep. 2005/1014012 Yes unpublished	N	BASF
	Blaschke U.	2007	Residue study (unit to unit variation) with BAS 584 00 F applied to apples in Germany and Spain in 2006 Huntingdon Life Sciences Ltd.; Huntingdon Cambridgeshire PE28 4HS; United Kingdom 2007/1018308 Yes unpublished	N	BASF
	Todd M.	1992	Dithianon stability in pears Hazleton UK; Harrogate North Yorkshire; United Kingdom DT-326-003 Yes unpublished	N	BASF

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
	Todd M.	1992	Dithianon stability in apples Hazleton UK; Harrogate North Yorkshire; United Kingdom DT-326-005 Yes unpublished	N	BASF
	Curl M.G.	1992	Dithianon: Stability in grape samples Hazleton UK; Harrogate North Yorkshire; United Kingdom DT-326-007 Yes unpublished	N	BASF
	Dale T.	2003	Freezer storage stability of BAS 216 F (Dithianon) in wine, grape juice, grape pomace, grape must and apple sauce BASF Agro Research Gosport; Gosport; United Kingdom 2003/1001123 Yes unpublished	N	BASF
	Todd M.A.	1992	Dithianon stability in grain and straw Hazleton UK; Harrogate North Yorkshire HG3 1PY; United Kingdom DT-326-004 Yes unpublished	N	BASF
	Bixler T.A.	1994	Freezer storage stability of Dithianon in apple and pear Huntingdon Analytical Services; Middleport NY; United States of America DT-123-019 Yes unpublished	N	BASF
	Weber H.	1994	Storage stability of Dithianon in hops and processed matrices Dr. Specht & Partner Chemische Laboratorien GmbH; Hamburg; Germany Fed.Rep. DT-326-010 Yes unpublished	N	BASF
	Weitzel R.	1999	Dithianon (CL 37114) / Cymoxanil (CL 309806): Storage stability of residues of Dithianon and Cymoxanil in wine grapes at <-18°C (Germany, 1997) Cyanamid Forschung GmbH; Schwabenheim; Germany Fed.Rep. DT-326-018 Yes unpublished	N	BASF
	Rawle N.W., Edwards J.	2005	Freezer storage stability of BAS 216 F (Dithianon) in wine, grape juice, grape pomace, grape must and apple sauce CEMAS - CEM Analytical Services Ltd.; North Ascot Berkshire SL5 8JB; United Kingdom 2005/1029468 Yes unpublished	N	BASF
	Tsalta C.	2001	AC 37114 (BAS 216 F): Effects of processing on the nature of the residues due to hydrolysis BASF Corporation Agro Research; Princeton NJ 08543-0400; United States of America DT-790-060 Yes unpublished	N	BASF
	Hassink J.	2009	BAS 216 F: Hydrolysis in apple juice during simulation of the processing step pasteurisation BASF SE; Limburgerhof; Germany Fed.Rep. 2009/1065632 Yes unpublished	N	BASF
	Smalley R	2002	BAS 216 03 F (Dithianon) 700 g as/kg WG (SF 09321): Decline curve residue study on Dithianon in apples - Italy, 2000 BASF Agro Research Gosport; Gosport; United Kingdom 2002/1011501 Yes unpublished	N	BASF

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
	Smalley R	2002	BAS 216 03 F (Dithianon) 700 g as/kg WG (SF 09321): At harvest residue study on Dithianon in apples - Italy, 2000 BASF Agro Research Gosport; Gosport; United Kingdom 2002/1011502 Yes unpublished	N	BASF
	Jones S.	2002	The magnitude of BAS 216 F residues in apple processed fractions BASF Agro Research Gosport; Gosport; United Kingdom 2002/1011555 Yes unpublished	N	BASF
	Anonymous	1987	Rueckstandsuntersuchungen mit Pflanzenschutzmitteln - Rueckstaende Trauben Shell Forschung Ingelheim; Ingelheim; Germany Fed.Rep. DT-713-031 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Eichler D.	1987	Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln: Dithianon - Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT-713-032 No, studies were conducted prior to the implementation of GLP but are scientifi	N	BASF
	Eichler D.	1987	Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln: Dithianon - Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT-713-033 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Anonymous	1988	Plan und Versuchsbericht Rueckstandsversuche - Rueckstaende Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT-713-034 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Anonymous	1988	Plan und Versuchsbericht Rueckstandsversuche - Rueckstaende Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT-713-035 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Eichler D.	1988	Plan und Versuchsbericht Rueckstandsversuche: Dithianon - Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT-713-036 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Eichler D.	1988	Plan und Versuchsbericht Rueckstandsversuche: Dithianon - Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT-713-037 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Eichler D.	1988	Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln: Dithianon - Weintrauben Celamerck GmbH & Co. KG; Ingelheim; Germany Fed.Rep. DT-713-038 No, studies were	N	BASF

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
			conducted prior to the implementation of GLP but are scientifically valid unpublished		
	Anonymous	1987	Rueckstandsuntersuchungen mit Pflanzenschutzmitteln - Rueckstaende Weintrauben Shell Forschung Ingelheim; Ingelheim; Germany Fed.Rep. DT-713-039 No, studies were conducted prior to the implementation of GLP but are scientifically valid unpublished	N	BASF
	Jones S.	2003	Processing study on the residue behaviour of BAS 216 F in grapes after application of BAS 216 03 F under field conditions in Germany, Spain, France (N), Italy, 2001 BASF Agro Research Gosport; Gosport; United Kingdom 2003/1014014 Yes unpublished	N	BASF
	Schulz H.	2004	Study on the residue behaviour of Dithianon in apples and processed products after treatment with BAS 216 03 F under field conditions in Germany, 2003 Institut Fresenius, Chemische und Biologische Laboratorien AG; Taunusstein; Germany Fed.Rep. 2003/1001126 Yes unpublished	N	BASF
	Furr H.	1993	Dithianon: The determination of residues in grape process fractions from the USA ACDS Research Inc., Phelps, NY, United States of America Hazleton UK; Harrogate North Yorkshire; United Kingdom Yes unpublished BASF DocID No. DT-713-056	N	BASF

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

List of data relied on and 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

Appendix 2 Detailed evaluation of the additional studies relied upon

Not relevant. No additional study was submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

~~A 3.1 TMDI calculations~~

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Dithianon

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.12**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 19

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
585%	NL toddler	58.46	323%	Apples	130%	Pears	46%	Table grapes		454%
527%	DE child	52.69	374%	Apples	41%	Table grapes	40%	Oranges		394%
308%	NL child	30.85	173%	Apples	36%	Pears	31%	Table grapes		210%
164%	FR toddler 2 3 yr	16.44	95%	Apples	23%	Mandarins	14%	Oranges		104%
160%	DE women 14-50 yr	16.00	77%	Apples	25%	Wine grapes	19%	Oranges		82%
154%	PT general	15.35	75%	Wine grapes	32%	Apples	10%	Pears		42%
152%	DE general	15.22	73%	Apples	25%	Wine grapes	16%	Oranges		76%
138%	FR child 3 15 yr	13.79	50%	Apples	34%	Oranges	11%	Wine grapes		59%
136%	RO general	13.58	50%	Wine grapes	43%	Apples	12%	Tomatoes		46%
133%	GEMS/Food G11	13.27	47%	Apples	31%	Wine grapes	13%	Table grapes		52%
132%	GEMS/Food G07	13.21	44%	Wine grapes	31%	Apples	14%	Oranges		35%
129%	IE adult	12.90	38%	Wine grapes	21%	Apples	15%	Mandarins		34%
128%	GEMS/Food G06	12.80	32%	Table grapes	28%	Apples	21%	Tomatoes		30%
121%	GEMS/Food G08	12.12	36%	Apples	31%	Wine grapes	10%	Table grapes		41%
120%	GEMS/Food G15	12.01	33%	Apples	30%	Wine grapes	10%	Table grapes		38%
118%	FR adult	11.77	70%	Wine grapes	23%	Apples	6%	Oranges		27%
116%	UK toddler	11.61	51%	Apples	20%	Oranges	8%	Mandarins		57%
115%	DK child	11.46	70%	Apples	20%	Pears	5%	Table grapes		90%
103%	NL general	10.34	44%	Apples	18%	Wine grapes	10%	Oranges		49%
95%	PL general	9.53	61%	Apples	10%	Table grapes	8%	Pears		70%
95%	GEMS/Food G10	9.46	23%	Apples	13%	Wine grapes	11%	Oranges		27%
94%	ES child	9.44	34%	Apples	22%	Oranges	13%	Pears		48%
90%	UK infant	9.01	47%	Apples	13%	Oranges	8%	Pears		54%
86%	DK adult	8.56	29%	Apples	29%	Wine grapes	10%	Pears		38%
84%	SE general	8.37	32%	Apples	13%	Mandarins	10%	Pears		42%
77%	ES adult	7.72	23%	Apples	13%	Oranges	12%	Wine grapes		33%
74%	FI 3 yr	7.44	28%	Apples	12%	Mandarins	7%	Table grapes		34%
73%	LT adult	7.28	56%	Apples	5%	Pears	4%	Tomatoes		61%
73%	FR infant	7.27	50%	Apples	5%	Pears	4%	Mandarins		56%
72%	IT toddler	7.15	27%	Apples	10%	Pears	9%	Tomatoes		37%
71%	UK vegetarian	7.14	24%	Wine grapes	18%	Apples	9%	Oranges		20%
71%	UK adult	7.09	32%	Wine grapes	12%	Apples	7%	HOPS (dried)		14%
60%	IT adult	6.03	24%	Apples	7%	Pears	7%	Tomatoes		31%
55%	FI 6 yr	5.50	17%	Apples	10%	Mandarins	5%	Pears		23%
48%	FI adult	4.80	17%	Apples	9%	Wine grapes	4%	Mandarins		19%
17%	IE child	1.70	10%	Apples	2%	Table grapes	1.0%	Currants (red, black and white)		11%

Conclusion:

The estimated TMDI/NEDI/IEDI was in the range of 0 % to 584.6 % of the ADI.
For 19 diet(s) the ADI is exceeded.

~~A 3.2 IEDI calculations~~

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Dithianon

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.12**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	84%	NL toddler	8.38	67%	Apples	17%	Pears				84%
	80%	DE child	7.99	77%	Apples	3%	Pears				80%
	41%	NL child	4.06	36%	Apples	5%	Pears				41%
	21%	FR toddler 2 3 yr	2.09	20%	Apples	1%	Pears				21%
	17%	DK child	1.70	14%	Apples	3%	Pears				17%
	17%	DE women 14-50 yr	1.65	16%	Apples	0.6%	Pears				17%
	16%	DE general	1.55	15%	Apples	0.5%	Pears				16%
	14%	PL general	1.38	13%	Apples	1%	Pears				14%
	12%	LT adult	1.22	12%	Apples	0.6%	Pears				12%
	11%	FR child 3 15 yr	1.15	10%	Apples	1%	Pears				11%
	11%	UK toddler	1.13	11%	Apples	0.7%	Pears				11%
	11%	FR infant	1.11	10%	Apples	0.7%	Pears				11%
	11%	UK infant	1.07	10%	Apples	1.0%	Pears				11%
	10%	GEMS/Food G11	1.03	10%	Apples	0.7%	Pears				10%
	10%	NL general	0.98	9%	Apples	0.7%	Pears				10%
	9%	RO general	0.92	9%	Apples	0.5%	Pears				9%
	9%	ES child	0.88	7%	Apples	2%	Pears				9%
	8%	GEMS/Food G08	0.81	8%	Apples	0.5%	Pears				8%
	8%	SE general	0.78	7%	Apples	1%	Pears				8%
	8%	PT general	0.78	7%	Apples	1%	Pears				8%
	7%	GEMS/Food G15	0.74	7%	Apples	0.6%	Pears				7%
	7%	DK adult	0.72	6%	Apples	1%	Pears				7%
	7%	GEMS/Food G07	0.69	6%	Apples	0.6%	Pears				7%
	7%	IT toddler	0.68	5%	Apples	1%	Pears				7%
	7%	FI 3 yr	0.65	6%	Apples	0.7%	Pears				7%
	6%	IE adult	0.61	4%	Apples	2%	Pears				6%
	6%	GEMS/Food G06	0.61	6%	Apples	0.3%	Pears				6%
	6%	ES adult	0.60	5%	Apples	1%	Pears				6%
	6%	IT adult	0.58	5%	Apples	0.9%	Pears				6%
	5%	FR adult	0.53	5%	Apples	0.6%	Pears				5%
	5%	GEMS/Food G10	0.53	5%	Apples	0.6%	Pears				5%
	4%	FI 6 yr	0.43	4%	Apples	0.7%	Pears				4%
	4%	UK vegetarian	0.40	4%	Apples	0.3%	Pears				4%
	4%	FI adult	0.38	4%	Apples	0.2%	Pears				4%
	3%	UK adult	0.28	3%	Apples	0.2%	Pears				3%
	2%	IE child	0.21	2%	Apples	0.1%	Pears				2%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Dithianon is unlikely to present a public health concern.

~~A 3.3 IESTI calculations - Raw commodities~~

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 2

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
346%	Pears	3 / 3	415
269%	Apples	3 / 3	323

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 2

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
76%	Pears	3 / 3	92
70%	Apples	3 / 3	84

IESTI new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): 2

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
154%	Apples	3 / 3	185
148%	Pears	3 / 3	178

Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation) 2

IESTI new
Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
89%	Pears	3 / 3	107
75%	Apples	3 / 3	90

~~A 3.4 IESTI calculations - Processed commodities~~

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
135%	Apples / juice	3 / 3	162	83%	Apples / juice	3 / 3	100
81%	Pears / juice	3 / 3	98	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list							

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new): 1				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI new				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
135%	Apples / juice	3 / 3	162	83%	Apples / juice	3 / 3	100
81%	Pears / juice	3 / 3	98	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Conclusion:
The estimated short term intake (IESTI) exceeded the toxicological reference value for 2 commodities.

For processed commodities, the toxicological reference value was exceeded in one or several cases.

~~A 3.5 IESTI calculations - Raw commodities~~

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children	**Results for adults**	**IESTI new** **Results for children**	**IESTI new** **Results for adults**
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---	No. of commodities for which ARfD/ADI is exceeded (IESTI): ---	No. of commodities for which ARfD/ADI is exceeded (IESTI new): 2	No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI

		MRL / input				MRL / input	
Highest % of ARfD/ADI	Commodities	for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	for RA (mg/kg)	Exposure (µg/kg bw)
96%	Apples	3 / 1.89	116	29%	Apples	3 / 1.89	35
55%	Pears	3 / 0.87	65	15%	Pears	3 / 0.87	18

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)** 2	

IESTI new

		MRL / input				MRL / input	
Highest % of ARfD/ADI	Commodities	for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	for RA (mg/kg)	Exposure (µg/kg bw)
154%	Apples	3 / 3	185	89%	Pears	3 / 3	107
148%	Pears	3 / 3	178	75%	Apples	3 / 3	90

~~A 3.6 IESTI calculations - Processed commodities~~

Processed commodities

Results for children				Results for adults				Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			1	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
28%	Apples / juice	3 / 0.62	34	17%	Apples / juice	3 / 0.62	21	135%	Apples / juice	3 / 3	162	83%	Apples / juice	3 / 3	100
11%	Pears / juice	3 / 0.39	13	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	81%	Pears / juice	3 / 3	98	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list															

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Dithianon is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant

Not relevant. No additional information provided.