

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: SHA 4100 A

Product name: HIFEN

Chemical active substance:

Thifensulfuron-methyl, 750 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem Ltd.

Submission date: September 2023.

MS Finalisation date: April 2024; February 2025

Version history

When	What
April 2024	ZRMs evaluated submitted dRR
February 2025	The final Registration Report.

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is submitted by SHARDA CROPCHEM Ltd. for approval of Thifensulfuron 75% WG, a water dispersible granule containing 750 g/kg of Thifensulfuron-methyl for use as herbicide on winter cereals (wheat, barley, rye, oats, triticale) in Central Europe.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	-	-
Central zone	Poland HIFEN	Romania, Hungary HIFEN
Southern zone	-	-
Inter-zonal	-	-

0.1.3 Regulatory history of the active

Table 0.1-2: Summary of regulatory history of CAS No: 79277-27-3

Status	
Approved in EU	Y
Original Inclusion Directive Commission Implementing Regulation	Commission Directive 2001/99/EC Commission Implementing Regulation (EU) No 2016/1424
RMS	RMS: UK Co-RMS: Austria Original RMS: France
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.11.2016
Current expiration of approval	31.10.2031
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the protection of groundwater
- the protection of non-target plants and aquatic organisms.

Conditions of use shall include risk mitigation measures and the obligation to monitor the groundwater, where appropriate.

The SANCO report for Thifensulfuron-methyl (SANTE/10150/2016 rev. 2 – 12/07/2016) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 2015 (EFSA Journal 2015;13(7):4201).

Table 0.1-3: Information on minimum purity of Thifensulfuron-methyl

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
960 g/kg	min. 980 g/kg Sharda source Equivalence report available: Y RMS: The UK (2016)

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**, If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

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

Mammalian toxicology

Taking into account the composition of the product and the provisions of the Regulation EC No. 1272/2008, the formulation SHA 4100 A / HIFEN containing thifensulfuron-methyl (750 g/L) does not require classification in regards to acute toxicology.

Exposure assessment:

Operator: According to the estimation based on AOEM, the use of SHA 4100 A / HIFEN causes acceptable health risk for unprotected operator (arms, body and legs covered). However, protective gloves and work wear during M&L and work wear during product application is recommended.

Worker: According to the estimation results (AOEM and EUROPOEM II), the use of SHA 4100 A / HIFEN does not cause unacceptable health risk for unprotected worker (inspection, 2h).

Bystander/Resident: The results of the exposure estimations suggest that the incidental short-time expo-

sure of bystander and resident (children and adult) to thifensulfuron-methyl contained in the formulation SHA 4100 A /HIFEN causes no risk to human health if the product is used in accordance to the intended uses listed in the GAP Table.

Metabolism and residues: uses are accepted.

Ecotoxicology section: uses are accepted.

Uses to be considered safe on the basis of EU methodology:

Efficacy section: 1

Mammalian toxicology: 1

Residues section: 1

Environmental fate and behavior section: 1

Ecotoxicology section: 1

Uses to be considered non-safe on the basis of EU methodology:

Efficacy section: none

Mammalian toxicology: none

Residues section: none

Environmental fate and behavior section: none

Ecotoxicology section: none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS: **none**

Residues section: All uses/ GAPs are covered by established MRLs

Appendix 1 ALL intended uses

GAP rev. 0, date: 2016-July-25th

PPP (product name/code): Thifensulfuron 75% WG
Active substance 1: Thifensulfuron-methyl
Active substance 2: -
Safener: -
Synergist: -
Applicant: SHARDA Cropchem Ltd.
Zone(s): Central
Verified by MS: yes/no

Formulation type: WG (Water dispersible granules)
Conc. of as 1: 750 g/kg
Conc. of as 2: -
Conc. of safener: -
Conc. of synergist: -
Professional use: ☒
Non professional use: ☐

Field of use: Herbicide

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

Remarks table heading:
(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife
International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be
given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out
when the notifier no longer supports this use.

Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions