FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: TOTO 75 SG

Product name(s): TOTO 75 SG/ TYTAN 75 SG/ HERKULES 75 SG

Chemical active substance(s):

Thifensulfuron-methyl, 682 g/kg
Metsulfuron-methyl, 68 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(renewal of authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: June 2021

MS Finalisation date: July 2021; October 2022

Version history

When	What
July 2021	ZRMs evaluated submitted dRR.
October 2022	Final Registration Report

Table of Contents

0 Product background, regulatory context and GAP information

0.1 Introduction

This document describes the acceptable use conditions required for renewal of authorization of TOTO 75 SG (TOTO 75 SG, TYTAN 75 SG, HERKULES 75 SG) containing thifensulfuron-methyl and metsulfuron-methyl in POLAND (ZRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 (except efficacy section – B3) and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required by the EU review. It also includes assessment of data and information relating to TOTO 75 SG where that data has not been considered in the EU review. Otherwise assessments for the safe use of TOTO 75 SG have been made using endpoints agreed in the EU review of Thifensulfuron-methyl and metsulfuron-methyl after renewal of these active substances..

This document describes the specific conditions of use and labelling required for the registration of (TOTO 75 SG, TYTAN 75 SG, HERKULES 75 SG), product code TOTO 75 SG.

0.1.1 Reason for application

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

In addition to the submission of studies as listed in section(s) B1-B10, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

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)**
Central zone	Poland: TOTO 75 SG TOTO 75 SG/ TYTAN 75 SG/ HERKULES 75 SG	Slovakia: TOTO 75 SG TOTO 75 SG/TYTAN 75 SG

0.1.3 Regulatory history of the active(s)

0.1.3.1 Thifensulfuron-methyl

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

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) 2016/1424 of 25 August 2016
RMS	UK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/11/2016
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/10/2031
Date of final Commission (re-registration) deadline (Step 2)	31/10/2031
Current expiration of approval	31/10/2031
Low risk substance or Candidate for Substitution?	Low risk

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 monitoring of the groundwater, where appropriate.

The SANCO report for thifensulfuron-methyl (SANTE/10150/2016 rev. 2 12 July 2016) is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

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	~~For the purity of active substance, please refer to PART C- confidantial information~~ Min purity of active substance: 975 g/Kg Equivalence report available: Y (available on CIRCA) RMS:UK (CRD)

* 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.

0.1.3.2 Metsulfuron-methyl

Table 0.1-4: Summary of regulatory history of CAS No: 74223-64-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Reg. (EU) 2016/139
RMS	DK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/04/2016
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	01/04/2016
Date of final Commission (re-registration) deadline (Step 2)	31/03/2023
Current expiration of approval	31/03/2023
Low risk substance or Candidate for Substitution?	CfS

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:

On the basis of the proposed and supported uses (as listed in Appendix II), the following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate: - the protection of consumers, - the protection of groundwater, - the protection of non-target terrestrial plants.

Conditions of use shall include risk mitigation measures, where appropriate.

The SANTE report for metsulfuron-methyl SANTE/10319/2015 Rev 4, 16 July 2020 is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

Table 0.1-5: Information on minimum purity of Metsulfuron-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**
967 g/kg	~~For the purity of active substance, please refer to PART C- confidantial information~~ Min purity of active substance: 975 g/Kg Equivalence report available: Y (available on CIRCA) RMS:UK (CRD)

0.1.4 Regulatory history of the product

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Table 0.1-4: Summary of regulatory history of the product TOTO 75 SG

09.08.2012 – first registration in Poland
26.02.2015 - First registration in Slovakia
01.2019 – send documentation for renewal of authorization

0.2 zRMS conclusion

risk mitigation at a national (non-core) level or the safety is to be confirmed by cMS.

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

1-8

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

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:

The risk mitigation measures for aquatic organism and non -target plants should be decided at MS level.

All uses/ GAPs are covered by established MRLs.

CONCLUSIONS:

Mammalian Toxicology:
Classification of the product: Eye Irrit. H319, STOT SE3, H335
Exposure:
Operator: protective gloves, eye/face protection and work wear (coverall) during mixing and loading and application.
Worker: work wear.
Bystander/resident: The incidental short-time exposure to TOTO 75/ TYTAN 75/ HERKULES 75 causes no risk to human health if the product is used in accordance to the intended uses listed in the GAP Table.
Fate and behavior: no risk for groundwater following application TOTO 75/ TYTAN 75/ HERKULES.

Appendix 1 ALL intended uses

PPP (product name/code):	TOTO 75 SG	Formulation type:	75 SG [a, b]
Active substance 1:	Thifensulfuron-methyl	Conc. of as 1:	682g/kg [c]
Active substance.3:	Metsulfuron-methyl	Conc. of as ….:	68 g/kg [c]
Safener:	n/a	Conc. of safener:	conc. [c]
Synergist:	n/a	Conc. of synergist:	conc. [c]
Applicant:	Innvigp Sp. z o.o.	Professional use:	☒
Zone(s):	northern/central/southern/interzonal [d]	Non professional use:	☐
Verified by MS:	yes/no		

Field of use: herbicidec

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. num-ber a) per use b) per crop/ season	Min. interval between ap-plications (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		
1													
2													
3													
4													
Field uses													
1	PL, SK	Winter wheat	F	weeds	spray medium	PL: BBCH 21-29 SK: BBCH 22-29	1	N/A	a) 0,07 b) 0,07	a) thifensul-furon methyl 47.7 g + metsulfuron methyl 4.8 g b) thifensul-furon methyl	200-300	N/A	PL: plus adiuvant ASYSTENT+90 EC in dose 0,1l/ha

										47.7 g + metsulfuron methyl 4.8 g			
2	PL, SK	Winter wheat	F	weeds	spray medium	PL: BBCH 30-31 SK: BBCH 30-31	1	N/A	c) 0,09 d) 0,09	a) thifensul-furon methyl 61,4 g + metsulfuron methyl 6,1 g b) thifensul-furon methyl 61,4 g + metsulfuron methyl 6,1 g	200-300	N/A	PL: plus adiuvant ASYSTENT+90 EC in dose 0,1l/ha
3	PL, SK	Winter triticale	F	Weeds	spray medium	BBCH 21 -29	1	N/A	a) 0,07 b) 0,07	a) thifensulfuron methyl 47.7 g + metsulfuron methyl 4.8 g b) thifensulfuron methyl 47.7 g + metsulfuron methyl 4.8 g			PL: plus adiuvant PARTNER+ in dose 0,5 l/ha SK – extention of registration is current-ly pending
4	PL, SK	Winter triticale	F	Weeds	spray medium	BBCH 30 -31	1	N/A	c) 0,09 d) 0,09	a) thifensulfuron methyl 61,4 g + metsulfuron methyl 6,1 g b) thifensulfuron methyl 61,4 g + metsulfuron methyl 6,1 g			PL: plus adiuvant PARTNER+ in dose 0,5 l/ha SK – extention of registration is current-ly pending
5	PL, SK	Winter rye	F	Weeds	spray medium	BBCH 21 -29	1	N/A	a) 0,07 b) 0,07	a) thifensulfuron methyl 47.7 g + metsulfuron methyl 4.8 g b) thifensulfuron methyl 47.7 g + metsulfuron methyl 4.8 g			PL: plus adiuvant PARTNER+ in dose 0,5 l/ha SK – extention of registration is current-ly pending
6	PL, SK	Winter rye	F	Weeds	spray medium	BBCH 30 -31	1	N/A	c) 0,09 d) 0,09	a) thifensulfuron methyl 61,4 g + metsulfuron			PL: plus adiuvant PARTNER+ in dose 0,5 l/ha

										methyl 6,1 g b) thifensulfuron methyl 61,4 g + metsulfuron methyl 6,1 g			SK – extention of registration is currently pending
7	PL, SK	Winter rye	F	Weeds	spray medium	BBCH 21 -31	1	N/A	a) 0,07 b) 0,07	a) thifensulfuron methyl 47,7 g + metsulfuron methyl 4,8 g b) thifensulfuron methyl 47,7 g + metsulfuron methyl 4,8 g			SK – extention of registration is currently pending: Tank Mix with Galaper (fluroksypyr) 250 EC in dose 0,25 l of product /ha PL: Tank Mix with Galaper (fluroksypyr) 250 EC in dose 0,25 l of product /ha + adiuvant Partner+ in dose 0,5 l/ha
8	PL, SK	Winter triticale	F	Weeds	spray medium	BBCH 21 -31	1	N/A	a) 0,07 b) 0,07	a) thifensulfuron methyl 47,7 g + metsulfuron methyl 4,8 g b) thifensulfuron methyl 47,7 g + metsulfuron methyl 4,8 g			SK – extention of registration is currently pending: Tank Mix with Galaper (fluroksypyr) 250 EC in dose 0,25 l of product /ha PL: Tank Mix with Galaper (fluroksypyr) 250 EC in dose 0,25 l of product /ha + adiuvant Partner+ in dose 0,5 l/ha
EU-wide uses (use on sowing seed, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3	-	-	-	-	-	-	-	-	-	-	-	-	-

4	-	-	-	-	-	-	-	-	-	-	-	-	-
Minor uses according to article 51													
5	-	-	-	-	-	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-	-	-	-	-	-