REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: RNB 072 A

Product name(s): **MATLAM**

Chemical active substance:

Florasulam, 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: XXXX

Submission date: June 2024

Evaluation date: February 2025

MS Finalisation date: May 2025

Version history

When	What
June 2024	Version submitted by the applicant
February 2025	Version evaluated by zRMS PL
November 2025	zRMS updated final version

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6 Mammalian Toxicology (KCP 7)

The composition of the product is comparable to plant protection product Kantor 050 SC Dow AgroSciences.

6.1 Summary

Table 6.1-1: Information on MATLAM*

Product name and code	RNB 072 A/ MATLAM
Formulation type	Suspension Concentrate; SC
Active substance(s) (incl. content)	Florasulam; 50 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 MATLAM 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 MATLAM according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Hazard pictograms or Code(s) for hazard pictogram(s):	GHS09
Signal word:	Warning
Hazard statement(s):	H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	P280- Wear protective gloves/protective clothing/eye protection/face protection. P273 – Avoid release to the environment. P391 – Collect spillage.
Additional labelling phrases:	EUH401 — 'To avoid risks to human health and the environment, comply with the instructions for use' EUH208 - Contains 1,2-Benzisothiazol-3(2H)-one. May produce an allergic reaction. Other non-active hazardous substances: 1,2-Benzisothiazol-3(2H)-one

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for MATLAM.

	Result	PPE / Risk mitigation measures
Operators	Acceptable	PPE –workwear at mixing/loading and during application
Workers	Acceptable	PPE working wear
Bystanders	Acceptable	None
Residents	Acceptable	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.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in the following table.

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)**	**Max. application rate kg as/ha a) Florasulam**	**Water L/ha min / max**			**Operator**	**Worker**	**Bystander**	**Residents**
1 - 4	Cereals	F	Foliar spraying, LCTM	1 ; -	a) 0.005	200 - 400	55 Spring 60 Winter	Operators, workers, bystanders and residents [OPEX]	A	A	A	A

* 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

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)

	Florasulam
Common Name	Florasulam (ISO); 2′,6′,8-trifluoro-5-methoxy[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonanilide

	Florasulam
CAS-No.	145701-23-1
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Code(s) for hazard pictogram(s): GHS09 Signal word: Warning Hazard statement(s): H400, H410 Precautionary statement(s): P273, 391, 501
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	0.05 mg/kg bw/d
Reference	EFSA Journal 2015;13(1):3984
Conditions to take into account/critical areas of concern with regard to toxicology	
Review Report/EFSA Conclusion for active substance	None

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for MATLAM 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.

zRMS PL:
As it have been demonstrated in confidential part C of this report the composition of product **MATLAM** is considered equivalent/ comparable to already registered Floras 50 SC in Poland. Applicant has provided the letter of access to the Floras 50 SC data. So, toxicological data taken from Floras 50 SC can be used to support product **MATLAM** registration in Poland.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for product MATLAM

Type of test, species, model system (Guideline)	**Result**	**Acceptability**	**Classification (acc. to the criteria in Reg. 1272/2008)**	**Reference**
LD_{50} oral, rat (OECD 423)	Not submitted, not necessary. Justification presented in Appendix 2			
LD_{50} dermal, rat	Not submitted, not necessary. Justification presented in Appendix 2			
LC_{50} inhalation, rat	Not submitted, not necessary. Justification presented in Appendix 2			
Skin corrosion, in vitro (OECD 431)	Non-corrosive	Acceptable as suportive study	None	XXXX, 2022
Skin irritation, in vitro (OECD 439)	Not submitted, not necessary.			
Eye irritation/damage, in vitro (OECD 438)	Not eye damage	Acceptable as suportive study	None	XXXX., 2022

Eye irritation/corrosion, in vivo (OECD 405)	Not submitted, not necessary.			
Skin sensitisation, ~~guinea pig~~ (OECD 442E; 442D)	Not skin sensitizer	Acceptable as suportive studies	None	XXXX.,2023 XXXX.,2022
Supplementary studies for combinations of plant protection products	No data – not required	-		

Table 6.3-2: Additional toxicological information relevant for classification/labelling of MATLAM

	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)	Florasulam (4.81 % (w/w))	Aquatic Acute 1; H400 Aquatic Chronic 1; H410	Reg. 1272/2008	Relevant Aquatic Acute 1; H400 Aquatic Chronic 1; H410
Toxicological properties of non-active substance(s) (relevant for classification of product)	1,2-Benzisothiazol-3(2H)-one	Acute Tox. 2, H330 Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Reg. 1272/2008 RAC Opinion	EUH208 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Further toxicological information	No data – not required			

6.4 Toxicological Evaluation of Groundwater Metabolites

The following data on metabolites with the potential to reach the groundwater in concentrations above 0.1 µg/L and requiring relevance assessment were submitted. Note that the relevance assessment of the metabolites is reported in Part B.10; the submitted toxicological studies are summarized in this document.

6.4.1 ASTCA

An overview of the results of the accepted toxicological studies for groundwater metabolite ASTCA is given in the following table.

~~Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).~~

Table 6.4-1: Summary of the results of toxicity studies for ASTCA

Type of test, species (Guideline)	Result	Acceptability	Reference*
Microsome Reverse Mutation Assay (OECD 471 and 472)	Non-mutagenic	The study not provided, but it was evaluated within EU peer review process (EFSA Journal 2015; 13(1):3984)	2008; study number: 071120, 6736-196
Chinese Hamster Ovary Cell/Hypoxanthine-Guanine-Phosphoribosyl Transferase (CHO/HGPRT) Mutation Assay (OECD 476)	Non-mutagenic	The study not provided, but it was evaluated within EU peer review process (EFSA Journal 2015; 13(1):3984)	2008, study number: 071133
In Vitro Chromosomal Aberration Assa (OECD 473)	Non-genotoxic	The study not provided, but it was evaluated within EU peer review process (EFSA Journal 2015; 13(1):3984)	2008, study number: 071132

* indicates that a study was reviewed at EU level

zRMS:
According to EFSA conclusions (EFSA Journal 2015; 13(1):3984) based on the available data and on the toxicological profile of florasulam, the metabolite ASTCA is not considered toxicologically relevant groundwater metabolite.

6.4.2 TSA

An overview of the results of the accepted toxicological studies for groundwater metabolite TSA is given in the following table. Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).

Table 6.4-2: Summary of the results of toxicity studies for TSA

Type of test, species (Guideline)	Result	Acceptability	Reference*
Bacterial Reverse Mutation Assa (OECD 471)	Non-mutagenic		Nagane, R.M., 2011; study number: 110432
Chinese Hamster Ovary Cell Mutation Assay (OECD 476)	Non-mutagenic		2011, study number: 110430
In Vitro Chromosomal Aberration Assa (OECD 473)	Non-genotoxic		2011, study number: 110431

* indicates that a study was reviewed at EU level

zRMS:
According to EFSA conclusions (EFSA Journal 2015; 13(1):3984) based on the available data and on the toxicological profile of florasulam, the metabolite TSA is not considered toxicologically relevant groundwater metabolite.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in MATLAM are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substance in MATLAM.

	Florasulam	
	Value	**Reference**
Concentrate	50 %	EFSA Journal 2017;15(6):4873 SANTE/2018/10591 rev.1 24 October 2018
Dilution	50 %	

6.5.1 Justification for proposed values – Florasulam

No data on dermal absorption for florasulam in MATLAM 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 florasulam

	Value	**Justification for value**	**Acceptability of justification**
Concentrate	50 %	A default dermal absorption value of 50% may be applied for (in use) dilutions water-based/dispersed or solid-formulated. A "dilution" when the active substance is present in the plant protection product at a concentration lower than or equal to 50 g/L (or 50g/Kg or 5%).	Acceptable. EFSA Journal 2017;15(6):4873
Dilution	50 %	A default dermal absorption value of 50% may be applied for (in use) dilutions water-based/dispersed or solid-formulated.	Acceptable. EFSA Journal 2017;15(6):4873

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

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

Product name and code	MATLAM
Formulation type	SC
Category	Herbicide
Container size(s), short description	Please, refer to Part B1,B2 and B4
Active substance(s)	**Florasulam**

(incl. content)	50 g/L
AOEL systemic	0.05 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	Concentrate: 50 % Dilution: 50 % EFSA Journal 2017;15(6):4873 SANTE/2018/10591 rev.1 24 October 2018

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/ EU 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 MATLAM according to the critical uses 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 uses	Cereals (max. 0.1 L product/ha)
Model	OPEX EFSA (European Food Safety Authority), Charistou A, Coja T, Craig P, Hamey P, Martin S, Sanvido O, Chiusolo A, Colas M and Istace F, 2022. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032

Table 6.6-3: Estimated operator exposure

		Florasulam	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Vehicle mounted Application rate: 0.005 kg a.s./ha			
Cereals			
OPEX Body weight: 60 kg	no PPE (mixing/loading/application)	0.04	78.8
	PPE (Protective clothing) (mixing/loading/application)	-	57.1

zRMS:
The potential exposure of operator as well as the exposure of operator not wearing PPE, but wearing a work clothing (long sleeved shirt, long trousers) and applying product MATLAM (formulation RNB 072 A) on low crops (cereals) at maximal dose of 0.1 L/ha, using tractor-mounted/trailed sprayer (downward spraying, calculated with the EFSA AOEM 2022 are both below of 100% of AOEL for Florasulam, an active substance of the product, therefore it is concluded that operator is not at unacceptable risk if applying MATLAM (formulation RNB 072 A) according to its intended use.

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 data – even without PPE protection, a study to provide measurements of operator exposure was not necessary and was therefore not performed.

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 MATLAM 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 uses	Cereals (max. 0.1 L product/ha)
Model	OPEX EFSA (European Food Safety Authority), Charistou A, Coja T, Craig P, Hamey P, Martin S, Sanvido O, Chiusolo A, Colas M and Istace F, 2022. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032

Table 6.6-5: Estimated worker exposure

		Florasulam	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Number of applications and application rate: max. 1 x 5 g a.s./ha			
Maize			
OPEX Outdoor Work rate: 2 hours/day, DT_{50}: 30 days Initial DFR: 3 µg/cm2/kg a.s./ha Body weight: 60 kg	no PPE	0.003	6.3
	PPE (arm, body and legs covered)	0.0004	0.7

	PPE (Hands, arms, body and legs covered)	0.0003	0.6

zRMS:
The potential systemic exposure of worker as well as exposure of worker not wearing PPE, but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals sprayed with product MATLAM (formulation RNB 072 A) calculated using acceptable model (EFSA 2022 AOEM model) demonstrates that such exposures are below of 100% of AOEL for Florasulam, an active substance of the product. Thus it is concluded that the application of a product MATLAM (formulation RNB 072 A) does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice.

6.6.4.2 Refinement of generic DFR value (KCP 7.2)

No applicable.

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.

6.6.5 Bystander and resident exposure (KCP 7.2.2)

6.6.5.1 Estimation of bystander and resident exposure

Błąd! Nie można odnaleźć źródła odwołania. shows the exposure model(s) used for estimation of bystander and resident exposure to Florasulam. Detailed calculations are in Appendix 3.
As no AAOEL is allocated the bystander exposure is covered by resident risk assessment.

Table 6.6-6 Exposure models for intended uses

Critical uses	Cereals (max. 0.1 L product/ha)
Model	OPEX EFSA (European Food Safety Authority), Charistou A, Coja T, Craig P, Hamey P, Martin S, Sanvido O, Chiusolo A, Colas M and Istace F, 2022. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032

Table 6.6-7-1: Estimated bystander and resident exposure – model OPEX

	Florasulam	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted; Field crops Application rate: max. 1 x 0.005 kg a.s./ha		
Maize		
Bystanders (adult)	As no AAOEL is allocated the bystander exposure is covered by resident	

	risk assessment.	
Bystanders (children)	As no AAOEL is allocated the bystander exposure is covered by resident risk assessment.	
Residents (adult) Buffer strip: 2-3 m; Body weight: 60 kg	Drift (75th perc.)	8e-05 (0.2%)
	Vapour (75th perc.)	0.0003 (0.5%)
	Deposits (75th perc.)	2e-05 (0.03%)
	Re-entry (75th perc.)	0.0002 (0.5%)
	Sum (mean)	0.0005 (1%)
Residents (children) Buffer strip: 2-3 m Body weight: 10 kg	Drift (75th perc.)	0.0003 (0.7%)
	Vapour (75th perc.)	0.0008 (1.6%)
	Deposits (75th perc.)	4e-05 (0.08%)
	Re-entry (75th perc.)	0.0004 (0.8%)
	Sum (mean)	0.001 (2.7%)

zRMS:
The exposure estimation of residents (adult and child) to Florasulam, an active substance of a product MATLAM (formulation RNB 072 A) applied on cereals in line with GAP at dose of 0.1 L/ha calculated with the EFSA AOEM 2022 demonstrates that such a exposure in all cases is well below AOEL, therefore the application of product MATLAM (formulation RNB 072 A) does not pose an unacceptable risk to the health of adult and child residents for its intended use within good agricultural practice.

No bystander acute exposure estimation for to Florasulam, an active substance of a product MATLAM (formulation RNB 072 A) is required since no acute acceptable operator exposure value (AAOEL) has be set for any of this active substance. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to Florasulam as a result of application of a product MATLAM (formulation RNB 072 A) ALLY with accordance with intended use within good agricultural practice.

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 Florasulam 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.

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
KCP 7.1.5/01	XXXX	2022	Floras 50 SC: Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage Study code: ICE-03-22 XXXX GLP; Unpublished	Y	XXXX
KCP 7.1.4/01	XXXX	2022	Floras 50 SC: In Vitro Skin Corrosion: Reconstructed Human Epidermis (RHE) Test Method Study code: SCT-02-22 XXXX GLP; Unpublished	~~Y~~ N	XXXX
KCP 7.1.6/01	XXXX	2023	Floras 50 SC: In Vitro Skin Sensitisation: Human cell line activation test Study code: HCLA-03-22 XXXX GLP; Unpublished	~~Y~~ N	XXXX
KCP 7.1.6/02	XXXX	2023	Floras 50 SC: In Vitro Skin Sensitisation: ARE-Nrf2 Luciferase Test Method Study code: KST-03-22 XXXX GLP; Unpublished	~~Y~~ N	XXXX

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
CA 5.8_1		2008	Salmonella Escherichia coli/Mammalian-Microsome Reverse Mutation Assay Preincubation Method with a Confirmatory Assay with ASTCA Metabolite of Florasulam DAS Report No.: 071120, 6736-196 (Accession Number) 257169 GLP/GEP (Y/N): Y Published (Y/N): N	N	XXXX
CA 5.8_2		2008	Evaluation of Florasulam ASTCA Metabolite in the Chinese Hamster ovary Ell/hypoxanthine-guanine-phosphoribosyl Transferase (cho/hgprt) Forward Mutation Assay DAS Report No.: 071133 (Accession Number) 257174 GLP/GEP (Y/N): Y Published (Y/N): N	N	XXXX
CA 5.8_3		2008	Evaluation of Florasulam ASTCA Metabolite in an in vitro Chromosomal Aberration Assay Utilizing Rat Lymphocytes DAS Report No.: 071132 (Accession Number) 257142 GLP/GEP (Y/N): Y Published (Y/N): N	N	XXXX
CA 5.8_4	Nagane, R.M.	2011a	Bacterial Reverse Mutation Test of TSA Metabolite of Florasulam using Salmonella typhimurium Jai Research Foundation DAS Report No.: 110432 (Accession Number) 2010127 GLP/GEP (Y/N): Y Published (Y/N): N	N	XXXX

CA 5.8_5		2011b	In vitro Mammalian Cell Gene Forward Mutation Test at the hgprt Locus of the Chinese Hamster Ovary (CHO)-K1 Cell Line using TSA metabolite of florasulam DAS Report No.: 110430 (Accession Number) 2010107 GLP/GEP (Y/N): Y Published (Y/N): N	N	XXXX
CA 5.8_6		2011c	In vitro Mammalian Chromosome Aberration Test of TSA Metabolite of Florasulam in Human Peripheral Blood Lymphocytes DAS Report No.: 110431 (Accession Number) 2010112 GLP/GEP (Y/N): Y Published (Y/N): N	N	XXXX

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	**Author(s)**	**Year**	**Title Company Report No. Source (where different from company) GLP or GEP status Published or not**	**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

The bridging was not necessary.

A 2.2 Acute oral toxicity (KCP 7.1.1)

No studies submitted.
Calculation method indicates that content (concentration) of raw materials classified as harmful via oral toxicity, not cause such classification for product.

An alternative approach under Regulation (EC) No 1272/2008 may be presented. Toxicity can be determined by the calculation based on the data for relevant ingredients. Details of ingredients and content – see dRR Part C.

Sum of ingredients with classification H302 - Harmful if swallowed: 0.0125 %

Equation:

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

Converted acute toxicity point, according to Table 3.1.2 of regulation 1272/2008.
ATEmix = 3 600 000 mg/kg bw.
ATEmix > 2 000 mg/kg bw.
Product is not classified as Harmful if swallowed.

Comments of zRMS:	The evaluation of acute oral toxicity of a product MATLAM (formulation RNB 072 A) which has been done based on known classification of its ingredients using rules given in Regulation 1272/2008, point 3.1.3.6.1. (see Part C) indicates that product MATLAM (formulation RNB 072 A) does not require classification for acute oral toxicity.

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

No studies submitted.
Calculation method indicates that content (concentration) of raw materials classified as harmful via dermal toxicity, not cause such classification for product.

An alternative approach under Regulation (EC) No 1272/2008 may be presented. Toxicity can be determined by the calculation based on the data for relevant ingredients. Details of ingredients and content – see dRR Part C.

The product does not contain ingredients which are classified as dermally toxic according to regulation 1272/2008. Details of ingredients and content – see dRR Part C

Comments of zRMS:	The evaluation of acute dermal toxicity of a product MATLAM (formulation RNB 072 A) which has been done based on known classification of its ingredients us-

	ing rules given in Regulation 1272/2008, point 3.1.3.6.1. (see Part C) indicates that product MATLAM (formulation RNB 072 A) does not require classification for acute dermal toxicity.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

No data on acute inhalation toxicity for MATLAM. Studies not submitted, not necessary.
The recommended way of spraying formulation MATLAM results in production of medium drops size. MATLAM contains active substance with a vapour pressure below 1×10^{-2} Pa. Thus, according to the regulations (Commission Regulation (EU) No 284/2013), the study of acute inhalation toxicity for MATLAM is not required.
Additivity formula to classification was used.
Sum of ingredients with classification H330 - Harmful if swallowed: 0.0125 %

Equation:

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

Converted acute toxicity point, according to Table 3.1.2 of regulation 1272/2008.
ATEmix = 4 000 mg/L.
ATEmix > 20 mg/L.
Product is not classified as Harmful if inhaled.

Comments of zRMS:	The evaluation of acute inhalation toxicity of a product MATLAM (formulation RNB 072 A) which has been done based on known classification of its ingredients using rules given in Regulation 1272/2008, point 3.1.3.6.1. (see Part C) indicate that product MATLAM (formulation RNB 072 A) does not require classification for acute inhalation toxicity.

A 2.5 Skin irritation (KCP 7.1.4)

A 2.5.1 Study 1

Reference:	KCP 7.1.4
Report	In Vitro Skin Corrosion: Reconstructed Human Epidermis (RHE) Test Method; XXXX., 2022. Study code: SCT-02-22
Guideline(s):	OECD Guideline No. 431 / EU Method B.40.BIS
Deviations:	From study plan: - the concentration of carbon dioxide (CO2) in the incubator was temporary inadequate. However, such short-term changes in carbon dioxide had no effect on the test. Therefore, this deviation did not affect the course and results of the study. - the scheme in the main test differs from the one presented in the Study Plan. It was a mistake connected with distribution of samples on the 96-well plate and had no effect on the course and results of the study. From OECD 431: - permissible variations in temperature, carbon dioxide concentration, humidity and incubation times (according to MatTek protocol [9]). The devia-

tion is to carry out the test under standard laboratory conditions and it does not affect the results obtained. The concentration of carbon dioxide (CO2) in the incubator decreased once to the level below 4.0%.
- The acceptance criterion for the difference in viability of tissues exposed to the test item has been changed. According to OECD guideline 431, a coefficient of variation (CV) would have to be calculated, which should not be greater than 30%. However, according to the kit manufacturer's recommendations (MatTek protocol [9]), the appropriate criterion for two tissues is to calculate the difference in viability between them (this difference should not exceed 30%), as is the case in the other RHE methods listed in OECD guideline 431.This deviation is in accordance with the kit manufacturer's protocol and does not affect the results obtained.

GLP: Yes

Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	Floras 50 SC date of production: 05.04.2022. Batch No. RFEAR0501
Species	EpiDerm™ kit (MatTek In Vitro Life Science Laboratories in Bratislava).
Study course:	Skin corrosion refers to the production of irreversible tissue damage following the application of a test item. The test consists of a topical exposure of the neat test item to a human reconstructed epidermis model followed by a cell viability test. Cell viability is measured by dehydrogenase conversion of MTT, present in cell mitochondria, into a blue formazan salt that is quantitatively measured after extraction from tissues. The percentage reduction of cell viability in comparison of untreated negative controls is used to predict the skin corrosion potential. Two inserts with tissues of the human skin model EpiDerm™ were treated with the test item for 3 minutes and for 60 minutes. The test item was applied directly to each tissue and spread to match the tissue size. Deionized water was used as negative control and 8N KOH solution was used as positive control.
Remarks	None

Results and discussions:

All acceptance criteria (absorbance value for negative control, mean value of relative tissue viability of positive control, variation within the tissue replicates, compliance with historical data) were within the appropriate range. Therefore, the experiment is considered as valid.
After the 3-minute exposure to the test item, the mean value of relative tissue viability was equal to 102%. After the 1-hour exposure to the test item, the mean value of relative tissue viability was equal to 83.7%. These values are above the threshold of non-corrosive effects on the skin (viability ≥50 % after 3-minutes exposure and ≥15 % after 60-minutes exposure).

The test item, Floras 50 SC, is identified as non-corrosive in the Reconstructed human Epidermis (RHE) test method. It cannot be classified as category 1 in the UN GHS classification. Therefore, further testing on skin irritation potential with another suitable in vitro study may be required to classify this test item.

An alternative approach under Regulation (EC) No 1272/2008 may be presented. Toxicity can be determined by the calculation based on the data for relevant ingredients. Details of ingredients and content –

see dRR Part C.

The concentration triggering classification for skin corrosion (0.005%< 2% SCL) is not exceeded. The sum of ratio of concentrations to trigger values (0.01125) is below 1. Thus, the product is not classified in that hazard class.

Product is not classified as Causes severe skin burns damage or Causes skin irritation.

Comments of zRMS:	The study KCP 7.1.4 In Vitro Skin Corrosion: Reconstructed Human Epidermis (RHE) Test Method (XXXX, 2022) of a product Floras 50 SC is acceptable. The RhEmethod according to OECD TG 431 is used for regulatory purposes to distinguish corrosive from non-corrosive substances as well as support sub-categorization of corrosives. Since viability measured after exposure time of 3 and 60 minutes was well above ≥ 50% after 3 min exposure and ≥ 15% after 60 min exposure the test item, Floras 50 SC, is identified as non-corrosive in the Reconstructed human Epidermis (RHE) test method.. Therefore, further testing on skin irritation potential of a product Floras 50 SC with another suitable *in vitro* study may be required. The product Floras 50 SC is identical to the product MATLAM (see part C). In the alternative evaluation of skin corrosion/irritation of a product MATLAM (formulation RNB 072 A) which has been done based on known classification of its ingredients using rules given in Regulation 1272/2008, it was shown that product MATLAM (formulation RNB 072 A) does not require classification for skin irritation (see Part C).

A 2.6 Eye irritation (KCP 7.1.5)

A 2.6.1 Study 1

Reference:	KCP 7.1.5/01
Report	Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage; XXXX., 2022. Study code: ICE-03-22
Guideline(s):	OECD Guideline No. 438 / EU Method B.48
Deviations:	From OECD 438: - Due to confusing entries in the guideline (suggesting a typing error), the categorization was based on the criteria contained in the drafts for guidelines. These are criteria originally developed by Cazelle et al (2014) and adopted by the OECD
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	Floras 50 SC – Production date: 05.04.2022
Species	Eyes used in the study were obtained from healthy approximately 7-week-old chickens whose body weight ranged from 1.5 to 2.5 kg killed for consumption in a licensed slaughterhouse, i.e. Ubojnia

	Drobiu HYBRO Sp. z o.o.in Kaniów
Study course:	Undamaged chicken eyes (corneal opacity ≤ 0.5, fluorescein retention ≤ 0.5) with similar thickness (± 10%) were placed in superfusion apparatus (32 ± 1.5°C with saline drops). The test item and the material used in the positive control (benzalkonium chloride) were applied uniformly over the surface of the cornea in amount of 0.03 mL, while the material used in the negative control (saline) was applied in volume of 0.03 mL. Then they were rinsed with saline. Three eyeballs were used for the test item and three for each control item. The corneas treated with the test item and the control items were evaluated prior to treatment and at 30, 75, 120, 180, and 240 minutes (± 5 minutes) after the post-treatment rinse. At all observation time points, corneal opacity and swelling were evaluated, whereas morphological changes of the corneal surface were recorded. The quantitative determination of fluorescein retention was performed only prior to treatment and 30 minutes after the end of the exposure. After final evaluation, the eyeballs were fixed in a 4% formaldehyde solution for histopathological evaluation.
Remarks	None

Results and discussions

For eyeballs treated with the test item:
- the mean fluorescein retention value was equal to 0.0 (ICE class I),
- the maximum mean corneal opacity value was equal to 0.5 (ICE class I),
- the maximum mean corneal swelling value was equal to -14.8% (ICE class I),
- test item on the surface was not observed.

Histopathological examinations were not able to classify test item as category 1.

On the grounds of the study results described in this Report and the overall in vitro Irritancy Classification, it may be stated that the test item, i.e. Floras 50 SC should not have a negative effect.
According to UN GHS classification criteria no prediction can be made, since the ICE Class combination of the 3 endpoints were: 3 x I (no category). Based on the results obtained during the histopathological evaluation, it can be concluded that the test item should not have a negative effect on the cornea of chickens in the ICE test. The test item can be put into “no category”.
The other additional researches (in vivo or in vitro) are not necessary for classification of this test Item

An alternative approach under Regulation (EC) No 1272/2008 may be presented. Toxicity can be determined by the calculation based on the data for relevant ingredients. Details of ingredients and content – see dRR Part C.

The sum of ratio of concentrations to trigger values (0.007) is below 1. Thus, the product is not classified as corrosion to eyes.
The sum of ratio of concentrations to trigger values (0.0225) is below 1. Thus, the product is not classified as irritant to eyes.

Product is not classified as Causes severe skin burns damage or Causes skin irritation.

Comments of zRMS:	The study KCP 7.1.5 Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage according to OECD TG OECD 438 (XXXX, 2022, 2022) of a product Floras 50 SC is acceptable. This method can identify chemicals that cause serious eye damage (category 1 according to GHS system) as well as chemicals that do not require classification for eye irritation or

	serious eye damage (no category according to GHS system). The in vitro classification for a product Floras 50 SC assessed based on the combination of categories for corneal swelling, corneal opacity, and fluorescein retention as described in Table 7 of OECD TG OECD 438 is "no category", thus the product will not cause adverse effects on eye. The product Floras 50 SC is identical to the product MATLAM (see part C). In the alternative evaluation of eye damage/eye irritation of a product MATLAM (formulation RNB 072 A) which has been done based on known classification of its ingredients using rules given in Regulation 1272/2008, it was shown that product MATLAM (formulation RNB 072 A) does not require classification for eye irritation (see Part C).

A 2.7 Skin sensitisation (KCP 7.1.6)

A 2.7.1 Study 1

Reference:	KCP 7.1.6/01
Report	Floras 50 SC In Vitro Skin Sensitisation: Human cell line activation test; XXXX., 2023, Study code: HCLA-03-22
Guideline(s):	Yes (ECD Guideline No. 442E / EU Method B.71)
Deviations:	From study plan: - For a low viability sample, the cytometric analysis takes more than 60 seconds (not longer than 210 seconds). The analysis time depends on the set flow rate of the cytometer. The Guava cytometer will take approximately 200 µl of low-concentration cell suspension in 210 seconds. The same volume can be taken in 1 minute at the high flow rate setting, but this increases the measurement inaccuracy of the instrument. Therefore, increasing the collection time allowed more cells to be counted with greater accuracy. This deviation did not affect the course and results of the study. - Temperatures in the refrigerator increased twice to not higher than 9.38°C. This was related to the normal use of the refrigerator (opening and closing the door). After a few minutes, the temperature returned to normal and it did not affect the experiment. - CO2 level in the incubator decreased once to not less than 3.5% and returned to normal after several minutes. This was related to the normal use of the incubator (opening and closing the door). After a few minutes, the temperature returned to normal and it did not affect the experiment. - Humidity in the incubator decreased once to not lower than 79.7% for several minutes. Cells are cultured in bottles with liquid medium, so such short fluctuations of environmental changes in the incubator have no effect on the culture. - The address of the Sponsor has changed from Elvita Sp. Zoo. (Różewo 78-627) to Elvita Sp. z o. o. (Dworcowa 4, 87-400 Golub-Dobrzyń). This change did not affect the course and results of the study. - The study was completed in January 2023 instead of December 2022. This deviation did not affect the course and results of the study From OECD 442D: - Maintenance medium without mercaptoethanol and with the addition of glutamine is used for the culture of THP-1 cells. This deviation does not affect the obtained results, which was confirmed by the validation study, in which the correct results of reference materials were obtained.

• The permissible range of carbon dioxide concentration in the incubator and the permissible range of temperatures have been added so that the test can be performed under laboratory conditions. This deviation does not affect the obtained results, which was confirmed by the validation study, in which the correct results of reference materials were obtain

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Materials and methods

Test material (Lot/Batch No.)	Floras 50 SC date of production: 05.04.2022. Batch No. RFEAR0501
Test system	The cell line THP-1 was supplied by CLS and cultured by Toxicology Research Group staff
Study course	The h-CLAT method quantifies changes of cell surface marker expression (i.e. CD86 and CD54) on a THP-1 cells, following 24 hours exposure to the test item. The changes of surface marker expression were measured by flow cytometry following cell staining with fluorochrome-tagged antibodies. Cytotoxicity measurement (PI uptake) was also conducted concurrently to assess whether upregulation of surface marker expression occurs at sub-cytotoxic concentrations. The RFI of surface markers were calculated and used in the prediction model to support the discrimination between sensitizers and non-sensitizers. Prior to testing, the solubility of the test item in medium was determined and medium (RPMI 1640 with 25 mM HEPES) was chosen as the solvent. Therefore, the medium control was used as a reference for the test item. A range finder test was then performed to determine the concentration of CV75. In the first range finder assay the CV75 was not determined, so another test was conducted with different concentration of the test item. In that test CV75 was equal to 3132.6 µg/mL, so the highest final concentration of the test item in the main test was 3760 µg/mL and a geometric series (factor 1.2) of 7 dilutions was prepared from this stock solution (3760 µg/mL; 3133.3 µg/mL; 2611.1 µg/mL; 2175.9 µg/mL; 1813.3 µg/mL; 1511.1 µg/mL; 1259.2 µg/mL; 1049.3 µg/mL). DNCB (2.5 µg/mL) was used as positive control with DMSO as solvent control.
Remarks	None

Results and discussions

Three independent runs were carried out, as the first run did not meet the acceptance criteria (first experiment was found invalid). In run 2 and 3 all acceptance criteria were met, therefore, the study was considered valid. Two valid runs produced negative results (RFIs for CD86 and CD 54 were below 150 and 200, respectively). Therefore, according to the h-CLAT prediction model the result of this study is negative. EC150 and EC200 could not be calculated.

Conclusion

It can be concluded that, under the experimental conditions of this study, the test item has no ability to activate dendritic cells (one of the four key events in skin sensitisation) and therefore should not be con-

sidered as potentially skin sensitizing. However, this is only one of the key events in the skin sensitisation process, so additional tests may be required to fully classify the item.

Comments of zRMS:	The study KCP 7.1.6/01 Floras 50 SC. In Vitro Skin Sensitisation: Human cell line activation test performed according to the OECD Guideline No. 442E / EU Method B.71 (XXXX, 2023) of a product Floras 50 SC is acceptable. This method quantifies changes in the expression of cell surface markers associated with the process of activation of monocytes and dendritic cells (DC) (i.e. CD86 and CD54), in the human monocytic leukaemia cell line THP-1, following exposure to sensitisers . The measured expression levels of CD86 and CD54 cell surface markers are then used for supporting the discrimination between skin sensitisers and non-sensitisers. The relative fluorescence intensity (RFI) of CD86 marker in all runs did not exceed ≥150% at any concentrations and the RFI value of CD54 did not exceed ≥200% at any concentrations. This means that the test item does not have the ability to activate THP-1 monocytes. Therefore, according to the h-CLAT prediction model the result of this study is negative. The Floras 50 SC is unlikely to have skin sensitising properties and should not be considered as potentially skin sensitizing. The product Floras 50 SC is identical to the product MATLAM (see part C). In the alternative evaluation of skin sensitisation of a product MATLAM (formulation RNB 072 A) which has been done based on known classification of its ingredients using rules given in Regulation 1272/2008 (see Part C) it was shown that product MATLAM (formulation RNB 072 A) does not require classification for skin sensitisation. The concentration of 1,2-Benzisothiazolin-3-one in the product MATLAM (formulation RNB 072 A) is above a limit for elicitation, thus a statement EUH208 — Contains 1,2-Benzisothiazolin-3-one. May produce an allergic reaction- should be insert on the label of the product .

A 2.7.2 Study 2

Reference:	KCP 7.1.6/02
Report	Floras 50 SC In Vitro Skin Sensitisation: ARE-Nrf2 Luciferase Test Method; XXXX, 2022, Study code: KST-03-22
Guideline(s):	Yes (ECD Guideline No. 442D / EU Method B.60)
Deviations:	From OECD 442D: - an alternative luminescence measurement is used. This is related to the use of another microplate reader than described in the guideline. Nevertheless, control experiments (validation study) were carried out, which were successfully completed; - the cytotoxicity assay was performed according to the validation protocol DB-ALM no. 155 with additional reference wavelength. According to this protocol, the MTT concentration in the medium is 0.6 mg/mL instead of 5 mg/mL. Isopropanol was used instead of the SDS solution to extract the formazan, because it is a faster and safer way of detection. Absorbance should be measured at 570 nm as this is the more appropriate wavelength for formazan dissolved in isopropanol. The additional use of the reference wavelength (690 nm) is an improvement in the measurement, as it eliminates the background signal (plastic bottom of the plate, cells, unrinsed material deposited on the

bottom). This deviation does not affect the test results as the cell viability obtained is referenced to the negative control;
- the permissible range of carbon dioxide concentration in the incubator and the permissible range of incubation times have been added so that the test can be performed under laboratory conditions.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

Materials and methods

Test material (Lot/Batch No.)	Floras 50 SC date of production: 05.04.2022. Batch No. RFEAR0501
Test system	KeratinoSens™ (Givaudan)
Study course	The ARE-Nrf2 luciferase test method makes use of an immortalised adherent cell line named KeratinoSens™. The cell line contains the luciferase gene under the transcriptional control of a constitutive promoter fused with an ARE from a gene that is known to be up-regulated by contact sensitizers. This allows quantitative measurement (by luminescence detection) of luciferase gene induction. The measured endpoint is the up-regulation of luciferase activity after 48 hours of incubation with test item. Simultaneously, cell viability is measured by MTT cytotoxicity assay. A stock solution containing 40 mg/mL test item in DMSO was prepared, and used to prepare a two-fold dilutions (12 concentrations). These concentrations were further diluted to obtain following final concentrations: 0.195 µg/mL, 0.39 µg/mL, 0.78 µg/mL, 1.56 µg/mL, 3.125 µg/mL, 6.25 µg/mL, 12.5 µg/mL, 25 µg/mL, 50 µg/mL, 100 µg/mL, 200 µg/mL, 400 µg/mL. Trans-cinnamaldehyde was used as positive control in the final concentration range from 4 to 64 µM. To determine the skin sensitization potential of the test item, two independent and valid runs were performed. The results were compared to negative control (only solvent)
Remarks	None

Results and discussions

All acceptance criteria (luciferase activity induction, and EC1.5 value for PC, the average CV of the luminescence reading for NC) were within the appropriate range. Therefore, the experiment is valid.
After the treatment with the test item:
- the overall IC50 could not be calculated (IC50 was calculated only for the first run, and equal to 391.6 µg/mL) and IC30 was equal to 245.5±13.7 µg/mL
- the overall maximal fold induction of luciferase activity (oImax) value for two independent runs was 1.2,
- the overall EC1.5 could not be calculated,
- in both runs the viability of cells above 70% (based on IC30) for the lowest concentration, in which 1.5-fold induction of luciferase activity was noted (EC1.5 concentration) could not be calculated,
- the clear concentration-response relationship for the luciferase activity was not observed for both runs.

Conclusion

In two independent runs, none of the requirements for positive results were met. Therefore, it can be con-

cluded that the test item is negative in the KeratinoSens assay, and should not be considered as potentially skin sensitizing. However, this is only one of the key events in the skin sensitisation process, so additional tests may be required to fully classify the item.

An alternative approach under Regulation (EC) No 1272/2008 may be presented. Toxicity can be determined by the calculation based on the data for relevant ingredients. Details of ingredients and content – see dRR Part C.

Ingredient with classification H317: 0.013 % (SCL: 0.036%)
Concentration triggering classification of a mixture as H317: 0.036 %
Concentration triggering classification of a mixture as EUH208: 0.0036 %

Thus, the mixture is classified as EUH208. Details of ingredients and content – see dRR Part C.

Comments of zRMS:	The study KCP 7.1.6/02 Floras 50 SC. In Vitro Skin Sensitisation: ARE-Nrf2 Luciferase Test Method performed according to the OECD Guideline No. 442D / EU Method B.60. Method B.71 (XXXX, 2022) of a product Floras 50 SC is acceptable. The in vitro ARE-Nrf2 luciferase KeratinoSens™ test method is considered scientifically valid to be used as part of an IATA, to support the discrimination between skin sensitisers and non-sensitisers for the purpose of hazard identification. In this test Floras 50 SC gave a negative results in all repetitions. Therefore, the final results are negative in this assay. This means that Floras 50 SC is unlikely to have skin sensitising properties. The product Floras 50 SC is identical to the product MATLAM (see part C). In the alternative evaluation of skin sensitisation of a product MATLAM (formulation RNB 072 A) which has been done based on known classification of its ingredients using rules given in Regulation 1272/2008 (see Part C) it was shown that product MATLAM (formulation RNB 072 A) does not require classification for skin sensitisation. The concentration of 1,2-Benzisothiazolin-3-one in the product MATLAM (formulation RNB 072 A) is above a limit for elicitation, thus a statement EUH208 — Contains 1,2-Benzisothiazolin-3-one. May produce an allergic reaction- should be insert on the label of the product .

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

No additional studies.

Appendix 3 Exposure calculations

Table	Model / scenario	File
A 3.1	Operator, worker, bystander and resident exposure. EFSA 2022 calculator.	MATLAM_20240403.docx

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)

No additional data.