

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 4100 A

Product name(s): HIFEN

Chemical active substance:

Thifensulfuron-methyl, 750 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem Ltd.

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Version history

When	What
02.2024	zRMS assessment
02.2025	The final Registration Report.

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Stability of residues

The available storage stability data are considered sufficient.

Residue trials are valid in relation to storage stability data.

No additional tests are required.

Storage stability of Thifensulfuron-methyl was demonstrated for a period of at least 24 months in Corn grain, and 42 months in wheat grain and 14 months in wheat straw.

Metabolism

The intended uses are covered by the available metabolism studies reported in the EU.

Plant residue definition for monitoring Thifensulfuron-methyl (parent for oilseeds and cereals) (EFSA 2015)

Plant residue definition for risk assessment For oilseeds and cereals: thifensulfuron-methyl and provisionally IN A4098 a (EFSA, 2015)

Animal residue definition for monitoring Thifensulfuron-methyl (parent) (EFSA 2015)

Animal residue definition for risk assessment Sum of thifensulfuron-methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron-methyl and provisionally triazine amine (IN-A4098) (EFSA 2015)

Metabolite IN-A4098 is provisionally included in the residue definition for risk assessment for plant commodities (pending the outcome of the confirmatory data requirement on genotoxic potential).

Evaluation of IN-A4098 is not finished yet. EFSA PPR panel is currently assessing it (*EFSA Supporting publication 2020:EN-1627*).

Magnitude of residues in plants

Winter Cereals: Wheat, barley, rye, oat, triticale

Proposed GAP: BBCH 13-39, 1 application 30 g as/ha, PHI covered by the time remaining between application and harvest.

Accepted EU GAPs for winter cereals (*Thifensulfuron-methyl*, SANTE/10150/2016 rev. 2 12 July 2016):

- Winter Cereals (wheat): BBCH 13-39, 1 application 30 g as/ha, PHI covered by the time remaining between application and harvest.
- Winter cereals (wheat, barley, triticale, rye, oat): BBCH 13-39, 1 application 22.5-37.5 g as/ha, PHI covered by the time remaining between application and harvest.
- Winter wheat, Rye, Triticale: BBCH 13-39, 1 application 0.051 g as/ha, PHI covered by the time remaining between application and harvest.

Proposed GAP is within accepted EU GAP.

Applicant refers to studies from RAR, 2014 (previously evaluated in the DAR for original approval). These studies were accepted during renewal. All results were below LOQ of 0.02 mg/kg.

As the MRL is 0.01 mg/kg applicant also refers to metabolism studies submitted in the DAR, 1996 (p. 121; P. I. Friedman, L. E. Stevenson, 1986 AMR 498-86, I. E. Stevenson, 1986 AMR 783-87, P. I. Friedman, F. T. Lichtner, 1986, AMR 513-86, J. C. Cottelman, 1987 AMR 795-87) and then re-evaluated at renewal. Studies on the nature of residues in wheat has been conducted with exaggerated doses (74.2 or 80 g as/ha), more than twice higher than intended uses (30 g as/ha). And it was concluded that no significant residues of thifensulfuron-methyl or its metabolites are expected. RAR (page 6-7):

In conclusion, the elimination of thifensulfuron-methyl in wheat was rapid (DT50- estimated to 2 days). There were no significant residues of thifensulfuron-methyl or its metabolites (<0.01 ppm) in mature field-wheat grain (two months after treatment at the 5 leaf stage).

The plant metabolism data demonstrate that residues in the harvestable crop will be <LOQ (EFSA Journal 2015;13(7):420)1.

Taking into consideration the rate and results from the metabolism studies it can be concluded there is no

risk to exceed MRL (0.01 mg/kg) values for wheat grain and no further studies should be required.

Magnitude of residues in livestock

Input values and dietary burden calculation are accepted.

The requested uses do not modify the theoretical maximum daily intake for animals, and regarding available feeding data, there is no risk for animal MRL to be exceeded.

Magnitude of residues in processed commodities

No data on the effect of processing on the magnitude of residues are required as residues in the raw agricultural commodities are below the limit of determination.

Magnitude of residues in representative succeeding crops

No data are required. Previously evaluated rotational crop metabolism studies confirm the absence of residues in rotational crops when thifensulfuron-methyl is applied according to the EU critical GAP.

Estimation of exposure through diet and other means

The input values used for the chronic and acute risk assessments are the current EU MRLs contained in Regulation (EU) No. 617/2014. Calculation is accepted.

TMDI (% ADI) according to EFSA PRIMo rev.3.1	12 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo rev.3.1	Not relevant, since TMDI does not exceed ADI
IENTI (% ARfD) according to EFSA PRIMo rev.3.1	Raw commodities Based on children: Wheat: 0.01% Rye, barley and oat: 0.00% Based on adults: Wheat, rye, barley and oat: 0.00% Processed commodities Based on children: Wheat/milling (flour): 0.0% Wheat/milling (wholemeal)-baking: 0.0% Rye/boiled: 0.0% Oat/boiled: 0.0% Barley/cooked: 0.0% Rye/milling (wholemeal)-baking: 0.0% Oat/milling (flakes): 0.0% Barley/milling (flour): 0.0% Based on adults: Barley/beer: 0.0% Wheat/bread/pizza: 0.0% Wheat/pasta: 0.0% Wheat/bread (wholemeal): 0.0% Oat/boiled: 0.0%

The proposed uses of thifensulfuron-methyl in the formulation SHA 4100 A do not represent unacceptable acute and chronic risks for the consumer.

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 SHA 4100 A are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Europe for winter cereals. A list of all intended uses within the Central Europe zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of

0.01 mg/kg for thifensulfuron-methyl as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of thifensulfuron-methyl residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, Poland agrees with the authorization of the intended use(s).

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 or L product / ha a) max. rate per appl. b) max. total rate per crop/season	water L/ha min max	kg as/ha min max		
1	Winter cereals (wheat, barley, rye, oats, triticale)	CEU	SHA 4100 A	F	Broadleaved weeds	WG	750 g/kg	Foliar spray	BBCH 13-39 (Spring)	1	-	0.04	200-400	0.03	-	A

* 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 4100 A is composed of thifensulfuron-methyl.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Thifensulfuron-methyl					
ADI	EFSA	2015	0.01 mg/kg bw/d	2-year rat study	100
ARfD	EFSA	2015	2 mg/kg bw	Rate developmental toxicity study	100

7.1.2.1 Summary for thifensulfuron-methyl

Table 7.1-3: Summary for thifensulfuron-methyl

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	Winter cereals	Yes	Yes	Yes	Yes	Yes	No	No

7.1.2.2 Summary for SHA 4100 A

Table 7.1-4: Information on SHA 4100 A (KCA 6.8)

Crop	PHI for SHA 4100 A proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for SHA 4100 A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Thifensulfuron-methyl		
Winter cereals	NR	NR		

NR: not relevant

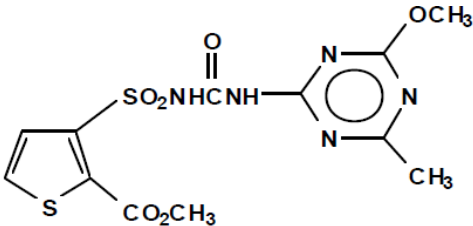
* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

7.2 Thifensulfuron-methyl

General data on thifensulfuron-methyl are summarized in the table below (last updated 2020/05/06)

Table 7.2-1: General information on thifensulfuron-methyl

Active substance (ISO Common Name)	Thifensulfuron-methyl
IUPAC	methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylate
Chemical structure	
Molecular formula	C ₁₂ H ₁₃ N ₅ O ₆ S ₂
Molar mass	387.39 g/mol
Chemical group	Sulfonylurea compounds
Mode of action (if available)	ALS inhibitors
Systemic	Yes
Company (ies)	Du Pont de Nemours and EU TSM AIR 2 Task Force (Rotam Agrochemical Europe and Cheminova ASà)
Rapporteur Member State (RMS)	Original RMS: France RMS: UK Co-RMS: Austria
Approval status	Approved Date of (01/11/2016) and reference to decision (COMMISSION DIRECTIVE 2001/99/EC - REGULATION (EU) No 2016/1424)
Restriction	Only uses as herbicide may be authorised.
Review Report	SANTE/10150/2016 rev. 2 12/07/2016
Current MRL regulation	Regulation (EU) No. 617/2014
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes (EFSA Journal 2015;13(7):4201)
EFSA Journal: conclusion on article 12	Yes (EFSA Journal 2012;10(8):2863)
Current MRL applications on intended uses	EFSA-Q-2008-636 All commodities Status: Reasoned opinion available (EFSA Journal 2012;10(8):2863)

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 $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat grain	High starch content	42 months	EFSA Journal 2015;13(7):4201
Wheat straw	Dry content	14 months	EFSA Journal 2015;13(7):4201
Corn	High starch content	24 months	EFSA Journal 2015;13(7):4201

Conclusion on stability of residues during storage

Storage stability of Thifensulfuron-methyl was demonstrated for a period of at least 24 months in Corn grain, and 42 months in wheat grain. Storage stability of Thifensulfuron-methyl was demonstrated for a period of at least 14 months in wheat straw.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Conclusion on stability of residues in sample extracts

Not relevant, residues in sample extract was not investigated during the EU review of Thifensulfuron-methyl.

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)	Re-marks	
EU data								
Pulses and oilseeds	Soya bean	Thiophene-2- ¹⁴ C	Foliar, G	0.016	1	0, 7, 30, 100		H. M. Brown, 1987
		Thiophene-2- ¹⁴ C	Foliar, G	0.008 (+0.25% surfactant*)	1	0, 7, 30, 100		Report No. AMR 672-86 RAR, UK, 2014 EFSA, 2015
		Triazine-2- ¹⁴ C	Foliar, G	0.016	1	0, 7, 30, 100		L. B. Brattsten, 1987
		Triazine-2- ¹⁴ C	Foliar, G	0.008 (+0.25% surfactant*)	1	0, 7, 30, 100		Report No. AMR 547-86 RAR, UK, 2014 EFSA, 2015
Cereals	Wheat	Thiophene-2- ¹⁴ C	Foliar, F	0.074	1	0, 4, 8, 21, 28, 63		I. E. Stevenson, 1986 Report No. AMR 783-87; L. P. Friedman, I. E. Stevenson, 1986 Report No. AMR 498-86 DAR, France, 1996 EFSA, 2015
		Triazine-2- ¹⁴ C	Foliar, F	0.080	1	0, 4, 8, 21, 28, 63		J. C. Cotterman, 1987 Report No. AMR-794-87; P. L. Friedman, F. T. Lichtner, 1986 Report No. AMR 513-86 DAR, France, 1996 EFSA, 2015
	Maize	Thiophene-2- ¹⁴ C	Foliar, F	0.036	1	0, 3, 10, 30, 72, 113		V. A. Wittenbach, 1987 Report No. AMR 532-86 DAR, France, 1996 EFSA, 2015
		Triazine-2- ¹⁴ C	Foliar, F	0.039	1	0, 3, 10, 30, 72, 113		

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2012;10(8):2863 are reported below:

In wheat and maize grain total radioactive residues were too low (0.016-0.036 mg/kg) to characterise individual metabolites. The major metabolites detected in plant parts (wheat straw and forage, maize

foliage) were formed following de-esterification (Thifensulfuron acid), de-methylation (O-demethyl Thifensulfuron-methyl) and hydrolysis (triazine urea, 2-ester-3-sulfonamide¹⁶, O-demethyl triazine amine, triazine amine¹⁷ and 2-acid-3-sulfonamide) products. Overall, an extensive degradation of the parent compound with incorporation of residues into natural plant constituents was observed.

Soya bean plants treated post-emergence, the following absolute TRR levels at harvest (100 days after application) were identified for thiophene-2-¹⁴C Thifensulfuron-methyl in soybean seeds (0.002 mg/kg) and pods (0.009 mg/kg) and for triazine-2-¹⁴C-thifensulfuron-methyl in soybean seeds (<0.001 mg/kg) and pods (0.002 mg/kg) at an application rate of 16 g a.s./ha. At 0, 7, and 30 days after application the absolute TRR levels in soybean foliage were 0.860 mg/kg, 0.484 mg/kg and 0.098 mg/kg respectively for thiophene-2-¹⁴C-thifensulfuron-methyl and 0.582 mg/kg, 0.506 mg/kg and 0.066 mg/kg respectively for triazine-2-¹⁴C-thifensulfuron-methyl at an application rate of 16 g a.s./ha

Conclusion on metabolism in primary crops

The residue definition for risk assessment for fodder crops is sum of Thifensulfuron-methyl and Thifensulfuron acid (IN-L9225), expressed as Thifensulfuron-methyl, and provisionally IN-A4098 The residue definition for risk assessment for other plant commodities (food commodities) is Thifensulfuron-methyl and provisionally IN-A4098 to be considered separately pending on the toxicological profile of this compound. The plant residue definition for monitoring is proposed as Thifensulfuron-methyl only,

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.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Root and tuber vegetables	Beet root	Thiophene-2- ¹⁴ C	Soil spraying, G	86-94	30, 120	At harvest		P. T. Hardesty, 1984 Report No. AMR 256-84 DAR, France, 1996 EFSA, 2015
		Triazine-2- ¹⁴ C	Foliar treatment, G	36	45, 75	At harvest		A. M. Brown Report No. AMR 582-86 DAR, France, 1996 EFSA, 2015
Pulses and	Sunflower	Thiophene-	Soil	86-94	30-120	At har-		P. T.

oilseeds	Pea	2- ¹⁴ C	spraying, G			vest		Hardesty, 1984 Report No. AMR 256- 84 DAR, France, 1996 EFSA, 2015
		Triazine-2- ¹⁴ C	Foliar treatment, G	36	45, 75	At har- vest		A. M. Brown Report No. AMR 582- 86 DAR, France, 1996 EFSA, 2015
Cereals	Wheat	Thiophene-2- ¹⁴ C	Soil spraying, G	33.6	90, 241	At har- vest		E. M. Fer- guson, 1992 Report No. AMR 858- 87 DAR, France, 1996 EFSA, 2015
		Triazine-2- ¹⁴ C	Soil spraying, G	33.6	90-241	At har- vest		

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2012;10(8):2863 are reported below:

Radiolabelled residues did not accumulate in rotational crops (beets, peas and sunflowers) grown in soil treated 30 and 120 days earlier with Thifensulfuron-methyl [thiophene-2-¹⁴C] (86-94 g as/ha, respectively). In mature crop samples the level of radiolabelled residues were found to be < 0.01 mg/kg.

Residues at the LOQ (<0.01 mg/kg) were observed in edible portions (beetroot, peas, pea pod, sunflower seeds and heads) of crops planted 45 or 75 days following treated (36 g as/ha) wheat cultivation and incorporation into soil. Thifensulfuron-methyl was not detected in any edible crop parts. There were minor detectable residues (0.053 mg/kg and 0.015 mg/kg) in animal feed items (pea foliage and sunflower foliage respectively).

There were no substantial residues (≤ 0.01 mg/kg) in mature wheat grain (both thiophene-2-¹⁴C and triazine-2-¹⁴C) from crops planted 90- and 241-days following soil treatment. Thifensulfuron-methyl was not detected in any edible crop parts. Minor detectable residues (no compound greater than 0.034 mg/kg) were detected in mature ¹⁴C-triazine straw.

In the three studies, 2-acid-3-sulfonamide, triazine amine, triazine urea and O-demethyl triazine amine were detected in plant tissues. Therefore, the primary plant metabolism study corresponds with the residues observed in rotational crops where the majority of the radioactivity could be attributed to incorporation into natural compounds or minor unidentified fractions

Conclusion on metabolism in rotational crops

Residues in rotational crops were similar to the primary crops and the residue definition for plants does not require a particular consideration for rotational crops.

No new data submitted in the framework of this application.

As the residues of plant origin are not expected to exceed LOQ the studies on the nature of residues in processed commodities are not required.

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	Cereals (wheat and maize) and oilseeds (soya bean)
Rotational crops covered	Beet root, sunflower, pea and wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes, the metabolites identified in primary crops and rotational crops are in a high degree the same. Metabolites found in rotational crops but not in the primary crop are only found in minor amounts and evaluated to be of no toxicological significance.
Processed commodities	Not required as residues are < 0.1 mg/kg
Residue pattern in processed commodities similar to pattern in raw commodities?	Not relevant.
Plant residue definition for monitoring	Thifensulfuron-methyl (Regulation (EU) No. 617/2014)
Plant residue definition for risk assessment	Thifensulfuron-methyl and provisionally triazine amine (IN-A4098) For Animal feed items (grass / alfalfa): Sum of thifensulfuron-methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron-methyl and provisionally triazine amine (IN-A4098) (EFSA Journal 2015;13(7):4201)
Conversion factor from enforcement to RA	None.

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	Thiophene-2- ¹⁴ C	2	0.71	7	Milk	twice daily	Report No. AMR 326-85, 1986 DAR, France, 1996 EFSA, 2015
		Triazine-2- ¹⁴ C				Urine and faeces	daily	
						Tissues	at sacrifice	

Summary of animal metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2012;10(8):2863 are reported below:

Lactating goats were dosed with 0.71 mg/kg bw per d of Thifensulfuron-methyl corresponding to approximately 25 times the maximum exposure of meat ruminants. The studies demonstrate that the transfer of residues to milk and tissues, at this rate is relatively low.

Following the repeated oral administration of radiolabelled Thifensulfuron-methyl to goats a high proportion of the dose was eliminated in the excreta. Approximately 53-64 % and 28-33% of the administered radioactivity were detected in the urine and faeces respectively. There was no evidence of any significant accumulation of radioactivity in milk or edible tissues (In the goat study levels in milk plateaued in less than 3 days). Total radioactive residue (TRR) levels in milk ranged from 0.1-0.2 mg/kg representing less than 0.9 % of the administered radioactivity, in kidney where the highest levels were found, 0.10-0.16 mg/kg, liver 0.04-0.05 mg/kg and muscle 0.03 mg/kg.

The major metabolic pathway involved cleavage of the carboxyl ester linkage, resulting in the formation of Thifensulfuron acid. Oxidative O-demethylation occurred to a limited extent. The major residue in milk, muscle and tissues was Thifensulfuron-methyl. The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs. It is noted however that the contribution of the different metabolites to the total residue were not clearly reported in the DAR (France, 1996). A detailed evaluation report regarding this metabolism study is therefore still considered desirable.

Conclusion on metabolism in livestock

The residue definition for enforcement in livestock matrices is Thifensulfuron-methyl. The definition for risk assessment is sum of thifensulfuron-methyl and thifensulfuron acid (IN-L9225) expressed as thifensulfuron-methyl and provisionally triazine amine (IN-A4908).

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
Time needed to reach a plateau concentration	Milk plateau reached in less than 3 days.
Animal residue definition for monitoring	Thifensulfuron-methyl (Regulation (EU) No. 617/2014)
Animal residue definition for risk assessment	Sum of thifensulfuron-methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron-methyl and provisionally triazine amine (IN-A4098) (EFSA Journal 2015;10(7):4201)
Conversion factor	None

Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

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 SHA 4100 A 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
Wheat grain → extrapolated to barley, oat, rye, triticale	RAR, 2014 (previously evaluated in the DAR for original approval)	N-EU	GAP on which EU a.s. assessment is based: 1 x 41-61 g as/ha, outdoor Grain: 4 x n.d. (<0.02)	N/A				
	Overall supporting data for cGAP	N-EU	Grain: 4 x n.d. (<0.02)	<0.02	<0.02	<0.02	0.01	Yes
Wheat straw → extrapolated to barley, oat, rye, triticale	RAR, 2014 (previously evaluated in the DAR for original approval)	N-EU	GAP on which EU a.s. assessment is based: 1 x 41-61 g as/ha, outdoor Straw: 4 x n.d. (<0.05)					
	Overall supporting	N-EU	Straw: 4 x n.d. (<0.05)	<0.05	<0.05	<0.05	-	Yes

	data for cGAP							
Oat grain → extrapolated to wheat, barley, rye, triticale	RAR, 2014 (previously evaluated in the DAR for original approval)	N-EU	GAP on which EU a.s. assessment is based: 1 x 41 g as/ha, outdoor Grain: 5 x n.d. (<0.02)					
	Overall supporting data for cGAP	N-EU	Grain: 5 x n.d. (<0.02)	<0.02	<0.02	<0.02	0.01	Yes
Oat straw → extrapolated to wheat, barley, rye, triticale	RAR, 2014 (previously evaluated in the DAR for original approval)	N-EU	GAP on which EU a.s. assessment is based: 1 x 41 g as/ha, outdoor Straw: 5 x n.d. (<0.05)					
	Overall supporting data for cGAP	N-EU	Straw: 5 x n.d. (<0.05)	<0.05	<0.05	<0.05	-	Yes
Barley grain	RAR, 2014 (previously evaluated in the DAR for original approval)	N-EU	GAP on which EU a.s. assessment is based: 1 x 41 g as/ha, outdoor Grain: 2 x n.d. (<0.02)					
	Overall supporting data for cGAP	N-EU	Grain: 2 x n.d. (<0.02)	<0.02	<0.02	<0.02	0.01	Yes
Barley straw	RAR, 2014 (previously evaluated in the DAR for original approval)	N-EU	GAP on which EU a.s. assessment is based: 1 x 41 g as/ha, outdoor Straw: 2 x n.d. (<0.05)					

	Overall supporting data for cGAP	N-EU	Straw: 2 x n.d. (<0.05)	<0.05	<0.05	<0.05	-	Yes
Rye grain	RAR, 2014 (previously evaluated in the DAR for original approval)	N-EU	GAP on which EU a.s. assessment is based: 1 x 61 g as/ha, outdoor Grain: 2 x n.d. (<0.02)					
	Overall supporting data for cGAP	N-EU	Grain: 2 x n.d. (<0.02)	<0.02	<0.02	<0.02	0.01	Yes
Rye straw	RAR, 2014 (previously evaluated in the DAR for original approval)	N-EU	GAP on which EU a.s. assessment is based: 1 x 61 g as/ha, outdoor Straw: 2 x n.d. (<0.05)					
	Overall supporting data for cGAP	N-EU	Straw: 2 x n.d. (<0.05)	<0.05	<0.05	<0.05	-	Yes

* Source of EU MRL: Regulation (EU) No. 617/2014

All residue trials from DAR, France, 1996 the applicant is relying on were conducted using at least 25% higher dose of active substance/ha than in the GAP under evaluation. Therefore current MRL values are not expected to be exceeded.

7.2.3.2 Conclusion on the magnitude of residues in plants

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

According to appendix D of EU guidelines, extrapolation to winter cereals is possible with 4 N-EU trials on wheat and 5 N-EU trials on oats, which is the case here.

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

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 evaluated in Art. 12 procedure and the uses under consideration) (animal model calculation, 2017)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment (RAR, UK, 2014)	Input value (mg/kg)	Comment (RAR, UK, 2014)
Thifensulfuron-methyl and provisionally triazine amine (IN-A4098) (EFSA, 2015)				
Barley straw	0.05	Median residue	0.36	Highest residue
Oat straw	0.05	Median residue	0.05	Median residue
Rye straw	0.05	Median residue	0.05	Median residue
Wheat straw	0.05	Median residue	0.36	Highest residue
Barley grain	0.02	Median residue	0.02	Median residue
Corn, field (Maize) grain	0.02	Median residue (0.05) * PF (3)	0.02	Median residue (0.05) * PF (3)
Oat grain	0.02		0.02	Median residue
Wheat grain	0.02	Median residue	0.02	
Brewer's grain	0.07	Median residue (0.02) * PF (3.3)	0.07	Median residue (0.02) * PF (3.3)
Corn, field milled by-pdts	0.02	Median residue (0.02) * PF (1)	0.02	Median residue (0.02) * PF (1)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment (RAR, UK, 2014)	Input value (mg/kg)	Comment (RAR, UK, 2014)
Corn, field hominy meal	0.12	Median residue (0.02) * PF (6)	0.12	Median residue (0.02) * PF (6)
Corn, field gluten feed	0.05	Median residue (0.02) * PF (2.5)	0.05	Median residue (0.02) * PF (2.5)
Corn, field gluten, meal	0.02	Median residue (0.02) * PF (1)	0.02	Median residue (0.02) * PF (1)
Distiller's grain dried	0.07	Median residue (0.02) * PF (3.3)	0.07	Median residue (0.02) * PF (3.3)
Wheat gluten meal	0.04	Median residue (0.02) * PF (1.8)	0.04	Median residue (0.02) * PF (1.8)
Wheat milled by-pdts	0.14	Median residue (0.02) * PF (7)	0.14	Median residue (0.02) * PF (7)

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)
Risk assessment residue definition: Thifensulfuron-methyl					
Cattle (all diets)	0.003	0.007	Barley straw	0.18	Yes
Cattle (dairy only)	0.003	0.007	Barley straw	0.18	Yes
Sheep (all diets)	0.005	0.013	Barley straw	0.31	Yes
Sheep (ewe only)	0.003	0.010	Barley straw	0.31	Yes
Swine (all diets)	0.003	0.003	Wheat milled by-pdts	0.09	No
Poultry (all diets)	0.004	0.006	Wheat straw	0.09	No
Poultry (layer only)	0.004	0.006	Wheat straw	0.09	No

* These categories correspond to those (formerly) assessed at EU level.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

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

7.2.5.1 Available data for all crops under consideration

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

7.2.5.2 Conclusion on processing studies

As the residues of plant origin are not expected to exceed 0.1 mg/kg the studies on the residues in processed commodities are not required.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

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 SHA 4100 A. 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 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

The input values used for the chronic and acute risk assessments are the current EU MRLs contained in Regulation (EU) No. 617/2014.

Table 7.2-11: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev.3.1	12 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo rev.3.1	-
IESTI (% ARfD) according to EFSA PRIMo* rev.3.1	Raw commodities Based on children: Wheat: 0.01%

	Rye: 0.00% Barley: 0.00% Oat: 0.00% Based on adults: Wheat: 0.00% Rye: 0.00% Barley: 0.00% Oat: 0.00% Processed commodities Based on children: Wheat/milling (flour): 0.0% Wheat/milling (wholemeal)-baking: 0.0% Rye/boiled: 0.0% Oat/boiled: 0.0% Barley/cooked: 0.0% Rye/milling (wholemeal)-baking: 0.0% Oat/milling (flakes): 0.0% Barley/milling (flour): 0.0% Based on adults: Barley/beer: 0.0% Wheat/bread/pizza: 0.0% Wheat/pasta: 0.0% Wheat/bread (wholemeal): 0.0% Oat/boiled: 0.0%
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

The proposed uses of thifensulfuron-methyl in the formulation HIFEN (SHA 4100 A) do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance thifensulfuron-methyl. EFSA Journal 2015;13(7):4201

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for thifensulfuron-methyl according to Article 12 of Regulation (EC) No. 396/2005. EFSA Journal 2012;10(8): 2863

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
KCP 8.2.1/1	J. C. Cotterman	1987	Metabolism of [Triazine-2- ¹⁴ C] DPX-M6316 in field grown wheat: radioactive residues in forage and straw Report No. AMR 794-87 Non-GLP Published	N	DuPont
KCP 8.2.1/2	I. E. Stevenson	1986	Metabolism of [Thiophene-2- ¹⁴ C] DPX-M6316 in field grown wheat: radioactive residues in forage and straw. Report No. AMR 783-87 Non-GLP Published	N	DuPont

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 8.2.1/3	L. P. Friedman, I. E. Stevenson	1986	Metabolism of [Thiophene-2- ¹⁴ C] DPX-M6316 in field grown wheat: radioactive residues in mature grain Report No. AMR 498-86 Non-GLP Published	N	DuPont
KCP 8.2.1/4	L. P. Friedman, F. T. Lichtner	1986	Metabolism of [Triazine-2- ¹⁴ C] DPX-M6316 in field grown wheat: radioactive residues in mature grain. Report No. AMR 513-86 Non-GLP Published	N	DuPont
KCP 8.2.1/5	V. A. Wittenbach	1987	Metabolism of [thiophene-2- ¹⁴ C] DPX-M6313 and [triazine-2- ¹⁴ C] DPX-M6316 in field-grown corn. Report No. AMR 532-86 Non-GLP Published	N	DuPont
KCP 8.2.1/6	L. B. Brattsten	1987	Metabolism of [triazine-2- ¹⁴ C] DPX-M6316 in green-house grown soybean plants. Report No. AMR 547-86 Non-GLP Published	N	DuPont
KCP 8.2.1/7	H. M. Brown	1987	Metabolism of [thiophene-2- ¹⁴ C] DPX-M6316 in greenhouse-grown soybeans. Report No. AMR 572-86 Non-GLP Published	N	DuPont
KCP 8.6.1/1	P. T. Hardesty	1984	Crop rotation studies with DPX-M6316 [Thiophene-2- ¹⁴ C] in the greenhouse. Report No. AMR 256-84 Non-GLP Published	N	DuPont
KCP 8.6.1/2	A. M. Brown	1987	Greenhouse accumulation study of [triazine-2- ¹⁴ C] DPX-M6316 on rotational crops. Report No. AMR 582-86	N	DuPont

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
			Non-GLP Published		
KCP 8.6.1/3	E. M. Ferguson	1992	Confined Accumulation Study of ¹⁴ C-DPX-M6316 on Wheat as a Rotational Crop. Report No. AMR 858-87 Non-GLP Published	N	DuPont
KCP 8.2.2/1	Unknown	1986	Goat metabolism study of ¹⁴ C-DPX-M6316. Report No. AMR 326-85 Non-GLP Published	Y	DuPont

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

A 2.1 Thifensulfuron-methyl

A 2.1.1 Stability of residues

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

A 2.1.2 Nature of residues in plants, livestock and processed commodities

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

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Wheat

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2015)	1	22.5-37.5 g as/ha	-	BBCH 12-39	-
Intended cGAP (number*)	1	30	-	BBCH 13-39	-

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

Table A 20: Summary of the study in N-EU

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Thifensulfuron- methyl		
BAT 86-13/N- EU/Germany/1987	Winter wheat	10/1984 - -	61	-	-	04/1985	-	Green plant Green plant Green plant Green plant Grain Straw	2.87 <0.05 <0.05 <0.05 <0.05 <0.02 <0.05	0 40 62 75 125 125	DAR, France, 1996
BAT 86-13/N- EU/Germany/1987	Winter wheat	10/1984 - -	61	-	-	04/1985	-	Green plant Green plant Green plant Green plant Grain Straw	2.70 <0.05 <0.05 <0.05 <0.05 <0.02 <0.05	0 35 68 83 126 126	DAR, France, 1996
BAT-88-16/N- EU/Germany/1989	Spring wheat	04/1986	41	-	-	05/1986	-	Green plant Green plant Green plant Green plant Grain Straw	3.56 <0.05 <0.05 <0.05 <0.05 <0.02 <0.05	0 11 43 59 101 101	DAR, France, 1996
BAT-88-16/N- EU/Germany/1989	Spring wheat	03/1986	41	-	-	05/1986	-	Green plant Green plant Green plant Green plant Grain Straw	0.91 <0.05 - <0.05 <0.02 <0.05	0 24 48 70 94 94	DAR, France, 1996

Wheat, Switzerland, 1985 (3 trials)

Previous evaluation:	In DAR for original approval (1996)
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Study Cicotti (1987) - report number BAT-86-12 - GLP (analysis)
Formulation HARMONY M (equivalent)
Storage conditions In 2/3 trials samples were not frozen immediately after harvest - stability in frozen state was demonstrated in separate studies
of samples
Limit of quantification grain = 0.02 ppm
Thifensulfuron-methyl straw = 0.05 ppm
Control samples: < LOQ
Recovery 82 to 98%

Location	Crop	Date of 1) sowing or planting 2) application	Rate (g a.s./ha)	Portion analysed	Days after treatment	Residues (ppm)
Switzerland (*)	Winter wheat	1) 10/1984 2) 05/1985	61	Grain Straw	101 101	< 0.02 < 0.05
Switzerland (*)	Winter wheat	1) 10/1984 2) 05/1985	61	Grain Straw	105 105	< 0.02 < 0.05
Switzerland	Winter wheat	1) 03/1985 2) 05/1985	41	Grain Straw	88 88	< 0.02 < 0.05

(*): results were considered as indicative only since samples were not immediately frozen.

Wheat, barley, UK, 1984 (7 trials)

Previous evaluation:	In DAR for original approval (1996)
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Study Upstone (1985) - report number THIF/RES 4 - No GLP
Formulation HARMONY (equivalent)
Storage conditions Frozen 7 days after harvest - stability in frozen state was demonstrated in separate studies
of samples
Limit of quantification grain = 0.02 ppm
Thifensulfuron-methyl straw = 0.05 ppm
Control samples: < LOQ
Recovery 71 to 93%

Thifensulfuron-methyl was applied at rates of 60 and 120 g a.s./ha. on spring and winter barley and winter wheat. At harvest (87 to 130 days after application) residues were < LOQ in grain and straw. This study was considered as indicative only.

Wheat, barley, France (north), 1984 (2 trials)

Previous evaluation:	In DAR for original approval (1996)
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Study Cicotti (1985) - report number BAT-9008 - GLP (analysis)
Formulation HARMONY (equivalent)
Storage conditions Not frozen immediately after harvest - stability in frozen state was demonstrated in separate studies
of samples

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Thifensulfuron-methyl - Volume 3, Annex B.7 : Residues

July 2014

Limit of quantification grain = 0.02 ppm
Thifensulfuron-methyl straw = 0.05 ppm
Control samples: < LOQ
Recovery 72 to 118%

Thifensulfuron-methyl was applied at rate of 45 g a.s./ha. on winter barley and wheat. At harvest (141 days after application in one trial and not stated in the other) residues were < LOQ in grain and straw. This study was considered as indicative only.

A 2.1.3.2 Barley

Table A 21: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2015)	1	22.5-37.5 g as/ha	-	BBCH 12-39	-
Intended cGAP (number*)	1	30	-	BBCH 13-39	-

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

Table A 22: Summary of the study in N-EU

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Thifensulfuron- methyl		
BAT 86-13/N- EU/Germany/1987	Spring Barley	04/1985 - -	41	-	-	05/1985	-	Green plant Green plant Green plant Green plant Grain Straw	1.08 <0.05 <0.05 <0.05 <0.02 <0.05	0 18 42 53 102 102	DAR, France, 1996
BAT 86-13/N- EU/Germany/1987	Spring Barley	03/1984 - -	41	-	-	05/1985	-	Green plant Green plant Green plant Ears Stalks Grain Straw	2.06 <0.05 <0.05 <0.05 <0.02 <0.02 <0.05	0 9 27 59 59 87 87	DAR, France, 1996

Barley, UK, 1983 (5 trials)

Previous evaluation:	In DAR for original approval (1996)
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Study	Upstone (1985) - report number THIF/RES 3 - No GLP
Formulation	HARMONY (equivalent)
Storage conditions of samples	Frozen 7 days after harvest - stability in frozen state was demonstrated in separate studies
Limit of quantification	grain = 0.02 ppm
Thifensulfuron-methyl	straw = 0.05 ppm
Recovery	Control samples: < LOQ 77 to 95%

Thifensulfuron-methyl was applied at rates ranging from 16 to 128 g a.s./ha. on spring and winter barley. At harvest (49 to 114 days after application) residues were < LOQ in grain and straw. This study was considered as indicative only.

A 2.1.3.3 Oat

Table A 23: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2015)	1	22.5-37.5 g as/ha	-	BBCH 12-39	-
Intended cGAP (number*)	1	30	-	BBCH 13-39	-

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

Table A 24: Summary of the study in N-EU

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Thifensulfuron- methyl		
BAT 85-15/N- EU/Germany/1987	Oat	04/1986 - -	41	-	-	05/1986	-	Green plant Green plant Green plant Green plant Grain Straw	1.84 <0.02 <0.02 <0.02 <0.02 <0.02 <0.05	0 18 29 38 74 74	DAR, France, 1996
BAT-88-16/N- EU/Germany/1989	Oat	04/1986	41	-	-	05/1986	-	Green plant Green plant Green plant Green plant Grain Straw	1.62 <0.05 <0.05 <0.05 <0.02 <0.05	0 15 55 71 92 92	DAR, France, 1996
BAT-88-16/N- EU/Germany/1989	Oat	05/1986	41	-	-	07/1986	-	Green plant Green plant Green plant Green plant Grain Straw	5.57 <0.05 <0.05 <0.05 <0.02 <0.05	0 35 56 63 85 85	DAR, France, 1996
BAT-88-16/N- EU/Germany/1989	Oat	04/1986	41	-	-	05/1986	-	Green plant Green plant Green plant Green plant Grain Straw	1.56 <0.05 <0.05 <0.05 <0.02 <0.05	0 35 56 63 85 85	DAR, France, 1996
BAT-88-16/N- EU/Germany/1989	Oat	04/1986	41	-	-	05/1986	-	Green plant Green plant Green plant Ears Stalks Grain Straw	1.41 <0.05 <0.05 <0.05 <0.05 <0.02 <0.05	0 10 41 71 71 99 99	DAR, France, 1996

A 2.1.3.4 Rye

Table A 25: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2015)	1	22.5-37.5 g as/ha	-	BBCH 12-39	-
Intended cGAP (number*)	1	30	-	BBCH 13-39	-

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

Table A 26: Summary of the study in N-EU

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Thifensulfuron- methyl		
BAT 85-15/N- EU/Germany/1987	Winter rye	10/1985 - -	61	-	-	03/1986	-	Green plant Green plant Green plant Green plant Grain Straw	5.35 <0.02 <0.02 <0.02 <0.02 <0.05	0 25 54 89 119 119	DAR, France, 1996
BAT-88-16/N- EU/Germany/1989	Winter rye	09/1985 - -	61	-	-	04/1986	-	Green plant Green plant Green plant Green plant Grain Straw	12.7 0.14 <0.05 <0.05 <0.02 <0.05	0 21 45 62 111 111	DAR, France, 1996

A 2.1.4 Magnitude of residues in livestock

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

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new studies were submitted in the framework of this application

A 2.1.6 Magnitude of residues in representative succeeding crops

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

A 2.1.7 Other/Special Studies

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

Appendix 3 Pesticide Residue Intake Model (PRIMo rev. 3.1)

A 3.1 TMDI calculations



European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Thifensulfuron-methyl

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day): 0.01 ARID (mg/kg bw): 2

Source of ADI: Source of ARID:

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

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

Exposure resulting from

MRLs set at the LOQ (in % of ADI) commodities not under assessment (in % of 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)
12%	NL toddler	1.24	6%	Milk: Cattle	1%	Apples	0.7%	Maize/corn	11%	0.5%
7%	NL child	0.66	2%	Milk: Cattle	0.8%	Sugar beet roots	0.6%	Apples	6%	0.4%
6%	DE child	0.64	2%	Milk: Cattle	1%	Apples	0.4%	Wheat	5%	0.5%
6%	UK infant	0.61	4%	Milk: Cattle	0.3%	Potatoes	0.3%	Wheat	5%	0.3%
6%	FR toddler 2-3 yr	0.56	3%	Milk: Cattle	0.3%	Apples	0.3%	Wheat	5%	0.3%
6%	FR child 3-15 yr	0.55	2%	Milk: Cattle	0.5%	Wheat	0.4%	Sugar beet roots	5%	0.5%
4%	UK toddler	0.45	2%	Milk: Cattle	0.4%	Wheat	0.3%	Potatoes	4%	0.4%
4%	GEMSFood G11	0.42	0.8%	Milk: Cattle	0.4%	Potatoes	0.4%	Soybeans	3%	0.4%
4%	DK child	0.41	1%	Milk: Cattle	0.6%	Rye	0.4%	Wheat	3%	1%
4%	GEMSFood G07	0.38	0.6%	Milk: Cattle	0.4%	Wheat	0.4%	Potatoes	3%	0.5%
4%	GEMSFood G06	0.38	0.7%	Wheat	0.4%	Tomatoes	0.2%	Milk: Cattle	2%	0.7%
4%	GEMSFood G15	0.38	0.7%	Milk: Cattle	0.5%	Wheat	0.4%	Potatoes	3%	0.6%
4%	GEMSFood G08	0.38	0.6%	Milk: Cattle	0.4%	Wheat	0.4%	Potatoes	3%	0.6%
4%	RO general	0.38	1%	Milk: Cattle	0.5%	Wheat	0.4%	Potatoes	3%	0.5%
4%	ES child	0.38	1%	Milk: Cattle	0.4%	Wheat	0.3%	Cocoa beans	3%	0.4%
4%	SE general	0.37	1%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.4%	Potatoes	3%	0.3%
4%	DE women 14-50 yr	0.37	1%	Milk: Cattle	0.5%	Sugar beet roots	0.3%	Apples	3%	0.3%
4%	GEMSFood G10	0.37	0.5%	Milk: Cattle	0.4%	Wheat	0.3%	Soybeans	3%	0.5%
4%	DE general	0.36	1%	Milk: Cattle	0.4%	Sugar beet roots	0.2%	Apples	3%	0.3%
4%	FI adult	0.35	3%	Coffee beans	0.1%	Potatoes	0.1%	Rye	3%	0.1%
3%	IE adult	0.33	0.4%	Milk: Cattle	0.4%	Sweet potatoes	0.2%	Wheat	3%	0.3%
3%	NL general	0.30	0.8%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Potatoes	2%	0.2%
3%	FR infant	0.29	2%	Milk: Cattle	0.2%	Potatoes	0.2%	Apples	3%	0.1%
2%	FR adult	0.22	0.4%	Milk: Cattle	0.2%	Wine grapes	0.2%	Wheat	2%	0.2%
2%	PT general	0.21	0.5%	Potatoes	0.4%	Wheat	0.2%	Wine grapes	0.9%	0.4%
2%	ES adult	0.21	0.5%	Milk: Cattle	0.2%	Wheat	0.1%	Oranges	2%	0.3%
2%	FI 3 yr	0.18	0.5%	Potatoes	0.1%	Bananas	0.1%	Wheat	0.9%	0.2%
2%	IT toddler	0.16	0.7%	Wheat	0.2%	Other cereals	0.1%	Tomatoes	0.8%	0.7%
2%	DK adult	0.16	0.5%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	1%	0.2%
2%	LT adult	0.16	0.4%	Milk: Cattle	0.3%	Potatoes	0.2%	Apples	1%	0.2%
1%	UK vegetarian	0.15	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1.0%	0.2%
1%	FI 6 yr	0.14	0.4%	Potatoes	0.1%	Cocoa beans	0.1%	Wheat	0.7%	0.2%
1%	UK adult	0.14	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1.0%	0.2%
1%	IT adult	0.12	0.4%	Wheat	0.1%	Tomatoes	0.1%	Apples	0.7%	0.4%
1.0%	PL general	0.10	0.3%	Potatoes	0.2%	Apples	0.1%	Tomatoes	0.6%	
0.8%	IE child	0.08	0.4%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	0.6%	0.1%

A 3.2 IEDI calculations

Not relevant.

A 3.3 IESTI calculations - Raw commodities

Show results of IESTI calculation only for crops with GAPs under assessment							
Results for children No. of commodities for which ARID/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI):			
IESTI				IESTI			
Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.01%	Wheat	0.01 / 0.01	0.14	0.00%	Wheat	0.01 / 0.01	0.08
0.00%	Rye	0.01 / 0.01	0.08	0.00%	Rye	0.01 / 0.01	0.05
0.00%	Barley	0.01 / 0.01	0.08	0.00%	Barley	0.01 / 0.01	0.05
0.00%	Oat	0.01 / 0.01	0.01	0.00%	Oat	0.01 / 0.01	0.01
Expand/collapse list							
Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)							

A 3.4 IESTI calculations - Processed commodities

Processed commodities	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):			
	-----				-----			
	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)
	0.0%	Wheat / milling (flour)	0.01 / 0.01	0.12	0.0%	Barley / beer	0.01 / 0	0.07
	0.0%	Wheat / milling (wholemeal)-t	0.01 / 0.01	0.06	0.00%	Wheat / bread/pizza	0.01 / 0.01	0.04
	0.0%	Rye / boiled	0.01 / 0.01	0.04	0.00%	Wheat / pasta	0.01 / 0.01	0.04
	0.0%	Oat / boiled	0.01 / 0.01	0.04	0.00%	Wheat / bread (wholemeal)	0.01 / 0.01	0.03
	0.0%	Barley / cooked	0.01 / 0.01	0.04	0.00%	Oat / boiled	0.01 / 0.01	0.02
	0.0%	Rye / milling (wholemeal)-bal	0.01 / 0.01	0.04				
	0.0%	Oat / milling (flakes)	0.01 / 0.01	0.03				
	0.0%	Barley / milling (flour)	0.01 / 0.01	0.02				

Appendix 4 Additional information provided by the applicant

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