FINAL REGISTRATION REPORT

Part A

Risk Management

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 Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

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

Correction date: 08/2024; 10/2024

MS Finalisation date: 12/2024; 03/2025; 04/2025; 08/2025; 09/2025

Version history

When	What
January 2024	First submission to zRMS
August 2024	Applicant`s update
October 2024	Second Applicant's update
October 2024	Third Applicant's update
December 2024	ZRMs evaluated updated (three times) dRR submitted by Applicant.
March 2025	ZRMs made changes in dossier according to reviewed comments
April 2025	zRMS updated Final Registration Report
April 2025	Lists of data considered for national authorization has been verified by ZRMS
August 2025	Correction made by the environmental section.
August 2025	Evaluation of applicant's additions
September 2025	ZRMs updated risk mitigation

Table of Contents

PART A
RISK MANAGEMENT

1 Details of the application

This application is submitted by company CIECH Sarzyna Spółka Akcyjna, ul. Chemików 1, 37-310 Nowa Sarzyna, Poland in January 2024.
The information, data and assessments provided in Registration Report, Parts B includes assessment of data and information related to DNT-162OD-R-CPd/ EVRITELL 162 OD where that data has not been considered in the EU review. Otherwise assessments for the safe use of DNT-162OD-R-CPd/ EVRITELL 162 OD have been performed based on endpoints agreed in the EU review of dicamba, nicosulfuron and thifensulfuron-methyl.

1.1 Application background

This application is submitted under Article 33 of Regulation 1107/2009 for the purpose of the first authorisation of the herbicide DNT-162OD-R-CPd/ EVRITELL 162 OD (containing dicamba 110 g/l, nicosulfuron 40 g/l and thifensulfuron-methyl 12 g/l). The zRMS is Poland, while the cMSs are Slovakia and Hungary. The product DNT-162OD-R-CPd/ EVRITELL 162 OD is intended to be used for control of annual broadleaved and grass weeds in maize at BBCH growth stage of 12 – 16.

1.2 Letters of Access

Not applicable. Data protection for studies for the active substance dicamba, nicosulfuron and thifensulfuron-methyl has expired.

1.3 Justification for submission of tests and studies

All tests and studies for DNT-162OD-R-CPd/ EVRITELL 162 OD are submitted to meet the requirements of Regulation (EC) No. 284/2013. The studies are necessary to gain the authorisation.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	DNT-162OD-R-CPd
Product name in MS	EVRITELL 162 OD

Authorization number	Submission for the purpose of the first authorisation
Function	herbicide
Applicant	CIECH Sarzyna S.A.
Active substance(s) (incl. content)	dicamba 110 g/L nicosulfuron 40 g/L thifensulfuron-methyl 12 g/L
Formulation type	oil-based suspension concentrate [Code: OD]
Packaging	0.25, 0.5, 1 L HDPE bottle 5, 10, 20, 60 L HDPE canister 120, 200 L HDPE drum 0.25, 0.5, 1 L HDPE/PA bottle 2, 3, 5, 10 L HDPE/PA canister 0.25, 0.5, 1 L HDPE/EVOH bottle 5 L HDPE/EVOH canister professional user
Coformulants of concern for national authorizations	N/A The composition of DNT-162OD-R-CPd / EVRITELL 162 OD has been verified in terms of Regulation 2023/574 of March 2023 and no neutral ingredients prohibited in plant protection products have been identified according in Annex III to Regulation (EC) No 1107/2009.
Restrictions related to identiy	N/A
Mandatory tank mixtures	N/A
Recommended tank mixtures	N/A

2.2 Conclusion

EVRITEL 162 OD can be granted in Poland in line to the accepted GAP table and label project.

Section B2:
Noticed data gap:
- Ambient temperature shelf life study

Authorization can be granted for one year only.

Section B3: Overall summaries are not necessary here. However, in the briefly summary it can be stated that EVRITEL 162 OD can be granted in Poland in line to accepted GAP table and label project.

Section B8: The evaluation of the application for EVRITELL 162 OD resulted in the decision to grant the authorization.

Section 7: Use is accepted.

Section B9: The application has been approved provisionally. 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*).

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 concentration. 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 substance 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.

The evaluator also verified whether the co-formulants contained in plant protection product Evritell 162 OD are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product Evritell 162 OD does not contain any unacceptable co-formulant/ingredient listed in the **Commission Regulation (EU) 2021/383** amending **Annex III** to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection product Evritell 162 OD meets the Annex to **Regulation (EU) 2023/574** criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of Regulation (EU)2023/574 can be found in RR Part C or annex to Part C of this submission (section 1.2.2).

2.3 Substances of concern for national monitoring

Not applicable

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Aquatic Acute 1, H400 Very toxic to aquatic life. Aquatic Chronic 1, H410 Very toxic to aquatic life with long lasting effects.

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	**GHS09**

Signal word:	**Warning**
Hazard statement(s):	Aquatic Acute 1, H400 Very toxic to aquatic life. **Aquatic Chronic 1, H410 Very toxic to aquatic life with long lasting effects.**
Precautionary statement(s):	**WARNING SECTION OF THE LABEL (first page):** **P273 Avoid release to the environment.** **P391 Collect spillage.** Other section of the label: ~~P270~~ Do not eat, drink or smoke when using this product. And ~~P280~~ as follows: „*Stosować rękawice ochronne oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu*." "Wear protective gloves and work wear during mixing/loading and work wear during application". Section First Aid: ~~P308+P313~~ IF exposed or concerned: Get medical advice/attention
Additional labelling phrases:	**To avoid risks to man and the environment, comply with the instructions for use. [EUH401]**

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-

The composition of DNT-162OD-R-CPd / EVRITELL 162 OD has been verified in terms of Regulation 2023/574 of March 2023 and no neutral ingredients prohibited in plant protection products have been identified according in Annex III to Regulation (EC) No 1107/2009.

See Part C, B6 and B9 for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms respect an vegetative unsprayed buffer zone of 10m to surface water bodies.
Spe3	~~To protect non-target plants respect an unsprayed buffer zone of 1 m with 50% drift reduction~~ ~~or a 5 m buffer strip with no drift reduction to non-agricultural land~~. To protect non-target plants respect an unsprayed buffer zone of 1 m with 90% drift reduction or 5 m buffer strip with 50% drift reduction, or 10 m buffer strip with no drift reduction to non-agricultural land

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No

1107/2009)

-	N/A

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
-	Workwear and gloves during mixing/loading Workwear during application
Worker protection:	
respective code if available	None
Integrated pest management (IPM)/sustainable use:	
respective code if available	-
Environmental protection	
SPe3	~~To protect aquatic organisms respect an vegetative unsprayed buffer zone of 10 m to surface water bodies.~~ ~~To protect non-target plants respect an unsprayed buffer zone of 1 m with 90% drift reduction or a 5 m buffer strip.~~ ~~buffer strip with 50% drift reduction, or 10 m buffer strip with no drift reduction to non-agricultural land~~ To protect non-target plants respect an unsprayed buffer zone of 1 m with 90% drift reduction or 5 m buffer strip with 50% drift reduction, or 10 m buffer strip with no drift reduction to non-agricultural land
Other specific restrictions	
respective code if available	N/A

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:	Relevant for use no.

respective code if available	-	-
Environmental protection:		Relevant for use no.
respective code if available	-	-

2.6 Intended uses (only NATIONAL GAP)

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: develop-mental 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 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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Maize ZEAMX	F	Annual monocotyledonous weeds TTTMS; Annual dicotyledonous weeds TTTDS	Spraying, broadcast	Spring Post emer-gence 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 as 2: 40 g /ha as 3: 12 g /ha	100 - 300	n.a.	Dose range: 0.75-1L/ha **Eff. section**: product should be applied at spring

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

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is homogeneous liquid, cream suspension, not transparent. It is not explosive (the individual components of the product are not classified as explosive - i.e. the active substances and the co-formulants do not contain any groups associated with explosive properties in their structures; the particular SDSs for all of the co-formulants and active substances also demonstrate that they are not explosive), has no oxidizing properties (the individual components of the product are not oxidizing, basing on their structural characteristics and individual SDSs). The product is not flammable as it does not contain flammable liquids and has a self-ignition temperature of 253 °C. In aqueous solution, it has a pH value around 4.8 at 21.4 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 12 weeks at 35 °C, neither the active ingredient content nor the technical properties were changed. Its technical characteristics are acceptable for an OD formulation.
The intended concentration of use is 0.25% to 1%.
Ambient temperature shelf life study is declared to be ongoing. Authorization can be granted for one year only.

3.2 Efficacy (Part B, Section 3)

EVRITELL 162 OD is a herbicide in form of oil dispersion (OD) containing 110 g/L of the active substance Dicamba, 40 g/L of Nicosulfuron and 12 g/L of Thifensulfuron-methyl, which is intended to use for control of annual broadleaved and grass weeds in foliar post-emergence application in maize in Central Zone countries: Poland, Hungary and Slovakia. ZRMs presents the assessment for all studies submitted by Applicant. cMS from HU and SK are not included in GAP table in report part A as it is only national assessment for Poland. Those cMs are included in B3 and B0.

3.3 Efficacy data

Preliminary tests and justification for the mixture: EVRITELL 162 OD is a herbicide with three ac-tive compounds: dicamba (110 g/L), nicosulfuron (40 g/L) and thifensulfuron-methyl (12 g/L) for control weeds in maize. Herbicidal activities of those compounds are known, so preliminary tests were not re-quired in the opinion of ZRMs.

Dicamba has been used as a herbicide since the early 1960s. Its application in maize fields became more prevalent with the development and approval of dicamba-tolerant varieties in recent years. This active compound is valued for its effectiveness against broadleaf weeds. Dicamba has been utilized for over 50 years and continues to be an essential tool in weed management strategies for maize.

Nicosulfuron has been used as a post-emergence herbicide in corn field since its introduction in the late 1980s. It is part of the sulfonylurea family of herbicides and is specifically designed to target and control a variety of grass and broadleaf weeds. Over the years, it has become a significant component of Integrated Weed Management practices in corn farming due to its efficacy and relatively favourable environmental profile. Nicosulfuron has been used for over 30 years to control various weeds in corn, including corolla weeds and continues to be valuable tool for farmers in managing weed pressure in their crops.

Thifensulfuron-methyl is another member of the sulfonylurea class of herbicides, has been used primarily in soybean, wheat and other cereal crops rather than maize. This herbicide was introduced in the market in the

late 1980s. It is highly effective in controlling broadleaf weeds and some grassy weeds. This duration of its effectiveness can vary, but is typically provides control for several weeks. Its use in maize specifically has not been as widespread or as long-standing as that of nicosulfuron, which is more commonly used in this crop.

Combining herbicides like dicamba, nicosulfuron and thifensulfuron-methyl can provide more effective weed control in maize compared to using them individually. Each of these herbicides targets different types of weeds and mechanisms (dicamba – a systemic herbicide that control broadleaf weeds; nicosulfuron – a post-emergence herbicide effective against grasses and some broadleaf weeds; thifensulfuron-methyl – effective against broadleaf weeds). By combining these, farmers can cover a wider range of weed species.
Using multiple herbicides with different modes of action helps in managing weed resistance. Weeds are less likely to develop resistance when exposed to multiple herbicidal actions simultaneously.
The mixture can improve the efficiency of weed control by attacking weeds at different growth stages or providing immediate and residual control compared to sequential applications. Applying a mixture can reduce the number of passes required in a field, saving time, labor and operational costs. Applying the mixture at the right growth stage of both the maize and weeds ensures optimal absorption and effective-ness.

The active substances of EVRITELL 162 OD is a herbicide with three active compounds: dicamba (110 g/L), nicosulfuron (40 g/L) and tifensulfuron-methyl (12 g/L) are registered and have been commonly used in agricultural practice for many years. So, many efficacy trials are available to evaluate the effec-tiveness of products containing those active compounds. However, no PPP with those three active sub-stances are registered in Poland yet. Applicant did not submitted any justification to combine all three active ingredients in EVRITELL 162 OD. Applicant did not submit trials for preliminary studies. But in the presented efficacy trials, all of these three compounds demonstrated the activity against studied weeds in maize. Lack of this comparison and trials should been acceptable in the opinion of ZRMs. Especially, when during efficacy trials Applicant used in trials different references products (Principal Plus 66.5 WG, Principal Forte, Diniro, Adigor, Tudor 11 OD, Trend 90 EC, Spandis). Efficacy of EVRITELL 162 OD was comparable to efficacy from st. ref. products used during efficacy trials. Therefore, in the opinion of ZRMs the inclusion of proposed amount of dicamba (110 g/L), nicosulfuron (40 g/L) and thifensulfuron-methyl (12 g/L) in the formulation of EVRITELL 162 OD can be stated as fully justified. Decision, about acceptance of lack of those trials is left to cMS from Slovakia and Hungary. In Poland – lack of those trials can be acceptable.

MED (Minimum Effective Dose):

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 the recommended dose, to that which would be recommended. It is utilized to achieve the desired effect. During field tests Applicant used different doses of herbicide – EVRITELL 162 OD (product code: DNT-162OD-R-CPd). So, in the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2). What is more, herbicides containing those three active compounds (dicamba, nicosulfuron and thifensulfuron-methyl) have been allowed to use for many years. Also, in the literature of crop protection vast amounts of information can be found on efficacy of the plant protection product containing dicamba and/or nicosulfuron and/or thifensulfuron-methyl. For evaluate the minimum effective dose of EVRITELL 162 OD for control weeds in maize following doses were studied: 0.5 L/ha; 0.75 L/ha and 1.0 L/ha.

Results for MED dose: ZRMs presented by different colors the sensitivity of studied weeds. Used class of sensitivity is in line to Polish rules. However, cMS from Slovakia and Hungary can see the impact of particular dosages. Therefore, that way of presented MED results can be useful in the opinion of ZRMs also for cMS.

- ✓ ***Maritime EPPO code:***

Weed EPPO code	No trials	Utd	Assessment timing: A1 10-14 DA-A	Assessment timing: A2 21-37 DA-A	Assessment timing: A3 49-67 DA-A

	at the first ass't timing			EVRITELL 162 OD			EVRITELL 162 OD			EVRITELL 162 OD		
		% ground cover	*(plants/m²)*	0.5 L/ha	0.75 L/ha	1 L/ha	0.5 L/ha	0.75 L/ha	1 L/ha	0.5 L/ha	0.75 L/ha	1 L/ha
AMARE (12-14)	2	1-3%	6.75-13	89.53	90.15	94.15	92.15	96.4	97.65	95.15	96.4	97.65
ANGCO (12)	1	5%	6.25	12.5	12.5	20	17.5	40	52.5	17.5	25	42.5
BRSNN (12)	1	3%	7	77.75	91.5	94	90.25	95.75	97	95	99	99
CAPBP (14)	1	2%	9.3	45	57.5	62.5	75	92.5	98.75	-	-	-
CHEAL (12-16)	8	1-12%	7.38-113	73.6	78.57	83.98	87.56	91.07	94.75	86.78	91.16	95.53
GALAP (15)	1	1%	5	95	95	95	95	95	93.8	98.8	99	96.8
LAMAM (16)	1	2%	14.25	82	90.25	95	99	99	99	99	99	99
MATCH (14)	2	2-8%	7-39	32.5	47.5	60	48.75	62.25	88.88	20	22.5	30
POLCO (14-15)	3	1-5%	6-19	63.1	66.92	71.75	64	71.35	75.85	56.1	71.17	82.33
SOLNI (12)	1	9%	43	15	18.8	23.8	25	42.5	32.5	15	17.5	22.5
SOLPS (12)	1	4%	10.5	86.3	92.5	96.3	85	91.7	95	87.5	90	95
STEME (12)	1	7%	23	45	47.5	50	100	100	100	100	100	100
THLAR (14)	1	5%	9.5	75	91.25	98.25	92.5	100	100	100	100	100
VERPE (15)	1	1%	6	71.3	82.5	72.5	72.5	73.8	81.3	71.3	77	83
VIOAR	2	2%	12.5-14.8	70.75	81.63	91.38	79	89.13	96.38	67	77	87

(12-14)												
CONAR (15)	1	1%	52.5	73.8	88.8	90.5	80	92.8	91.8	88.8	93.3	92.8
ECHCG (12-14)	7	1-42%	3.63-281.75	70.54	76.39	85.61	85.15	91.79	95.69	81.71	90.36	94.61
LOLMU (14)	1	2%	9.5	95	98.5	100	65	90.25	98.5	45	65	100

✓ ***N-E EPPO zone***:

Weed EPPO code	No trials at the first ass't timing	Utd		Assessment timing: A1 11-14 DA-A EVRITELL 162 OD			Assessment timing: A2 28 DA-A EVRITELL 162 OD			Assessment timing: A3 49-53 DA-A EVRITELL 162 OD		
		% ground cover	*(plants/m²)*	0.5 L/ha	0.75 L/ha	1 L/ha	0.5 L/ha	0.75 L/ha	1 L/ha	0.5 L/ha	0.75 L/ha	1 L/ha
AMARE (14)	2	1%	6-8	74.13	83.63	91.38	85	92.25	97.88	83.5	91.63	97.63
BRSNN (14)	1	1%	5	91.25	93.75	96	91.25	95.75	98	93.75	98	98.25
CAPBP (13-16)	2	1%	5-6	86.5	90.13	91.63	90.13	94.5	97	91.38	94.75	97.38
CHEAL (13-15)	6	1-3%	5-10	74.21	80.67	84.08	84.63	90.38	97.33	87.29	93.92	98.5
GALAP (13-15)	2	1%	5-6	76.13	83.5	88	79.38	90.5	96.63	78.75	91.63	96.75
GASPA (15)	1	1%	6	76.25	86.5	95	93	99.25	99	93	99.25	99.25
MATIN (12-15)	3	1-2%	5-6.05	76.75	84.42	91.33	79.5	86.92	95	79	85.92	95.17
POLCO (12-14)	4	1-2%	5-8	68.25	74.63	78	77.75	85.81	93.13	79.44	87.94	92.25
STEME (12-14)	2	1%	7	78.5	87	91.25	89.13	94.38	97.5	88.75	94.25	99
THLAR (12-13)	2	1%	5-5.1	81.25	88	92.75	88.63	93.38	98.25	87.13	92.5	98.25

VIOAR (12-15)	3	1-3%	5-7	57.92	63.75	64.92	70.08	73.67	84.83	75.92	81.08	84
GERPU (14)	1	1%	5	45.25	45.25	46.25	72.2	73.2	97.05	85.5	94	97.05
AVEFA (14)	1	3%	9.4	75.5	85	91	88	91	95	86.5	91	95.25
ECHCG (12-14)	6	1-3%	5-8.75	65.88	74.42	81.04	76.79	83.5	95.46	77.33	84.75	95.04

✓ ***S-E EPPO zone:***

Weed EPPO code	No tri-als	Utd		Assessment timing: A1 13-14 DA-A			Assessment timing: A2 22-28 DA-A			Assessment timing: A3 49-56 DA-A		
	at the first ass't timing			EVRITELL 162 OD			EVRITELL 162 OD			EVRITELL 162 OD		
		% ground cover	*(plants/m²)*	0.5 L/ha	0.75 L/ha	1 L/ha	0.5 L/ha	0.75 L/ha	1 L/ha	0.5 L/ha	0.75 L/ha	1 L/ha
ABUTH (11-12)	2	1-4%	3-8	95.25	97.25	97.25	95.5	98.05	98.9	92.25	96.4	97.65
AMARE (12-14)	3	1-6%	5-10	70.03	80.87	90.43	71.53	81.87	92.87	69.43	80.87	90.67
AMBEL (11)	1	1%	5	95.8	96.5	98.3	96.5	97.5	98	93.5	96	96.5
CHEAL (10-15)	6	1.88-6%	5-14	83	92.58	97.65	83.65	92.45	97.23	82.98	91.4	96.33
CHEHY (10)	1	1%	5	95	98.3	99	97.3	98.5	99	96.5	98.5	99
DATST (10-14)	2	2-3.8%	5-8	71.9	83.4	84	71.9	89.9	91.4	76.25	87.5	93.25
GALAP (32)	1	2%	6	33.8	46.3	55	28.8	42.5	55	28.8	40	52.5
MATIN (14)	1	5%	7	87.5	92.5	92.5	88.8	93.97	97	85	90	95
MERAN (11)	1	1.88%	5	85	87.5	90	87.5	91.3	92.5	87.5	92.5	92.5

POLAV (13)	1	5%	7	88.8	93.8	94.5	86.5	94.5	97	83.8	87.5	91.3
POLCO (12)	1	4%	6	86.3	87.5	91.3	87.5	90	93.8	85	89.5	88.8
CIRAR (12)	1	5%	13	61.3	71.3	81.3	52.5	66.3	81.3	53.8	63.8	78.8
ECHCG (10-14)	8	0.2-10%	5-100	65.57	81.03	87.94	72.8	87.63	92.63	75.39	86.16	90.56
PANMI (10)	1	2.25%	7	25	36.3	43.8	35	41.3	48.8	35	41.3	48.8
SETPU (12)	1	1%	5	91.8	93.3	96.5	85	90.5	91.5	75	82.5	83.8
SETVI (14)	1	5%	20	55	82	90.8	63.8	82.5	91.8	63.8	83.3	90.8
SORHA seed (13)	1	3%	50	30	75	80	71.3	91.3	95	80	95	97.3
SORHA rhizome (32)	1	3%	15	18.8	70	76.3	66.3	90	95	75	90	98

Determining the minimum effective dose (MED) for herbicides like dicamba, nicosulfuron and thifensulfuron-methyl for controlling weeds in maize at BBCH 12-16, it is necessary to consider the specific wed spectrum and local conditions.

Dicamba – dose 0.14 to 0.28 kg active ingredient per hectare (ai/ha) which corresponds to 140-280 grams ai/ha is usually recommended for controlling broadleaf weeds.

Nicosulfuron – dose 0.035 to 0.06 kg ai/ha (35 to 60 grams ai/ha) against annual grasses and broadleaf weeds. Lower doses are usually sufficient for early-season control.

Thifensulfuron-methyl – dose 0.006 to 0.012 kg ai/ha (6 to 12 grams ai/ha) against a wide range of broadleaf weeds.

EVRITELL 162 OD is recommended to use at BBCH 12-16 of maize when weeds are small and actively growing. Tank-mix of dicamba, nicosulfuron and thifensulfuron-methyl is recommended for use at dose 0.75 L/ha (which corresponds to 82.5 g/ha of dicamba, 30 g of nicosulfuron and 9 g/ha of thifensulfuron-methyl per hectare) and 1.0 L/ha (which corresponds to 110 g of dicamba, 40 g of nicosulfuron and 12 g of thifensulfuron-methyl). **Results of evaluated trials showed that irrespective to the EPPO zone where the trials were carried out, the dose 0.75 L/ha and 1.0 L/ha can be recommended. However, the higher dose (1.0 L/ha) should be used in the case of worse weather conditions and high level of infestation.** The rate of 1 liter of product/ha is required to give optimum total control in most situations. In some cases, when the conditions are known to be more favorable for a higher herbicide efficacy (sensitive flora, less advanced weed development and density, favorable weather conditions, etc.), the rate can be reduced to 0.75 L product/ha.

Efficacy:

EPPO Standard PP/226 Number of efficacy trials provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose. Where authorization is sought across a range of diverse conditions, such as across an authorization zone (PP 1/278 Principles of zonal data production and evaluation), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered, and over at least 2 years.

The Applicant was notified that according to PP 1/226 at least 6 trials from each climatic zone are required (in case of reduced number of trials in major pest on major crops). Number of trials for efficacy from Maritime (8 trials), N-E EPPO zone (6 trials) and S-E EPPO zone (8 trials) is sufficient for those EPPO zones.

Applicant submitted in total 22 efficacy trials conducted on maize in two different growing seasons (2022 and 2023), which is in line with appropriate EPPO standard:

- *Maritime EPPO zone*: trials from 2022 (3: DE-2, CZ-1) and 2023 (5:DE-3, CZ-2).
- *N-E EPPO zone*: trials from 2022 (4: PL) and 2023 (2: PL)
- *S-E EPPO zone*: trials from 2022 (5: HU-2, RO-2, SK-1) and 2023 (3: HU).

Different cultivars of maize were studied during efficacy trials:

- *Maritime zone***:** Darro, DKC3419, Korynt, KWS Inteligens, KWS Kashmir, SY Kardona, Korynt, P8307, Severeen. Suitable for grain is: Darro, DKC3419, KWS Kashmir, SY Kardona, P8307. Suitable for silage is: DKC3419, Korynt, KWS Inteligens, KWS Kashmir. Suitable for bioethanol is: Severeen
- *North-East zone***:** Amaizi, DKC3999, Kwinns, LG31.250, Rosomak, Volodia. Suitable for grain is: Amaizi, DKC3999, LG31.250, Rosomak, Volodia. Suitable for silage is: DKC3999, Kwinns, LG31.250, Rosomak. Suitable for bioethanol: Volodia.
- *South-East zone**:*** DKC4897, DKC4943, DKC5092, Limanova, MV Tarján, P8567, P8834, SY Zephir. Suitable for grain: DKC4897, DKC4943, DKC5092, Limanova, MV Tarján, P8567, P8834, SY Zephir. Suitable for silage: DKC4943, Limanova, SY Zephir. Suitable for bioethanol is: P8834.

In the opinion of ZRMs, PPP – EVRITELL 162 OD should be used on maize cultivated for grain, silage and bioethanol.

Timing of application: *Maritime zone*: May-July; *North-East zone*: May-June; *South-East zone*: May-June. So, timing for application is spring.

Maize was treated by EVRITELL 162 OD at BBCH 12-16. So, given application window for EVRITELL 162 OD (BBCH 12-16) can be accepted.

Recommended water volume: 100-300 L/ha is in line to water volumes studied during efficacy trials. So, it can be accepted.

Concerned Member States will need to consider the relevance of the submitted formulation comparabilty data in relation to the current authorized uses for the reference product in their own Member State. The evaluation was conducted in accordance with Uniform Principles.

Number of results for particlular weed is limited. Only trials with greater than 5 weeds/m^2 or over 2% ground cover should be taken for assesmsent.

ASSESSSMENT for cMS:

- ✓ ***Maritime EPPO zone:***

Following weed species should been excluded, due to not enough number of trials (only one trial for each weed were presented): ANGCO, BRSNN, CAPBP, GALAP, LAMAM, MATCH, SOLNI, SOLPS, STEME, THLAR, VERPE, CONAR, LOLMU

cMS should consider registration the following weed species. For each at least two valid trials were presented: AMARE (2 trials), CHEAL (8 trials), POLCO (3 trials), VIOAR (2 trials), ECHCG (6 trials).

- ✓ ***N-E EPPO zone:***

Following weed species should been excluded, due to not enough number of trials (only one trial for each weed were presented): BRSNN, BASPA, GERPU, AVEFA.

cMS should consider registration the following weed species. For each at least two valid trials were presented: AMARE (2 trials), CAPBP (2 trials), CHEAL (6 trials), GALAP (2 trials), MATIN (3 trials), POLCO (4 trials), STEME (2 trials), THLAR (2 trials), VIOAR (3 trials), ECHCG (6 trials).

- ✓ ***S-E EPPO zone:***

Following weed species should been excluded, due to not enough number of trials (only one trial for each weed were presented): AMBEL, CHEHY, GALAP, MATIN, MERAN, POLAV, POLCO, CIRAR, PANMI, SETPU, SETVI, SORHA (seed), SORHA (rhizome).

cMS should consider registration the following weed species. For each at least two valid trials were presented: ABUTH (2 trials), AMARE (3 trials) , CHEAL (6 trials), DATST (2 trials), ECHCG (8 trials).

In generally, only a very limited number of results is available for each zone. According to EPPO PP 1/226 at least 6 fully 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. Considering comparable results in all zones, it is recommended to take into account results from all zones to get more reliable set of data. The results should be adjusted to known efficacy from long term use of dicamba, nicosulfuron and thifensulfuron-methyl standard products by cMS. Therefore, **the suffi-ciency of results should be considered on the national level based on importance of weed in their country.**

Applicant presented sensitivity of studied weeds according to SANCO scale. cMS should decide if SANCO is acceptable. If not, cMS should determine the sensitivity of the accepted weed species in accordance with their applicable internal regulations.

SUMMARY: EVRITELL 162 OD (product code: DNT-162OD-R-CPd) is an early post-emergence herbi-cide in maize (BBCH 12-16) to control weeds. Weeds should be classiifed on the national level.

Crop: maize grown for grain, silage and bioethanol

Growth stage of the crop: BBCH 12-16

Product dose rate: 0.75 L/ha and 1.0 L/ha. Higher dose should be used in case of higher level of infesttaion and/or worse weather conditions.

Water: 100-300 L/ha.

ASSESSMENT FOR POLAND:

Results from neighbouring countries (ex. DE, CZ and SK) were consider by ZRMs for Poland. Number of trials for maize (15) is acceptable, according to EPPO rules (PL-6 trials, CZ-3 trials, DE-5 trials, SK-1 trial). Those trials were performed in two growing seasons (2022, 2023).

Applicant correctly presented results for Poland with using data from DE and CZ from Maritime EPPO zone above in the tables and in the text of this dRR. However, also results from Slovakia could been included in this statement by Applicant as a neighbouring country to Poland. In one trial from Slovakia: ECHCH, PANMI, CHEAL, CHEHY, DATST and MERAN were studied. All weeds were characterized by suffiicent level of infestation. Assessment from this trial were presented below by ZRMs together with trials form DE, CZ and PL.

Accepted weed species should be presented to following scale of sensitivity: S (susceptible) >85%; MS (moderately susceptible) 70-95%; MT (moderately tolerant) 60-70%; T (toleant) < 60%.

We are dealing with the active substances used commonly for many years in many countries. However, no PPP with those three ative compounds (dicamba, nicosulfuron, thifensulfuron-methyl) is registered in PL yet. Evritell 162 OD will be the first on the Polish market. So, in the list of weeds controlled should include only those species that occured (with appropriate intensity) a minimum of three localizations, and in the case oft he species with the highest hazard oft he plants at least in six locations. Only trials with greater than 5 weeds/m^2 or over 2% ground cover have been included.

ANGCO (CZ), LAMAM (DE), MATCH (DE), SOLNI (DE), SOLPS (DE), VERPE (DE), CONAR (DE), LOLMU (DE), GASPA (PL), GERPU (PL), AVEFA (PL), PANMI (SK), CHEHY (SK), DATST (SK) and MERAN (SK) should be excluded from Polish label due to not enough trials (only 1 trial was presented fro each weed).

***Following weed species can be accepted in Polish label*:**

CHEAL –major weed in maize, so 15 valid trials are acceptable (CZ-3, DE-5, PL-6, SK-1). It can be concluded that EVRITELL 162 OD effectively control CHEAL at dose 0.75 L/ha (eff. from N-E – 93.9% and from Maritime – 91.2% and SK from S-E: 98.0%) and 1.0 L/ha (eff. from N-E – 98.5% and from Maritime – 95.5% and SK from S-E – 99.5%). Results were comparable to st. ref. product.

ECHCG – major weed in maize, so 13 valid trials are acceptable (CZ-3, DE-3, SK-1, PL-6). It can be concluded that EVRITELL 162 OD effectively control ECHCG at dose 0.75 L/ha (eff. from N-E – 84.75% and from Maritime – 90.4 % and SK from S-E – 91.3%) and dose 1.0 L/ha (eff. from N-E – 95.04% and from Maritime – 94.6% and SK from S-E: 95%). Results were comparable to st. ref. product. In the opinion of ZRMs for dose 0.75 L/ha it should be classified as a sensitive weed – the average from N-E is 84.75% and from S-E and Maritime – more than 90%.

GALAP – minor weed in maize, so 3 trials are acceptable (DE-1, PL-2). It can be concluded that EVRITELL 162 OD effectively control GALAP at dose 0.75 L/ha (eff. from N-E – 91.63% and from Maritime – 99.0 %) and dose 1.0 L/ha (eff. from N-E – 96.75% and from Maritime – 96.8%). Results were comparable to st. ref. product.

MATIN – minor weed in maize, so 3 valid trials are acceptable (PL). It can be concluded that EVRITELL 162 OD effectively control MATIN at dose 0.75 L/ha (eff. from N-E – 85.92%) and dose 1.0 L/ha (eff. from N-E – 95.17%). Results were comparable to st. ref. product.

POLCO – major weed in maize, so 7 trials are acceptable (CZ-1, DE-2, PL-4). It can be concluded that EVRITELL 162 OD moderately effectively control POLCO at dose 0.75 L/ha (eff. from N-E – 87.94% and from Maritime – 71.2 %) and effectively control at dose 1.0 L/ha (eff. from N-E – 92.25% and from Maritime – 82.3%). Results were comparable to st. ref. product. POLCO was classified for dose 0.75 L.ha as a moderately effective weed cause the average from N-E and Maritime is lower than 85%.

STEME – minor weed in maize, so 3 trials are acceptable (DE-1, PL-2). It can be concluded that EVRITELL 162 OD effectively control STEME at dose 0.75 L/ha (eff. from N-E – 94.3% and from Maritime – 100 %) and dose 1.0 L/ha (eff. from N-E – 99.0% and from Maritime – 100%). Results were comparable to st. ref. product.

THLAR – minor weed in maize, so 3 trials are acceptable (DE-1, PL-2). It can be concluded that EVRITELL 162 OD effectively control THLAR at dose 0.75 L/ha (eff. from N-E – 92.5% and from Maritime – 100 %) and dose 1.0 L/ha (eff. from N-E – 98.3% and from Maritime – 100%). Results were comparable to st. ref. product.

VIOAR – minor weed in maize, so 5 trials are acceptable (DE-2, PL-3). It can be concluded that EVRITELL 162 OD moderately effectively control VIOAR at dose 0.75 L/ha (eff. from N-E – 81.1% and from Maritime – 77.0 %) and effectively control at dose 1.0 L/ha (eff. from N-E – 84.0% and from Maritime – 87.0%).

Results were comparable to st. ref. product. VIOAR was clasified as a moderately susceptible weed at dose 0.75 L/ha (cause ist efficacy from N-E was lower than 85%) and a susceptible weed at dose 1.0 L/ha.

Also, from Polish label following weeds should be excluded:

AMARE –major weed in maize, so only 4 trials (PL-2, DE-2) are not acceptable. AT least 6 trials should be presented. AMARE should be excluded from Polish label project.

BRSNN – minor weed in maize, so only 2 trials are not acceptable (DE-1, PL-1). This weed should be excluded from Polish label.

CAPBP –minor weed in maize, so at least 3 trials are required. Only 2 trials are not acceptable (PL), so this weed should be excluded from Polish label.

SUMMARY: EVRITELL 162 OD (product code: DNT-162OD-R-CPd) is an early post-emergence herbicide in maize (BBCH 12-16) to control weeds. Weeds should be classiifed on the national level.

Crop: maize grown for grain, silage and bioethanol

Growth stage of the crop: BBCH 12-16

Product dose rate: 0.75 L/ha and 1.0 L/ha. Higher dose should be used in case of higher level of infesttaion and/or worse weather conditions.

Water: 100-300 L/ha.

In the opinion of ZRMs, this scale of sensitivity weeds can be accepted in Polish label:

- ✓ ***dose 0.75 L/ha***: *S (susceptible weeds >85%):* CHEAL, ECHCG, GALAP, MATIN, STEME, THLAR and *MS (moderately susceptible weeds 70-85%)*: POLCO, VIOAR.
- ✓ ***dose 1.0 L/ha:*** *S (susceptible weeds >85%):* CHEAL, ECHCG, GALAP, MATIN, STEME, POLCO, THLAR, VIOAR.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Dicamba is a chlorinated benzoic acid derivative which is similar to phenoxyacetic acids in terms of chemical structure and hormonal effect in plants. Herbicides of this group have a systemic action against broadleaf weeds with a high selectivity on cereals and maize. Dicamba is a systemic and selective herbicide that is absorbed through the leaves and roots in the fast pace. After the absorption by the plant, dicamba is distributed thoroughly within the plant. Working as auxin mimic, dicamba causes the uncontrolled growth of plant cells, which leads to curling of the stems and leaves, leaves withering that later leads to plant death.

Nicosulfuron belongs to the sulfonylurea class. In sulfonylurea susceptible plants, a herbicide attaching or binding to an enzyme (acetolactate synthase or ALS) is responsible for disrupting amino acid biosynthesis. The effects are stunting of grass plants, with interveinal yellowing (chlorosis) or purpling. Corn plants may be stunted and show symptoms of root inhibition such as pruning of lateral roots. Leaves emerging from the corn whorl may not unfurl properly and may be yellow to translucent in appearance. Broadleaf plants may be stunted and chlorotic or purple.

Thifensulfuron-methyl is another representative of the sulfonylurea class. Works as enzyme inhibitor, it blocks the acetolactate synthase – an enzyme that takes part in amino acids synthesis.

Herbicides of ALS inhibitors group have a systemic action against broadleaf weeds with a high selectivity on cereals and maize. The florasulam is a systemic and selective herbicide that is absorbed mainly through

the leaves in the fast pace, and also partially via the roots. After the absorbtion by the plant, substance spreads thoroughly within the plant.

The Resistance Action Committee (HRAC) classified EVRITELL 162 OD active substances as follows:

- Dicamba - 'Auxin mimics' mode of action with HRAC group 4 (Legacy O).
- Nicosulfuron and Thifensulfuron-methyl - 'Inhibition of Acetolactate Synthase' mode of action with HRAC group 2 (Legacy B).

Evidence of resistance

For HRAC group 4, where dicamba belongs, the latest (December 2023) HRAC data base lists 43 resistant species world-wide and only four resistant species across Europe.
Dicamba resistance has been discovered and described for 10 weed species worldwide. First case of resistance was described for *Sinapis arvensis* in 1990 in Canada, and the most recent cases were described in 2020, these were: *Raphanus raphanistrum* from Australia and *Amaranthus pameri* from TN, USA. The only case of dicamba resistance from Europe comes from year 2012 and it was *Centaurea cyanus* found and described in Poland in 2012.

For HRAC group 2, where nicosulfuron and thifensulfuron-methyl belongs, the latest (December 2023) HRAC data base lists 697 cases of weeds resistant to ALS inhibitors which constitutes 174 resistant species. 167 cases out of 697 mentioned above, were discovered in Europe. Up to date (December 2023), In Europe 10 cases of weeds that have developed resistance to nicosulfuron were discovered and 8 cases of weeds that have developed resistance to thifensulfuron-methyl.

Cross resistance

According to HRAC, weed species resistant to dicamba (and other Group 4 herbicides) have cross resistance to herbicides from groups: Group 2 (Legacy B), Group 5 (Legacy C1 C2), Group 9 (Legacy G), Group 14 (Legacy E) and HRAC Group 27 (Legacy F2).

In case of nicosulfuron and thifensulfuron-methyl (and other ALS inhibitor herbicides) resistant species, cross resistance contains the herbicide groups: Group 1 (Legacy A), Group 3 (Legacy K1), Group 4 (Legacy O), Group 5 (Legacy C1 C2), Group 6 (Legacy C3), Group 9 (Legacy G), Group 14 (Legacy E), Group 22 (Legacy D) and Group 27 (Legacy F2).

In Europe there was only one case of a species of a weed resistant to auxin mimics (group 4 herbicides) and one other MOA herbicide. In case of dicamba resistance, no cross resistance was discovered so far.

Couple weed species have developed resistance to ALS inhibitors in Europe. Most significant number of cross resistance to other MoA's was discovered in *Alopecurus myosuroides* populations.
The rest of ALS resistant weeds, in which cross resistance also occurred were: *Ambrosia artemisiifolia, Apera spica-venti, Avena fatua* and *Avena sterilis, Conyza sumatrensis, Echinochloa crus-gali, Kochia scoparia, Lolium perenne ssp. Multiflorum, Papaver r*hoeas and *Sorghum halepens*.

From the abovementioned species, only two are drawing attention, because they were present in the efficacy field trials and are considered as major weeds in maize crops. The species are:

- *Echinochloa crus-gali* – which case was not resistant to sulfonylurea compounds present in EVRITELL 162 OD formulation (nicosulfuron or thifensulfuron-methyl)
- *Sorghum halepense* – which was resistant to nicosulfuron, but not for another sulfonylurea compound from EVRITELL 162 OD – thifensulfuron methyl.

Acceptability of the resistance risk

Despite the facts that many cases of resistance to MoA's of the EVRITELL 162 OD active substances (synthetic auxin and ALS inhibitor) were discovered worldwide, the area infested with weeds resistant to these

active substances and number of species that have developed resistance in Europe is quite low. Especially considering only the species that are major weeds in target crops - maize, and the results obtained in the efficacy field trials.

Despite the quite significant number of weed resistance cases, **t**he resistance risk can be considered as low due to the fact that EVRITELL 162 OD utilizes three active substances of two different MoA's, and product is used under adherence to the management strategy and label recommendations.

Summary: Applicant submitted detailed information's about possible development of resistance or cross-resistance. ZRMs accepted the strategy management about possible development of resistance or cross-resistance proposed by Applicant. Final assessment of the resistance risk has to be carried out on member state level since the agronomic factors influencing the risk of resistance development tend to vary between the Member. Without any precautions the resistance risk is unacceptable. The abidance of the requirements within the good agricultural practice is necessary. The resistance management is coordinated by HRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.

Accepted resistance management strategy for label:

This product contains an active ingredient belonging to the acetyl lactase synthase (ALS) inhibitor group of herbicides. The use of consecutive herbicides with the same mechanism of action may lead to the selection of resistant weeds. To minimize the risk of weed resistance to herbicides occurring and developing according to Good Agricultural Practice:

- *Follow strictly the directions on the plant protection product label – apply the product at the recommended rate, at the recommended date for optimum weed control,*
- *Adjust the selection of the herbicide and the decision to carry out the treatment to the prevailing (possibly potential) weed infestation, taking into account the dominant species and the damage thresholds,*
- *Use a rotation of herbicides (active substances) with different mechanisms of action,*
- *Use a mixture of herbicide (active substances) with different mechanisms of action,*
- *Use in rotation and/or mixture herbicides acting on several weed life processes (with different mechanism of action),*
- *Adapt tillage operations to field conditions, especially to the type and severity of weeds,*
- *Use a variety of weed control methods, including crop rotation, etc.,*
- *Use certified seed,*
- *Clean agricultural machinery to prevent the transfer of weed propagating material to other sites,*
- *Inform the permit holder of unsatisfactory weed control,*
- *For more details, contact your advisor, the permit holder or the permit holder's representative.*

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop:

Herbicides such as dicamba, nicosulfuron and thifensulfuron-methyl are commonly used in maize to control broadleaf and grassy weeds. However, their use sometimes lead to phytotoxic effects, which can affect the growth and health of the maize, particularly when applied at specific growth stages such as BBCH 12-16 (second to sic leaf stage).

Dicamba – is generally safe for maize, but off-target movement due to volatility or drift can damage sensitive crops. Symptoms include leaf cupping, chlorosis and stunting.

Nicosulfuron – maize generally has a good tolerance but environmental stresses like cold and wet conditions can enhance toxicity, causing chlorosis and temporary stunting. Herbicide interactions or high dosages can also lead to root and foliar injury.

Thifensulfuron-methyl – maize typically tolerates this herbicide well. However under certain conditions (e.g. low temperatures or combined with other stressors), phytotoxic effects such as foliar chlorosis, stunting and root pruning can occur.

When used together, these active compounds can potentially enhance each other's phytotoxic effects due to combined modes of action. Timing is crucial. Applying them at BBCH 12-16 can be safe but must be carefully managed. Stressful conditions such as drought, poor nutrition or extreme temperatures can exacerbate phytotoxic effects. Proper calibration and adherence to recommended rates are vital.
The Applicant submitted in total 22 selectivity trials carried out on maize in different growing seasons (2022 and 2023). Those trials were conducted in line to appropriate EPPO standards. Different varieties of maize were studied during those trials. Appropriate plot area, crop stage and water volume was studied.

The selectivity evaluation of the herbicide is to be performed 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. Dose N and 2N was studied.

Applicant submitted in total 22 selectivity trials carried out on maize in Maritime EPPO zone (CZ-3, DE-5), N-E (PL-6 trials) and S-E (HU-5, RO-2, SK-1) in two growing seasons (2022, 2023). In the opinion of ZRMs, number of trials is sufficient for all three EPPO zones (Maritime, N-E and S-E). Also, possibly phytotoxic effects was studied during 22 efficacy trials carried out in those EPPO zones. The selectivity of EVRITELL 162 OD when applied in maize was studied in 22 selectivity and 22 efficacy trials. In none of the efficacy trials, phytotoxic effect on the crop was observed after application of EVRITELL 162 OD and standard reference product. In the selectivity trials, phytotoxicity symptoms were observed in only two trials which happened to be situated in Maritime EPPO zone. Consequently, it is justified to claim that one application of EVRITELL 162 OD at dose range -.75-1.00 L/ha (82.5-110 g ai/ha of dicamba, 30-40 g ai/ha nicosulfuron, 9-12 g ai/ha thifensulfuron-methyl) in maize, to control annual dicot and monocot weeds, is safe for the crop since it has no negative impact on the yield.

Applicant proposed following entries in the label of EVRITELL 162 OD:

Those entries were accepted by ZRMs and recommended for use in practice of using EVRITELL 162 OD:

[1)] Due to the possibility of phytotoxicity symptoms on some maize varieties (especially new varieties), it is recommended that before applying the product to these varieties:

- carry out a trial treatment on each crop to check for symptoms of plant injury, or
- contact an advisor or representative of the registration holder.

[2)] Do not apply the product:

- on crops which have been weakened or damaged by pests, frost, flooding or drought,
- in windy conditions that may cause spray drift onto adjacent crops
- in sweet corn, cracked corn and in the cultivation of propagating material
- on maize at the stage above 6 proper leaves
- on maize plants where growth has been arrested due to low temperatures; the treatment may be applied after intensive growth of the maize has resumed
- on plants weakened and damaged by frost, drought, pests or diseases
- on wet plants (dew, rain)

- immediately after a prolonged period of cold weather
- at air temperatures below 10ºC and above 25ºC
- during periods when the night temperature is below 5ºC
- after soil insecticides containing active substances from the group of organophosphorus compounds have been applied to a maize plantation
- in a mixture with liquid or foliar fertilizers.

Impact on the yield:

The use of herbicide with dicamba, nicosulfuron and thifensulfuron-methyl can significantly influence the yield of maize, particularly when applied at BBCH 12-16 growth stages. BBCH 12-16 corresponds to the early growth stages of maize, from the second leaf (BBCH 12) through the sixths leaf (BBCH 16). During this period, maize is particularly vulnerable to both competition from weeds and potential herbicide injury. Effective control of weeds during these early stages can lead to significant improvements in maize yield. Weeds complete with maize for water, nutrients and light, and if not controlled, can cause substantial yield losses. Properly managed, the use of EVRITELL 162 OD should result in higher yields due to reduced competition from weeds. Studies typically show that when applied correctly, maize yields can increase significantly compared to untreated controls.

The effects of EVRITELL 162 OD on the yield of maize was evaluated in 22 selectivity trials carried out in Maritime EPPO zone (8 trials: CZ-3, DE-5), N-E EPPO zone (6 trials: PL) and S-E EPPO zone (8 trials: HU-5, RO-2, SK-1) in two growing seasons (2022, 2023). In those trials, yield was assessed after application of a single N dose and 2N dose. Statistical analysis of yield and its parameters were reported. All results were comparable with standard reference products. In the opinion of ZRMs, the number of trials is sufficient for those three EPPO zones. No statistical differences in yield were observed between the plots treated with EVRITELL 162 OD and the control plots. So, it can be stated that EVRIRELL 162 OD is safe for maize yield.

Based on the absence of negative effects (statistically significant decrease in yield) across all selectivity trials in all both grain and silage maize, at maximum intended dose and twice as much, it is reasonable to conclude that a single application of EVRITELL 162 OD at up to the highest proposed label rate in the proposed range of 0.75-1.00 L product/ha, and applied according to label recommendations, has no adverse impact on crop yield in cultivars of maize, no matter if the application is done in grain or silage varieties.

Impact on the quality of yield:

The use of herbicide such as dicamba, nicosulfuron and thifensulfuron-methyl in maize during the BBCH 12-16 growth stages can impact both weed control efficacy and maize yield quality. In line to EPPO 1/50, the crops tested should be harvested, but this is not necessary in the case of weed control. The following data should be included: (a) total weight of fresh cobs without husks; (b) total grain yield in kg ha-1 adjusted to the established moisture content (national standard); (c) dry and fresh weight of fodder. Evaluations of quality parameters of the harvested maize have been carried out following application of EVRITELL 162 OD, only in those trials where crop was harvested for silage. For seed maize no further quality analysis are required according to EPPO PP 1/135 (4) and 1/50(4). Out of 22 selectivity trials performed, maize was harvested for silage in 4 trials total. Among these trials 2 were set in Maritime EPPO climatic zone (DE2), 1 was set in North-East climatic zone (PL) and 1 in South-East EPPO zone (HU). Based on the absence of negative effects across all selectivity trials at maximum intended dose and twice the maximum dose, it is reasonable to conclude that a single application of EVRITELL 162 OD up to highest proposed label rate in the proposed range of 0.75-1 L product/ha and applied according to label recommendations, has no adverse impact on the quality of plants or plant products in maize.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on the transformation processes:

The application of herbicides, especially those containing compounds like dicamba, nicosulfuron and thifensulfuron-methyl , can potentially impact the transformation processes such as fermentation or the production of bioethanol form maize. These impacts can arise from various factors, including changes in plant physiology, gain composition and microbial interactions. The composition of maize grains, particularly the starch, sugar and protein content, is crucial for fermentation efficiency and bioethanol yield. The presence of herbicide residues in the grain could inhibit the growth of fermentative microorganisms, such as yeast, thus affecting fermentation efficiency. The application of herbicide with dicamba, nicosulfuron and thifensulfuron-methyl at growth stages BBCH 12-16 can have significant effects on the transformation processes of maize. The extent of these depends on the concentration, timing and specific formulation of the herbicide used, as well as the maize variety and environmental conditions. Considering that product is applied at early stage of the crop and maize is not a typical crop used for subsequent processing, it could be agreed that no negative impact on processing is expected. The latest time of application for EVRITELL 162 OD is crop growth stage BBCH 16. Since application of EVRITELL 162 OD is made at an early stage in the crop's development there is no risk that the actives would be translocated to the grain. Also, the germination of maize seeds will be not negatively affected by the application of EVRITELL 162 OD, in the opinion of ZRMs.

Impact on the propagating purposes:

The combination of three active compounds (dicamba, nicosulfuron and thifensulfuron-methyl) can provide broad-spectrum weed control, helping maize to grow more robustly by reducing competition for resources, crucial for healthy propagation. The application of herbicide with dicamba, nicosulfuron and thifensulfuron-methyl during the BBCH 12-16 stages can significantly impact the propagating purposes of maize. These effects can range from reduced seed quality and germination rates to ;potential genetic and epigenetic alternations that affect the next generation. Careful consideration and management of herbicide application, including dosage and timing are crucial to minimize these potential negative impacts and ensure the successful propagation of healthy and vigorous maize plants.

ZRMs agree with Applicant that According to EPPO PP 1/135(4), data on plant parts used for propagation purposes are not considered to be required in terms of herbicides which are applied at or after inflorescence initiation, and when there were no residues detected in propagation.

Impact on the succeeding crops:

Using a herbicide that combines dicamba, nicosulfuron and thifensulfuron-methyl can have various effects on succeeding crops, depending on several factors including soil type, weather conditions, crop rotation practices and the sensitivity of subsequent crops to these compounds.

Dicamba – is known for its volatility, dicamba can persist in the soil for a period that varies with conditions but typically degrades within a few weeks to months.

Nicosulfuron and *thifensulfuron-methyl* – both are sulfonylurea herbicides, which can persist in the soil for several weeks to months, depending on soil pH, organic matter and moisture level.

High pH and cooler temperatures can slow the degradation process of sulfonylurea herbicides, potentially leading to higher residue levels. Adequate rainfall can help with herbicide degradation through leaching and microbial activity, whereas drought conditions can enhance persistence.

Crops like legumes, certain cereals and vegetables can be highly sensitive to residues of sulfonylurea herbicides, showing symptoms like stunted growth and chlorosis. If dicamba residue is present, it could affect broadleaf crops, causing leaf cupping, growth inhibition, etc.

Best practices to mitigate effects:

- proper application timing
- rotation planning

- soil testing
- adherence to label instructions

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 product on succeeding crops if studies and evaluation presented in the other part of dossier, show that significant residues of the dicamba, nicosulfuron and thifensulfuron-methyl, their metabolites or degradation products, which have or may have a 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 presented the assessment of the possible effects of EVRITELL 162 OD 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 product. Factors influencing half-life: soil pH, temperature, soil moisture and organic matter.

In the opinion of ZRMs, necessary precautions to prevent negative impact on succeeding crops should be included in the label claim. Detailed assessment of impact on succeeding crops is presented in section B7. In the opinion of ZRMs following entry can be included in the label of EVRITELL 162 OD:

"*If it is necessary to plough the treated plantation in advance (as a result of damage to maize by hail, disease, pests or frost), the field may be cultivated:*

- *maize grown for grain or for fodder. AT the same time, it should be borne in mind that temporary and quickly passing phytotoxic symptoms may appear immediately after emergence,*
- *cereals, after ploughing to a depth of min. 20 cm*.

After harvesting maize treated with the product, winter cereals can be sown in reduced tillage (without ploughing).

One year after the application of the product, all crops can be cultivated with the exception of species highly sensitive to the product, i.e.: peas, lettuce, onions."

Impact on the adjacent crops:

The impact of an herbicide containing dicamba, nicosulfuron and 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.

Dicamba – is highly volatile and can drift from the application rate, especially under certain weather conditions. This drift can affect neighbouring fields, causing damage to sensitive crops. Impacted plants may exhibit cupped leaves, stunted growth and reduced yield. Buffer zones and precision equipment should be use and adhere application to minimize off-target movement.

Nicosulfuron – has relatively low volatility, but it can drift, especially during spraying. Additionally, its residues can persist in the soil, affecting subsequent plantings. Sensitive crops might show chlorosis, reduced growth and necrosis. For mitigate – proper timing of applications, considering wind speeds and soil testing help reduce risks.

Thifensulfuron-methyl – known for its mobility in soil and water, posing potential risks to adjacent crops through runoff and leaching. Affecting plants could display browning or purling of leaves, stunted growth and yield reduction. Mitigation – employing buffer zones, avoiding applications before heavy rains and accurate dosing are crucial.

Detailed assessment about impact on the adjacent crops is presented in section B9. However, general mitigation strategies are:

- establishing no-spray zones between fields of different crops
- spraying during low wind conditions and cooler temperatures to reduce volatilization and drift
- using drift-reducing nozzles and lower spray heights
- regularly monitoring weather forecasts and soil conditions before application
- following local regulations and guidelines for herbicide application.

While herbicide with dicamba, nicosulfuron and thifensulfuron-methyl is effective for weed control, they can adversely impact adjacent crop if not managed properly. Adhering to best practices and preventive ensures can help mitigate these risks, ensuring that non-target plants remain unaffected.

Impact on the beneficial and non-target organisms:

Detailed assessment about impact of EVRITELL 162 OD on the beneficial and non-target organisms is presented in Section 9.

Dicamba – can affect beneficial insects like pollinators (bees) and natural predator's (ladybugs). Its high concentrations can inhibit microbial activity, potentially altering soil microbial communities and nutrient cycling. It may be toxic to aquatic plants and algae.

Nicosulfuron – it is selective for grassy and broadleaf weeds in maize crops but can harm non-target plants if not applied correctly. Nicosulfuron is generally low in toxicity to mammals, birds and aquatic organisms. However, its effects on soil microbes and non-target plants can disrupt local ecosystems, potentially reducing soil fertility and biodiversity over time.

Thifensulfuron-methyl – its low toxicity to mammals, birds ad aquatic life is reassuring, but it can still pose risks to beneficial insects and soil organisms. By altering plant communities, thifensulfuron-methyl can impact the food resources and habitats of various organisms, indirectly affecting biodiversity and ecosystem health.

The combined use of these herbicides can lead to significant changes in plant community compositions, potentially reducing the availability of food and habitat for beneficial insects and other wildlife. Beneficial insects, such as pollinators and natural pest controllers, can be particularly vulnerable to herbicide exposure, either directly or through habitat modification. Soil health can also be impacted due to changes in soil microbial communities, which lay a crucial role in nutrient cycling and plant health.

To mitigate these impacts, it is essential to follow best management practices:

- applying herbicide under suitable environmental conditions to minimize drift
- using integrated pest management (IPM) approaches to reduce reliance on chemical controls

monitoring non-target impacts and adjusting practices accordingly to protect beneficial organisms and maintain ecosystem balance.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

The method for assay of dicamba, nicosulfuron and thifensulfuron methyl in GF-3969 formulated product is based on analysis by RP-HPLC-UV-DAD method with external standard calibration.

The validation results for the analytical method to determine dicamba, nicosulfuron and thifensulfuron methyl content, meet the current requirements as set in SANCO/3030/99 rev.5. The method can be used to support the registration of EVRITELL 162 OD.

There are no impurities of toxicological and/or ecotoxicological or environmental concern in the active substances of which the product consists.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue

definitions.

Data gap:

- Nicosulfuron - Table 5.3.11

Analytical methods for commodities with high water content, high acid content and high oil content are missing. ~~The applicant should complete the Table before registration~~.

August 2025
The applicant's addition was accepted. The table has been completed. These analytical methods were not submitted at the EU substance approval level. The methods should be supplemented after the renewal of the active substance. No additional data is required.

Commodity/crop	Supported/ Not supported
Maize	Supported

3.5 Mammalian toxicology (Part B, Section 6)

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended. For further details please refer to point 3.5.2-3.5.4 presented below.

3.5.1 Acute toxicity

The product DNT-162OD-R-CPd / EVRITELL 162 OD containing dicamba, nicosulfuron, thifensulfuron-methyl has a low toxicity in respect to acute oral, inhalation and dermal toxicity. It is also not irritant for skin and eyes and not sensitising to skin.

3.5.2 Operator exposure

According to the estimation based on Calculator OPEX version v.1.0.1, the use of DNT-162OD-R-CPd / EVRITELL 162 OD containing dicamba (110 g/kg), nicosulfuron (40 g/L), thifensulfuron-methyl (12 g/L) **causes unacceptable health risk for the unprotected operator due to results of exposure to thifensulfuron-methyl** that exceeds AOEL for this substance**.** Operator 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.

Consequently, the following sentence regarding the use of PPE is recommended by the evaluator to be placed on the label.
„*Stosować rękawice ochronne, oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu.*"
"Wear protective gloves, and work wear (coverall) during mixing/loading and work wear during application".

3.5.3 Worker exposure

The results of the exposure estimations based on EFSA calculator (OPEX version 1.0.1) calculator show that the use of DNT-162OD-R-CPd / EVRITELL 162 OD according intended uses presented in GAP Table, causes no health risk for the worker without any PPE.

3.5.4 Bystander and resident exposure

The estimations performed according to EFSA calculator indicate that the systemic exposure of resident to dicamba, nicosulfuron, thifensulfuron-methyl contained in the formulation DNT-162OD-R-CPd / EVRITELL 162 OD does not exceed the values of AOEL for this active substance.
The incidental short-time exposure of bystander and resident (children and adult) to dicamba, nicosulfuron, thifensulfuron-methyl contained in the formulation DNT-162OD-R-CPd / EVRITELL 162 OD causes no risk to human health if the product is used in accordance to the intended uses listed in the GAP Table.

3.6 Residues and consumer exposure (Part B, Section 7)

Fundamental residue data on dicamba, nicosulfuron and thifensulfuron methyl like stability, nature and magnitude are already evaluated previously and is described in detail in the respective DARs. The additional residue trials have been generated for maize to demonstrate conformity with existing MRLs for dicamba, nicosulfuron and thifensulfuron methyl. The use of product EVRITELL 162 OD does not lead to unacceptable risk for consumer when applied according to the recommendations.

3.6.1 Residues

Dicamba

Stability of Residues
Dicamba and 5-OH Dicamba residues were stable in maize (forage, fodder and grain) when stored at -17°C for up to 36 months.
In animal matrices, dicamba and DCSA residues were stable at -12°C for at least 18 months, in beef tissues and milk.
These data are sufficient to demonstrate the stability of dicamba residues in high starch commodities. It is concluded that the residue data are valid with regard to storage stability.
Metabolism in plants
No new data submitted in the framework of this application.
Plant residue definition for monitoring Dicamba (Reg. (EU) 2015/845)
Plant residue definition for risk assessment Dicamba + 5-OH-dicamba, free and conjugated (EFSA Journal 2011;9(1):1965)
Magnitude of residues in plants
Proposed GAP:
Maize
BBCH 12-16; 1 application 0.110 kg as./ha; PHI: N/A
EU GAP (maize) (SANCO/829/08 – final rev. 2, 12 July 2016):
BBCH until 16; 1 application 360 g as./ha; PHI: N/A
New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.
Trials GAP: 1 x 0.110 kg as/ha, BBCH 16, outdoor
Residues: 4 x <0.01 mg/kg
Sufficient trials on maize are available to support the proposed uses. The residues arising from the proposed use will not exceed the MRLs established for maize (Reg. (EU) No. 2015/845: 0.5 mg/kg).
Magnitude of residues in livestock
Animals are not exposed to residues via feed above the trigger value: 0.004 mg/kg. Therefore livestock feeding studies are not required.
Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

As quantifiable residues of dicamba are not expected in edible part of crops based on available residue data, there is no need to investigate the effect of industrial and/or household processing.

Magnitude of residues in representative succeeding crops

Conclusion drawn from EFSA, 2011 are reported below:

DT90 is <100 days, therefore no studies are needed according to guidelines. No residues > 0.01 mg/kg of dicamba, DCSA or 5-OH-dicamba were seen 32, 131 and 365 DAT, respectively in mustards tops, turnips tops and roots, wheat forage, wheat straw, wheat grain and wheat chaff in a confined rotational crop study.

There is no need to introduce any restrictions.

Other / special studies

Maize has not melliferous capacity. Additionally, the product is applied early in the growing season when bee foraging activity is low. Studies are not required.

Estimation of exposure through diet and other means

The proposed uses of Dicamba in the formulation EVRITELL 162 OD do not represent unacceptable chronic and acute risks for the consumer (calculation was conducted using EFSA PRIMo rev.3.1).

Nicosulfuron

Storage stability

Storage stability of active substances was investigated in the framework of the EU pesticides peer re-view. No new data was submitted in the framework of this application. Information provided is sufficient. It is concluded that the residue data are valid with regard to storage stability.

No further data are required to support the proposed uses.

Nicosulfuron is stable for up to 9 months when stored at temperatures of -20ºC in whole plant and ears and for up to 12 months in sweet corn, dried kernels, stover and forage.

Metabolism in plants and animals

The metabolism in plants and livestock for the active substance was reviewed during the Annex I inclusion process. No additional studies are available in the framework of this application.

Plant residue definition for monitoring and risk assessment: nicosulfuron (Reg. (EU) No 617/2014, EFSA 2007)

Animal residue definition for monitoring and risk assessment: nicosulfuron (EFSA 2007, EFSA Journal 2012;10(12):3048)

Magnitude of residues in plants

Maize

Proposed GAP: 1 application; BBCH 12-16, 40 g as/ha; PHI: n.a.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 1 x 0.04 kg as/ha, BBCH 16, outdoor

4 x <0.01 mg/kg

The data submitted show that exceedance of the MRL (0.01 mg/kg) is unlikely. The proposed use is considered acceptable.

Magnitude of residues in livestock

Animals are not exposed to residues via feed above the trigger value: 0.004 mg/kg. Therefore livestock feeding studies are not required.

There is no risk for animal MRL to be exceeded. Additional studies are no required.

Processing studies

Additional studies are not required since residues are below 0.01 mg/kg.

Residues in Representative Succeeding Crops

Occurrence of nicosulfuron residues in rotational crops was already investigated during the peer review of this substance. It was concluded that significant residues in rotational crops are not expected. No additional studies on rotational crops are considered necessary. No restrictions are necessary.

Other / special studies

Maize has not melliferous capacity. Additionally, the product is applied early in the growing season when bee foraging activity is low. Studies are not required.

Consumer risk assessment

The proposed uses of nicosulfuron in the formulation EVRITELL 162 OD does not represent unacceptable chronic risks for the consumer. As ARfD was not deemed necessary, acute risk assessment is not relevant. PRIMo rev. 3.1 calculations are accepted.

Thifensulfuron methyl

Stability of residues

The available storage stability data are considered sufficient.
Residue trials are valid in relation to storage stability data.
Storage stability of Thifensulfuron-methyl was demonstrated for a period of at least 24 months in Corn grain, and 42 months in wheat grain and 12 months in wheat straw.

Metabolism

The intended uses are covered by the available metabolism studies reported in the EU.
Plant residue definition for monitoring Thifensulfuron-methyl (parent for oilseeds and cereals) (EFSA 2015, Reg. (EU) No 617/2014)
Plant residue definition for risk assessment For oilseeds and cereals: thifensulfuron-methyl and provisionally IN A4098 a (EFSA, 2015)
Animal residue definition for monitoring Thifensulfuron-methyl (parent) (EFSA 2015, Reg. (EU) No 617/2014)
Animal residue definition for risk assessment Sum of thifensulfuron-methyl and thifensulfuron acid (IN-L9225), expressed as thifensulfuron-methyl and provisionally triazine amine (IN-A4098) (EFSA 2015)
Metabolite IN-A4098 is provisionally included in the residue definition for risk assessment for plant commodities (pending the outcome of the confirmatory data requirement on genotoxic potential).
Evaluation of IN-A4098 is not finished yet. EFSA PPR panel is currently assessing it (EFSA Supporting publication 2020:EN-1627).

Magnitude of residues in plants

Maize
Proposed GAP: 1 application; BBCH 12-16, 12 g as/ha; PHI: n.a.
New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.
New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.
Trials GAP: 1 x 0.012 kg as/ha, BBCH 16, outdoor
4 x <0.01 mg/kg
The data submitted show that exceedance of the MRL (0.01 mg/kg) is unlikely. The proposed use is considered acceptable.

Magnitude of residues in livestock

Animals are not exposed to residues via feed above the trigger value: 0.004 mg/kg. Therefore livestock feeding studies are not required.

Magnitude of residues in processed commodities

No data on the effect of processing on the magnitude of residues are required as residues in the raw agricultural commodities are below the limit of determination.

Magnitude of residues in representative succeeding crops

No data are required. Based on the rapid degradation of thifensulfuron-methyl in soil and the findings of the metabolism studies assessed in DAR, detectable residues are not expected in rotational crops.

Other / special studies

Maize has not melliferous capacity. Additionally, the product is applied early in the growing season when bee foraging activity is low. Studies are not required.

Estimation of exposure through diet and other means

The input values used for the chronic and acute risk assessments are the current EU MRLs contained in Regulation (EU) No. 617/2014. Calculation is accepted.

The proposed uses of thifensulfuron-methyl in the formulation EVRITELL 162 OD do not represent unacceptable acute and chronic risks for the consumer.

3.6.2 Consumer exposure

The chronic and acute consumer risk assessment was carried out using the EFSA PRIMo model rev. 3.1 (TMDI calculation). The estimated Theoretical Daily Intakes (TMDI), and National Theoretical Daily Intakes (NTMDI) based on MRLs were below the ADI.
The proposed uses of dicamba, nicosulfuron and thifensulfuron-methyl in the formulation EVRITELL 162 OD do not represent unacceptable acute and chronic risks for the consumer.

3.7 Environmental fate and behaviour (Part B, Section 8)

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

The PEC values of EVRITELL 162 OD, dicamba, nicosulfuron and thifensulfuron-methyl and its metabolites in soil have been assessed with the ESCAPE model (version 2.0), the focus groundwater interception values taken from FOCUS guidance (Generic Guidance for Tier 1 FOCUS Ground Water Assessments (version: 2.2, May 2014)) and the DT_{50} values established in the EU peer review for dicamba (EFSA Journal 2011;9(1):1965), nicosulfuron (EFSA Scientific Report (2007)120, 1-91) & thifensulfuron-methyl (EFSA Journal 2015;13(7):4201)).

Obtained PEC_{SOIL} values were used in the risk assessment for soil organisms.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

Results of modelling with FOCUS PELMO & PEARL show that the active substance dicamba and metabolite DCSA are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses of EVRITELL 162 OD in maize.

In the assessment of the product, the results for nicosulfuron in the Hamburg scenario exceed the threshold value of 0.10 µg/l, while all other scenarios for nicosulfuron were below the threshold value. The unacceptable value was obtained = 0.13 µg/L at Tier 1 (PUF=0).
However, considering the results of three lysimeter studies with nicosulfuron (described in DAR: Kurth, 1995, Marmouni and Burgener (1996a and b), which were conducted at an application rate of 40 g nicosulfuron/ha, it appears that the active ingredient nicosulfuron has no potential to enter groundwater at annual average concentrations above 0.1 µg/L.

In addition, the applicant provided a second set of PECgw calculations, in line with the EU established endpoint reported in EFSA 2007 (PUF=0.5). The results of the Tier 2 modeling for PECgw show that the active substance nicosulfuron can enter groundwater at concentrations < 0.1 µg/l with the intended use in maize. In Tier II the EU agreed parameter (PUF=0.5) for nicosulfuron was used in the simulation. Consideration of endpoint reported in EFSA Journal (2007) 120, 1-91 in groundwater modelling showed that groundwater concentrations of < 0.1µg/L in Hamburg scenario. According last harmonisation PL, PUF 0,5 can be used only if appropriate study is available. However, when refining the risk, the applicant submitted other option, for example performing simulations for the use of nicosulfuron every second. However for PL
For three metabolites (AUSN, ASDM and MU-466), pH-dependent adsorption values were found, so two

sets of PECgw values were used for these metabolites at high and low soil pH values. Nicosulfuron shows a clay-dependent sorption and therefore has specific KF values for each level, derived from the equation KF = 0.026 x % clay. None of groundwater metabolites was predicted to be exceed the trigger of 10 µg/L. The lysimeter studies indicate that the level of 0.1 µg /L is exceeded by ASDM (i.e. 0.88-0.99 µg/L in the first year and 0.18-0.3 µg/L in the second year), AUSN (i.e. 0.24 µg/L in the first year and 0.43-0.59 µg/L in the second year) and UCSN (i.e. 0.18-0.22 µg/L in the first year and no contamination in the second year).
Taking all above information into account it can be concluded that application of EVRITELL 162 OD to maize at a maximum rate of 1 L/ha (equivalent to 40 g a.s./ha) will not pose a risk of groundwater contamination by nicosulfuron. Moreover, during EU review of nicosulfuron none of the groundwater metabolites (HMUD, AUSN, UCSN, ASDM and MU-466) was considered to be relevant according to the current EU guidance document on relevance of metabolites.

Results of the groundwater modelling show that the active substance thifensulfuron methyl and its major soil metabolite IN-L9225, IN-A4098, IN-U5F72, IN-L9226, IN-A5546, IN-V7160 and IN-W8268 are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the groundwater FOCUS scenarios.
On the basis of the obtained results PECgw values for metabolites IN-L9223 & IN-JZ789 were > 0.1 µg/L for application.

Taking into account performed calculations it can be concluded that the results of PEC_{GW} values for dicamba, nicosulfuron & thifensulfuron methyl in comparison with the regulatory threshold of 0.1 µg/L indicate an acceptable risk for the scenarios considered. Thereby, it could be stated that the use of EVRITELL 162 OD according to recommendations will not pose a risk.

However, in Poland, the results of lysimetry studies were accepted to clarify the risk to groundwater. In conclusion, it can be stated that EVITRELL 162 OD can be used every year in the same field.

All details on the calculations are included in the Reports RR/18/23 & RR/10/24 attached to Part B, Section 8.

Predicted environmental concentrations in surface water (PEC_{sw})

The surface water modelling was performed for the intended use pattern of EVRITELL 162 OD in line with recommendations of respective FOCUS guidance documents using most up-to-date versions of the models. Obtained $PEC_{SW/SED}$ values were used in the risk assessment for aquatic organisms.

3.7.3 Predicted environmental concentrations in air (PEC_{air})

No unacceptable contamination of the atmosphere is expected following the intended uses of EVRITELL 162 OD.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

The risk for birds arising from acute and long-term exposure to EVRITELL 162 OD is acceptable. Moreover, the risk for birds due to uptake of contaminated drinking water and via secondary poisoning is also acceptable.
The TER values, calculated for recommended scenarios, exceed the trigger value of 10 for acute risk. However, first-tier TER value calculated for one scenario did not exceed the relevant trigger values of 5 for reproductive risk and acceptable risk to mammals was confirmed based on higher tier assessment.

The risk to mammals is acceptable following use of EVRITELL 162 OD according to the proposed use pattern.

3.8.2 Effects on aquatic species

Based on PEC/RAC calculations, no unacceptable risk is indicated for aquatic organisms considering all envisaged GAP uses for EVRITELL 162 OD, assuming that following risk mitigation measures are taken into account:

- a vegetative buffer strip of 10 m to surface water bodies is required when conventional spraying techniques are applied.

The evaluation of the risk for aquatic organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters" (EFSA Journal 2013;11(7):3290). Based on PEC/RAC calculations, no unacceptable risk is indicated for aquatic organisms considering all envisaged GAP uses for EVRITELL 162 OD, assuming that following risk mitigation measures are tak-en into account: However, as aquatic plants are the most sensitive group of aquatic organisms, further studies should be provided at Member State level. The study with *Myriophyllum* and product **EVRITELL 162 OD** should be conducted in accordance with OECD 239. A final conclusion on the risk to the aquatic environment from the formulation EVRITELL 162 OD can only be drawn after the studies with the formulation and aquatic plants are made available. This should be addressed during product authorisation at Member State level. Justification: Evritell 162 OD is a herbicide containing 3 active substances, where the data on the toxicity of the active substance dicamba on aquatic plants show that Myriophyllum spicatum is the most sensitive species.

DATA GAP: In case formulation Myriophyllum: 1. Risk assessment for aquatic plants (*M. spicatum*) has been not performed (insufficient data set - data gap). 2. The new study the product EVRITELL 162 OD and *M.spicatum* should be performed.

Updated November 2024

To address the current data gap for *Myriophyllum spicatum* conducted by Applicant according to the OECD Guidelines. The new study for *Myriophyllum spicatum* with formulated product EVRITELL 162 OD has been accepted by zRMS. Toxicity data and risk assessment for Myriophyllum spicatum was available for the PPP EVRITELL 162 OD and a low risk was demonstrated for this species. The use EVRITELL 162 OD according to the label will not pose risk to aquatic organisms (ratio PEC/RAC is below 1) with apply 10 meters vegetative buffer zone. The use EVRITELL 162 OD according to the label will not pose risk to aquatic organisms (ratio PEC/RAC is below 1) with apply 10 meters vegetative buffer zone.

3.8.3 Effects on bees

The HQ values are lower than the trigger of 50, indicating low risk to bees from following application of EVRITELL 162 OD. In addition, the chronic studies for bees were submitted by the applicant. The chronic study for adult bees and a study effects on honey bee development and other honey bee life stages were accepted by zRMS. The risk assessment based on these studies should be considered when GD for Bees, 2013 is implemented at EU level. Final decision should be taken into account at MSs level.

Updated November 2024
The risk assessment for bees according EFSA 2013 guidance was performed by Applicant. The risk assessment was accepted by zRMS. First tier chronic evaluation of the risk to adult bees exposed to EVRITELL

162 OD resulted with ETR value above the trigger in weeds scenario indicating potentially unacceptable risk. No data enabling refinement of the risk was available. Nevertheless, since the EFSA Bee Guidance Document is yet to be implemented (2013), this result should be treated as indication of area that should be covered in the future, once the guidance document is officially noted and accepted. Further assessments from chronic exposure could be required at national level. It also should be noted that product EVRITELL 162 OD is an herbicide that is mostly applied at early stage (BBCH 12-16), when the treated plant are small and do not have flowers. Flowering weeds in fields treated with EVRITELL 162 OD might be attractive to bees. However, in the case of weeds present, application of EVRITELL 162 OD leads to a significant reduction/unattractiveness of the ground cover in the treated fields within a very few days, so flowering, if any, will take place only a very short time period. Thus, the likelihood of bees found in treated fields can be considered as low and exposure to bees, if any, is restricted to a very short time period and a limited number of individuals. On the other hand, maize are not a melliferous plant, so it is not attractive to the bees and other pollinators. In conclusion in Poland, no adverse effects on populations and communities need to be expected in consideration of the intended GAP uses of **EVRITELL 162 OD.**

3.8.4 Effects on other arthropod species other than bees

The field risk for non-target arthropod species *Coccinella septempunctata* (TER = 3.53) is not clarified. The field risk assessment fails for the two indicator species *Coccinella septempunctata* and *Chrysoperla carnea.* Only the risk for the most sensitive species *Chrysoperla carnea* is clarified. However, clarification of the risk for *Coccinella septempunctata* is also required. After re-examining the documentation and your arguments, I maintain my request to clarify the risk for the second species *Coccinella septempunctata*. Justification: 1. Escort 2 recommends that the most sensitive species should be indicated in laboratory tests and then more detailed tests should be performed on the most sensitive species. However, ESCORT 3 clearly indicates that tests should not be limited to the most sensitive species, but should include other important non-target organisms in order to ensure a comprehensive assessment. ESCORT 3 emphasizes a more comprehensive assessment, covering many species, realistic exposure scenarios and a broader view of ecological aspects. This approach ensures a thorough risk assessment and protection of the entire ecosystem. *Chrysoperla carnea* has been identified as the most sensitive species taking into account the mortality parameter and in this case conducting tests - aged residue study - can provide key information on the persistence and impact of pesticide residues on this species. However, this does not necessarily provide adequate protection for *Coccinella septempunctata*. Although ESCORT 2 suggests using the most sensitive species, in my opinion the risk assessment should not overlook other species that have shown unacceptable risk in the initial assessments. Given that the risk quotient for *Coccinella septempunctata* is also above the threshold, it is prudent to conduct an aged residue study for both species to obtain a more comprehensive risk profile. Differences in morphology, ecological roles, physiological responses and behavioural patterns between *Chrysoperla carnea* and *Coccinella septempunctata* significantly influence their sensitivity to pesticides. Conducting an aged residue study on both species will allow for a more comprehensive risk assessment, providing a thorough assessment of the ecological impact on a range of beneficial arthropods. 2. Additionally, in the extended laboratory study, the emergence rate for *Coccinella septempunctata* is reduced by approximately 16.2% at the highest dose tested compared to the control. However, the hatch rate for *Chrysoperla carnea* is reduced by about 9.5% and we do not observe a clear dose-response pattern here regarding the reproduction parameter. In the extended laboratory study, the average number of eggs that one female is able to lay per day and that are capable of hatching for *Coccinella septempunctata* is reduced by about 40% for the highest tested dose compared to the control and a clear dose-response pattern is visible. Considering the reproduction parameter, it is *Coccinella septempunctata* and not *Chrysoperla carnea* that is more sensitive. Therefore the refinement risk for *Coccinella septempunctata* is also required.

The field risk for non-target arthropod species *Coccinella septempunctata* (TER = 3.53) is not clarified. The field risk assessment fails for the two indicator species *Coccinella septempunctata* and *Chrysoperla carnea*. Only the risk for the most sensitive species *Chrysoperla carnea* is clarified. However, clarification of the risk

for *Coccinella septempunctata* is also required. Therefore the refinement risk for *Coccinella septempunctata* is also required. The off-field risk of **EVRITELL 162 OD** to non-target arthropods was assessed from Hazard Quotients (HQ) between toxicity endpoints estimated from the formulated product EVRITELL 162 OD as well as off-field predicted environmental rate. No risk was determined off-field after application of **EVRITELL 162 OD** at maximum rate of 1 L/ha.
DATA GAP: The refinement risk for Coccinella septempunctata is also required.

Updated November 2024
The additional age residue for *Coccinella septempunctata* and **EVRITELL 162 OD** conducted by Applicant. The new study for *Coccinella septempunctata* with formulated product **EVRITELL 162 OD** has been accepted by zRMS.
Moreover to complete the "in-field" risk assessment the Applicant perform additional age residue study on Coccinella septempunctata with the product EVRITELL 162 OD. The impact of the freshly-dried and field-aged residues of the test item on the *Coccinella sep-tempunctata* were evaluated under extended laboratory conditions on following bioassays: 0 DAT, 14 DAT and 28 DAT. The test item achieved <50% mortality and <50% reduction in reproductive performance (relative to the control) in two subsequent bioassays at 14 DAT and 28 DAT for rate 1000 mL of the test item/200 L of water/ha thus in-field recovery is expected within this time scale (14 - 28 days). The risk assessment was accepted by RMS. Further refinement is not needed.

3.8.5 Effects on soil organisms

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. Risk assessments for EVRITELL 162 OD with the proposed use pattern was carried out according to the guidance for risk assessment for terrestrial ecotoxicology "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). However, risk assessments are accepted provisionally. The studies for formulation of **EVRITELL 162 OD** for earthworms and Folsomia candida and *Hypoapsis aculeifer* with risk assessment was accepted by zRMS only provisionally. The toxicity endpoints were based on nominal concentration. 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 substance 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.

Risk assessments conducted with relevant PEC_{soil} for active substances dicamba, nicosulfuron, thifensulfuron-methyl and its relevant metabolites and in EVRITELL162 OD indicate a low risk to soil microorganisms when applied to the proposed use rates.

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.

3.8.6 Effects on non-target terrestrial plants

For the proposed use of EVRITELL 162 OD, based on the highest application rate the risk for non-target

plants in the off-crop area is indicated to be acceptable when ~~either 1 m buffer strip with 50% drift reduction or a 5 m buffer strip with no drift reduction is applied as risk mitigation measure.~~
To protect non-target plants respect an unsprayed buffer zone of 1 m with 90% drift reduction
or 5 m buffer strip with 50% drift reduction,
or 10 m buffer strip with no drift reduction to non-agricultural land

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No further relevant data available and considered necessary.

3.9 Relevance of metabolites (Part B, Section 10)

For the metabolite of dicamba, concentrations above 0.1 µg/L in groundwater can be excluded. Therefore, a relevance assessment is not necessary.

The metabolites of nicosulfuron HMUD, ASDM, AUSN, UCSN and MU-466 are predicted to occur in groundwater at concentrations above 0.1 µg/L (see core assessment, part B, section 8, chapter 8.8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 is therefore required (see part B10).
The relevance assessment concludes that no risk arises for the groundwater.

Following metabolites of thifensulfuron-methyl have the potential to reach the groundwater in concentrations above 0.1 µg/L: IN-L9223 & IN-JZ789 .

All details are included in Part B, Section 10 of this dRR.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Product EVRITELL 162 OD contains nicosulfuron which is approved as a candidate for substitution because it meets two of the criteria to be considered a PBT substance. Therefore, a comparative assessment is foreseen.

As a conclusion of the comparative assessment, use in maize (use number 1 from the GAP table presented in point 2.6) is not suitable for substitution. Taking into account all possible scenarios referring to limited availability of herbicide MoA's and a high probability of the occurrence of resistance, low to none availability of useful non-chemical alternatives without having significant practical or economic impact, and the fact that the discussed product contains three active substances that represent two different mode of actions, EVRITEL 162 OD is not suitable for substitution.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Authorization can be granted for 1 year only.

Analytical methods for residues

Data gap:

- Nicosulfuron - Table 5.3.11

Analytical methods for commodities with high water content, high acid content and high oil content are missing. ~~The applicant should complete the Table before registration~~

August 2025

The applicant's addition was accepted. The table has been completed. These analytical methods were not submitted at the EU substance approval level. The methods should be supplemented with the renewal of the active substance. No additional data is required.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

UWAGI DO ETYKIETY:

Sekcja skuteczność: Zmieniono listę zaakceptowanych gatunków chwastów i klasyfikację ich wrażliwości. Dodano informację, iż produkt można stosować na kukurydzę uprawianą na ziarno, kiszonkę i bioetanol. Aplikacja produktu powinna odbywać się wiosną w fazie kukurydzy BBCH 12-16.

Los i zachowanie w środowisku: brak uwag.

Ekotoksykologia: Zastosowanie zostało zaakceptowane ~~tymczasowo~~. ~~Wnioskodawca powinien uzupełnić informacje dotyczące danych analitycznych w badaniach wpływu środka ochrony roślin EVRITELL 162 OD na organizmy glebowe.~~ Przedstawione wyjaśnienie zostało zaakceptowane. Dodatkowa ocena ryzyka w tym zakresie nie jest wymagana. Zastosowanie zostało zaakceptowane.

Sekcja pozostałości: brak uwag

Załącznik do zezwolenia MRiRW nr R - ……z dnia…….

Posiadacz zezwolenia:
CIECH Sarzyna S.A., ul. Chemików 1, 37-310 Nowa Sarzyna, tel.: +48 17 24 07 111,
e-mail: sarzyna@ciechgroup.com, www.ciechagro.pl

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

EVRITELL 162 OD

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:
dikamba (związek z grupy pochodnych kwasu benzoesowego) - 110 g/l (10.8%)
nikosulfuron (substancja z grupy pochodnych sulfonylomocznika) - 40 g/l (3.9 %)
tifensulfuron metylowy (substancja z grupy pochodnych sulfonylomocznika) - 12 g/l (1.2%)

Zezwolenie MRiRW nr R – …../….. z dnia …….

Uwaga

H410 Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki
EUH 401 - W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia
P273 Unikać uwolnienia do środowiska.
P391 Zebrać wyciek

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym, stosowany nalistnie w postaci zawiesiny olejowej (OD) do rozcieńczania wodą.
Zgodnie z klasyfikacją HRAC substancja czynna dikamba została zaklasyfikowana do grupy 4, natomiast substancje nikosulfuron i tifensulfuron metylowy zostały zaklasyfikowane do grupy 2.

DZIAŁANIE NA CHWASTY

Środek jest pobierany głównie przez liście chwastów i następnie są szybko przemieszczane w roślinie. Dikamba, należąca do regulatorów wzrostu, powoduje deformacje i zahamowanie wzrostu prowadzące do zamierania chwastów. Nikosulfuron oraz tifensulfuron metylowy są zaliczane do inhibitorów syntazy acetylomleczanowej (ALS), doprowadzają do zaburzeń w biosyntezie białek, objawiające się zahamowaniem wzrostu a następnie stopniowym przebarwianiem się chwastów, co prowadzi do śmierci roślin.
Zabieg wykonać po wschodach chwastów w okresie, gdy mają one rozwinięte 2-6 liści, najlepiej, gdy większość z nich znajduje się w fazie 4 liści. Pełną skuteczność produkt osiąga po około 3-4 tygodniach od zabiegu. Ciepła i wilgotna pogoda sprzyjająca rozwojowi roślin, wzmaga działanie chwastobójcze środka.

Dawka 0,75 l/ha

Chwasty wrażliwe:	chwastnica jednostronna, gwiazdnica pospolita, komosa biała, maruna bezwonna, przytulia czepna, ~~samosiewy rzepaku, szarlat szorstki, tasznik pospolity,~~ tobołki polne
Chwasty średniowrażliwe:	fiołek polny, rdestówka powojowata
~~Chwasty średnioodporne:~~	~~rumianek pospolity~~

Dawka 1,0 l/ha

Chwasty wrażliwe:	chwastnica jednostronna, gwiazdnica pospolita, fiołek polny, komosa biała, maruna bezwonna, przytulia czepna, rdestówka powojowata~~,~~ ~~rumianek pospolity, samosiewy rzepaku, szarlat szorstki, tasznik pospolity~~, tobołki polne

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Kukurydza uprawiana na ziarno, kiszonkę i bioetanol

Maksymalna dawka dla jednorazowego zastosowania: 1,0 l/ha.
Zalecana dawka dla jednorazowego zastosowania: 0,75 - 1,0 l/ha.
Termin stosowania środka: środek stosować w fazie 2-6 liści kukurydzy (BBCH 12-16), aplikacja wiosenna
Zalecana ilość wody: 100 – 300 l/ha.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Uwaga:
Dawkę środka należy dostosować do gatunków chwastów, ich fazy rozwojowej i liczebności na polu. Środek działa najskuteczniej na młode, intensywnie rosnące chwasty. Niższą dawkę stosować na chwasty mniej wyrośnięte, we wczesnych fazach rozwojowych i gdy zachwaszczenie jest mniejsze.

ŚRODKI OSTROŻNOŚCI ORAZ SZCZEGÓLNE WARUNKI STOSOWANIA

1. Ze względu na możliwość wystąpienia objawów fitotoksyczności na niektórych odmianach kukurydzy (szczególnie na nowych odmianach) przed zastosowaniem środka w tych odmianach zaleca się:
   – wykonanie na każdej uprawie próbnego zabiegu w celu sprawdzenia czy nie występują objawy uszkodzenia roślin lub
   – skontaktowanie się z doradcą albo przedstawicielem podmiotu posiadającego zezwolenie.
2. Środka nie stosować w liniach wsobnych kukurydzy na plantacjach nasiennych oraz w kukurydzy cukrowej i kukurydzy pękającej.
3. Opryskiwać co najmniej 6 godzin przed spodziewanym deszczem – zawsze z włączonym mieszadłem.
4. Strategia zarządzania odpornością:
   Środek zawiera substancję czynną należącą do herbicydów z grupy inhibitorów syntazy acetylomleczanowej (ALS). Stosowanie po sobie herbicydów o tym samym mechanizmie działania może prowadzić do wyselekcjonowania chwastów odpornych. W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:
   – postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce, w zalecanym terminie zapewniającym optymalne zwalczanie chwastów,
   – dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
   – stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
   – stosować mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,
   – stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
   – dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
   – używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
   – używać kwalifikowanego materiału siewnego,
   – czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
   – informować posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
   – w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

5. Środka nie stosować:
   - na rośliny osłabione lub uszkodzone przez szkodniki, przymrozki, zalanie lub suszę,
   - podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie rośliny uprawne
   - w kukurydzy cukrowej, pękającej i w uprawie materiałów hodowlanych,
   - na kukurydzę znajdującą się w fazie powyżej 6 liści właściwych,
   - na rośliny kukurydzy, których wzrost został zahamowany wskutek niskich temperatur; zabieg można wykonać po wznowieniu intensywnego wzrostu kukurydzy,
   - na rośliny osłabione i uszkodzone przez przymrozki, suszę, szkodniki lub choroby,
   - na rośliny mokre (rosa, deszcze),
   - bezpośrednio po okresie długotrwałych chłodów,
   - w temperaturze powietrza poniżej 10°C i powyżej 25°C,
   - w okresie, gdy temperatura nocą jest niższa niż 5°C,

- po zastosowaniu na plantacji kukurydzy insektycydów doglebowych zawierających substancje czynne z grupy związków fosforoorganicznych,
- w mieszaninie z nawozami płynnymi lub nawozami do dolistnego dokarmiania roślin.

6. Podczas stosowania środka nie dopuścić do:
   – znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
   – nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

OKRESY KARENCJI

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):
Niewymagany

NASTĘPSTWO ROŚLIN

W przypadku konieczności wcześniejszego zaorania plantacji potraktowanej środkiem (w wyniku uszkodzenia kukurydzy przez grad, choroby, szkodniki lub przymrozki) na polu można uprawiać:

- kukurydzę uprawianą na ziarno lub przeznaczoną na paszę. Jednocześnie należy się liczyć, że zaraz po wschodach mogą pojawić się tymczasowe i szybko przemijające objawy fitotoksyczne,

- zboża, po wykonaniu orki na głębokość min. 20 cm.

Po zbiorze kukurydzy traktowanej produktem można zasiać zboża ozime w uprawie uproszczonej (bez orki).

Po roku od zastosowania produktu można uprawiać wszystkie rośliny, z wyjątkiem gatunków bardzo wrażliwych na środek tj.: groch, sałata, cebula.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed zabiegiem wyczyścić dokładnie wszystkie filtry w opryskiwaczu.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz, postępować zgodnie z instrukcją producenta opryskiwacza. Wypełnić zbiornik do połowy czystą wodą i rozpocząć łagodne mieszanie. Zawartością opakowania przed użyciem wstrząsnąć. Dodać wymaganą ilość produktu do zbiornika i odczekać, aż zostanie w pełni zdyspergowany.
Opróżnione opakowania przepłukać trzykrotnie wodą za pomocą zintegrowanej płuczki ciśnieniowej lub ręcznie, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Nie przerywać mieszania aż do zużycia mieszaniny.
Oprysk prowadzić natychmiast po wymieszaniu. Nie pozostawiać cieczy użytkowej w urządzeniu do oprysku.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej należy:
– jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
– unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
– unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.
Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

Ze względu na bardzo dużą wrażliwość niektórych roślin uprawnych nawet na znikome ilości środka, bardzo ważne jest dokładne wymycie opryskiwacza po zabiegu, zwłaszcza przed użyciem w innych roślinach uprawnych niż zalecane.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne oraz odzież roboczą (kombinezon) ~~ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin w~~ trakcie przygotowywania cieczy użytkowej oraz odzież roboczą w trakcie wykonywania zabiegu.
.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.
Nie myć aparatury w pobliżu wód powierzchniowych.
Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych.

W celu ochrony roślin niebędących celem działania środka konieczne jest:

- ~~wyznaczenie nieopryskiwanej strefy ochronnej od terenów nieużytkowanych rolniczo o szerokości 1 m w połączeniu z techniką redukującą znoszenie cieczy użytkowej (50%) lub~~
- ~~wyznaczenie nieopryskiwanej strefy ochronnej od terenów nieużytkowanych rolniczo o szerokości 5 m.~~

To protect non-target plants respect an unsprayed buffer zone of 1 m with 90% drift reduction
or 5 m buffer strip with 50% drift reduction,
or 10 m buffer strip with no drift reduction to non-agricultural land

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:
– w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
– w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
– w temperaturze 0°C - 30°C.
Chronić przed mrozem.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.
Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.
Opróżnione opakowania po środku zaleca się zwrócić do sprzedawcy środków ochrony roślin lub można je potraktować jako odpady komunalne. W razie wątpliwości dotyczących postępowania z opakowaniami poradź się sprzedawcy środków ochrony roślin.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe
W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności - 1 rok
Data produkcji -……
Zawartość netto - ……
Nr partii - ……

Appendix 3 Letter of Access

Not applicable. Data protection for studies for the active substance dicamba, nicosulfuron and thifensulfuron-methyl has expired.

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 ~~KCP 2.7.2~~ KCP 2.7.4 KCP 2.8.2 ~~KCP 2.8.3.2~~ KCP 2.8.3.3 KCP 2.8.5.1.2 KCP 2.8.7.2	Posłuszna K.	2023	DNT-162OD-R-CPd Determination of physicochemical properties Report No STAB.23-03/INIT CIECH Agro GLP GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
~~KCP 2.3.2~~ KCP 2.3.3	Pachnicki P.	2023	DNT-162OD-R-CPd Determination of auto-ignition temperature Report No BC-28/23 Łukasiewicz Research Network – Institute of Industrial Organic Chemisty GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 2.7.1 KCP 2.7.3	Posłuszna K.	2023	DNT-162OD-R-CPd Accelerated storage – 12 weeks at 35 °C	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Report No STAB.23-03/ACC35 CIECH Agro GLP GLP Unpublished				
KCP 5.1.1	Posłuszna K.	2023	DNT-162OD-R-CPd, Determination of physicochemical properties STAB.23-03/INIT CIECH Agro GLP ul. Chemików 1 31-310 Nowa Sarzyna Poland GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.1.2_01	V. FAESSEL	2023	Validation of the Analytical Method for the Analysis of Dicamba (sum of Dicamba, 5-OH-dicamba and their conjugates expressed as Dicamba) and Fenoxaprop-p-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one (expressed as Fenoxaprop-p-ethyl) in Winter Wheat grain. R C2140 ANADIAG 16 rue Ampère 67500 HAGUENAU – FRANCE GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.1.2_02	C. Lefebvre	2023	Determination of MCPA, Dicamba and Fenoxaprop-P-Ethyl Residues in winter wheat following one foliar application with MDF-368EW-R-CPd under field conditions in Northern Europe in 2022 R C2136 ANADIAG 16 rue Ampère 67500 HAGUENAU – FRANCE GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2_03	E. Schneider	2023	Determination of MCPA and Dicamba Residues in Maize following foliar application with C-340SL-Roz-C under Field Conditions in Northern Europe in 2022 R C2146 ANADIAG 16 rue Ampère 67500 HAGUENAU – FRANCE GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.1.2_04	V. FAESSEL	2023	Validation of the Analytical Method for the Analysis of Nicosulfuron, Thifensulfuron-methyl and Triazine amine IN-A4098 in Maize grain R C2160 ANADIAG 16 rue Ampère 67500 HAGUENAU – FRANCE GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.1.2_05	E. Thomas - Delille	2023	Determination of Dicamba, Nicosulfuron and Thifensulfuron-methyl Residues in Maize Following Foliar application with DNT-162OD-R-CPd under Field Conditions in Northern Europe in 2022 C2156 ANADIAG 16 rue Ampère 67500 HAGUENAU – FRANCE GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.1.2_06	P. Parma	2022	Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test EMI/4/62/2022 Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2_07	P. Parma	2022	Honeybees (Apis mellifera L.) Larval Toxicity Test, Repeated Exposure EMI/4/63/2022 Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.1.2_08	S. Szlauer	2022	Daphnia sp., Acute Immobilisation Test EMI/4/70/2022 Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.1.2_09	S. Szlauer	2022	Freshwater Alga and Cyanobacteria, Growth Inhibition Test EMI/4/71/2022 Ecomelius Institute Sp. z o. o. Kalinowa 2, Zaborze 43-520 Chybie, Poland GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.1.2_10	Z. Kacperek-Karetta	2023	DNT-162OD-R-CPd Navicula pelliculosa SAG 1050-3, Growth inhibition test W-11-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Ecotoxicology Research Group Doswiadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.1.2_11	Z. Kacperek-Karetta	2023	DNT-162OD-R-CPd W-12-23 Lemna gibba CPCC 310, Growth inhibition test	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished				
KCP 5.1.2_12	A.Wojciech	2023	DNT-162OD-R-CPd Bumblebees (Bombus spp.), Acute Oral Toxicity Test STUDY CODE: B-56-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.1.2_13	A.Wojciech	2023	DNT-162OD-R-CPd Bumblebees (Bombus spp.), Acute Contact Toxicity Test STUDY CODE: B-57-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.1.2_14	P. Pieczka	2023	DNT-162OD-R-CPd Terrestial Plant Test: Vegetative Vigour Test STUDY CODE: G-33-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43-200 Pszczyna, Poland	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 5.1.2_15	P. Pieczka		DNT-162OD-R-CPd Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test STUDY CODE: G-34-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.2_01	Martinez, M. P.	2021	Validation of the analytical method for the determination of Dicamba in bovine fat CH-0667/2021 ChemService S.r.l. Controlli e Ricerche GLP Studies Department Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI) Italy GLP: Yes Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.2_02	Longhi D.	2021	Independent laboratory validation of the analytical method 0667/2021 for the determination of Dicamba in Bovine Fat samples GLP-STUDY-21-115 LabAnalysis s.r.l. GLP Studies Department Via Europa 5 27041 Casanova Lonati (PV) Italy GLP: Yes Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2_03	Martinez M. P.	2023	Integration to the Analytical Methods Validations for the Determination of Dicamba in animal matrices CH – 1124-2022 ChemService S.r.l. Controlli e Ricerche GLP Studies Department Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI) Italy GLP: Yes Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.2_04	Martinez, M. P	2021	Validation of the Analytical Method for the Determination of Dicamba in Bovine muscle CH – 0670/2021 ChemService S.r.l. Controlli e Ricerche GLP Studies Department Via Fratelli Beltrami, 15 20026 Novate Milanese (MI) Italy GLP: Yes Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A
KCP 5.2_05	Longhi D.	2021	Independent laboratory validation of the analytical method 0670/2021 for the determination of Dicamba in Bovine Muscle samples GLP-STUDY-21-116 LabAnalysis s.r.l. GLP Studies Department Via Europa 5 27041 Casanova Lonati (PV) Italy GLP: Yes Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A
KCP 5.2_06	Martinez, M. P	2021	Validation of the Analytical Method for the Determination of Dicamba in Bovine kidney CH – 0671/2021 ChemService S.r.l. Controlli e Ricerche	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Studies Department Via Fratelli Beltrami, 15 20026 Novate Milanese (MI) Italy GLP: Yes Unpublished				
KCP 5.2_07	Longhi D.	2021	Independent laboratory validation of the analytical method 0671/2021 for the determination of Dicamba in Bovine Kidney samples GLP-STUDY-21-117 LabAnalysis s.r.l. GLP Studies Department Via Europa 5 27041 Casanova Lonati (PV) Italy GLP: Yes Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.2_08	Martinez, M. P	2021	Validation of the Analytical Method for the Determination of Dicamba in Bovine milk CH – 0672/2021 ChemService S.r.l. Controlli e Ricerche GLP Studies Department Via Fratelli Beltrami, 15 20026 Novate Milanese (MI) Italy GLP: Yes Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.2_09	Longhi D.	2021	Independent laboratory validation of the analytical method 0672/2021 for the determination of Dicamba in Bovine Milk samples GLP-STUDY-21-118 LabAnalysis s.r.l. GLP Studies Department Via Europa 5 27041 Casanova Lonati (PV)	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Italy GLP: Yes Unpublished				
KCP 5.2_10	Longhi D.	2022	Validation of an analytical method for the quantification of Dicamba in poultry eggs GLP-STUDY-22-1 LabAnalysis s.r.l. GLP Studies Department Via Europa 5 27041 Casanova Lonati (PV) Italy GLP: Yes Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.2_11	E. Rigamonti	2022	Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Dicamba in Poultry Eggs CH – 0992/2021 ChemService S.r.l. Controlli e Ricerche GLP Studies Department Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI) Italy GLP: Yes Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.2_12	Martinez, M. P	2020	Validation of the Analytical Method for the Determination of Dicamba, Dicamba-5-Hydroxy and Dicamba-desmethyl in Drinking Water CH – 0472/2020 ChemService S.r.l. Controlli e Ricerche GLP Studies Department Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI) Italy GLP: Yes Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.2_13	A. Sala	2020	Independent Laboratory Validation (ILV) of the analytical method for the Determination of Dicamba, Dicamba-5-hydroxy	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			and Dicamba-desmethyl in Drinking Water GLP-STUDY-20-62 LabAnalysis s.r.l. GLP Studies Department Via Europa 5, 27041 Casanova Lonati (PV), Italy GLP: Yes Unpublished				
KCP 5.2_14	D. Longhi	2023	Validation of an analytical method for the quantification of Dicamba in bovine urine LBN-0004-2023 Labanalysis s.r.l. GLP Studies Department Via Europa 5. 27041 Casanova Lonati (PV) Italy GLP: Yes Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.2_15	K. Rudziński	2020	VALIDATION OF A METHOD FOR DETERMINATION OF NICOSULFURON IN DRINKING WATER BY LIQUID CHROMATOGRAPHY 20/FSL/04 Food Safety Laboratory Research Institute of Horticulture 13B Pomologiczna Street 96-100 Skierniewice GLP: Yes Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 5.2_16	Blumberg Olga	2024	Validation of an Analytical Method for Nicosulfuron in Food of Animal Origin and Body Fluids S23-107311 Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL	KCP 5.2_16
KCP 5.2_17	Jooss Sandro	2024	Independent Laboratory Validation of an Analytical Method for Determination of Nicosulfuron in Food of	N	Y	Data/study report never submitted before to PL	KCP 5.2_17

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Animal Origin and Body Fluids S23-107248 Eurofins Agroscience Services EAG Laboratories GmbH GLP Unpublished				
KCP 6.2/1	A.Pey	2022	FIELD STUDY TO EVALUATE THE EFFICACY OF DNT-162OD-R-CPD AGAINST WEEDS IN MAIZE, CZECH RE-PUBLIC, 2022 SynTech Research Czech s.r.o. SRCZ22-771-21HE GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/2	A.Pey	2023	Evaluation of the efficacy of DNT-162OD-R-CPd against weeds in maize 2023 EPPOMAR Zone CZECH REPUBLIC SynTech Research Czech s.r.o. CZOR-ZCO23-ZEAMX-001SYT GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/3	A.Pey	2023	Evaluation of the efficacy of DNT-162OD-R-CPd against weeds in maize 2023 EPPOMAR Zone CZECH REPUBLIC SynTech Research Czech s.r.o. CZOR-ZCO23-ZEAMX-002SYT GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/4	F.Lindemann	2022	Field study to evaluate the efficacy of DNT-162OD-R-CPd against weeds in maize Hetterich Fieldwork GbR DNT-162OD-R-CPd_EFF_DE_1 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/5	D.Krüger	2022	Field study to evaluate the efficacy of DNT-162OD-R-CPd against weeds in maize	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Hetterich Fieldwork GbR DNT-162OD-R-CPd_EFF_DE_2 GEP Unpublished				
KCP 6.2/6	F.Friedrich	2023	Field study to evaluate the efficacy of DNT-162OD-R-CPd against weeds in maize Quintus GmbH M-124-QUI-23-248 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/7	J.Rohr	2023	Field study to evaluate the efficacy of DNT-162OD-R-CPd against weeds in maize Trialtec GmbH DNT_EFF_23_DE_2 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/8	M.Huth	2023	Field study to evaluate the efficacy of DNT-162OD-R-CPd against weeds in cereals BioChem agrar GmbH 23 1069 5122 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/9	A.Szemendera	2022	Field study to evaluate the efficacy of DNT-162OD -R_CPd against weeds in maize, Poland 2022 Fertico Sp. z o.o. 114_01_F22_220 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/10	A.Szemendera	2022	Field study to evaluate the efficacy of DNT-162OD -R_CPd against weeds in maize, Poland 2022 Fertico Sp. z o.o. 114_01_F22_221 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2/11	A.Szemendera	2022	Field study to evaluate the efficacy of DNT-162OD -R_CPd against weeds in maize, Poland 2022 Fertico Sp. z o.o. 114_01_F22_222 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/12	A.Szemendera	2022	Field study to evaluate the efficacy of DNT-162OD -R_CPd against weeds in maize, Poland 2022 Fertico Sp. z o.o. 114_01_F22_223 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/13	A.Szemendera	2023	Field study to evaluate the efficacy of DNT-162OD-RCPd against weeds in maize, Poland 2023 Fertico Sp. z o.o. 217_01_F23_498 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/14	A.Szemendera	2023	Field study to evaluate the efficacy of DNT-162OD-RCPd against weeds in maize, Poland 2023 Fertico Sp. z o.o. 217_01_F23_499 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/15	D.Kondics	2022	FIELD STUDY TO EVALUATE THE EFFICACY OF DNT-162OD-R-CPD AGAINST WEEDS IN MAIZE CPR Europe Kft. CPRHU20-392-027HE GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/16	L.Hódi	2022	FIELD STUDY TO EVALUATE THE EFFICACY OF DNT-162OD-R-CPD AGAINST WEEDS IN MAIZE CPR Europe Kft.	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			CPRHU20-393-027HE GEP Unpublished				
KCP 6.2/17	P.Iszak	2023	FIELD STUDY TO EVALUATE THE EFFICACY OF DNT-162OD-R-CPD AGAINST WEEDS IN MAIZE CPR Europe Kft. CPRHU23-425-027HE GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/18	J.Ritecz	2023	FIELD STUDY TO EVALUATE THE EFFICACY OF DNT-162OD-R-CPD AGAINST WEEDS IN MAIZE CPR Europe Kft. CPRHU23-427-026HE GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/19	E.Zoltán	2023	FIELD STUDY TO EVALUATE THE EFFICACY OF DNT-162OD-R-CPD AGAINST WEEDS IN MAIZE CPR Europe Kft. CPRHU23-427-027HE GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/20	G.Botoman	2022	Field study to evaluate the efficacy of DNT-162OD-R-CPd against weeds in maize GEP Trial, ROMANIA, 2022 AgroProspect SRL DNT-162OD-R-CPd_EFF_RO_1 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.2/21	G.Botoman	2022	Field study to evaluate the efficacy of DNT-162OD-R-CPd against weeds in maize GEP Trial, ROMANIA, 2022 AgroProspect SRL DNT-162OD-R-CPd_EFF_RO_1 GEP	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2/22	J.Banicova	2022	Field study to evaluate the efficacy of DNT-162OD-R-CPd against weeds in maize, in Slovakia 2022 Fyse, Ltd. 101202206 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/1	A.Pey	2022	EVALUATE THE SELECTIVITY OF DNT-162OD-R-CPD APPLIED IN MAIZE, CZECH REPUBLIC, 2022 SynTech Research Czech s.r.o. SRCZ22-771-22HE GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/2	A.Pey	2023	Field study to evaluate the selectivity of DNT-162OD-R-CPd applied in maize, 2023. EPPOMAR Zone CZECH REPUBLIC SynTech Research Czech s.r.o. CZOR-ZCO23-ZEAMX-003SYT GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/3	A.Pey	2023	Field study to evaluate the selectivity of DNT-162OD-R-CPd applied in maize, 2023. EPPOMAR Zone CZECH REPUBLIC SynTech Research Czech s.r.o. CZOR-ZCO23-ZEAMX-004SYT GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/4	G.Dürr	2022	Field study to evaluate the selectivity of DNT-162OD-R-CPd applied in maize Hetterich Fieldwork GbR DNT-162OD-R-CPd_SEL_DE_1 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/5	G.Dürr	2022	Field study to evaluate the selectivity of DNT-162OD-R-CPd applied in maize Hetterich Fieldwork GbR DNT-162OD-R-CPd_SEL_DE_2	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.4/6	E.Weiß	2023	Field study to evaluate the efficacy of DNT-162OD-R-CPd applied in maize Field Research Support FRS 083/23-V1 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/7	E.Weiß	2023	Field study to evaluate the efficacy of DNT-162OD-R-CPd applied in maize Field Research Support FRS 083/23-V2 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/8	F.Friedrich	2023	Field study to evaluate the efficacy of DNT-162OD-R-CPd against weeds in maize Quintus GmbH M-124-QUI-23-249 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/9	A.Szemendera	2022	Field study to evaluate the selectivity of DNT-162OD-R-CPd applied in maize, Poland 2022 Fertico Sp. z o.o. 115_01_F22_224 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/10	A.Szemendera	2022	Field study to evaluate the selectivity of DNT-162OD-R-CPd applied in maize, Poland 2022 Fertico Sp. z o.o. 115_01_F22_225 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/11	A.Szemendera	2022	Field study to evaluate the selectivity of DNT-162OD-R-CPd applied in maize, Poland 2022 Fertico Sp. z o.o.	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			115_01_F22_226 GEP Unpublished				
KCP 6.4/12	A.Szemendera	2023	Field study to evaluate the selectivity of DNT-162OD-R-CPd applied in grain maize, Poland 2023 Fertico Sp. z o.o. 218_01_F23_500 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/13	A.Szemendera	2023	Field study to evaluate the selectivity of DNT-162OD-R-CPd applied in silage maize, Poland 2023 Fertico Sp. z o.o. 218_01_F23_501 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/14	A.Szemendera	2023	Field study to evaluate the selectivity of DNT-162OD-R-CPd applied in grain maize, Poland 2023 Fertico Sp. z o.o. 218_01_F23_502 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/15	D.Kondics	2022	FIELD STUDY TO EVALUATE THE SELECTIVITY OF DNT-162OD-R-CPD APPLIED IN MAIZE CPR Europe Kft. CPRHU22-394-027HE GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/16	J.Ritecz	2022	FIELD STUDY TO EVALUATE THE SELECTIVITY OF DNT-162OD-R-CPD APPLIED IN MAIZE CPR Europe Kft. CPRHU22-395-027HE GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/17	P.Iszak	2023	FIELD STUDY TO EVALUATE THE SELECTIVITY OF DNT-162OD-R-CPD APPLIED IN MAIZE	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			CPR Europe Kft. CPRHU23-428-027HS GEP Unpublished				
KCP 6.4/18	G.Bese	2023	FIELD STUDY TO EVALUATE THE SELECTIVITY OF DNT-162OD-R-CPD APPLIED IN MAIZE CPR Europe Kft. CPRHU23-429-027HS GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/19	J.Ritecz	2023	FIELD STUDY TO EVALUATE THE SELECTIVITY OF DNT-162OD-R-CPD APPLIED IN MAIZE CPR Europe Kft. CPRHU23-430-027HS GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/20	G.Botoman	2022	Field study to evaluate the selectivity of DNT-162OD-R-CPd applied in maize GEP Trial, ROMANIA, 2022 AgroProspect SRL DNT-162OD-R-CPd_SEL_RO_1 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/21	G.Botoman	2022	Field study to evaluate the selectivity of DNT-162OD-R-CPd applied in maize GEP Trial, ROMANIA, 2022 AgroProspect SRL DNT-162OD-R-CPd_SEL_RO_2 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 6.4/22	J.Soltesz	2022	FIELD STUDY TO EVALUATE THE SELECTIVITY OF DNT-162OD-R-CPD APPLIED IN MAIZE Fyse, Ltd. 101202207 GEP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3/01	Thomas-Delille E.	2023	Determination of Dicamba, Nicosulfuron and Thifensulfuron-methyl Residues in Maize Following Foliar application with DNT-162OD-R-CPd under Field Conditions in Northern Europe in 2022 C2156 Anadiag GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCA 6.3/02	Thomas-Delille E.	2023	Amendment no. R C2156_230908 to final report no. R C2156 Anadiag GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 9.2.4	Łożuk I.	2023	Calculation of the predicted environmental concentrations of dicamba, nicosulfuron and thifensulfuron- methyl and its metabolites in groundwater after application of EVRITELL 162 OD (FOCUS PEARL, FOCUS PELMO and MACRO in FOCUS) CIECH Sarzyna S.A., Poland RR/18/23 non GLP Unpublished	N	N	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 9.2.4/1	Łożuk I.	2024	Calculation of the predicted environmental concentrations of dicamba, nicosulfuron and thifensulfuron- methyl and its metabolites in groundwater after application of EVRITELL 162 OD (FOCUS PEARLand FOCUS PELMO in FOCUS) QEMETICA Agricultural Solutions Poland S.A RR/10/24 non GLP Unpublished	N	N	Data/study report never submitted before to PL	QEMETICA Agricultural Solutions Poland S.A
KCP 9.2.5	Łożuk I.	2023	Calculation of the predicted environmental concentrations of dicamba, nicosulfuron and thifensulfuron- methyl and its metabolites in surface water and water sediment after application of EVRITELL 162 OD (STEPS 1-2 in FOCUS, SWASH & SWAN) CIECH Sarzyna S.A., Poland RR/17/23 non GLP	N	N	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 10.2.1/01	Kacperek-Karetta Z.	2023	DNT-162OD-R-CPd Navicula pelliculosa SAG 1050-3, Growth inhibition test W-11-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.2.1/02	Szlauer S.	2022	DNT-162OD-R-CPd Daphnia sp., Acute Immobilisation Test EMI/4/70/2022 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.2.1/03	Szlauer S.	2023	DNT-162OD-R-CPd Freshwater Alga and Cyanobacteria, Growth Inhibition Test EMI/4/71/2022 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.2.1/04	Kacperek-Karetta Z.	2023	DNT-162OD-R-CPd Lemna gibba CPCC 310, Growth inhibition test W-12-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.2.1/05	Brzozowska – Wojoczek K.	2024	DNT-162OD-R-CPd Water-sediment Myriophyllum spicatum toxicity test ETOX-2024-39 EcoTox Alliance Sp. z o. o. GLP Unpublished	N	Y	Data/study report never submitted before to PL	QEMETICA Agricultural Solutions Poland S.A.
KCP 10.3.1/01	Parma P.	2022	Honeybees (*Apis mellifera* L.), Acute oral toxicity test, DNT-162OD-R-CPd EMI/4/64/2022	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Ecomelius Institute sp.z o.o. GLP Unpublished				
KCP 10.3.1/02	Parma P.	2022	Honeybees (*Apis mellifera* L.), Acute contact toxicity test, DNT-162OD-R-CPd EMI/4/65/2022 Ecomelius Institute sp.z o.o. GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.3.1/03	Parma P.	2023	Honeybees (*Apis mellifera* L.),Chronic Oral Toxicity Test, DNT-162OD-R-CPd EMI/4/62/2022 Ecomelius Institute sp.z o.o. GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.3.1/04	Parma P.	2023	Honeybees (*Apis mellifera* L.), Larval Toxicity Test, Repeated Exposure, DNT-162OD-R-CPd EMI/4/63/2022 Ecomelius Institute sp.z o.o. GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.3.1/05	Wojciech A.	2023	DNT-162OD-R-CPd Bumblebees (*Bombus* spp.), Acute Oral Toxicity Test B-56-23 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.3.1/06	Wojciech A.	2023	DNT-162OD-R-CPd Bumblebees (Bombus spp.), Acute Contact Toxicity Test B-57-23 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2/01	Kręglewska M.	2023	Extended laboratory test to evaluate effects on *Aphidius rhophalosiphi* (DeStephani-Perez) of the test item DNT-162OD-R-CPd according to IOBC, BART and EPPO Joint Initiative. M.P. Candolfi, et al. (2000) and Mead-Briggs M.A. et al. (2010) 0016/0178/E SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.3.2/02	Kręglewska M.	2022	Extended laboratory test to evaluate effects on *Typhlodromus pyri* (Scheuten) of the test item DNT-162OD-R-CPd according to IOBC, BART and EPPO Joint Initiative, M.P. Candolfi, et al. (2000) and S. Blümel, et al. (2000) 0016/0175/E SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.3.2/03	Domagała J.	2023	Extended laboratory test to determine the effects of the test item DNT-162OD-R-CPd on the ladybird beetle (*Coccinella septempunctata*) 0016/0177/E SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.3.2/04	Kubisiak K.	2023	Extended laboratory test to determine the effects of the test item DNT-162OD-R-CPd on the green lacewing (*Chrysoperla carnea*) 0016/0176/E SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.3.2/05	Domagała J.	2023	Aged-residue test to determine the effects of the test item DNT-162OD-R-CPd on the green lacewing (*Chrysoperla carnea*) according to IOBC, BART, EPPO Joint Initiative, Vogt et al., 2000 and ESCORT 2, Candolfi et al. 2001 0016/0224/E SORBOLAB Research Laboratory LLC	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 10.3.2/06	Domagała J.	2024	Aged-residue extended laboratory test to determine the effects of the test item DNT-162OD-R-CPd on the ladybird beetle (*Coccinella septempunctata*) according to IOBC, BART and EPPO Joint Initiative. Schmuck R. et al. (2000), ESCORT 2, Candolfi M.P. et al. (2001) 0016/0244/E SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	Data/study report never submitted before to PL	QEMETICA Agricultural Solutions Poland S.A.*
KCP 10.4.1.1	Pieczka P.	2023	DNT-162OD-R-CPd Earthworm reproduction test (Eisenia andrei) G-24-23 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.4.2.1-01	Pieczka P.	2023	DNT-162OD-R-CPd Collembolan (Folsomia candida) Reproduction Test G-31-23 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.4.2.1-02	Pieczka P.	2023	DNT-162OD-R-CPd Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil G-32-23 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.5	Sajdok-Czernecka S.	2023	DNT-162OD-R-CPd Soil Microorganisms: Nitrogen Transformation Test EMI/4/67/2022	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Ecomelius Institute Sp. z o. o. GLP Unpublished				
KCP 10.6.2-01	P. Pieczka	2023	DNT-162OD-R-CPd Terrestial Plant Test: Seedling Emergence and Seedling Growth Test G-34-23 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
KCP 10.6.2-02	P. Pieczka	2023	DNT-162OD-R-CPd Terrestial Plant Test: Vegetative Vigour Test G-33-23 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to PL	CIECH Sarzyna S.A.
*CIECH Sarzyna S.A. change its company name ito Qemetica Agricultural Solutions Poland S.A.							

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KIIA 5.8	Wollny, H.	1995a	Salmonella typhimurium reverse mutation assay with AUSN Report no. CCR 521300; 1995-11-29 GLP: Yes Published: No	N	N	-	ISK
KIIA 5.8	Wollny, H.	2003b	Cell mutation assay at the thymidine kinase locus (TK+/-) in mouse lymphoma L5178Y cells, with AUSN	N	N	-	ISK

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Report no. 786402, 2023-08-19 GLP: Yes Published: No				
KIIA 5.8	Schulz, M.	2003a	In vitro chromosomes ab- beration test in chinese ham- ster V79 cells with AUSN Report no. 786401, 2003- 08-27 GLP: Yes Published	N	N	-	ISK
KIIA 5.8	[redacted]	1996	Acute oral toxicity study with AUSN in rats Report no. RCC 601863 GLP: Yes Published	Y	N	-	ISK
KIIA 5.8	[redacted]	1996	Acute oral toxicity study with UCSN in rats RCC 601874 GLP: Yes Published	Y	N	-	ISK
KIIA 5.8	Wollny, H.-E.	1995	Salmonella typhimurium reverse mutation assay with UCSN Report no. RCC 601918 CCR 521400 GLP: Yes Published: No	N	N	-	ISK
KIIA 5.8	Wollny, H.	2003	Cell Mutation Assay at the Thymidine Kinase Locus (TK+/-) in Mouse Lymphoma L5178Y Cells with UCSN Report no. 786502 GLP: Yes Published	N	N	-	ISK
KIIA 5.8	Schulz, M.	2003	In vitro chromosomes ab- beration test in chinese ham- ster V79 cells with UCSN Report no. 786501 GLP: Yes Published	N	N	-	ISK
KIIA 5.8	Seki, H.	1991	A reverse mutation assay of N,N-dimethyl- 2-aminosulfonyl-3-pyridinecarboxyamide using bacteria Report no. 1970 GLP: No Published	N	N	-	ISK
KIIA 5.8	May, K.	1993	ASDM: Assessment of mutagenic potential in histidine auxotrophs of salmonella typhimurium (the Ames test)	N	N	-	ISK

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Report no. 93/0572 ! ISK/200 ! 93/ISK200/0572 GLP: Yes Published				
KIIA 5.8	Dance, C. A.	1993	In vitro assessment of the clastogenic activity of ASDM in cultured human lymphocytes Report no. 93/0728 ! ISK/201 ! 93/ISK201/0728 GLP: Yes Published	N	N	-	ISK
KIIA 5.8	Wollny, H.	2003	Cell mutation assay at the thymidine kinase locus (TK+/-) in mouse lymphoma L5178Y cells with ASDM Report no. 786700 GLP: Yes Published	N	N	-	ISK
KIIA 5.8	[redacted]	1995	ASDM: Mouse micronucleus test to comply with O.E.C.D. Guideline 474 (1983) Report no. 95/ISK214/0633 ! 95/0633 GLP: Yes Published	Y	N	-	ISK
KIIA 5.8	[redacted]	1993	ASDM: Acute oral toxicity study in the rat Report no. 93/0591 ! ISK/195 ! 93/ISK195/0591 GLP: Yes Published	Y	N	-	ISK
KIIA 5.8	[redacted]	1992	ASDM: Acute oral toxicity study in mice Report no. IET 92-0103 GLP: Yes Published	Y	N	-	ISK
KIIA 5.8	[redacted]	1993	ASDM: Acute percutaneous toxicity study in the rat Report no. 93/0605 ! ISK/196 ! 93/ISK196/0605 GLP: Yes Published	Y	N	-	ISK
KIIA 5.8	[redacted]	1993	Twenty-eight-day repeated-dose oral toxicity study of ASDM in rats Report no. D-3335 ! D92-1087 ! B11-0183 GLP: Yes Published	Y	N	-	ISK
KIIA 5.8	[redacted]	1998	DAM 520: 13 week toxicity study in rats with administration by gavage	Y	N	-	ISK

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Report no. 15167 ! 453683 GLP: Yes Published				
KIIA 5.8	[redacted]	1998	DAM 520: One generation reproduction study in rats Report no. 16041 ! 491776 GLP: Yes Published	Y	N	-	ISK
KIIA 5.8	[redacted]	1998	DAM 520: Developmental toxicity study in rats Report no. 15251 ! 491760 GLP: Yes Published	Y	N	-	ISK
KCA 6.1/01	[redacted]	1996	Stability of Dicamba and 3,6-Dichlorosalicylic acid in stored frozen beef tissues and milk SAN837/5242 ! 5242 ! 480068 ! 151 ! DP-304489 ! 95/01/09A [redacted] GLP: Yes Published: No	Y	N	-	SYD
KCA 6.1/02	Jimenez, N. C.	1995	Stability of Dicamba and 5-Hydroxy Dicamba in stored frozen field corn SAN837/5433 ! 5433 ! 480068 ! 127 ! DP-301949 Novartis Crop Protection AG, Basel, Switzerland GLP: Yes Published: No	N	N	-	SYD
KCA 6.1/03	Schulz, M.; Ullrich-Mitzel, A.	1995	Storage stability of SL-950 and its metabolites ASDM and ADMP in corn plants and ears RCC 304762 GLP: Yes Published: No	N	N	-	ISK Task Force Nico-sulfuron
KCA 6.1/04	Schanné, C.	1991	^{14}C-SL-950 (P) Plant metabolism study with corn in the greenhouse RCC Umweltchemie AG, GLP: Yes Published: No	N	N	-	ISK Task Force Nico-sulfuron
KCA 6.1/05	Sadgrove, L.	2012	THIFENSULFURON-METHYL AND METSULFURONMETHYL: Storage Stability of Residues in Wheat Matrices When Stored at Approximately -20°C for Twelve Months HLS Ltd Report No.: PII0018	N	N	-	ROT

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, Unpublished				
KCA 6.2.1/01	Mamouni, A.	1995	^{14}C-SL-950 (P) Plant metabolism study with corn in the greenhouse 272158 GLP: Open Published: Open	N	N	-	ISK Task Force Nico-sulfuron
KCA 6.2.1/02	Butz, R. G.	1982	Foliar absorption, metabolism and translocation of Dicamba by cotton plants SAN837/5140 ! 5140 ! 44 ! DP 302643 ! 480068 Novartis Crop Protection AG, Basel, Switzerland GLP: Yes Published: No	N	N	-	SYD
KCA 6.2.1/03	Butz, R. G.	1984	Characterization of radiocarbon from seeds of 14C-Dicamba treated cotton plants after acid hydrolysis SAN837/5255 ! 5255 ! 70 ! DP302642 ! 480068 Novartis Crop Protection AG, Basel, Switzerland GLP: Yes Published: No	N	N	-	SYD
KCA 6.2.1/04	Butz, R. G.; Atallah, Y. H.	1981	Metabolic fate of Dicamba in sugarcane plants SAN837/5160 ! DP302640 ! 480068 ! 24 Novartis Crop Protection AG, Basel, Switzerland GLP: No Published: No	N	N	-	SYD
KCA 6.2.1/05	Butz, R. G.; Atallah, Y. H.	1982	Foliar absorption, metabolism and translocation of Dicamba by soybeans at early podfill and late senescent stages SAN837/5260 ! 5260 ! 39 ! 480068 ! DP 302641 Novartis Crop Protection AG, Basel, Switzerland GLP: No Published: No	N	N	-	SYD
KCA 6.2.1/06	Völlmin, S.	1999	Metabolism and behavior of Dicamba in fieldgrown spring wheat after application of [Phenyl-(U)-14C] material SAN837/5879 ! 97SV01 Novartis Crop Protection AG, Basel, Switzerland GLP: Yes Published: No	N	N	-	SYD

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.1/07	Brattsten, L. B.	1987	Metabolism of [triazine-2- 14C]DPX-M6316 in greenhouse-grown soybean plants DuPont Experimental Station AMR 547-86, Revision No. 1 GLP: Yes Published: No	N	N	-	DuPont
KCA 6.2.1/08	Brown, H.M.	1987	Metabolism of [thiophene-2- 14C] DPX-M6316 in greenhouse-grown soybeans DuPont Experimental Station AMR 572-86 GLP: No Published: No	N	N	-	DuPont
KCA 6.2.1/09	Cotterman J.C.	1987	Metabolism of [Triazine-2- 14C] DPX-M6316 in field grown wheat: radioactive residues in forage and straw DuPont Experimental Station, Wilmington, Delaware, USA AMR 794-87 GLP: No Published: No	N	N	-	DuPont
KCA 6.2.1/10	Steveson I.E..	1986	Metabolism of [Thiophene-2- 14C] DPX-M6316 in field grown wheat: radioactive residues in forage and straw DuPont Experimental Station, Wilmington, Delaware, USA AMR 783-87 GLP: No Published: No	N	N	-	DuPont
KCA 6.2.1/11	Friedman P.L. and Stevenson I.E	1986	Metabolism of [Thiophene-2- 14C] DPX-M6316 in field grown wheat: radioactive residues in mature grain DuPont Experimental Station, Wilmington, Delaware, USA AMR 498-86 GLP: No Published: No	N	N	-	DuPont
KCA 6.2.1/12	Friedman P.L. and Lichtner F.T.	1986	Metabolism of [Triazine-2- 14C] DPX-M6316 in field grown wheat: radioactive residues in mature grain DuPont Experimental Station, Wilmington, Delaware, USA AMR 513-86 GLP: No	N	N	-	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Published: No				
KCA 6.2.1/13	Wittenbach V.A.	1987	Metabolism of [thiophene-2- 14C] DPX-M6316 and [triazine-2-14C] DPX-M6316 in field –grown corn DuPont Experimental Station, Wilmington, Delaware, USA AMR 532-86 GLP: No Published: No	N	N	-	DuPont
KCA 6.2.2-6.2.5/01	[redacted]	1994	Metabolism of Dicamba in lactating goats SAN837/5286 ! 5286 ! 28 ! 480065 ! DP-301499 [redacted] GLP: Yes Published: No	Y	N	-	SYD
KCA 6.2.2-6.2.5/02	[redacted]	1994	Dicamba: Metabolism in laying hens SAN837/5285 ! 5285 ! 25 ! 480065 ! DP301493 [redacted] GLP: Yes Published: No	Y	N	-	SYD
KCA 6.2.2-6.2.5/03	[redacted]	1980	Metabolic fate of the herbicide Dicamba in a lactating cow CBK 101'296/87 ! SAN837/5145 GLP: No Published: No	Y	N	-	SYD
KCA 6.2.2-6.2.5/04	[redacted]	1983	Pharmacokinetics and metabolism of 14C-Dicamba in hens SAN837/5254 ! CBK 12 144/88 ! 480068 ! 65 ! DP 302659 ! CBK 101 428/87 [redacted] GLP: No Published: No	Y	N	-	SYD
KCA 6.2.2-6.2.5/05	[redacted]	1986	Goat metabolism study of ^{14}C-DPX-M6316 AMR 326-85 GLP: No Published: No	Y	N	-	DuPont
KCA 6.2.2-6.2.5/06	[redacted]	1992	Metabolism of ^{14}C-DPX-M6316 in laying hens AMR-2022-91 GLP: No Published: No	Y	N	-	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.5.1	Grout, S. J.	2003	Aqueous hydrolysis at 90, 100 & 120°C. SAN837/6087 ! 6087 ! RJ3333B Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No	N	N	-	SYD
KCA 6.6.1/01	Moore, P. A.; Butz, R. G.	1989	Confined accumulation studies of Dicamba on rotational crops after spring application SAN837/5108 ! CBK 13'004/89 ! 16 ! 480065 ! DP 302788 Novartis Crop Protection AG, Basel, Switzerland GLP: No Published: No	N	N	-	SYD
KCA 6.6.1/02	Pierotti, M. V.	1995	Confined accumulation studies of Dicamba on rotational crops SAN837/5282 ! 5282 ! 22 ! DP 301712 ! 480065 Novartis Crop Protection AG, Basel, Switzerland GLP: Yes Published: No	N	N	-	SYD
KCA 6.6.1/03	Hardesty P.T	1984	Crop rotation studies with DPX-M6316 [Thiophene-2- 14C] in the greenhouse DuPont Experimental Station, Wilmington, Delaware, USA AMR 256-84 GLP: No Published: No	N	N	-	DuPont
KCA 6.6.1/04	Brown A.M	1987	Greenhouse accumulation study of [triazine-2- 14C]DPX-M6316 on rotational crops DuPont Experimental Station, Wilmington, Delaware, USA AMR 582-86 GLP: No Published: No	N	N	-	DuPont
KCA 6.6.1/05	Ferguson E.M.	1992	Confined Accumulation Study of 14C-DPX-M6316 on Wheat as a Rotational Crop DuPont Experimental Station, Wilmington, Delaware, USA AMR 858-87 GLP: No Published: No	N	N	-	DuPont
DICAMBA – Method of analysis							

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KIIA 4.2.1.2/05 DAR, 2007	Maffezoni M.	2004	Dicamba (SAN 837): Validation of Residue Method REM 193.01 in Corn, Rape Seed, Pasture and Oranges Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No SYN/DIC/03041 GLP Not Published Syngenta File N° SAN837/6146	N	N	-	SYNGENTA
KIIA 4.2.1.2/06 DAR, 2007	Steinhauer, S.	2004	Dicamba (SAN 837): Independent Laboratory Validation of Residue Method REM 193.01 for the determination of Dicamba (SAN837) and 5-OH Dicamba (NOA 405873) in Maize (Grain) and Pasture Syngenta Crop Protection AG, Basel, Switzerland Dr. Specht & Partner Chem. Laboratorien GmbH, Hamburg, Germany, Report No ADE-0402V Az. G04-0039 GLP Not Published Syngenta File N° SAN837/6260	N	N	-	SYNGENTA
KIIA 4.2.2 DAR, 2007	Gasser, A.	2000a	Determination of Parent Compound Dicamba and Metabolite Dichlorosalicylic Acid by Gas Chromatography (MSD) Novartis Crop Protection AG, Basel, Switzerland, Report No REM 193.02 GLP Not Published Syngenta File N° SAN837/5927	N	N	-	SYNGENTA
KIIA 4.2.2 DAR, 2007	Gasser, A.	2000b	Validation of Method REM 193.02 : Validation by Analysis of Soil Specimens Fortified with Dicamba (SAN 837) and its metabolite Dichlorosalicylic Acid (DCSA) and determination of Recoveries Novartis Crop Protection AG, Basel, Switzerland, Report No 301/00 GLP Not Published Syngenta File N° SAN837/5928	N	N	-	SYNGENTA

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
IIA 4.2.4 DAR, 2007	Kettner, R., Kara-pally, J.	1993	Determination of Dicamba in Air Novartis Crop Protection AG, Basel, Switzerland Sandoz AG, Basel, Switzerland, Report No 21401 GLP Not Published Syngenta File N° SAN837/5366	N	N	-	SYNGENTA
NICOSULFURON – Method of analysis							
IIA, 4.2.1/ 05 DAR 2006	Wolf, St.	2000	Development and validation of the residue analytical method for SL-950 (nicosulfuron) in maize (corn and straw). ISK RCC Ltd, report no. 793596, 2000-12-04 GLP, unpublished	N	N	-	ISK
IIA, 4.2.1/ 06 DAR 2006	Ginzburg, N.	2000	Independent laboratory validation (ILV) of the residue analytical method for SL-950 (nicosulfuron) in maize (corn and straw). ISK Battelle, report no. A-22-00- 04, 2000-12-20 GLP, unpublished	N	N	-	ISK
IIA, 4.2.2/ 01 DAR 2006	Wais, A.	2000a	Validation of the residue analytical method for SL-950 (nicosulfuron) in soil. ISK RCC Ltd, report no. 770117, 2000-05-03 GLP, unpublished	N	N	-	ISK
IIA, 4.2.3 Final ad-dendum to the DAR 2007	Wolf S.	2007	Development and validation of a residue analytical method for nicosulfuron in drinking water and surface water RCC Ltd Report: B25773 GLP: yes Published: No	N	N	-	Ishihara Sangyo Kaisha Ltd.
IIA, 4.2.2/ 01	Wais, A.	2000c	Validation of the residue analytical method for SL-950 (nicosulfuron) in air.	N	N	-	ISK

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
Final ad-dendum to the DAR 2007			ISK RCC Ltd, report no. 765358, 2000-05-17 GLP, unpublished				
THIFENSULFURON-METHYL - Method of analysis							
IIA, 4.7/01 RAR 2015	Bacher, R.	2001	Development and validation of analytical methods for the determination of seven sulfonylurea herbicides in air PTRL Europe DuPont-4560 GLP: Yes Published: No	N	N	-	DuPont
IIA, 4.7/01 RAR 2015	Sadgrove, L.	2012c	Thifensulfuron-methyl: Validation of Methodology for the Determination of Residues in Air. Huntingdon Life Sciences Ltd. EU TSM AIR 2 Task Force Report No. PII0023 and amendment 1 GLP, Unpublished	N	N	-	EU TSM AIR 2 Task Force
IIA, 4.5./01 RAR 2015	Devine, T.J., Jin, L.	2004	Analytical method for the determination and confirmation of 13 DuPont sulfonylurea herbicides in water using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-5491, Revision No. 1 **GLP: No** Published: No	N	N	-	DuPont
IIA, 4.5/04 RAR 2015	Pentz, A.M., Cabusas, M.E.Y.	2014	Analytical method for the determination and confirmation of 13 DuPont sulfonylurea herbicides in water using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-5491, Supplement No. 1 **GLP: No** Published: No	N	N	-	DuPont
IIA, 4.5/01 RAR 2015	Sadgrove, L.	2012b	Thifensulfuron-methyl and thifensulfuron-acid: Validation of Methodology for the Determination of Residues in Surface Water. Huntingdon Life Sciences Ltd. EU TSM AIR 2 Task Force Report No. PII0024 and amendment 1	N	N	-	EU TSM AIR 2 Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, Unpublished				
IIA, 4.5./02 RAR 2015	Henze, R.M., Stry, J.J	2013	Analytical method for the determination of thifensulfuron methyl in water using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-35704 GLP: No Published: No	N	N	-	DuPont
IIA, 4.5/03 RAR 2015	Mason, B.J.	2013	Independent laboratory validation of DuPont-35704, "Analytical method for the determination of thifensulfuron methyl in water using LC/MS/MS" Morse Laboratories, Inc. DuPont-36531 GLP: Yes Published: No	N	N	-	DuPont
IIA, 4.4./02 RAR 2015	Hill, S.J., Stry, J.J.	2001	Analytical method for the determination of 13 DuPont sulfonylurea herbicides in soil using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-5082, Revision No. 1 GLP: No Published: No	N	N	-	DuPont
IIA, 4.4/04 RAR 2015	Stry, J.J.	2013	Analytical method for the determination of 13 DuPont sulfonylurea herbicides in soil using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-5082, Revision No. 1, Supplement No. 1 GLP: No Published: No	N	N	-	DuPont
IIA, 4.3/03 RAR 2015	Sadgrove, L.	2012a	Thifensulfuron-methyl and thifensulfuron-acid: Validation of Methodology for the Determination of Residues in Soil. Huntingdon Life Sciences Ltd. EU TSM AIR 2 Task Force Report No. PII0022 and amendment 1 GLP, Unpublished	N	N	-	EU TSM AIR 2 Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
IIA, 4.3/05 RAR 2015	Charles, E., Doran, A.M.	2004	Independent laboratory validation of analytical method DuPont-13412 for the determination of Thifensulfuron-methyl, ethametsulfuron methyl, rimsulfuron, tribenuron methyl and chlorimuron ethyl in olives and soybean seed using SPE purification and LC/MS/MS detection Inveresk Research International (IRI) Limited (Scotland) DuPont-13398 GLP: Yes Published: No	N	N	-	DuPont
IIA, 4.3/07 RAR 2015	Devine, T.J., Nanita, S.C.	2007	Multiresidue analytical method for the determination of sulfonyurea herbicides in oily, watery, acidic and dry crops using SPE purification and LC/MS/MS detection DuPont Stine-Haskell Research Center DuPont-13412, Supplement No. 1 GLP: No Published: No	N	N	-	DuPont
IIA, 4.3/15 RAR 2015	Pentz, A.M., Bram-ble, F.Q.	2015	Analytical method for the determination of nicosulfuron, Thifensulfuron-methyl, ethametsulfuron methyl, rimsulfuron, tribenuron methyl, and chlorimuron ethyl in oily crop matrices using SPE purification and LC/MS/MS detection DuPont Stine-Haskell Research Center DuPont-13412, Revision No. 1 GLP: No Published: No	N	N	-	DuPont
IIA 4.3/16 RAR 2015	Pentz, A.M., Bram-ble, F.Q., Stry, J.J.	2011	Analytical method for the determination of thifensulfuron methyl and metabolites in crops using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-28527 GLP: No Published: No	N	N	-	DuPont
IIA 4.3/27 RAR 2015	Henze, R.M., Stry, J.J.	2014	Multiresidue analytical method for the determination of sulfonylurea herbicides in oily, watery, acidic and dry crops using SPE purification and LC/MS/MS detection. DuPont Stine-Haskell Research Center	N	N	-	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			DuPont-13412, Supplement No. 4, Revision No. 1 GLP: No Published: No				
IIA, 4.3/01 RAR 2015	Seck, C.	2008	Determination of Residues of Metsulfuron-methyl and Thifensulfuron-methyl in Cereal - Method Validation. Battelle UK Ltd. Rotam Report No. QG/07/021 GLP, Unpublished	N	N	-	DuPont
IIA, 4.3/02	Watson, G.	2010	Independent Laboratory Validation of the analytical procedure detailed in the study performed under Rotam ID Number 74-07-47 'Determination of residues of metsulfuron-methyl and Thifensulfuron-methyl in cereal – method validation'. Eurofins Agroscience Services Rotam Report No. S09-02905 GLP, Unpublished	N	N	-	DuPont
IIA, 4.3/23 Confirma-tory infor-mation RAR 2019	Schwartz, N.L.	2010c	Independent laboratory validation of "Enforcement method for the determination of Thifensulfuron-methyl, metsulfuron methyl and chlorsulfuron in milk and animal tissues" ABC Laboratories, Inc. (Missouri) DuPont-30911 GLP: Yes Published: No	N	N	-	DuPont
IIA, 4.3/06 RAR 2015, originally evaluated in 2001	de Bernard, P.A., Powley, C.R.	1993	Enforcement method for the determination of Thifensulfuron-methyl, metsulfuron methyl, and chlorsulfuron in milk and animal tissues DuPont Experimental Station AMR 2715-93 GLP: No Published: No	N	N	-	DuPont
IIA, 4.3/11 Confirma-tory infor-mation RAR 2019	Henze, R.M., Stry, J.J.	2007a	Analytical method for the determination of ten DuPont sulfonylurea herbicides in eggs using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-24187 GLP: No Published: No	N	N	-	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
IIA, 4.3/17 Confirma-tory infor-mation RAR 2019	Pentz, A.M., Cabusas, M.E.Y.	2014	Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS DuPont-30449 Supplement No. 1 DuPont Stine-Haskell Research Center GLP: No Published: No REGISTRATION REPORT Product code: GF-3969 (Poland - Dragster®) Part B, Section 5, Analytical Methods	N	N	-	DuPont
IIA, 4.3/22 Confirma-tory infor-mation RAR 2019	Schwartz, N.L.	2010b	Independent laboratory validation of "Analytical method for the determination of 13 DuPont sulfonylurea herbicides in skim milk, whole milk, and cream using LC/MS/MS" and "Analytical method for the determination of ten DuPont sulfonylurea herbicides in eggs using LC/MS/MS" ABC Laboratories, Inc. (Missouri) DuPont-30910 GLP: Yes Published: No	N	N	-	DuPont
IIA, 4.3/21 Confirma-tory infor-mation RAR 2019	Schwartz, N.L.	2010a	Independent laboratory validation of "Analytical method for the determination of 13 DuPont sulfonylurea herbicides in skim milk, whole milk, and cream using LC/MS/MS" and "Analytical method for the determination of ten DuPont sulfonylurea herbicides in eggs using LC/MS/MS" pertaining to: Independent laboratory validation of "Analytical method for the determination of 13 DuPont sulfonylurea herbicides in skim milk, whole milk, and cream using LC/MS/MS" ABC Laboratories, Inc. (Missouri) DuPont-30909 GLP: Yes Published: No	N	N	-	DuPont
IIA, 4.3/08 Confirma-tory infor-mation RAR 2019	Gant, A.G.	2012	Independent laboratory validation of DuPont-30449, "Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS" ABC Laboratories, Inc. DuPont-30450 GLP: Yes	N	N	-	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
			Published: No				
CP 5.2 Product code: GF-3969; Dragster®	Henze, R.M., Stry, J.J.	2016a	Analytical method for the determination of chlorsulfuron, metsulfuron methyl, thifensulfuron methyl and tribenuron methyl in plasma and urine by LC/MS/MS DuPont Stine-Haskell Research Center DuPont-47394 Not GLP Unpublished	N	N	-	DuPont

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KIIA 5.8	Matsumoto, K.	2004a	HMUD: Reverse mutation test Institute of Environmental Toxi-cology, Japan IET 04-0052 GLP: Yes Published: No	N	N	-	ISK Task Force Nicosulfuron

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KIIA 5.8	Matsumoto, K.	2004b	HMUD: Gene mutation test in mouse lymphoma cells Institute of Environmental Toxicology, Japan IET 04-0054 GLP: Yes Published: No	N	N	-	ISK Task Force Nicosulfuron
KIIA 5.8	Matsumoto, K.	2004c	HMUD: In vitro chromosome aberration test Institute of Environ-mental Toxicology, Japan IET 04-0053 GLP: Yes Published: No	N	N	-	ISK Task Force Nicosulfuron