FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: DNT-162OD-R-CPd

Product name(s): EVRITELL 162 OD

Chemical active substance(s):

dicamba, 110 g/L
nicosulfuron, 40 g/L
thifensulfuron-methyl, 12 g/L

Central

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: QEMETICA Agricultural Solutions Poland S.A. (formerly: CIECH Sarzyna S.A.).

Submission date: 01/2024

MS Finalisation date: 11/2024, 03/2025, 04/2025

Version history

When	What
January 2024	First submission to zRMS.
November 2024	Initial assessment of submitted dRR.
March 2025	Final Registration Report
April 2025	zRMS updated 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 under Article 33 of Regulation 1107/2009 is submitted for the purpose of the first authorisation of the product DNT-162OD-R-CPd/ EVRITELL 162 OD, containing dicamba 110 g/l, nicosulfuron 40 g/l and thifensulfuron-methyl 12 g/l. The application follows the data requirements of:
- Regulation (EC) No. 283/2013 for the active substances and,
- Regulation (EC) No. 284/2013 for the plant protection product.

Details on the sources of technical active substance are provided in Part C.

The Applicant CIECH Sarzyna S.A. is the owner of all studies conducted for DNT-162OD-R-CPd/ EVRITELL 162 OD. A reference to active substances and reference product data evaluated at EU level is made in the appropriated sections. These data are already out of protection.

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	Not applicable	-
Central zone	Poland	Hungary Slovakia
Southern zone	Not applicable	-
Inter-zonal	Not applicable	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Active substance 1 - dicamba

Table 0.1-2: Summary of regulatory history of CAS No: 1918-00-9

Status	
Approved in EU	Y
Original Inclusion Directive	COMMISSION DIRECTIVE 2008/69/EC

Status	
or Commission Implementing Regulation	of 1 July 2008 Commission Implementing Regulation (EU) No 540/2011 Reg. (EU) 2023/2592 Reg. (EU) 2022/1480 Reg. (EU) 2021/1449 Reg. (EU) No 1100/2011
RMS	DK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	N/A
Date of final Commission (re-registration) deadline (Step 2)	N/A
Current expiration of approval	31.03.2027
Low risk substance or Candidate for Substitution?	No

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 non-target plants. Only uses as herbicide may be authorised.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on dicamba, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.

Conclusion on the peer review of the pesticide risk assessment of the active substance dicamba (EFSA Journal 2011;9(1):1965), 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 dicamba

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 *, **
850 g/kg	980 g/kg Equivalence report available: Y RMS: BE and PL for details refer to Part C

* 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.

0.1.3.2 Active substance 2 - nicosulfuron

Table 0.1-4: Summary of regulatory history of CAS No: 111991-09-4

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	COMMISSION DIRECTIVE 2008/40/EC of 28 March 2008 Commission Implementing Regulation (EU) No 540/2011 Reg. (EU) 2023/2592 Reg. (EU) 2022/1480 Reg. (EU) 2020/1511 Reg. (EU) 2021/1449
RMS	UK RMS for ongoing/upcoming approval/renewal LV
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	N/A
Date of final Commission (re-registration) deadline (Step 2)	N/A
Current expiration of approval	31.03.2027
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:
— the potential exposure of the aquatic environment to metabolite DUDN when nicosulfuron is applied in regions with vulnerable soil conditions,
— the protection of aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones,
— the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no spray buffer zone,
— the protection of groundwater and surface water under vulnerable soil and climatic conditions.

Only uses as herbicide may be authorised.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on nicosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.

The SANCO report for nicosulfuron (SANCO/3780/07 – rev. 1 – 22 January 2008) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report (2007) 120, 1-91 was made available on 29 November 2007.

Table 0.1-5: Information on minimum purity of nicosulfuron

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 *, **
930 g/kg	950 g/kg Equivalence report available: Y RMS: UK, PL and LT for details refer to Part C

* 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.

0.1.3.3 Active substance 3 – thifensulfuron-methyl

Table 0.1-6: 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 renewing the approval of the active substance thifensulfuron-methyl in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 Reg. (EU) 2016/1424 Reg. (EU) 2016/549
RMS	~~UK~~ FR was RMS for the inclusion RMS responsible for the last approval: 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)	N/A
Date of final Commission (re-registration) deadline (Step 2)	N/A
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.

For the implementation of the uniform principles, as referred to in Article 29(6) of the Regulation 1107/2009, the conclusions of the review report on thifensulfuron-methyl, and in particular Appendices I and II thereof, shall be taken into account.

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. An EFSA Scientific Report (EFSA Journal 2015;13(7):4201) was made available on 23rd of July 2015.

Table 0.1-7: 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	980 g/kg Equivalence report available: Y RMS: LV For details refer to Part C

* 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.

0.1.4 Regulatory history of the product

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:

Section B3, Efficacy: 1

Section B6, Mammalian toxicology: 1.

Section B7, Metabolism and residues: 1

Section B9, Ecotoxicology: 1. However, The Applicant should provide information on the analytical measurements in the studies on the effect of the product EVRITELL 162 OD on soil organisms (earthworms, *Folsomia candida* and *Hypoaspis aculeifer*).

April 2025 updated

The information regarding the analytical measurements of active substances during the soil studies for formulation of EVRITELL 162 OD (DNT-162OD-R-CPd) with earthworms and *Folsomia candida* and *Hypoapsis aculeifer* was accepted by zRMS. No additional risk assessment for earthworms and other soil macroorganism is required.

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

Section B3, Efficacy: None

Section B6, Mammalian toxicology: None

Section B7, Metabolism and residues: none
Section B9, Ecotoxicology: None. However, The Applicant should provide information on the analytical measurements in the studies on the effect of the product EVRITELL 162 OD on soil organisms (earthworms, *Folsomia candida* and *Hypoaspis aculeifer*).

April 2025 updated
The information regarding the analytical measurements of active substances during the soil studies for formulation of EVRITELL 162 OD (DNT-162OD-R-CPd) with earthworms and *Folsomia candida* and *Hypoapsis aculeifer* was accepted by zRMS. No additional risk assessment for earthworms and other soil macroorganism is required.

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

Metabolism and residues: Use/ GAP is covered by established MRLs

Section B2, Phys-chem:

Noticed data gap:

- Ambient temperature shelf life study

Authorization can be granted for one year only.

Section B3, Efficacy:

EVRITEL 162 OD can be granted in Poland in line to accepted GAP table and label project. cMS from Slovakia and Hungary should decide about possibility of granted EVRITELL 162 OD at commenting period.

Section B6, Mammalian toxicology.

Taking into account the composition of the product, the formulation DNT-162OD-R-CPd / EVRITELL 162 OD does not require classification regarding acute systemic toxicity, skin and eye irritation and skin sensitisation.

Exposure:

Operator: The exposure to the product is safe when an **operator is equipped with protective gloves and work wear** (arms, body, and legs covered) during mixing/loading and work wear during application.

Worker: The product causes acceptable health risk for an unprotected worker taking assuming that the work rate does not exceed 2 hours (inspection, irrigation). However, considering the hygienic rules, the use of work wear and protective gloves is recommended when entering a treated area.

Bystander/resident: The results of exposure estimations demonstrate that the use of DNT-162OD-R-CPd / EVRITELL 162 OD, according to the list of intended uses presented in the GAP Table and anticipating the introduction of buffer zone presented (2-3m), causes acceptable health risk for bystander/resident (adult and child).

Section B7, Metabolism and residues: use is accepted.

Section B9, Ecotoxycology: The application was accepted. However, The Applicant should provide information on the analytical measurements in the studies on the effect of the product EVRITELL 162 OD on

soil organ-isms (earthworms, *Folsomia candida* and *Hypoaspis aculeifer*).

Justification: The risk assessment for earthworms and other soil macroorganism for a.s. (dicamba and nicosulfuron and thifensulfuron-methyl) and their metabolites as well as, the product EVRITELL 162 OD was accepted by zRMS only provisionally. The toxicity endpoints were based on nominal concen-tration. At the end on the studies concentration of substances active were not reported. The analytical measurements should be performed and reported at least at the start, middle, and end of the study. The intermediate measurements should be to capture the degradation of the substance (i.e., designed sub-stance property dependent). The TWA or geometric mean measured concentration should be calculated over the duration of the test and used if the concentration falls under 80% of nominal. Please complete the information regarding the analytical measurements of active substances during the study.

April 2025 updated

The information regarding the analytical measurements of active substances during the soil studies for formulation of EVRITELL 162 OD (DNT-162OD-R-CPd) with earthworms and *Folsomia candida* and *Hypoapsis aculeifer* was accepted by zRMS. No additional risk assessment for earthworms and other soil macroorganism is required.

It should be considered at MSs level.

Appendix 1 ALL intended uses

GAP rev. 1, date: 2023-01-03

PPP (product name/code):	EVRITELL 162 OD/DNT-162OD-R-CPd	Formulation type:	oil-based suspension concentrate (OD) [a, b]
Active substance 1:	dicamba	Conc. of as 1:	110 g/l [c]
Active substance 2:	nicosulfuron	Conc. of as 2:	40 g/l [c]
Active substance 3:	thifensulfuron-methyl	Conc. of as 3:	12 g/l [c]
Safener:	n.a.	Conc. of safener:	n.a. [c]
Synergist:	n.a.	Conc. of synergist:	n.a. [c]
Applicant:	CIECH Sarzyna S.A.	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	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: developmental 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	PL, SK, HU	Maize ZEAMX	F	Annual monocotyledonous weeds TTTMS; Annual dicotyledonous weeds TTTDS	Spraying, broadcast	Spring Post emergence of weeds; crop BBCH 12-16	a) 1 b) 1	n.a.	a) 1 L/ha b) 1 L/ha	a) as 1: 110 g /ha as 2: 40 g /ha as 3: 12 g /ha b) as 1: 110 g /ha	100 - 300	n.a.	Dose range: 0.75 - 1.0 L/ha

										as 2: 40 g /ha as 3: 12 g /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
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