

REGISTRATION REPORT

Part A

Risk Management

Product code: 041-02-04

Product name(s): SIMULE

Chemical active substance(s):

mesotrione, 75 g/L

nicosulfuron, 30 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Life Scientific Ltd.

Date: 10/11/2025

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PART A

RISK MANAGEMENT

1 Details of the application

The company LIFE SCIENTIFIC LTD has requested a marketing authorisation in France for the product SIMULE (product code: 041-02-04), containing 75 g/L mesotrione¹ and 30 g/L nicosulfuron² as a herbicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of LIFE SCIENTIFIC LTD's application submitted on 21/12/2022 to market SIMULE in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2023-0993) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009³, the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")⁴. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of SIMULE has been made using endpoints agreed in the EU peer reviews of mesotrione and nicosulfuron. It also includes assessment of data and information related to SIMULE where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁵, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of SIMULE.

¹ COMMISSION IMPLEMENTING REGULATION (EU) 2017/725 of 24 April 2017 renewing the approval of the active substance mesotrione in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

² COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances

³ REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁴ SANCO document "risk envelope approach", European Commission (14 March 2011). [Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5](#)

⁵ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

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1.2 Letters of Access

Not necessary:

- active substance data for nicosulfuron are not protected any more.
- the applicant has provided equivalent studies to those essential for renewal of mesotrione, via a data matching table (DMT).

1.3 Justification for submission of tests and studies

According to the applicant:

« In order to address the product data requirements, the applicant is submitting a complete product data package in line with the requirements of Regulation 284/2013. »

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 3.

2 Details of the authorisation decision

2.1 Product identity

Product code	041-02-04
Product name in MS	SIMULE
Authorisation number	-
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	LIFE SCIENTIFIC LTD
Active substance(s) (incl. content)	mesotrione, 75 g/L nicosulfuron, 30 g/L
Formulation type	Oil dispersion [OD]
Packaging	Containers of PET ⁶ (5L, 20L) Containers of HDPE/PA ⁷ (5L, 20L) Containers of fluorinated HDPE ⁸ (5L, 20L)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

⁶ Polyethylene terephthalate

⁷ High density polyethylene / Polyamid

⁸ High density polyethylene

2.2 Conclusion

The evaluation of the application for SIMULE resulted in the decision to refuse the authorisation.




2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Reproductive toxicity, category 2 Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	   GHS06 GHS08 GHS09
Signal word:	Warning
Hazard statement(s):	H361d: Suspected of damaging the unborn child. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
	For other restrictions refer to 2.5

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁹ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 12 April 2021¹⁰ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation¹¹ is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 1	To protect groundwater, following an application on maize, do not apply this or any other product containing nicosulfuron more than every third year on maize.

⁹ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

¹⁰ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

¹¹ SANCO document “guidance document: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

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SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 5 metres to non-agricultural land.
Other specific restrictions	
Re-entry period	48 hours.
Storage	The formulation must be stored at a temperature below 40 °C.
Risk mitigation measures	None

2.5.2 Specific restrictions linked to the intended uses

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

None.

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2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date:10/11/2025

PPP (product name/code): SIMULE / 041-02-04

Formulation type: Formulation code ^(a, b)

Active substance 1: mesotrione

Conc. of a.s. 1: 75 g/L ^(c)

Active substance 2: nicosulfuron

Conc. of a.s. 2: 30 g/L ^(c)

Applicant: LIFE SCIENTIFIC LTD

Professional use: ☒

Zone(s): Southern Zone ^(d)

Non-professional use: ☐

Verified by MS: Yes

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergis per ha (⁽ⁱ⁾)
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Maize	F	Annual broad leaved weeds and annual grasses	Tractor mounted or self- propelled hydraulic sprayer giving overall applicatio n	BBCH 12-19	1	N/A	1.5	112.5 g mesotrione 45 g Nicosulfuron	100- 300	F	Not acceptable (Composition of the product, aquatic organisms, selectivity on sorghum)

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Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d) Select relevant
	(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c) g/kg or g/l	(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1 Numeration necessary to allow references	7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2 Use official codes/nomenclatures of EU Member States	8 The maximum number of application possible under practical conditions of use must be provided.
	3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9 Minimum interval (in days) between applications of the same product
	4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10 For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		13 PHI - minimum pre-harvest interval
		14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

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

Data have been generated which show satisfactory chemical and physical properties for product 041-02-04 before and after storage for 8 weeks at 40 °C at glass bottles. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of the product is that of an off-white suspension, with a weak vegetable oil odour. It is not explosive and has no oxidising properties. The product is not flammable and does not have a flash point below boiling temperature. In a 1% aqueous dispersion, it has a pH value of 3.38. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. Its technical characteristics are acceptable for an oil dispersion formulation.

The intended application rate is 1.5 L/ha, equivalent to 112.5 g mesotrione/ha and 45 g nicosulfuron/ha. The concentration of active substance in the diluted spray solution is 0.375-1.125 g/L mesotrione and 0.15-0.45 g/L nicosulfuron, when used in a water volume of 100-300 L/ha. which is equivalent to 0.5% v/v-1.5% v/v.

For some coformulants in the product's composition, the information provided does not ensure compliance with Regulation (EU) No 2021/383. Hence, the evaluation of product SIMULE cannot be finalized.

The commercial packaging used are containers of PET, HDPE/PA and HDPE-F materials
The product should not be stored above 40°C.

A shelf life study for 2 years at ambient temperature in commercial packaging is to be provided.

3.2 Efficacy (Part B, Section 3)

- The efficacy level of SIMULE applied post-emergence at 1.5 L/ha in maize is considered satisfactory for the control of annual dicotyledonous and grass weeds ;

- **The selectivity level of SIMULE is considered acceptable for the claimed use, except on sorghum. In the absence of selectivity data on sorghum, a risk of phytotoxicity cannot be excluded. The evaluation of the selectivity of SIMULE cannot therefore be finalised for this crop.**

As a lot of different genitors can be used for maize seed production and as their sensitivity may vary, it is considered impossible to test the selectivity of one product on all those genitors and to insure that there is no risk on propagation. It is therefore on the behalf of the seed producer to consult the breeder before application ;

- The risks of negative impact on yield, quality, processing procedures and propagation are considered acceptable ;
- The risk of negative impact on succeeding crops is considered acceptable. Nevertheless, specific attention should be paid to the conditions of establishment of susceptible succeeding crops following product application ;

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- The risk of negative impact on adjacent crops is considered acceptable. Nevertheless, specific attention should be paid to susceptible adjacent crops ;
- The risk of resistance to mesotrione does not require the set-up of a survey. However, there is risk of resistance of *Ambrosia artemisiifolia*, *Digitaria sanguinalis*, *Echinochloa crus-galli*, *Senecio vulgaris* and *Setaria* sp to nicosulfuron requiring a survey.

3.3 Methods of analysis (Part B, Section 5)

Sufficiently sensitive and selective analytical methods are available for the active substance mesotrione and nicosulfuron and relevant impurities in the plant protection product.

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

There are no data gaps outstanding relating to analytical methods for mesotrione and nicosulfuron.

It is considered that all commodities (maize) under consideration are supported.

Commodity/crop	Supported/ Not supported
Maize	Supported

There are no noticed data gaps reported in the EFSA Conclusion.

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

For the following ecotoxicological methods, some information will need to be specified during the comments phase for the methods to be fully validated (see comments of zRMS):

3.3.1 Analytical method for the formulation

3.3.2 Analytical methods for residues

3.4 Mammalian toxicology (Part B, Section 6)

Product name and code	041-02-04	
Formulation type	OD	
Category	Herbicide	
Active substances (incl. content)	Mesotrione 75 g/L	Nicosulfuron 30 g/L

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AOEL systemic	0.005 mg/kg bw/d	0.8 mg/kg bw/d
AAOEL	None	None
Inhalation absorption	100%	100%
Oral absorption	50%	40%
Dermal absorption	Concentrate: 1.6% Dilution: 1.6% (0.375 g/L) (Based on product (formulation))	Concentrate: 40% Dilution: 40% (Default)
Vapour Pressure	<5.7 x 10 ⁻⁶ Pa at 20°C (99.7% pure)	< 8 x 10 ⁻¹⁰ Pa at 25°C (99.8%)

3.4.1 Acute toxicity

SIMULE has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to skin or eye and is not a skin sensitizer.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model 2014¹²:

Long term exposure

		Mesotrione		Nicosulfuron	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to maize					
Application rate		0.1125 kg a.s./ha		0.045 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A + gloves M/L and A	0.0003	6.4	0.0021	0.27

According to the exposure assessment using the EFSA model, operator exposure to SIMULE is below the AOEL value of mesotrione and nicosulfuron, with a working coverall and gloves during mixing/loading and application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for crop inspection/irrigation activities. Therefore, estimation of the worker exposure was calculated according to EFSA model 2014:

¹² AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

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		Mesotrione		Nicosulfuron	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Crop inspection and irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha					
Number of applications and application rate		1 × 0.1125 kg a.s./ha		1 × 0.045 kg a.s./ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0003	5.0	0.0025	0.3

According to the exposure assessment performed by the EFSA model 2014, worker exposure to SIMULE is below the AOEL value of mesotrione and nicosulfuron, with a working coverall.

3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set¹³.

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): “No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.”

3.4.5 Resident exposure

Resident exposure was assessed according to EFSA model 2014 without mitigation measures, (i.e. without drift reduction technology and a buffer zone of 2-3 meters):

		Mesotrione		Nicosulfuron	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to maize Buffer zone: 2-3(m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha					

¹³ Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

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Number of applications and application rate		1 × 0.1125 kg a.s./ha		1 × 0.045 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0005	10	0.0048	0.6
	Vapour (75 th perc.)	0.0011	21	0.0011	0.1
	Deposits (75 th perc.)	0.0001	1.4	0.0003	0.03
	Re-entry (75 th perc.)	0.0003	6.1	0.0030	0.4
	Sum (mean)	0.0016	33	0.0064	0.8
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0001	2.4	0.0012	0.1
	Vapour (75 th perc.)	0.0002	4.6	0.0002	0.03
	Deposits (75 th perc.)	0.00001	0.3	0.0001	0.02
	Re-entry (75 th perc.)	0.0002	3.4	0.0017	0.2
	Sum (mean)	0.0004	8.6	0.0022	0.3

According to the exposure assessment performed by the EFSA model 2014, resident exposure to SIMULE is below the AOEL value of mesotrione and nicosulfuron, without mitigation measures.

3.4.6 Combined exposure

A cumulative assessment for operators, residents (adult and child) and workers was performed. At the first tier, combined exposure was calculated as the sum of the component exposures, without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQ) for each substance and the hazard index (HI: sum of hazard quotients) are detailed in the table below.

Application scenario		Mesotrione Estimated expo- sure / AOEL (HQ)	Nicosulfuron Estimated expo- sure / AOEL (HQ)	Cumulative Exposure – Hazard In- dex
Operators	Working coverall and gloves during mixing/loading and application	0.064	0.0027	0.0667
Worker	Working coverall and gloves	0.05	0.003	0.053
Resident - child	Drift	0.1	0.006	0.106
	Vapour	0.21	0.001	0.211
	Deposits	0.014	0.000	0.014
	Re-entry	0.061	0.004	0.065
	Sum of all pathways	0.33	0.008	0.338
Resident - adult	Drift	0.024	0.001	0.025
	Vapour	0.046	0.000	0.046
	Deposits	0.003	0.000	0.003
	Re-entry	0.034	0.002	0.036
	Sum of all pathways	0.086	0.003	0.089

The combined exposure to all substances in SIMULE (Hazard Index) for operators, workers and residents (adult and child) is < 1.

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

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for maize of 0.01* mg/kg for both mesotrione and nicosulfuron as laid down in Reg. (EU) 396/2005 is not expected.

The chronic intake of mesotrione and nicosulfuron residues is unlikely to present a public health concern. The short-term intakes of mesotrione residues are unlikely to present a public health concern. No acute risk assessment for nicosulfuron was calculated as ARfD was not deemed necessary.

As far as consumer health protection is concerned, FR zRMS agrees with the authorization of the proposed uses.

According to available data, no specific mitigation measures should apply.

Summary for 041-02-04

Table: Information on 041-02-04 (KCA 6.8)

Crop	PHI for 041-02-04 proposed by ap- plicant	PHI sufficiently supported for		PHI for 041-02-04 proposed by zRMS	zRMS Comments (if different PHI pro- posed)
		mesotrione	nicosulfuron		
Maize	F (BBCH 12-19)	Yes	Yes	F (BBCH 12-19)	

NR: not relevant

Waiting periods before planting succeeding (rotational or replacement) crops

Not relevant

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

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009.

The PEC of active substances and their metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models and the endpoints established in the EU conclusions.

PEC soil derived for the active substances and their metabolites are used for the ecotoxicological risk assessment.

PEC_{sw/sed} derived for mesotrione are used for the ecotoxicological risk assessment and mitigation measures are proposed.

PEC_{sw/sed} of nicosulfuron provided by the applicant do not cover the entire intended application period. Thus, in absence of reliable PEC_{sw/sed} values, the risk assessment **for non-target aquatic organisms cannot be finalized for nicosulfuron for the intended use on maize.**

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PEC_{gw} for both active substances and their metabolites do not occur at levels exceeding those mentioned in regulation EU No 546/2011 and guidance document SANCO 221/2000¹⁴ when a single application every third year on maize is considered. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses in the conditions of uses reported under Point 2.5.1.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance(s) and its/their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses in the conditions of uses described under 2.5. For aquatic organisms: PEC_{sw/sed} of nicosulfuron provided by the applicant do not cover the entire intended application period. Thus, in absence of reliable PEC_{sw/sed} values, the risk assessment for non-target aquatic organisms cannot be finalized for the intended use on maize.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

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

SIMULE (041-02-04) contains nicosulfuron approved as a candidate for substitution as two of the criteria for PBT are met (persistent and toxic).

Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) N° 1107/2009)

Use on Maize, millet crops, Hungarian millet, miscanthus

As the request for marketing authorisation concerns a plant protection product (PPP), for which similar products hold a marketing authorisation for the requested uses on Maize, millet crops, Hungarian millet, and miscanthus.

The comparative assessment will be implemented at the time of the re-evaluation of the active substance and jointly with that of the corresponding similar products under Article 43 of Regulation (EC) N°1107/2009.

Use on sorghum

¹⁴ SANCO (2003) Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Regulation (EC) No 1107/2009. Sanco/221/2000-rev.11, 21 October 2021.

Step 1 (French guidance document 27 July 2015):

Taking into account the management of resistance: In accordance with Article 50(1)(c) of Regulation (EC) N 1107/2009, in the frame of resistance emergence prevention, As the diversity of modes of action is not sufficient, substitution will not be considered for the corresponding use on sorghum.

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

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

A survey of resistance to nicosulfuron should be put in place based on the analysis of field efficacy failures, in particular on *Ambrosia artemisiifolia*, *Digitaria sanguinalis*, *Echinochloa crus-galli*, *Senecio vulgaris* and *Setaria* sp. A report on the results of this survey should be provided at the time of the demand of renewal for the product or at any moment in case the applicant has any information available related to the development of resistance (Article 56 point 4 of regulation 1107/2009).

5.1.2 Post-authorisation data requirements

The following data should be provided :

- A shelf life study for 2 years at ambient temperature in commercial packaging

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Appendix 1 Copy of the product authorisation



SIMULE_PAMM_202
3-0993_D.pdf



Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

SIMULE HERBICIDE

Nom homologué : SIMULE
N° d'A.M.M. : XXXXXX
Détenteur de l'A.M.M. : Life Scientific Ltd. – Block 4, Belfield Office Park, Beech Hill Road,
DUBLIN 4 (Irlande)
Type d'action : Herbicide de post-levée (HRAC F2 et B)
Formulation : Suspension concentrée huileuse (OD)
Composition : 75 g/L (7.7% p/p) de mésotrione et
30 g/L (3.1% p/p) de nicosulfuron

Herbicide anti-dicotylédones et anti-graminées de post-levée du maïs.

SIMULE (N° d'A.M.M. : XXXXXX)	
Attention	H361d Susceptible de nuire à la fertilité ou au fœtus.
	H410 Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
	EUH401 Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.
	Délai de rentrée : 6 heures.
	P102 Tenir hors de portée des enfants.
	P280 Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage
	P391 Recueillir le produit répandu.
	P501 Éliminer le contenu/récipient dans une installation agréée d'élimination des déchets.
SP1	Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination <i>via</i> les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.
SPe1	Pour protéger les eaux souterraines, ne pas appliquer du nicosulfuron plus d'une fois tous les deux ans sur des sols dont la teneur en argile est inférieure à 10 %.
SPe3	Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau.
SPe3	Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.
Distribué par : LIFE SCIENTIFIC FRANCE - 11-13 rue des Aulnes - 69760 Limonest - Une question sur ce produit ? N° vert : 0 800 912 759 (appel gratuit depuis un poste fixe) www.lifescientific.com	

EN CAS D'URGENCE**Composer le 15, le 112 ou contacter le centre anti-poison le plus proche**

Puis signaler vos symptômes au réseau Phyt'Attitude, N° Vert: 0 800 887 887 (appel gratuit depuis un poste fixe).

Consulter ce livret avant toute utilisation.



**RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL.
RÉEMPLOI DE L'EMBALLAGE INTERDIT.**

Fiche de Données de Sécurité disponible sur : www.quickfds.com.

Contenu : x L e

N° de lot et date de fabrication : voir emballage

Xxxxxx EMB (PACKER REF)

Fabriqué en UE

Version No xx

PREMIERS SOINS

S'éloigner de la zone dangereuse.

En cas de contact cutané : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.

En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. En cas d'irritation, consulter un spécialiste.

En cas d'inhalation : transporter la victime à l'extérieur et la maintenir au repos dans une position où elle peut confortablement respirer. En cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre ~~anti-poison~~.

En cas d'ingestion : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir. Contacter sans délai les secours : le 15, le 112 ou un centre ~~anti-poison~~.

Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la Fiche de Données de Sécurité.

En cas d'intoxication animale : contacter votre vétérinaire.

DESCRIPTIF DU PRODUIT

Modes d'action

La mésotrione appartient au groupe HRAC F2 des inhibiteurs de l'enzyme HPPD nécessaire à la synthèse des caroténoïdes. C'est un herbicide systémique absorbé par les feuilles et les racines. La mésotrione a également une action anti-germinative.

Le nicosulfuron appartient au groupe HRAC B des inhibiteurs de l'ALS. C'est une sulfonilurée. Le nicosulfuron est absorbé principalement par les voies foliaires, mais aussi racinaires. C'est un inhibiteur de l'acétolactate synthase qui entraîne l'arrêt de la croissance des adventices.

Tableau des usages

Culture	Cibles	Dose homologuée	Nombre max. d'appl.	Stade d'application - Délai avant récolte (DAR)	ZNT aquatique
Maïs	Dicotylédones et graminées annuelles	1.5 L/ha	1 appl. / an Fractionnement possible, sans dépasser la dose totale de 1.5 L/ha	Entre BBCH 12 et BBCH 19 (2 à 9 feuilles étalées) DAR couvert par les conditions d'application	5 mètres

Limites maximales de résidus (LMR) : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse: <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/>

Spectre d'efficacité de SIMULE :

Dicotylédones annuelles	1 application à 1.5 L/ha	2 applications à 0.75 L/ha
Amarante réfléchie	Très sensible	Très sensible
Capselle bourse-à-pasteur	Très sensible	Très sensible
Chénopode à feuilles de figuier	Très sensible	Très sensible
Chénopode blanc	Très sensible	Très sensible
Matricaire camomille	Sensible	Moyennement sensible
Morelle noire	Sensible	Sensible
Mouron des oiseaux	Moyennement sensible	Sensible
Moutarde des champs	Très sensible	Très sensible
Pensée des champs	Peu sensible	Sensible
Renouée à feuilles de patience	Très sensible	Sensible
Véronique de Perse	Moyennement sensible	Sensible
Graminées annuelles	1 application à 1.5 L/ha	2 applications à 0.75 L/ha
Panic pied-de-coq	Sensible	Sensible

Niveau de sensibilité	Efficacité (%)
Très Sensible	95 - 100
Sensible	85 - 94.9
Moyennement sensible	75 - 84.9
Peu sensible	50 - 74.9

Ce spectre d'efficacité indique les adventices testées avec SIMULE. Il n'est pas exhaustif, d'autres espèces d'adventices non indiquées dans ce spectre peuvent être contrôlées par SIMULE.

RECOMMANDATIONS D'EMPLOI

Appliquer SIMULE du stade BBCH 12 (2 feuilles étalées) jusqu'au stade BBCH 19 (9 feuilles étalées ou plus) du maïs.

SIMULE doit être appliqué sur une culture en bon état végétatif.

Une phytotoxicité transitoire et/ou une réduction de la vigueur de la culture peuvent parfois survenir après l'application, mais ces effets sont généralement temporaires et n'entraînent pas de réduction du rendement de la culture.

Appliquer SIMULE sur des adventices jeunes.

Conditions météorologiques

Traiter par temps calme pour éviter toute dérive de pulvérisation. Porter une attention particulière à éviter la dérive sur les cultures adjacentes.

Recommandations pour les mélanges

Les mélanges extemporanés doivent être mis en œuvre conformément à la réglementation en vigueur.

Préparation de la bouillie

Bien agiter le bidon avant emploi. Remplir aux 3/4 la cuve avec de l'eau et mettre en marche l'agitation. Verser la quantité nécessaire de SIMULE dans la cuve du pulvérisateur. Remplir la cuve avec de l'eau au volume requis. Maintenir l'agitation durant toute la durée de l'application. Ne pas laisser la bouillie dans la cuve du pulvérisateur pendant de longues périodes (par exemple pendant le temps des repas).

Cultures suivantes et de remplacement

A l'automne, après la récolte d'un maïs traité au printemps avec SIMULE, seule une culture de céréale peut être semée.

Au printemps de l'année suivant l'application, toute culture peut être semée sans restriction.

PRÉVENTION ET GESTION DE LA RÉSISTANCE

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques et respecter les conditions d'emploi du produit. Il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation. En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de cette préparation liée à ces phénomènes de résistance. De ce fait, Life Scientific Ltd. décline toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.

BONNES PRATIQUES PHYTOSANITAIRES




Stockage du produit

Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées.

Protection de l'opérateur et du travailleur

Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée.

Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.

Caractéristiques des EPI		PROTECTION DE L'UTILISATEUR PENDANT LES PHASES DE :			PROTECTION DU TRAVAILLEUR en cas d'intervention sur les parcelles traitées
		MÉLANGE / CHARGEMENT et NETTOYAGE	PULVÉRISATEUR PORTÉ OU TRAINÉ À RAMPE PULVÉRISATION VERS LE BAS TRACTEUR AVEC CABINE	TRACTEUR SANS CABINE	
GANTS EN NITRILE réutilisables (certifiés EN 374-3) ou à usage unique (certifiés EN 374-2)		Réutilisables	À usage unique, si intervention sur le matériel de pulvérisation *	À usage unique, si intervention sur le matériel de pulvérisation	
EPI VESTIMENTAIRE 65% polyester / 35% coton ≥ 230 g/m² + traitement déperlant conforme à la norme NF EN ISO 27065		EPI vestimentaire ET EPI partiel			
EPI PARTIEL blouse ou tablier à manches longues catégorie III type PB3 certifié EN 14605+A1					

* EN CAS D'INTERVENTION À L'EXTÉRIEUR ; DANS CE CAS, LES GANTS DOIVENT ÊTRE STOCKÉS ET PORTÉS À L'EXTÉRIEUR DE LA CABINE.

Protection de l'opérateur :

Pendant le mélange/chargement et le nettoyage du matériel de pulvérisation, porter :

- Gants en nitrile certifiés EN 374-3,
- Combinaison de travail en polyester 65% / coton 35% avec un grammage de 230 g/m² ou plus avec traitement déperlant,
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

Pendant l'application, porter :

Si application avec tracteur avec cabine :

- Combinaison de travail en polyester 65% / coton 35% avec un grammage de 230 g/m² ou plus avec traitement déperlant,
- Gants en nitrile certifiés EN 374-2 à usage unique dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine.

Si application avec tracteur sans cabine :

- Combinaison de travail en polyester 65% / coton 35% avec un grammage de 230 g/m² ou plus avec traitement déperlant,
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation.

Pour protéger le travailleur :

Dans les cas où le travailleur serait amené à intervenir sur les parcelles traitées, porter une combinaison de travail en polyester 65% / coton 35% avec un grammage de 230 g/m² ou plus avec traitement déperlant.

Rapporter les équipements de protection individuelle (EPI) usagés dans un sac translucide à votre distributeur partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination de produits dangereux.

AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite.

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous la responsabilité de l'utilisateur, de tous les facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...

Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les autorités compétentes françaises. Pour les denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.