REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

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

CORE ASSESSMENT

(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

Version history

When	What
April 2025	zRMS Assessment
July 2025	Following commenting period Verification of reference list

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on AMINO 30 SL/El Camino 30 SL, Ranchero 30 SL *

Product name and code	AMINO 30 SL/El Camino 30 SL, Ranchero 30 SL
Formulation type	SL
Active substance(s) (incl. content)	aminopyralid; 30 g/L
Function	Herbicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of AMINO 30 SL/El Camino 30 SL, Ranchero 30 SL can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for AMINO 30 SL/El Camino 30 SL, Ranchero 30 SL according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Eye Dam. 1, H318
Hazard pictograms or Code(s) for hazard pictogram(s):	GHS05
Signal word:	Danger
Hazard statement(s):	H318 – Causes serious eye damage.
Precautionary statement(s):	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.
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.

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for AMINO 30 SL/El Camino 30 SL, Ranchero 30 SL

	Result	PPE / Risk mitigation measures
Operators	Acceptable	~~workwear~~ eye protection or face protection during mixing/loading (due to the fact that the product is classified as Eye Dam. 1 H318)

	Result	PPE / Risk mitigation measures
		~~and workwear during application~~
Workers	Acceptable	~~workwear~~ None
Bystanders	Acceptable	~~2 3 buffer zone~~ None
Residents	Acceptable	~~2 3 buffer zone~~ None

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1-3 are applied.

Table 6.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use-No.*	**Crops and situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ******	**Application**		**Application rate**		**PHI (d)**	**Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, bystander or resident exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind (incl. application technique ***	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**Max. application rate kg as/ha a) aminopyralid**	**Water L/ha min / max**			**Operator**	**Worker**	**Bystander**	**Residents**
1	Winter oilseed rape (Autumn BBCH 10-18)	F	Spray, medium spray LCTM	a) 1 b) 1	a) 0.006-0.00801	200 - 300	-	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032				

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

Data gaps

Noticed data gaps are:
None

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

	Aminopyralid
Common Name	Aminopyralid
CAS-No.	150114-71-9
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Eye Dam. 1, H318 Code(s) for hazard pictogram(s): GHS05 Signal word: Danger Hazard statement(s): H318 – Causes serious eye damage. Precautionary statement(s): 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.
Additional C&L proposal	N/A
Agreed EU endpoints	
AOEL systemic	0.26 mg/kg bw/d (No correction for oral absorption was applied when using a study with rabbits)
Reference	EFSA Journal 2013;11(9):3352
Confitions to take into account/critical areas of concern with regard to toxicology	
EFSA Conclusion for active substance EFSA Journal 2013;11(9):3352	None

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Comments of zRMS:	AMINO 30 SL/ El Camino 30 SL, Ranchero 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/ El Camino 30 SL, Ranchero 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. For specific target organ toxicity the alternative method (calculation) according to the Regulation (EC) 1272/2008 was applied. Details of the calcula-

	tion can be found in Part C. In order to avoid tests on animals, the use of alternative method for the purposes of hazard classification is preferred. Proposed classification based on alternative method according to Regulation (EC) 1272/2008 is acceptable by the zRMS.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral (calculation method – alternative method)	> 2000 mg/kg bw	Yes	None	Dobersztyn A. (2025)
LD_{50} dermal (calculation method – alternative method)	> 2000 mg/kg bw	Yes	None	Dobersztyn A. (2025)
LC_{50} inhalation (calculation method – alternative method)	> 20 mg/L air	Yes	None	Dobersztyn A. (2025)
Skin irritation (calculation method – alternative method)	Non-irritant	Yes	None	Dobersztyn A. (2025)
Eye irritation (calculation method – alternative method)	Corrosive	Yes	**Eye Dam. 1, H318**	Dobersztyn A. (2025)
Skin sensitisation (calculation method – alternative method)	Non-sensitising	Yes	None	Dobersztyn A. (2025)
Supplementary studies for combinations of plant protection products	No data – not required	Yes		
Specific target organ toxicity - single exposure (calculation method – alternative method)	Not classified	Yes	None	Dobersztyn A. (2025)

Table 6.3-2: Additional toxicological information relevant for classification/labelling of AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	aminopyralid (3 % w/w)	Eye Dam. 1, H318 (criteria ≥ 3 %)	Reg. 1272/2008	Eye Dam. 1, H318
Toxicological properties of non-active substance(s) (relevant for classification of product)	2-aminoethanol (< 1.0 % w/w)	Eye Dam. 1, H318 (criteria ≥ 3 %)	Reg. 1272/2008	Eye Dam. 1, H318
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10 % or > 1 %) as provided in MSDS.

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

No metabolites are expected to occur in groundwater – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

Comments by zRMS:	Dermal absorption assessment provided by the applicant is based on the current version of EFSA Guidance document on dermal absorption (2017). zRMS noted that default dermal absorption for concentrate should be 50% since concentration of a.s in the product is below 5%. According to Guidance on Dermal Absorption (EFSA, 2017) and SANTE/2018/10591 rev.1, 24 October 2018), plant protection product should be considered as "dilution" when concentration of a.s in the product is below 5%. According to Guidance on Dermal Absorption (EFSA, 2017) a default dermal absorption value of 50% may be applied for (in use) dilutions of water-based/dispersed soluble concentrate.

A summary of the dermal absorption rates for the active substances in AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in AMINO 30 SL/El Camino 30 SL, Ranchero 30 SL

	Aminopyralid	
	Value	**Reference**
Concentrate	~~10~~50 %	EFSA Journal 2017;15(6):4873 and SANTE/2018/10591
Dilution	50 %	EFSA Journal 2017;15(6):4873

6.5.1 Justification for proposed values - Aminopyralid

No data on dermal absorption for aminopyralid in AMINO 30 SL/El Camino 30 SL, Ranchero 30 SL is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for aminopyralid

	Value	Justification for value	Acceptability of justification
Concentrate	~~10~~50 %	~~Based on product (formulation)~~ Default value	Acceptable
Dilution	50 %	~~Based on product (formulation)~~ Default value	Acceptable

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Comments by zRMS:	zRMS noted that default dermal absorption for concentrate used in exposure assessment should be 50% since concentration of a.s in the product is below 5%. Dermal absorption for concentrate used in exposure assessment submitted by the Applicant is correct (50%). zRMS noted that dermal absorption for in-use dilution used in exposure assessment submitted by the Applicant is 70% . According to Guidance on Dermal Absorption (EFSA, 2017) a default dermal absorption value of 50% may be applied for (in use) dilutions water-based/dispersed soluble concentrate. Since 70% is worst case than 50% zRMS has not revised exposure assessment using 50% as dermal absorption for in-use dilutions.

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL
Formulation type	SL
Category	Herbicide
Container size(s), short description	HDPE range from 250 ml to 5000 ml bottle / 800 ml to 2000 ml jar / 3000 ml to 22000 ± 50 ml container / 4000 ml to 20000 ml cannister HDPE/PA range from 275 ml to 5850 ± 150 ml bottle / 5000 ml cannister / 10000 ± 150 ml container HDPE/F range from 312 ± 12.5 ml to 5950 ± 100 ml bottle / 5880 ± 100 ml to 10000 ml cannister HDPE/EvOH range from 250 ml to 1200 ± 50 ml bottle / 5000 ml to 20000 ml container / 5650 ml cannister
Active substance(s) (incl. content)	**Aminopyralid** 30 g/L
AOEL systemic	0.26 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	Concentrate: 10 % Dilution: 50 % (Based on product (formulation))

6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-4. A list of all intended uses within the zone is given in Part B, Section 0.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL according to the critical use(s) is presented in Table 6.6-2. Outcome of the estimation is presented in Table 6.6-3. Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Winter oilseed rape (max. 0.267 L product/ha)
Model(s)	OPEX version 1.0.2

Table 6.6-3: Estimated operator exposure

		Aminopyralid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 1 x 0.00801 kg a.s./ha			
OPEX version 1.0.2 Body weight: 60 kg	no PPE	0.056	20.9
	with PPE (workwear during mixing/loading and workwear during application)	0.04	15

Short term exposure

Mixing/loading	Application	Aminopyralid (% AOEL) Normal & vehicle-mounted
		20.9
		15

3.1.1.1. Summary data - Short term exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Aminopyralid	Number of applications and application rate: 1 x 0.00801 kg a.s./ha Dermal absorption (concentrate): 50 % Dermal absorption (in-use dilution): 70 %		
	M/L: Workwear App: Workwear	0.04	15

6.6.3 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

Comments of zRMS study comment 6.6.2	The applicant presented calculations for the application of AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL on winter oilseed rape max. 1x 0.267 L product/ha using the tractor-mounted on field. The exposure calculations were conducted by the applicant using the EFSA online calculator OPEX v 1.0.2.
agreed endpoints 6.6.2	According to EFSA OPEX calculations, it can be concluded that the risk of operator exposure during mixing & loading and application of AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL using the tractor-mounted on field is acceptable under conditions of intended use without PPE. Due to the fact that the product is classified as Eye Dam. 1 H318, eye protection would be necessary, thus the operator should wear eye protection or face protection during mixing/loading.

6.6.4 Worker exposure (KCP 7.2.3)

6.6.4.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with AMINO 30 SL/El Camino 30 SL, Ranchero 30 SL according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5. Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Winter oilseed rape (max. 0.267 L product/ha)
Model	OPEX version 1.0.2

Table 6.6-5: Estimated worker exposure

		Aminopyralid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate:		1 x 0.00801 kg a.s./ha	
Inspection, irrigation, outdoor, 2 hours/day (1), TC (potential): 12500 cm²/person/h TC (workwear (arms, body and legs covered)): 1400 cm²/person/h TC (workwear (arms, body and legs covered) and gloves): 1250 cm²/person/h TC (gloves): NA cm²/person/h (2) Body weight: 60 kg	no PPE (3)	0.007	2.7
	with PPE (workwear) (4)	0.0008	0.3
	with PPE (workwear and gloves) (4)	0.0007	0.3

(1) e.g. 8 h/day for professional applications for harvesting, pruning, tying, thinning or weeding activities etc. or 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.
(2) e.g. EUROPOEM II, 2002, Post-Application Exposure of Workers to Pesticides in Agriculture or US-EPA policy paper [EPA, Science Advisory Council for Exposure; Agricultural Transfer Coefficients, Policy # 3.]. TC: Transfer coefficient
(3) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves
(4) with PPE: *type of PPE* / see 'Instructions for use'

	Level of PPE	**Total absorbed dose [mg/kg bw per day]**	**% of systemic AOEL**	**Re-entry restriction [days]**
				Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA Body weight: 60 kg TC (potential): 12500 cm²/h TC (workwear (arms, body and legs covered)): 1400 cm²/h TC (workwear (arms, body and legs covered) and gloves): 1250 cm²/h TC (gloves): NA cm²/h
Aminopyralid				Number of applications & application rate: 1 x 0.00801 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days
Potential		0.007	2.7	0
Workwear		0.0008	0.3	0
Workwear and gloves		0.0007	0.3	0
Hands covered, no workwear				

6.6.4.2 Refinement of generic DFR value (KCP 7.2)

Not required.

6.6.4.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

Comments of zRMS study comment 6.6.4	The applicant presented calculations for worker exposure after entry into a previously treated area treated with AMINO 30 SL/El Camino 30 SL, Ranchero 30 SL max. 1x 0.267 L product/ha using the tractor-mounted.The exposure calculations were conducted using the EFSA online calculator OPEX v 1.0.2. The calculations provided by the applicant were done correctly.
agreed endpoints 6.6.4	According to EFSA OPEX calculations, it can be concluded that the risk of worker exposure during re-entry activities on area treated with AMINO 30 SL/ El Camino 30 SL, Ranchero 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.

6.6.5 Bystander and resident exposure (KCP 7.2.2)

6.6.5.1 Estimation of bystander and resident exposure

Table 6.6-6 shows the exposure model(s) used for estimation of bystander and resident exposure to aminopyralid. Outcome of the estimation is presented in Table 6.6-7. Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Winter oilseed rape (max. 0.267 L product/ha)
Model	OPEX version 1.0.2

Table 6.6-7: Estimated bystander and resident exposure

	Aminopyralid	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 1 x 0.00801 kg a.s./ha		
Bystanders (adult)	AAOEL is not specified; Refer to resident risk assessment	AAOEL is not specified; Refer to resident risk assessment
Bystanders (children)	AAOEL is not specified; Refer to resident	AAOEL is not specified; Refer to resident

	risk assessment	risk assessment
Residents (adult) Drift rate: 100 % (2-3 m) Body weight: 60 kg	0.0008	0.3
Residents (children) Drift rate: 100 % (2-3 m) Body weight: 10 kg	0.002	0.8

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
			Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 l
Aminopyralid			Number of applications and application rate: 1 x 0.00801 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0008	0.3
	Vapour (75th perc.)	0.0008	0.3
	Deposits (75th perc.)	9e-05	0.03
	Re-entry (75th perc.)	0.0009	0.4
	Sum (mean)	0.002	0.8
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0002	0.07
	Vapour (75th perc.)	0.0003	0.1
	Deposits (75th perc.)	4e-05	0.01
	Re-entry (75th perc.)	0.0005	0.2
	Sum (mean)	0.0008	0.3

6.6.5.2 Measurement of bystander and/or resident exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for aminopyralid will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

Comments of zRMS study comment 6.6.4	The applicant presented calculations for resident exposure after application of AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL on winter oilseed rape: max. 1x 0.267 L product/ha using the tractor-mounted (field). The exposure calculations were conducted by the applicant using the EFSA online calculator OPEX v 1.0.2. The calculations provided by the applicant were done correctly.
agreed endpoints 6.6.4	The exposure assessment for residents also covers bystander exposure. According to calculations, it can be concluded that there is no unacceptable risk to any resident (child and adult) and bystander after application of AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL.

6.6.6 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

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	Owner
-	-	-	-	-	-

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	Owner
-	-	-	-	-	-

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	Owner
-	-	-	-	-	-

List of data relied on 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	Owner
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Not required.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	The hazard assessment has been conducted by the applicant based on the alternative method (calculation) according to the Regulation (EC) 1272/2008 and is acceptable.

Reference:	KCP 7.1.1
Report	Toxicological classification of product AMINO 30 SL based on calculation method taking into consideration health hazards of constituent substances; A. Dobersztyn; 2025
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes/~~No/Supplementary~~

According to point 7.1.1 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:
" A test for acute oral toxicity shall be carried out, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute oral toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture."

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation AMINO 30 SL are known, the acute oral toxicity test is not necessary.

Materials and methods

We use the summation method using the formula:

$$ATE_{mix} = \frac{100}{\sum_{i=1}^{n} \frac{C_i}{ATE_i}}$$

Where:

- Ci - concentration of ingredient i (% w/w or % v/v)
- i – the individual ingredient from 1 to n
- n – the number of ingredients

- ATE_i - Acute Toxicity Estimate of ingredient i.

We use the table:

Table 3.1.2 Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for classification for the respective routes of exposure.

Exposure routes	Classification Category or experimentally obtained acute toxicity range estimate	Converted acute toxicity point estimate (see Note 1)
Oral (mg/kg bodyweight)	0 < Category 1 ≤ 5 5 < Category 2 ≤ 50 50 < Category 3 ≤ 300 300 < Category 4 ≤ 2 000	0,5 5 100 500
Dermal (mg/kg body-weight)	0 < Category 1 ≤ 50 50 < Category 2 ≤ 200 200 < Category 3 ≤ 1 000 1 000 < Category 4 ≤ 2 000	5 50 300 1 100
Gases (ppmV)	0 < Category 1 ≤ 100 100 < Category 2 ≤ 500 500 < Category 3 ≤ 2 500 2 500 < Category 4 ≤ 20 000	10 100 700 4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5 0,5 < Category 2 ≤ 2,0 2,0 < Category 3 ≤ 10,0 10,0 < Category 4 ≤ 20,0	0,05 0,5 3 11
Dust/mist (mg/l)	0< Category 1 ≤ 0,05 0,05 < Category 2 ≤ 0,5 0,5 < Category 3 ≤ 1,0 1,0 < Category 4 ≤ 5,0	0,005 0,05 0,5 1,5

Note 1 These values are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results.

Only one ingredient is relevant in this class of hazard:

- 0.78 % (Acute Tox. 4, H302); ATE = 1361 mg/kg bw

$$ATE_{mix} = \frac{100}{\sum_{i=1}^{n} \frac{C_i}{ATE_i}} = \frac{100}{\frac{0.78}{1361}} = \frac{100}{0.0006} = 166\,667$$

According to the table 3.1.2, result (166 667 mg/kg bw) is higher than generic concentration level (2 000 mg/kg bw).

Conclusion

According to calculation method, the result 166 667 mg/kg bw is significantly higher than result triggering classification. Therefore the formulation is not classified as Acute Tox. 4, H302.

According to point 7.1.1 of part A of Annex Regulation No 284/~~20142013~~, it is possible to waive from performing acute oral toxicity tests.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	The hazard assessment has been conducted by the applicant based on the alternative method (calculation) according to the Regulation (EC) 1272/2008 and is acceptable.

Reference:	KCP 7.1.2
Report	Toxicological classification of product AMINO 30 SL based on calculation method taking into consideration health hazards of constituent substances; A. Dobersztyn; 2025
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes~~/No/Supplementary~~

According to point 7.1.2 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:
”A test for dermal toxicity shall be carried out on a case by case basis, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute dermal toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.
Findings of severe skin irritation or corrosion in the dermal study may be used instead of performing a specific irritation study.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation AMINO 30 SL are known, the acute dermal toxicity test is not necessary.

Materials and methods

We use the summation method using the formula:

$$ATE_{mix} = \frac{100}{\sum_{i=1}^{n} \frac{C_i}{ATE_i}}$$

Where:

- Ci - concentration of ingredient i (% w/w or % v/v)
- i – the individual ingredient from 1 to n
- n – the number of ingredients
- ATE_i - Acute Toxicity Estimate of ingredient i.

We use the table:

Table 3.1.2 Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for classification for the respective routes of exposure.

Exposure routes	Classification Category or experimentally obtained acute toxicity range estimate	Converted acute toxicity point estimate (see Note 1)
Oral (mg/kg bodyweight)	0 < Category 1 ≤ 5 5 < Category 2 ≤ 50 50 < Category 3 ≤ 300	0,5 5 100

	300 < Category 4 ≤ 2 000	500
Dermal (mg/kg body-weight)	0 < Category 1 ≤ 50 50 < Category 2 ≤ 200 200 < Category 3 ≤ 1 000 1 000 < Category 4 ≤ 2 000	5 50 300 1 100
Gases (ppmV)	0 < Category 1 ≤ 100 100 < Category 2 ≤ 500 500 < Category 3 ≤ 2 500 2 500 < Category 4 ≤ 20 000	10 100 700 4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5 0,5 < Category 2 ≤ 2,0 2,0 < Category 3 ≤ 10,0 10,0 < Category 4 ≤ 20,0	0,05 0,5 3 11
Dust/mist (mg/l)	0< Category 1 ≤ 0,05 0,05 < Category 2 ≤ 0,5 0,5 < Category 3 ≤ 1,0 1,0 < Category 4 ≤ 5,0	0,005 0,05 0,5 1,5

Note 1 These values are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results.

Only one ingredient is relevant in this class of hazard:

- 0.78 % (Acute Tox. 4, H312)

Estimated values of LD_{50} were taken.

$$ATE_{mix} = \frac{100}{\sum_{i=1}^{n} \frac{C_i}{ATE_i}} = \frac{100}{\frac{0.78}{1100}} = \frac{100}{0.0007} = 142\,857$$

According to the table 3.1.2, result (142 857 mg/kg bw) is higher than generic concentration level (2 000 mg/kg bw).

Conclusion

According to calculation method, the result 142 857 mg/kg bw is significantly higher than result triggering classification. Therefore the formulation is not classified as Acute Tox. 4, H312.

According to point 7.1.2 of part A of Annex Regulation No 284/~~2014~~2013, it is possible to waive from performing acute ~~oral~~dermal toxicity tests.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	The hazard assessment has been conducted by the applicant based on the alternative method (calculation) according to the Regulation (EC) 1272/2008 and is acceptable.

Reference:	KCP 7.1.3
Report	Toxicological classification of product AMINO 30 SL based on calculation method taking into consideration health hazards of constituent substances; A. Dobersztyn; 2025
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-

GLP: No

Acceptability: Yes/~~No/Supplementary~~

Inhalation study on AMINO 30 SL is not required. ~~a~~According to point 7.1.3 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products the inhalation test must be carried out ~~since~~ when the preparation is:

- a gas or liquefied gas,
- a smoke generating formulation or fumigant,
- used with fogging equipment,
- a vapor releasing preparation,
- an aerosol,
- a powder containing a significant proportion of particles of diameter <50 µm (> 1% on a weight basis),
- to be applied from aircraft in cases where inhalation exposure is relevant,
- contains an active substance with a vapor pressure > 1x10-2 Pa and is to be used in enclosed spaces such as warehouses or glasshouses,
- ~~to be applied in a manner which generates a significant proportion of particles or droplets of diameter < 50 µm (> 1% on a weight basis).~~
- to be applied by spraying.

A study shall not be required if the applicant can justify an alternative approach under Regulation (EC) No 1272/2008, where applicable.

~~The active substances and the other co-formulants are not classified as acute inhalation toxic, it can be assumed that entire formulation is not classified in this class.~~ According to point 7.1.3 of part A of Annex Regulation No 284/2014, it is possible to waive from acute inhalation toxicity test.

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Materials and methods

We use the summation method using the formula:

$$ATE_{mix} = \frac{100}{\sum_{i=1}^{n} \frac{C_i}{ATE_i}}$$

Where:

- Ci - concentration of ingredient i (% w/w or % v/v)
- i – the individual ingredient from 1 to n
- n – the number of ingredients
- ATE_i - Acute Toxicity Estimate of ingredient i.

We use the table:

Table 3.1.2 Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for classification for the respective routes of exposure.

Exposure routes	Classification Category or experimentally obtained acute toxicity range estimate	Converted acute toxicity point estimate (see Note 1)
Oral (mg/kg bodyweight)	0 < Category 1 ≤ 5 5 < Category 2 ≤ 50 50 < Category 3 ≤ 300 300 < Category 4 ≤ 2 000	0,5 5 100 500
Dermal (mg/kg body-weight)	0 < Category 1 ≤ 50 50 < Category 2 ≤ 200 200 < Category 3 ≤ 1 000 1 000 < Category 4 ≤ 2 000	5 50 300 1 100
Gases (ppmV)	0 < Category 1 ≤ 100 100 < Category 2 ≤ 500 500 < Category 3 ≤ 2 500 2 500 < Category 4 ≤ 20 000	10 100 700 4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5 0,5 < Category 2 ≤ 2,0 2,0 < Category 3 ≤ 10,0 10,0 < Category 4 ≤ 20,0	0,05 0,5 3 11
Dust/mist (mg/l)	0< Category 1 ≤ 0,05 0,05 < Category 2 ≤ 0,5 0,5 < Category 3 ≤ 1,0 1,0 < Category 4 ≤ 5,0	0,005 0,05 0,5 1,5

Note 1 These values are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results.

Only one ingredient is relevant in this class of hazard:

- 0.78 % (Acute Tox. 4, H332); ATE = 1.86 mg/l

$$ATE_{mix} = \frac{100}{\sum_{i=1}^{n} \frac{C_i}{ATE_i}} = \frac{100}{\frac{0.78}{1.86}} = \frac{100}{0.42} = 238$$

According to the table 3.1.2, result (238 mg/l) is higher than generic concentration level (20 mg/l).

Conclusion

According to calculation method, the result 238 mg/l is significantly higher than a result triggering classification. Therefore the formulation is not classified as Acute Tox. 4, H332.

According to point 7.1.3 of part A of Annex Regulation No 284/~~2014~~2013, it is possible to waive from performing acute oral toxicity tests.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	The hazard assessment has been conducted by the applicant based on the alternative method (calculation) according to the Regulation (EC) 1272/2008 and is acceptable.

Reference:	KCP 7.1.4
Report	Toxicological classification of product AMINO 30 SL based on calculation method taking into consideration health hazards of constituent substances; A. Dobersztyn; 2025

Guideline(s): Regulation (EC) No. 1272/2008

Deviations: -

GLP: No

Acceptability: Yes/~~No/Supplementary~~

Materials and methods

According to point 7.1.4 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:
" The skin irritancy of the plant protection product shall be reported based on the tiered approach, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin irritation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture."

The complete composition of the formulation with the classification of individual ingredients is available in part C.
Due to the fact, that all components of the formulation AMINO 30 SL are known, skin corrosive test is not necessary.

Table 3.2.3 Generic concentration limits of ingredients classified for skin corrosive/irritant hazard (Category 1 or 2) that trigger classification of the mixture as corrosive/irritant to skin.

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin Corrosive	Skin Irritant
	Category 1 (see note below)	Category 2
Skin Corrosive Categories 1A, 1B, 1C	≥ 5 %	≥ 1 % but < 5 %
Skin irritant Category 2		≥ 10 %
10 × Skin Corrosive Category 1A, 1B, 1C) + Skin irritant Category 2		≥ 10 %

Note
The sum of all ingredients of a mixture classified as Skin Corrosive Category 1A, 1B or 1C respectively, shall each be ≥ 5 % respectively in order to classify the mixture as either Skin Corrosive Category 1A, 1B or 1C. If the sum of the Skin Corrosive Category 1A ingredients is < 5 % but the sum of Category 1A+1B ingredients is ≥ 5 %, the mixture shall be classified as Skin Corrosive Category 1B. Similarly, if the sum of Skin Corrosive Category 1A+1B ingredients is < 5 % but the sum of Category 1A+1B+1C ingredients is ≥ 5 % the mixture shall be classified as Skin Corrosive Category 1C.

Only one ingredient is relevant in this class of hazard:

- 0.78 % (Skin Corr 1B, H314)

The concentration of this ingredient (0.78 %) is below result triggering skin hazard classification (≥ 1 ~~< 5~~ %).

Conclusion

The concentration of this ingredient 0.78 % is below result triggering skin hazard classification (≥ 1 < 5 %). Therefore the whole formulation is not classified in this class of hazard.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	The hazard assessment has been conducted by the applicant based on the alternative method (calculation) according to the Regulation (EC) 1272/2008 and is acceptable.

Reference:	KCP 7.1.5
Report	Toxicological classification of product AMINO 30 SL based on calculation method taking into consideration health hazards of constituent substances; A. Dobersztyn; 2025
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes/~~No/Supplementary~~

Materials and methods

According to point 7.1.5 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:
" Eye irritation tests shall be provided, unless it is likely that severe effects on the eyes may be produced or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, eye irritation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture."

The complete composition of the formulation with the classification of individual ingredients is available in part C.
Due to the fact, that all components of the formulation AMINO 30 SL are known, eye corrosion test is not necessary.

For consideration of corrosive and irritant properties the following table applies:

Table 3.3.3 Generic concentration limits of ingredients of a mixture classified as Skin corrosive Category 1 and/ or eye Category 1 or 2 for effects on the eye that trigger classification of the mixture for effects on the eye (Category 1 or 2).

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Irreversible Eye Effects	Reversible Eye Effects
	Category 1	Category 2
Eye Effects Category 1 or Skin Corrosive Category 1A, 1B, 1C	≥ 3 %	≥ 1 % but < 3 %
Eye Effects Category 2		≥ 10 %
(10 × Eye Effects Category 1) + Eye effects Category 2		≥ 10 %
Skin Corrosive Category 1A, 1B, 1C + Eye effects Category 1	≥ 3 %	≥ 1 % but < 3 %
10 × (Skin Corrosive Category 1A, 1B,		≥ 10 %

1C + Eye Effects Category 1) + Eye Effects Category 2		

Two ingredients is relevant in this class of hazard:

- 3.07 % (Eye Dam. 1, H318)
- 0.78 % (Eye Dam. 1, H318)

The sum of this ingredients (3.85 %) is higher than result triggering eye hazard classification (3 %).

Conclusion

According to calculation method, the result 3.85 % is higher than generic concentration level (3 %)
Therefore the whole formulation is classified as corrosive to eyes, **Eye Dam. 1, H318.**

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	The hazard assessment has been conducted by the applicant based on the alternative method (calculation) according to the Regulation (EC) 1272/2008 and is acceptable.

Reference:	KCP 7.1.6
Report	Toxicological classification of product AMINO 30 SL based on calculation method taking into consideration health hazards of constituent substances; A. Dobersztyn; 2025
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes/~~No/Supplementary~~

According to point 7.1.6 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

”The skin sensitisation test shall be carried out unless the active substances or co-formulants are known to have sensitising properties or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin sensitisation properties of all components shall be provided or reliably predicted with a validated method.
Consideration shall be given to the possible effects of components on the sensitising potential of the total mixture.” Due to the fact, that all components of the formulation AMINO 30 SL are known, skin sensitisation test is not necessary.

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Materials and methods

We use the table:

Table 3.4.5
Generic concentration limits of ingredients of a mixture classified as either skin sensitisers or respiratory sensitisers that trigger classification of the mixture

Ingredient classified as:	Concentration triggering classification of a mixture as:		
	Skin Sensitiser	Respiratory Sensitiser	
	All physical states	Solid/Liquid	Gas
Skin Sensitiser Category 1	≥ 1,0 %	-	-
Skin Sensitiser Category 1A	≥ 0,1 %	-	-
Skin Sensitiser Category 1B	≥ 1,0 %		
Respiratory Sensitiser Category 1	-	≥ 1,0 %	≥ 0,2 %
Respiratory Sensitiser Category 1A	-	≥ 0,1 %	≥ 0,1 %
Respiratory Sensitiser Category 1B		≥ 1,0 %	≥ 0,2 %

No relevant ingredients classified in this class of hazard.

Conclusion

According to calculation method, the formulation not cause skin sensitisation.

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co- formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

Not required.

A 2.11 Other/Special Studies

A 2.11.1 Specific target organ toxicity

Reference:	KCP 7.1.7
Report	Toxicological classification of product AMINO 30 SL based on calculation method taking into consideration health hazards of constituent substances; A. Dobersztyn; 2025
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	Yes/~~No/Supplementary~~

According to point 3.8.3 of Regulation (EC) No 1272/2008 as regards the data requirements for plant protection products:
" Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures shall be classified for specific target organ toxicity following single exposure.
Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate generic concentration limit as mentioned in Table 3.8.3 for Category 1 and 2 respectively".

Materials and Methods

For consideration of specific target organ toxicity, the following table applies:

Table 3.8.3 Generic concentration limits of ingredients of a mixture classified as a specific target organ toxicant that trigger classification of the mixture as Category 1 or 2.

Ingredient classified as:	Generic concentration limits triggering classification of the mixture as:	
	Category 1	Category 2
Category 1 Specific Target Organ Toxicant	Concentration ≥ 10 %	1,0 % ≤ concentration < 10 %
Category 2 Specific Target Organ Toxicant		Concentration ≥ 10 % [(Note 1)]

Note 1 If a Category 2 specific target organ toxicant is present in the mixture as an ingredient at a concentration
≥ 1,0 % a SDS shall be available for the mixture upon request.
We also took into account the point 3.8.3.4.5.: "Care shall be exercised when extrapolating toxicity of a mixture that contains Category 3 ingredient(s). A generic concentration limit of 20 % is appropriate; however, it shall be recognised that this concentration limit may be higher or lower depending on the Category 3 ingredient(s) and that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20 % value. Expert judgement shall be exercised."

Only one ingredient is classified in this class of hazard.

- 0.78 % (STOT SE 3; SCL: H335: C ≥ 5 %)

The concentration of one of the ingredients (0.78 %) is below specific concentration level triggering STOT SE 3, H335 classification of whole formulation (5 %).

Conclusions
The concentration of the ingredient 0.78 % is below specific concentration level triggering STOT SE 3, H335 classification of whole formulation (5 %). Therefore, the product is not classified in this class of hazard.

Appendix 3 Exposure calculations

AMINO 30 SL_20241106_11h09_opex1.0.2.zip

AMINO 30 SL_20241106.docx

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for aminopyralid

Table A 11: Input parameters considered for the estimation of operator exposure
Scenario 1 : Outdoor, normal, downward spraying, vehicle-mounted
Aminopyralid, input data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	**Name of active substance**	Aminopyralid
Concentration of active substance [g a.s./l or kg]	30	**Crops**	Field crops
Area treated [ha/day]	50	**Application method**	Downward spraying
Dermal absorption [%] (concentrate)	50	**Application technique**	Vehicle-mounted
Dermal absorption [%] (dilution)	70	**Indoor/outdoor**	Outdoor
Oral absorption [%]	100	**Drift reduction [%]**	0
Inhalation absorption [%]	100	**Type of cultivation**	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.26		
AAOEL [mg/kg bw]			

Aminopyralid , Per body part - Short term exposure

Activity	**Systemic exposure per body part**	**With workwear**	**With workwear + PPE/RPE**
Mixing and loading (µg/kg bw per day)	*Hand protection*	*None*	*None*
	Hands exposure	**37.7**	**37.7**
	Body protection	*Workwear*	*Workwear*
	Body exposure	**0.2**	**0.2**
	Head protection	*None*	*None*
	Head exposure	**0.2**	**0.2**
	Inhalation protection	*None*	*None*

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
	Inhalation exposure	**0.04**	**0.04**
Application (µg/kg bw per day)	*Hand protection*	*None*	*None*
	Hands exposure	**0.7**	**0.7**
	Body protection	*Workwear*	*Workwear*
	Body exposure	**0.01**	**0.01**
	Head protection	*None*	*None*
	Head exposure	**0.02**	**0.02**
	Inhalation protection	*None*	*None*
	Inhalation exposure	**0.01**	**0.01**
Total	Total systemic exposure [mg/kg bw per day]	0.04	0.04
	% of AOEL	15	15

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for aminopyralid

Table A 12: Input parameters considered for the estimation of worker exposure Scenario 1 : Outdoor, normal

Aminopyralid , Input data

Indoor/outdoor	Outdoor	**AOEL [mg/kg bw/day]**	0.26
Re-entry activity	Inspection, irrigation	**Dermal transfer coefficient - Total potential exposure [cm²/h]**	12500
Crops	Field crops	**Dermal transfer coefficient - Arm, body and legs covered [cm²/h]**	1400
Application method	Downward spraying	**Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]**	1250
Application technique	Vehicle-mounted	**Dermal transfer coefficient - Hands covered, no workwear [cm²/h]**	
Max. application rate of the product [l or kg/ha]	0.267	**DFR refined worker [µg/cm² foliage per kg a.s./ha]**	3

Max. no. of applications	1	**DT50 foliar worker [days]**	30
Interval between multiple applications [days]	NA		
Multiple application factor	1		
Body weight (kg)	60		
Name of active substance	Aminopyralid		
Dermal absorption [%] (dilution)	70		
Inhalation absorption [%]	100		
Time [hours per day]	2		

Aminopyralid , Exposure per body part

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	0.4	0.05	0.04	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
Total	Total systemic exposure [mg a.s. per day]	0.4	0.05	0.04	NA
	Total systemic exposure [mg/kg bw per day]	0.007	0.0008	0.0007	NA
	% of AOEL	2.7	0.3	0.3	NA

A 3.3 Bystander and resident exposure calculations (KCP 7.2.1.1)

A 3.3.1 Calculations for aminopyralid

Table A 13: Input parameters considered for the estimation of resident exposure Scenario 1 : Outdoor, season not relevant

	Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
				Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 l

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Aminopyralid	Number of applications and application rate: 1 x 0.00801 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0008	0.3
	Vapour (75th perc.)	0.0008	0.3
	Deposits (75th perc.)	9e-05	0.03
	Re-entry (75th perc.)	0.0009	0.4
	Sum (mean)	0.002	0.8
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0002	0.07
	Vapour (75th perc.)	0.0003	0.1
	Deposits (75th perc.)	4e-05	0.01
	Re-entry (75th perc.)	0.0005	0.2
	Sum (mean)	0.0008	0.3

Table A 14: Input parameters considered for the estimation of bystander exposure Scenario 1 : Outdoor, season not relevant

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AAOEL
			Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 l
Aminopyralid	Number of applications and application rate: 1 x 0.00801 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.002	
	Vapour (95th perc.)	0.0008	
	Deposits (95th perc.)	0.0003	
	Re-entry (95th perc.)	0.0009	
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.0005	
	Vapour (95th perc.)	0.0003	
	Deposits (95th perc.)	0.0001	
	Re-entry (95th perc.)	0.0005	

A 3.4 Combined exposure calculations

Not required.

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Not required.