

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 4100 A

Product name: HIFEN

**Chemical active substance:
Thifensulfuron-methyl, 750 g/kg**

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem Ltd.

Submission date: September 2023

**MS Finalisation date: April 2024; April 2025; corr. October
2025**

Version history

When	What
April 2024	ZRMs evaluated dRR submitted by Applicant.
February 2025	The final Registration Report.
April 2025	Corrected of final Registration Report.
October 2025	Corrected II.

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by SHARDA CROPChem Ltd.

This application is for approval of Thifensulfuron 75% WG, a water dispersible granule containing 750 g/kg of Thifensulfuron-methyl, as an herbicide on winter cereals (wheat, barley, rye, oats and triticale).

zRMS: Poland

cMS: Romania, Hungary

1.2 Letters of Access

Not applicable. Letter of access not needed

1.3 Justification for submission of tests and studies

This dossier relies on new tests and studies, providing data and information specific to the formulation Thifensulfuron 75% WG as required by the EU regulations.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	SHA 4100 A
Product name in MS	HIFEN
Authorization number	First authorisation
Function	Herbicide
Applicant	SHARDA Cropchem Ltd.
Active substance(s) (incl. content)	Thifensulfuron-methyl, 750 g/kg
Formulation type	Water dispersible granules [Code: WG]

Packaging	100 mL, 200 mL, 500 mL, 750 mL, 2L COEX (HDPE-EVOH) 1L, 5L professional user
Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

The evaluation of the application for Thifensulfuron 75% WG resulted in the decision to grant the authorization.

Physical and chemical properties: Shelf life – 2 years.

Efficacy section: All uses for HIFEN were accepted in the GAP table for Poland. Recommended water volume is 200-300 L/ha. List of accepted weed species and their sensitivity are presented in this dRR and label project. CMS should decide about possibility of acceptance claimed uses in GAP table on the basis on documentation submitted by Applicant and its detailed assessment presented in this dRR.

Fate and behaviour:

~~All uses are considered acceptable, however following mitigation measure are required:~~

~~SPe2: To protect ground water apply this product every 2 years in alkaline silty loam soils with M.O. content greater than 3.7% (Kremsmünster).~~

~~SPe2: To protect~~

All uses are considered acceptable, however following mitigation measure are required:

SPe2: To protect ground water apply this product every 3 years on the same cultivation area

Ecotoxicology section: All uses are considered acceptable.

However, according to Reg. 284/2009 the chronic adult and chronic larvae tests are required: for bees should be submitted by the applicant. The chronic risk assessment based on chronic studies for bees (adult and larvae) should be performed in line with the EFSA 2013 guideline during the transition period. **The Applicant should provide the chronic risk assessment based on chronic studies for bees (adult and larvae) performed in line with the EFSA 2013 guideline.**

Updated March 2025

The chronic tests for adult bee and larvae were submitted by Applicant.

The screening step risk assessment in line with EFSA (2013) has been performed by the Applicant, using endpoints from submitted studies.

Conclusion:

PL

D3, D4, R1 scenario are relevant.

SPe3: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies or an unsprayed buffer zone of 5 m to surface water bodies with 50% of nozzles reduction or an unsprayed buffer zone of 10 m to surface water bodies

~~The risk assessment for aquatic organisms with risk mitigation measured should be considered by MSs.~~

Evaluators verified whether the co-formulants contained in plant protection product HIFEN are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product HIFEN does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection product HIFEN meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of Regulation (EU) 2023/574 can be found in the dRR Part C.

2.3 Substances of concern for national monitoring

Not relevant.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Aquatic Acute 1; Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GH09
Signal word:	Warning
Hazard statement(s):	H400, H410
Precautionary statement(s):	P391, P501 Other section of the label: P270: Do not eat, drink or smoke when using this product. And P280 as follows: „Stosować rękawice ochronne oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu”

	“Wear protective gloves and work wear (coverall) during mixing/loading and work wear during application”. Storage: P102: Keep out of reach of children. Section First aid: P101: If medical advice is needed, have product container or label at hand.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
~~SPe2~~	~~To protect ground water apply this product every 2 years in alkaline silty loam soils with M.O. content greater than 3.7%.~~
SPe2	To protect ground water apply this product every 3 years on the same cultivation area
SPe3	To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies or an unsprayed buffer zone of 5 m to surface water bodies with 50% of nozzles reduction or an unsprayed buffer zone of 10 m to surface water bodies.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection: none	
-	-
Worker protection:	none
-	-
Integrated pest management (IPM)/sustainable use:	

-	-
Environmental protection	
SPe3	PL: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies or an unsprayed buffer zone of 5 m to surface water bodies with 50% of nozzles reduction or an unsprayed buffer zone of 10 m to surface water bodies
SPe2	To protect ground water apply this product every 3 years on the same cultivation area
Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
-	-	-

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): **SHA 4100 A / Thifensulfuron 75% WG** Formulation type: **WG (Water dispersible granules)**
Active substance 1: **Thifensulfuron-methyl** Conc. of as 1: **750 g/kg**
Active substance 2: **-** Conc. of as 2: **-**
Safener: **-** Conc. of safener: **-**
Synergist: **-** Conc. of synergist: **-**
Applicant: **SHARDA Cropchem Ltd.** Professional use: ☒
Zone(s): **Central** Non professional use: ☐
Verified by MS: **yes** GAP rev. 0, date: 2016-July-25th

Field of use: **Herbicide**

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ⁽ⁱ⁾
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CEU	Winter cereals (wheat, barley, rye, oats, triticale)	F	Broadleaved weeds	Foliar Spray	BBCH 13-39	a) 1 b) 1	N.A	a) 0.04 b) 0.04	a) 0.03 b) 0.03	200- 300 400	-	Efficacy section: Uses for PL – accepted. cMS will decide at national level about acceptation of uses claimed in GAP.. Recommended water volume: 200-300 L/ha.

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPG-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPG-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of beige solid granules with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it has a pH value around 5.49 at 21 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed.

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE commercial packaging*. Its technical characteristics are acceptable for *water dispersible granules* formulation.

The intended concentration of use is 0.01% to 0.02% of (PPP).

3.2 Efficacy (Part B, Section 3)

Thifensulfuron 75% WG is a Water dispersible granules (WG) formulation containing 750 grams per kilogram (g/kg) thifensulfuron-methyl for use in winter cereals. In compliance with the GAP the following dose rates are applied for registration:

- Single application to broadleaved weeds, target rate: 0.04 L/ha

This document serves the registration of Thifensulfuron 75% WG (750 g/L thifensulfuron) in the Central zone of the EU. The objective of this document is to prove and support the label claims of the herbicidal efficacy and crop safety of Thifensulfuron 75% WG in winter cereals, as claimed in the GAP table.

Comprehensive field trials were conducted in Czech Republic, Germany, Slovakia, Poland, Lithuania and Latvia in 2014/15 and 2020 season. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

3.3 Efficacy data

Preliminary tests

No results of the preliminary range findings tests were submitted by the Applicant. The active substance of HIFEN – thifensulfuron methyl is registered and have been commonly used in agricultural practice for many years. A large-scale efficacy trials are available to evaluate the effectiveness of products containing thifensulfuron-methyl as an active compound. Therefore, there was no need for preliminary range findings tests in the opinion of ZRMs.

Minimum effective dose tests

In order to provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least one lower dose(s), for example: 60-80% of recommended dose, to that which would be recommended.

No information on the importance of each of the target weeds (major or minor) in each MS has been provided.

It should be noted that where the proposed use is across a substantive geographical area such as an authorization zone (as defined in PP 1/278 Principles of zonal data production and evaluation), the major

target species and/or major crop may vary and there may be differences in population pressures. Therefore, particular consideration should be given to trials location.

The trials submitted to support the MED of HIFEN (product code 4100 A) are the same as the efficacy trials described under next section.

It is utilized to achieve the desired effect. During field trials Applicant used different doses: 0.010 kg/ha (0.25N); 0.020 kg/ha (0.5N); 0.030 kg/ha (0.75N) and 0.040 kg/ha (N dose). So, in the appropriate researches of efficacy were tested different doses and to register was chosen the lowest effective, which is in line to EPPO 1/225 (2). What is more herbicides containing active ingredient – thifensulfuron-methyl have been allowed to use for many years.

To ensure that a satisfactory level of control is achieved with the proposed dose rate of 0.040 kg/ha, it is recommended that HIFEN is applied under optimal conditions, i.e. early growth stage of the weeds and optimal weather conditions.

In the Maritime EPPO zone following weeds species were studied (application post-emergence, assessment was made 31-36 days after treatment): MATCH (DE-2), LAMPU (4-CZ), GALAP (3-CZ), VERPE (2-CZ), MATIN (3-CZ), PAPRH (1-DE, 2-CZ), POLPE (2-DE), STEME (1-DE, 2-CZ), BRSNW (1-DE), GERDI (1-DE), MYOAR (1-CZ), VERAR (1-DE) and VIOAR (1-DE).

For Maritime EPPO zone classification of weed sensitivity was made in line to SANCO scale.

On the basis on obtained results it has been noted that:

- **for dose 0.010 kg/ha** – lack of weeds classified as a highly susceptible weed, one weed was susceptible (PAPRH), 4 weeds were classified as a moderately susceptible weed (MATCH, STEME, BRSNW, GERDI), one weed was moderately tolerant (POLPE) and two weeds were tolerant (VERAR, VIOAR).
- **for dose 0.020 kg/ha** – lack of weeds classified as a highly susceptible, one weed was susceptible (MATCH), 11 weeds were moderately susceptible (LAMPU, GALAP, VERPE, MATIN, PAPRH, POLPE, STEME, BRSNW, GERDI, MYOAR, VIOAR) and one weed was tolerant (VERAR).
- **for dose 0.030 kg/ha** – one weed was classified as a highly susceptible (MATCH), 7 weeds were susceptible (GALAP, MATIN, POLPE, BRSNW, GERDI, MYOAR, VIOAR), 5 weeds were moderately susceptible (LAMPU, VERPE, PAPRH, STEME, VERAR), lack of weeds moderately tolerant and tolerant.
- **for dose 0.040 kg/ha** – 6 weeds were classified as a highly susceptible (MATCH, LAMPU, VERPE, MATIN, PAPRH, BRSNW) and 7 weeds were susceptible (GALAP, POLPE, STEME, GERDI, MYOAR, VERAR, VIOAR). Lack of weeds moderately susceptible, moderately tolerant and tolerant.

In the N-E EPPO zone following weeds species were studied (application post-emergence, assessment made 15-66 days after treatment): BRSNW (1-PL), CAPBP (4-PL), CENCY (2-PL), GAESS (2-LV), GALAP (2-PL, 2-LT), GEARPU (1-PL), LAMPU (4-PL, 3-LV), MATCH (1-LV), MATIN (6-PL, LT-1, LV-2), MYOAR (PL-1, LV-2), PAPRH (3-PL), POLCO (1-LT), SINAR (1-LT), STEME (3-PL, 3-LT, 1-LV), THLAR (4-PL, LT-2), VERAG (1-PL), VIOAR (6-PL, LT-2, LV-2).

For N-E EPPO zone classification of weed sensitivity was made in line to SANCO scale.

On the basis on obtained results it has been noted that:

- **for dose 0.010 kg/ha** – 2 weed species were classified as a highly susceptible (GAESS, SINAR), 3 weeds were susceptible (CAPBP, POLCO, THLAR), 2 weeds were moderately susceptible (BRSNW, GALAP), 2 weeds were moderately tolerant (GERPU, MATIN, STEME) and 7 weeds were classified as a tolerant weeds (CENCY, LAMPU, MATCH, MYOAR, PAPRH, VERAG, VIOAR).
- **for dose 0.020 kg/ha** – 2 weeds were classified as a highly susceptible (GAESS, SINAR), 3 weeds were susceptible (CAPBP, POLCO, THLAR), 5 weeds were moderately susceptible (BRSNW, GALAP, GERPU, MATIN, STEME), 2 weeds were moderately tolerant (PAPRH, VIOAR) and 5 were tolerant (CENCY, LAMPU, MATCH, MYOAR, VERAG).
- **for dose 0.030 kg/ha** – 2 weeds were classified as a highly susceptible weeds (GAESS, SINAR), 3 weeds were susceptible (CAPBP, POLCO, THLAR), 6 weeds were moderately susceptible (BRSNW, GALAP, GERPU, MATIN, PAPRH, STEME), 4 weeds were moderately tolerant (LAMPU, MATCH, MYOAR, VIOAR) and 2 weeds were tolerant (CENCY, VERAG).

- **for dose 0.040 kg/ha** – 2 weeds were classified as a highly susceptible (GAESS, SINAR), 8 weeds were susceptible (BRSNW, CAPBP, GALAP, GERPU, MATCH, MATIN, POLCO, THLAR), 4 weeds were moderately susceptible (MYOAR, PAPRH, STEME, VIOAR), 1 weed was moderately tolerant (LAMPU) and 2 weeds were tolerant (CENCY, VERAG).

ASSESSMENT OF MED DOSE FOR POLAND (on the basis trials from PL, LT, LV, CZ and DE)

Classification of weed sensitivity was made in Polish rules: S >85%; MS 70-84.9%; MT 60-69.9% and T <60%.

On the basis on obtained results it has been noted that:

- **for dose 0.010 kg/ha** – 5 weeds were characterized by susceptible (CAPBP, GAESS, POLCO, SINAR, THLAR), 5 weeds were moderately susceptible (BRSNW, GALAP, GERDI, PAPRH, STEME), 2 weeds were moderately tolerant (GERPU, MATIN) and 8 weeds were tolerant (CENCY, LAMPU, MATCH, MYOAR, POLPE, VERAR, VERAG, VIOAR).
- **for dose 0.020 kg/ha** – 5 weeds were characterized by susceptible (CAPBP, GAESS, POLCO, SINAR, THLAR), 10 weeds were moderately susceptible (BRSNW, GALAP, GERDI, GERPU, MATIN, MATCH, MYOAR, PAPRH, POLPE, STEME), 1 weed was moderately tolerant (VIOAR) and 4 weeds were tolerant (CENCY, LAPMU, VERAR, VERAG).
- **for dose 0.030 kg/ha** – 8 weeds were characterized by susceptible (BRSNW, CAPBP, GAESS, GERDI, POLCO, POLPE, SINAR, THLAR), 9 weeds were moderately susceptible (GALAP, GERPU, MATIN, MATCH, MYOAR, PAPRH, STEME, VERAR, VIOAR), 1 weed was moderately tolerant (LAMPU) and 2 weeds were tolerant (CENCY, VERAG).
- **for dose 0.040 kg/ha** – 15 weeds were characterized by susceptible weeds (BRSNW, CAPBP, GAESS, GALAP, GERDI, GERPU, MATIN, MATCH, PAPRH, POLCO, POLPE, SINAR, STEME, THLAR, VERAR), 2 weeds were moderately susceptible (MYOAR, VIOAR), 1 weed was moderately tolerant (LAMPU) and 2 weeds were tolerant (CENCY, VERAG).

In the opinion of ZRMs, trials submitted by Applicant are sufficient for MED dose. The clear dose responses were observed for the most of studied weed species. The most effective was dose 0.040 kg/ha.

Summary for MED dose:

Surfactants belong to activating adjuvants. They are well soluble in both water and fats. By lowering the surface tension of the spray liquid, they contribute to increased droplet adhesion and surface wetting. They also facilitate the penetration of herbicide into plant cells through small spaces between wax particles covering the plant surface, thereby increasing the amount of active substance at the site of action. Surfactants can also significantly enhance the effectiveness of herbicides in adverse weather conditions. Surfactants can greatly affect reducing the costs of pesticide application by reducing their dosage, and, importantly, in terms of environmental protection, by reducing the amount and shortening the time of herbicide residue in the soil. However, adjuvants exhibit high specificity in their action towards different herbicides: they can improve their effectiveness, but they can also show no effect or even worsen their performance. Therefore, proper selection of adjuvants is crucial. During efficacy trials in which MED dose was also studied, Applicant used surfactants only in Polish trials (N-E EPPO zone). In trials performed in LT and LV in N-E and from Maritime EPPO zone efficacy was studied in trials carried out without surfactants. Differences in efficacy in trials with and without surfactants were observed. The results varied. In some studies with surfactants, the effectiveness was higher than in studies without them. However, for other weeds, the opposite effect was observed, meaning studies without surfactants showed higher effectiveness than studies with surfactants. So, no clear impact or trend can be determined. Especially since the influence of weather, agro-technical conditions (varying by country), and differing levels of weed infestation cannot be ruled out. However, ZRMs accepts all presented studies. In the next subsection, it presents the average effectiveness rating for all studies submitted by Applicant (with and without surfactants together).

The claimed dose for HIFEN (product code: SHA 4100 A) is rate 0.040 kg/ha. The minimum effective dose was tested in winter cereals. In the Maritime EPPO zone trials were carried out on winter wheat and

winter barley and in N-E EPPO zone on winter wheat and winter rye. The dose 0.040 kg/ha gives control of many of the main weeds in winter cereals.

Lack of MED trials carried out in S-E EPPO zone and MED EPPO zone. Applicant indicated Hungary and Romania as a cMS, but without submitting any MED or efficacy trials for this EPPO zone. So, in the opinion of ZRMs, cMS from S-E should consider the possibility of extrapolating results from other EPPO zone or usage data from st. reference products containing thifensulfuron-methyl as an active compound if such approach can be acceptable to their national rules. The ZRMs acknowledges that the number of trials on which to base the use of out of protection data may vary across MS and that other MS may not have access to out of protection data from similar thifensulfuron-methyl products. If access to data out of protection is not possible or using results from other zone, then the ZRMs would consider the MED post-emergence for S-E EPPO zone to be insufficiently supported,

Efficacy tests and conclusions regarding authorization of intended uses

All details about efficacy methodology used during efficacy trials (in total 18) were presented above by Applicant. Submitted reports were from field trials carried out on winter cereals (winter wheat – 13 trials, winter barley – 4 trials, winter rye – 1 trial) include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying, etc.

Applicant properly presented efficacy results. Only trials with greater than 4-5 weeds/m² or over 2% ground cover should be taken for assessment. According to EPPO PP 1/226 at least 6 fully supportive results for major weeds and 2 trials for minor weeds should be required. Therefore, based on knowledge of major/minor status of weeds in each country, weeds with insufficient results should be excluded. In Poland, 27 PPPs with thifensulfuron methyl are registered and commonly used for protect crops against weeds. So, in line to Polish rules for major weeds – at least 4 trials are required and for minor – at least 2.

According to EPPO 1/181 at least two growing seasons should be studied. Trials from Maritime EPPO zone were carried out in two different growing seasons: 2014/2015 and 2022 but trials from N-E EPPO zone were performed only in one growing season (2014/2015). For Poland, number of trials and number of growing seasons is acceptable due to possibility of usage trials from countries neighbouring to PL from other zones (DE, CZ in this case). cMS from S-E EPPO zone should consider the possibility of extrapolating results from other EPPO zone or usage data from st. reference products contains thifensulfuron methyl as an active compound if such approach can be acceptable to their national rules.

Accepted weed species for Poland (N-E EPPO zone) should be presented to following scale of sensitivity:

- S (susceptible) > 85%,
- MS (moderately susceptible) 70-85%,
- MT (moderately tolerant) 60-70%,
- T (tolerant) <60%.

Accepted by cMS weeds for label should be classified in line to their national rules (ex. SANCO scale for cMS).

Studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief inspector of Plant Health and Seed Inspection and are officially GEP recognized.

The zRMS considers the reference products used to be acceptable. All trials had 4 replicates, a randomised block design and a minimum plot size of 10 m². Water volumes of 200-300 L/ha were tested, which not encompasses the full range proposed in the GAP table (200-400 L/ha). In the opinion of ZRMS, recommended and accepted on the basis on submitted documentation should be 200-300 L/ha water volume.

Applicant proposed following window application: BBCH 13-39 in spring. However during trials following BBCH were studied: 29-30 in the Maritime EPPO zone and 21-32 BBCH in N-E EPPO zone. In the opinion of ZRMs, proposed by Applicant application window BBCH 13-39 can be accepted in compliance with application deadlines for thifensulfuron-methyl for winter cereals based on cereal protection programs.

Studied weed species were presented together for studied winter cereals in Maritime EPPO zone (winter

barley: 4 trials in CZ and winter wheat: 2 trials in DE) and N-E EPPO zone (winter wheat: LT- 3 trials, LV- 2 trials, PL-6 trials and winter rye: 1 trial in LV).

Below, ZRMs presented results from recommended dose of HIFEN and st. reference products:

- ✓ **for winter cereals in Maritime EPPO zone:** classification of weed sensitivity was made in line to SANCO scale

Weed	Number of trials	Level of infestation (no/m ²)	Mean eff at 0.040 kg/ha	St. Ref. Rpdct used during trials
MATCH	2	6.5-8.0	100%	100%
LAMPU	4	7.0-9.0	96.9%	100%
GALAP	3	6.0-7.0	94.2%	100%
VERPE	2	7.0-13.0	100% ³	100%
MATIN	3	7.0-21.0	98.3%	100%
PAPRH	3	7.0-12.0	96.7%	100%
POLPE	2	5.8-8.5	94.6%	94.6%
STEME	3	6.0-11.8	93.3%	100%
BRSNW	1	19.5	100%	100%
GERDI	1	6.3	92.5%	98.3%
MYOAR	1	7.0	93.0%	100%
VERAR	1	22.5	94.8%	92.8%
VIOAR	1	18.8	94.3%	90.0%

HS 95-100 %  S 85-94.9%  MS 70-84.9%  MT 50-69.9%  T 0-49.9% 

Classification marked by colour and eff. of weeds sensitivity according to SANCO rules

All weed species presented above in the table were presented by sufficient level of infestation. So, all trials can be taken for the assessment as a valid.

Weeds represented only by one trial should be excluded from the assessment. Excluded weed species due to very limited number of trials (only one) are: BRSNW, GERDI, MYOAR, VERAR and VIOAR.

cMS should decide about accepted list of weed species on the basis on their major/minor status at national level. Lack of weeds represented at least 6 trials, so major weeds should not be accepted. Following weeds species were characterized by at least 2 trials: LAMPU (4), GALAP (3), MATIN (3), PAPRH (3), STEME (3), MATCH (2), VERPE (2) and POLPE (2). So, cMS should decide at national level about possibility of acceptance them. Also, classified of accepted weed species should be done on national level in line to national rules. Their classification according to the SANCO scale is shown above.

In all submitted trials standard reference products were used. Efficacy of them is presented in the table above. In generally it can be stated that HIFEN (product code: SHA 4100 A) have comparable efficacy or slightly lower effectiveness without affecting the sensitivity classifications of the tested weeds species.

- ✓ **for winter cereals in N-E EPPO zone:** classification of weed sensitivity was made in line to SANCO scale

Weed	Number of trials	Level of infestation (min-max)		Mean eff at 0.040 kg/ha	Chlorsulfuron 49 + Thifensulfuron 469 WG Ref. Prod.		Thifensulfuron 50% SG Ref. Prod.
		Ground (%)	COUPLA (no/m ²)		70 g/ha	90 g/ha	
BRSNW	1	2.3	-	85.0%	83.0%	86.0%	not studied
CAPBP	3	6.0	6.0-7.4	94.0%	92.7%	95.0%	not studied
CENCY	2	-	18.5-43.8	1.3%	18.8%	76.3%	not studied
GAESS	2	2.9-11.3	11.7-16.7	98.5%	not studied	not studied	97.5%
GALAP	3	5.8-22.5	-	86.5%	65.0%	70.0%	92.5%
LAMPU	7	4.5-23.8	4.0-13.7	65.5%	62.4%	66.5%	68.3%
MATCH	1	17.6	87.0	85.0%	not studied	not studied	85.0%
MATIN	9	5.0-47.3	6.3-129.0	87.0%	88.0%	92.3%	82.6%
MYOAR	3	5.0-10.2	58.0-105.7	70.6%	93.0%	93.0%	58.8%
PAPRH	3	4.5	8.4-13.5	82.3%	77.7%	84.3%	not studied
POLCO	1	7.5	-	92.0%	not studied	not studied	94.0%
SINAR	1	30.0	-	99.0%	not studied	not studied	98.5%

STEME	7	6.3-70.0	4.0-112.0	83.0%	74.7%	78.7%	88.3%
THLAR	6	12.5-17.5	4.0-7.6	96.7%	99.8%	99.8%	90.4%
VERAG	1	-	5.2	0.00%	0.00%	10.0%	not studied
VIOAR	10	4.5-17.8	4.0-66.0	72.4%	70.4%	75.8%	69.9%

HS 95-100 % S 85-94.9% MS 70-84.9% MT 50-69.9% T 0-49.9%

Classification marked by colour and eff. of weeds sensitivity according to SANCO rules

Most weed species presented above in the table were presented by sufficient level of infestation. Only in one trial against CAPBP (trial: SH15PZ120B), GALAP (trial: SH15PZ119B) and GERPU (trial: SH15PZ119B) the level was not sufficient (only at level 3.0/m², whilst at least 4-5 should be noted). Trials with insufficient level of infestation were not taken for the assessment and their results were not included in the table above.

Weeds represented only by one trial should be excluded from the assessment. Excluded weed species due to very limited number of trials (only one) are: BRSNW, GERPU, MATCH, POLCO, SINAR and VERAG.

cMS should decide about accepted list of weed species on the basis on their major/minor status at national level. LAMPU (7), MATIN (9), STEME (7), THLAR (6) and VIOAR (10) were characterized by at least 6 trials. Following weeds species were characterized by at least 2 trials: CENCY (2), CAPBP (3), GAESS (2), GALAP (3), MYOAR (3) and PAPRH (3). So, cMS should decide at national level about possibility of acceptance them. Also, classified of accepted weed species should be done on national level in line to national rules. Their classification according to the SANCO scale is shown above.

In all submitted trials standard reference products were used. Efficacy of them is presented in the table above. In generally it can be stated that HIFEN (product code: SHA 4100 A) have comparable efficacy or slightly lower effectiveness than st. ref. products.

ASSESSMENT OF HIFEN EFFICACY FOR POLAND (trials from PL, LT, LV, CZ and DE):

For Poland we can take into assessment results from neighbouring countries to PL from other zone. So, below ZRMs presented valid trials together for PL, DE and CZ.

Only trials with at least 4-5 number of weeds per meter ground or at least 2% ground cover were taken for the assessment by ZRMs.

- ✓ **for winter cereals in Poland (N-E EPPO zone):** classification of weed sensitivity was made in line to Polish rules

Weed	Number of trials	Mean eff at 0.040 kg/ha	Chlorsulfuron 49 + Thifensulfuron 469 WG Ref. Prod.		Thifensulfuron 50% SG Ref. Prod. 1N	St. Ref. Rproduct used during trials
			70 g/ha	90 g/ha		
BRSNW	2	92.5%	83.0%	86.0%	not studied	100%
CAPBP	3	94.0%	92.7%	95.0%	not studied	not studied
CENCY	2	1.3%	18.8%	76.3%	not studied	not studied
GAESS	2	98.5%	not studied	not studied	97.5%	not studied
GALAP	6	90.4%	65.0%	70.0%	92.5%	100%
GERDI	1	92.5%	not studied	not studied	not studied	98.3%
LAMPU	7	65.5%	62.4%	66.5%	68.3%	100%
MATIN	12	92.7%	88.0%	92.3%	82.6%	100%
MATCH	3	92.5%	not studied	not studied	85.0%	100%
MYOAR	4	81.8%	93.0%	93.0%	58.8%	100%
PAPRH	6	89.5%	77.7%	84.3%	not studied	100%
POLCO	1	92.0%	not studied	not studied	94.0%	not studied
POLPE	2	94.6%	not studied	not studied	not studied	94.6%
SINAR	1	99.0%	not studied	not studied	98.5%	not studied
STEME	10	88.2%	74.7%	78.7%	88.3%	100%
THLAR	6	96.7%	99.8%	99.8%	90.4%	not studied
VERAR	1	94.8%	not studied	not studied	not studied	92.8%
VERAG	1	0.0%	0.00%	10.0%	not studied	not studied
VIOAR	11	83.4%	70.4%	75.8%	69.9%	90.0%

S 85-100% MS 70-84.9% MT 60-69.9% T < 60%

Classification marked by colour and eff. of weeds sensitivity according to Polish rules

Most weed species presented above in the table were presented by sufficient level of infestation. Only in one trial against CAPBP (trial: SH15PZ120B), GALAP (trial: SH15PZ119B) and GERPU (trial: SH15PZ119B) the level was not sufficient (only at level 3.0/m², whilst at least 4-5 should be noted). Trials with insufficient level of infestation were not taken for the assessment and their results were not included in the table above.

Weeds represented only by one trial should be excluded from the assessment. Excluded weed species due to very limited number of trials (only one) are: GERDI, GERPU, POLCO, SINAR, VERAG and VERAR.

Also, CENCY should be excluded from label. It is a major weed in winter cereals, not sufficient number of trials were presented (required is at least 4, whilst submitted were only 2). BRSNW is excluded for winter wheat, winter triticale and winter barley.

GAESS – It is a minor weed in winter cereals. On the basis on 2 trials it can be accepted as a sensitive weed against HIFEN at dose 0.040 kg/ha. However, this weed cannot be included in Polish label in line to harmonization findings. The weed susceptibility classification refers to the species of the weed in question (e.g. *Galeopsis tetrahit*) and not to its genus (e.g. seedpods), family (e.g. buttercups) or weed group.

For major weeds at least 4 valid trials are required in PL, and for minor weeds at least – 2 valid trials.

Following weeds can be accepted in Polish label:

BRSNW – 2 trials – it is a major weed in winter wheat, winter barley, winter triticale and a minor weed in winter rye. On the basis on 2 trials it can be only accepted in winter rye as a sensitive weed against HIFEN at dose 0.040 kg/ha.

CAPBP – 3 trials – it is a minor weed in winter cereals. On the basis on 3 valid trials it can be accepted as a sensitive weed against HIFEN at dose 0.040 kg/ha.

GALAP – 6 trials – it is a major weed in winter cereals. On the basis on 6 trials it can be accepted as a sensitive weed against HIFEN at dose 0.040 kg/ha.

LAMPU – 7 trials – it is a minor weed in winter cereals. On the basis on 7 trials it can be accepted as a moderately tolerant weed against HIFEN at dose 0.040 kg/ha.

MATIN – 12 trials – it is a major weed in winter cereals. On the basis on 12 trials it can be accepted as a sensitive weed against HIFEN at dose 0.040 kg/ha.

MATCH – 3 trials – it is a minor weed in winter cereals. On the basis on 3 trials it can be accepted as a sensitive weed against HIFEN at dose 0.040 kg/ha.

MYOAR – 4 trials – it is a minor weed in winter cereals. On the basis on 4 trials it can be accepted as a moderately sensitive weed against HIFEN at dose 0.040 kg/ha.

PAPRH – 6 trials – it is a major weed in winter wheat, winter barley, winter triticale and is a minor weed in a winter rye. On the basis on 6 trials it can be accepted as a sensitive weed against HIFEN at dose 0.040 kg/ha.

POLPE – 2 trials – it is a minor weed in winter cereals. On the basis on 2 trials it can be accepted as a sensitive weed against HIFEN at dose 0.040 kg/ha.

STEME – 10 trials – it is a minor weed in winter cereals. On the basis on 10 trials it can be accepted as a susceptible weed against HIFEN at dose 0.040 kg/ha.

THLAR – 6 trials – it is a minor weed in winter cereals. On the basis on 6 trials it can be accepted as a susceptible weed against HIFEN at dose 0.040 kg/ha.

VIOAR – 11 trials – it is a major weed in winter wheat, winter barley, winter triticale and a minor weed in winter rye. On the basis on 11 trials it can be accepted as moderately susceptible weed against HIFEN at dose 0.040 kg/ha.

In all submitted trials standard reference products were used. Efficacy of them is presented in the table above. In generally it can be stated that HIFEN (product code: SHA 4100 A) have comparable efficacy or

slightly lower effectiveness than st. ref. product used during trials.

Accepted list of weed species and their sensitivity for Polish label against recommended dose (0.040 kg/ha) of HIFEN:

- ✓ *Susceptible weeds:* BRSNW (only in winter rye), CAPBP, GALAP, MATIN, MATCH, PAPRH, POLPE, STEME, THLAR;
- ✓ *Moderately sensitive weeds:* MYOAR, VIOAR;
- ✓ *Moderately tolerant weeds:* LAMPU.

Conclusions for cMS and Poland: The claimed dose for HIFEN (product code: SHA 4100 A) is rate 0.040 kg/ha. In the Maritime EPPO zone trials were carried out on winter wheat and winter barley and in N-E EPPO zone on winter wheat and winter rye. The dose 0.040 kg/ha gives control of many of the main weeds in winter cereals. **On the basis on submitted documentation winter wheat** (13 efficacy trials: PL-6, LT-3, LV-2, DE-2 and 11 selectivity trials: PL-4, LV-3, DE-2, SK-2), **winter barley** (4 efficacy trials: CZ and 12 selectivity trials: DE-2, LT-1, LV-3, PL-4, SK-2), **winter rye** (1 eff. trial: LV and 9 selectivity trials: PL-6, LT-1, CZ-2) and **winter triticale** (0 eff. trial and 9 selectivity trials: CZ-2, LT-1, PL-6). Also, **winter oat can be accepted** in PL label on the basis on 0 eff. trials and 7 selectivity trials (PL-6, CZ-1). Even if no eff. trials is presented for winter cereal species (oat, triticale in this case) or very limited eff. trials (winter barley: 4 trials, winter rye: 1 trial) then extrapolating results from other winter cereal (for example from winter wheat) is possible when at least 3-4 selectivity trials were presented for each crop. Those extrapolation is possible in line to Polish harmonization agreements.

Lack of efficacy trials carried out in S-E EPPO zone. Applicant indicated Hungary and Romania as a cMS, but without submitting any efficacy trials from this zone. So, in the opinion of ZRMs cMS from S-E should consider the possibility of extrapolating results from other EPPO zone or usage data from st. reference products contains thifensulfuron methyl as an active compound if such approach can be acceptable to their national rules. The zRMS acknowledges that the number of trials on which to base the use of out of protection data may vary across MS and that other MS may not have access to out of protection data from similar thifensulfuron-methyl products. If access to data out of protection is not possible or using results from other zone, then the zRMS would consider the post-emergence for S-E EPPO zone to be insufficiently supported. However, **we encourage the regulatory authorities (cMS) to consider the possibility of extrapolating efficacy studies from another zone, especially since the Applicant has provided selectivity studies for the specified crops in the GAP table: for winter wheat (4 trials: SK-2, HU-2), winter triticale (3 trials: HU), winter barley (4 trials: HU-2, SK-2), winter rye (4 trials: HU) and winter oat (4 trials: HU).**

As only efficacy studies with a surfactant (Trend 90 EC applied at a dose of 0.1% (100ml/100 L water) were presented for Polish trials carried out on winter wheat and no clear additional effect on the reported efficacy has been demonstrated (e.g. in comparison with studies on winter wheat in other north-eastern countries – LT, LV), it is recommended that no recommendation for use with an adjuvant/surfactant be included in the product label. Especially, when in some selectivity trials with surfactant some phytotoxicity effect was observed. The Applicant has not included in either the GAP or the draft label any recommendations regarding the use of adjuvants/surfactants, and therefore no changes to the label, including deletions, need to be made.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Resistance to pesticides is the major threat. As the number of approved actives decreases the likelihood of resistance build-up increases as the number of modes of action in use decreases. Examples of resistance can be found across the categories of PPPs. Being a biological process, the future development of resistance is not easy to predict. It interacts in complex ways with the 'toolkit' of PPP available, and the farming practices employed. However, the trajectory of build-up is unlikely to improve from that seen

over recent years and could well get worse. For thifensulfuron-methyl the risk of loss can be considered as low/medium.

Resistance is the naturally occurring inheritable ability of some weed biotypes within a given weed populations to survive an herbicide treatment that should, under normal use conditions, effectively control weed population.

The major reason herbicides are selective against weeds in crops is because crop plants are able to metabolize the herbicide to a non-toxic form. The basis for herbicides selectivity relies on enzymatic system present in the plant's normal metabolic processes. There are several processes in plants which can lead to resistance (target site alternations, enhanced metabolism, changes in uptake and translocation).

Immunity risk assessments should be presented in accordance with the standard: EPPO PP1 PP 1/213 (4) resistance risk analysis. Applicant properly presented the risk of resistance against thifensulfuron-methyl in the opinion of ZRMS.

Below, ZRMs present the performed risk assessment of resistance development. Thifensulfuron-methyl is an herbicide, which acts by inhibition of acetolactate synthase, It belongs to HRAC group 2 (Legacy group B).

In terms of mode of action, thifensulfuron-methyl act as inhibitors of acetolactate synthase. ALS,(acetohydroxyacid synthase AHAS). It is the sulfonyleurea urea class. The sulfonyleureas are the largest chemical class within this group. There are mainly three groups of amino acid synthesis inhibitors commonly used as herbicides: the sulfonyleureas, the imidazolinones and aminoacid derivative herbicide families. Sulfonyleurea herbicides inhibit the production of three essential branch-chain amino acids by inhibiting one key plant enzyme. This key plant enzyme is called acetolactate synthase (ALS) or acetohydroxy acid synthase (AHAS). In general, injury symptoms due to the use of herbicides with this mode of action are slow to develop (one or two weeks) and include stunting or delayed plant growth, leading to eventual death of the plant. Herbicides in the sulfonyleurea family can be taken up through plant foliage and roots and are mobile in both xylem and phloem.

Group B/2 herbicides bind to the substrate binding site of the acetolactate synthase (ALS) enzyme, thus preventing the production of essential amino acids, and without these amino acids, the plant eventually dies. The mechanism of resistance found against sulfonyleureas is a so-called target site mechanism. Target site resistance is caused by mutation on the enzyme at the site where the herbicide molecule binds, thus stopping the plant's normal biochemical processes.

Resistance against B/2 herbicides is known for various species. In the database of www.weedscience.org – 93 cases of resistance against thifensulfuron-methyl are documented.

Since ALS inhibiting herbicides were introduced, they have mainly been targeted at broadleaves weeds. Targeting has mainly been through selection with sulfonyleurea herbicides (presumably because they have been in commercial use for the longest period). In the vast majority of cases of resistance following selection with sulfonyleurea herbicides, the resistance mechanism is a change in the target site enzyme ALS (reviewed by Saari et al., 1994). In most cases, the sulfonyleurea resistant biotypes with resistant ALS enzyme exhibit varying levels of target site cross resistance to the chemically dissimilar but ALS inhibiting imidazolinone and/or triazolopyrimidine herbicides (Hall and Devine, 1990; Christopher et al., 1992; Saari et al., 1990, 1992, 1994).

There are several multiple resistance reported within the group sulfonyleureas, but only *Kochia scoparia* is affected with the chemicals focused on this report.

According to HRAC, sensitivity monitoring was carried out in Austria, France, Spain, Portugal, Italy, Germany and Australia in commercial fields. Other information in context of sensitivity data is reported on [https://hracglobal.com/files/Monitoring-and-Mitigation-of-Herbicideresistance .pdf](https://hracglobal.com/files/Monitoring-and-Mitigation-of-Herbicideresistance.pdf).

As sulfonyleureas, actives belong to a HRAC group with a high resistance risk. Several dicotyledonous weed species have been reported with resistance to ALS inhibitors worldwide and also in Europe. Most of these were found to be resistant to sulfonyleureas. **The inherent risk of thifensulfuron-methyl has to classified as high.**

Resistance may be a result of repeated use of the same herbicide, or several herbicides with the same mode of action and is often associated with crop monoculture as well as reduced cultivation practices. For instance, increasing infestation of *Alopecurus myosuroides* and *Apera spica-venti* is associated with continuous winter cereal production, minimal cultivation and/or direct drilling. Furthermore, seeds of *A. myosuroides* and *A. spica-venti* are spread widely in the field through modern harvesting equipment.

The principle of crop rotation as a resistance management tool is to avoid successive crops in the same field which require herbicides with the same mode of action for control of the same weeds species.

Cultural (or non-chemical) weed control methods do not exert a chemical selection pressure and assist greatly in reducing the soil seed bank. Cultural techniques must be incorporated into the general agronomy of the crop and other weed control strategies.

The use of chemical mixtures to prevent resistance: Mixtures can be a useful tool in managing or preventing the establishment of resistant weeds.

For chemical mixtures to be effective, they should include active ingredients which both give high level of control of the target weeds, and include active ingredients with different modes of action.

Conclusions on risk of the possible occurrence of the development of resistance or cross-resistance:

- ✓ The product has a high inherent and agronomical risk for resistance weed development,
- ✓ A resistance risk management as proposed by the HRAC will avoid resistance of weeds to HIFEN,
- ✓ Experts of the HRAC follow development on potential resistance issues for sulfonylurea herbicides very closely,
- ✓ Recommendations of the HRAC will be followed in labelling:
 - “When herbicide with the same mode of action are used repeatedly over several years in the same field, selection of resistance biotypes can take place. These can propagate and may become dominating. A weed species is considered resistant to a herbicide if it survives a correctly applied treatment at the recommended dose.
 - Development of resistance within a weed species can be avoided or delayed by sequencing or tank mixing with suitable products having a different mode of action.
 - A strategy for preventing and managing resistance should be adopted”.

In order to minimize the risk of occurrence and development of herbicide weed resistance we should follow Good Agricultural Practice:

- ✓ Follow strictly the directions provided in the plant protection product label.
- ✓ Plant protection product should be used at the recommended dose in the recommended time to ensure optimum weed control.
- ✓ Use integrated weed control practices covering fields such as history crop rotation, herbicides used and various tillage (mechanical, cultural, biological and chemical).
- ✓ Use rotation of herbicides (active substances) with different mechanism of action.
- ✓ Use a mixture of herbicides (active substances) with different mechanism of action, use herbicide acting on several life processes in rotation and/or mixture weeds (with different mechanisms of action).

In the opinion of ZRMs, each cMS can change or adjust risk assessment considering the national requirements and may designate additional measures relating to resistance prevention on the national level.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

In the evaluation process the fact that the active ingredient – thifensulfuron methyl is used in many plant protection products and have been commonly used in crop protection were taken into consideration by ZRMs.

The Applicant submitted in total 63 selectivity trials (N-E EPPO zone: 35 trials; Maritime EPPO zone: 9 trials and S-E EPPO zone: 19 trials) conducted on herbicide – HIFEN) product code: SHA 4100 A) containing thifensulfuron-methyl as an active compound. The selectivity evaluation of the herbicide is to be performed according to listed below EPPO guidelines. The evaluation of herbicide selectivity was carried out 4-5 per season. Results were described in percent of destruction of plant for herbicides treatment compared to plant for untreated, where 0% means no phytotoxicity and 100%-complete destruction.

Phytotoxicity assessment was carried out with the use of different cultivars (commercially grown varieties). Dosage N (recommended) and 2N (doubled recommended) were studied during selectivity trials. Experimental details and assessment methods were in line to EPPO standards. Detailed information's were presented by Applicant.

Selectivity trials were performed on winter wheat (12 trials: MAR-1, N-E-7, S-E-4), winter barley (15 trials: MAR-3, N-E-8, S-E-4) and winter oat (11 trials: MAR-1; N-E-6; S-E-4).

Winter wheat: No adverse effects in regard to phytotoxicity were observed in all selectivity trials.

Winter barley: No adverse effects in regard to phytotoxicity were observed in all selectivity trials, in the exception on one trial carried out in N-E EPPO zone. In this trial in the first week following the application of the herbicides Bartosz winter barley developed properly (HORVW – BBCH 31-32), with no adverse effects and delays in its growth and development. Over the next weeks, the sites treated and delays in its growth and development. Over the next weeks, the sites treated with herbicides experienced 5-20% delay in growth of winter barley. Winter barley growth delays of 10-20% were first discovered in the sites treated with the double doses of the test products and a week later 5-8% growth delays were reported for the sites treated with the recommended dose of the product. 4-5 weeks after the application of product, when winter barley crop was at the stages of heading and blooming, the trial also found deformities of the flag leaves and heads (recommended rates: 3-5%, double rates: 6-11%), which somewhat subsided in the following weeks (recommended rates: 0-1%, double rates 0.3-4%).

In the most trials no negative effects were observed. So, in the opinion of ZRMs it can be concluded that HIFEN applied at recommended dose is safe for winter barley crops. It may be worth considering including a note on the label stating that some winter barley may be sensitive against HIFEN (ex. Variety Bartosz).

Winter triticale: No adverse effects in regard to phytotoxicity were observed in all selectivity trials.

Winter rye: No adverse effects in regard to phytotoxicity were observed in all selectivity trials.

Winter oat: No adverse effects in regard to phytotoxicity were observed in all selectivity trials.

In most of the assessments no phytotoxicity symptoms were observed for any tested dosage for all tested crops. The same observations was noted against st. ref. products. Only in one trial performed on winter barley in N-E EPPO zone negative effect of HIFEN was observed. In the opinion of ZRMs it can be concluded that HIFEN applied at recommended dose is safe for winter cereals without any negative effect on the plants. However, it may be worth considering including a note on the label stating that some winter barley (ex. variety Bartosz) may be sensitive against HIFEN. Some selectivity studies have looked at HIFEN alone and with surfactant. They did not find any negative effect of the product used alone or with the surfactant on the treated cereals. Therefore, a statement on the susceptibility of a particular winter barley variety should be included in the label in the opinion of ZRMs.

Effects on yield

In the opinion of ZRMs, submitted trials by Applicant are sufficient for N-E EPPO zone and should be acceptable for claimed cMS from S-E EPPO zone. cMS from Maritime EPPO zone is not claimed, trials for this EPPO zone seems to be not acceptable due to their limited number.

Impact of HIFEN (product code: SHA 4100 A) on yield was evaluated during 63 selectivity trials carried out in Maritime EPPO zone (9 trials), N-E EPPO zone (35 trials) and S-E EPPO zone (19 trials). The evaluation was carried out in accordance with EPPO guidelines.

For winter wheat – Applicant presented 13 trials (DE-2, HU-2, SK-2, LV-3, PL-4), winter barley – 14 trials (DE-2, HU-2, LT-1, LV-3, PL-4, SK-2), winter oat – 11 trials (CZ-1, HU-4, PL-6), winter rye – 13 trials (CZ-2, HU-4, LT-1, PL-6) and winter triticale – 12 trials (CZ_2, HU-3, LT-1, PL-6).

HIFEN (Thifensulfuron 75% WG) applied at the recommended dose rate (40 g/ha) did not significantly affect crop yield in the vast majority of the 63 trials conducted on winter cereals. Additionally, in most of the trials, Thifensulfuron 75% WG applied at dose rates higher than the recommended rate, representative of sprayer overlap, did not significantly affect crop yield.

In the following trials the negative impact of HIFEN on the yield was observed:

1) In one Polish trial conducted on the variety Bogatka, Thifensulfuron 75% WG applied with a surfactant caused a significant reduction in yield in the plots treated with the recommended dose rate (40 g/ha). However, as no significant reduction was observed in the plots treated with the overlapping dose rate (80 g/ha), it is assumed that the differences observed were not treatment related. In the trial where reduced yield was recorded, no adverse effects, such as PHYGEN, were observed. The differences were significant only on object 2. There was no significant differences between treatments in results concerning moisture, bulk density of grain and thousand grain weight compared to the untreated plot and standard herbicide.

2) In one Polish trial, conducted on the variety Bartosz, all four treatments, which were applied with surfactant, cause a significant reduction in yield. In the trial where reduced yield was recorded, adverse effects as general phytotoxicity, stunting, as well as deformation of flag-leaf as well as ear. The symptoms were visible for the duration of the trial. The results obtained from the trial showed a significant decrease in grain yield and TGW of Bartosz winter barley across all sites treated with herbicides.

In the opinion of ZRMs it can be concluded that HIFEN applied at recommended dose is safe for winter cereals, without any negative effect on the yield. However, it may be worth considering including a note on the label stating that some winter barley (ex. variety Bartosz) and winter wheat (ex. variety Bogatka) may be sensitive against HIFEN.

The possibility of usage data from st. reference products contains thifensulfuron methyl as an active compound should be assessed on the national level. The zRMS acknowledges that the number of trials on which to base the use of out of protection data may vary across MS and that other MS may not have access to out of protection data from similar thifensulfuron-methyl products. For Poland this approach is not acceptable, especially without the full package of bridging trials and without rearranging the access list to the requested data.

Some selectivity studies have looked at HIFEN alone and with surfactant. They did not find any negative effect of the product used alone or with the surfactant on the treated cereals. Therefore, a statement on the susceptibility of a particular winter barley variety and winter wheat variety should be included in the label in the opinion of ZRMs.

Effects on the quality of yield

In the most of selectivity trials (in total 63) no detrimental effect on the quality of yield was recorded at the proposed dose rate and even at the double dose rate. Application of HIFEN (product code: SHA 4100 A) provided a quality of yield similar to the untreated plots and those treated with the reference products. No statistical differences were observed between untreated and treated plots and also between the tested

product and the standard products. Parameters such as a hectolitre weight, thousand grain weight, protein content and moisture content was assessed during selectivity trials.

In the following trials the negative impact of HIFEN on the quality of yield was observed:

1) In one Polish trial carried out on winter barley, where also reduced yield as well as adverse effects as reduction in general crop health (PHYGEN) was observed, a significant reduction in thousand grain weight was recorded for both treatments with the test products as well as both treatments of the reference product (Chisel Nowy 51.6 WG at 70 and 130 g/ha). The results obtained from the trial showed a significant decrease in grain yield and TGW of Bartosz winter barley across all sites treated with herbicides.

In the opinion of ZRMs, it can be concluded that HIFEN applied at recommended dose is safe for winter cereals without any negative effect on the quality of yield. However, it may be worth considering including a note on the label stating that some winter barley (ex. variety Bartosz) may be sensitive against HIFEN.

The possibility of usage data from st. reference products containing thifensulfuron-methyl as an active compound should be assessed on the national level. The ZRMs acknowledges that the number of trials on which to base the use of out of protection data may vary across MS and other MS may not have access to out of protection data from similar thifensulfuron-methyl products. For Poland this approach is not acceptable, especially without the full package of bridging trails and without rearranging the access list to the requested data.

Effect on transformation processes

Primary processing involves several different processes, designed to clean, sort and remove the inedible fractions from the grains. Primary processing of cereals includes cleaning, grading, hulling, milling, pounding, grinding, tempering, parboiling, soaking, drying, sieving. Secondary processing of cereals (or 'adding' value to cereals) is the utilisation of the primary products (whole grains, flakes or flour). Secondary processing of cereals includes the following processes: fermentation, baking, puffing, flaking, frying and extrusion.

According to EPPO 1/243 in the case of low or lack of residues in grain, it can be concluded that if the Applicant can demonstrate that the residues of plant protection products are trace amounts or that they will not impact yeast, supported by arguments, a case-by-case basis may be sufficient to meet these requirements. Data from preliminary screening of biological activity can provide valuable evidence of no impact on yeast or lactic acid bacteria. However, their absence seems acceptable given that thifensulfuron-methyl has been used for many years on cereals, and market available product labels do not contain warnings that the product may affect processing processes.

Summary: In the opinion of ZRMs, no negative impact of HIFEN on transformation processes is expected when PPP will be used in line to accepted GAP table and label project. Also, as no quantifiable thifensulfuron-methyl residues (<LOQ of 0.01 mg/kg) were found in any cereal samples at the time of harvest. Therefore, no processing study is required.

Impact on treated plants or plant products to be used for propagations

The impact of thifensulfuron methyl on the propagating purposes of cereals (such a wheat, barley and rye) can be generally considered to be minimal when the herbicide is used according to label's recommendation.

Thifensulfuron methyl is a type of sulfonylurea herbicide that inhibits the activity of acetolactate synthase (ALS), an enzyme essential for the biosynthesis of branched-chain amino acids in plants. This inhibition selectivity affects the growth of certain weeds.

It's essential for farmers to carefully read and follow the instructions provided on the herbicide label and consult with agricultural extension services or agronomists for specific guidance tailored to their region and crops. Additionally, carried out field studies on studies against germination may provide more detailed information about impact on the propagating purposes.

Propagating material originating from crops examined for selectivity (both with a normal and increased dose) should be assessed for phytotoxic effects by comparison with a reference product and a crop where

the agent was not applied. Table 2 in EPPO 1/135 (4) presents the circumstances in which information regarding plant parts intended for propagation is required. The impact on viability, germination capability, and seed development should be confirmed by standard seed testing methods (ISTA). Depending on the results, conducting further studies under controlled conditions or field conditions may be useful, following the methods outlined above in section 5. The impact on vegetative propagating material is assessed using methods outlined in specific standards for particular crops. According to Table 2 from EPPO 1/135 for herbicides applied foliar post-emergence the seed germination tests were required.

To ascertain that the applied treatments do not impact the germination of grains from treated cereal plants, the results of germination tests conducted on harvested grains from seven selectivity trials were incorporated into this dossier. The trials encompassed winter wheat (2), winter barley (3), winter rye (1), and winter triticale (1) in both the North-east EPPO zone (3 trials, i.e., Lithuania) and the South-east EPPO zone (4 trials, i.e., Slovakia). No reduction in the germination rate of grains was recorded in treated plots compared to untreated plots during those trials. **On the basis on data from selectivity trials and lack of phytotoxicity effects observed during trials and results from GERMIN tests, it can be concluded that HIFEN (product code: SHA 4100 A) can be considered as a safe PPP for propagating purposes of cereals.**

3.3.3 Observations on other undesirable or unintended side-effects

Impact on succeeding crops.

The EU requirements on plant protection products requires, that sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection products on succeeding crops if studies and evaluations presented in the other part of dossier, show that significant residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials up to sowing or planting time of possible succeeding crops. Therefore, the Applicant should present the assessment of the possible effect of HIFEN (product code: SHA 4100 A) on crops grown as rotational or replacement crops following crops treated with that product, prepared in line to EPPO Standard Efficacy evaluation of plant protection products.

Effects on succeeding crops (PP 1/207). This standard is intended as a general standard on the methods used to examine whether the active substance of a plant protection product can cause negative effects on crops grown after a crop treated with that products. These crops can be grown as normal rotational crops as well as replacement crops in case of crop failure.

Thifensulfuron methyl is designed to target certain broadleaf weeds by inhibiting the growth of their acetolactate synthase (ALS) enzyme. It is generally considered selective for broadleaf weeds and has a limited impact on grasses when used as directed. However, it's essential to follow the product label instructions carefully to minimize the risk of unintended effects on succeeding crops or non-target plants.

Component of HIFEN is known for long time and is commonly used for control weeds in cereal crops. In the opinion of ZRMS, restrictions on rotational crops are well-known. According to the scientific data, the half dissipation time (DT₅₀) of thifensulfuron-methyl in soil is very short: 3-20 days in the field conditions and 0.85-3.1 days in laboratory conditions. So, it can be assumed that the herbicide HIFEN (product code: 4100 A) is degraded in the soil during the growing season to a level that does not pose a risk to a succeeding crops.

ZRMs agree with Applicant that *“HIFEN (product code: SHA 4100 A) has little residual activity and, when used as recommended, there are no restrictions on crops which can be sown in normal rotation following treated cereals. In the event of crop failure for any reason, cereals or grass should only be sown within one month application.”*

Impact on other plants including adjacent crops

The impact of an herbicide containing thifensulfuron-methyl on adjacent crops can vary based on several factors, including the sensitivity of the crops, application rates, timing, environmental conditions, and the

herbicide formulation. Thifensulfuron-methyl is a selective herbicide commonly used to control broadleaf weeds in various crops.

The HIFEN (product code: SHA 4100 A) is effective against some dicotyledonous weeds. In this situation, this plant protection product may also cause discoloration and damage to non-target foliage plants, including adjacent crops. Based on the probabilistic risk assessment, the risk for non-target terrestrial plants is considered acceptable if nozzles providing a drift reduction of 75% are taken into account, or a buffer zone of 5m. If thifensulfuron-methyl is applied with a surfactant, the risk for non-target terrestrial plants is considered acceptable if nozzles providing a drift reduction of 50% and a buffer zone of 5m are taken into account, or a buffer zone of 10m.

Detailed assessment about impact on adjacent crops is presented in other section: Ecotoxicology (Part B, Section 9).

The information in this registration report and label warns against overlapping and drift of the spray liquid is sufficient in the opinion of ZRMs.

Effects on beneficial and other non-target organisms

During the course of the trial non-target organisms did not occur in significant amount during eff. and selectivity trials submitted by Applicant. No effects on non-target organisms were observed. No effects on adjacent crops were observed during trial conduct.

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarized in Ecotoxicology section

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

The method of analysis of thifensulfuron-methyl in the test item HIFEN (SHA 4100 A) has been successfully validated according to SANCO/3030/99 rev. 4 and 5. For details see dRR Part B5.

3.4.2 Analytical methods for residues

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

Noticed data gaps are:

- Analytical methods for animal matrices and for body fluids and tissues (these methods were not provided during EU review).
- ILV method for drinking water (this method was not provided during EU review).

Above methods will be required when renewing the product.

Commodity/crop	Supported/ Not supported
High starch content (Winter cereals (wheat, barley, rye, oats, triticale)	Supported

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity for Thifensulfuron 75% WG were not evaluated as part of the EU review of Thifensulfuron-methyl. Therefore, all relevant data were provided and are considered adequate.

The toxicological classification of Thifensulfuron Methyl 75% WG is derived from calculations and ex-

perimental data with the formulation for the eye irritation properties.

3.5.1 Acute toxicity

All relevant data were provided and are considered adequate.

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat	> 2000 mg/kg bw	Yes	None	Calculated (additivity formula)
LD ₅₀ dermal, rat	> 2000 mg/kg bw	Yes	None	Calculated (additivity formula)
LC ₅₀ inhalation, rat	> 5 mg/L air	Yes	None	Calculated (additivity formula)
Skin irritation, rabbit	Non-irritant	Yes	None	Calculated (additivity formula)
Eye irritation, rabbit (OECD 405)	Non-irritant	Yes	None	Shreyas S. Patel, 2016
Skin sensitisation, guinea pig	Non-sensitising	Yes	None	Calculated (additivity formula)

3.5.2 Operator exposure

Operator exposure to SHA 4100 A/ HIFEN was not evaluated as part of the EU review of Thifensulfuron-methyl for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential operator exposure have been undertaken for Thifensulfuron-methyl using EFSA OPEX and default dermal absorption values (10% concentrate and 50% dilution).

Conclusions: According to the estimation based on AOEM (calculator version: 1.0.1), the use of SHA 4100 A / HIFEN containing Thifensulfuron-methyl (750 g/kg) causes acceptable health risk for unprotected operator. The potential exposure to the active substance amounts to the value significantly lower than the AOEL for Thifensulfuron-methyl. Taking into account the hygienic rules governing the handling of pesticides, protective gloves and work wear during M&L and work wear during product application is recommended.

Thus, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label:

„Stosować rękawice ochronne oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu”

“Wear protective gloves and work wear (coverall) during mixing/loading and work wear during application”.

3.5.3 Worker exposure

Worker exposure to SHA 4100 A/ HIFEN was not evaluated as part of the EU review of Thifensulfuron-methyl for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential worker exposure have been undertaken for Thifensulfuron-methyl using EUROPOEM II and EFSA OPEX and default dermal absorption values

(10% concentrate and 50% dilution).

Conclusion: According to the estimations, the use of SHA 4100 A /HIFEN containing Thifensulfuron-methyl (750 g/kg) does not cause unacceptable health risk for unprotected worker (inspection, 2h) because the exposure level to the active substances is below the AOEL value.

Nevertheless, it is forbidden to re-enter area treated with SHA 4100 A /HIFEN until spray deposit on plant surfaces has dried.

Bearing in minds the hygienic rules, the use of work wear and protective gloves is recommended by the evaluator during inspection of the treated area.

3.5.4 Bystander and resident exposure

Bystander and resident exposure to SHA 4100 A/ HIFEN was not evaluated as part of the EU review of Thifensulfuron-methyl for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential residents and bystander's exposures have been undertaken for Thifensulfuron-methyl using EFSA OPEX and default dermal absorption value (10% concentrate and 50% dilution).

Conclusion: The incidental short-time exposure of bystander and resident (children and adult) to Thifensulfuron-methyl contained in the formulation SHA 4100 A /HIFEN causes no risk to human health if the product is used in accordance to the intended uses listed in the GAP Table.

Implication for labelling: Buffer zone: 2-3m

3.6 Residues and consumer exposure (Part B, Section 7)

The preparation Thifensulfuron 75% WG is composed 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

3.6.1 Residues

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.

3.6.2 Consumer exposure

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.

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

TMDI (% ADI) according to EFSA PRIMo (Rev 3.1)	12 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo (Rev 3.1)	-
IENTI (% 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) **	-

3.7 Environmental fate and behaviour (Part B, Section 8)

Concentrations of Thifensulfuron-methyl in various environmental compartments are predicted following the proposed use pattern. The predicted concentrations (PEC value) in soil, surface water, sediment and ground water are provided.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} calculations have been conducted with Thifensulfuron-methyl using the EU agreed endpoints (EFSA Journal 2015;13(7):4201). Maximum PEC_{soil} value for Thifensulfuron-methyl is 0.040 mg/kg following the highest application rate of 30 g Thifensulfuron-methyl/ha.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PEC_{gw} have been realised for Thifensulfuron-methyl and its relevant metabolites. Maximum PEC_{gw} value

for Thifensulfuron-methyl is below 0.001 µg/L, 0.573 µg/L for IN-L9225, 1.122 µg/L for IN-JZ789, 0.283 µg/L for 2-acid-3-triuret, 3.174 µg/L for IN-L9223, 0.279 µg/L for IN-A4098, 0.343 µg/L for IN-W8268 and PEC_{gw} values were all below 0.001 µg/L for IN-V7160 and IN-A5546.

After refined evaluator propose following next mitigation measure:

~~SPe2: To protect ground water apply this product every 2 years in alkaline silty loam soils with M.O. content greater than 3.7% (Kremsmünster).~~

SPe2: To protect ground water apply this product every 3 years on the same cultivation area.

Toxicological relevance of metabolites:

IN-L9225: Taking into account the toxicological data, the metabolite IN-L9225 is considered toxicologically non-relevant. The use of SHA 4100 A (HIFEN) according to the list of intended uses presented in GAP Table, causes no risk for health of the adults, toddlers and infants.

IN-JZ789: Taking into account the toxicological data, the metabolite IN-JZ789 is considered toxicologically non-relevant. The results of consumer risk calculations indicate that the use of SHA 4100 A (HIFEN) according to the list of intended uses presented in GAP Table, causes no risk for health of the adults, toddlers and infants.

IN-L9223: According to the available toxicological data, the metabolite IN-L9223 is considered not genotoxic and without pesticidal activity. However, the toxicological profile of this metabolite is incomplete for full consumer risk assessment and does not allow to establish the reference dose (data gap). The results generated with OECD QSAR toolbox indicate that IN-L9223 might be more toxic than the parent substance (predicted oral LD₅₀ value) (RAR, Thifensulfuron-methyl - Volume 3, Annex B.6 : Toxicology and Metabolism). The parent substance is not classified in regards to mammalian toxicology. The maximum PEC_{gw} of IN-L9223 (acc. to the application rate presented in the GAP table) amounts to 3.174 µg/L. Since the predicted max. PEC_{gw} value (3.174 µg/L) is above the upper limit for metabolites (≥0.75 µg/L), the consumer risk calculation for this metabolite is required. The max. consumer exposure resulting from drinking water to IN-L9223 amounts to 4.8 % of ADI for parent substance and 24.4 % of maximum allowable concentration (MAC).

IN-A4098: Acc. to EFSA Journal 2015;13(7):4201, the metabolite IN-A4098 has no pesticidal activity and has moderate acute toxicity: Acute Tox 4., oral LD₅₀ = 1000 mg/kg bw, rat (noteworthy, higher than parent substance). According to EFSA supporting publication 2020:EN-1627, 86 pp. doi:10.2903/sp.efsa.2020.EN-N1627, metabolite IN-A4098 is not toxicologically relevant.

IN-W8268: Acc. to EFSA Journal 2015;13(7):4201, the metabolite IN-W8268 has no pesticidal activity. The available data indicate that the genotoxic potential of metabolite IN-W8268 cannot be ruled out (data gap). It might be of concern for consumer exposure because the results exceed the limit for the relevant metabolites, i.e. 0.01 µg/L (the maximum PEC_{gw} amounts to 0.343 µg/L).

2-acid-3-triuret: Acc. to EFSA Journal 2015;13(7):4201, the toxicological data on the metabolite 2-acid-3-triuret is not available. The maximum PEC_{gw} of 2-acid-3-triuret (acc. to the application rate presented in the GAP table) amounts to 0.283 µg/L and is below the upper limit for metabolites (<0.75 µg/L).

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The PEC_{sw/sed} of Thifensulfuron-methyl and its relevant metabolites have been assessed with the models FOCUS STEP 1, 2, 3 and 4 (when necessary). Please refer to Part B, Section 8, Point 8.9 for more details about the result obtained.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The vapour pressure at 20 °C of the active substance Thifensulfuron-methyl is < 10⁻⁵ Pa. Hence the active substance Thifensulfuron-methyl is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Thifensulfuron-methyl due to volatilization with subsequent deposition should not be considered.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

- **Birds:**

According to the screening assessments for winter cereals, all the TERa and TERlt values for Thifensulfuron-methyl are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 4100 A/ HIFEN presents no unacceptable acute and long-term risk to birds according to the intended uses on winter cereals.

- **Mammals:**

According to the screening, first-tier and higher-tier assessment for winter cereals, all the TERa and TERlt values for Thifensulfuron-methyl are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 4100 A/ HIFEN presents no unacceptable acute and long-term risk to mammals according to the intended uses on winter cereals.

3.8.2 Effects on aquatic species

Based on this assessment with consideration PECsw STEP 4 the following risk mitigation measures are required to surface water bodies.

- for D3 (ditch), D4 (stream), ~~D5 (stream)~~, D6 (ditch) scenarios: 5 meter buffer zone + 50 % drift reduction nozzles or 10 meter buffer zone
- for R1 (stream) scenario: 5 m drift buffer zone + 5 meter vegetative buffer strip
- ~~for R3 (stream) scenario: 5 m drift buffer zone + 5 meter vegetative buffer strip + 50% drift reduction nozzles or 10 m drift buffer zone + 10 meter vegetative buffer strip~~
- ~~for R4 (stream) scenario: 5 m drift buffer zone + 5 meter vegetative buffer strip~~

SPe3: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 10 m to surface water bodies ~~(the worst case for R3 scenario)~~

PL

D3, D4, R1 scenario are relevant.

SPe3: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies or an unsprayed buffer zone of 5 m to surface water bodies with 50% of nozzles reduction or an unsprayed buffer zone of 10 m to surface water bodies

The risk assessment for aquatic organisms with risk mitigation measured should be considered by MSs.

Metabolite of Thifensulfuron-methyl: For all the intended uses on winter cereals, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

3.8.3 Effects on bees

The QHO and QHC values for, thifensulfuron-methyl and the formulation are all below the trigger of 50 and so indicate acceptable acute risk to bees based on the maximum intended use of HIFEN. According to Reg. 284/2009 the chronic adult and chronic larvae tests for bees should be submitted by the applicant. The chronic risk assessment based on chronic studies for bees (adult and larvae) should be performed in line with the EFSA 2013 guideline during the transition period. **The Applicant should provide the**

chronic risk assessment based on chronic studies for bees (adult and larvae) performed in line with the EFSA 2013 guideline.

Updated March 2025

The chronic tests for adult bee and larvae were submitted by Applicant.

The screening step risk assessment in line with EFSA (2013) has been performed by the Applicant, using endpoints from submitted studies.

3.8.4 Effects on other arthropod species other than bees

The in-field and off-field HQ values calculated for the product SHA 4100 A / HIFEN for the representative species *Typhlodromus pyri* and *Aphidius rhopalosiphi* are lower than the trigger of 2 for Tier I tests, indicating no risk to non-target arthropods in vegetated off-field areas following application according to the proposed use pattern. In addition, the PER in- and off-field values are below rate with ≤ 50 % effect for two species *Chrysoperla carnea* and *Orius laevigatus* indicating an acceptable risk in-field and off-field for these species.

3.8.5 Effects on soil organisms

- **Non-target soil meso- and macrofauna:**

The acute and chronic TER for Thifensulfuron-methyl were above the relevant Annex VI trigger of 10 and 5, respectively. Therefore, it is concluded that active substance does not pose an acute and long-term risk to earthworms and other soil-macro- and mesofauna when applied according to the proposed uses rates

- **Soil microbial activity:**

Risk assessments conducted with relevant PECsoil for active substance Thifensulfuron-methyl and its relevant metabolites and in SHA 4100 A/ HIFEN formulation indicate a low risk to soil microorganisms when applied according to the proposed use rates.

3.8.6 Effects on non-target terrestrial plants

The risk to non-target plants for SHA 4100 A/ HIFEN is considered to be acceptable when applied according to the proposed use rates.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

The result from the activated sludge studies indicate that microbial activity in such systems is at low risk from Thifensulfuron-methyl. Contamination of sewage treatment systems via agricultural use of Thifensulfuron-methyl in the representative formulations is considered to be low.

3.9 Relevance of metabolites (Part B, Section 10)

The metabolites IN-L9225, IN-JZ789, 2-acid-3-triuret, IN-L9223, IN-A4098 and IN-W8268 are predicted to occur in groundwater at concentrations above 0.1 µg/L (see Section B.8, Chapter 8.8).

The relevance of the groundwater metabolites has already been assessed according to the criterial laid down in the EC guidance document SANCO/221/2000 -rev.11.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not relevant, Thifensulfuron 75% WG does not contain active substance considered as candidate for substitution.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.
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Appendix 2 Copy of the product label

Sekcja fizchem: brak uwag.

Sekcja skuteczności:

Do etykiety produktu dodano zapis nt. następstwa roślin oraz zaproponowano strategię zarządzania odpornością. W uwagach dodano informację nt. wrażliwości niektórych odmian jęczmienia ozimego (odm. Bartosz) czy pszenicy ozimej (odm. Bogatka). Wprowadzono zmiany do listy zaakceptowanych gatunków chwastów oraz klasyfikacji ich wrażliwości. Zalecana ilość wody powinna wynosić 200-300 L/ha.

Sekcja metabolizm i pozostałości: brak uwag.

Sekcja los i zachowanie w środowisku: skorygowano zapis dotyczący ochrony wód podziemnych

Sekcja ekotoksykologii: brak uwag.

Posiadacz zezwolenia:

Sharda Cropchem Ltd., 2nd Floor, Prime Business Park, Dashrathlal Joshi Road, Vile Parle (West), Mumbai – 400 056, Indie, tel.: + 91 22 6261 5615, fax: + 91 22 6678 2828/ 2808, e-mail: regn@shardaintl.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin: (...)

Podmiot odpowiedzialny za końcowe etykietowanie środka ochrony roślin: (...)

HIFEN

Środek przeznaczony do stosowania przez użytkowników profesjonalnych.

Zawartość substancji czynnej:

Tifensulfuron metylowy (substancja z grupy pochodnych sulfonilomocznika) - 750 g/kg (75,0 %)

Zezwolenie MRiRW nr ... z dnia ... r.



Uwaga

H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P391	Zebrać rozsypany produkt.

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym, stosowany nalistnie, w formie granul do sporządzania zawiesiny wodnej (WG).

Zgodnie z klasyfikacją HRAC substancja czynna tifensulfuron metylowy zaliczana jest do grupy 2 (dawnej grupy B).

DZIAŁANIE NA CHWASTY

Herbicyd zawiera substancję czynną zaliczaną do inhibitorów syntazy acetylmleczanowej (ALS), co prowadzi do blokowania biosyntezy aminokwasów rozgałęzionych, a tym samym do zaburzeń w biosyntezie białek, a w efekcie zahamowania rozwoju i wzrostu chwastów. Środek jest pobierany głównie przez liście. Pierwsze objawy działania chwastobójczego w postaci przebarwień liści widoczne po kilku dniach od zabiegu. Pełne działanie w ciągu dwóch do czterech tygodni.

Chwasty wrażliwe:	~~poziwnik szorstki, gorczyca polna, tobołki polne, samosiewy rzepaku (tylko w życie ozimym), tasznik pospolity, przytulia czepna, bodziszek drobny, rumianek pospolity, maruna bezwonna, rdest powojowaty, rdest plamisty, mak polny, gwiazdnica pospolita~~
Chwasty średnio wrażliwe:	~~niezapominajka polna, mak polny, gwiazdnica pospolita, fiołek polny, jasnota purpurowa~~
Chwasty średnio odporne:	~~habar bławatek, przetacznik rolny~~ jasnota purpurowa.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieźnego lub ciągnikowego opryskiwacza polowego

Zboża ozime (pszenica, jęczmień, żyto, owies, pszenżyto)

Chwasty liściaste

Maksymalna /zalecana dawka dla jednorazowego zastosowania: 0.04 kg/ha

Termin stosowania środka: stosować po pojawieniu się chwastów, od fazy trzeciego liścia do fazy liścia flagowego całkowicie rozwiniętego (BBCH 13-39)

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: 200-300 400 l/ha.

Zalecane opryskiwanie: średniokropliste

NASTĘPSTWO ROŚLIN

Środek rozkłada się w ciągu okresu wegetacji do poziomu niestwarzającego zagrożenia dla roślin uprawianych następnie.

HIFEN gdy jest stosowany zgodnie z zaleceniami, nie ma ograniczeń co do upraw, które można wysiewać w normalnym płodozmianie po zbożach poddanych działaniu środka. W przypadku niepowodzenia uprawy z jakiegokolwiek powodu, zboża lub trawę należy wysiewać tylko w ciągu jednego miesiąca od zastosowania.

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie wymagany

1. Intensywność działania środka zależy od fazy rozwojowej rośliny uprawnej, odmiany, stanowiska oraz warunków atmosferycznych. Najsilniejszemu skróceniu ulegają międzywęzła intensywnie wydłużające się w okresie stosowania środka. Odmiany genetycznie wysokie reagują na działanie środka silniejszym skróceniem międzywęzli.
2. Warunki sprzyjające działaniu środka to:
 - temperatura około 10-15°C,
 - silne naświetlenie,
 - niebo bezchmurne lub lekko zachmurzone,

- łan suchy, aktywnie rosnący.

3. Słabszego działania można się spodziewać stosując środek w warunkach:

- silnego zachmurzenia,
- pogody deszczowej,
- wilgotnego łanu,
- temperatury poniżej 5°C,
- słabego wzrostu roślin.

4. Środka nie stosować:

- na rośliny poddane działaniu niekorzystnych czynników środowiska, takich jak np.: nadmierna wilgotność podłoża, mróz, susza, choroby lub szkodniki;
- na rośliny słabo rosnące, np.: w okresie długotrwałej suszy, upałów lub w przypadku niedostatecznego nawożenia,
- podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie rośliny uprawne.

5. Podczas stosowania nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

6. Strategia zarządzania odpornością:

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy przestrzegać zasad Dobrej Praktyki Rolniczej:

- ściśle przestrzegać wskazówek zawartych w etykiecie środka ochrony roślin,
- środek ochrony roślin powinien być stosowany w zalecanej dawce w zalecany czas, aby zapewnić optymalne zwalczanie chwastów,
- stosować zintegrowane praktyki zwalczania chwastów obejmujące pola, takie jak historyczny płodozmian, stosowane herbicydy i różne metody uprawy (mechaniczne, kulturowe, biologiczne i chemiczne),
- stosować rotację herbicydów (substancji czynnych) o różnych mechanizmach działania,
- stosowanie mieszaniny herbicydów (substancji czynnych) o różnym mechanizmie działania, stosowanie herbicydów działających na kilka procesów życiowych w płodozmianie i / lub mieszaniu chwastów (o różnych mechanizmach działania).

7. Niektóre odmiany jęczmienia ozimego (np. odmiana Bartosz) i pszenicy ozimej (np. odmiana Bogatka) mogą być wrażliwe na działanie środka (obserwowano m.in. zahamowanie wzrostu, a także deformacje liścia flagowego).

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub

- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO:

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg. Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

~~Aby chronić wody gruntowe, stosuj ten produkt co 2 lata na glebach gliniasto-piaszczystych o zasadowym odczynie i zawartości M.O. większej niż 3,7%.~~

Aby chronić wody gruntowe, stosuj ten produkt co 3 lata na tej samej powierzchni uprawnej.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych lub 5m z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%. W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej w odległości 5 m od zbiorników i cieków wodnych.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C-30°C,
- w dobrze wentylowanym miejscu.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych. Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

~~W przypadku dostania się do dróg oddechowych: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.~~

~~W przypadku złego samopoczucia skontaktować się z ośrodkiem zatruc/ lekarzem.~~

Okres ważności – 2 lata.

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

No letter of Access to protected data are required.

Appendix 4 Lists of data considered for national authorization

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.2.1 KCP 2.2.2 KCP 2.3.2 KCP 2.3.3 KCP 2.4.1 KCP 2.4.2 KCP 2.6.2 KCP 2.7.1 KCP 2.7.3 KCP 2.8.1 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 CP 2.8.5.1.1 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.5.2.1 KCP 2.8.5.3 KCP 2.8.7.1	J. A. Escudero	2017	Physico-Chemical Characterization of THIFENSULFURON MEHYL 75% WG. Laboratorios Munuera Report No. 15-4150-19 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.7.5	J. A. Escudero	2019	Storage stability for two years at 25 ± 2°C of THIFENSULFURON METHYL 75% WG. Laboratorios Munuera Report No. 15-4150-20 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.11	J. A. Escudero	2019	Cleaning application equipment – Small scale jar test protocol for THIFENSULFURON MEHYL 75% WG. Laboratorios Munuera Report No. 16-4150-14 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 5.1.1	J. A. Escudero	2017	Physico-Chemical Characterization of THIFENSULFURON MEHYL 75% WG. Laboratorios Munuera Report No. 15-4150-19 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.0-001	Anonymous	2023	Biological Assessment Dossier: Thifensulfuron 75% WG (750 g/kg thifensulfuron-methyl WG) – EU Central zone Sharda Cropchem Ltd -, - Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-01 <u>Also cited in:</u> 6.2.2 6.4.1	Zickart, U.	2016	Post emergence efficacy of Thifensulfuron 75% WG against dicotyledonous weeds in winter cereals, spring application. Testing facility: BioChem Agrar, DE CRO Trial number: 15 1067 1766 Sharda Reference no.: THI 1 trial 1 GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-02 <u>Also cited in:</u> 6.2.2 6.4.1	Zickart, U.	2016	Post emergence efficacy of Thifensulfuron 75% WG against dicotyledonous weeds in winter cereals, spring application. Testing facility: BioChem Agrar, DE CRO Trial number: 15 1060 5064 Sharda Reference no.: THI 1 trial 2 GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-03 <u>Also cited in:</u> 6.2.2 6.4.1	Głazek, M.	2015	Biological assessment of efficacy of herbicide Thifensulfuron 75 WG for dicotyledonous weeds control in winter wheat. Testing facility: IOR-PIB Sośnicowice, PL CRO Trial number: 18 H/2015 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-04 <u>Also cited in:</u> 6.2.2	Rogowski, J.	2015	Efficacy evaluation of Thifensulfuron 75% WG applied on winter wheat. Testing facility: IOR-PIB Poznan, PL	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
6.4.1			CRO Trial number: SH15PZ114W Sharda Reference no.: - GEP, Unpublished				
KCP 6.2.1-05 <u>Also cited in:</u> 6.2.2 6.4.1	Rogowski, J.	2015	Efficacy evaluation of Thifensulfuron 75% WG applied on winter wheat. Testing facility: IOR-PIB Poznan, PL CRO Trial number: SH15PZ115W Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-06 <u>Also cited in:</u> 6.2.2 6.4.1	Miziniak, W.	2015	Efficacy evaluation of herbicides Thifensulfuron 75% WG in winter wheat. Testing facility: IOR-PIB Poznan, PL CRO Trial number: SH15PZ118T Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-07 <u>Also cited in:</u> 6.2.2 6.4.1	Snarska, K.	2015	Study of the effectiveness of the herbicide Thifensulfuron 75% WG, used in the cultivation of winter wheat. Testing facility: IOR-PIB Poznan, PL CRO Trial number: SH15PZ119B Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-08 <u>Also cited in:</u> 6.2.2 6.4.1	Konecki, R.	2015	Study of the effectiveness of the herbicide Thifensulfuron 75% WG, used in the cultivation of winter wheat. Testing facility: IOR-PIB Poznan, PL CRO Trial number: SH15PZ120B Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-09 <u>Also cited in:</u> 6.2.2 6.4.1	Putramentaitė, A. & Kadžienė, G.	2015	Efficacy of herbicide Thifensulfuron 75% WG (thifensulfuron 750 g/kg) in winter wheat. Testing facility: LRCAF, LT CRO Trial number: 151542731 Sharda Reference no.: LTZIHE2015TRZAW5-01 GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-10 <u>Also cited in:</u> 6.2.2 6.4.1	Putramentaitė, A. & Kadžienė, G.	2015	Efficacy of herbicide Thifensulfuron 75% WG (thifensulfuron 750 g/kg) in winter wheat. Testing facility: LRCAF, LT CRO Trial number: 151542741 Sharda Reference no.: LTZIHE2015TRZAW5-02	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2.1-11 <u>Also cited in:</u> 6.2.2 6.4.1	Putramentaitė, A. & Kadžienė, G.	2015	GEP, Unpublished Efficacy of herbicide Thifensulfuron 75% WG (thifensulfuron 750 g/kg) in winter wheat. Testing facility: LRCAF, LT CRO Trial number: 151542751 Sharda Reference no.: LTZIHE2015TRZAW5-03 GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-12 <u>Also cited in:</u> 6.2.2 6.4.1	Mintale, Z., et al.	2015	Efficacy evaluation of herbicide Thifensulfuron 75% WG in winter rye. Testing facility: LPPRC, LV CRO Trial number: H-15-1-02-ZM-2263 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-13 <u>Also cited in:</u> 6.2.2 6.4.1	Mintale, Z., et al.	2015	Efficacy evaluation of herbicide Thifensulfuron 75% WG in winter wheat. Testing facility: LPPRC, LV CRO Trial number: H-15-1-02-ZM-2264 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-14 <u>Also cited in:</u> 6.2.2 6.4.1	Mintale, Z., et al.	2015	Efficacy evaluation of herbicide Thifensulfuron 75% WG in winter wheat. Testing facility: LPPRC, LV CRO Trial number: H-15-1-02-ZM-2265 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-15 <u>Also cited in:</u> 6.2.2 6.4.1	Hrabovsky, J.	2022	Efficacy of Herbicide Thifensulfuron 75%WG at BBCH 13-39 post emergence application at HORVW. Testing facility: ZZS Kujavy, CZ CRO Trial number: SWEPL-KUJ21-HORVW-H20A Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-16 <u>Also cited in:</u> 6.2.2 6.4.1	Hrabovsky, J.	2022	Efficacy of Herbicide Thifensulfuron 75%WG at BBCH 13-39 post emergence application at HORVW. Testing facility: ZZS Kujavy, CZ CRO Trial number: SWEPL-KUJ21-HORVW-H20B Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.2.1-17	Hrabovsky, J.	2022	Efficacy of Herbicide Thifensulfuron 75%WG at BBCH 13-39	N	Y	Data/study report never submitted	SHARDA

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
<u>Also cited in:</u> 6.2.2 6.4.1			post emergence application at HORVW. Testing facility: ZZS Kujawy, CZ CRO Trial number: SWEPL-KUJ21-HORVW-H20C Sharda Reference no.: - GEP, Unpublished			before to Poland	Cropchem Limited
KCP 6.2.1-18 <u>Also cited in:</u> 6.2.2 6.4.1	Hrabovsky, J.	2022	Efficacy of Herbicide Thifensulfuron 75%WG at BBCH 13-39 post emergence application at HORVW. Testing facility: ZZS Kujawy, CZ CRO Trial number: SWEPL-KUJ21-HORVW-H20D Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-01 <u>Also cited in:</u> 6.4.2 6.4.3	Zickart, U.	2015	Crop safety in winter barley at application between BBCH 13-31 in spring. Testing facility: BioChem Agrar, DE CRO Trial number: 15 1060 1767 Sharda Reference no.: THI 2 trial 3 GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-02 <u>Also cited in:</u> 6.4.2 6.4.3	Labusch, U.	2015	Selectivity thifensulfuron Testing facility: BioChem Agrar, DE CRO Trial number: 15 1069 5066 Sharda Reference no.: THI 2 trial 4 GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-03 <u>Also cited in:</u> 6.4.2 6.4.3	Głazek, M.	2015	Biological assessment of selectivity of herbicide Thifensulfuron 75 WG in winter wheat. Testing facility: IOR-PIB Sośnicowice, PL CRO Trial number: 19 H/2015 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-04 <u>Also cited in:</u> 6.4.2 6.4.3	Głazek, M.	2015	Biological assessment of selectivity of herbicide Thifensulfuron 75 WG in winter wheat. Testing facility: IOR-PIB Sośnicowice, PL CRO Trial number: 20 H/2015 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-05 <u>Also cited in:</u> 6.4.2 6.4.3	Rogowski, J.	2015	Phytotoxicity evaluation of Thifensulfuron 75% WG applied on winter wheat. Testing facility: IOR-PIB Poznan, PL CRO Trial number: FH15PZ116W	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Sharda Reference no.: - GEP, Unpublished				
KCP 6.4.1-06 <u>Also cited in:</u> 6.4.2 6.4.3	Rogowski, J.	2015	Phytotoxicity evaluation of Thifensulfuron 75% WG applied on winter wheat. Testing facility: IOR-PIB Poznan, PL CRO Trial number: FH15PZ117W Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-07 <u>Also cited in:</u> 6.4.2 6.4.3	Mintale, Z., et al.	2015	Selectivity evaluation of herbicide Thifensulfuron 75% WG in winter wheat. Testing facility: LPPRC, LV CRO Trial number: H-15-1-01-ZM-2266 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-08 <u>Also cited in:</u> 6.4.2 6.4.3	Mintale, Z., et al.	2015	Selectivity evaluation of herbicide Thifensulfuron 75% WG in winter wheat. Testing facility: LPPRC, LV CRO Trial number: H-15-1-01-ZM-2267 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-09 <u>Also cited in:</u> 6.4.2 6.4.3	Mintale, Z., et al.	2015	Selectivity evaluation of herbicide Thifensulfuron 75% WG in winter wheat. Testing facility: LPPRC, LV CRO Trial number: H-15-1-01-ZM-2268 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-10 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Toth, F.	2016	Determination of Crop safety of Thifensulfuron 75%WG applied in spring on cereals. Gem. Michalovce, Slovakia 2015. Testing facility: Gernerprodukt Valice, SK CRO Trial number: SHAR-PHY2-SKGM15 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-11 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Toth, F.	2016	Determination of Crop safety of Thifensulfuron 75%WG applied in spring on cereals. Slovakia 2015. Testing facility: Gernerprodukt Valice, SK CRO Trial number: SHAR-PHY2-SKRS15 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.1-12 <u>Also cited in:</u> 6.4.2 6.4.3	Labusch, U.	2015	Selectivity of Thifensulfuron Testing facility: BioChem Agrar, DE CRO Trial number: 15 1069 5065 Sharda Reference no.: THI 2 trial 1 GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-13 <u>Also cited in:</u> 6.4.2 6.4.3	Kästner, K.	2015	Crop safety in winter barley at application between BBCH 13-31 in spring. Testing facility: BioChem Agrar, DE CRO Trial number: 15 1060 1866 Sharda Reference no.: THI 2 trial 2 GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-14 <u>Also cited in:</u> 6.4.2 6.4.3	Głazek, M.	2015	Biological assessment of selectivity of herbicide Thifensulfuron 75 WG in winter barley. Testing facility: IOR-PIB Sośnicowice, PL CRO Trial number: 21 H/2015 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-15 <u>Also cited in:</u> 6.4.2 6.4.3	Głazek, M.	2015	Biological assessment of selectivity of herbicide Thifensulfuron 75 WG in winter barley. Testing facility: IOR-PIB Sośnicowice, PL CRO Trial number: 22 H/2015 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-16 <u>Also cited in:</u> 6.4.2 6.4.3	Rogowski, J.	2015	Phytotoxicity evaluation of Thifensulfuron 75% WG applied on winter barley. Testing facility: IOR-PIB Poznan, PL CRO Trial number: FH15JZ103W Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-17 <u>Also cited in:</u> 6.4.2 6.4.3	Rogowski, J.	2015	Phytotoxicity evaluation of Thifensulfuron 75% WG applied on winter barley. Testing facility: IOR-PIB Poznan, PL CRO Trial number: FH15JZ104W Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-18 <u>Also cited in:</u> 6.4.2	Putramentaitė, A. & Kadžienė, G.	2015	Selectivity of herbicide Thifensulfuron 75% WG in winter barley. Testing facility: LRCAF, LT CRO Trial number: 151542761	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
6.4.3 6.4.5			Sharda Reference no.: LTZIHS2015HORVW6-04 GEP, Unpublished				
KCP 6.4.1-19 <u>Also cited in:</u> 6.4.2 6.4.3	Mintale, Z., et al.	2015	Selectivity evaluation of herbicide Thifensulfuron 75% WG in winter barley. Testing facility: LPPRC, LV CRO Trial number: H-15-1-04-ZM-2269 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-20 <u>Also cited in:</u> 6.4.2 6.4.3	Mintale, Z., et al.	2015	Selectivity evaluation of herbicide Thifensulfuron 75% WG in winter barley. Testing facility: LPPRC, LV CRO Trial number: H-15-1-04-ZM-2270 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-21 <u>Also cited in:</u> 6.4.2 6.4.3	Mintale, Z., et al.	2015	Selectivity evaluation of herbicide Thifensulfuron 75% WG in winter barley. Testing facility: LPPRC, LV CRO Trial number: H-15-1-04-ZM-2271 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-22 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Toth, F.	2016	Determination of Crop safety of Thifensulfuron 75%WG applied in spring on cereals. Gem. Michalovce, Slovakia 2015. Testing facility: Gernerprodukt Valice, SK CRO Trial number: SHAR-PHY2-HORVW-SKGM15 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-23 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Toth, F.	2016	Determination of Crop safety of Thifensulfuron 75%WG applied in spring on cereals. Gem. Michalovce, Slovakia 2015. Testing facility: Gernerprodukt Valice, SK CRO Trial number: SHAR-PHY2-HORVW-SKRS15 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-24 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Putramentaitė, A. & Kadžienė, G.	2015	Selectivity of herbicide Thifensulfuron 75% WG in winter rye. Testing facility: LRCAF, LT CRO Trial number: 151542771 Sharda Reference no.: LTZIHS2015SECCW6-06 GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-25	Putramentaitė,	2015	Selectivity of herbicide Thifensulfuron 75% WG in triticale.	N	Y	Data/study report never submitted	SHARDA

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
<u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	A. & Kadžienė, G.		Testing facility: LRCAF, LT CRO Trial number: 151542781 Sharda Reference no.: LTZIHS2015TTLSS6-05 GEP, Unpublished			before to Poland	Cropchem Limited
KCP 6.4.1-26 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in winter rye, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 311_01_F20_61 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-27 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in winter rye, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 311_02_F20_62 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-28 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in winter rye, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 311_03_F20_63 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-29 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in winter rye, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 311_04_F20_64 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-30 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in winter rye, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 311_05_F20_65 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-31 <u>Also cited in:</u> 6.4.2 6.4.3	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in winter rye, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 311_06_F20_66	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
6.4.5			Sharda Reference no.: GEP, Unpublished				
KCP 6.4.1-32 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in winter oat, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 312_01_F20_67 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-33 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in oat, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 312_02_F20_68 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-34 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in oat, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 312_03_F20_69 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-35 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in win oat, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 312_04_F20_70 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-36 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in oat, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 312_05_F20_71 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-37 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in oat, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 312_06_F20_72 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.1-38 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in winter triticale, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 313_01_F20_73 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-39 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in winter triticale, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 313_02_F20_74 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-40 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in winter triticale, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 313_03_F20_75 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-41 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in winter triticale, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 313_04_F20_76 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-42 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in winter triticale, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 313_05_F20_77 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-43 <u>Also cited in:</u> 6.4.2 6.4.3 6.4.5	Badan, K.	2020	Selectivity of Thifensulfuron 75% WG in control of weeds in winter triticale, Poland 2020. Testing facility: Fertico, PL CRO Trial number: 313_06_F20_78 Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-44 <u>Also cited in:</u>	Sikora, A.	2022	Crop safety of Herbicide Thifensulfuron 75%WG at BBCH 13-39 post emergence application at AVESW.	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
6.4.2 6.4.3			Testing facility: ZZS Kujavy, CZ CRO Trial number: SWEPL-KUJ21-AVESW-H20B Sharda Reference no.: GEP, Unpublished				Limited
KCP 6.4.1-45 <u>Also cited in:</u> 6.4.2 6.4.3	Sikora, A.	2022	Crop safety of Herbicide Thifensulfuron 75%WG at BBCH 13-39 post emergence application at SECCW. Testing facility: ZZS Kujavy, CZ CRO Trial number: SWEPL-KUJ21-SECCW-H20A Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-46 <u>Also cited in:</u> 6.4.2 6.4.3	Sikora, A.	2022	Crop safety of Herbicide Thifensulfuron 75%WG at BBCH 13-39 post emergence application at SECCW. Testing facility: ZZS Kujavy, CZ CRO Trial number: SWEPL-KUJ21-SECCW-H20B Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-47 <u>Also cited in:</u> 6.4.2 6.4.3	Sikora, A.	2022	Crop safety of Herbicide Thifensulfuron 75%WG at BBCH 13-39 post emergence application at TTLWI. Testing facility: ZZS Kujavy, CZ CRO Trial number: SWEPL-KUJ21-TTLWI-H20A Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-48 <u>Also cited in:</u> 6.4.2 6.4.3	Sikora, A.	2022	Crop safety of Herbicide Thifensulfuron 75%WG at BBCH 13-39 post emergence application at TTLWI. Testing facility: ZZS Kujavy, CZ CRO Trial number: SWEPL-KUJ21- TTLWI -H20B Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-49 <u>Also cited in:</u> 6.4.2 6.4.3	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021. Testing facility: CPR, HU CRO Trial number: CPRHU20-845-065HS Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-50 <u>Also cited in:</u> 6.4.2 6.4.3	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021. Testing facility: CPR, HU CRO Trial number: CPRHU20-006-065HS	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Sharda Reference no.: GEP, Unpublished				
KCP 6.4.1-51 <u>Also cited in:</u> 6.4.2 6.4.3	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021. Testing facility: CPR, HU CRO Trial number: CPRHU20-844-065HS Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-52 <u>Also cited in:</u> 6.4.2 6.4.3	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021. Testing facility: CPR, HU CRO Trial number: CPRHU20-005-065HS Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-53 <u>Also cited in:</u> 6.4.2 6.4.3	Gracza, L.	2021	Thifensulfuron 75% WG selectivity in triticales. Testing facility: Plant-Art Research Kft., HU CRO Trial number: H20-SEL-TIFENSULF-TTLWI-XII-2020-PLA Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-54 <u>Also cited in:</u> 6.4.2 6.4.3	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021. Testing facility: CPR, HU CRO Trial number: CPRHU20-848-065HS Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-55 <u>Also cited in:</u> 6.4.2 6.4.3	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021. Testing facility: CPR, HU CRO Trial number: CPRHU20-852-065HS Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-56 <u>Also cited in:</u> 6.4.2 6.4.3	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021. Testing facility: CPR, HU CRO Trial number: CPRHU20-847-065HS Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.1-57 <u>Also cited in:</u> 6.4.2 6.4.3	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021. Testing facility: CPR, HU CRO Trial number: CPRHU20-850-065HS Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-58 <u>Also cited in:</u> 6.4.2 6.4.3	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021. Testing facility: CPR, HU CRO Trial number: CPRHU20-851-065HS Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-59 <u>Also cited in:</u> 6.4.2 6.4.3	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021. Testing facility: CPR, HU CRO Trial number: CPRHU20-012-065HS Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-60 <u>Also cited in:</u> 6.4.2 6.4.3	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021. Testing facility: CPR, HU CRO Trial number: CPRHU20-011-065HS Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-61 <u>Also cited in:</u> 6.4.2 6.4.3	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021. Testing facility: CPR, HU CRO Trial number: CPRHU20-846-065HS Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-62 <u>Also cited in:</u> 6.4.2 6.4.3	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021. Testing facility: CPR, HU CRO Trial number: CPRHU20-849-065HS Sharda Reference no.: GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.4.1-63 <u>Also cited in:</u>	Kondár, L.	2022	Investigation of crop safety of Thifensulfuron 75% WG (with and without adjuvant). Hungary, 2020/2021.	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
6.4.2 6.4.3			Testing facility: CPR, HU CRO Trial number: CPRHU20-007-065HS Sharda Reference no.: GEP, Unpublished				Limited
KCP 7.1.1	Shreyas S. Patel	2016	Acute eye irritation study of Thifensulfuron-methyl 75% WDG in rabbits Jai Research Foundation report No. 407-1-01-12771 GLP/Unpublished	Y	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-01	█	2016	Thifensulfuron 75% WDG rainbow trout, acute toxicity tests █	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-02	Ewa Nierzedzka	2016	Thifensulfuron 75% WDG Daphnia magna, acute immobilization test Institute of Industrial Organic Chemistry, Branch Pszczyna report No.W/165/16 GLP/Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-03	Ewa Nierzedzka	2016	Thifensulfuron 75% WDG Pseudokirchneriella subcapitata SAG 61.81 growth inhibition tests Institute of Industrial Organic Chemistry, Branch Pszczyna report No.W/164/16 GLP/Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-04	Ewa Nierzedzka	2016	Thifensulfuron 75% WDG Lemna gibba CPCC 310, growth inhibition tests Institute of Industrial Organic Chemistry, Branch Pszczyna report No.W/166/16 GLP/Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.1.1	Pawel Parma	2016	Thifensulfuron 75% WDG, Honeybees (<i>Apis mellifera</i> L.), acute oral toxicity test Institute of Industrial Organic Chemistry, Branch Pszczyna report No.B/140/15 GLP/Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.1.2	Pawel Parma	2016	Thifensulfuron 75% WDG, Honeybees (<i>Apis mellifera</i> L.), acute contact toxicity test Institute of Industrial Organic Chemistry, Branch Pszczyna report No.B/141/15 GLP/Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.2	Mohanraj, M.	2024	Chronic Oral Toxicity Study of Thifensulfuron-methyl 75% WDG	N	Y	Data/study report never submitted	SHARDA

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			on adult honey bee (<i>Apis mellifera</i>) Bioscience Research Foundation. Report No.: 14183/2023 GLP/Unpublished			before to Poland	Cropchem Limited
KCP 10.3.1.3	Mohanraj, M.	2024	Effect of Thifensulfuron-methyl 75% DWG on larvae of honey bee, <i>Apis mellifera</i> (L.) following repeated exposure Bioscience Research Foundation. Report No.: 14184/2023 GLP/Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3-01-01	Pawel Parma	2018	A laboratory test for evaluating the effects of Thifensulfuron 75% WDG on the predatory mite, <i>Typhlodromus pyri</i> (Sch.) Institute of Industrial Organic Chemistry, Branch Pszczyna report No.B/138/15 GLP/Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.2.1-02	Angayarkanni V.	2021	A laboratory test for evaluating the effects of Thifensulfuron-methyl 75% WDG on the parasitic wasp, <i>Aphidius rhopalosiphii</i> (De Stefani - Perez) Study code: 8250/2021 Bioscience Research Foundation GLP/Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.4.1.1	Marta Knapik	2016	Thifensulfuron-methyl 75% WDG, earthworm reproduction test (<i>Eisenia fetida</i>) Institute of Industrial Organic Chemistry, Branch Pszczyna report No. G/257/15 GLP/Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.4.2.1-01	Marta Knapik	2016	Thifensulfuron-methyl 75% WDG, Collembolan (<i>Folsomia candida</i>) Reproduction test Institute of Industrial Organic Chemistry, Branch Pszczyna report No. G/258/15 GLP/Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.4.2.1-02	Angayarkanni V.	2021	Effects of Thifensulfuron-methyl 75% WDG on the Reproductive Output of the Predatory Soil Mite <i>Hypoaspis</i> (Geolaelaps) aculeifer Canestrini (Acari: Laelapidae) in Artificial Soil Study code: 8249/2021 Bioscience Research Foundation GLP/Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.5	Weronika Dec	2016	Thifensulfuron-methyl 75% WDG Soil microorganisms: Nitrogen Transformation Test Institute of Industrial Organic Chemistry, Branch Pszczyna report No. G/256/15	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.6.2-01	Radha S.	2021	GLP/Unpublished Effect of Thifensulfuron-methyl 75% WDG on vegetative vigour of terrestrial plants Study code: 8248/2020 Bioscience Research Foundation GLP/Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.6.2-02	Radha S.	2021	Effect of Thifensulfuron-methyl 75% WDG on seedling emergence and seedling growth of terrestrial plants Study code: 8247/2020 Bioscience Research Foundation GLP/Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/1	A. M. Pentz, F. Q. Bramble	2005	Analytical method for the determination of nicosulfuron, Thifensulfuron-methyl, ethametsulfuron methyl, rimsulfuron, tribenuron methyl and chlorimuron ethyl in oily crop matrices using SPE purification and LC/MS/MS detection Report No. DuPont-13412, Revision No. 1 Non-GLP Published	N	N	Study already evaluated at the EU level.	DuPont
	E. Charles, A. M. Doran	2004	Independent laboratory validation of analytical method DuPont-13412 for the determination of Thifensulfuron-methyl, ethametsulfuron methyl, rimsulfuron, tribenuron methyl and chlorimuron ethyl in oilseeds and soybean seed using SPE purification and LC/MS/MS detection Report No. DuPont-13398 GLP Published	N	N	Study already evaluated at the EU level.	DuPont
KCP 5.2/2	T. J. Devine, S. C. Nanita	2007	Multi-residues analytical method for the determination of sulfonylurea herbicides in oily, watery, acidic and dry crops using SPE purification and LC/MS/MS detection.	N	N	Study already evaluated at the EU level.	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report DuPont-13412, Supplement No. 1 Non-GLP Published				
KCP 5.2/3	B. Platridge	2006	Independent laboratory validation of a multi-residue method for the analysis of sulfonylurea herbicides in crops, DuPont-13412, Rev. 1. Report No. DuPont-17207 GLP Published	N	N	Study already evaluated at the EU level.	DuPont
KCP 5.2/4	F. M. Brookey, G. L. Westberg	2007	Analytical method for the determination of Thifensulfuron-methyl, metsulfuron methyl, chlorsulfuron, tribenuron methyl and flupyrsulfuron methyl in lettuce and tribenuron methyl and ben-sulfuron methyl in citrus (oranges) Report No. DuPont-5367, Supplement No. 1 Non-GLP Published	N	N	Study already evaluated at the EU level.	DuPont
KCP 5.2/5	J. S. Amoo, W. Jones	2001	Analytical enforcement method for the determination of Thifensulfuron-methyl, metsulfuron methyl, chlorsulfuron, tribenuron methyl and flupyrsulfuron methyl in cereals (wheat, grain, forage and straw Report No. DuPont-5367 Non-GLP Published	N	N	Study already evaluated at the EU level.	DuPont
KCP 5.2/6	A. M. Pentz, F. Q. Bramble	2002	Independent Laboratory Validation of DuPont-5367, „Analytical enforcement method for the determination of Thifensulfuron-methyl and flupyrsulfuron methyl in cereals (wheat grain, forage and straw)” in wheat grain barley grain, corn grain and tomato. Report No. Dupont-8054 GLP Published	N	N	Study already evaluated at the EU level.	DuPont
KCP 5.2/7	C. Seck	2008	Determination of Residues of Metsulfuron-methyl and Thifensulfuron-methyl in Cereal – Method Validation. Report No. QG/07/021 GLP Published	N	N	Study already evaluated at the EU level.	DuPont Cheminova ROTAM
KCP 5.2/8	G. Watson	2010	Independent Laboratory Validation of the analytical procedure detailed in the study performer under Rotam ID numer 7407047 „Determination of residues of metsulfuron-methyl and Thifensulfuron-methyl in cereal – method validation’ Report No. S09-02905	N	N	Study already evaluated at the EU level.	DuPont Cheminova ROTAM

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Published				
KCP 5.2/9	S. J. Hill, J. J. Stry	2001	Analytical method for the determination of 13 DuPont sulfonylurea herbicides in soil using LC/MS/MS. Report No. DuPont-5082 Non-GLP Published	N	N	Study already evaluated at the EU level.	DuPont
KCP 5.2./10	L. Sadgrove	2012	Thifensulfuron-methyl and thifensulfuron-acid: Validation of methodology for the Determination of Residues in Soil. Report No. PII0022 and amendment 1 GLP Published	N	N	Study already evaluated at the EU level.	DuPont Cheminova ROTAM
KCP 5.2/11	T. J. Devine, L. Jin	2004	Analytical method for the determination and confirmation of 13 DuPont sulfonylurea herbicides in water using LC/MS/MS. Report No. DuPont-5491, Rev 1 Non-GLP Published	N	N	Study already evaluated at the EU level.	DuPont
KCP 5.2/12	L. Sadgrove	2012	Thifensulfuron-methyl and thifensulfuron-acid: Validation of Methodology for the Determination of Residues in Surface Water. Report No. PII0024 and amendment 1 GLP Published	N	N	Study already evaluated at the EU level.	DuPont Cheminova ROTAM
KCP 5.2/13	R. Bacher	2001	Development and validation of analytical methods for the determination of seven sulfonylurea herbicides in air (amended). Report DuPont-4560 GLP Published	N	N	Study already evaluated at the EU level.	DuPont
KCP 5.2/14	L. Sadgrove	2012	Thifensulfuron-methyl: Validation of methodology for the Determination of Residues in Air. Report No. PII0023 and amendment 1 GLP Published	N	N	Study already evaluated at the EU level.	DuPont Cheminova ROTAM
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	N	Study already evaluated at the EU level.	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	N	N	Study already evaluated at the EU level.	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			783-87 Non-GLP Published				
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	N	Study already evaluated at the EU level.	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	N	Study already evaluated at the EU level.	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	N	Study already evaluated at the EU level.	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	N	Study already evaluated at the EU level.	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	N	Study already evaluated at the EU level.	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	N	Study already evaluated at the EU level.	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 Non-GLP Published	N	N	Study already evaluated at the EU level.	DuPont
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	N	Study already evaluated at the EU level.	DuPont
KCP	Unknown	1986	Goat metabolism study of ¹⁴ C-DPX-M6316. Report No. AMR	Y	N	Study already evaluated at the EU	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
8.2.2/1			326-85 Non-GLP Published			level.	

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	Data protection claimed Y/N	Justification if data protection is claimed	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner