FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: CHR/H/ETO 500 SC

Product name(s): BITT 500 SC, BETRON 500 SC, ETONAL 500 SC

Chemical active substance(s):

Ethofumesate, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: June 2021

MS Finalisation date: 10.2021; 01/2022

Version history

When	What
October 2021	zRMS evaluation
January 2022	Final version prepared by zRMS after Commenting period

Table of Contents

0 Product background, regulatory context and GAP information

0.1 Introduction

This document describes the acceptable use conditions required for zonal registration of CHR/H/ETO 500 SC (BITT 500 SC, BETRON 500 SC, ETONAL 500 SC) containing ethofumesate in POLAND (ZRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 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 CHR/H/ETO 500 SC where that data has not been considered in the EU review. Otherwise assessments for the safe use of CHR/H/ETO 500 SC have been made using endpoints agreed in the EU review of ethofumesate.

This document describes the specific conditions of use and labelling required for the registration of (BITT 500 SC, BETRON 500 SC, ETONAL 500 SC), product code CHR/H/ETO 500 SC.

In the following document, data for active substance ethofumesate was described during its renewal process in 2016. Were reference to active substance data in the current risk assessment has been made, it was based on the data presented by Bayer.
In June 14th, 2018r Kemiron Koncentrat 500SC product has been renewed in Poland thus according to the art. 59 reg. 1107/2009, data protection for mentioned data expired 30 months from date of first renewal of authorisation of product containing that active substance (in this case December, 14th 2020).
Considering analogous arguments (art. 59 reg 1107/2009) – data protection of studies presented by UPL for renewal of product Bettix Combi 500 SC (renewal of authorisation granted in Poland 14.02.2019 r.) expires August 14th, 2021.
Taking into account that some data was presented by others Notyfiers, Applicant would like to emphasise that unprotected Bayer's endpoints and input parameters accepted during renewal of active substance, should be treated as an equivalent matching data in cases where any of endpoints might be protected.

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) B0-10, 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 CHR/H/ETO 500 SC BITT 500 SC, BETRON 500 SC, ETONAL	NR

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
	500 SC	

0.1.3 Regulatory history of the active(s)

0.1.3.1 Ethofumesate

Table 0.1-2: Summary of regulatory history of CAS No: 26225-79-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	COMMISSION IMPLEMENTING REGULATION (EU) 2016/1426 of 25 August 2016
RMS	AT
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?	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 risk to aquatic organisms.

The SANCO report for ethofumesate (SANTE/10119/2016 Rev. 3 - 12 July 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 19.01.2016.

Table 0.1-3: Information on minimum purity of ethofumesate

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~~ 970 mg/kg	For the purity of active substance, please refer to PART C- confidantial information Equivalence report available: please refer to LoA RMS: please refer to LoA

* 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

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

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

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:

All uses/ GAPs are covered by established MRLs except for use in crop. An application for amending the MRL has been submitted by MS to EFSA EFSA Project Number (if applicable).

Physical-chemical section:

Data gap: The shelf-life study is on-going. One-year conditional registration of the product is possible and proposed.

Appendix 1 ALL intended uses

GAP, date: 2020-07-27

PPP product name:		Formulation type:	SC [a, b]
product code:	CHR/H/ETO		
Active substance 1:	ethofumesate	Conc. of as 1:	500 g/l [c]
Active substance 2:	-	Conc. of as 2:	- [c]
Active substance 3:	-	Conc. of as 3:	-
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	Innvigo Sp. z o.o.	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐
Verified by MS:	no		

Field of use: herbicide

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
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: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]	ZRMs Conclusion
					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	PL,CZ	Sugar beet *Beta vulgaris* subsp. *vulgaris* var. *altissi-ma* (BEAVA)	F	Dicotylenous weeds	Spray, medium sprayer	Spring BBCH 11-18	a) 2 b) 2	5	a) 1.0 l/ha b) 2.0 l/ha	a) 0.5 kg a.s./ha b) 1.0 kg a.s./ha	200 - 300			
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
2	PL, CZ	Sugar beet *Beta vulgaris* subsp. *vulgaris* var. *altissi-ma* (BEAVA)		Dicotylenous weeds	Spray, medium sprayer	Spring BBCH 11-18	a) 3 b) 3	5	a) 0,6 l/ha b) 1,8 l/ha	a) 0,3 kg a.s/ha b) 0,9 kg a.s/ha	200 - 300			
3														
Minor uses according to Article 51 (zonal uses)														
4														
5														
Minor uses according to Article 51 (interzonal uses)														
6														
7														

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
2 Use official codes/nomenclatures of EU Member States
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)
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
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.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
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
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
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.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** 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