

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SHA 4100 A

Product name: HIFEN

Chemical active substance: Thifensulfuron 750 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(new authorization)

Applicant: Sharda Cropchem Ltd

Submission date: September 2023

MS Finalisation date: March 2024; February 2025

Version history

When	What
March 2024	ZRMs evaluated dRR submitted by Applicant
February 2025	The final Registration Report.

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Comments of zRMS are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are marked by grey colour).
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

In the briefly summary, **all uses were accepted in 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 the GAP table** on the basis on documentation submitted by Applicant and its detailed assessment presented in this dRR by ZRMs.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fn G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)	
					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, tritica- le)	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	-	Recommended water volume: 200-300 L/ha	PL	cMS

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product **Thifensulfuron 75% WG (HIFEN; Product code: SHA 4100 A)** containing the active substance thifensulfuron, which was included into Annex I of Council Directive 91/414/ EEC and 1107/2009, after re-evaluation.

The SANCO reports for thifensulfuron-methyl (SANCO/7577/VI/1997 final and SANTE/10150/ 2016 rev. 2) are considered to provide the relevant review information or a reference to where such information can be found.

The Annex I Inclusion Directives for thifensulfuron-methyl (2001/99/EC, 2010/77/EU, 540/2011, 2016/549 and 2016/1424) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the active substance thifensulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29/Jun/2001 shall be taken into account. Consideration of active substance for Annex 1 inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of thifensulfuron-methyl relating to efficacy.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

The detailed assessment of the individual trial and study data is located in the following report:

Report:	KCP 6.0/001 Biological Assessment Dossier Thifensulfuron 75% WG, Central
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Description of the plant protection product

Thifensulfuron 75% WG is a Water dispersible granules (WG) formulation containing 750 grams per kilogram (g/kg) thifensulfuron-methyl for use in winter cereals. Please refer to Table 3.1-1 to see the GAP covered by this document.

To support the registration of Thifensulfuron 75% WG in the GAP claimed crop, trials have been set up in winter cereal field crops. In 15 of the 81 cereal trials, conducted in Latvia (9) and Lithuania (6), the thifensulfuron WG formulation prepared by Sharda Cropchem Ltd – Thifensulfuron 75% WG – was compared against a reference thifensulfuron formulation currently on the market in Central and North Europe (Harmony 50 SX; 500 g/kg thifensulfuron-methyl SG). In four Slovakian selectivity trials, Thifensulfuron 75% WG was compared against a national standard reference product containing tribenuron (Granstar 75 WG; tribenuron 750 g/kg WG). In the remaining trials, Thifensulfuron 75% WG was compared against a co-formulation containing sulfonylureas, i.e. in six German and fifteen Hungary trials, a thifensulfuron + tribenuron co-formulation was used as reference product (Refine Extra SX; thifensulfuron 333 g/kg + tribenuron 166 g/kg WG and Granstar Super 50 SC; thifensulfuron 250 g/kg + tribenuron 250 g/kg SG, respectively) and in the remaining 32 Polish and 9 Czech trials, a thifensulfuron + chlorsulfuron co-formulation was used as reference product (Chisel Nowy; thifensulfuron 469 g/kg + chlorsulfuron 47 g/kg WG). The trials were conducted in 2014/15 and 2020 season in a range of European countries in the Maritime (i.e. Germany and Czech Republic), the North-east (i.e. Poland, Lithuania and Latvia) and the South-east (i.e. Slovakia and Hungary) EPPO zones.

According to the GAP, the proposed application rate of Thifensulfuron 75% WG is 40 grams per hectare (g/ha), with a maximum of one application per season, for post-emergence control of broadleaved weeds in winter cereals. This will deliver 30 g thifensulfuron per hectare. In the treated crops, the test product was tested against registered rates of the reference products employed, currently marketed in the countries where the trials were conducted.

The data presented in this dossier fully support the label claim for Thifensulfuron 75% WG for the control of broadleaved weeds in cereals.

Table 3.2-1: Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Winter cereals (wheat, barley, rye, oats, triticale)	Broadleaved weeds	CEU	0.04 kg/ha	Post-emergence application

Further details are in the table “All intended uses” in Part B - Section 0.

Description of active substance thifensulfuron

Thifensulfuron-methyl is a selective post-emergence herbicide used in cereals and other crops for broad-spectrum control of important broadleaved weeds across all climatic zones of Europe. The herbicidal activity of thifensulfuron-methyl was first reported in 1985 and in 1988, first approvals were obtained. It belongs to the chemical group of Sulfonylureas.

Thifensulfuron-methyl is applied as a foliar spray where it is rapidly absorbed by the foliage and is translocated throughout the plant to the growing points. After it is taken up, the active ingredient is immediately distributed in the weed plants that immediately stop growing. The best efficacy is achieved during conditions of rapid growth.

Today, thifensulfuron-methyl is registered and commercialised in several formulations around the world.

Table 3.2-2: Identity of thifensulfuron

Common name	Thifensulfuron
IUPAC name	3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylic acid
CA name	3-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-2-thiophenecarboxylic acid
CIPAC No	452
CAS Registry No.	79277-67-1
EEC No	N.a.
Minimum purity	N.a.
Structural formula¹	
Empirical formula	C ₁₁ H ₁₁ N ₅ O ₆ S ₂
Molecular mass	373.0 g/mol

¹ Source: Royal Society of Chemistry (RSC). Internet, Monday April 13th, 2020. URL: <http://www.chemspider.com/Chemical-Structure.82829.html>

Mode of action

Thifensulfuron-methyl acts by inhibiting the action of acetolactate synthase (ALS), also known as aceto-hydroxyacid synthase (AHAS). Without this enzyme, the plant cannot produce specific amino acids (isoleucine, leucine and valine) thereby preventing protein formation. This effectively prevents growth at the growing points of the plant, namely the apical meristem and root tip. Due to the primary target site and the chemical subgroup, thifensulfuron is classified as a HRAC group B herbicide (Imidazolinones and others). In the WSSA resistance classification system the Sulfonylureas are classified as group 2.

For further physico-chemical properties, please refer to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Information on similar formulations and current approvals

Thifensulfuron 75% WG is a WG formulation containing 750 grams per kilogram (g/kg) thifensulfuron. Data presented in this dossier is generated using this formulation in comparison with e.g. the DuPont reference products containing thifensulfuron. Thifensulfuron is currently registered under a variety of trade names and formulations throughout Europe and a selection of these are described in table below.

Table 3.2-3: Current approvals of thifensulfuron in the EU Central zone as well as connected EPPO zones where trials were conducted. Reference products as well as surfactants used in trials are also included

Country	Product	Active ingredient	Approval number
Austria	Harmony 50 SX	Thifensulfuron 481.9 g/kg SG	2941-1
Belgium	Harmony Pasture	Thifensulfuron-methyl 500 g/kg SG	9509P/B
Czech Republic	Refine 50 SX	Thifensulfuron-methyl 500 g/kg SG	4598-0
	Chisel 51.6 WG	Chlorsulfuron 49 g/kg + Thifensulfuron-methyl 469 g/kg SG	5010-1
Germany	Harmony SX	Thifensulfuron-methyl 500 g/kg SG	005950-00
	Refine Extra SX	Thifensulfuron-methyl 333 g/kg + Tribenuron-methyl 166 g/kg SG	006099-00
Hungary	Refine 50 SX	Thifensulfuron-methyl 500 g/kg SG	04.2/127-2/2018
Latvia	Harmonijs 50 š.g.	Thifensulfuron 481.9 g/kg SG	0300
	Calibre 50 SX	Thifensulfuron-methyl 333 g/kg + Tribenuron-methyl 166 g/kg SG	0301
	Kemiwet Plus	90% alcohol ethoxylate	n.a.
Lithuania	Harmony 50 SX	Thifensulfuron 481.9 g/kg SG	n.r.
	Calibre 50 SX	Thifensulfuron-methyl 333 g/kg + Tribenuron-methyl 166 g/kg SG	AS2-27H(2018)
	Trend	90% alcohol isodecyclic ethoxyl	n.a.
Netherland	Harmony SX	Thifensulfuron-methyl 500 g/kg SG	14710
Poland	Chisel Nowy 51.6 WG	Chlorsulfuron 47 g/kg + Thifensulfuron-methyl 469 g/kg SG	R-113/2014
	Trend 90 EC	90% alcohol isodecyclic ethoxyl	n.a.
Slovakia	Refine 50 SX	Thifensulfuron-methyl 500 g/kg SG	18-00400-AU
	Granstar 75 WG	Tribenuron 750 g/kg WG	19-00444-AU
	Trend 90	90% alcohol isodecyclic ethoxyl	n.a.
UK	Harmony SX	Thifensulfuron-methyl 500 g/kg SG	12181

Description of the target pests

The damaging economic effects of broadleaved weeds in cereals are well established, and justification for their control well documented. Thifensulfuron 75% WG control a number of very important broadleaved weeds found in cereals. Among the species that are controlled by Thifensulfuron 75% WG are broad-leaved weeds, like *Capsella bursa-pastoris*, *Chenopodium album*, *Stellaria media*, *Polygonum* spp. and *Matricaria* spp.

All the listed weeds are present throughout or in parts of the Central zone and in relevant EPPO zones. These weed species compete with the crops for light, moisture and nutrients, reducing crop yields and may obstruct harvestability.

Table 3.2-4: Glossary of pests mentioned in the report.

EPPO code	Scientific name	Common name
BRSNX	<i>Brassica napus</i>	Oilseed rape (volunteer)
CAPBP	<i>Capsella bursa-pastoris</i>	Shepherd's purse
CENCY	<i>Cyanus segetum</i>	Cornflower
GAESS	<i>Galeopsis spp.</i>	Hemp-nettle
GALAP	<i>Galium aparine</i>	Cleavers
GERDI	<i>Geranium dissectum</i>	Cut-leaved cranesbill
GERPU	<i>Geranium pusillum</i>	Small-flowered cranesbill
LAMPU	<i>Lamium purpureum</i>	Purple deadnettle
MATCH	<i>Matricaria chamomilla</i>	Scented mayweed
MATIN	<i>Tripleurospermum inodorum</i>	Scenless mayweed
MYOAR	<i>Myosotis arvensis</i>	Field forget-me-not
PAPRH	<i>Papaver rhoeas</i>	Common poppy
POLCO	<i>Fallopia convolvulus</i>	Black bindweed
POLPE	<i>Persicaria maculosa</i>	Redshank
SINAR	<i>Sinapis arvensis</i>	Charlock
STEME	<i>Stellaria media</i>	Common chickweed
THLAR	<i>Thlaspi arvense</i>	Field pennycress
VERAG	<i>Veronica agrestis</i>	Green field speedwell
VERAR	<i>Veronica arvensis</i>	Corn speedwell
VIOAR	<i>Viola arvensis</i>	Field violet

Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Winter wheat	CEU	-	Mono- and dicotyledon weeds	CEU	-
Winter barley	CEU	-	Mono- and dicotyledon weeds	CEU	-
Winter rye	CEU	-	Mono- and dicotyledon weeds	CEU	-
Winter triticale	CEU	-	Mono- and dicotyledon weeds	CEU	-
Winter oat	CEU	-	Mono- and dicotyledon weeds	CEU	-

Compliance with the Uniform Principles

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.

Information on trials submitted (6.2 Efficacy data)

Trials in this report were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this report have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application for registration of Thifensulfuron 75% WG, 18 efficacy trials were conducted in the Maritime EPPO zone (6) and the North-east EPPO zone (12).

In the 18 efficacy trials, the level of control obtained by Thifensulfuron 75% WG was assessed on dicotyledonous weeds present in the trials. Data on each individual weed species is only included from trials in which a minimum of 5 plants per m² or 1% ground cover were seen at the timing of the assessment.

Table 3.2-6: Presentation of efficacy trials (efficacy trials, preliminary trials...)

Use(s)	Target(s)	Country	Years	Type of trial	Number of trials (number of valid trials)				GEP, non- GEP, official	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
Winter cereals	Broadleaved weeds	Germany	2014/15	MED + E + S	2 (2)	-	-	-	GEP	Without surfactant
		Czech Rep.	2020/21	MED + E	4 (4)	-	-	-	GEP	Without surfactant
		Poland	2014/15	MED + E + S	-	-	-	6 (6)	GEP	With surfactant
		Lithuania	2014/15	MED + E + S	-	-	-	3 (3)	GEP	Without surfactant
		Latvia	2014/15	MED + E + S	-	-	-	3 (3)	GEP	Without surfactant
		Total, winter cereals (post-em)			6 (6)	-	-	12 (12)	-	

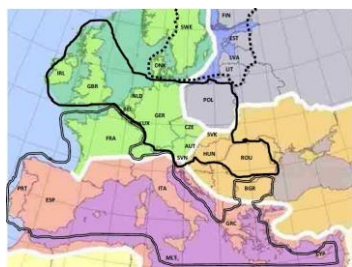
Climatic zones

Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country².

Germany and Czech Republic are located in the Maritime EPPO zone; Poland, Lithuania and Latvia are located in the North-east EPPO zone; and Slovakia is located in the South-east EPPO zone (Figure 3.2-1).

² Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, E. Bouma, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)



This Registration Report is prepared to support the submission of Thifensulfuron 75% WG throughout the Central Registration zone, therefore data from the Maritime, the South-east and the North-east EPPO zones are included. The data from each climatic zone is summarised separately.

Agronomic conditions

Cultural conditions of cereals and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between Germany, Czech Republic, Slovakia, Poland, Lithuania and Latvia. In cereals, the same thifensulfuron containing herbicides are already registered and used in the countries where tested for the same uses, i.e. to control broad-leaved weed species in winter cereals with post-emergence application.

(i) Weed physiology

Shepherd's-purse (*Capsella bursa-pastoris*), common lambsquarters (*Chenopodium album*), common chickweed (*Stellaria media*), *Polygonum* spp. and *Matricaria* spp. are all controlled by Thifensulfuron 75% WG and are all key weeds throughout Central Europe. In each country these weeds are very common and can cause large reductions in yield.

A number of cases of resistance to SU's has been reported from Europe on broadleaved weeds, but still, when treating the same weeds at the same application timing, no differences in level of control was observed between the countries and therefore the efficacy results from one country should be valid in another country.

(ii) Site selection

Although trials were performed throughout the EU, in each country the sites were carefully selected to ensure that for each weed species the level of control was assessed on a range of populations and application timings. To exert maximum control pressure and to exacerbate treatment differences in each country, this included some trials which contained high weed densities. No differences in the level of control were apparent between the different countries or regions in which the trials were conducted. For each weed species equivalent levels of control were recorded in Germany, Czech Republic, Poland, Lithuania and Latvia.

(iii) Agronomic practices

Agronomic practices in cereal field crops are similar throughout the Central zone as well as in the countries in the connected EPPO zones where trials were conducted. The levels of inorganic fertilizers and other crop inputs are similar between the countries.

(iv) Varieties

Although crop varieties tend to differ between countries, the crop safety of Thifensulfuron 75% WG has been tested on a wide range of varieties in both the selectivity- and efficacy trials. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance and yield data generated in one country is therefore relevant in another Member state.

(v) *Trial methodology*

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(vi) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for cereal production due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

Thifensulfuron is mainly a foliar acting herbicide but with some limited soil activity. In each country, trials have been conducted on a range of soil types with no difference seen in the level of control.

On the basis that the above factors do not influence the overall performance of Thifensulfuron 75% WG, it is the applicant's contention that data from Czech Republic, Germany, Slovakia and Poland is equally valid in demonstrating the products performance throughout the Central EU zone and the data from Lithuania and Latvia is valid as supporting data.

In six of the 18 efficacy trials, the performance of Thifensulfuron 75% WG was measured against a commercial standard thifensulfuron SG formulation currently on the market in Central and North Europe (Harmony 50 SX; 500 g/kg thifensulfuron-methyl SG). In the remaining eight efficacy trials, Thifensulfuron 75% WG was compared against a co-formulation containing sulfonylureas, i.e. in two German trials, a thifensulfuron + tribenuron co-formulation was used as reference product (Refine Extra SX; thifensulfuron 333 g/kg + tribenuron 166 g/kg WG) and in the remaining six Polish and four Czech trials, a thifensulfuron + chlorsulfuron co-formulation was used as reference product (Chisel Nowy; thifensulfuron 469 g/kg + chlorsulfuron 47 g/kg WG). The trials were carried out on winter cereals, i.e. winter wheat and winter rye.

The reference products used in the efficacy trials are listed in Table 3.2-7.

Table 3.2-7: Presentation of reference standards and surfactants used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Thifensulfuron reference product					
Harmony 50 SX	SG	500 g/kg thifensulfuron-methyl	0.023	LT	3
			0.030	LV	3
Thifensulfuron + chlorsulfuron reference product					
Chisel Nowy 51.6 WG	WG	47 g/kg chlorsulfuron	0.070 kg/ha	PL	6
		469 g/kg thifensulfuron	0.090 kg/ha	CZ	4
Thifensulfuron + tribenuron reference product					
Refine Extra SX	SG	333 g/kg thifensulfuron-methyl	90 g/ha	DE	2
		166 g/kg tribenuron-methyl	180 g/ha		
Surfactants					
Trend 90	-	90% alcohol isodecyclic ethoxyl	0.05%	LT	3 (ref. only)
			0.1%	PL	
			0.2%		
Kemiwet Plus	-	90% alcohol ethoxylate	0.1 L/ha	LV	3 (ref. only)

Comments of zRMS:	This document summarizes the information related to the efficacy of the plant protection product – HIFEN (product code: SHA 4100 A). SHA 4100 A is a water dispersible granules (WG) formulation containing 750 g/kg of thifensulfuron methyl. For now, this mentioned active substance is on the list of approved active substances.
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	Thifensulfuron methyl is a selective post-emergence herbicide used in cereals and other crops for broad-spectrum control of important broadleaved weeds across all climatic zones of Europe. The herbicidal activity of thifensulfuron methyl was first reported in 1985 and in 1988, first approvals were obtained. Thifensulfuron methyl belongs to the chemical group of sulfonylureas. All necessary information's about tested plant protection product (SHA 4100 A), active substance, studied weeds, reference products, etc. are correctly presented in this dRR by Applicant. In Poland 26 plant protection products containing thifensulfuron methyl are already registered in Poland (based on Registry of PPP dated 29.02.2024). The product – HIFEN (product code: 4100 A) containing thifensulfuron-methyl by Sharda Cropchem España has not been previously evaluated in any country according to Uniform Principles. Poland is a ZRMs. Romania and Hungary are cMS.
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3.2.1 Preliminary tests (KCP 6.1)

The activity of thifensulfuron is well known; as the active has been marketed for the use in a range of crops to control broadleaved weeds for more than 30 years, i.e. thifensulfuron-methyl has been approved since 1988. Based on the knowledge of the active substance and the experiences with the active in the label claimed crops, the necessary application rates to obtain sufficient control of broadleaved weeds are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Comments of zRMS:	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. 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.
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3.2.2 Minimum effective dose tests (KCP 6.2.1)

Thifensulfuron 75% WG was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Thifensulfuron 75% WG applied at 10 g/ha, 20 g/ha, 30 g/ha and 0.40 g/ha was evaluated in 18 winter cereal trials for the control of the dicotyledonous weeds present in the trials. The dose rates tested reflects 25%, 50%, 75% and 100% of the recommended rate of Thifensulfuron 75% WG, in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”. The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy was tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the Maritime EPPO zone (6, i.e. Germany and Czech Republic) and the North-east EPPO zone (12, i.e. Poland (6), Lithuania (3) and Latvia (3)) in winter wheat (13), winter barley (4) and winter rye (1).

Summary and evaluation of Minimum Effective Dose results for 0.040 kg/ha Thifensulfuron 75% WG target rate against broadleaved weeds in winter cereals, post-emergence application

To prove and to support the requested dose rate of 0.040 kg/ha Thifensulfuron 75% WG [30 g thifensulfuron-methyl per hectare] applied post-emergence for the control of broadleaved weeds in winter cereals, the assessment results of 18 efficacy trials performed in the Maritime EPPO zone (6) and the North-east EPPO zone (12) in 2014/15 and 2020/21 season are reported. Thifensulfuron 75% WG was included in these trials at 0.040 kg/ha to demonstrate the recommended dose rate as well as at three lower than recommended dose rates (0.010 kg/ha [7.5 g thifensulfuron-methyl per hectare], 0.020 kg/ha [15 g thifensulfuron-methyl per hectare] and 0.030 kg/ha [22.5 g thifensulfuron-methyl per hectare]).

The control of frequently occurring dicotyledonous weeds in winter cereals was assessed at different timings throughout the trial period. However, as the most accurate representation of whole plot product performance, the data obtained from the assessment carried out at approximately two to nine weeks after application is presented in the following summary tables. Table 3.2-8 and Table 3.2-9 therefore contains a summary of the assessment data obtained by visually estimating control obtained by the applied products at 15-66 days after post-emergence application in the Maritime EPPO zone and the North-east EPPO zone, respectively.

Maritime EPPO zone

In the Maritime EPPO zone, the average control of the assessed dicotyledonous weed species at the assessment carried out 31-36 days after application was 60.1%, 77.6% and 87.9% following a post-emergence application of Thifensulfuron 75% WG at 10, 20 and 30 g/ha, respectively, compared to 98.1% control achieved by the recommended rate, i.e. 40 g/ha. A satisfactory level of control may be achieved

with lower than recommended dose rate when applied post-emergence, but if weeds have already emerged, or if less susceptible broadleaved weed species are part of the flora in the field, Thifensulfuron 75% WG should be applied at the recommended dose rate to obtain a satisfactory control.

Table 3.2-8: Maritime zone: Minimum effective dose of Thifensulfuron 75% WG applied against frequently occurring broadleaved weeds in winter cereals. Efficacy rating at 31-36 days after post-emergence application

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with			
				Thifensulfuron 75% WG without surfactant at:			
				Mean (min-max)			
				0.010 kg/ha (25%)	0.020 kg/ha (50%)	0.030 kg/ha (75%)	0.040 kg/ha (100%)
MATCH	17-35	2	6.5-8	80 (-)	93.8 (92.5-95)	98.5 (97-100)	100 (-)
LAMPU	27-62	4	7.0-9.0	-	78.8 (70.0-85.0)	84.2 (75.0-94.0)	96.9 (92.5-100)
GALAP	27-32	3	6.0-7.0	-	79.2 (62.5-90.0)	85.2 (72.5-93.0)	94.2 (82.5-100)
VERPE	62	2	7.0-13.0	-	70.0 (65.0-75.0)	81.5 (78.0-85.0)	100 (100-100)
MATIN	24-27	3	7.0-21.0	-	81.0 (78.0-85.0)	87.6 (83.0-95.0)	98.3 (95.0-100)
PAPRH	19	3	7.0-12.0	85	80.2 (67.5-95.8)	83.3 (72.5-100)	96.7 (90.0-100)
POLPE	23-35	2	5.8-8.5	54.3 (36-72.5)	78.8 (75-82.5)	86.3 (85-87.5)	94.6 (94.3-95)
STEME	25-59	3	6.0-11.8	77.5	76.6 (70.0-82.5)	82.1 (72.5-98.8)	93.3 (87.5-100)
BRSNW	23-35	1	19.5	75	75	86.3	100
GERDI	16-33	1	6.3	70	77.5	88.8	92.5
MYOAR	24	1	7.0	-	83.0	88.0	93.0
VERAR	25-59	1	22.5	0	31	70.5	94.8
VIOAR	25-59	1	18.8	25	72.8	85	94.3
Mean of all assessments		27		60.1 (0-85)	77.6 (31-95.8)	87.9 (70.5-100)	98.1 (92.5-100)

Statistical evaluation revealed that Thifensulfuron 75% WG at 40 g/ha performed significantly better than the 10 g/ha dose rate at all 27 assessments included in the summary table. At 19 of the 27 assessments, Thifensulfuron 75% WG at recommended dose rate also performed significantly better than the 20 g/ha dose rate and at 6 of the 27 assessments, Thifensulfuron 75% WG at recommended dose rate also performed significantly better than the 30 g/ha dose rate.

North-east EPPO zone

In the North-east EPPO zone, the average control of the assessed dicotyledonous weed species at the assessment carried out 15-66 days after application, irrespective if applied with a surfactant or without, was 64.0%, 70.5% and 74.2% following a post-emergence application of Thifensulfuron 75% WG at 10, 20 and 30 g/ha, respectively, compared to 78.3% control achieved by the recommended rate, i.e. 40 g/ha. A satisfactory level of control may be achieved with lower than recommended dose rate when applied post-emergence, but if weeds have already emerged, or if less susceptible broadleaved weed species are part of the flora in the field, Thifensulfuron 75% WG should be applied at the recommended dose rate to obtain a satisfactory control.

Table 3.2-9: North-east zone: Minimum effective dose of Thifensulfuron 75% WG applied against frequently occurring broadleaved weeds in winter cereals. Efficacy rating at 15-66 days after post-emergence application.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with			
				Thifensulfuron 75% WG with and without surfactant at:			
				Mean (min-max)			
				0.010 kg/ha (25%)	0.020 kg/ha (50%)	0.030 kg/ha (75%)	0.040 kg/ha (100%)
BRSNW	14-50	1	2.3	74	75	84	85
CAPBP	12-55	4	3-7.4	85.1 (79-97.5)	88.5 (84-100)	89.8 (85-100)	93.8 (89-100)
CENCY	30-31	2	18.5-43.8	0.0 (-)	0.0 (-)	0.0 (-)	1.3 (0-2.5)
GAESS	10-14	2	11.7-16.7	95.4 (93.5-97.3)	96.4 (96-96.8)	97.4 (96.8-98)	98.5 (98.3-98.8)
GALAP	12-36	4	3-22.5	74.1 (45-90)	82.9 (70-91.5)	84.4 (70-92)	87.1 (74-93)
GERPU	12-16	1	3	65	76	83	86
LAMPU	12-65	7	4-23.8	48.6 (17.5-75)	57.3 (17.5-82.5)	60.6 (17.5-85)	65.5 (25-90.3)
MATCH	10-17	1	87	45	55	67.5	85
MATIN	10-33	9	5-129	68.5 (15-90)	76.5 (27.5-91)	80.8 (47.5-91.5)	87.0 (67.5-97)

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with			
				Thifensulfuron 75% WG			
				with and without surfactant at:			
				Mean (min-max)			
				0.010 kg/ha (25%)	0.020 kg/ha (50%)	0.030 kg/ha (75%)	0.040 kg/ha (100%)
MYOAR	12-32	3	5-105.7	50.5 (17.5-74)	57.4 (16.3-86)	64.5 (31.3-86)	70.6 (37.5-93)
PAPRH	30-32	3	4.5-13.5	55.5 (39-67.5)	67.2 (59-72.5)	73.5 (63-80)	82.3 (77-85)
POLCO	10-31	1	7.5	88.8	91	91	92
SINAR	10-12	1	30	95.8	97	98	99
STEME	10-65	7	4-112	67.8 (32.5-91)	74.4 (35-91.5)	78.4 (37.5-92)	83.0 (52.5-94)
THLAR	12-65	6	4-17.5	85.2 (56-100)	90.8 (73-100)	92.2 (74-100)	93.0 (78-100)
VERAG	24-59	1	5.2	0	0	0	0
VIOAR	12-61	10	4-66	57.5 (8.8-87.5)	64.0 (15-88.8)	69.5 (30-90.3)	72.4 (35-90.5)
Mean of all assessments		63		64.0 (0-100)	70.5 (0-100)	74.2 (0-100)	78.3 (0-100)
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with			
				Thifensulfuron 75% WG			
				with surfactant at:			
				Mean (min-max)			
				0.010 kg/ha (25%)	0.020 kg/ha (50%)	0.030 kg/ha (75%)	0.040 kg/ha (100%)
BRSNW	14-50	1	2.3	74	75	84	85
CAPBP	12-55	4	3-7.4	85.1 (79-97.5)	88.5 (84-100)	89.8 (85-100)	93.8 (89-100)
CENCY	30-31	2	18.5-43.8	0.0 (-)	0.0 (-)	0.0 (-)	1.3 (0-2.5)
GALAP	12-36	2	3-5.8	59.5 (45-74)	75.0 (70-80)	77.5 (70-85)	81.5 (74-89)
GERPU	12-16	1	3	65	76	83	86
LAMPU	12-65	4	4-13.5	38.9 (17.5-64)	49.9 (17.5-74)	53.6 (17.5-74)	59.0 (25-84)
I	12-31	6	5-16.5	73.8 (60-83)	82.3 (73.8-89)	84.3 (75-90)	89.2 (76.3-97)
MYOAR	30	1	5	74	86	86	93
PAPRH	30-32	3	4.5-13.5	55.5 (39-67.5)	67.2 (59-72.5)	73.5 (63-80)	82.3 (77-85)
STEME	16-63	3	4-9.5	61.2 (32.5-76)	66.3 (35-89)	68.8 (37.5-89)	75.5 (52.5-90)
THLAR	12-65	4	4-7.6	86.5 (56-100)	92.5 (73-100)	93.3 (74-100)	94.3 (78-100)
VERAG	24-59	1	5.2	0	0	0	0
VIOAR	14-61	6	4-66	56.5 (35-70)	62.9 (36.3-76)	69.2 (55-75)	72.3 (56.3-84)
Mean of all assessments		38		60.7 (0-100)	67.9 (0-100)	71.1 (0-100)	75.3 (0-100)
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with			
				Thifensulfuron 75% WG			
				without surfactant at:			
				Mean (min-max)			
				0.010 kg/ha (25%)	0.020 kg/ha (50%)	0.030 kg/ha (75%)	0.040 kg/ha (100%)
GAESS	10-14	2	11.7-16.7	95.4 (93.5-97.3)	96.4 (96-96.8)	97.4 (96.8-98)	98.5 (98.3-98.8)
GALAP	10-14	2	15-22.5	88.8 (87.5-90)	90.8 (90-91.5)	91.4 (90.8-92)	92.8 (92.5-93)
LAMPU	21-65	3	4.5-23.8	61.7 (35-75)	67.1 (41.3-82.5)	70.0 (43.8-85)	74.3 (45-90.3)
MATCH	10-17	1	87	45	55	67.5	85
MATIN	10-33	3	10-129	57.9 (15-90)	64.9 (27.5-91)	73.8 (47.5-91.5)	82.7 (67.5-93.5)
MYOAR	12-32	2	58-105.7	38.8 (17.5-60)	43.1 (16.3-70)	53.8 (31.3-76.3)	59.4 (37.5-81.3)
POLCO	10-31	1	7.5	88.8	91	91	92
SINAR	10-12	1	30	95.8	97	98	99
STEME	10-65	4	22.5-112	72.8 (56.3-91)	80.4 (67.5-91.5)	85.6 (75-92)	88.6 (80-94)
THLAR	59-63	2	12.5-17.5	82.5 (81.3-83.8)	87.5 (-)	90.1 (90-90.3)	90.5 (90.3-90.8)
VIOAR	12-59	4	11.3-44.3	59.1 (8.8-87.5)	65.6 (15-88.8)	70.1 (30-90.3)	72.6 (35-90.5)
Mean of all assessments		25		69.1 (8.8-97.3)	74.3 (15-97)	79.0 (30-98)	83.0 (35-99)

Statistical evaluation revealed that Thifensulfuron 75% WG at 40 g/ha performed significantly better than the 10 g/ha dose rate at 48 of 58 assessments where the statistical evaluation was reported in the trial reports. At 32 of the 48 assessments, Thifensulfuron 75% WG at recommended dose rate also performed significantly better than the 20 g/ha dose rate and at 14 of the 48 assessments, Thifensulfuron 75% WG at recommended dose rate also performed significantly better than the 30 g/ha dose rate. At the remaining 10 assessments, no significant differences were observed between the tested Thifensulfuron 75% WG dose rates when applied post-emergence, however, the proposed dose rate of 40 g/ha achieved consistently higher levels of control than obtained with the reduced dose rates. At five of the 63 assessments included in the summary table, no statistical evaluation was reported in the trial reports, however, also in these, consistently higher levels of control were reported for the recommended dose rate.

Conclusion

Based on results achieved on dicotyledonous weeds in the 14 winter cereal trials, it can be concluded that to consistently control frequently occurring broadleaved weeds in winter cereals, Thifensulfuron 75% WG should be applied post-emergence at 0.040 kg/ha.

Summary of all uses claimed on the label

Thifensulfuron 75% WG applied post-emergence at 0.040 kg/ha to control broadleaved weeds achieved good to excellent control of all target weeds. Reducing the application rate of Thifensulfuron 75% WG from the proposed dose rate (0.040 kg/ha) to 25%, 50% or 75% of that rate, resulted in lower levels of efficacy. To ensure that a satisfactory level of control is achieved with the proposed dose rate of 0.040 kg/ha, it is recommended that Thifensulfuron 75% WG is applied under optimal conditions, i.e. early growth stage of the weeds and optimal weather conditions.

As weeds often occur as a complex of several weeds with different susceptibility towards thifensulfuron, one application of Thifensulfuron 75% WG at the recommended rate should be used to efficiently control all weeds claimed on the label.

As will be demonstrated in the following sections, this document clearly demonstrates that the efficacy and crop safety of Thifensulfuron 75% WG is equivalent to that of the standard formulations containing thifensulfuron to which it was compared. The applicant therefore wishes to cite the original registrant's data on thifensulfuron now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	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 the 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 differ 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 be 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), BRNSW (1-DE), GERDI (1-DE), MYOAR (1-CZ), VERAR (1-DE) and VIOAR (1-DE). <u>In the N-E EPPO zone following weed species were studied)</u>
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- 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), GERPU (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).

Below, ZRMs presented results for MED dose against HIFEN:

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

Weed	Number of trials	Mean eff. at 0.010 kg/ha	Mean eff. at 0.020 kg/ha	Mean eff. at 0.030 kg/ha	Mean eff at 0.040 kg/ha
MATCH	2	80.0%	93.8%	98.5%	100%
LAMPU	4	not studied	78.8%	84.2%	96.9%
GALAP	3	not studied	79.2%	85.2%	94.2%
VERPE	2	not studied	70.0%	81.5%	100%
MATIN	3	not studied	81.0%	87.6%	98.3%
PAPRH	3	85.0%	80.2%	83.3%	96.7%
POLPE	2	54.3%	78.8%	86.3%	94.6%
STEME	3	77.5%	76.6%	82.1%	93.3%
BRSNW	1	75.0%	75.0%	86.3%	100%
GERDI	1	70.0%	77.5%	88.8%	92.5%
MYOAR	1	not studied	83.0%	88.0%	93.0%
VERAR	1	0.0%	31.0%	70.5%	94.8%
VIOAR	1	25.0%	72.8%	85.0%	94.3%

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

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 were moderately susceptible (LAMPU, GALAP, VERPE, MATIN, PAPRH, POLPE, STEME, BRSNW, GERDI, MYOAR and 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.

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

Weed	Number of trials	Mean eff. at 0.010 kg/ha	Mean eff. at 0.020 kg/ha	Mean eff. at 0.030 kg/ha	Mean eff at 0.040 kg/ha
BRSNW	1	74.0%	75.0%	84.0%	85.0%
CAPBP	4	85.1%	88.5%	89.8%	93.8%
CENCY	2	0.0%	0.0%	0.0%	1.3%
GAESS	2	95.4%	96.4%	97.4%	98.5%
GALAP	4	74.1%	82.9%	84.4%	87.1%
GERPU	1	65.0%	76.0%	83.0%	86.0%
LAMPU	7	48.6%	57.3%	60.6%	65.5%
MATCH	1	45.0%	55.0%	67.5%	85.0%
MATIN	9	68.5%	76.5%	80.8%	87.0%
MYOAR	3	50.5%	57.4%	64.5%	70.6%
PAPRH	3	55.5%	67.2%	73.5%	82.3%
POLCO	1	88.8%	91.0%	91.0%	92.0%

	SINAR	1	95.8%	97.0%	98.0%	99.0%
	STEME	7	67.8%	74.4%	78.4%	83.0%
	THLAR	6	85.2%	90.8%	92.2%	93.0%
	VERAG	1	0.00%	0.00%	0.00%	0.00%
	VIOAR	10	57.5%	64.0%	69.5%	72.4%
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						
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), 3 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 (trials from PL, LT, LV, CZ and DE):						
✓ 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 0.010 kg/ha	Mean eff. at 0.020 kg/ha	Mean eff. at 0.030 kg/ha	Mean eff at 0.040 kg/ha	
BRSNW	2	74.5%	75.0%	85.2%	92.5%	
CAPBP	4	85.1%	88.5%	89.8%	93.8%	
CENCY	2	0.0%	0.0%	0.0%	1.3%	
GAESS	2	95.4%	96.4%	97.4%	98.5%	
GALAP	7	74.1%	81.1%	84.8%	90.7%	
GERDI	1	70.0%	77.5%	88.8%	92.5%	
GERPU	1	65.0%	76.0%	83.0%	86.0%	
LAMPU	7	48.6%	57.3%	60.6%	65.5%	
MATIN	12	68.5%	78.8%	84.2%	92.7%	
MATCH	3	41.7%	74.4%	83.0%	92.5%	
MYOAR	4	50.5%	70.2%	76.3%	81.8%	
PAPRH	6	70.3%	73.7%	78.4%	89.5%	
POLCO	1	88.8%	91.0%	91.0%	92.0%	
POLPE	2	54.3%	78.8%	86.3%	94.6%	
SINAR	1	95.8%	97.0%	98.0%	99.0%	
STEME	10	72.7%	75.5%	80.3%	88.2%	
THLAR	6	85.2%	90.8%	92.2%	96.7%	
VERAR	1	0.0%	31.0%	70.5%	94.8%	
VERAG	1	0.0%	0.0%	0.0%	0.0%	
VIOAR	11	41.3%	68.4%	77.3%	83.4%	
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						
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 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, LAMPU, 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. <u>ZRMs conclusion:</u> 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) carried out on winter wheat. 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. Therefore, 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. Appli-
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	cant indicated Hungary and Romania as a cMS, but without submitting any MED or 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 MED post-emergence for S-E EPPO zone to be insufficiently supported.
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3.2.3 Efficacy tests (KCP 6.2.2)

Data from 18 efficacy trials conducted in the Maritime EPPO zone (6, i.e. Germany (2) and Czech Republic (4)) and the North-east EPPO zone (12, i.e. Poland (6), Lithuania (3) and Latvia (3)) have been included in this biological assessment dossier to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone.

The 18 efficacy trials were conducted in winter cereals where test- and reference products were applied post-emergence of the crop.

Table 3.2-10: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152(4), PP 1/181(4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/93(3)
Experimental design	Plot design	RCBD (18)
	Plot size	10-27.5 m ²
	Number of replications	4 (18)
Crop	Trials per crop	Winter cereals (18), i.e. TRZAW (13), HORVW (4) and SECCW (1)
	Varieties per crop	Winter wheat (13): Ada (1), Akteur (1), JB Asano (1), Bamberka (1), Bogatka (2), Legenda (1), Patras (1), Skagen (5) Winter barley (4); KWS Kosmos (2), LG Triumph (2). Winter rye (1): Matador
	Sowing period	September 9 th to October 29 th
Application	Crop stage (BBCH)* at application	BBCH 21-32
	Timing Pest stage at appl. (1)	Post-emergence BBCH 08-65 – for details on the growth stage of the specific weed at application, please refer to summary tables in Appendix 5
	Number of appl. Intervals between appl.	1 (18) n.a.
	Spray volumes	200-300 L/ha

Assessment	Assessment types	- Visual estimation of biomass reduction per plot compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) or calculated, based on weed counts (COUPLA) or weed ground cover (GROUND) in a defined area, as compared to the untreated check. - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms.
	Assessment dates	7 to 93 DAT
Other relevant information	Soil type	Light to heavy soils
	Natural / artificial inoculation...	Natural
	Field / Greenhouse...	Field

For further information on the location of the trials, trialist and guidelines used in the trials from the Maritime EPPO zone and the North-east EPPO zone, please refer to Appendix 4, Table 1 and Appendix 4, Table 4, respectively. For further information on soils, trial design, crops and varieties in the trials from the Maritime EPPO zone and the North-east EPPO zone, please refer to Appendix 4, Table 2 and Appendix 4, Table 5, respectively. For further details on application in trials conducted in the Maritime EPPO zone and the North-east EPPO zone, please refer to Appendix 4, Table 3 and Appendix 4, Table 6, respectively. For further information on date of sowing, growth stage at application and reference products applied in the two EPPO zone, please refer to Appendix 5, Table 1 and Appendix 5, Table 2.

In the 18 trials, the level of control obtained by Thifensulfuron 75% WG was assessed on dicotyledonous weeds present in the trials. Data on each individual weed species is only included from trials in which a minimum of 5 plants per m² or 1% ground cover were seen at the timing of the assessment.

Use 001: Control of broadleaved weeds in winter cereals with a single application of 0.040 kg/ha Thifensulfuron 75% WG, applied post-emergence to the crop

The efficacy trials were conducted to prove the following label claims:

Description of Use 001

Crop, stage	Winter cereals, post-emergence BBCH 13-39
Use rate Use frequency Application timing	0.040 kg/ha Thifensulfuron 75% WG 1x Post-emergence to weeds and crop
Target weeds	Broadleaved weeds, e.g. <i>Capsella bursa-pastoris</i> , <i>Chenopodium album</i> , <i>Amaranthus spp.</i> , <i>Matricaria spp.</i> , <i>Stellaria media</i> , <i>Polygonum spp.</i>

The effectiveness of applying Thifensulfuron 75% WG post-emergence against dicotyledonous weeds was evaluated in 18 efficacy trials conducted in winter cereals (i.e. winter wheat (13), winter barley (4) and winter rye (1)). These trials were carried out in 2014/15 and 2020/21 season in the Maritime EPPO zone (6, i.e. Germany (2) and Czech Republic (4)) and the North-east EPPO zone (12, i.e. Poland (6), Lithuania (3) and Latvia (3)). The objective was to confirm the performance of Thifensulfuron 75% WG at 0.040 kg/ha (i.e. 30 g thifensulfuron per hectare) and compare this to reference products registered for similar uses. In the trials, one application was applied in the Spring (April-May).

In six of the 18 efficacy trials, Thifensulfuron 75% WG was tested alongside an EU approved thifensulfuron formulation, i.e. Harmony 50 SX (LT, LV), which was applied with a surfactant. In six Polish efficacy trials, Thifensulfuron 75% WG was compared against a national standard reference product containing thifensulfuron and chlorsulfuron (Chisel Nowy 51.6 WG; thifensulfuron 469 g/kg + chlorsulfuron 47 g/kg

WG), which also was applied with a surfactant. Finally, in the two German trials, Thifensulfuron 75% WG was tested alongside an EU approved thifensulfuron-methyl + tribenuron-methyl formulation, i.e. Refine Extra.

Maritime zone

To demonstrate the effectiveness of the test product at the recommended dose rate against broadleaved weeds following post-emergence application in winter cereals as well as compare it to the reference product included in the two German trials and four Czech trials, results are presented from one assessment carried out approx. one month (range: four to five weeks) after application.

When applied at 0.040 kg/ha post-emergence in the Maritime zone, Thifensulfuron 75% WG achieved good to excellent control of annual broadleaved weeds commonly found in winter cereals. In all species evaluated, the effect achieved with Thifensulfuron 75% WG was similar to the effect obtained with the thifensulfuron + tribenuron reference product applied at registered rate in the trials. Statistical evaluation of the 27 assessments included in the summary table revealed that no significant differences were observed between the two tested products.

Table 3.2-11: Maritime zone, winter cereals – Broadleaved weed control results by Thifensulfuron 75% WG applied at 0.040 kg/ha post-emergence and compared against control obtained with the thifensulfuron + tribenuron-containing reference product at registered rate in the efficacy tests 2014/15 and 2020/21 (Spring/early summer assessment, 28-58 DAA).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Thifensulfuron 75% WG at 30 g ai/ha is >, < or =, compared to the reference product at registered dose rate. = : ± 5% control			Overall
				Thifensulfuron 75% WG at:	Reference product at:				
				Mean (min-max)					
				0.040 kg/ha [30 g ai/ha]	1N	>	=	<	
Annual broadleaved weeds, Visual control									
MATCH	17-35	2	6.5-8	100 (-)	100 (-)		2		=
LAMPU	27-62	4	7.0-9.0	96.9 (92.5-100)	100 (100-100)		3	1	=
GALAP	27-32	3	6.0-7.0	94.2 (82.5-100)	100 (100-100)		2	1	=
VERPE	62	2	7.0-13.0	100 (100-100)	100 (100-100)		2		=
MATIN	24-27	3	7.0-21.0	98.3 (95.0-100)	100 (100-100)		2	1	=
PAPRH	19	3	7.0-12.0	96.7 (90.0-100)	100 (100-100)		2	1	=
POLPE	23-35	2	5.8-8.5	94.6 (94.3-95)	94.6 (93.5-95.8)		2		=
STEME	25-59	3	6.0-11.8	93.3 (87.5-100)	100 (100-100)		1	2	<
BRSNW	23-35	1	19.5	100	100.0		1		=
GERDI	16-33	1	6.3	92.5	98.3			1	<
MYOAR	24	1	7.0	93.0	100			1	<
VERAR	25-59	1	22.5	94.8	92.8		1		=
VIOAR	25-59	1	18.8	94.3	90.0		1		=
Mean, all assessments		27		98.1 (92.5-100)	97.0 (90-100)		19	8	=

In Table 3.2-12, the weed species are classified according to their average sensitivity to 0.040 kg/ha of Thifensulfuron 75% WG in the Maritime EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the broadleaved weed spectrum controlled after application of 0.040 kg/ha Thifensulfuron 75% WG post-emergence to weeds are listed in Table 3.2-15.

Table 3.2-12: Weed control spectrum of Thifensulfuron 75% WG at 0.040 kg/ha in the Maritime zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥ 95 %)		
<i>Brassica napus</i>	Volunteer oilseed rape	BRSNX
<i>Matricaria chamomilla</i>	Scented mayweed	MATCH
<i>Papaver rhoeas</i>	Common poppy	PAPRH
<i>Lamium purpureum</i>	purple archangel	LAMPU
<i>Veronica persica</i>	Buxbaum's speedwell	VERPE
<i>Tripleurospermum inodorum</i>	horse daisy	MATIN
Susceptible (85 – 94.9 %)		
<i>Geranium dissectum</i>	Cut-leaved cranesbill	GERDI
<i>Persicaria maculosa</i>	Redshank	POLPE
<i>Veronica arvensis</i>	Corn speedwell	VERAR
<i>Viola arvensis</i>	Field violet	VIOAR
<i>Stellaria media</i>	Common chickweed	STEME
<i>Galium aparine</i>	goosegrass	GALAP
<i>Myosotis arvensis</i>	common scorpiongrass	MYOAR
Moderately Susceptible (70 – 84.9 %)		
-	-	-
Moderately tolerant (50 – 69.9 %)		
-	-	-
Tolerant (0 – 49.9 %)		
-	-	-

North-east zone

To demonstrate the effectiveness of the test product at the recommended dose rate against broadleaved weeds following post-emergence application in winter cereals as well as compare it to the reference products included in the trials, results are presented from one assessment carried out approx. four weeks (range: two to eight weeks) after application.

Table 3.2-13: North-east zone, winter cereals – Broadleaved weed control results by Thifensulfuron 75% WG applied at 0.040 kg/ha post-emergence and compared against control obtained with the thifensulfuron-containing reference products at registered rate in the efficacy tests 2014/15. In the same table, the results obtained with the test product applied with a surfactant and without a surfactant at 0.040 kg/ha has been separated (Spring/early summer assessment, 15-66 DAA).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Thifensulfuron 75% WG at 30 g ai/ha is >, < or =, compared to the reference product at registered dose rate. = : ± 5% control			Overall	
				Thifensulfuron 75% WG with and without surfactant at:	Reference product with surfactant at:					
				Mean (min-max)						
				0.040 kg/ha [30 g ai/ha]	1N	>	=	<		
Annual broadleaved weeds, Visual control										
BRSNW	14-50	1	2.3	85	86	2	1		=	
CAPBP	12-55	4	3-7.4	93.8 (89-100)	95.8 (92-100)		4		=	
CENCY	30-31	2	18.5-43.8	1.3 (0-2.5)	76.3 (67.5-85)			2	<	
GAESS	10-14	2	11.7-16.7	98.5 (98.3-98.8)	97.5 (97.3-97.8)			2	=	
GALAP	12-36	4	3-22.5	87.1 (74-93)	86.6 (70-96)	2	3	1	=	
GERPU	12-16	1	3	86	96			1	<	
LAMPU	12-65	7	4-23.8	65.5 (25-90.3)	67.3 (30-89)			3	2	=
MATCH	10-17	1	87	85	85			1		=
MATIN	10-33	9	5-129	88.6 (67.5-100)	89.0 (70-100)	2	8	1	=	
MYOAR	12-32	3	5-105.7	70.6 (37.5-93)	70.2 (37.5-93)			3		=
PAPRH	30-32	3	4.5-13.5	82.3 (77-85)	84.3 (78-90)			3		=
POLCO	10-31	1	7.5	92	94			1		=

Weed Growth stage at application [BBCH] No. of trials			Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Thifensulfuron 75% WG at 30 g ai/ha is >, < or =, compared to the reference product at registered dose rate. = : ± 5% control			Overall	
				Thifensulfuron 75% WG with and without surfactant at:	Reference product with surfactant at:					
				Mean (min-max)						
				0.040 kg/ha [30 g ai/ha]	1N					
EPPO Code						>	=	<		
SINAR	10-12	1	30	99	98.5		1		=	
STEME	10-65	7	4-112	83.0 (52.5-94)	84.1 (50-95)		6	1	=	
THLAR	12-65	6	4-17.5	96.7 (90.3-100)	96.6 (90.3-100)		6		=	
VERAG	24-59	1	5.2	0	10			1	<	
VIOAR	12-61	10	4-66	72.4 (35-90.5)	73.4 (33.8-88.8)	2	5	3	=	
Mean, all assessments			63		78.9 (0-100)	82.3 (10-100)	4	47	12	=
Weed Growth stage at application [BBCH] No. of trials			Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Thifensulfuron 75% WG at 30 g ai/ha is >, < or =, compared to the thifensulfuron refer- ence product at registered dose rate. = : ± 5% control			Overall	
				Thifensulfuron 75% WG with- out surfactant at:	Thifensulfuron ref. prod. with surfactant at:					
				Mean (min-max)						
				0.040 kg/ha [30 g ai/ha]	1N					
EPPO Code						>	=	<		
Annual broadleaved weeds, Visual control										
GAESS	10-14	2	11.7-16.7	98.5 (98.3-98.8)	97.5 (97.3-97.8)		2		=	
GALAP	30-36	2	15-22.5	92.8 (92.5-93)	90.3 (90-90.5)		2		=	
LAMPU	21-65	3	13.7-23.8	74.3 (45-90.3)	68.3 (41.3-82.5)	2	1		>	
MATCH	10-17	1	87	85	85		1		=	
MATIN	10-33	3	10-129	82.7 (67.5-93.5)	82.6 (70-92)		3		=	
MYOAR	12-32	2	58-105.7	59.4 (37.5-81.3)	58.8 (37.5-80)		2		=	
POLCO	10-31	1	7.5	92	94		1		=	
SINAR	10-12	1	30	99	98.5		1		=	
STEME	10-65	4	22.5-112	88.6 (80-94)	88.3 (81.3-93)		4		=	
THLAR	59-63	2	12.5-17.5	90.5 (90.3-90.8)	90.4 (90.3-90.5)		2		=	
VIOAR	12-59	4	11.3-44.3	72.6 (35-90.5)	69.9 (33.8-88.8)	1	3		=	
Mean, all assessments			25		83.0 (35-99)	81.5 (33.8-98.5)	3	22		=
Weed Growth stage at application [BBCH] No. of trials			Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Thifensulfuron 75% WG at 30 g ai/ha is >, < or =, compared to the thifensulfuron + chlorsulfuron reference product at ~36.1 g ai/ha. = : ± 5% control			Overall	
				Thifensulfuron 75% WG with surfactant at:	Thifensulfuron + chlorsulfuron ref. prod. with surfactant at:					
				Mean (min-max)						
				0.040 kg/ha [30 g ai/ha]	0.070 kg/ha [~32.8+3.3 g ai/ha]					
EPPO Code						>	=	<		
Annual broadleaved weeds, Visual control										
BRSNW	14-50	1	2.3	85	83		1		=	
CAPBP	12-55	4	3-7.4	93.8 (89-100)	93.0 (88-100)		4		=	
CENCY	30-31	2	18.5-43.8	1.3 (0-2.5)	18.8 (17.5-20)			2	<	
GALAP	12-36	2	3-5.8	81.5 (74-89)	77.5 (65-90)	1	1		=	
GERPU	12-16	1	3	86	94			1	<	
LAMPU	12-65	4	4-13.5	59.0 (25-84)	62.4 (22.5-85)		3	1	=	
MATIN	12-31	6	5-16.5	91.5 (76.3-100)	88.0 (73.8-100)	3	3		=	
MYOAR	30	1	5	93	93		1		=	
PAPRH	30-32	3	4.5-13.5	82.3 (77-85)	77.7 (75-80)	1	2		=	
STEME	16-63	3	4-9.5	75.5 (52.5-90)	74.7 (40-93)	1	1	1	=	
THLAR	12-65	4	4-7.6	99.8 (99-100)	99.8 (99-100)		4		=	
VERAG	24-59	1	5.2	0	0		1		=	
VIOAR	14-61	6	4-66	72.3 (56.6-84)	70.4 (50-84)	1	5		=	
Mean, all assessments			38		76.2 (0-100)	76.1 (0-100)	7	26	5	=

When applied at 0.040 kg/ha post-emergence in the North-east zone, Thifensulfuron 75% WG achieved good to excellent control of annual broadleaved weeds commonly found in winter cereals. In all species evaluated, the effect achieved with Thifensulfuron 75% WG was similar to the effect obtained with the thifensulfuron reference product applied at registered rate in the trials. Statistical evaluation of the 25 assessments included in the summary table revealed that Thifensulfuron 75% WG at 0.040 kg/ha performed significantly better than the thifensulfuron reference product at three assessments. At the remaining 22 assessments, no significant differences were observed between the two tested products.

In six of the twelve trials, conducted in Poland, a national reference product containing thifensulfuron and chlorsulfuron (Chisal Nowy 51.6 WG) was included. In all species evaluated, except against CENCY, the

effect achieved with Thifensulfuron 75% WG was similar to the effect obtained with Chisal Nowy 51.6 WG at registered rate (90 g/ha) in the Polish trials. Statistical evaluation of 33 of the 38 assessments included in the summary table revealed that the reference product at registered rate (90 g/ha) performed significantly better than Thifensulfuron 75% WG at 0.040 kg/ha at six assessments. At the remaining 27 assessments, no significant differences were observed between the two tested products. At five of the 38 assessments included in the summary table, no statistical evaluation was reported in the trial reports. When comparing Thifensulfuron 75% WG against Chisal Nowy 51.6 WG at a dose rate comparable (0.070 kg/ha = ~33 g thifensulfuron/ha) to the recommended dose rate of Thifensulfuron 75% WG (30 g thifensulfuron/ha), statistical evaluation of 33 of the 38 assessments included in the summary table revealed that Thifensulfuron 75% WG at 0.040 kg/ha performed significantly better than the reference product at 70 g/ha at five assessments and at three assessments, the reference product performed significantly better than Thifensulfuron 75% WG. At the remaining 26 assessments, no significant differences were observed between the two tested products.

In Table 3.2-14, the weed species are classified according to their average sensitivity to 0.040 kg/ha of Thifensulfuron 75% WG in the North-east EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the broadleaved weed spectrum controlled after application of 0.040 kg/ha Thifensulfuron 75% WG post-emergence to weeds are listed in Table 3.2-15.

Table 3.2-14: Weed control spectrum of Thifensulfuron 75% WG at 0.040 kg/ha in the North-east zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥95 %)		
<i>Galeopsis spp.</i>	Hemp-nettle	GAESS
<i>Sinapis arvensis</i>	Charlock	SINAR
<i>Thlaspi arvense</i>	Field pennycress	THLAR
Susceptible (85 – 94.9 %)		
<i>Brassica napus</i>	Volunteer oilseed rape	BRSNX
<i>Capsella bursa-pastoris</i>	Shepherd's purse	CAPBP
<i>Galium aparine</i>	Cleavers	GALAP
<i>Geranium pusillum</i>	Small-flowered cranesbill	GERPU
<i>Matricaria chamomilla</i>	Scented mayweed	MATCH
<i>Tripleurospermum inodorum</i>	Scentless mayweed	MATIN
<i>Fallopia convolvulus</i>	Black bindweed	POLCO
Moderately Susceptible (70 – 84.9 %)		
<i>Myosotis arvensis</i>	Field forget-me-not	MYOAR
<i>Papaver rhoeas</i>	Common poppy	PAPRH
<i>Stellaria media</i>	Common chickweed	STEME
<i>Viola arvensis</i>	Field violet	VIOAR
Moderately tolerant (50 – 69.9 %)		
<i>Lamium purpureum</i>	Purple deadnettle	LAMPU
Tolerant (0 – 49.9 %)		
<i>Cyanus segetum</i>	Cornflower	CENCY
<i>Veronica agrestis</i>	Green field speedwell	VERAG

Summary and conclusion

Based on the results of 18 field efficacy trials carried out in 2014/15 and 2020/21 season, the following can be concluded for the intended use ‘Control of broadleaved weeds’ with Thifensulfuron 75% WG applied post-emergence at the rate of 0.040 kg/ha in winter cereals:

- Thifensulfuron 75% WG applied post-emergence at the proposed dose rate of 0.040 kg/ha provides a high level of control of a range of broadleaved weeds commonly found in winter cereals. As weeds often occur as a complex of several weeds with different susceptibility towards thifensulfuron, one application of Thifensulfuron 75% WG at 0.040 kg/ha in winter cereals should be used to efficiently control all weeds claimed on the label.
- Compared to the thifensulfuron straight reference product, the efficacy obtained with Thifensulfuron 75% WG is comparable against the weed species evaluated in the six trials.
- Compared to the thifensulfuron + chlorsulfuron co-formulated reference product, the efficacy obtained with Thifensulfuron 75% WG is comparable to slightly inferior against the weed species evaluated in the six trials.
- The trial results are considered valid for all intended Central zone countries.

Thifensulfuron 75% WG applied post-emergence is suitable for the control of broadleaved weeds in winter cereals.

All winter cereals claimed in the GAP offer similar levels of competition, so when treating the weeds at similar growth stages in the different winter cereals, the same level of control is obtained in the GAP claimed crops. Therefore, for any label claims not adequately supported for one crop type, the applicant requests that the zonal evaluators read across to the data on the other crop types.

As this Registration Report also clearly demonstrates that the efficacy and – as will be demonstrated in the following two sections – crop safety of Thifensulfuron 75% WG is equivalent to the standard thifensulfuron-methyl products to which it was compared. The applicant therefore wishes to cite the original registrant’s data on Harmony 50 SX®/Refine® now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant’s data and requests that the zonal evaluator extrapolate from those data.

The proposed label claims across uses, based on control achieved with Thifensulfuron 75% WG applied at 0.040 kg/ha, has been summarized in Table 3.2-15. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4 (October 3rd, 2013), however this does not replace individual MS systems for expressing control on national labels:

Susceptibility	Abbreviation	Level of control
Highly Susceptible	HS	95-100 %
Susceptible	S	85 – 94.9 %
Moderately Susceptible	MS	70 – 84.9 %
Moderately tolerant	MT	50 – 69.9 %
Tolerant	T	0 – 49.9 %

Table 3.2-15: Broadleaved weed spectrum controlled by 0.040 kg/ha Thifensulfuron 75% WG after post-emergence application to weeds, proven by testing results of the applicant in 2014/15 and 2020/21.

EPPO code	Scientific name	Application timings Post-emergence
Broadleaved weeds		
BRSNX	<i>Brassica napus</i>	HS
CAPBP	<i>Capsella bursa-pastoris</i>	HS
CENCY	<i>Cyanus segetum</i>	T
GAESS	<i>Galeopsis spp.</i>	HS
GALAP	<i>Galium aparine</i>	S

EPPO code	Scientific name	Application timings Post-emergence
GERDI	<i>Geranium dissectum</i>	S
GERPU	<i>Geranium pusillum</i>	S
LAMPU	<i>Lamium purpureum</i>	S
MATCH	<i>Matricaria chamomilla</i>	HS
MATIN	<i>Matricaria inodorum</i>	HS
MYOAR	<i>Myosotis arvensis</i>	S
PAPRH	<i>Papaver rhoeas</i>	HS
POLCO	<i>Fallopia convolvulus</i>	S
POLPE	<i>Persicaria maculosa</i>	HS
SINAR	<i>Sinapis arvensis</i>	HS
STEME	<i>Stellaria media</i>	HS
THLAR	<i>Thlaspi arvense</i>	HS
VERAG	<i>Veronica agrestis</i>	T
VERAR	<i>Veronica arvensis</i>	S
VIOAR	<i>Viola arvensis</i>	S

Applicant would like to refer to the EPPO standard PP 1/226(3) where is indicated that full number of trials in different years is required “particularly for plant protection products or active substances which not have been on the market in the EPPO region in which authorization is sought”. It is important to remark that the EPPO standard is referring to the region where registration is sought and not to a specific country, thus applicant considers that presence of standards has to be evaluated taking into account the registers in the whole Central Zone. The same EPPO PP 1/226(3) indicates that reduced number of trials can be presented “where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance on closely related pests or against the same pests on different crops”. Thifensulfuron formulations have been registered in Central Zone and in countries where trials were conducted for various years like Chisel Nowy 51.6 WG (reg nr R-112/2014) registered in Poland in 2014, Aneks SX 50 SG (reg nr R-109/2009) registered in Poland in 2009, Calibre SX 50 SG (reg nr R-106/2009) registered in Poland in 2009, Chenkar 750 WG (reg nr R-37/2014) registered in Poland in 2014, Refine extra SX (reg nr 006099-00) registered in Germany in 2011, Refine 50 SX (reg nr 4598-0) registered in the Czech Republic in 2013, Refine 50 SX (reg nr 02.5/120/2009) registered in Hungary in 2009. According to this, formulation has been widely proved in Central Zone where registration is sought, thus applicant considers that number of trials are enough to register formulation.

Comments of zRMS:	Applicant presented all details about efficacy methodology used during efficacy trials (in total 18) above. 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 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. Therefore, 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 been 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
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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. Product 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%	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 been 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). Therefore, 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	1N
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). Therefore, 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.	St. Ref. Product used during trials
			70 g/ha	90 g/ha	1N	
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.

In addition, 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. <i>Galeopsis tetrahit</i>) 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. <u>Following weeds can be accepted in Polish label:</u> 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 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. <u>Accepted list of weed species and their sensitivity for Polish label against recommended dose (0.040 kg/ha) of HIFEN:</u> ✓ <i>Susceptible weeds:</i> BRSNW (only in winter rye), CAPBP, GALAP, MATIN,
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	MATCH, PAPRH, POLPE, STEME, THLAR; ✓ <i>Moderately sensitive weeds</i>: MYOAR, VIOAR; ✓ <i>Moderately tolerant weeds</i>: 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). In addition, 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. That 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. Therefore, 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 were 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.
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3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

3.3.1 Summary and Conclusions

Resistance is a natural phenomenon embodied in the process of the evolution of biological systems and has been experienced over and over again in the past. According to Heap (2020³) resistance is the naturally occurring inheritable ability of some weed biotypes within a population to survive an herbicide treatment that would, under normal conditions of use, effectively control that weed population. Selection of resistant biotypes may eventually result in control failures.

The risk of resistance was analysed following the EPPO-Standard (2015⁴), the classification of the Herbicide Resistance Action Committee (HRAC)⁵ and the international Survey of Herbicide Resistant Weeds (Heap, 2020). So far, 84 cases of resistance with thifensulfuron-methyl in primarily broadleaved weeds have been reported worldwide. Of these, seven cases have been reported from Europe on six different broadleaved weed species. The active substance is therefore classified as having a high inherent risk.

The evaluation of the agronomic risk concludes, that Thifensulfuron 75% WG bears a low risk of resistance.

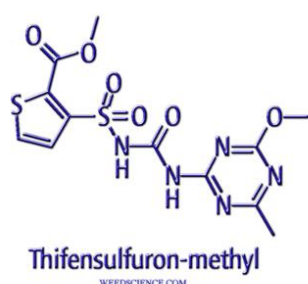
The Registration of Thifensulfuron 75% WG is endorsed.

3.3.2 Mode of Action

Thifensulfuron 75% WG is WG formulation composed of 750 g/kg thifensulfuron-methyl.

Thifensulfuron-methyl is an herbicide belonging to the group of sulfonylurea's (SU). When applied post emergence, thifensulfuron-methyl is effective on a wide range of broadleaved weeds. The chemical structures of thifensulfuron-methyl are shown in Figure 3.3-1.

Figure 3.3-1: Structure of thifensulfuron-methyl (Source: Heap, I.; The International Survey of Herbicide Resistant Weeds. Online. Internet. Wednesday, April 15th, 2020. Available at www.weedscience.com)



Mode of action, thifensulfuron-methyl

Thifensulfuron-methyl, with the chemical name methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylate (IUPAC), belongs to the chemical group of Sulfonylureas. Thifensulfuron is a selective post-emergence herbicide used in e.g. cereals, maize and soybean for broad-spectrum control of broadleaved weeds across all climatic zones of Europe.

³ Heap, I. M., 2020: The International Survey of Herbicide Resistant Weeds. Web site visited April 2020.
<http://www.weedscience.com>

⁴ EPPO 2015: Standard PP 1/213 (4): Resistance risk analysis.

⁵ HRAC: <http://www.HRACglobal.com>. Web site visited April 2020.

The herbicidal efficacy of thifensulfuron is caused by inhibition of a key enzyme; Acetolactate synthase (ALS). ALS is involved in the branched chain amino acid biosynthesis and is the first common enzyme in the pathway leading to leucine, isoleucine and valine (Smith et al, 1988). Crop tolerance towards herbicides like thifensulfuron is mainly caused by a rapid metabolism of the herbicide into harmless compounds (Smith et al, 1988, Sterling & Jochem, 1995). In susceptible plants the inhibition of the ALS enzyme leads to a build-up of the toxic α -ketobutyrate. The toxic compounds, combined with the reduced levels of branched amino acids, results in retardation of plant growth processes leading to death of the plant. Due to the primary target site and the chemical subgroup, thifensulfuron-methyl is classified as a HRAC group B herbicide (Imidazolinones and others). In the WSSA resistance classification system, the Sulfonylureas are classified as group 2.

- Mode of Action: Inhibition of acetolactate synthase (ALS)
- Chemical family: Sulfonylurea

3.3.3 Mechanism(s) of resistance

There are a couple of mechanisms known to cause resistance towards the ALS's. As mentioned earlier crop tolerance is mainly caused by rapid metabolism of the herbicide. There has been reports of the same type of resistance in *Lolium rigidum* (Annual Ryegrass) (Christopher et al., 1991), but most reports concurrently describes changes in the target site as the reason for weed resistance (Hanson et al, 2004, Reed et al., 1989; Saari et al., 1990; Saari et al. 1992, Smith et al, 1988; Thill et al., 1989; Tranel & Wright, 2002). Whether it might be a combination of enhanced metabolism and target site changes (Manley et al., 1999) or an overproduction of ALS (Harms et al. 1992) causing resistance has also been aired.

Target site resistance is caused by alterations in the ALS gene. ALS functions in the plastids but is coded in the nucleus, therefore it follows normal Mendelian inheritance. Mutations in the ALS gene, causing herbicide resistance, can therefore be spread by both pollen and seeds (Smith et al. 1988; Tranel & Wright, 2002). The ALS gene is to a high degree conserved in between plant biotypes. So far, at least five conserved amino acids have been identified in the ALS gene and substitution in one of them is known to cause resistance in various plants (Tranel & Wright, 2002). Whether other mutations in the plant can cause resistance is most likely, both regarding enhanced metabolism and especially target site alterations.

3.3.4 Evidence of resistance

Thifensulfuron-methyl

To date, twenty-eight different weed species, i.e. one grass weed species and twenty-seven broadleaved weed species have been reported in 84 cases to have evolved resistance towards thifensulfuron-methyl (Heap, 2020). Of these, seven cases have been reported from Europe on different broadleaved weed species, i.e. AMARE, KCHSC, PAPRH, RUMOB, SONAS and STEME.

Worldwide, the following cases of rimsulfuron resistance have been reported:

Year	Species	Country	MoA
2003	<i>Amaranthus retroflexus</i>	Italy	B/2
1996	<i>Kochia scoparia</i>	Czech Republic	B/2, C1/5
1998	<i>Papaver rhoeas</i>	Greece	B/2
2017	<i>Rumex obtusifolius</i>	France	B/2
2016	<i>Sonchus asper</i>	UK	B/2
2012	<i>Stellaria media</i>	France	B/2
2011	<i>Stellaria media</i>	Germany	B/2

MoA: B=ALS inhibitors; C1=Photosystem II inhibitors.

ALS inhibitors

To date, 165 different weed species, mostly dicotyledonous, has been reported as resistant towards one or several HRAC group B herbicides (Heap, April 2020). The first report was from Australia in 1982 where *Lolium rigidum* (Rigid ryegrass) showed multiple resistance towards a range of herbicides with different modes of action, hereunder ALS inhibitors, like chlorosulfuron. Since then, new weeds have been added to the list and there is no reason to believe that this phenomenon will disappear. Many of the weed species has developed resistant independently in different countries and often against several SUs (Heap, 2012). There are many reports from especially US but also Australia and Canada are well represented. However, the below mention examples are from Europe. It is important to emphasise that the examples given below is not necessarily the complete picture of ALS resistance reported in the given countries but merely examples. Further information and updates regarding resistance and weed populations can be seen on www.weedscience.org.

Germany

In 2001, the first official case of resistant *Alopecurus myosuroides* (Blackgrass) was reported in a wheat field in Germany. In 2001, local weed scientist from the Federal Biological Research Centre for Agriculture and Forestry (BBA) suspected that resistant blackgrass occurred at least 6-10 places in Germany and that the area was increasing (Heap, 2012). To date, 33 species have been reported to have developed resistance towards one or several herbicide groups in Germany, hereof 11 species being resistant or cross-resistant to ALS inhibitors. The most common form of resistance is resistance towards Photosystem II inhibitors.

Belgium:

In 1996, ALS resistant *Alopecurus myosuroides* (Blackgrass) were reported in Belgium and weed scientists from the University in Gent estimate that multiple resistant Blackgrass in Belgium infests at least 2-5 sites and that the number of sites are increasing (Heap, 2012). The resistant blackgrass was resistant to five different modes of action. The resistant biotypes were collected from winter wheat and sugar beet field where poor weed control had been observed using Fenoxaprop and/or clodinafop, however, there are no other records of the agricultural production methods. Resistant blackgrass has also been reported in UK, France, Poland, the Netherlands, Germany, Czech Republic, Denmark, Sweden, Turkey and Spain (Heap, 2019). To date, 22 species have been reported to have developed resistance towards one or several herbicide groups in Belgium, hereof four species being resistant or cross-resistant to ALS inhibitors. The most current form of resistance is resistance towards Photosystem II inhibitors.

The Czech Republic:

In 1996, ALS resistant *Kochia scoparia* (Kochia) were reported in the Czech Republic and weed scientists from the Research Institute of Crop Production in Ruzyně estimate that multiple resistant Kochia in the Czech Republic infests at least 11-50 sites and that the number of sites are increasing (Heap, 2012). The kochia from Czech Republic was resistant to herbicides with two different modes of action (HRAC group B and C1). The resistant biotypes were collected from railways and roadsides. To date, 18 species have been reported to have developed resistance towards one or several herbicide groups in the Czech Republic, hereof three species being resistant or cross-resistant to ALS inhibitors. The most current form of resistance is resistance towards Photosystem II inhibitors.

Denmark:

In 1991, *Stellaria media* (Common chickweed) seeds were collected from a field where the plants had survived sulfonylurea herbicide treatments (Kudsk et al. 1995). Whole plant and *in vitro* assays confirmed resistance against various SU's. Spring barley had been grown continuously on the field since 1984 and treated with one application of SU every year. In 1990, the first unsatisfactory control of common chickweed was observed and the same pattern was seen in 1991. Even though half of the area was treated a second time in 1991 with tribenuron, it had no visual effect on common chickweed. A reduced tillage system had been practised on the field since 1984. To date, 13 species have been reported to have developed resistance towards one or several herbicide groups in Denmark, hereof eight species being resistant or cross-resistant to ALS inhibitors.

Resistant common chickweed has also been reported in Belgium, Canada, Finland, France, Germany, Ireland, Latvia, New Zealand, Norway, South Africa, Sweden, the UK and the US (Heap, 2019).

France:

Since 1993, an increasing number of sites with ALS resistant biotypes of *Alopecurus myosuroides* (Blackgrass) has been reported. From the time when the first resistant biotype of blackgrass was observed, an annual survey has been carried out by the French National Institute for Agricultural Research (INRA) (Heap, 2012). To date, 55 species have been reported to have developed resistance towards different herbicide groups in France. The most current form of resistance is resistance towards Photosystem II inhibitors. Cases of *Papaver* sp., and *Matricaria* sp. ALS resistant biotype are reported in several French regions. Of the 55 species reported to be resistant to herbicides in France, 22 species were resistant or cross-resistant to ALS-inhibitors.

Greece:

In 1998, ALS resistant *Papaver rhoeas* (Corn poppy) were reported in Greece and weed scientists from the National Agricultural Research Foundation in Thessaloniki estimate that resistant corn poppy in Greece only infests this site and that the number of sites are increasing (Heap, 2012). The resistant biotypes were collected from winter wheat. ALS-resistant field poppy has also been reported in Belgium, Denmark, France, Germany, Italy, Poland, Spain, Sweden and the UK (Heap, 2019). To date, 17 species have been reported to have developed resistance towards different herbicide groups in Greece, hereof five species being resistant to ALS inhibitors.

Ireland

In 1996, resistant *Stellaria media* (Common chickweed) plants were observed in cereal field in Ireland. Weed scientists from Rothamsted Research and The International Society for Horticultural Science has so far not reported ALS resistant biotypes other places in Ireland (Heap, 2017).

Italy:

In 2003, ALS resistant *Amaranthus retroflexus* (Redroot pigweed) were reported in Italy and weed scientists from the Italian National Research Council in Legnaro estimate that resistant redroot pigweed in Italy only infests this site and that the size of the infested area is 51-100 acres (Heap, 2012). The resistant biotypes were collected from Soybean. ALS-Resistant redroot pigweed has also been reported in Brazil, Canada, China, Germany, Israel, Serbia and the US (Heap, 2019). Multi-resistant *Papaver rhoeas* have also been reported from Italy, being resistant towards ALS-inhibitors and synthetic auxins. To date, 30 species have been reported to have developed resistance towards one or several herbicide groups in Italy, hereof 11 species being resistant or cross-resistant to ALS inhibitors.

Poland:

In 2005, ALS resistant *Apera spica-venti* (Wind bentgrass) were reported in Poland and weed scientists from the Institute of Plant Protection in Poznan, among others, estimate that resistant wind bentgrass in Poland infests 51-100 sites (Heap, 2012). The resistant wind bentgrass was resistant to sulfonyl ureas, among others, in the HRAC Group B. The resistant biotypes were collected from winter wheat. ALS-resistant wind bentgrass has also been reported in Austria, Czech Republic, Denmark, France, Germany, Latvia, Lithuania and Sweden (Heap, 2019). To date, 22 species have been reported to have developed resistance towards one or several herbicide groups in Poland, hereof 8 species being resistant or cross-resistant to ALS inhibitors. The same number of weed species was reported to being resistant towards Photosystem II inhibitors in Poland.

Portugal:

In 1995, ALS resistant *Alisma plantago-aquatica* (common waterplantain) were reported in Portugal and weed scientists from the Ministerio da Agricultura Do Desenvolvimento Rural in Oeiras estimate that resistant wind bentgrass in Portugal infests 6-10 sites (Heap, 2012). The resistant common waterplantain was resistant to bensulfuron-methyl. The resistant biotypes were collected from rice. ALS-resistant common water plantain has also been reported in Chile, Italy, Spain and Turkey (Heap, 2019). To date, 5 species have been reported to have developed resistance towards different herbicide groups in Portugal.

Spain:

In 2011, ALS resistant *Sinapis arvensis* (wild mustard) were reported in Spain and weed scientists from the Agricultural technologies and Infrastructures Institute of Navarra estimate that resistant wild mustard in Spain infests only this one site with an area of 1-5 acres (Heap, 2012). The resistant wild mustard was resistant to iodosulfuron and tribenuron. The resistant biotypes were collected from cereals. ALS-resistant wild mustard has also been reported in Australia, Canada, Iran, Italy, Turkey and the US (Heap, 2019). To

date, 39 species have been reported to have developed resistance towards one or several herbicide groups in Spain, hereof 9 species being resistant or cross-resistant to ALS inhibitors. The most problematic resistant weed in Spain is multi-resistant *Papaver rhoeas*, which have been reported to be resistant towards ALS-inhibitors and synthetic auxins.

Sweden:

In 1995, resistant *Stellaria media* (Common chickweed) was reported in Sweden, ALS enzyme tests confirmed the suspicion. The field where the biotype was found had been grown with cereals continuous cereals for 10 years and repeatedly treated with sulfonylurea herbicides. To date, 11 species have been reported to have developed resistance towards one or several herbicide groups in Sweden, hereof six species being resistant or cross-resistant to ALS inhibitors.

UK

In 2000, amidosulfuron- and metsulfuron resistant *Stellaria media* (Common chickweed) was found on a cereal field in the UK. According to weed scientists at Rothamsted Research this is the only known site of SU resistant common chickweed in the UK. Metsulfuron resistant *Papaver rhoeas* (Corn Poppy) was located in 2001 by Rothamsted Research, it is estimated that there are at least 2-5 sites with SU resistant corn poppy. In 1994, multiple resistant (including ALS resistance) *Avena fatua* (Wild Oat) was found in the UK in canola, cereal and wheat fields. At least 11 -50 sites are today infested with multiply resistant wild oats and the number is presumably increasing. Chlorsulfuron resistant blackgrass was reported back in 1984. The number of resistant blackgrass sites in the UK is unknown (Heap, 2012). To date, 29 species have been reported to have developed resistance towards one or several herbicide groups in UK, hereof eight species being resistant or cross-resistant to ALS inhibitors.

Hungary

In 2015, foramsulfuron- and nicosulfuron resistant *Sorghum halepense* (Johnsongrass) were found on maize and fallow fields in Hungary. According to weed scientists from Fejér County, the nicosulfuron resistance is an increasingly important problem. ALS-resistant Johnsongrass has also been reported in Chile, Hungary, Israel, Italy, Mexico, Serbia, Spain, the US and Venezuela (Heap, 2019). To date, three species have been reported to have developed resistance towards one or several herbicide groups in Hungary, hereof only *Sorghum halepense* being resistant to ALS inhibitors.

Conclusion

ALS resistant weeds are present worldwide, many cases of resistance occur after several years of monocropping and repeatedly use of SU's. On www.weedscience.com, new occurrences of herbicide resistance is monitored, today 165 weed species have been reported as resistant toward one or several ALS's.

3.3.5 Cross-resistance

“When a plant expressing resistance to an herbicide also demonstrates resistance to other herbicides that target the same plant process even though the plant has not been exposed to the other herbicides, the resistance is termed cross-resistance” (Prather et al. 2000).

B herbicides: Since all the ALS's are active towards a single target site, cross resistance is a well-known phenomenon in this group of chemicals. It is therefore important to keep the label recommended limitations concerning the frequency by which the ALS should be used.

As far back as 1987 one of the first signs of cross resistant weeds were evident (Primiani et al. 1990). Seeds from *Kochia scoparia* were collected from a field treated with chlorsulfuron for five consecutive years (in total 106g/ha) and greenhouse test showed enhanced resistance towards other ALS's as well, since then numerous reports of cross resistance in between the ALS's has been published (primarily SU's).

Cross-resistance between different SU and other ALS herbicides e.g. Imazethapyr is also well documented (Heap, 2012; Baumgartner et al. 1999; Lovell et al 1996; Rashid et al, 2003). Resistance toward herbicides with different modes of action has also been proven. Studies of *Amaranthus hybridus* showed that resistance towards atrazine (Photosystem II inhibitor) and ALS inhibiting herbicides

occurred in the same biotypes but that the reason for resistance was located on different genes (Maertens et al., 2003).

Multiple-resistance between ALS inhibiting herbicides, ACCase inhibitors e.g. clodinafop and Arylamino propionic acids e.g. Flamprop-M was reported in 1994 in the UK in several wild oats biotypes (Heap, 2012).

There are numerous of other cases, further information and updates on the subject can be seen on www.weedscience.com.

3.3.6 Sensitivity data

Weeds vary in their sensitivity towards herbicides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. ALS inhibitors have been tested and used worldwide for almost 40 years, and it is therefore difficult to find unexposed weed populations. No true base line sensitivity data can therefore be established.

3.3.7 Use pattern

Thifensulfuron 75% WG is composed of thifensulfuron-methyl which is a selective herbicide applied post-emergence. In the EU Central zone, the formulation is proposed for use against broadleaved weeds in winter cereals. The recommended dose rate is 0.040 kg/ha, which will deliver 30 g thifensulfuron per hectare. The maximum number of applications is one application per growing season.

Since many broadleaved crops e.g. peas, canola, sugar beets etc. are extremely sensitive to ALS's, it is important to respect the, on the label recommended, crop rotation restrictions into consideration.

Thifensulfuron has been used as straight product as well as in mixtures for many years.

3.3.8 Resistance Risk Assessment of unrestricted use patterns

To avoid resistance, it is important to have a reasonable crop rotation and respect the label recommended application rates and doses. Resistance has often developed where mono-cropping, reduced tillage and subsequent use of ALS inhibitors has been practiced. There is a risk of developing resistance towards thifensulfuron and other SU's if the recommended application interval is exceeded as well as if lower than recommended dose rates are applied.

The inherited resistance towards thifensulfuron should be considered as high due to the mode of action, the short life cycle of many of the target weeds etc. Furthermore, the genes involved in resistance are transmitted both by pollen and seeds and many of the broadleaved weeds produce large amounts of seeds which are dispersed over large areas.

The degradation time of thifensulfuron is slower in alkaline soils compared to acidic soils, which might have an influence on the inherited risk in alkaline soils.

3.3.9 Acceptability of the resistance risk

Without any precautions, the resistance risk is unacceptable. However, taking the right precautions and following Good Agricultural Practise, the risk is acceptable. Should resistant populations arise, control could be achieved through use of alternative products.

3.3.10 Management strategy for Thifensulfuron 75% WG

Good Agricultural Practices and Good Plant Protection Practices (EPPO Standard 2/1 (2)) should be the followed in the weed management strategy.

Thifensulfuron 75% WG should be used in alternation with herbicides comprising different modes of action to avoid the build-up of resistant biotypes and cross resistance.

Uses of mixtures with herbicides with different modes of action and weed spectrum is recommended, in order to obtain a high degree of weed control and get rid of eventually resistant weeds in the field and prevent resistance build up.

Follow the label recommendations regarding application rate (max. 1 application per year), growth stage, doses etc.

Apply Thifensulfuron 75% WG:

- Preferably shortly after emergence of the weeds and not later than the BBCH 14 stage of the weeds.
- Apply the dose rate as recommended

Avoid:

- Late applications – when the weeds are too developed.
- Use of reduced rates particularly where late applications are made.

Do Not:

- Apply to weeds where target site resistance to any of the herbicide classes included in Thifensulfuron 75% WG has been confirmed.

Remember, herbicide usage should only form part of a strategy to manage herbicide resistance. Where appropriate seed samples should be tested to establish the type and severity of resistance present as this will aid decisions on future herbicide control programmes. Always follow the recommendations of the Weed Resistance Action Group ([WRAG](#)) with respect to the integration of chemical and cultural control measures.

Cultural practices:

Since cross resistance between different modes of action cannot be excluded, application limitations and the alternation of herbicides should be supported by additional agricultural measures. To minimize the weed pressure, deep soil cultivation (plough) and late sowing are recommended.

3.3.11 Implementation of the management strategy

The basic recommendations for resistance risk management (maximum 1 application for weed control) will be clearly recommended on the label. Additional recommendations for product alternations and cultural practices will be given on the label.

3.3.12 Monitoring, reporting and reaction to changes in performance

Allegations of weeds control failures in Europe and around the world are monitored.

Sharda will inform the regulatory authorities of any new confirmed occurrence of resistance regarding the use of Rimsulfuron 15% + Nicosulfuron 30% WG.

Comments of zRMS:	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 biologi-
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cal 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 herbicide selectivity relies on enzymatic systems 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: EP-PO 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 sulfonylurea urea class. The sulfonylureas are the largest chemical class within this group. There are mainly three groups of amino acid synthesis inhibitors commonly used as herbicides: the sulfonylureas, the imidazolinones and amino acid derivative herbicide families. Sulfonylurea 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 to two weeks) and include stunting or delayed plant growth, leading to eventual death of the plant. Herbicides in the sulfonylurea family can be taken up through plant foliage and roots and are mobile in both the 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 sulfonylureas is a so-called target site mechanism. Target site resistance is caused by a 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.

Most Recent Cases of Herbicide Resistant Weeds Entered into the Database of [weedscience.org](http://www.weedscience.org) for group 2 (legacy B):

#	Species	Country	First Year	Site of Action
1	<i>Alopecurus myosuroides</i>	Switzerland	2019	Multiple Resistance: 3 Sites of Action Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A) Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)
2	<i>Alopecurus myosuroides</i>	Ireland	2021	Multiple Resistance: 2 Sites of Action Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A) Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)

				Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
3	<i>Amaranthus hybridus (syn: quitensis)</i>	Italy	2018	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
4	<i>Amaranthus hybridus (syn: quitensis)</i>	Paraguay	2022	Multiple Resistance: 2 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G)
5	<i>Amaranthus palmeri</i>	United States (Kansas)	2021	Multiple Resistance: 6 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2) PSII inhibitors - Histidine 215 Binders HRAC Group 6 (Legacy C3) Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E) Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2) Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G)
6	<i>Amaranthus palmeri</i>	South Africa	2018	Multiple Resistance: 2 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G)
7	<i>Amaranthus powellii</i>	Canada (Ontario)	2019	Multiple Resistance: 2 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) Auxin Mimics HRAC Group 4 (Legacy O)
8	<i>Amaranthus retroflexus</i>	United States (North Carolina)	2022	Multiple Resistance: 3 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E) Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2)
9	<i>Amaranthus retroflexus</i>	United States (North Carolina)	2020	Multiple Resistance: 2 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E)
10	<i>Amaranthus retroflexus</i>	Ukraine	2020	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
11	<i>Amaranthus tuberculatus (=A. rudis)</i>	Canada (Ontario)	2021	Multiple Resistance: 5 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2) Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E) Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2) Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G)
12	<i>Amaranthus tuberculatus (=A. rudis)</i>	United States (North Carolina)	2020	Multiple Resistance: 5 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2) Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E) Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2) Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G)
13	<i>Ambrosia artemisiifolia</i>	Ukraine	2023	Multiple Resistance: 2 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E)

14	<i>Ambrosia artemisiifolia</i>	France	2013	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
15	<i>Ambrosia artemisiifolia</i>	Serbia	2019	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
16	<i>Ammannia auriculata</i>	China	2023	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
17	<i>Ammannia multiflora</i>	China	2022	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
18	<i>Anthriscus caucalis</i>	Germany	2017	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
19	<i>Arabidopsis thaliana</i>	United States (Virginia)	2015	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
20	<i>Arctotheca calendula</i>	Australia (Western Australia)	2020	Multiple Resistance: 3 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) Phytoene Desaturase inhibitors HRAC Group 12 (Legacy F1) Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G)
21	<i>Bromus commutatus</i>	United Kingdom	2020	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
22	<i>Bromus diandrus</i>	New Zealand	2024	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
23	<i>Bromus diandrus</i>	United Kingdom	2020	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
24	<i>Bromus sterilis</i>	United Kingdom	2020	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
25	<i>Bromus sterilis</i>	Czech Republic	2017	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
26	<i>Chenopodium album</i>	Ukraine	2022	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
27	<i>Chloris radiata</i>	Colombia	2019	Multiple Resistance: 2 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G)
28	<i>Conyza bonariensis</i>	Jordan	2022	Multiple Resistance: 2 Sites of Action PS I Electron Diversion HRAC Group 22 (Legacy D) Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E)
29	<i>Cyperus difformis</i>	India	2017	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
30	<i>Cyperus esculentus</i>	Italy	2017	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
31	<i>Digitaria sanguinalis</i>	New Zealand	2022	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
32	<i>Echinochloa crus-galli var. crus-galli</i>	Brazil	2018	Multiple Resistance: 3 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) Inhibition of Cellulose Synthesis HRAC Group 29 (Legacy L) Auxin Mimics HRAC Group 4 (Legacy O)
33	<i>Echinochloa crus-galli var. crus-galli</i>	India	2017	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
34	<i>Echinochloa crus-galli var. crus-galli</i>	Viet Nam	2017	Multiple Resistance: 2 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)

				Inhibition of Cellulose Synthesis HRAC Group 29 (Legacy L)
35	<i>Echinochloa phyllopogon</i> (= <i>E. oryzicola</i>)	China	2023	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
36	<i>Galium spurium</i>	Greece	2022	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
37	<i>Lolium perenne</i> ssp. <i>multiflorum</i>	China	2022	Multiple Resistance: 2 Sites of Action Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A) Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
38	<i>Lolium perenne</i> ssp. <i>multiflorum</i>	United States (North Carolina)	2022	Multiple Resistance: 4 Sites of Action Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A) Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) PS I Electron Diversion HRAC Group 22 (Legacy D) Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G)
39	<i>Lolium perenne</i> ssp. <i>multiflorum</i>	Switzerland	2020	Multiple Resistance: 3 Sites of Action Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A) Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)
40	<i>Lolium perenne</i> ssp. <i>multiflorum</i>	Ireland	2021	Multiple Resistance: 2 Sites of Action Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A) Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
41	<i>Lolium perenne</i> ssp. <i>multiflorum</i>	Switzerland	2018	Multiple Resistance: 2 Sites of Action Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A) Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
42	<i>Lolium perenne</i> ssp. <i>multiflorum</i>	Switzerland	2018	Multiple Resistance: 2 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)
43	<i>Monochoria vaginalis</i>	Indonesia	2022	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
44	<i>Oryza sativa</i> var. <i>sylvatica</i>	Turkey	2020	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
45	<i>Panicum dichotomiflorum</i>	United States (Illinois)	2019	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
46	<i>Panicum miliaceum</i> var. <i>ruderalis</i> Kitag.	China	2023	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
47	<i>Poa annua</i>	Ireland	2021	Multiple Resistance: 2 Sites of Action Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A) Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
48	<i>Poa annua</i>	United States (Tennessee)	2017	Multiple Resistance: 7 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2) Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E) Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G) Inhibition of Glutamine Synthetase HRAC Group 10 (Legacy H) Inhibition of Microtubule Assembly HRAC Group 3 (Legacy K1) Inhibition of Cellulose Synthesis HRAC Group 29 (Legacy L)
49	<i>Polygonum pensylvanicum</i>	United States (Arkansas)	2020	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)

50	<i>Raphanus raphanistrum</i>	Australia (Western Australia)	2020	Multiple Resistance: 3 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2) Auxin Mimics HRAC Group 4 (Legacy O)
51	<i>Raphanus raphanistrum</i>	Australia (Western Australia)	2015	Multiple Resistance: 5 Sites of Action Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B) PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2) Phytoene Desaturase inhibitors HRAC Group 12 (Legacy F1) Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2) Auxin Mimics HRAC Group 4 (Legacy O)
52	<i>Rapistrum rugosum</i>	Australia (New South Wales)	2021	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
53	<i>Sorghum halepense</i>	Serbia	2018	Multiple Resistance: 2 Sites of Action Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A) Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
54	<i>Stellaria media</i>	United States (California)	2022	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
55	<i>Tripleurospermum perforatum</i> (= <i>T. inodorum</i>)	Czech Republic	2021	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)

Since ALS inhibiting herbicides were introduced, they have mainly been targeted at broad-leaves weeds. Targeting has mainly been through selection with sulfonylurea herbicides (presumably because they have been in commercial use for the longest period). In the vast majority of cases of resistance following selection with sulfonylurea herbicides, the resistance mechanism is a change in the target site enzyme ALS (reviewed by Saari et al., 1994). In most cases, the sulfonylurea 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 resistances reported within the group sulfonylureas, 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>.

As sulfonylureas, 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 in Europe. Most of these were found to be resistant to sulfonylureas. **The inherent risk of thifensulfuron-methyl has to classify 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 infestations 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 weed 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 manag-

	ing or preventing the establishment of resistant weeds. For chemical mixtures to be effective, they should include active ingredients which both give high levels 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 but 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: – <i>“When herbicides with the same mode of action are used repeatedly over several years in the same field, selection of resistant biotypes can take place. These can propagate and may become dominating. A weed species is considered resistant to an herbicide if it survives a correctly applied treatment at the recommended dose.</i> – <i>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.</i> – <i>A strategy for preventing and managing resistance should be adopted.”</i> In order to minimize the risk of occurrence and development of herbicide weed resistance we should follow Good Agricultural Practice: ✓ <i>follow strictly the directions provided in the plant protection product label,</i> ✓ <i>plant protection product should been used at the recommended dose in the recommended time to ensure optimum weed control,</i> ✓ <i>use integrated weed control practices covering fields such as history crop rotation, herbicides used and various tillage (mechanical, cultural, biological and chemical),</i> ✓ <i>use rotation of herbicides (active substances) with different mechanisms of action,</i> ✓ <i>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).</i> 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.
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3.4 Adverse effects on treated crops (KCP 6.4)

Data from 63 selectivity trials conducted in the Maritime EPPO zone (9, i.e. Germany (4) and Czech Republic (5)), the North-east EPPO zone (35, i.e. Poland (26), Lithuania (3) and Latvia (6)) and the South-east EPPO zone (19, i.e. Slovakia (4) and Hungary (15)) have been included in this biological assessment dossier to support the label claims and recommendations on selectivity in the EU Central Registration zone.

The 63 selectivity trials were conducted in winter wheat (13), winter barley (14), winter rye (13), winter oat (11) and winter triticale (12). In eight of the 63 trials, Thifensulfuron 75% WG was applied with a surfactant (Trend 90).

Trial with surfactant where included since this favours the possibility of appearance of phytotoxicity so represent a worst case and can be valid for registration.

Information on trials submitted (6.4 Adverse effects on treated crops)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The GEP-requirement and the Uniform Principles are therefore taken care of.

On the basis of the EPPO guideline 1/241(2) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

Table 3.4-1: Presentation of selectivity trials

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MAR	MED	S-E	N-E			
TRZAW	Germany	Q + Y + S	2	-	-	-	2014/15	GEP	Without surfactant
	Slovakia	Q + Y + S	-	-	2	-	2014/15	GEP	Without surfactant
	Poland	Q + Y + S	-	-	-	4	2014/15	GEP	With surfactant
	Latvia	Q + Y + S	-	-	-	3	2014/15	GEP	Without surfactant
	Hungary	Q + Y + S	-	-	2	-	2020/21	GEP	With and without surfactant
	Total, Winter wheat (Sel.)		2	-	4	7			
HORVW	Germany	Q + Y + S	2	-	-	-	2014/15	GEP	Without surfactant
	Slovakia	Q + Y + S	-	-	2	-	2014/15	GEP	Without surfactant
	Poland	Q + Y + S	-	-	-	4	2014/15	GEP	With surfactant
	Lithuania	Q + Y + S	-	-	-	1	2014/15	GEP	Without surfactant
	Latvia	Q + Y + S	-	-	-	3	2014/15	GEP	Without surfactant
	Hungary	Q + Y + S	-	-	2	-	2020/21	GEP	With and without surfactant
Total, Winter barley (Sel.)		2	-	4	8				
SECCW	Lithuania	Q + Y + S	-	-	-	1	2014/15	GEP	Without surfactant
	Poland	Q + Y + S	-	-	-	6	2020	GEP	With and without surfactant
	Czech Rep.	Q + Y + S	2	-	-	-	2020/21	GEP	With and without surfactant
	Hungary	Q + Y + S	-	-	4	-	2020/21	GEP	With and without surfactant
	Total, Winter rye (Sel.)		2	-	4	7			
TTLWI	Lithuania	Q + Y + S	-	-	-	1	2014/15	GEP	Without surfactant
	Poland	Q + Y + S	-	-	-	6	2020	GEP	With and without surfactant
	Czech Rep.	Q + Y + S	2	-	-	-	2020/21	GEP	With and without surfactant
	Hungary	Q + Y + S	-	-	3	-	2020/21	GEP	With and without surfactant
	Total, Winter triticale (Sel.)		2	-	3	7			
AVESW	Poland	Q + Y + S	-	-	-	6	2020	GEP	With and without surfactant
	Czech Rep.	Q + Y + S	1	-	-	-	2020/21	GEP	With and without surfactant

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MAR	MED	S-E	N-E			
	Hungary	Q + Y + S	-	-	4	-	2020/21	GEP	With and without surfactant
	Total, Winter oat (Sel.)		1	-	4	6			
Total, All crops (Sel.)			9	-	19	35			

Table 3.4-2: Details on selectivity trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(3,4)
	Specific guidelines	EPPO PP 1/93(3)
Experimental design	Plot design	RCBD (63)
	Plot size	12.75-30 m ²
	Number of replications	4 (63)
Crop	Trials per crop	Winter wheat (13), Winter barley (14), Winter rye (13), winter oat (11) winter triticale (12)
	Varieties per crop	<u>Wheat</u> : Akteur (1), Arezzo (1), Bamberka (1), bogatka (1), Košútka (1), Lukullus (1), Mewa (1), Skagen (3), Tobak (1), Bologna (2) <u>Barley</u> : Ahinghi (1), Bartosz (1), Campus (1), Carola (2), Galation (1), Holmes (1), Karavan-Karakan (2), Malwinta (2), Tenor (1), SU Ellen (2) <u>Rye</u> : Agronom (1), D. Rubin (1), SU Performer (2), Horyzo (1), Agat (1), D. Amber (1), Protector (3), Performer (1), Inspector (1), SU Nasri (1), <u>Triticale</u> : Remiko (1), Tulus (2), Probus (1), grenado (1), Rotondo (2), Gringo (1), GK Szemes (1), Fredo (1), Leontino (1), Securo (1), Tulus <u>Oat</u> : RGT Black beauty (2), RGT Lineout (4), GK Arany (2), GK Impala (2), MV Hopehely (1)
	Sowing period	September 1 st to October 29 th
Application	Application period	Winter cereals, post-emergence (63): March 27 th to December 5 th
	Crop stage (BBCH)* at application	Winter cereals, post-emergence (63): BBCH 13-31
	Number of appl. Intervals between appl.	1 (63) n.a.
	Spray volumes	200-300 L/ha
Assessment	Assessment types	- Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms. - crop vigour - Crop yield was assessed in all selectivity trials conducted on winter cereals. Yield assessments included grain yield [t/ha] as well as different quality parameters (i.e. moisture content, hectolitre weight, thousand grain weigh and/or protein content). - Germination was evaluated in seven of the 25 selectivity trials.
	Assessment dates	As a rule 3 crop injury ratings
Other relevant information	Soil type	Clay loam (2), Clayey sand (1), Loam (10), Loamy sand (5), Sandy clay (9), Sandy clay loam (12), Sandy loam (10), Silt (4), Silt loam (3), Silty clay loam (4), Sand (3)

	Organic matter content	<1.5%(21), 1.5 to 2.49%(32); 2.5 to 3.5%(6), >3.5%(2); not indicated(1)
	pH	4.8-7.4 (mean = 6.29, n = 25; not indicated (0))
	Natural / artificial inoculation...	Preferably weed-free conditions
	Field / Greenhouse...	Field

Reference products

In 9 of the 63 cereal trials, conducted in Latvia (6) and Lithuania (3), the thifensulfuron WG formulation prepared by Sharda Cropchem Ltd – Thifensulfuron 75% WG – was compared against a reference thifensulfuron formulation currently on the market in Central and North Europe (Harmony 50 SX; 500 g/kg thifensulfuron-methyl SG). In Slovakian and Hungarian selectivity trials, Thifensulfuron 75% WG was compared against a national standard reference product containing tribenuron (Granstar 75 WG; tribenuron 750 g/kg WG). In the remaining selectivity trials, Thifensulfuron 75% WG was compared against a co-formulation containing sulfonylureas, i.e. in four German trials, a thifensulfuron + tribenuron co-formulation was used as reference product (Refine Extra SX; thifensulfuron 333 g/kg + tribenuron 166 g/kg WG) and in the remaining Polish and Czech republic trials, a thifensulfuron + chlorsulfuron co-formulation was used as reference product (Chisel Nowy; thifensulfuron 469 g/kg + chlorsulfuron 47 g/kg WG). In all trials, except 4 German trials, the reference product was applied with a surfactant which in Polish, Lithuanian and Slovakian trials was Trend 90 and in six Latvian trials, the added surfactant was Kemiwet Plus. Only in eight Polish selectivity trials, Thifensulfuron 75% WG was also applied with Trend 90 as surfactant. The trials were carried out on winter cereals, i.e. winter wheat, winter barley, winter rye and winter triticale.

The reference products used in the trials are listed in Table 3.4-3.

Table 3.4-3: Presentation of reference standards used in trials (selectivity trials, transformation trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Thifensulfuron test product					
Thifensulfuron 75 WG	WG	750 g/kg thifensulfuron-methyl	40 g/ha	DE	4
			80 g/ha	PL	8
				LT	3
				LV	6
				SK	4
Thifensulfuron reference product					
Harmony 50 SX	SG	500 g/kg thifensulfuron-methyl	23 g/ha	LT	3
			30 g/ha	LV	6
			46 g/ha		
			60 g/ha		
Tribenuron reference product					
Granstar 75 WG	WG	750 g/kg tribenuron-methyl	25 g/ha 50 g/ha	SK	4
Thifensulfuron + tribenuron reference product					
Refine Extra SX	SG	333 g/kg thifensulfuron-methyl 166 g/kg tribenuron-methyl	90 g/ha 180 g/ha	DE	4
Granstar Super 50 SX	SG	250 g/kg Thifensulfuron-methyl + 250 g/kg Tribenuron methyl	60 g/ha 120 g/ha	HU	15
Thifensulfuron + chlorsulfuron reference product					

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Chisel Nowy 51.6 WG	WG	47 g/kg chlorsulfuron 469 g/kg thifensulfuron	70 g/ha 130 g/ha 90 g/ha 180 g/ha	PL CZ	26 5
Surfactants					
Trend 90	-	90% alcohol isodecyclic ethoxyl	0.05% 0.1% 0.2%	LT PL SK	3 (ref. only) 8 4 (ref. only)
Kemiwet Plus	-	90% alcohol ethoxylate	0.1 L/ha	LV	6 (ref. only)

Also surfactants (Trend 90 EC) was used in trials carried out in HU (TRZAW, HORVW, SECCW, TTLWI AVESW), CZ (SECCW, TTLWI, AVESW) and PL (TZRAW, SECCW, TTLWI, AVESW). In those trials HIFEN was used solo and with surfactant (Trend 90 EC).

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

The crop safety of Thifensulfuron 75% WG was assessed in winter cereals in 18 efficacy trials (6 MAR and 12 N-E) where Thifensulfuron 75% WG was applied at dose rates ranging from 10 g/ha to 40 g/ha, and in 63 crop safety trials (9 MAR, 35 N-E and 19 S-E) where Thifensulfuron 75% WG was applied at 40 g/ha to 180 g/ha. In the efficacy- and selectivity trials conducted in cereals, Thifensulfuron 75% WG was applied post-emergence, i.e. in the spring when the cereal crop was at growth stages ranging between BBCH 13 and BBCH 32. In six efficacy trials and eight selectivity trials, Thifensulfuron 75% WG was applied with a surfactant whereas in the remaining trials, the test product was applied without a surfactant.

The trials were conducted in the Maritime zone (15; i.e. Germany (6) and Czech Republic (9)), the North-east zone (47, i.e. Poland (32), Lithuania (6) and Latvia (9)) and the South-east zone (19, i.e. Slovakia (4) and Hungary (15)) in 2014/15 and 2020/21 season, to evaluate the crop safety of Thifensulfuron 75% WG in winter cereals.

Trial with surfactant were included since this favours the possibility of appearance of phytotoxicity so represent a worst case and can be valid for registration.

3.4.1.1 Summary and evaluation of winter wheat trials treated post-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Thifensulfuron 75% WG was applied post-emergence, at growth stages ranging from BBCH 13 to BBCH 32, at the rate of 10 to 80 g/ha in winter wheat. 80 g/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to termination of the trial.

Phytotoxicity in winter wheat trials, Maritime EPPO zone

Two efficacy trials and two selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter wheat, i.e. post-emergence. The trials were conducted on commercially available varieties. No surfactants were applied with the test product nor the reference products.

No adverse effects in regard to phytotoxicity were observed in either of the two efficacy trials nor were any adverse effects observed in either of the two selectivity trials conducted in the Maritime EPPO zone. Furthermore, the applied treatments did not have any significant detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in winter wheat trials, North-east EPPO zone

Eleven efficacy trials and seven selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter wheat, i.e. post-emergence. The trials were conducted on commercially available varieties. In ten of the 18 trials, Thifensulfuron 75% WG was applied with the addition of a surfactant, i.e. in six efficacy trials and four selectivity trials. In all 18 trials, the reference products were applied with a surfactant.

No adverse effects in regard to phytotoxicity were observed in any of the 11 efficacy trials as well as no adverse effects were observed in any of the seven selectivity trials conducted in the North-east EPPO zone. Furthermore, the applied treatments did not have any significant detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in winter wheat trials, South-east EPPO zone

Four selectivity trials were conducted in the South-east EPPO zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter wheat, i.e. post-emergence. The trials were conducted on commercially available varieties. In both selectivity trials, the reference product (Granstar 75 WG) was applied with a surfactant, whereas Thifensulfuron 75% WG was applied without.

No adverse effects in regard to phytotoxicity were observed in either of the Slovakian and Hungarian selectivity trials. Furthermore, the applied treatments did not have any significant detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

3.4.1.2 Summary and evaluation of winter barley trials treated post-emergence

Crop phytotoxicity was evaluated in selectivity trials where Thifensulfuron 75% WG was applied post-emergence, at growth stages ranging from BBCH 23 to BBCH 31, at the rate of 40 and 80 g/ha in winter barley. 80 g/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to termination of the trial.

Phytotoxicity in winter barley trials, Maritime EPPO zone

Four efficacy trials and two selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter barley, i.e. post-emergence. The trials were conducted on commercially available varieties. No surfactants were applied with the test product nor the reference products.

No adverse effects in regard to phytotoxicity were observed in either of the two selectivity and four efficacy trials conducted in the Maritime EPPO zone. Furthermore, the applied treatments did not have any significant detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in winter barley trials, North-east EPPO zone

Eight selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter barley, i.e. post-emergence. The trials were conducted on commercially available varieties. In four of the 8 selectivity trials, Thifensulfuron 75% WG was applied with the addition of a surfactant. In all eight trials, the reference products were applied with a surfactant.

No adverse effects in regard to phytotoxicity were observed in seven of the eight selectivity trials conducted in the North-east EPPO zone. Thus, adverse effects were observed in one selectivity trial from the second assessment and symptoms were visible until the last assessment (49 DAT), however, at reduced levels.

The maximum phytotoxicity observed in the North-east selectivity trial is presented in Table 3.4-4. Where the symptoms are significantly more severe compared to untreated, the number is marked with bold.

In this trial, besides observing the adverse effects as general phytotoxicity, stunting, as well as deformation of flag-leaf as well as ear, a significantly reduced yield as well as significantly reduced Thousand Grain weight was observed. The same level of reduction in yield was observed in the plots treated with the reference product. In the remaining seven selectivity trials, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Table 3.4-4: Visual assessment of crop phytotoxicity in winter barley treated with Thifensulfuron 75% WG and reference products in selectivity trials (maximum crop phytotoxicity observed) as well as relationship to yield (t/ha in untreated and % relative to untreated in treated columns (Untreated = 100%).

Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phyto- toxicity
				Thifensulfuron 75% WG + Surfactant		Chlorsulfuron + Thifensulfuron Ref. Prod. + Surfactant		
				40 g/ha	80 g/ha	70 g/ha	130 g/ha	Symptom
Selectivity trials								
22 H/2015	Bartosz	21/28	0.0	7.0	20.0	8.0	20.0	PHYGEN (%)
		21/28	0.0	7.0	20.0	8.0	20.0	PHYSTU (%)
		28	0.0	4.0	7.0	4.0	11.0	FLLDEF (%)
		28	0.0	5.0	8.0	5.0	11.0	EARDEF (%)
		97	5.85	85	77	84	79	Yield (% rel.)

Phytotoxicity in winter barley trials, South-east EPP0 zone

Four selectivity trials were conducted in the South-east EPP0 zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter barley, i.e. post-emergence. The trials were conducted on commercially available varieties. In both selectivity trials, the reference product (Granstar 75 WG) was applied with a surfactant, whereas Thifensulfuron 75% WG was applied without.

No adverse effects in regard to phytotoxicity were observed in either of the two Slovakian and two Hungarian selectivity trials. Furthermore, the applied treatments did not have any significant detrimental effects on the yield or grain quality in the two Slovakian trials, as will be demonstrated in the following sections.

3.4.1.3 Summary and evaluation of winter rye trials treated post-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Thifensulfuron 75% WG was applied post-emergence, at growth stages ranging from BBCH 13 to BBCH 30, at the rate of 10 to 80 g/ha in winter rye. 80 g/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to termination of the trial.

Phytotoxicity in winter rye trials, Maritime EPP0 zone

Two selectivity trials were conducted in the Maritime EPP0 zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter rye, i.e. post-emergence. The trials were conducted on commercially available varieties. In 2 trials, the reference product (Chisel) was applied without a surfactant.

No adverse effects in regard to phytotoxicity were observed in the Czech selectivity trials.

Phytotoxicity in winter rye trials, North-east EPPO zone

One efficacy trial and 7 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter rye, i.e. post-emergence. The trials were conducted on commercially available varieties. In 2 trials, the reference product (Harmony 50 SX) was applied with a surfactant, in the rest of the trials Chisel Nowy was applied as a reference product, whereas Thifensulfuron 75% WG was applied without.

No adverse effects in regard to phytotoxicity were observed in the Latvian efficacy trial as well as no adverse effects were observed in the Lithuanian and Polish selectivity trials. Furthermore, the applied treatments did not have any significant detrimental effects on the yield or grain quality in the Lithuanian and Polish trial harvested, as will be demonstrated in the following sections.

Phytotoxicity in winter rye trials, South-east EPPO zone

Four selectivity trials were conducted in the South-east EPPO zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter rye, i.e. post-emergence. The trials were conducted on commercially available varieties. In 4 trials, the reference product (Granstar Super 50SX) was applied without a surfactant.

No adverse effects in regard to phytotoxicity were observed in the Hungarian selectivity trials.

3.4.1.4 Summary and evaluation of winter triticales trials treated post-emergence

Crop phytotoxicity was evaluated in 12 selectivity trials where Thifensulfuron 75% WG was applied post-emergence, at growth stage BBCH 13-30 (range: BBCH 13-30), at the rate of 40 and 80 g/ha in winter triticales. 80 g/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in the trial at various intervals, from application and up to termination of the trial.

Phytotoxicity in winter triticales trials, Maritime EPPO zone

Two selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter triticales, i.e. post-emergence. The trials were conducted on commercially available varieties. In 2 trials, the reference product (Chisel) was applied without a surfactant.

No adverse effects in regard to phytotoxicity were observed in the Czech selectivity trials. Furthermore, the applied treatments did not have any significant detrimental effects on the yield or grain quality in the Czech trials harvested, as will be demonstrated in the following sections.

Phytotoxicity in winter triticales trials, North-east EPPO zone

Seven selectivity trial was conducted in the North-east EPPO zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter triticales, i.e. post-emergence. The trials were conducted on different commercially available varieties. In the Lithuanian and Polish selectivity trials, the reference product (Harmony 50 SX) was applied with a surfactant and Chisel Nowy without it, whereas Thifensulfuron 75% WG was applied without.

No adverse effects in regard to phytotoxicity were observed in the Lithuanian and Polish selectivity trial. Furthermore, the applied treatments did not have any significant detrimental effects on the yield or grain quality in the Lithuanian and Polish trial harvested, as will be demonstrated in the following sections.

Phytotoxicity in winter triticales trials, South-east EPPO zone

Three selectivity trials were conducted in the South-east EPPO zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter triticales, i.e. post-emergence. The trials were

conducted on commercially available varieties. In 3 trials, the reference product (Chisel) was applied without a surfactant.

No adverse effects in regard to phytotoxicity were observed in the Hungarian selectivity trials. Furthermore, the applied treatments did not have any significant detrimental effects on the yield or grain quality in the Hungarian trials harvested, as will be demonstrated in the following sections.

3.4.1.5 Summary and evaluation of winter oat trials treated post-emergence

Crop phytotoxicity was evaluated in 11 selectivity trials where Thifensulfuron 75% WG was applied post-emergence, at growth stage BBCH 14-18 (range: BBCH 14-18), at the rate of 40 and 80 g/ha in winter oat. 80 g/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in the trial at various intervals, from application and up to termination of the trial.

Phytotoxicity in winter oat trials, Maritime EPPO zone

One selectivity trial was conducted in the Maritime EPPO zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter oat, i.e. post-emergence. The trials were conducted on commercially available varieties. In 1 trial, the reference product (Chisel) was applied without a surfactant.

No adverse effects in regard to phytotoxicity were observed in the Czech selectivity trial. Furthermore, the applied treatments did not have any significant detrimental effects on the yield or grain quality in the Czech trial harvested, as will be demonstrated in the following sections.

Phytotoxicity in winter oat trials, North-east EPPO zone

Six selectivity trial was conducted in the North-east EPPO zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter oat, i.e. post-emergence. The trials were conducted on different commercially available varieties. In the Polish selectivity trials, the reference product (Chisel Nowy) and Thifensulfuron 75% WG was applied without a surfactant.

No adverse effects in regard to phytotoxicity were observed in the Polish selectivity trial. Furthermore, the applied treatments did not have any significant detrimental effects on the yield or grain quality in the Polish trial harvested, as will be demonstrated in the following sections.

Phytotoxicity in winter oat trials, South-east EPPO zone

Four selectivity trials were conducted in the South-east EPPO zone to assess the crop safety of Thifensulfuron 75% WG when applied as recommended in winter oat, i.e. post-emergence. The trials were conducted on commercially available varieties. In 4 trials, the reference product (Granstar Super 50 SX) was applied without a surfactant.

No adverse effects in regard to phytotoxicity were observed in the Hungarian selectivity trial. Furthermore, the applied treatments did not have any significant detrimental effects on the yield or grain quality in the Hungarian trials harvested, as will be demonstrated in the following sections.

3.4.1.6 Overall conclusion

Winter cereals are claimed on the label. The claims of crop safety on winter cereals are supported with a total of 63 trials conducted in Germany, Slovakia, Hungarian, Czech Republic, Poland, Lithuania and Latvia in 2014/15 and 2020/21 season. In all trials, Thifensulfuron 75% WG proved to be crop safe and in the vast majority of the trials did not significantly affect the crop adversely when applied at a range of growth stages within the label recommended range, at the maximum proposed label recommended rates

of 40 g/ha in winter cereals. The same was observed in the treatments where Thifensulfuron 75% WG was applied at twice the recommended rate, representative of sprayer overlap.

Post-emergence application in winter cereals are claimed on the label. For crops and recommendation claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in winter wheat, winter barley, winter rye, winter oat and winter triticale where post-emergence applications with and without the use of surfactants were tested. This BAD also clearly demonstrates that the efficacy and crop safety of Thifensulfuron 75% WG is equivalent to the standard thifensulfuron-methyl products to which it was compared in the trials. The applicant therefore wishes to cite the original registrant's data on thifensulfuron-methyl (Harmony 50 SX®/Refine®) now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

Table 3.4-5: Phytotoxicity of product – winter wheat

Number of trials with...		Selectivity trials (13 trials)				Efficacy trials (13 trials)	
		Test product		Standard		Test product	Standard
		40 g/ha	80 g/ha	1N	2N	40 g/ha	1N
Maximum of phytotoxicity recorded during the trials	0% to 5%	13	13	13	13	13	13
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	13	13	13	13	13	13
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

Table 3.4-6: Phytotoxicity of product – winter barley

Number of trials with...		Selectivity trials (14 trials)				Efficacy trials (4 trials)	
		Test product		Standard		Test product	Standard
		40 g/ha	80 g/ha	1N	2N	40 g/ha	1N
Maximum of phytotoxicity recorded during the trials	0% to 5%	13	13	13	13	4	4
	>5% to 10%	1	0	1	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	1	0	1	0	0
Level of symptoms at the last assessments	0% to 5%	13	13	13	13	4	4
	>5% to 10%	0	1	0	0	0	0
	>10% to 15%	0	0	0	1	0	0
	>15 %	0	0	0	0	0	0

Table 3.4-7: Phytotoxicity of product – winter rye and winter triticale

Number of trials with...		Selectivity trials (20/19 12 trials)				Efficacy trials (40 trial)	
		Test product		Standard		Test product	Standard
		40 g/ha	80 g/ha	1N	2N	40 g/ha	1N
Maximum of phytotoxicity recorded during the	0% to 5%	20/19 12	20/19 12	20/19 12	20/19 12	1/0	1/0
	>5% to 10%	0	0	0	0	0	0

Number of trials with...		Selectivity trials (20/19 12 trials)				Efficacy trials (1/0 trial)	
		Test product		Standard		Test product	Standard
		40 g/ha	80 g/ha	1N	2N	40 g/ha	1N
trials	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	20/19 12	20/19 12	20/19 12	20/19 12	1/0	1/0
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

Winter rye / winter triticale

Table 3.4-8a: Phytotoxicity of product – winter rye

Number of trials with...		Selectivity trials (13 trials)				Efficacy trials (1 trial)	
		Test product		Standard		Test product	Standard
		40 g/ha	80 g/ha	1N	2N	40 g/ha	1N
Maximum of phytotoxicity recorded during the trials	0% to 5%	13	13	13	13	1	1
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	13	13	13	13	1	1
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

Table 3.4-9: Phytotoxicity of product – winter oat

Number of trials with...		Selectivity trials (11 trials)			
		Test product		Standard	
		40 g/ha	80 g/ha	1N	2N
Maximum of phytotoxicity recorded during the trials	0% to 5%	11	11	11	11
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	11	11	11	11
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

Comments of zRMS:	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
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	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. Phytoxiicty 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 assessments methods were in line to EPPO standards. Applicant presented detailed information's. 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), winter triticale (11 trials: MAR-1; N-E-7; S-E-3), winter rye (14 trials: MAR-3, N-E-7; S-E-4) and winter oat (11 trials: MAR-1; N-E-6; S-E-4). Winter wheat: No adverse effects about phytotoxicity were observed in all selectivity trials. Winter barley No adverse effects about phytotoxicity were observed in all selectivity trials, in the exception of 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 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 doses of the products. 4-5 weeks after the application of products, 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 was observed. Therefore, 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.
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3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

63 selectivity trials were conducted 2014/15 and 2020/21 season to evaluate the effect of Thifensulfuron 75% WG on yield of winter cereals. In selectivity trials conducted in winter cereals, Thifensulfuron 75% WG was applied post-emergence, when the crop was at growth stages ranging between BBCH 13 and BBCH 31. In eight of the 63 selectivity trials harvested, Thifensulfuron 75% WG was applied with a surfactant, whereas in the remaining trials, the test product was applied without a surfactant. In 41 of the 63 selectivity trials, the reference products were applied with a surfactant, i.e. only in German selectivity trials, the reference product was applied without the use of a surfactant.

All trials conducted on winter cereals presented in this Biological Assessment Dossier were located within the Maritime zone (9), the North-east zone (35) or the South-east zone (19), as defined by EPPO Standard PP1/241 (2).

3.4.2.1 Summary and evaluation of crop yield from winter cereal field trials treated post-emergence

A summary of the mean yield assessments expressed as %-relative of the untreated, from winter cereal trials treated with post-emergence applications in the Maritime, the North-east and the South-east EPPO zone, are presented in Table 3.4-10.

Winter wheat (TRZAW)

Thirteen selectivity trials conducted in winter wheat were harvested. The trials were conducted in Germany (2), Slovakia (2), Hungary (2), Poland (4) and Latvia (3) in 2014/15 and 2020/21 season. In these trials, Thifensulfuron 75% WG was applied post-emergence at 40 g/ha (i.e. 30 g thifensulfuron per hectare) and 80 g/ha (i.e. 60 g thifensulfuron per hectare). The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 13 and BBCH 31. In the four Polish trials, Thifensulfuron 75% WG was applied with a surfactant (Trend 90).

The harvest results obtained in twelve of the 13 trials demonstrate that Thifensulfuron 75% WG did not significantly affected the yield of winter wheat (Table 3.4-10) when applied at the recommended dose rate (40 g/ha) or the overlapping dose rate (80 g/ha). In one Polish trial, conducted on the variety Bogatka, Thifensulfuron 75% WG applied with a surfactant cause 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 recorded.

The results obtained in these trials supports the label claim that Thifensulfuron 75% WG is safe to be applied post emergence at the recommended dose rate in winter wheat, at the recommended application interval.

Winter barley (HORVW)

Fourteen selectivity trials conducted in winter barley were harvested. The trials were conducted in Germany (2), Hungarian (2), Slovakia (2), Poland (4), Lithuania (1) and Latvia (3) in 2014/15 and 2020/21 season. In these trials, Thifensulfuron 75% WG was applied post-emergence at 40 g/ha (i.e. 30 g thifensulfuron per hectare) and 80 g/ha (i.e. 60 g thifensulfuron per hectare). The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 23 and BBCH 31. In the four Polish trials, Thifensulfuron 75% WG was applied with a surfactant (Trend 90).

The harvest results obtained in ~~eleven~~ 13 of the ~~12~~ 14 trials demonstrate that Thifensulfuron 75% WG did not have any significant adverse effects on the yield of winter barley (Table 3.4-10) obtained in the trials, when applied at the recommended dose rate (40 g/ha) or the overlapping dose rate (80 g/ha). In one Polish trial, conducted on the variety Bartosz, all four treatments, which were applied with a 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.

Table 3.4-10: Maritime, North-east and South-east zone – Crop yield (t/ha) of winter wheat, winter barley, winter rye and winter triticale treated with Thifensulfuron 75% WG, single application post-emergence, as % of untreated (Untreated = 100%).

Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG with and without surfactant at:		National Ref. prod. with and without surfactant at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1N	2N
Winter wheat, grain yield						
Maritime EPPO zone	2	9.8 (9.4-10.2)	99 (98-100)	100 (99-102)	100 (99-102)	100 (99-101)
North-east EPPO zone	7	8.1 (7.2-9.5)	100 (94-104)	102 (98-108)	101 (98-103)	101 (99-105)
South-east EPPO zone	4	7.21 (6.19-8.2)	99.8 (96.3-103)	98.2 (96.1-100)	101 (99.0-106)	98.8 (96.1-101)
Winter barley, grain yield						
Maritime EPPO zone	2	9.7 (9.2-10.2)	103 (102-103)	104 (101-107)	99 (96-101)	100 (97-103)
North-east EPPO zone	8	7.0 (3.9-9.7)	99 (85-104)	99 (77-108)	103 (84-117)	99 (79-112)
South-east EPPO zone	4	8.04 (7.4-8.7)	102 (100-106)	100 (99.0-102)	100 (99.0-102)	99.8 (99.0-101)
Winter rye, grain yield						
Maritime EPPO zone	2	21.7 (18.8-24.6)	100 (99.5-101)	101 (101-101)	100 (100-100)	100 (99.1-101)
North-east EPPO zone	7	5.4 (4.0-6.31)	102.4 (99.2-113)	101.4 (97.7-105)	100.8 (98-105)	100.9 (99.3-103)
South-east EPPO zone	4	3.51 (3.27-4.45)	98.9 (94.8-102)	102 (98.0-107)	98.5 (88.7-108)	98.2 (95.1-102)
Winter triticale, grain yield						
Maritime EPPO zone	2	21.0 (20.7-21.2)	99.8 (98.6-101)	101 (99.0-102)	101 (100-102)	101 (100-102)
North-east EPPO zone	7	6.3 (4.99-7.9)	101.9 (98.2-104.6)	101.2 (97.4-104.7)	101.6 (97.5-106.9)	101.9 (99.0-105.5)
South-east EPPO zone	3	4.69 (3.51-6.37)	103 (96.7-110)	101 (93.8-109)	102 (100-106)	102 (93.8-112)
Winter oat, grain yield						
Maritime EPPO zone	1	7.08	101	99.0	101	102
North-east EPPO zone	6	4.4 (3.75-4.92)	100.4 (98.7-102.6)	100.3 (96.6-104.3)	101.3 (98.1-108.5)	101.8 (99.8-105.4)
South-east EPPO zone	4	4.25 (3.07-5.62)	99.3 (97.3-100)	100 (94.0-107)	96.1 (93.2-98.0)	98.8 (95.1-104)
Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG without surfactant at:		National Ref. prod. with and without surfactant at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1N	2N
Winter wheat, grain yield						
Maritime EPPO zone	2	9.8 (9.4-10.2)	99 (98-100)	100 (99-102)	100 (99-102)	100 (99-101)
North-east EPPO zone	3	8.0 (7.2-9.5)	101 (100-102)	101 (100-102)	101 (100-103)	101 (100-102)
South-east EPPO zone	2	8.0 (7.8-8.2)	100 (-)	100 (99-100)	100 (99-100)	99 (-)
Winter barley, grain yield						
Maritime EPPO zone	2	9.7 (9.2-10.2)	103 (102-103)	104 (101-107)	99 (96-101)	100 (97-103)
North-east EPPO zone	4	7.8 (6.3-9.7)	102 (100-104)	101 (98-103)	105 (101-108)	101 (100-102)
South-east EPPO zone	2	7.5 (7.4-7.5)	100 (-)	99 (-)	100 (99-100)	99 (-)
Winter rye, grain yield						
North-east EPPO zone	7	5.4 (4.0-6.31)	102.4 (99.2-113)	101.4 (97.7-105)	100.8 (98-105)	100.9 (99.3-103)
Winter triticale, grain yield						
North-east EPPO zone	7	6.3 (4.99-7.9)	101.9 (98.2-104.6)	101.2 (97.4-104.7)	101.6 (97.5-106.9)	101.9 (99.0-105.5)
Winter oat, grain yield						
North-east EPPO zone	6	4.4 (3.75-4.92)	100.4 (98.7-102.6)	100.3 (96.6-104.3)	101.3 (98.1-108.5)	101.8 (99.8-105.4)
Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG with surfactant at:		National Ref. prod. with surfactant at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1N	2N
Winter wheat, grain yield						
North-east EPPO zone	4	8.2 (7.4-9.1)	100 (94-104)	103 (98-108)	100 (98-103)	102 (99-105)
Winter barley, grain yield						
North-east EPPO zone	4	6.2 (3.9-8.4)	95 (85-100)	96 (77-108)	100 (84-117)	98 (79-112)
Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG without surfactant at:		Thifensulfuron Ref. prod. with surfactant at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1N	2N

Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG with and without surfactant at:		National Ref. prod. with and without surfactant at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1N	2N
Winter wheat, grain yield						
North-east EPPO zone	3	8.0 (7.2-9.5)	101 (100-102)	101 (100-102)	101 (100-103)	101 (100-102)
Winter barley, grain yield						
North-east EPPO zone	4	7.8 (6.3-9.7)	102 (100-104)	101 (98-103)	105 (101-108)	101 (100-102)
Winter rye, grain yield						
North-east EPPO zone	1	4.0	113	105	105	103
Winter triticale, grain yield						
North-east EPPO zone	1	7.9	103	104	101	105

The results obtained in these trials supports the label claim that Thifensulfuron 75% WG is safe to be applied post emergence at the recommended dose rate in winter barley, at the recommended application interval.

Winter rye (SECCW)

Twelve 13 selectivity trials conducted in winter rye was were harvested. The trials were conducted in 2014/15 and 2020/21 season and in Poland, Lithuania, Czech Republic and Hungary. In these trials, Thifensulfuron 75% WG was applied post-emergence at 40 g/ha (i.e. 30 g thifensulfuron per hectare) and 80 g/ha (i.e. 60 g thifensulfuron per hectare). The trials were sprayed when the majority of the crop was at growth stage BBCH 13-28 (range: BBCH 13-30). In these trials, only the reference product was applied with a surfactant in one trial.

The harvest results obtained in the trial demonstrate that Thifensulfuron 75% WG did not have any significant adverse effects on the yield of winter rye (Table 3.4-10) when applied at the recommended dose rate (40 g/ha) or the overlapping dose rate (80 g/ha).

The results obtained in this trial supports the label claim that Thifensulfuron 75% WG is safe to be applied post emergence at the recommended dose rate in winter rye, at the recommended application interval.

Winter triticale (TTLWI)

Twelve selectivity trials conducted in winter triticale was were harvested. The trials were conducted in Lithuania in 2014/15 and in Poland, Czech Republic and Hungary in 2020/21 season. In these trials, Thifensulfuron 75% WG was applied post-emergence at 40 g/ha (i.e. 30 g thifensulfuron per hectare) and 80 g/ha (i.e. 60 g thifensulfuron per hectare). The trials were sprayed when the majority of the crop was at growth stage BBCH 13-28 (range: BBCH 13-30). In these trials, only the reference product was applied with a surfactant in one trial.

The harvest results obtained in the trial demonstrate that Thifensulfuron 75% WG did not have any significant adverse effects on the yield of winter triticale (Table 3.4-10) when applied at the recommended dose rate (40 g/ha) or the overlapping dose rate (80 g/ha).

The results obtained in this trial supports the label claim that Thifensulfuron 75% WG is safe to be applied post emergence at the recommended dose rate in winter triticale, at the recommended application interval.

Winter oat (AVESW)

Eleven selectivity trial conducted in winter oat was harvested. The trials were conducted in Poland, Czech Republic and Hungary in 2020/21 season. In these trials, Thifensulfuron 75% WG was applied post-emergence at 40 g/ha (i.e. 30 g thifensulfuron per hectare) and 80 g/ha (i.e. 60 g thifensulfuron per hectare). The trials were sprayed when the majority of the crop was at growth stage BBCH 14-18 (range: BBCH 14-18). In these trials, all the reference product was applied without a surfactant.

The harvest results obtained in the trials demonstrate that Thifensulfuron 75% WG did not have any significant adverse effects on the yield of winter oat (Table 3.4-10) when applied at the recommended dose rate (40 g/ha) or the overlapping dose rate (80 g/ha).

The results obtained in these trials supports the label claim that Thifensulfuron 75% WG is safe to be applied post emergence at the recommended dose rate in winter oat, at the recommended application interval.

3.4.2.2 Conclusion

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

Post-emergence application in winter cereals is claimed on the label. For crops and recommendation claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in winter wheat, winter barley, winter rye, winter oat and winter triticale where post-emergence applications with and without surfactants were tested. This BAD also clearly demonstrates that the efficacy and crop safety of Thifensulfuron 75% WG is equivalent to the standard thifensulfuron formulations to which it was compared in 47 of the 63 selectivity trials harvested. The applicant therefore wishes to cite the original registrant's data on thifensulfuron now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

Comments of zRMS:	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 its 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. <u>In the following trials the negative impact of HIFEN on yield was observed:</u> 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.
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	2) In one Polish trial, conducted on the variety Bartosz, all four treatments, which were applied with a 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 thifensulfuronmethyl, 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.
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3.4.2.3 Relationship between phytotoxicity and yield

Adverse effects were observed in one selectivity trial in which crop yield was assessed.

In the table presented in section 3.4.1.1, the maximum level of phytotoxic symptoms, recorded as reduction in general crop health (PHYGEN), stunting (PHYSTU) as well as deformation of flag-leaf as well as ear, are presented as well as the grain yield achieved from untreated and treated plots in the affected trial. In this specific trial, both dose rates of Thifensulfuron 75% WG as well as both dose rates of the reference product (Chisel Nowy 51.6 WG, at 70 to 180 g/ha) caused a significant reduction in crop yield.

In the remaining selectivity trials, no significant reductions in crop yield were recorded in any of the plots treated with Thifensulfuron 75% WG at dose rates representative of the recommended dose rate or the 2N rate.

Comments of zRMS:	ZRMs agree with Applicant that no significant reductions in crop yield were recorded in any of the plots treated with Thifensulfuron 75% WG at dose rates representative of the recommended dose rate or the 2N rate.
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3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

63 selectivity trials treated with Thifensulfuron 75% WG were harvested and yields recorded. Besides recording yield, assessments were also carried out on the potential impact of treatment on a range of quality parameters including moisture content, protein content, hectolitre weight and thousand grain weight.

The materials and methods of these trials are described in Section 3.4.

Winter wheat (TRZAW)

The results obtained from assessments on the quality of the harvested winter wheat grains are presented in Table 3.4-11.

Table 3.4-11: Maritime, North-east and South-east zone – Quality of harvested winter wheat grains – crop treated with Thifensulfuron 75% WG, single application post-emergence, as % of untreated (Untreated = 100%).

Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG without surfactant at:		Thifensulfuron 333 + Tribenuron 166 SG reference prod. without surfactant at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1N	2N
Selectivity trials – Maritime zone						
Moisture content (%)	2	14.1 (13.4-14.8)	100 (-)	100 (-)	100 (-)	100 (-)
HectoLitre Weight (kg/hL)	2	77.0 (74.8-79.1)	100 (-)	100 (99-100)	100 (-)	100 (-)
Thousand Grain Weight (g)	4	49.5 (32.2-78.5)	100 (100-101)	99.5 (99.0-100)	99.5 (98.1-100)	99.1 (99.1-99.4)
Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG with and without surfactant at:		National reference prod. with surfactant at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1N	2N
Selectivity trials – North-east zone						
Moisture content (%)	2	15.3 (14.9-15.8)	101 (-)	101 (100-103)	100 (98-102)	98 (97-99)
HectoLitre Weight (kg/hL)	5	80.9 (79.5-81.8)	100 (-)	100 (-)	100 (99-101)	100 (100-101)
Thousand Grain Weight (g)	7	47.0 (36.2-55.4)	102 (99-103)	101 (99-103)	100 (99-102)	100 (97-102)
- Results from trials with surfactant						
Moisture content (%)	2	15.3 (14.9-15.8)	101 (-)	101 (100-103)	100 (98-102)	98 (97-99)
HectoLitre Weight (kg/hL)	2	80.7 (80.6-80.9)	100 (-)	100 (-)	99 (99-100)	100 (-)
Thousand Grain Weight (g)	4	45.1 (36.2-53.0)	103 (102-103)	101 (100-103)	101 (100-102)	100 (97-102)
- Results from trials without surfactant						
HectoLitre Weight (kg/hL)	3	81.0 (79.5-81.8)	100 (-)	100 (-)	100 (99-101)	100 (100-101)
Thousand Grain Weight (g)	3	49.6 (44.5-55.4)	100 (99-100)	100 (99-100)	100 (99-100)	100 (99-101)
Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG without surfactant at:		Tribenuron reference prod. with surfactant at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1N	2N
Selectivity trials – South-east zone						
Moisture content (%)	2	11.8 (11.5-12.0)	101 (-)	101 (-)	101 (-)	101 (-)
HectoLitre Weight (kg/hL)	2	83.7 (83.2-84.2)	100 (-)	100 (-)	100 (-)	100 (-)
Protein content (%)	2	12.2 (12.1-12.3)	100 (-)	101 (-)	100 (-)	101 (-)
Thousand Grain Weight (g)	2	43.7 (43.4-44.0)	100 (-)	99 (99-100)	100 (-)	99 (-)

In all trials evaluated, Thifensulfuron 75% WG as well as the reference products tested in the trials had no detrimental effect on the quality parameters assessed on the harvested winter wheat grains. When comparing the results obtained with Thifensulfuron 75% WG against the results obtained with the reference products, hereunder the thifensulfuron SG reference product included in three of the 13 selectivity trials, both products performed statistically similar on all quality parameters assessed.

Winter barley (HORVW)

The results obtained from assessments on the quality of the harvested winter barley grains are presented in Table 3.4-12.

Table 3.4-12: Maritime, North-east and South-east zone – Quality of harvested winter barley grains – crop treated with Thifensulfuron 75% WG, single application post-emergence, as % of untreated (Untreated = 100%).

Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG without surfactant at:		Thifensulfuron 333 + Tribenuron 166 SG reference prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1N	2N

Selectivity trials – Maritime zone						
Moisture content (%)	2	13.7 (13.4-14.0)	101 (100-102)	101 (100-101)	100 (100-101)	100 (100-101)
HectoLitre Weight (kg/hL)	2	60.0 (57.6-62.3)	100 (-)	100 (99-100)	100 (99-100)	93 (86-100)
Thousand Grain Weight (g)	2	49.1 (45.7-52.5)	102 (101-103)	101 (99-103)	97 (92-102)	98 (95-101)
Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG with and without surfactant at:		National reference prod. with surfactant at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1N	2N
Selectivity trials – North-east zone						
Moisture content (%)	3	11.3 (9.9-12.3)	100 (96-104)	99 (94-102)	102 (98-104)	100 (97-103)
HectoLitre Weight (kg/hL)	6	64.5 (62.0-67.5)	100 (100-101)	100 (99-101)	100 (100-101)	100 (99-101)
Thousand Grain Weight (g)	8	43.8 (37.2-50.1)	99 (94-101)	98 (88-103)	100 (93-104)	98 (88-102)
- Results from trials with surfactant						
Moisture content (%)	2	10.7 (9.9-11.5)	99 (96-101)	98 (94-102)	101 (98-104)	100 (97-103)
HectoLitre Weight (kg/hL)	2	65.8 (64.0-67.5)	101 (100-101)	100 (100-101)	100 (100-101)	100 (99-100)
Thousand Grain Weight (g)	4	40.6 (37.2-47.1)	98 (94-101)	97 (88-103)	99 (93-104)	97 (88-102)
- Results from trials without surfactant						
Moisture content (%)	1	12.3	104	101	103	101
HectoLitre Weight (kg/hL)	4	63.9 (62.0-65.8)	100 (100-101)	100 (99-101)	101 (100-101)	100 (100-101)
Thousand Grain Weight (g)	4	47.0 (43.6-50.1)	100 (99-101)	99 (97-101)	101 (99-103)	99 (99-100)
Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG without surfactant at:		Tribenuron reference prod. with surfactant at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1N	2N
Selectivity trials – South-east zone						
Moisture content (%)	2	12.7 (12.6-12.8)	100 (100-101)	101 (100-102)	100 (100-101)	101 (-)
HectoLitre Weight (kg/hL)	2	71.4 (71.4-71.4)	100 (-)	100 (-)	100 (-)	100 (-)
Protein content (%)	2	9.1 (9.1-9.1)	101 (-)	101 (101-102)	101 (-)	102 (101-102)
Thousand Grain Weight (g)	4	51.3 (50.9-51.8)	100 (99-100)	99 (-)	100 (99-100)	99 (99-100)

In 13 of the 14 trials evaluated, Thifensulfuron 75% WG as well as the reference products tested in the trials had no detrimental effect on the quality parameters assessed on the harvested winter barley grains. In one Polish trial, 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).

In the remaining trials, when comparing the results obtained with Thifensulfuron 75% WG against the results obtained with the reference products, hereunder the thifensulfuron SG reference product included in four of the 14 selectivity trials, both products performed statistically similar on all quality parameters assessed.

Winter rye (SECCW)

The results obtained from assessments on the quality of the harvested winter rye grains are presented in Table 3.4-13.

Table 3.4-13: Maritime, North-east and South-east zone – Quality of harvested winter rye grains – crop treated with Thifensulfuron 75% WG, single application post-emergence, as % of untreated (Untreated = 100%).

Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG without surfactant at:		Thifensulfuron Ref. prod. with and without surfactant at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1 N	2 N
Selectivity trials – North-east zone						
Moisture content (%)	7	13.0 (11.3-14.13)	100.1 (99-101.1)	99.9 (97.8-102)	100.6 (99.1-103)	100.2 (98.6-101.5)
HectoLitre Weight (kg/hL)	7	64.8 (41.25-78.48)	100.1 (99.6-101)	99.9 (99-100.2)	99.9 (98.7-101)	99.9 (99.7-100.2)
Thousand Grain Weight (g)	7	41.2 (28.9-69.45)	100.2 (99-103.3)	100.1 (99.7-100.6)	100.1 (99.7-101.6)	100 (99.4-100.8)
Selectivity trials – Maritime zone						
Moisture content (%)	2	11.1 (10.5-11.6)	99.4 (98.7-100)	100 (99.7-101)	99.2 (98.7-99.6)	99.3 (98.8-99.8)

HectoLitre Weight (kg/hL)	2	73.37 (72.7-74.6)	100.5 (100-101)	100.5 (100-101)	100.5 (100-101)	100.5 (100-101)
Thousand Grain Weight (g)	2	29.6 (26.4-32.8)	101 (99.5-102)	101 (99.4-102)	97.1 (96.6-97.6)	101 (99.4-103)
Selectivity trials – South-east zone						
HectoLitre Weight (kg/hL)	4	64.0 (46.9-70.4)	99.6 (98.0-101)	99.8 (98.7-101)	99.9 (99.6-100)	99.6 (97.6-101)
Thousand Grain Weight (g)	4	31.6 (26.4-34.6)	101 (100-102)	100 (98.9-102)	97.2 (94.5-99.9)	99.9 (96.8-103)

In the winter rye trials harvested, Thifensulfuron 75% WG as well as the reference products did not have any detrimental effect on the quality parameters assessed on the harvested winter rye grains.

Winter triticale (TTLWI)

The results obtained from assessments on the quality of the harvested winter triticale grains are presented in Table 3.4-14.

Table 3.4-14: Maritime, North-east and South-east zone – Quality of harvested winter triticale grains – crop treated with Thifensulfuron 75% WG, single application post-emergence, as % of untreated (Untreated = 100%).

Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG without surfactant at:		Thifensulfuron Ref. prod. with and without surfactant at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1 N	2 N
Selectivity trials – North-east zone						
Moisture content (%)	7	13.0 (11.7-14.15)	99.4 (97.8-100.4)	100 (98.8-101.3)	100.2 (98-103.9)	99.8 (98.5-100.4)
HectoLitre Weight (kg/hL)	7	73.7 (62.53-78.9)	99.9 (99-100.2)	100.1 (99.6-100.3)	100 (99.7-100.3)	100.2 (99.8-100.7)
Thousand Grain Weight (g)	7	39.5 (33.48-44.8)	100.5 (99.7-100.8)	100.1 (99-102.3)	100 (98.3-100.9)	100.7 (99.9-101.7)
Selectivity trials – Maritime zone						
Moisture content (%)	2	9.76 (9.69-9.82)	98.2 (96.3-100)	100 (100-100)	98.7 (97.4-100)	99.4 (98.7-100)
HectoLitre Weight (kg/hL)	2	71.4 (71.1-71.7)	100.5 (100-101)	100.5 (100-101)	100.5 (100-101)	100.5 (100-101)
Thousand Grain Weight (g)	2	41.5 (41.3-41.7)	102 (100-104)	100 (98.1-102)	99.3 (97.6-101)	100.5 (100-101)
Selectivity trials – South-east zone						
HectoLitre Weight (kg/hL)	3	71.8 (67.9-74.3)	100 (99.6-101)	99.5 (98.9-100)	100 (99.6-101)	100 (99.2-101)
Thousand Grain Weight (g)	3	42.7 (40.4-46.0)	99.6 (97.8-101)	100 (99.1-101)	99.5 (97.8-101)	99.4 (98.1-100)

In the winter triticale trials harvested, Thifensulfuron 75% WG as well as the reference product did not have any detrimental effect on the quality parameters assessed on the harvested winter triticale grains.

Winter oat (AVESW)

The results obtained from assessments on the quality of the harvested winter oat grains are presented in Table 3.4-144.

Table 3.4-15: Maritime, North-east and South-east zone – Quality of harvested winter oat grains – crop treated with Thifensulfuron 75% WG, single application post-emergence, as % of untreated (Untreated = 100%).

Crop, trial type	No. of trials	Untreated	Thifensulfuron 75% WG without surfactant at:		Thifensulfuron Ref. prod. without surfactant at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.040 kg/ha [30 g ai/ha]	0.080 kg/ha [60 g ai/ha]	1 N	2 N
Selectivity trials – North-east zone						
Moisture content (%)	6	13.1 (12.05-14.0)	100.3 (98.2-101.3)	100.3 (99.3-100.9)	101.4 (99.6-104.7)	100.6 (97.1-102.5)
HectoLitre Weight (kg/hL)	6	50 (46.5-53.97)	99.6 (98.6-100.4)	100.4 (99.4-102.8)	100.2 (99.5-101.1)	100.1 (99.1-101.2)
Thousand Grain Weight (g)	6	34.6 (27.85-39.9)	100.9 (99.5-105)	100.6 (99.5-101.1)	101.4 (100.1-105.1)	101.2 (100.1-104.8)
Selectivity trials – Maritime zone						
Moisture content (%)	1	13.4	98.1	97.8	99.1	96.1
HectoLitre Weight (kg/hL)	1	39.9	81.4	72.8	93.8	93.0
Thousand Grain Weight (g)	1	31.3	105	96.5	98.9	94.3
Selectivity trials – South-east zone						
HectoLitre Weight (kg/hL)	4	48.0 (46.2-49.8)	101 (99.4-103)	101 (98.7-103)	100 (99.4-101)	100 (99.6-101)
Thousand Grain Weight (g)	4	32.4 (28.3-35.6)	101 (100.5-101)	99.3 (95.8-102)	100 (96.5-103)	99.8 (96.7-101)

In the winter oat trials harvested, Thifensulfuron 75% WG as well as the reference product did not have any detrimental effect on the quality parameters assessed on the harvested winter oat grains.

3.4.3.1 Conclusion

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

Post-emergence application in winter cereals is claimed on the label. For crops and recommendation claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in winter wheat, winter barley, winter rye, winter oat and winter triticale where post-emergence applications with and without surfactants were tested. This BAD also clearly demonstrates that the efficacy and crop safety of Thifensulfuron 75% WG is equivalent to the standard thifensulfuron formulations to which it was compared in nine of the 63 selectivity trials harvested. The applicant therefore wishes to cite the original registrant's data on thifensulfuron now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

Comments of zRMS:	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 a hectolitre weight, thousand grain weight, protein content and moisture content was assessed during selectivity trials. <u>In the following trials the negative impact of HIFEN on the quality of yield was observed:</u> 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 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.
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3.4.4 Effects on transformation processes (KCP 6.4.4)

Thifensulfuron 75% WG is composed of thifensulfuron, which has been widely used for several years on a range of crops without identifying any quality problems on the treated crops.

Thifensulfuron 75% WG is applied early in the season (up to BBCH 39), before inflorescence emergence and heading, and it is not expected that the active ingredient is transferred to the grains. For further information on residues, please refer to Part B, Section 7: Metabolism and residues.

To give additional support to these arguments, the applicant wishes to refer to the DAR (Volume 3, Annex B, B.6.6 (1996)) where results obtained with a number of residue trials are presented. According to the DAR on thifensulfuron, there were a total of 14 Northern Europe residues trials conducted in accordance with the representative GAP, the majority of which had analysis of both grain and straw. Additional 20 residue trials, which were considered suitable for evaluation, were conducted in the US (Pacific Coast, Western, Mid Western and Southern locations). The results from the submitted field residue studies showed that no quantifiable residues of Thifensulfuron methyl were determined in any cereal crop matrix when harvested at maturity or at intervals following typical agricultural practice, even when treated at exaggerated rates. In cereals, residues of Thifensulfuron methyl fell below detectable levels about 7 days after application.

As no quantifiable thifensulfuron residues (<LOQ of 0.01 mg/kg) were found in any cereal samples at the time of harvest. Therefore, no processing study is required.

Comments of zRMS:	Thifensulfuron methyl is a herbicide used to control weeds in agricultural crops, including cereal crops. Herbicides typically aim to combat weed plants and their impact on crop plants can vary. Thifensulfuron methyl works by inhibiting the enzyme acetolactate synthase (ALS), which is essential for amino acid biosynthesis. As a result, weeds are destroyed, allowing agricultural crops to thrive without competition for weeds. Herbicides from the ALS group can influence metabolic processes in plants, but they are usually well tolerated by crops plants such as cereals when applied according to the label's recommendations. Cultivated plants like wheat, rye and barley often have mechanisms to resistance to the effects of herbicides, minimizing negative consequences. It is important for herbicides to be applied in accordance with the label's recommendations and in compliance with environmental safety and human health standards and regulations. Improper herbicides use can lead to uncontrolled damage to crop plants, resulting in negative economic consequences. It is always advisable to check label's recommendations and research regarding a specific herbicide to obtain the most up-to-date information on its impact on plant transformation processes, especially in cereals. There may not be specific, widely documented information regarding the direct impact of thifensulfuron methyl on grain transformation processes. The primary focus of herbicide like thifensulfuron methyl is typically on weed control during the growing phase crops, rather than on the harvested grain themselves. Thifensulfuron 75% WG (HIFEN) is applied early in the season (up to BBCH 39), before inflorescence emergence and heading, and it is not expected that the active ingredient be transferred to the grains in the opinion of ZRMs. <u>However, it is crucial to consider several factors and best practices related to herbicide use and grain processing:</u> ✓ Residue level: regulator authorities often set maximum residue limits (MRLs) for herbicide residues in harvested crops, including grains. It is essential to adhere these limits to ensure food safety. This was assessed by residue section
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	for HIFEN. ✓ Pre-harvest Intervals (PHI): herbicide labels provide information on the recommended pre-harvest intervals. Following these guidelines ensures that residue have sufficiently degraded before the crop is harvested. This was assessed by residue section for HIFEN. ✓ Good Agriculture Practice (GAP): adhering to Good Agricultural Practices help minimize the risk of herbicide residues in harvested crops. This includes following recommended application rates, application timings and other guidelines. HIFEN is recommended for use in line to Good Agricultural Practice. ✓ Grain Quality: while herbicides are designed to target specific pathways in weed plants, it is crucial to monitor and assess the overall quality of the harvested grain. Any adverse effects on grain quality could impact processing. The grain quality was assessed during selectivity trials. No negative impact of HIFEN on the quality of yield studied cereals was observed. ✓ Regulatory Compliance: farmers and processors must comply with local regulations and guidelines related to herbicide use, residue levels, and food safety standards. 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, par-boiling, 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 residues (<LOQ of 0.01 mg/kg) were found in any cereal samples at the time of harvest. Therefore, no processing study is required.
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3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Thifensulfuron 75% WG is composed of thifensulfuron, which has been widely used for several years on cereals without identifying any issues in regard to ability of grains of treated plants to germinate.

Thifensulfuron 75% WG is applied early in the season (early post-emergence), before inflorescence emergence and heading, and it is not expected that the active ingredient is transferred to seeds and grains. Thus, no influence on the ability of plant parts from treated crops to germinate is expected (EPPO guideline PP 1/135 (4) “Phytotoxicity assessment”, Table 2). Furthermore, phytotoxicity assessments in the performed trials demonstrated the cropsafety of the product and the absence of any negative effect on the plants or plant products in the vast majority of the trials.

However, to demonstrate that the applied treatments do not affect the germination of grains from treated cereal plants, the results from germination tests carried out on harvested grains from seven selectivity trials conducted on winter wheat (2), winter barley (3), winter rye (1) and winter triticale (1) from the North-east EPPO zone (3; i.e. Lithuania) and the South-east EPPO zone (4; i.e. Slovakia) were included in this dossier.

3.4.5.1 Materials and Methods

Thifensulfuron 75% WG was applied in the seven selectivity trials at 0.040 kg/ha and 0.080 kg/ha. The reference product used in the Lithuanian trials was Harmony 50 SX, a SG formulation of thifensulfuron, at 23 g/ha and 46 g/ha, and in the Slovakian trials, a WG formulation of tribenuron methyl (Granstar 75 WG) was used as reference product at 25 g/ha and 50 g/ha. Both reference products were applied with a surfactant (Trend 90), whereas Thifensulfuron 75% WG was applied without a surfactant in all seven trials.

Grains were sampled from each plot and placed in moist conditions at a constant temperature. After approximately 4 and 8 days, the samples were assessed for the number of grains germinated.

3.4.5.2 Summary and evaluation of trial results

The % grains germinated at the last assessment timing are presented in Table 3.4-16. Neither Thifensulfuron 75% WG nor the reference products did have any significant impact on the germination of seeds in any of the trials sampled.

Table 3.4-16: North-east and South-east zone – Number and % grains germinated.

Trial number	Variety	Ass. date DAA	UTC -	Germination [%]				Type of Assessment on Germination
				Thifensulfuron 75% WG		Reference product + Surfactant		
				40 g/ha	80 g/ha	1N	2N	
Selectivity trials, North-east zone								
151542761 [Winter barley]	Ahinghi	213	100	99	99	99	99	GERMIN (%-rel. GERMIN (no.)
151542771 [Winter rye]	Agronom	191	100	99	100	98	99	GERMIN (%-rel. GERMIN (no.)
151542781 [Winter triticale]	Remiko	200	100	100	101	100	101	GERMIN (%-rel. GERMIN (no.)
Selectivity trials, South-east zone								
SHAR-PHY2-SKGM15 [Winter wheat]	Košútka	109	94.0	93.3	92.0	92.8	91.3	GERNOR (%)
		109	0.3	0.8	1.3	0.8	1.8	GERANO (%)
		109	5.8	6.0	6.8	6.5	7.3	NONGER (%)
SHAR-PHY2-SKRS15 [Winter wheat]	Lukullus	110	92.8	92.5	91.5	92.0	91.0	GERNOR (%)
		110	1.5	1.5	2.0	1.8	2.3	GERANO (%)
		110	5.8	6.0	6.5	6.3	6.8	NONGER (%)
SHAR-PHY2-HORVW-SKGM15 [Winter barley]	Malwinta	129	95.3	94.8	93.8	94.3	92.8	GERNOR (%)
		129	0.5	0.8	1.3	1.0	1.5	GERANO (%)
		129	4.3	4.5	5.0	4.8	5.8	NONGER (%)
SHAR-PHY2-HORVW-SKRS15 [Winter barley]	Malwinta	132	95.3	94.3	93.5	94.3	93.3	GERNOR (%)
		132	0.3	0.8	1.0	0.5	1.3	GERANO (%)
		132	4.5	5.0	5.5	5.3	5.5	NONGER (%)

The product complies with the Uniform Principles.

Comments of zRMS:	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
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	branched-chain amino acids in plants. This inhibition selectivity affects the growth of certain weeds. Below, ZRMs presents some points to consider: ✓ Selectivity: Thiensulfuron methyl is designed to be selective, meaning it targets specific metabolic pathways in weeds while having minimal impact on crop plants like cereals. Crops often have natural tolerance or resistance mechanisms to ALS-inhibiting herbicides. ✓ Application Timing: Following recommended application timing and rates is crucial. Herbicide applications are typically made during the early stages of weed development, minimizing the potential impact on cereal crops that are already established. ✓ Pre-harvest Intervals (PHI): Thifensulfuron methyl, like other herbicides has a specified pre-harvest interval (PHI). This is the time that must elapse between the last herbicide application and the harvest of the crop. Adhering to this interval ensures that residues have sufficiently degraded before harvest. ✓ Seed viability: If there are concerns about the impact on seed viability or germination, it is advisable to check the specific guidelines and research related to thifnsulfuron methyl. However, in general, herbicides are designed to minimize effects on seed quality. ✓ Regulatory Compliance: Farmers should always follow local regulations and guidelines related to herbicide use, including any restrictions on propagating material or seed quality. It is 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 phytotoxic 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.
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3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

As per the Peer review report on thifensulfuron-methyl (EFSA Journal 2015;13(7):4201), average DT₅₀ is 1.39 days (range: 0.85-3.1 days, n=6) for the parent compound. Thus, the persistence of thifensulfuron-methyl can be considered as very low to low and therefore no studies are needed according to guidelines. The persistence of the key metabolites (IN-L9225 (= thifensulfuron; moderate to high; range: 14.4-154.4 days, n=11), 2-acid-3-triuret (moderate to high; range: 38.4-132 days, n=8), IN-A4098 (moderate to high; range: 67.3->1000 days, n=16), IN-JZ789 (low to very high; range: 8.06-1000 days, n=8), IN-L9223 (high to very high; range: 107->1000 days, n=4), IN-W8268 (low to medium; range: 2.6-64.2 days, n=6), IN-A5546 (low; range: < 3 days, n=5) and IN-L9226 (very low to low; Range: 0.3-3.3 days, n=6) are ranging from very low to very high.

Radiolabelled residues were found not to accumulate in rotational crops (beets, peas and sunflowers) grown in soil treated 30 and 120 days earlier with thifensulfuron-methyl. In mature crop samples, the level of radiolabelled residues was found to be < 0.01 mg/kg. Additionally, there were no substantial residues (< 0.01 mg/kg) in mature wheat grain from crops planted 90 and 241 days following soil treatment. Thifensulfuron-methyl was not detected in any edible crop parts. Minor residues were detected in ¹⁴C-triazine labelled straw, but no one compound was greater than 0.034 mg/kg.

Label recommendation – Succeeding crops

Thifensulfuron 75% WG 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 of application.

Comments of zRMS:	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
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	0.85-3.1 days in laboratory conditions. Therefore, 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 <i>“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.”</i>
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3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

During the conduct of efficacy trials and selectivity trials, no observations about negative or positive effects on other plants or neighbouring crops were reported.

EPPO guidelines PP1/256(1) is intended to examine whether the active substance of a plant protection product can cause negative effects on crop which would be in contact with that product. Based on the actual drift value calculated with the Ganzelmeier model and on the EC₅₀ value obtained from herbicidal screening studies presented in the DAR, TER values are obtained.

- If the active substance has no activity against plants at the highest doses tested in the bioassays. Then field trials are unnecessary.
- If the TER values are > 5. Then no further testing is necessary.
- If the TER values are ≤ 5. Damage to the relevant adjacent crop is possible and further field testing is necessary as described in the EPPO guideline.

The maximum proposed rate of Thifensulfuron 75% WG is 0.040 kg/ha, which would deliver 30 g thifensulfuron per hectare.

The following risk assessment is based upon reported Non-Target Plant endpoints from unprotected studies presented by Dupont and Rotam Agrochemical Europe / the Cheminova A/S task force with their respective test formulations Thifensulfuron methyl 50 SG (thifensulfuron-methyl 500 g/kg SG) and Thifensulfuron 75% WG (CHA 8730 and FH-009; Thifensulfuron-methyl 750 g/kg WG) in the RAR, summarized in the Peer review of thifensulfuron-methyl (EFSA Journal 2015;13(7):4201).

A summary of the results reported in laboratory dose response tests are presented in the table below.

Table 3.5-1: Results of laboratory dose response tests – deterministic risk assessment (EF-SA Peer Review (2015))

Most sensitive species	Test substance	ER ₅₀ (g a.s./ha) vegetative vigour	ER ₅₀ (g a.s./ha) seedling emergence	Exposure (g a.s./ha) ¹	TER vegetative vigour	TER seedling emergence	Trigger
<i>Beta vulgaris</i>	Thifensulfuron methyl 50 SG	0.606	0.613 *	1.04 (1m)	0.58	0.6	5
				0.214 (5m)	2.83	2.9	5
				0.109 (10m)	5.56	5.6	5
<i>Beta vulgaris</i>	Thifensulfuron-methyl 50 SG + surfactant	0.142	53	1.04 (1m)	0.1	51	5
				0.214 (5m)	0.7	-	5
				0.109 (10m)	1.3	-	5
				0.075 (15m)	1.9	-	5
				0.056 (20m)	2.5	-	5
				0.038 (30m)	3.7	-	5
				0.026 (40m)	5.5	-	5
<i>Allium cepa</i>	CHA 8730	>2.47	0.62	1.41 (1m)	1.8/	0.4	5
				0.291 (5m)	8.5	2.1	5
				0.148 (10m)	16.7	4.2	5
<i>Lycopersicon lycopersicum</i>	FH-009	NA	1.63	1.41 (1m)	NA	1.2	5
				0.291 (5m)	NA	5.6	5

¹endpoint from testing with the a.s.

Table 3.5-2: Results of laboratory dose response tests – deterministic risk assessment (EF-SA Peer Review (2015))

Most sensitive species	Test substance	Median HR ₅ (g a.s./ha) vegetative vigour	Median HR ₅ (g a.s./ha) seedling emergence	Exposure (g a.s./ha) ¹	TER vegetative vigour	TER seedling emergence	Trigger
NA	Thifensulfuron methyl 50 SG	NA	0.315*	1.04 (1m)	NA	0.30	1
				0.214 (5m)	NA	1.47	1
				0.109 (10m)	NA	2.89	1
NA	Thifensulfuron methyl 50 SG + surfactant	0.107	NA	1.04 (1m)	0.10	NA	1
				0.214 (5m)	0.5	NA	1
				0.109 (10m)	0.98	NA	1
				0.075 (15m)	1.43	NA	1
NA	CHA 8730	NA	0.395	1.41 (1m)	NA	0.3	1
				0.291 (5m)	NA	1.6	1
NA	FH-009	NA	0.402	1.41 (1m)	NA	0.3	1
				0.291 (5m)	NA	1.4	1

¹endpoint from testing with the a.s.

Taking into account the endpoints reported in the Peer review of thifensulfuron, the most sensitive dicotyledonous species was *Beta vulgaris*, with ER₅₀ of 0.613 g ai/ha. The most sensitive monocotyledonous species was *Allium cepa* with ER₅₀ of 0.62 g ai/ha.

Risk assessment

Terrestrial non-target plants may be exposed to Thifensulfuron 75% WG by spray drift in the vicinity of the treated area. Thifensulfuron is mainly taken up via the leaves, but to a lesser extent, the active is also taken up via the roots of the plants. The maximum proposed dose rate of thifensulfuron-methyl, when applying Thifensulfuron 75% WG as recommended, is 30 g ai/ha.

The most sensitive of the species and parameters tested in seedling emergence and vegetative vigour studies was sugarbeet, which has an ER₅₀ of 0.606 g ai/ha when applied without adjuvant and if applied with an adjuvant, the ER₅₀ was 0.142 g ai/ha. The risk was assessed by calculation of the toxicity to exposure ratio (TER), and comparison of this value with the EPPO trigger of 5.

Results are presented in the table below:

Table 3.5-3: Effects on non-target plants

Test substance	Buffer distance (m)	Application rate (g a.s./ha)	Drift value ^a (%)	Drift reducing nozzles (%)	Drift rate (g a.s./ha)	Timing	ER ₅₀ (g a.s./ha)	TER	Trigger
Thifensulfuron 75% WG	1	1 x 30	2.77	0	0.83	Post-emergence	0.606	0.73	5
		1 x 30	2.77	50	0.42		0.606	1.46	5
		1 x 30	2.77	75	0.21		0.606	2.92	5
		1 x 30	2.77	90	0.08		0.606	7.29	5
	5	1 x 30	0.57	0	0.17		0.606	3.54	5
		1 x 30	0.57	50	0.09		0.606	7.09	5
	10	1 x 30	0.29	0	0.09		0.606	6.97	5
		1 x 30	0.29	0	0.09		0.606	6.97	5
		1 x 30	0.29	0	0.09		0.606	6.97	5
Thifensulfuron 75% WG w. surfactant	1	1 x 30	2.77	0	0.83	Post-emergence	0.142	0.17	5
		1 x 30	2.77	50	0.42		0.142	0.34	5
		1 x 30	2.77	75	0.21		0.142	0.68	5
		1 x 30	2.77	90	0.08		0.142	1.71	5
	5	1 x 30	0.57	0	0.17		0.142	0.83	5
		1 x 30	0.57	50	0.09		0.142	1.66	5
		1 x 30	0.57	75	0.04		0.142	3.32	5
		1 x 30	0.57	90	0.02		0.142	8.30	5
	10	1 x 30	0.29	0	0.09		0.142	1.63	5
		1 x 30	0.29	50	0.04		0.142	3.26	5
		1 x 30	0.29	75	0.02		0.142	6.53	5
		1 x 30	0.29	90	0.01		0.142	13.06	5
	20	1 x 30	0.15	0	0.05		0.142	3.16	5
		1 x 30	0.15	50	0.02		0.142	6.31	5
		1 x 30	0.15	75	0.01		0.142	12.62	5
		1 x 30	0.15	90	0.005		0.142	25.24	5
	30	1 x 30	0.10	0	0.03		0.142	4.73	5
		1 x 30	0.10	50	0.02		0.142	9.47	5
		1 x 30	0.10	75	0.01		0.142	18.94	5
		1 x 30	0.10	90	0.005		0.142	37.88	5
	40	1 x 30	0.07	0	0.02		0.142	6.76	5
		1 x 30	0.07	50	0.01		0.142	13.52	5
		1 x 30	0.07	75	0.005		0.142	27.04	5
		1 x 30	0.07	90	0.002		0.142	54.08	5

^a Drift estimates are based on 90th percentile values for field crops (BBA 2000); ER₅₀ values on *Beta vulgaris*, as the worst case

Without risk mitigation measures, the calculated TER values are below the trigger of 5, indicating a potential risk to non-target plants, if applied for weed control in winter cereals in the spring. When applying thifensulfuron-methyl without a surfactant, a TER trigger of above 5 (according to SANCO 10329/2002, rev. 2) is achieved when taking 50% drift reduction and a buffer zone of 5 m into account, or a buffer zone of 10 m. If applied with a surfactant, a TER trigger of above 5 is achieved when taking 75% drift reduction and a buffer zone of 10 m into account, or 50% drift reduction and a buffer zone of 20 m.

The effect endpoints used in the terrestrial non-target plant risk assessment (i.e. ER₅₀ for the plant species tested in seedling emergence and vegetative vigour) were re-evaluated to construct a species sensitive distribution from which an HR₅ was obtained. The lowest HR₅ end points are based on the results of the tests conducted with Thifensulfuron 50 SG. Greater than data were regarded as outliers, i.e. not considered for the HC₅ evaluation.

Based on this methodology, for seedling emergence, the lowest HR₅ is 0.315 g ai/ha. For vegetative vigour, the only HR₅ reported is 0.107 g ai/ha for Thifensulfuron 50 SG applied with a surfactant.

According to the Guidance Document on Terrestrial Ecotoxicology SANCO/10329/2002, Rev. 2 (final), the risk for terrestrial plants is assumed to be acceptable if the ER/EC₅₀ for less than 5% of the species is below the highest predicted exposure level. As this is the case for terrestrial non-target plants, for the refined risk assessment, the TER values considering the HR₅ are compared to a trigger of 1.

Table 3.5-4: Effects on non-target plants

Test substance	Buffer distance (m)	Application rate (g a.s./ha)	Drift value ^a (%)	Drift reducing nozzles (%)	Drift rate (g a.s./ha)	Timing	HR ₅ (g a.s./ha)	TER	Trigger
Thifensulfuron 75% WG	1	1 x 30	2.77	0	0.83	Post-emergence	0.315	0.38	1
		1 x 30	2.77	50	0.42		0.315	0.76	1
		1 x 30	2.77	75	0.21		0.315	1.52	1
		1 x 30	2.77	90	0.08		0.315	3.79	1
	5	1 x 30	0.57	0	0.17		0.315	1.84	1
		1 x 30	0.57	50	0.09		0.315	3.68	1
	10	1 x 30	0.29	0	0.09		0.315	3.62	1
		1 x 30	0.29	0	0.09		0.315	3.62	1
		1 x 30	0.29	0	0.09		0.315	3.62	1
Thifensulfuron 75% WG w. surfactant	1	1 x 30	2.77	0	0.83	Post-emergence	0.107	0.13	1
		1 x 30	2.77	50	0.42		0.107	0.26	1
		1 x 30	2.77	75	0.21		0.107	0.52	1
		1 x 30	2.77	90	0.08		0.107	1.29	1
	5	1 x 30	0.57	0	0.17		0.107	0.63	1
		1 x 30	0.57	50	0.09		0.107	1.25	1
		1 x 30	0.57	75	0.04		0.107	2.50	1
		1 x 30	0.57	90	0.02		0.107	6.25	1
	10	1 x 30	0.29	0	0.09		0.107	1.23	1
		1 x 30	0.29	50	0.04		0.107	2.46	1
		1 x 30	0.29	75	0.02		0.107	4.92	1
	20	1 x 30	0.15	0	0.05		0.107	2.38	1
		1 x 30	0.15	50	0.02		0.107	4.76	1
	30	1 x 30	0.10	0	0.03		0.107	3.57	1
		1 x 30	0.10	50	0.02		0.107	7.13	1
	40	1 x 30	0.07	0	0.02		0.107	5.10	1
		1 x 30	0.07	0	0.02		0.107	5.10	1

^a Drift estimates are based on 90th percentile values for field crops (BBA 2000); HR₅ values as the worst case

Based on the probabilistic risk assessment, when applying thifensulfuron-methyl without a surfactant, a TER trigger of 1 is achieved when taking 75% drift reduction into account, or a buffer zone of 5 m. If applied with a surfactant, a TER trigger of above 5 is achieved when taking 50% drift reduction and a buffer zone of 5 m into account, or a buffer zone of 10 m.

Conclusion

The non-target plant studies show that there is a potential risk to adjacent crops from an application of Thifensulfuron 75% WG, therefore care should be taken to avoid drift onto adjacent crops. However, based on the probabilistic risk assessment, the risk for non-target terrestrial plants is considered acceptable if nozzles giving a drift reduction of 75% is taken into account, or a buffer zone of 5 m. If thifensulfuron-methyl is applied with a surfactant, the risk for non-target terrestrial plants is considered acceptable if nozzles giving a drift reduction of 50% and a buffer zone of 5 m is taken into account, or a buffer zone of 10 m.

Please, for more information, refer to Registration Report, Part B, Section 9.

Comments of zRMS:	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
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	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.
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3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

From the experimentation carried out with Thifensulfuron 75% WG in 2014/15 and 2020/21 season, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 9.

Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

Comments of zRMS:	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.
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3.6 Other/special studies

3.6.1 Tank-cleaning (KCP 6.6.1)

Please refer to Section dRR part B124 to see complete information about tank cleaning.

Comments of zRMS:	Statement accepted. ZRMs accepted information has included in label project by Applicant. <u>Following entry was accepted:</u> PREPARATION OF SPRAY SOLUTION <i>Prepare the spray solution immediately before use. Before preparing the spray solution, determine the required volume along with the quantity of the product. When filling the sprayer, follow the manufacturer's instructions for the sprayer. In the absence of instructions, add the measured amount of the product to the partially filled sprayer tank (with the agitator turned on). Rinse emptied containers three times with water, and pour the rinsate into the sprayer tank with the spray</i>
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3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

[illegible]

ZZS Kujavy	MAR	CZ				2
Lithuanian Research Centre for Agriculture and Forestry (LRCAF)	N-E	LT		1		
Fertico	N-E	PL				6
CPR	S-E	HU				3
Total, Winter triticale				1		11
Winter oat						
ZZS Kujavy	MAR	CZ				1
Fertico	N-E	PL				6
CPR	S-E	HU				4
Total, Winter oat						11

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

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