

REGISTRATION REPORT

Part A

Risk Management

Product code: AMINO 30 SL

Product name(s): El Camino 30 SL, Ranchero 30 SL

Chemical active substance:

Aminopyralid, 30 g/L

Central Zone

Zonal Rapporteur Member State: PL

**NATIONAL ASSESSMENT Poland
(authorization)**

Applicant: Innvigo Sp. z o.o.

Submission date: 01/2025

zRMS Assessment: 18/04/2025

Following commenting period/Verification of reference list:
01/07/2025

Supplementary on crop rotation: 06/08/2025

Version history

When	What
April 2025	zRMS Assessment
July 2025	Following commenting period Verification of reference list
August 2025	Supplementary on crop rotation

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PART A

RISK MANAGEMENT

1 Details of the application

This document describes the acceptable use conditions required for zonal registration of AMINO 30 SL (El Camino 30 SL, Ranchero 30 SL) containing aminopyralid in POLAND (ZRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required by the EU review. It also includes assessment of data and information relating to AMINO 30 SL where that data has not been considered in the EU review. Otherwise assessments for the safe use of AMINO 30 SL have been made using endpoints agreed in the EU review of aminopyralid.

This document describes the specific conditions of use and labelling required for the registration of (El Camino 30 SL, Ranchero 30 SL), product code AMINO 30 SL.

1.1 Application background

This application was finalized by Innvigo Sp. z o.o. in January 2025. Innvigo Sp. z o.o. is a company located at Aleje Jerozolimskie 178, 02-486 Warsaw, Poland and registered in the Polish National Court Registry of entrepreneurs (KRS), with the number 0000540684 r .

The application is for the approval of AMINO 30 SL a soluble concentrate type formulation (SL) containing 30 g/L aminopyralid for use as a herbicide for winter oilseed rape. It is applied by spray once per season:

- winter oilseed rape: once per season at BBCH 10-18.

To obtain authorisation the product AMINO 30 SL must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed endpoints.

This application was submitted in order to allow the first authorisation of this product in Poland, in accordance with the above.

1.2 Letters of Access

Not relevant.

1.3 Justification for submission of tests and studies

In accordance with Art. 33 (3), the submitted studies presented in Appendix 4 are relevant and necessary to obtain the first authorisation the product AMINO 30 SL in Poland and other countries.

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	AMINO 30 SL
Product name in MS	El Camino 30 SL, Ranchero 30 SL
Authorization number	N/A
Function	herbicide
Applicant	Innvigo Sp. z o.o.
Active substance(s) (incl. content)	Aminopyralid; 30 g/L
Formulation type	Soluble concentrate [SL]
Packaging	<p>HDPE range from 250 ml – 22 L</p> <p>More specific:</p> <p>250 ml in HDPE bottle, 564 ml in HDPE bottle, 500 ml in HDPE bottle, 510 ml in HDPE bottle, 600 ml in HDPE bottle, 800 ml in HDPE jar, 800 ml in HDPE bottle, 1000 ml in HDPE bottle, 2000 ml in HDPE jar, 2000 ml in HDPE bottle, 3000 ml in HDPE container, 4000 ml in HDPE cannister, 5000 ml in HDPE container, 5000 ml in HDPE cannister, 5000 ml in HDPE bottle, 5850 ml±150 ml in HDPE container, 6000 ml in HDPE cannister, 10000 ml in HDPE container, 10000 ml in HDPE cannister, 11220±50 ml in HDPE container, 20000 ml in HDPE container, 20000 ml in HDPE cannister, 22000 ml in HDPE container, 22000 ml ± 50 ml in HDPE container.</p> <p>HDPE/PA:</p> <p>275 ml in HDPE/PA bottle, 323 ± 5 ml in HDPE/PA bottle, 574 ml in HDPE/PA bottle, 550 ml in HDPE/PA bottle, 1000 ml in HDPE/PA bottle, 1100 ml in HDPE/PA bottle, 5000 ml in HDPE/PA bottle,</p>

	5000 ml in HDPE/PA cannister, 5500 ml in HDPE/PA bottle, 5850 ml±150 ml in HDPE/PA bottle, 10000 ml ± 150 ml in HDPE/PA container. HDPE/F: 312 ± 12.5 ml in HDPE/F bottle, 318 ± 12.5 ml in HDPE/F bottle, 570 ± 12.5 ml in HDPE/F bottle, 575 ± 12.5 ml in HDPE/F bottle, 580 ± 12.5 ml in HDPE/F bottle, 585 ± 12.5 ml in HDPE/F bottle, 1150 ± 20 ml in HDPE/F bottle, 1160 ± 20 ml in HDPE/F bottle, 1170 ± 20 ml in HDPE/F bottle, 1185 ± 20 ml in HDPE/F bottle, 1200 ± 20 ml in HDPE/F bottle, 5880 ± 100 ml in HDPE/F cannister, 5950 ml ± 100 ml in HDPE/F bottle, 5950 ml ± 100 ml in HDPE/F cannister, 10 000 ml in HDPE/F cannister. HDPE/EVOH: 250 ml in HDPE/EOH bottle, 310 ml in HDPE/EOH bottle, 500 ml in HDPE/EOH bottle, 579 ml in HDPE/EOH bottle, 1000 ml in HDPE/EOH bottle, 1200 ± 50 ml in HDPE/EOH bottle, 5000 ml in HDPE/EOH container, 5650 ml in HDPE/EOH cannister, 10 000 ml in HDPE/EOH container, 20 000 ml in HDPE/EOH container.
Coformulants of concern for national authorizations	N/A
Restrictions related to identity	N/A
Mandatory tank mixtures	N/A
Recommended tank mixtures	N/A

2.2 Conclusion

The evaluation of the application for AMINO 30 SL resulted in the decision to grant the authorization.

The evaluator also verified whether the co-formulants contained in plant protection product El Camino 30 SL, Ranchero 30 SL (product code: AMINO 30 SL) 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 MSDS and other information provided by applicant or manufacturer of co-formulant, the product El Camino 30 SL, Ranchero 30 SL (product code: AMINO 30 SL) 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 El Camino 30 SL, Ranchero 30 SL (product code: AMINO 30 SL) 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.

2.3 Substances of concern for national monitoring

This point is not relevant for authorisation of AMINO 30 SL.

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:	Eye Dam. 1, H318; Aquatic Chronic 2, H411
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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:	GHS05, GHS09
Signal word:	Danger
Hazard statement(s):	H318 – Causes serious eye damage. H411 – Toxic to aquatic life with long lasting effects.
Precautionary statement(s):	P273 – Avoid release to the environment. P280 – Wear protective gloves/protective clothing /eye protection/face protection. P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 – Immediately call a POISON CENTER/doctor. P391 – Collect spillage.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Hazardous ingredients that must be listed on the label: 2-aminoethanol.

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:	
	Hazardous ingredients that must be listed on the label: 2-aminoethanol.

See Part C 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).
SPe 3	To protect non-target plants respect an unsprayed buffer zone of (1 m and use of 50% drift reducing nozzles or 5 m with no drift reducing technology 1 m and 90% drift reducing nozzles or 5 m and 50% drift reducing nozzles or 10 m with no drift reducing nozzles) to non-agricultural land/surface water bodies.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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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:	
	eye protection or face protection during Workwear at mixing and loading + Workwear at application for crop (due to the fact that the product is classified as Eye Dam. 1 H318)
Worker protection:	
	Workwear None
Integrated pest management (IPM)/sustainable use:	
	The risk of resistance is considered to be low and acceptable. The use of product needs to be implemented with IPM restrictions and recommendations from label.
Environmental protection	
SPe 3	To protect non-target plants respect an unsprayed buffer zone of (1 m and use of 50% drift reducing nozzles or 5 m with no drift reducing technology 1 m and 90% drift reducing nozzles or 5 m and 50% drift reducing nozzles or 10 m with no drift reducing nozzles) to non-agricultural land/surface water bodies.
Other specific restrictions	
Bystander/Resident	use 2-3 meters buffer zone None

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

Integrated pest management (IPM)/sustainable use:	
N/A	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorization is applied.

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):

Environmental protection:		Relevant for use no.
P273	Avoid release to the environment.	1
P391	Collect spillage.	1

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):		El Camino 30 SL, Ranchero 30 SL / AMINO 30 SL	Formulation type:	SL ^(a, b)	GAP rev. , date: year-month-day
Active substance 1:		aminopyralid	Conc. of as 1:	30 g/l ^(c)	
Active substance 2:		-	Conc. of as 2:	-	
Active substance....:		-	Conc. of as:	- ^(c)	
Safener:		-	Conc. of safener:	- ^(c)	
Synergist:		-	Conc. of synergist:	- ^(c)	
Applicant:		Innvigo Sp. z o.o.	Professional use:	<input checked="" type="checkbox"/>	
Zone(s):		central ^(d)	Non professional use:	<input type="checkbox"/>	
Verified by MS:		yes			

Field of use: herbicide

[illegible]

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L prod- uct / 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			
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty stor- age rooms)														
3														
4														
Minor uses according to Article 51 (zonal uses)														
5														
6														
Minor uses according to Article 51 (interzonal uses)														
7														
8														

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

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

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

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

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

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 that of homogenous red-orange clear liquid, with a delicate odour. It is not explosive, has no oxidising properties. The product is not flammable. It has not a self ignition temperature. In aqueous solution, it has a pH value around 8.56 at 8.66 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a *SL* formulation.

The intended concentration of use is 0.089% to 0.15%.

3.2 Efficacy (Part B, Section 3)

The Applicant has submitted data collected from 9 efficacy field trials in winter oilseed rape carried out in 2023 in the North-East EPPO zone within the Central registration zone to evaluate the efficacy of applied to the control dicotyledonous weeds in winter oilseed rape at the proposed label rate:

0.2-0.267 L/ha – postemergence application once a season, which are corresponding to 6-8.01 g a.s./ha (aminopyralid).

Trials were conducted in different regions in the North-East EPPO zone in Poland where winter oilseed rape are grown commercially.

Tested herbicide was applied at the growth stage in BBCH 10-18.

Details are provided in dRR Part B section 3 in KCP point 3.2 and KCP 6.2 point 3.2.3.

The submitted efficacy data (reports from 9 field trials) and additional information fulfill requirements and conditions determined in the following EPPO guidelines:

- PP 1/135 (4) Phytotoxicity assessment
- PP 1/152 (4) Design and analysis of efficacy evaluation trials
- PP 1/181 (5) Conduct and reporting of efficacy evaluation trials including good experimental practice

They were carried out on the field in the conditions of natural weeds infestation. The efficacy trials were concluded according to the EPPO standards:

- PP 1/049 (3) Weeds in brassica oil crops

The studies fulfil also requirements of the Commission Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products.

The formulation of Amino 30 SL is soluble concentrate (SL) and it comprises active substance aminopyralid 30 g/l . The applicant submitted 9 reports in total in winter oilseed rape showing the results in research into product efficacy carried out in 2023 in winter oilseed rape.

Details are provided in dRR Part B section 3 in KCP point 3.2 and KCP 6.2 point 3.2.3.

The obtained data in performed trials show that AMINO 30 SL provides benefits against the most important weeds in winter oilseed rape as shown in the tables below.

The following table describes the effectiveness of weeds

S (Susceptible)	> 85%
MS (Moderately Susceptible)	70 – 85%
MT (Moderately Tolerant)	60 – 70%
T (Tolerant)	< 60%

Dose 0.16 L/ha

Susceptible: *Centaurea cyanus* (CENCY), *Matricaria chamomilla* (MATCH), *Papaver rhoeas* (PAPRH), *Tripleurospermum inodorum* (MATIN),

Moderately Susceptible: *Viola arvensis* (VIOAR), *Capsella bursa-pastoris* (CAPBP).

Dose 0.2 L/ha

Susceptible: *Centaurea cyanus* (CENCY), *Matricaria chamomilla* (MATCH), *Papaver rhoeas* (PAPRH), *Tripleurospermum inodorum* (MATIN), *Capsella bursa-pastoris* (CAPBP), *Viola arvensis* (VIOAR).

Dose 0.267 L/ha

Susceptible: *Centaurea cyanus* (CENCY), *Matricaria chamomilla* (MATCH), *Papaver rhoeas* (PAPRH), *Tripleurospermum inodorum* (MATIN), *Capsella bursa-pastoris* (CAPBP), *Viola arvensis* (VIOAR).

Herbicide Amino 30 SL has demonstrated good crop tolerance to winter oilseed rape. Therefore concluded that Amino 30 SL is safe usage at proposed rate and this support the label claim for the use in winter oilseed rape.

Undesirable effects are not expected on succeeding crops, adjacent crop, part of plants used for propagating purposes and beneficial organisms.

According to the above, the plant protection product AMINO 30 SL can be approved to the market and use in Poland according to proposed range of use – GAP

Based on submitted data the following regulation on the label is proposed:

Poland:

Winter oilseed rape

Recommended dose at: once a season AMINO 30 SL 0.2-0.267 l/ha at BBCH 10-18.

Recommended volume of water 200-300 l/ha

Recommended medium droplet spraying

Use of AMINO 30 SL according to the proposed GAP does not represent a hazard to rotational crops and does not justify a specific labelling. AMINO 30 SL is not persistent in soil or is it taken up by succeeding crops.

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

Resistance Risk Assessment (*according to EPPO PP 1/213 (4) Resistance risk analysis*)

Mode of action

AMINO 30 SL is a herbicide containing active substance: aminopyralid 30 g/L, which belong to 4 (legacy O) HRAC group - Inhibition of pyridine-carboxylates.

Aminopyralid is a herbicidal active substance belonging to the chemical class of auxin mimics for the post-emergence control of dicotyledonous weed species. Aminopyralid is rapidly absorbed by plants via foliar uptake and translocated, accumulating in meristematic tissue. This active substance moves systemically throughout the plant and deregulates plant growth metabolic pathways affecting growth of the plant. This disruption of plant growth is achieved by binding of aminopyralid at receptor sites normally used by the natural growth hormones of target plant, which leads to its senescence. The symptoms are observable within hours or days after application, depending on the weed species. Impact of aminopyralid on target plants causes variety of symptoms such as thickened, curved and twisted stems and leaves, cupping and crinkling of leaves, stem breaking, narrowing of leaves, hardened stem growth, enlarged roots and proliferated growth.

Mechanism of resistance

AMINO 30 SL is a herbicide containing active substance: aminopyralid 30 g/L, which belong to 4 (legacy O) HRAC group - Inhibition of pyridine-carboxylates.

According to EPPO PP 1/213 (4) Resistance risk analysis weeds usually only produce one generation per year and development of resistance is usually a relatively slow process. It is difficult to class any weed species as inherently more or less likely to develop resistance to a particular herbicide.

Evidence of resistance

AMINO 30 SL is a herbicide containing active substance: aminopyralid 30 g/L, which belong to 4 (legacy O) HRAC group - Inhibition of pyridine-carboxylates. This group of herbicides is quite well known and has been applied commercially for decades.

According to the Herbicide Resistance Action Committee (HRAC) website www.weedscience.org, 89 cases of resistance in weeds to auxin mimics herbicides have been reported worldwide.

Weeds have also developed a resistance mechanism to aminopyralid. 2 cases of resistance were reported to *Papaver rhoeas* in France, 1 case of resistance was reported to *Amaranthus tuberculatus* in United States and 1 case of resistance was reported to *Chenopodium album* in New Zealand (Table 3.3-1).

Table 3.3-1. Reported cases of weed resistance to aminopyralid worldwide [www.weedscience.org].

Year	Species	Country	MOAs	Actives
2005	<i>Chenopodium album</i>	New Zealand	Auxin Mimics (O/4)	aminopyralid, clopyralid, dicamba
2009	<i>Amaranthus tuberculatus</i>	United States	Auxin Mimics (O/4), ALS inhibitors (B/2), PSII inhibitors (C1 C2/5)	2,4-D, aminopyralid, atrazine, chlorimuron-ethyl, imazethapyr, picloram
2015	<i>Papaver rhoeas</i>	France	Auxin Mimics (O/4)	2,4-D, aminopyralid
2016	<i>Papaver rhoeas</i>	France	Auxin Mimics (O/4), ALS inhibitors (B/2)	2,4-D, aminopyralid, iodosulfuron-methyl-Na, MCPA, mesosulfuron-methyl, metsulfuron-methyl

According to the Aminopyralid DAR_03_Vol_3_B1-B5_public.pdf

Aminopyralid is the amino analogue of clopyralid, belonging to the pyridine carboxylic acid group of herbicides, a well-established mode of action. Other pyridine carboxylic acid herbicides such as fluroxypyr, clopyralid, and triclopyr have been used in agriculture over a long period of time, but as yet, there have been no reported field cases of resistance. Overall, the inherent risk for the use of aminopyralid may be considered to be low.

Cross-resistance

According to <https://hracglobal.com/files/Herbicide-Cross-Resistance-and-Multiple-Resistance-in-Plants.pdf>

Cross resistance is defined as the expression of a genetically-endowed mechanism conferring the ability to withstand herbicides from different chemical classes. There are two broad cross resistance categories; target site cross resistance and non-target site cross resistance.

According to <https://hracglobal.com/files/Weed-Resistance-to-Synthetic-Auxin-Herbicides.pdf>

In range of global view, the most important synthetic auxin resistant weeds are *Kochia scoparia*, *Raphanus raphanistrum*, *Sinapis arvensis* and *Papaver rhoeas*. The risk of additional herbicide-resistant biotypes developing with altered target sites is considered to be low. The complex interaction with the auxin perception and responsive pathway makes resistance through overexpression of the target proteins posing a low probability (Busi, Roberto, et al. 2018).

Since there are only 4 evidences of resistance to aminopyralid, it can be stated that AMINO 30 SL has low resistance occurrence potential, however the awareness of full support of implementation of best herbicide resistance management practices needs to be kept.

Sensitivity data

The Applicant did not conduct separate trials for sensitivity data, this data was evaluated in efficacy trials. The 9 field post-emergence trials were established in order to determine the sensitivity of weeds in winter oilseed rape. AMINO 30 SL was tested at doses: 0,16, 0,2 to 0,267 L/ha (4,8-8,01 g of active substance) in winter oilseed rape for the control of dicotyledonous weeds. Detailed studies on the weeds sensitivity are submitted and summarised in 3.2 Efficacy data (KCP 6.2).

Use pattern

Herbicide AMINO 30 SL has demonstrated good crop tolerance to winter oilseed rape. Therefore concluded that AMINO 30 SL is safe usage at proposed rate and this support the label claim for the use in winter oilseed rape.

Undesirable effects are not expected on succeeding crops, adjacent crop, part of plants used for propagating purposes and beneficial organisms.

Based on submitted data the following regulation on the label is proposed:

in winter oilseed rape in autumn, applied once per season post-emergence BBCH 10-18:

- solo at the dose range 0,2-0,267 L/ha which are corresponding to 6-8,01 g a.s./ha of aminopyralid per application for the control of most important weed species.

The product AMINO 30 SL should be used once per season in autumn post-emergence of crop and weeds. To avoid resistance, products contain active substance with the same group should not be used year after year on the same field.

Recommended volume of water 200-300 L/ha

Recommended medium droplet spraying

Resistance risk assessment of unrestricted use pattern

According to EPPO PP 1/213 (4) Resistance risk analysis weeds usually only produce one generation per year and development of resistance is usually a relatively slow process. In case of aminopyralid the cross resistance is relatively low, with 4 cases of resistance have been recorded, it is considered reasonable that no specific resistance management strategy will be required. However, to avoid the development of resistance, the user must follow the general principles of integrated pest management and the label of the plant protection product.

Test methods

Not applicable

Acceptability of the resistance risk

AMINO 30 SL is herbicide containing active substance: aminopyralid 30 g/L, which belongs to 4 (legacy O) HRAC group - Inhibition of pyridine-carboxylates. This group of herbicides is quite well known and has been applied commercially for decades.

According to the Herbicide Resistance Action Committee (HRAC) website www.weedscience.org, 4 cases of resistance in weeds were reported worldwide in use of aminopyralid.

According to EPPO PP 1/213 (4) Resistance risk analysis weeds usually only produce one generation per year and development of resistance is usually a relatively slow process.

In conclusion, in the Applicant's opinion, this level of weeds resistance risk should be considered to be acceptable, provided always that the provisions on the label are followed.

Management strategy

According to *Herbicide Resistance Action Committee (HRAC)* (<https://hracglobal.com/prevention-management/best-management-practices>)

Integrated Weed Management (IWM) refers to using chemical, cultural, mechanical and biological methods, in an integrated fashion, to control weeds. It does not rely excessively on any one method. When used in a integrated approach, the following tools help reduce selection pressure and survival of resistant weeds.

- Chemical - Applying herbicides to a crop.
- Mechanical - Includes measures such as hand-weeding using cultivation or ploughing to control emerged plants and bury non-germinated seed. It also includes harvest weed seed destruction such as stubble burning and cutting for hay or silage to prevent the weeds from setting seed.
- Cultural - Includes altering the crop planting date, row spacing and harvest timing to disrupt the weed cycle. It also includes planting crops that can out-compete weeds, buying certified seed that's free of weeds and using a diverse crop rotation. Growers should also sanitize farm equipment when moving between fields.
- Biological - Includes introducing insects and pathogens that control target weed species and introducing post-harvest grazing of growing weeds.

Using a diversified crop rotation allows farmers to use these different weed techniques. Avoid successive crops that use herbicides with the same mechanism of action to control the same weed species in the same field.

Guidelines for the sustainable use of herbicide site of action groups:

- Use mixtures or sequential treatments of herbicides having different sites of action. Each herbicide in the mixture should target the same weed species.
- Consider all chemical control options before planting, in-crop and after harvest.

- Avoid continued use of the same herbicides, or herbicides with the same site of action in the same field, unless integrated with other weed control practices.
- Limit the number of applications of a single herbicide or herbicides with the same site of action in a single growing season.
- Herbicide mixtures and herbicide rotations alone are not enough to prevent resistance. They must be used in a diversified plan than also incorporates mechanical, cultural and biological practices.

Growers should also do the following:

- Follow label use instructions, such as application rates, timing and equipment recommendations.
- Know the weeds in their fields and nearby non-crop areas and tailor their weed control program to weed densities and economic thresholds.
- Monitor herbicide results and be aware of any trends or changes in weed populations.
- Maintain detailed field records to confirm cropping and herbicide history.

Implementation of the management strategy

The herbicide label provides all the necessary information for preventing weed resistance to herbicides.

Monitoring, reporting and reaction to changes in performance

According to <https://hracglobal.com/files/Monitoring-and-Mitigation-of-Herbicide-Resistance.pdf>

Managing the risk of herbicide resistance (HR) is an area of strategic importance for leading herbicide technology providers and is the focus of the Global Herbicide Resistance Action Committee (HRAC), an organization comprised of 8 major companies working as a part of Crop Life International. Early detection of HR, understanding the scope of HR in a defined area, and potential mitigation of resistance through efforts to limit its spread are important aspects of managing the risk of HR. Monitoring for HR populations has been employed by public and private weed scientists for both early detection and defining the scope of resistance. The primary methods used to monitor for resistance include:

- 1) field surveys where seed from putative resistant plants are collected and tested in a controlled environment using bioassay procedures,
- 2) market research surveys of farmers and weed management experts, and
- 3) tracking farmer performance inquiries with appropriate follow up field evaluation and testing.

The most common monitoring method is the use of field surveys designed to either qualitatively (i.e., determine whether the level of resistance is high, medium, or low) or quantitatively (i.e., determine the area infested with HR populations) define existing HR. The primary method to detect resistance in new species and in new geographies is to track farmer performance inquiries. Once resistance is detected, steps may be taken to mitigate its impact. A critical aspect to mitigation is the implementation of best management practices (BMPs) which is facilitated by effective education and training programs. Education efforts can be enhanced with information obtained from monitoring studies and early detection of resistant populations using appropriate monitoring methods can improve the outcome of mitigation efforts.

3.2.2 Adverse effects on treated crops

The selectivity trials in winter oilseed rape have been carried out in 2023 in Poland on a wide range of commercially grown varieties. There were not observed any phytotoxicity symptoms on tested product in trials except one trial where phytotoxicity symptoms were transient.

The herbicide AMINO 30 SL has demonstrated crop tolerance to winter oilseed rape. Therefore concluded that AMINO 30 SL is safe usage at proposed rate 0.2-0.267 L/ha and this supports the label claim for the use in winter oilseed rape. Undesirable effects are not expected on succeeding crops, adjacent crop, part of plants used for propagating purposes and beneficial organisms.

Details will be provided in the dRR Part B Section 3 KCP 6.4 point 3.4.

Conclusions of the evaluator.

This document summarises information related to the efficacy of the plant protection product AMINO 30 SL, supporting its registration process under Article 33 of Regulation (EC) No. 1107/2009. Poland is the zonal Rapporteur Member State (zRMS), and there are no concerned Member States. AMINO 30 SL is a soluble concentrate formulation (SL) containing 30 g/L aminopyralid. It is proposed for use as a post-emergence (BBCH 10–18) agricultural herbicide in winter oilseed rape. AMINO 30 SL has a proposed maximum individual dose of 0.267 L/ha (delivering 8.01 g a.s./ha aminopyralid) and is applied with a water volume of 200–300 L/ha. Only one application may be made per crop and season.

Preliminary range-finding tests

Preliminary range-finding tests are not required since AMINO 30 SL contains aminopyralid which is existing active substance. The evaluator supports this statement.

Minimum effective dose

To determine the minimum effective dose, efficacy trials were conducted at three rates: the full rate of 0.267 L/ha and two reduced rates – 0.2 L/ha (the lowest recommended rate) and 0.16 L/ha (equivalent to 0.60N). For weeds such as CAPBP, CENCY, MATCH, PAPRH, VIOAR, and MATIN, the 0.2 L/ha and 0.267 L/ha rates provided optimal control, with the full rate (0.267 L/ha) being the most effective. The test results presented by the applicant clearly indicate that a dose of 0.2 L/ha may be sufficient under optimal conditions (e.g., low weed pressure, favourable environmental conditions, or the presence of less sensitive weed species). In such cases, the lower rate may still provide acceptable control. Therefore, the requested dose of 0.2 L/ha can be considered the minimum effective rate and is justified.

Efficacy tests

AMINO 30 SL demonstrated a very high level of efficacy across all dose rates, with mean control exceeding 85% against major broad-leaved weeds such as CENCY and MATIN, as well as minor weeds including CAPBP, MATCH, PAPRH, and VIOAR in winter oilseed rape. For all tested weed species, the 0.267 L/ha dose of AMINO 30 SL performed comparably to the reference product, Runway, applied at the same rate (0.267 L/ha). Notably, under optimal climatic conditions and lower weed pressure, even a reduced dose of AMINO 30 SL may provide sufficient efficacy.

Resistance risk assessment

In terms of resistance risk, the evaluator concludes that the risk of resistance developing to aminopyralid from the proposed use of AMINO 30 SL is low to moderate. The resistance management strategy proposed by the applicant is considered to be acceptable to reduce the risk of resistance development.

Adverse effects on treated crops

Specific selectivity trials were conducted in weed free conditions to assess the crop safety of AMINO 30 SL. The phytotoxicity data indicate that the proposed uses are unlikely to cause significant injury to the crops. Any damage observed tended to be minor and/or transient. Additionally, these trials demonstrate that the uses of AMINO 30 SL are unlikely to have a negative impact on the yield or yield quality.

Observations on other undesirable or unintended side-effects

The applicant provided acceptable risk assessments in accordance with EPPO to consider the risk to both succeeding and adjacent crops. The evaluator considers that restrictions are necessary for following crops in normal rotation and in crop failure situations following an application of AMINO 30 SL. The evaluator considers that the following is supported as part of this core assessment;

- **Crop Failure:**

In the event of crop failure, oilseed rape, cereals, and maize may be sown after cultivating the soil to a depth of 5 cm. Alternatively, vegetables, root vegetables, bulbs, legumes, and other root crops may be sown 110 days after the application of AMINO 30 SL, provided the soil is cultivated to a depth of 5 cm.

- **Rotational Crops:**

If the crop is harvested as normal, all crops may be sown after cultivating the soil to a depth of 5 cm, except for oilseed rape, which may be sown even without soil cultivation.

3.2.3 Observations on other undesirable or unintended side-effects

No phytotoxic effects were observed in the commissioned trials. Tested herbicides did not influence on yield, weight of 1000 grains, oil content it is expected the product is safe for plants of adjacent crops. Amino 30 SL effectively controlled dicotyledons plants therefore users must exercise caution to avoid drift or vapors which may cause discoloration and damage to non-target foliage.

Details will be provided in the dRR Part B Section 3 KCP 6.5 point 3.5.

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarized in Part B, Section 9 (Ecotoxicology).

3.3 Methods of analysis (Part B, Section 5)

Analytical methods for determination of aminopyralid and their relevant impurities and relevance of CI-PAC methods in AMINO 30 SL were not evaluated as part of the EU review of aminopyralid. Therefore all relevant data are provided and are considered adequate.

3.3.1 Analytical method for the formulation

An overview on the acceptable methods and possible data gaps for analysis of aminopyralid in plant protection product is provided as follows:

The method for determination of active substances and its relevant impurities in AMINO 30 SL preparation is specific. The validation parameters for linearity, instrument precision, repeatability and accuracy are within the acceptance range.

3.3.2 Analytical methods for residues

In the context of this submission sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

With regard to selectivity, accuracy and precision, the analytical methods were applied successfully for each analytical set when analysing the specimens of the study.

3.4 Mammalian toxicology (Part B, Section 6)

Based on available data AMINO 30 SL should be classified as Eye Dam. 1 H318. According to model calculations it can be concluded that the risk of operator exposure during mixing & loading and application of AMINO 30 SL is acceptable under conditions of intended use without PPE.

Due to the classification of AMINO 30 SL the operator should wear eye protection or face protection during mixing/loading.

According to the model calculations, it can be concluded that the risk of worker exposure during re-entry activities on area treated with AMINO 30 SL is acceptable under conditions of intended uses without PPE.

3.4.1 Acute toxicity

AMINO 30 SL was not a representative formulation reviewed during the Annex I inclusion/active substances renewal and was not previously evaluated in any EU countries. For the product registration no experimental acute toxicity data are available. An assessment of acute toxicity including irritancy and skin sensitisation properties of AMINO 30 SL has been conducted by the applicant based on the alternative method (calculation) according to the Regulation (EC) 1272/2008. Classification of all relevant ingredients were considered by the applicant. Details of the calculation can be found in Part C. Based on available data AMINO 30 SL should be classified as Eye Dam. 1 H318. Proposed classification based on alternative method according to Regulation (EC) 1272/2008 is acceptable.

~~The skin irritation, eye damage and inhalation acute toxicity of AMINO 30 SL properties have been estimated in part C of draft registration report by calculation methods based on the classification and content of product ingredients as recommended in Regulation (EC) No 1272/2008. The method and results of estimation are acceptable.~~

3.4.2 Operator exposure

Operator exposure

According to the OPEX version 1.0.2 calculations it can be concluded that the risk for the operator exposure during mixing & loading and application of AMINO 30 SL is acceptable under conditions of intended use without with PPE i.e. work wear during mixing & loading and application step.

Due to the fact that the product is classified as Eye Dam. 1 H318 the operator should wear eye protection or face protection during mixing/loading.

3.4.3 Worker exposure

Worker exposure

~~The worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL for aminopyralid will not be exceeded under conditions of intended uses provided that the worker is using protective clothes.~~

According to OPEX version 1.0.2 calculations, it can be concluded that the risk of worker exposure during re-entry activities on area treated with AMINO 30 SL is acceptable under conditions of intended use without PPE, but the worker should wear an adequate workwear within good agricultural practice. As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

3.4.4 Bystander and resident exposure

According to the OPEX version 1.0.2 calculations, it can be concluded that the risk for the bystanders and residents is acceptable.

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

3.5.1 Residues

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for Aminopyralid of 0.05 mg/kg for oilseed rape as laid down in Reg. (EU) 2021/1841 is not expected. The chronic and the short-term intakes of aminopyralid residues are unlikely to present a public health

concern.

3.5.2 Consumer exposure

The proposed uses of aminopyralid in the formulation AMINO 30 SL do not represent unacceptable acute and chronic risks for the consumer.

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

No new studies are presented; all data were reviewed in the EU review of aminopyralid. The appropriate endpoints from the EU review were used to calculate predicted environmental concentrations for AMINO 30 SL, aminopyralid in soil, surface water, ground water and air for the intended use patterns.

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

The PEC_s of aminopyralid in soil have been assessed with the DT₅₀ values established in the EU review. Based on the recommended use rate of Aminopyralid.

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

The PEC_{gw} values for active substance were below the trigger value of 0.1 µg/L for relevant Central Zone scenarios apart Piacenza scenario if formulation is used every other year. For Member States where Piacenza scenario is relevant the acceptable dose of aminopyralid is 6.0 g a.s/ha every other year or 8.01 g a.s/ha every third year.

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

The PEC surface water of aminopyralid in surface water (PEC_{sw} and PEC_{sed}) have been assessed using the FOCUS SW models and the DT₅₀ water/sediment values established in the EU review.

Based on the maximum recommended use rate of 8.01 g aminopyralid/ha the maximum PEC values for surface water and sediment have been calculated according to FOCUS Steps 1-2 for the parent.

PEC_{sw} of AMINO 30 SL for winter oil seed rape was calculated using the Drift calculator into surface water from SWASH ver. 5.3. The mitigation measures are not necessary.

The results for PEC surface water for the active substances were used for the ecotoxicological risk assessment.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

AMINO 30 SL poses no unacceptable risk to birds and mammals while used according to the label.

3.7.2 Effects on aquatic species

The relevant predicted environmental concentrations in water (PEC_{sw}) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate). The initial risk assessment was based on the worst case PEC_{sw} values and the results of laboratory toxicity testing. The PEC_{sw} Step 1-2 (for active substance) were used.

AMINO 30 SL applications close to surface water pose acceptable risk to aquatic organisms without the need for appropriate risk mitigation measures.

The product AMINO 30 SL is classified as **Aquatic Chronic 2, H411**.

3.7.3 Effects on bees

The evaluation of the acute risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SAN-CO/10329/2002 rev.2 (final), October 17, 2002).

AMINO 30 SL poses no unacceptable risk to bees according to the label.

The data requirements in accordance with Commission Regulation (EU) No 284/2013 for the chronic toxicity to adult honeybees and honeybee larvae are fulfilled.

3.7.4 Effects on other arthropod species other than bees

Based on the results of the conducted risk assessments it can be concluded that low risk for non-target arthropods is expected from the use of AMINO 30 SL according to the proposed use pattern. No unacceptable effects on non-target arthropods are expected in in-field and off-field habitats. No mitigation measures are required.

3.7.5 Effects on soil organisms

AMINO 30 SL poses no unacceptable risk to non-target soil meso- and macrofauna and microbial activity according to the label.

3.7.6 Effects on non-target terrestrial plants

AMINO 30 SL poses no unacceptable risk to non-target terrestrial plants according to the label with appropriate buffer zone (1m and use of 50% drift reducing nozzles or 5m with no drift reducing technology 1 m and 90% drift reducing nozzles or 5 m and 50% drift reducing nozzles or 10 m with no drift reducing nozzles to non-agricultural land).

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.8 Relevance of metabolites (Part B, Section 10)

The metabolites of aminopyralid are not predicted to occur in groundwater at concentrations above 0.1 µg/L (see PART B Section 8 of AMINO 30 SL).

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

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Załącznik do zezwolenia MRiRW nr R- / z dnia . . . r.

Posiadacz zezwolenia:

INNVIGO Sp. z o.o., Al. Jerozolimskie 178, 02 - 486 Warszawa, tel. +48 22 468 26 70, e -
mail: biuro@innvigo.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

...

EL CAMINO 30 SL

Środek przeznaczony do stosowania przez użytkowników profesjonalnych.

Zawartość substancji czynnej:


aminopyralid (związek z grupy pochodnych kwasów pirydynokarboksylowych) - 30 g/l (2,95%)

Inne substancje niebezpieczne, niebędące substancją czynną:

2-aminoetanol.

W celu ochrony wód gruntowych środków zawierających substancję czynną aminopyralid nie stosować jesienią częściej niż co dwa lata na tym samym obszarze.

Zezwolenie MRiRW nr R - / z dnia . . . r.

	
Niebezpieczeństwo	
H318 H411	Powoduje poważne uszkodzenie oczu. Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P273 P280 P305+P351+P338	Unikać uwolnienia do środowiska. Stosować rękawice ochronne/odzież ochronną ochronę oczu/lub ochronę twa- rzy.
P310 P391	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem. Zebrać wyciek

OPIS DZIAŁANIA

Herbicyd, selektywny o działaniu układowym, stosowany nalistnie, występujący w formie koncentratu rozpuszczalnego w wodzie (SL). Zgodnie z klasyfikacją HRAC substancja czynna aminopyralid zaliczona jest do grupy O.

DZIAŁANIE NA CHWASTY

Środek pobierany jest poprzez liście i korzenie kiełkujących chwastów, a następnie szybko przemieszczany w roślinie do stref wzrostowych rośliny. Substancja czynna aminopyralid powoduje blokadę auksyn, tj. hormonów roślinnych odpowiedzialnych za wzrost roślin. Ponadto, zakłóca proces oddychania na poziomie komórkowym. Pierwszym objawem działania herbicydu jest zahamowanie wzrostu, następnie chwasty ulegają deformacji, powstają chlorozy prowadzące do nekroz i zamierania.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

Dawka 0,2-0,267 l/ha

Chwasty wrażliwe	<i>chaber bławatek, fiołek polny, mak polny, maruna bezwonna, rumianek pospolity, tasznik pospolity</i>
------------------	---

Po zastosowaniu środka EL CAMINO 30 SL, środki zawierające substancję aminopyralid można zastosować na tym samym polu najwcześniej za 2 lata.

Rzepak ozimy

Chwasty dwuliścienne

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,267 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,2-0,267 l/ha.

Termin stosowania: powschodowo od fazy w pełni rozwiniętych liścieni do fazy ośmiu liści właściwych (BBCH 10 - 18), na chwasty znajdujące się w fazie liścieni do 4 liści właściwych.

Zalecana ilość wody: 200 – 300 l/ha

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

NASTĘPSTWO ROŚLIN

Na polu, na którym zastosowano środek, po zbiorze rzepaku ozimego można uprawiać rzepak ozimy bez konieczności wykonania orki zaś wszystkie pozostałe rośliny można uprawiać po uprzednim wykonaniu orki gleby na głębokość 5 cm.

W przypadku wcześniejszego zaorania plantacji potraktowanej środkiem (w wyniku uszkodzenia roślin przez przymrozki, mrozy, choroby lub szkodniki) na polu tym można uprawiać:

- rzepak ozimy i jary ~~bez potrzeby~~ po wykonaniu orki na głębokość 5 cm,
- zboża i kukurydzę ~~bez potrzeby~~ po wykonaniu orki na głębokość 5 cm, jednak nie wcześniej niż po 90 dniach po zastosowaniu środka,
- ~~wszystkie rośliny uprawne bez potrzeby po wykonywaniu orki, jednak nie wcześniej niż po 4 miesiącach od zastosowania środka.~~
- warzywa korzeniowe, rośliny cebulowe, rośliny strączkowe po upływie 110 dni od zastosowania środka i wykonaniu orki na głębokość 5 cm.

Po jesiennym zastosowaniu środka w normalnym płodozmianie roślinami następczymi mogą być:

- jesienią następnego roku kalendarzowego - zboża, rzepak ozimy

– wiosną kolejnego roku kalendarzowego - wszystkie rośliny.

Środek El Camino 30 SL zawarty w resztkach poźniwnych rzepaku (słoma, ściern) ulega rozkładowi mikrobiologicznemu dopiero po ich wymieszaniu z glebą. Słoma pochodząca z roślin opryskanych środkiem El Camino 30 SL musi pozostać na polu. Nie wolno jej zbierać i wywozić z pola, ani przeznaczać na paszę dla zwierząt. Należy rozdrobnić słomę i wymieszać z glebą wszystkie części traktowanych roślin rzepaku pozostałe po zbiorze rzepaku, włącznie z ściernią, najszybciej jak to możliwe, najpóźniej wczesną jesienią.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

Nie dotyczy.

1.Strategia zarządzania odpornością.

Aby zminimalizować ryzyko wystąpienia i rozwoju odporności chwastów:

- postępuj zgodnie z zaleceniami zawartymi w etykiecie środka ochrony roślin,
- stosuj środek w zalecanej dawce, w zalecanym terminie zapewniającym najlepsze efekty zwalczania chwastów,
- dostosuj zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- używaj różnych metod kontroli zachwaszczenia, w tym zmianowanie upraw, itp.,
- stosuj rotację i/lub mieszanki herbicydów o odmiennym mechanizmie działania,
- stosuj w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów,
- stosuj herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
- informuj posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
- w celu uzyskania szczegółowych informacji skontaktuj się z doradcą lub z producentem środka ochrony roślin.

2. Warunki stresowe (długotrwała susza, spadki temperatury poniżej 5 °C, przymrozki) w trakcie lub po zastosowaniu środka mają negatywny wpływ na działanie herbicydu, które mogą czasami powodować niewielkie i przejściowe zahamowanie wzrostu, i deformacje liści rzepaku, które nie wpływają negatywnie na proces kwitnienia, dojrzewania, wylegania roślin rzepaku oraz na plon nasion i zawartość oleju.

3. Środka nie stosować:

- na rośliny mokre, chore i uszkodzone,
- w temperaturze powietrza poniżej 8° C i powyżej 25°C,
- w czasie nadmiernej suszy,
- po nocnych przymrozkach oraz przed spodziewanymi przymrozkami.

4. Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W

przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

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.

Uwaga:

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 niż zalecane.

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

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, **ochronę oczu lub twarzy** oraz odzież roboczą w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

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 strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

W celu ochrony roślin ~~oraz stawonogów~~ niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m i zastosowanie ~~50%~~ 90% redukcji dysz lub 5 m i zastosowanie 50% redukcji dysz lub 10 m bez redukcji dysz od terenów nieużytkowanych rolniczo.

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.

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 zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. Natychmiast skontaktować się z ośrodkiem za-truć/lekarzem.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Załącznik do zezwolenia MRiRW nr R- / z dnia . . . r.

Posiadacz zezwolenia:

INNVIGO Sp. z o.o., Al. Jerozolimskie 178, 02 - 486 Warszawa, tel. +48 22 468 26 70, e -
mail: biuro@innvigo.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

...

RANCHERO 30 SL

Środek przeznaczony do stosowania przez użytkowników profesjonalnych.

Zawartość substancji czynnej:


aminopyralid (związek z grupy pochodnych kwasów pirydynokarboksylowych) - 30 g/l (2,95%)

Inne substancje niebezpieczne, niebędące substancją czynną:

2-aminoetanol.

W celu ochrony wód gruntowych środków zawierających substancję czynną aminopyralid nie stosować jesienią częściej niż co dwa lata na tym samym obszarze.

Zezwolenie MRiRW nr R - / z dnia . . . r.

	
Niebezpieczeństwo	
H318 H411	Powoduje poważne uszkodzenie oczu. Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P273 P280 P305+P351+P338 P310 P391	Unikać uwolnienia do środowiska. Stosować rękawice ochronne/odzież ochronną /ochronę oczu/ lub ochronę twarzy. W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem. Zebrać wyciek

OPIS DZIAŁANIA

Herbicyd, selektywny o działaniu układowym, stosowany nalistnie, występujący w formie koncentratu rozpuszczalnego w wodzie (SL). Zgodnie z klasyfikacją HRAC substancja czynna aminopyralid zaliczona jest do grupy O.

DZIAŁANIE NA CHWASTY

Środek pobierany jest poprzez liście i korzenie kiełkujących chwastów, a następnie szybko przemieszczany w roślinie do stref wzrostowych rośliny. Substancja czynna aminopyralid powoduje blokadę auksyn, tj. hormonów roślinnych odpowiedzialnych za wzrost roślin. Ponadto, zakłóca proces oddychania na poziomie komórkowym. Pierwszym objawem działania herbicydu jest zahamowanie wzrostu, następnie chwasty ulegają deformacji, powstają chlorozy prowadzące do nekroz i zamierania.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

Dawka 0,2-0,267 l/ha

Chwasty wrażliwe	<i>chaber bławatek, fiołek polny, mak polny, maruna bezwonna, rumianek pospolity, tasznik pospolity</i>
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Po zastosowaniu środka EL CAMINO 30 SL, środki zawierające substancję aminopyralid można zastosować na tym samym polu najwcześniej za 2 lata.

Rzepak ozimy

Chwasty dwuliścienne

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,267 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,2-0,267 l/ha.

Termin stosowania: powschodowo od fazy w pełni rozwiniętych liścieni do fazy ośmiu liści właściwych (BBCH 10 - 18), na chwasty znajdujące się w fazie liścieni do 4 liści właściwych.

Zalecana ilość wody: 200 – 300 l/ha

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

NASTĘPSTWO ROŚLIN

Na polu, na którym zastosowano środek, po zbiorze rzepaku ozimego można uprawiać rzepak ozimy bez konieczności wykonania orki zaś wszystkie pozostałe rośliny można uprawiać po uprzednim wykonaniu orki gleby na głębokość 5 cm.

W przypadku wcześniejszego zaorania plantacji potraktowanej środkiem (w wyniku uszkodzenia roślin przez przymrozki, mrozy, choroby lub szkodniki) na polu tym można uprawiać:

- rzepak ozimy i jary ~~bez potrzeby~~ po wykonaniu orki na głębokość 5 cm,
- zboża i kukurydzę ~~bez potrzeby~~ po wykonaniu orki na głębokość 5 cm, jednak nie wcześniej niż po 90 dniach po zastosowaniu środka,
- ~~wszystkie rośliny uprawne bez potrzeby po wykonywaniu orki, jednak nie wcześniej niż po 4 miesiącach od zastosowania środka.~~
- warzywa korzeniowe, rośliny cebulowe, rośliny strączkowe po upływie 110 dni od zastosowania środka i wykonaniu orki na głębokość 5 cm.

Po jesiennym zastosowaniu środka w normalnym płodozmianie roślinami następczymi mogą być:

- jesienią następnego roku kalendarzowego - zboża, rzepak ozimy
- wiosną kolejnego roku kalendarzowego - wszystkie rośliny.

Środek Ranchero 30 SL zawarty w resztkach poźniwnych rzepaku (słoma, ściern) ulega rozkładowi mikrobiologicznemu dopiero po ich wymieszaniu z glebą. Słoma pochodząca z roślin opryskanych środkiem Ranchero 30 SL musi pozostać na polu. Nie wolno jej zbierać i wywozić z pola, ani przeznaczać na paszę dla zwierząt. Należy rozdrobnić słomę i wymieszać z glebą wszystkie części traktowanych roślin rzepaku pozostałe po zbiorze rzepaku, włącznie z ściernią, najszybciej jak to możliwe, najpóźniej wczesną jesienią.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

Nie dotyczy.

1. Strategia zarządzania odpornością.

Aby zminimalizować ryzyko wystąpienia i rozwoju odporności chwastów:

- postępuj zgodnie z zaleceniami zawartymi w etykiecie środka ochrony roślin,
- stosuj środek w zalecanej dawce, w zalecany terminie zapewniającym najlepsze efekty zwalczania chwastów,
- dostosuj zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- używaj różnych metod kontroli zachwaszczenia, w tym zmianowanie upraw, itp.,
- stosuj rotację i/lub mieszanki herbicydów o odmiennym mechanizmie działania,
- stosuj w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów,
- stosuj herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
- informuj posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
- w celu uzyskania szczegółowych informacji skontaktuj się z doradcą lub z producentem środka ochrony roślin.

2. Warunki stresowe (długotrwała susza, spadki temperatury poniżej 5 °C, przymrozki) w trakcie lub po zastosowaniu środka mają negatywny wpływ na działanie herbicydu, które mogą czasami powodować niewielkie i przejściowe zahamowanie wzrostu, i deformacje liści rzepaku, które nie wpływają negatywnie na proces kwitnienia, dojrzewania, wylegania roślin rzepaku oraz na plon nasion i zawartość oleju.

3. Środka nie stosować:

- na rośliny mokre, chore i uszkodzone,
- w temperaturze powietrza poniżej 8° C i powyżej 25°C,
- w czasie nadmiernej suszy,
- po nocnych przymrozkach oraz przed spodziewanymi przymrozkami.

4. Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W

przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszałem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

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.

Uwaga:

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 niż zalecane.

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

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, **ochronę oczu lub twarzy** oraz odzież roboczą w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

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 strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.~~

W celu ochrony roślin ~~oraz stawonogów~~ niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m i zastosowanie ~~50%~~ 90% redukcji dysz lub 5 m i zastosowanie 50% redukcji dysz lub 10 m bez redukcji dysz od terenów nieużytkowanych rolniczo.

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.

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 zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. Natychmiast skontaktować się z ośrodkiem zatrucia/lekarzem.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Not required.

Appendix 4 Lists of data considered for national authorization

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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1, KCP 2.3.1, KCP 2.3.2, KCP 2.4.1, KCP 2.4.2, KCP 2.5.2, KCP 2.6.1, KCP 2.7.2, KCP 2.7.4, KCP 2.8.2, KCP 2.8.4, KCP 2.11.1, KCP 2.11.2	Górka, I.	2024	Determination of physicochemical properties of AMINO 30 SL before and after accelerated storage test ICB/92/2024 ICB Pharma 10 Lema Street 43-600 Jaworzno Poland GLP Not published	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 2.2.1	Buczkowski, D.	2024	AMINO 30 SL Determination of explosive properties BW-22/24 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry 6 Annopol Str. 03-236 Warsaw GLP Not published	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 2.2.2, KCP 2.3.3	Pachnicki, P.	2024	AMINO 30 SL Determination of auto-ignition temperature and oxidizing properties BC-68/24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			6 Annopol Str. 03-236 Warsaw Poland GLP Not published				
KCP 2.5.1	Rymarzak, O.	2024	AMINO 30 SL Determination of viscosity BF-37/24 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Annopol 6 Street 03-236 Warsaw Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 5.1.1/01 KCP 5.1.1/02	Pniok, W.	2024	Validation of analytical method for AMINO 30 SL for determination of aminopyralid and picloram as impurity Study code: ICB/91/2024 ICB Pharma, 10 Lema Street 43-600, Jaworzno, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 5.1.2/01	Czarnynoga, M.	2024	Predatory mite (<i>Hypoaspis (Geolaelaps) aculeifer</i>) reproduction test in soil Study code: G-56-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 5.1.2/02	Czarnynoga, M.	2024	Earthworm (<i>Eisenia andrei</i>) reproduction test Study code: G-54-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland GLP/GEP (Y/N): Y	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Published (Y/N): N				
KCP 5.1.2/03	Czarnynoga, M.	2024	Collemboles (<i>Folsomia candida</i>) Reproduction Test Study code: G-55-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 5.1.2/04, KCP 10.2/04	Czarnynoga, M.	2024	AMINO 30 SL <i>Anabaena flos-aquae</i> UTEX B 1444, Growth inhibition test Study code: W-30-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 5.1.2/05, KCP 10.2/02	Maga, D.	2024	AMINO 30 SL <i>Daphnia magna</i> , Acute Immobilisation Test Study code: W-27-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 5.1.2/06, KCP 10.2/01	Maga, D.	2024	AMINO 30 SL <i>Lemna gibba</i> CPCC 310, Growth inhibition test Study code: W-29-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/07, KCP 10.2/03	Maga, D.	2024	AMINO 30 SL <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i>), Growth inhibition test Study code: W-28-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 5.1.2/08, KCP 10.2/05	Czarnecka, M.	2024	AMINO 30 SL Water-sediment <i>Myriophyllum spicatum</i> toxicity test Study code: W-26-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 10.3.1/01	Dybek, M.	2024	AMINO 30 SL Honeybees (<i>Apis mellifera</i> L.), Acute Contact Toxicity Test Study Code: B-96-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 10.3.1/02	Dybek, M.	2024	AMINO 30 SL Honeybees (<i>Apis mellifera</i> L.), Acute Oral Toxicity Test Study Code: B-95-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 5.1.2/09, KCP 10.3.1/03	Dybek, M.	2024	AMINO 30 SL Honeybees (<i>Apis mellifera</i> L.), Chronic Oral Toxicity Test Study code: B-94-24 Łukasiewicz Research Network –	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland GLP/GEP (Y/N): Y Published (Y/N): N				
KCP 5.1.2/10 KCP 10.3.1/06	Dybek, M.	2024	AMINO 30 SL Bumblebees (<i>Bombus</i> spp.), Acute Contact Toxicity Test Study code: B-89-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 5.1.2/11 KCP 10.3.1/05	Dybek, M.	2024	AMINO 30 SL Bumblebees (<i>Bombus</i> spp.), Acute Oral Toxicity Test Study code: B-88-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 10.3.1/04	Niškiewicz, M.	2024	Honey bee larval toxicity test following repeated exposure of the test item AMINO 30 SL according to OECD GD 239 ENV/JM/MONO(2016)34 Study code: 0038/0215/E SORBOLAB Research Laboratory LLC Zaniemyska Street 11 61-029 Poznań, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 5.1.2/12	Wróbel, A.	2024	Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study code: G-59-24	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection 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/GEP (Y/N): Y Published (Y/N): N				
KCP 5.1.2/13	Wróbel, A.	2024	Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study code: G-93-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 5.1.2/14	Czarnynoga, M.	2024	Terrestrial Plant Test: Vegetative Vigour Test Study code: G-58-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 5.1.2/15	Kanon, L.	2024	Validation of analytical method for determination of the active substance (aminopyralid) in the test item AMINO 30 SL solution in deionized water Study code: 0038/0214/FA SORBOLAB Research Laboratory LLC Zaniemyska Street 11 61-029 Poznań, Poland GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 10.3.2/01	Dybek, M.	2024	An extended laboratory test for evaluating the effects of AMINO 30 SL on the green lacewing, <i>Chrysoperla carnea</i> Study Code: B-93-24	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP (Y/N): Y Published (Y/N): N				
KCP 10.3.2/02	Dybek, M.	2024	An extended laboratory test for evaluating the effects of AMINO 30 SL on the ladybird beetle, <i>Coccinella septempunctata</i> (L.) Study Code: B-90-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 10.3.2/03	Dybek, M.	2024	An extended laboratory test for evaluating the effects of AMINO 30 SL on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani-Perez) Study Code: B-92-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 10.3.2/04	Dybek, M.	2024	An extended laboratory test for evaluating the effects of AMINO 30 SL on the predatory mite, <i>Typhlodromus pyri</i> (Sch.) Study Code: B-91-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 10.4/01	Gierbuszewska, A.	2024	AMINO 30 SL Earthworm (<i>Eisenia andrei</i>) reproduction test Study Code: G-54-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 10.4/02	Czarnynoga, M.	2024	AMINO 30 SL Collembolan (<i>Folsomia candida</i>) Reproduction Test Study Code: G-55-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP/GEP (Y/N): Y Published (Y/N): N				
KCP 10.4/03	Czarnynoga, M.	2024	AMINO 30 SL Predatory mite (<i>Hypoaspis (Geolaelaps) aculeifer</i>) reproduction test in soil Study Code: G-56-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 10.5/01	Wróbel, A.	2024	AMINO 30 SL Soil Microorganisms: Nitrogen Transformation Test Study Code: G-57-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 10.6/01	Czarnynoga, M.	2024	AMINO 30 SL Terrestrial Plant Test: Vegetative Vigour Test Study Code: G-58-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP (Y/N): Y	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 10.6/02	Wróbel, A.	2024	AMINO 30 SL Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study Code: G-59-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 10.6/03	Wróbel, A.	2024	AMINO 30 SL Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study Code: G-93-24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP (Y/N): Y Published (Y/N): N	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 6 KCP 6.2	Guzińska, J.	2023	Efficacy evaluation of herbicide AMINO 30 SL when applied into winter oilseed rape to control of weeds, Poland, 2023.	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Poland Report no.: A.T/2023/040/RZO GEP - yes Unpublished				
KCP 6 KCP 6.2	Guzińska, J.	2023	Efficacy evaluation of herbicide AMINO 30 SL when applied into winter oilseed rape to control of weeds, Poland, 2023. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Poland Report no.: A.T/2023/041/RZO GEP - yes Unpublished	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 6 KCP 6.2	Strzełiński, A.	2023	The evaluation efficacy of herbicide AMINO 30 SL in the control on weeds in the cultivation on winter rape. Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland Report no.: AH/23/RO/35/Mr/01 GEP - yes Unpublished	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 6 KCP 6.2	Strzełiński, A.	2023	The evaluation efficacy of herbicide AMINO 30 SL in the control on weeds in the cultivation on winter rape.	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			<p>Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland</p> <p>Report no.: AH/23/RO/35/Pr/02/a</p> <p>GEP - yes Unpublished</p>				
KCP 6 KCP 6.2	Strzełiński, A.	2023	<p>The evaluation efficacy of herbicide AMINO 30 SL in the control on weeds in the cultivation on winter rape.</p> <p>Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland</p> <p>Report no.: AH/23/RO/35/Pr/03</p> <p>GEP - yes Unpublished</p>	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 6 KCP 6.2	Strzełiński, A.	2023	<p>The evaluation efficacy of herbicide AMINO 30 SL in the control on weeds in the cultivation on winter rape.</p> <p>Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland</p> <p>Report no.: AH/23/RO/35/Ka/04</p> <p>GEP - yes Unpublished</p>	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 6 KCP 6.2	Strzełiński, A.	2023	<p>The evaluation efficacy of herbicide AMINO 30 SL in the control on weeds in the cultivation on winter rape.</p>	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			<p>Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland</p> <p>Report no.: AH/23/RO/35/Ma/05</p> <p>GEP - yes Unpublished</p>				
KCP 6 KCP 6.2	Strzełiński, A.	2023	<p>The evaluation efficacy of herbicide AMINO 30 SL in the control on weeds in the cultivation on winter rape.</p> <p>Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland</p> <p>Report no.: AH/23/RO/35/JaW/06</p> <p>GEP - yes Unpublished</p>	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 6 KCP 6.2	Strzełiński, A.	2023	<p>The evaluation efficacy of herbicide AMINO 30 SL in the control on weeds in the cultivation on winter rape.</p> <p>Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland</p> <p>Report no.: AH/23/RO/35/Zł/07</p> <p>GEP - yes Unpublished</p>	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 6.4	Guzińska, J.	2023	Field study to evaluate the crop safety of herbicide AMINO 30 SL	N	Y	Study report never submitted before	PUH Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3			when applied in winter oilseed rape, Poland 2023. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Poland Report no.: A.T/2023/042/RZO GEP - yes Unpublished			to Poland	sp. z o.o.
KCP 6.4 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Guzińska, J.	2023	Field study to evaluate the crop safety of herbicide AMINO 30 SL when applied in winter oilseed rape, Poland 2023. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Poland Report no.: A.T/2023/043/RZO GEP - yes Unpublished	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 6.4 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Strzełiński, A.	2023	The evaluation selectivity of herbicide AMINO 30 SL in the cultivation on winter rape. Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland Report no.: AH/23/RO/35/Zł/01 GEP - yes Unpublished	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 6.4 KCP 6.4.1 KCP 6.4.2	Strzełiński, A.	2023	The evaluation selectivity of herbicide AMINO 30 SL in the cultivation on winter rape.	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.3			Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland Report no.: AH/23/RO/35/Pr/02/b GEP - yes Unpublished				
KCP 6.4 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Strzełiński, A.	2023	The evaluation selectivity of herbicide AMINO 30 SL in the cultivation on winter rape. Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland Report no.: AH/23/RO/35/Br/03 GEP - yes Unpublished	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 6.4 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Strzełiński, A.	2023	The evaluation selectivity of herbicide AMINO 30 SL in the cultivation on winter rape. Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland Report no.: AH/23/RO/35/Ma/04 GEP - yes Unpublished	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 6.4 KCP 6.4.1	Strzełiński, A.	2023	The evaluation selectivity of herbicide AMINO 30 SL in the cultivation on winter rape.	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4.2 KCP 6.4.3			Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland Report no.: AH/23/RO/35/JaW/05 GEP - yes Unpublished				
KCP 6.4 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Strzełiński, A.	2023	The evaluation selectivity of herbicide AMINO 30 SL in the cultivation on winter rape. Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland Report no.: AH/23/RO/35/Ka/06 GEP - yes Unpublished	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.
KCP 6.4 KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	Strzełiński, A.	2023	The evaluation selectivity of herbicide AMINO 30 SL in the cultivation on winter rape. Poznań University of Life Sciences Research Center Złotniki Wojska Polskiego 28 60-637 Poznań Poland Report no.: AH/23/RO/35/Da/07 GEP - yes Unpublished	N	Y	Study report never submitted before to Poland	PUH Chemirol sp. z o.o.

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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.3.2.1 KCP 5.3.2.2	Wendelburg, B. M.; and Olberding, E. L.	2008a	Determination of Residues of Aminopyralid in Agricultural Commodities by Liquid Chromatography with Tandem Mass Spectrometric Detection Dow AgroSciences LLC, USA. Report No.: GRM 07.07, 071121 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS
KCP 5.3.2.1 KCP 5.3.2.2	Beck, I. C.; and Class, T.	2008a	Independent Laboratory Validation of Dow AgroSciences LLC Method GRM 07.07 - Determination of Residues of Aminopyralid in Agricultural Commodities by Liquid Chromatography with Tandem Mass Spectrometric Detection PTRL Europe GmbH, Germany Report No.: P 1466 G, 080117 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS
KCP 5.3.2.1 KCP 5.3.2.3	[REDACTED]	2008b	Determination of Residues of Aminopyralid in Bovine and Poultry Tissues, Milk, and Eggs by Liquid Chromatography with Tandem Mass Spectrometric Detection [REDACTED] GLP/GEP (Y/N): Y Published (Y/N): N	Y	N	Study used for active substance Annex I inclusion	DAS
KCP 5.3.2.1 KCP 5.3.2.3	[REDACTED]	2008b	Independent Laboratory Validation of Dow AgroSciences LLC Method GRM 07.08 - Determination of Residues of Aminopyralid in Bovine and Poultry Tissues, Milk, and Eggs by Liquid Chromatography with Tandem Mass Spectrometric Detection. [REDACTED] GLP/GEP (Y/N): Y Published (Y/N): N	Y	N	Study used for active substance Annex I inclusion	DAS
KCP 5.3.2.1 KCP 5.3.2.4	Wendelburg, B.M. and Olberding, E.L.	2008c	Determination of Residues of Aminopyralid in Soil by Liquid Chromatography with Tandem Mass Spectrometric Detection Dow AgroSciences LLC Report No.: GRM 07.09, 071121 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.3.2.1 KCP 5.3.2.5	Wendelburg, B.M. and Olberding, E.L.	2008d	Determination of Residues of Aminopyralid in Drinking Water, Ground Water, and Surface Water by Liquid Chromatography with Tandem Mass Spectrometric Detection Dow AgroSciences LLC Report No.: GRM 07.10, 071121 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 5.3.2.1 KCP 5.3.2.5	Beck, I.C. and Class, T.	2008d	Independent Laboratory Validation of Dow AgroSciences LLC Method GRM 07.10 - Determination of Residues of Aminopyralid in Drinking Water, Ground Water, and Surface Water by Liquid Chromatography with Tandem Mass Spectrometric Detection PTRL Europe GmbH Report No.: P 1464 G GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 5.3.2.1 KCP 5.3.2.6	Bacher, R.	2009	The Development and Validation of a Method for the Determination of Aminopyralid in Air PTRL Europe GmbH, Germany Report No.: P 1645 G, 091020 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 5.3.2.1 KCP 5.3.2.7	Mollica, J.; West, S.D.	2003	Method Validation for the Analysis of XDE-750 (Aminopyralid) in Human Blood and Urine Pyxant Labs Inc, CO, USA. Report No.: Pyxant Dow-1419/031005 (Masterfile Number) N/A GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 5.2.2	Devine, H.C.	2006	Residues of Clopyralid, Picloram and Aminopyralid in Oil Seed Rape at Intervals and at Harvest Following a Single Application of GF-1634, Germany, Poland and Hungary – 2005 CEM Analytical Services Ltd DAS Report No.: GHE-P-11273 (Masterfile Number) N/A GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for registration of Navigator 360 SL in Poland. more than 10 years ago.	DAS
KCP 5.2.2	Devine, H.C.	2007	Residues of Clopyralid, Picloram and Aminopyralid in Oil Seed Rape at Intervals and at Harvest Following a Single Application	N	N	Study used for registration of Navigator 360 SL in Poland more than	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			of GF-1633 or GF-871. Northern Europe – 2006 CEM Analytical Services Ltd DAS Report No.: GHE-P-11493 (Masterfile Number) N/A GLP/GEP (Y/N): Y Published (Y/N): N			10 years ago.	
KCP 6.1	Lindsay, D.A.	2004	Frozen Storage Stability of XDE-750 in Range Land and Pasture Grass and Hay and Wheat Straw and Wheat Grain. DAS, Indiana, USA Report No.: 030004.01 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS
KCP 7.2.2.5	[REDACTED]	2003	The Distribution and Metabolism of [¹⁴ C]-XDE-750 in the Lactating Goat [REDACTED] GLP/GEP (Y/N): Y Published (Y/N): N	Y	N	Study used for active substance Annex I inclusion	DAS
KCP 7.2.4.2	[REDACTED]	2004	Magnitude of XDE-750 Residues in Bovine Tissues and Milk from 28-Day Feeding Study [REDACTED] GLP/GEP (Y/N): Y Published (Y/N): N	Y	N	Study used for active substance Annex I inclusion	DAS
KCP 7.2.2.5	[REDACTED]	2004a	¹⁴ C XDE-750 Poultry Nature of Residue Study DAS Indiana, USA & Wildlife International, Ltd, Maryland, USA [REDACTED] GLP/GEP (Y/N): Y Published (Y/N): N	Y	N	Study used for active substance Annex I inclusion	DAS
KCP 7.2.2.1	Linder, S.J.	2007	A Nature of Residue Study with ¹⁴ C Labeled Aminopyralid Applied to Oilseed Rape Dow AgroSciences DAS Report No.: 060011 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for registration of Navigator 360 SL in Poland more than 10 years ago.	DAS
KCP 7.2.2.1	Magnussen, J. D. and Balcer, J. L.	2004	¹⁴ C XDE-750 Grass Nature or Residue Study. DAS, Indiana, USA Report No.: 010071 GLP/GEP (Y/N): Y	N	N	Study used for active substance Annex I inclusion	DAS

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			Published (Y/N): N				
KCP 7.2.2.1	Graper, L. K.; Smith, K. P.; Hilla, S.	2003	A Nature of the Residue Study with ¹⁴ C-Labeled XDE-750 Applied to Spring Wheat DAS, Indiana, USA & Research for Hire, California, USA Report No.: 020022 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS
KCP 7.2.2.2	Magnussen, J.D.	2004b	A Confined Rotational Crop Study with ¹⁴ C XDE-750. DAS, Indiana, USA & Research for Hire, California, USA. Report No.: 030008 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS
KCP 7.2.3	Devine, H.C.	2006	Residues of Clopyralid, Picloram and Aminopyralid in Oil Seed Rape at Intervals and at Harvest Following a Single Application of GF-1634, Germany, Poland and Hungary – 2005 CEM Analytical Services Ltd DAS Repor No.: GHE-P-11273 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for registration of Navigator 360 SL in Poland more than 10 years ago.	DAS
KCP 7.2.3	Devine, H.C.	2007	Residues of Clopyralid, Picloram and Aminopyralid in Oil Seed Rape at Intervals and at Harvest Following a Single Application of GF-1633 or GF-871, Northern Europe – 2006 CEM Analytical Services Ltd DAS Report No.: GHE-P-11493 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for registration of Navigator 360 SL in Poland more than 10 years ago.	DAS
KCP 7.2.2.3	Cook, W.L.	2003a	Hydrolysis of XDE-750 at pH 5,7, and 9. DAS, Indiana, USA. Report No.: 020067 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS
KCP 9.1.1.1	Yoder, R. N. and Smith, K.P.	2003a	Aerobic Soil Degradation of XDE-750 in Four European Soils DAS, Indiana, USA Report No.: 020054 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS
KCP 9.1.1.1	Rutherford, L.A. and Meitl, T.J.	2004	Anaerobic aquatic metabolism of XDE-750. DAS, Indiana, USA	N	N	Study used for active substance Annex I inclusion	DAS

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			Report No.: 020052 GLP/GEP (Y/N): Y Published (Y/N): N				
KCP 9.1.1.2.1	Anon	2004a	Further comments on environmental fate and behaviour following the outcome of the completeness check. Submitted to the UK on 18/06/2004 Dow AgroSciences Ltd, Hitchin, UK Report No.: - GLP/GEP (Y/N): N Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS
KCP 9.1.1.2.1	Havens, P.	2004	The Normalisation Procedure Dow AgroSciences LLC, Indianapolis, USA Report No.: - GLP/GEP (Y/N): N Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS
KCP 9.1.1.2.1	Anon	2004b	Further comments on the Normalisation Procedure. Submitted to the UK on 20/05/2005 Dow AgroSciences Ltd, Hitchin, UK Report No.: - GLP/GEP (Y/N): N Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS
KCP 9.1.2	Rutherford, L. A.	2002	Soil Batch Equilibrium Adsorption/Desorption of XDE-750 DAS, Indiana, USA Report No.: GH-C 5552 010064 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS
KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3	Yoder, R. N. & Smith, K.P.	2003b	Degradation of XDE-750 in 2 European and 1 US Sediment and Pond Water Systems DAS, Indiana, USA Report No.: 020062 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS
KCP 9.1.1.1	Rutherford, L.A.	2004	Photodegradation of XDE-750 on soil DAS Indiana, USA Report No.: 020080 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Annex I inclusion	DAS
KCP	Unsworth, C.,	2003	A one year field study to determine the dissipation of XDE-750	N	N	Study used for active substance	DAS

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9.1.1.2.1	Scrimshaw, O., Balluff, M., Lagrasse, S., Morgan, A.J. and Schelle, G.		through soil following a single application of GF-819, Europe – 2002-2003. Covance Laboratories Ltd, Yorkshire, UK Report No.: 295/154 GLP/GEP (Y/N): Y Published (Y/N): N			Anex I inclusion	
KCP 9.1.2	Rutherford, L. A.	2002	Soil Batch Equilibrium Adsorption/Desorption of XDE-750 DAS, Indiana, USA Report No.: GH-C 5552 010064 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 9.3, KCP 9.3.1	Knoch, E. and Heim, L.	2003	XDE-750 volatilisation – Atkinson calculation and volatilisation from soil and dwarf runner bean when formulated as 30 g ae/L EO (BBA Guideline Part IV, Section 6-1, 1990) Institut Fresenius, Herten, Germany Report No.: 010051 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 10.1.1/01	Gallagher, S.P., Grimes, J., Beavers, J.B.	2001	XDE-750: An Acute Oral Toxicity Study with the Northern Bobwhite Report No: 011046-379-106 DR-0293-9028-029 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 10.1.1/02	Gallagher, S.P., Beavers, J.B., Martin, K.H.	2001a	XDE-750: A Dietary LC50 Study with the Northern Bobwhite Report No: 011047 379-107 DR-0293-9028-031 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 10.1.1/03		2003a	Avian Reproduction Study with XDE-750 in Northern Bobwhite Quail (Colinus virginianus) GLP/GEP (Y/N): Y Published (Y/N): N	Y	N	Study used for active substance Anex I inclusion	DAS
KCP 10.1.1/04	Madsen, S.	2003	Determination of the n-octanol/water partition coefficient (shake flask method) of XDE-750 technical Dow AgroSciences, Indiana, USA Report No: FOR01009 (Masterfile Number) N/A GLP/GEP (Y/N): Y	N	N	Study used for active substance Anex I inclusion	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Published (Y/N): N				
KCP 10.1.2/01	[REDACTED]	2001a	XDE-750: Acute Oral Toxicity Study in Fischer 344 Rats [REDACTED] GLP/GEP (Y/N): Y Published (Y/N): N	Y	N	Study used for active substance Anex I inclusion	DAS
KCP 10.1.2/02	[REDACTED]	2004b	Supplemental report for GF-871: Oral Gavage Developmental Toxicity Study in New Zealand white rabbits [REDACTED] GLP/GEP (Y/N): Y Published (Y/N): N	Y	N	Study used for active substance Anex I inclusion	DAS
KCP 10.1.2/03	[REDACTED]	2004a	GF-871: Oral Gavage Developmental Toxicity Study in New Zealand white rabbits [REDACTED] GLP/GEP (Y/N): Y Published (Y/N): N	Y	N	Study used for active substance Anex I inclusion	DAS
KCP 10.2/05	[REDACTED]	2001	XDE-750 Herbicide: An Acute Toxicity Study with the Rainbow Trout <i>Oncorhynchus mykiss</i> Walbaum [REDACTED] GLP/GEP (Y/N): Y Published (Y/N): N	Y	N	Study used for active substance Anex I inclusion	DAS
KCP 10.2/06	[REDACTED]	2002a	Revised report for XDE-750- Acute Toxicity to Bluegill Sunfish (<i>Lepomis macrochirus</i>) Under Static Conditions [REDACTED] GLP/GEP (Y/N): Y Published (Y/N): N	Y	N	Study used for active substance Anex I inclusion	DAS
KCP 10.2/07	[REDACTED]	2002b	XDE-750 – Acute Toxicity to Sheepshead Minnow (<i>Cyprinodon variegatus</i>) Under Static Acute Conditions [REDACTED] GLP/GEP (Y/N): Y Published (Y/N): N	Y	N	Study used for active substance Anex I inclusion	DAS
KCP 10.2/08	Marino, T.S., Hales-McClymont, C.A., Yaroach, A.M.	2001	XDE-750 Herbicide: an Acute Toxicity Study with the Daphnid, <i>Daphnia magna</i> Straus The Dow Chemical Company, Midland, USA Report No.: 011079 DR-0293-9028-042 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 10.2/09	Henry, K.S., Marino, T.A., Staley, J.L.,	2003	XDE-750: 21-Day Chronic Toxicity with the Daphnid, <i>Daphnia magna</i> Straus	N	N	Study used for active substance Anex I inclusion	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
	McClymont, E.L.		The Dow Chemical Company, Midland, USA Report No.: 021085 DR-0293-9028-074 GLP/GEP (Y/N): Y Published (Y/N): N				
KCP 10.2/10	Cafarella, M.A.	2002	XDE-750 – Acute Toxicity to Eastern Oysters (<i>Crassostrea virginica</i>) under Flow-Through Conditions, Springborn Smithers Inc, Wareham, USA Report No.: 011268 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 10.2/11	Putt, A.E.	2002	XDE-750 - the Full Life-Cycle Toxicity to Midge (Chironomus riparius) Under Static Conditions Springborn Smithers Inc, Wareham, USA Report No.: U09304 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 10.2/12	Hoberg, J.R.	2002b	XDE-750 – Acute Toxicity to the Freshwater Diatom, <i>Navicula pelliculosa</i> . Springborn Smithers Inc. Wareham, USA Report No.: 12550.6199 011278 DR-0293-9028-065 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 10.2/13	Hoberg, J.R.	2002e	XDE-750 - Toxicity to Duckweed, Lemna gibba Springborn Smithers Inc, Wareham, USA Report No.: 011223R 12550.6160 DR-0293-9028-058R GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 10.2/14	Wenzel, A.	2012	Effect of aminopyralid on the growth of <i>Myriophyllum spicatum</i> in the presence of sediment with exposure via the water phase. Fraunhofer Institute for Molecular Biology and Applied Ecology (IME) Study ID: 120759 GLP: Yes Published: No	N	N	Study used for active substance Anex I inclusion	DAS
KCP 10.3.1/06	Aufderheide, J.	2001a	XDE-750: Acute Contact Toxicity Test with the Honeybee, <i>Apis mellifera</i>	N	N	Study used for active substance Anex I inclusion	DAS

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			ABC Laboratories Inc, Missouri, USA Report No.: 46595 011044 DR-0293-9028-028 GLP/GEP (Y/N): Y Published (Y/N): N				
KCP 10.3.1/07	Aufderheide, J.	2001b	XDE-750: Acute Oral Toxicity Test with the Honeybee (<i>Apis mellifera</i>) ABC Laboratories Inc, Missouri USA Report No.: 46596 011045 DR-0293-9028-028 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 10.4/04	Davies, N.	2004	XDE-750: Effects on Reproduction and Growth in the Earthworm, <i>Eisenia foetida</i> . CEM Analytical Services Limited, UK Report No.: 040285 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS
KCP 10.5/02	McMurray, A.	2002	A Laboratory Assessment of the Effects of XDE-750 on Soil Microflora Respiration and Nitrogen Transformation According to OECD Guidelines Chemex Environmental International Ltd, Cambridge, UK Report No.: GHE-T-1180 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	Study used for active substance Anex I inclusion	DAS

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	Vertebrate study Y/N	Data protection 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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner