REGISTRATION REPORT

Part A

Risk Management

Product code: AG-NS3-170 OD

Product name(s): ILLUMINA

Active Substance(s):

Sulcotrione, 150 g/L

Nicosulfuron, 20 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new authorisation)

Applicant: NUFARM S.A.S.

Date: 2018/08/08

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PART A – Risk Management

The company NUFARM S.A.S. has requested marketing authorisation in France for the product ILLUMINA (formulation code: AG-NS3-170 OD), containing 150 g/L sulcotrione and 20 g/L nicosulfuron for use as an herbicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to ILLUMINA (AG-NS3-170 OD) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of ILLUMINA (AG-NS3-170 OD) have been made using endpoints agreed in the EU peer review(s) of both sulcotrione and nicosulfuron.

This document describes the specific conditions of use and labelling required for France for the registration of ILLUMINA (AG-NS3-170 OD).

Appendix 1 of this document provides a copy of the French Decision.

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

Appendix 3 of this document is a copy of the letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of NUFARM S.A.S.'s application to market ILLUMINA (AG-NS3-170 OD) in France as an herbicide (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 MSs of the Southern zone.

1.2 Active substance approval

Sulcotrione

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.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulcotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: —the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate ; —the risk to insectivorous birds, aquatic and terrestrial non-target plants, and non-target arthropods. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further information on the degradation in soil and

water of the cyclohexadione moiety and the long-term risk to insectivorous birds. They shall ensure that the notifier at whose request sulcotrione has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest.
An EFSA conclusion is available (EFSA Scientific report (2008) 150, 1 – 86). A Review Report is available (SANCO/159/08 final, 6 January 2009).

Nicosulfuron

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.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on nicosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: —the potential exposure of the aquatic environment to metabolite DUDN when is applied in regions with vulnerable soil conditions, —the protection of aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones, —the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no-spray buffer zone, —the protection of groundwater and surface water under vulnerable soil and climatic conditions.
An EFSA conclusion is available (EFSA Scientific report (2007) 120, 1 – 91). A Review Report is available (SANCO/3780/07 rev 1, 22 January 2008).

1.3 Regulatory approach

The present application (2014-3661) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France. According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4th May 2017 [3] provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France.

[1] French Food Safety Agency, Afssa, before 1 July 2010
[2] 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
[3] 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 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

However, drift buffer zones may be reduced under some circumstances as explained in Appendix 3 of the above-mentioned French Order.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[4], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. 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 conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] provides that:

- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" 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 "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[7] 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.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ILLUMINA (AG-NS3-170 OD), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not necessary: the applicant has provided sufficient data to show that access is not required.

[4] 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

[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

[6] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

[7] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	ILLUMINA (AG-NS3-170 OD)
Authorisation number	-
Function	herbicide
Applicant	NUFARM S.A.S.
Composition	150 g/L sulcotrione 20 g/L nicosulfuron
Formulation type (code)	Oil dispersion (OD)
Packaging	HDPE (1 L ; 5 L ; 10 L ; 20 L)

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	-	
Health hazards	Skin sensitisation - Category 1B Serious eye damage - Category 1 Reproductive toxicity - Category 2 Specific target organ toxicity - Repeated exposure - Category 2	
Environmental hazards	Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Hazard pictograms		
Signal word	Danger	
Hazard statements	H317	May cause an allergic skin reaction
	H318	Causes serious eye damage
	H361d	Suspected of damaging the unborn child
	H373	May cause damage to organs through prolonged or repeated exposure
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		

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

2.2.2 Other phrases in compliance with Regulation (EU) No 547/2011

The authorisation of the preparation is linked for professional uses only to the following conditions:

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 20 meters[8] with an unsprayed vegetated buffer zone of 20 meters to surface water bodies.
SPe 3	To protect non-target plants respect an unsprayed buffer zone of 20 meters to non-agricultural land.

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment[9]: refer to the Decision in Appendix 1 for the details
Re-entry period[10]: 48 hours
Pre-harvest interval[11]: F- Application must be made at growth stage BBCH 19 at the latest
Other mitigation measures: - The formulation must be stored at a temperature below 40°C. - The formulation must be shaken before use. - In the framework of a crop failure only maize can be sown.
The label may include the following recommendations: - As a lot of different genitors can be used for maize seed production and as their sensitivity may vary, it can be considered as impossible to test the selectivity of one product on all those genitors and to insure that no risk on the propagation exists. It is on the behalf of the seed producer to consult the breeder before applying one product. The label must reflect the conditions of authorisation.

[8] The legal basis for this is **Titre III Article 12** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[9] If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

[10] The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[11] According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (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.

GAP, date: 2018-08-08

PPP (product name/code):	**ILLUMINA (AG-NS3-170 OD)**	Formulation type:	**OD** [a, b]
Active substance 1:	sulcotrione	Conc. of as 1:	**150 g/L** [c]
Active substance 2:	nicosulfuron	Conc. of as 2:	**20 g/L** [c]
Applicant:	**NUFARM S.A.S.**	Professional use:	☒
Zone(s):	southern [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/synergist per ha [f]
					Method / Kind	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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	France	Maize (ZEAMX)	F	Dicots, grass weeds	Foliar boom spray	BBCH 12-19	a) 1 b) 1	-	a) 3 L/ha b) 3 L/ha	a) 60 g as/ha nicosulfuron 450 g as/ha sulcotrione b) 60 g as/ha nicosulfuron 450 g as/ha sulcotrione	80 L/ha / 400 L/ha	-	**Not acceptable** (operator risk)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

The product ILLUMINA (AG-NS3-170 OD) is a beige color oily liquid, with characteristic odour oil based suspension concentrate. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. It is not explosive and has no oxidising properties. The product has a flash point >150°C. It has a self-ignition temperature >400 °C. In aqueous solution (1%), it has a pH value of 3.2 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. Slight bleeding has been observed but the preparation is homogeneous after inversions. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging. Its technical characteristics are acceptable for an OD formulation.
The formulation is not classified for the physico-chemical aspect. The formulation must be stored at a temperature below 40°C. The formulation must be shaken before use.

3.1.2 Methods of analysis

Analytical method for the determination of the active substances in the formulation is available and validated. Analytical methods for the determination of relevant impurities from sulcotrione should be provided with a LOQ=0.001256% for hydrogen cyanide and with LOQ=0.0628% for toluene in the preparation ILLUMINA (AG-NS3-170 OD).
Analytical methods are available in the Draft Assessment Report and in this dossier and validated for the determination of residues of sulcotrione and nicosulfuron in plants (dry commodities), soil, water (surface and drinking) and air. Analytical methods for the determination of residues of sulcotrione and nicosulfuron in foodstuffs of animal origin are not necessary.
The active substances are neither toxic nor very toxic hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment:

Active Substance: **sulcotrione**			
ADI	0.0004 mg kg bw/d		EU (2009)
ARfD	not applicable		
AOEL	0.0006 mg/kg bw/d		
Dermal absorption	Based on an in vitro human study performed on formulation:		
		Concentrate (tested) 150 g/L	Diluted formulation (tested) 0.40 g/L
	In vitro (human) %	7	5
		Concentrate (used in formulation) 150 g/L	Spray dilution (used in formulation) 0.40 g/L
	Dermal absorption endpoints %	**7 %**	**5 %**
Active Substance: **nicosulfuron**			
ADI	2 mg kg bw/d		EU (2009)
ARfD	not applicable		
AOEL	0.8 mg/kg bw/d		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 20 g/L	Spray dilution (used in formulation) 0.05 g/L
	Dermal absorption endpoints %	**75 %**	**75 %**

3.1.3.1 Acute Toxicity

The product ILLUMINA (AG-NS3-170-OD) containing 150 g/L of sulcotrione and 20 g/L of nicosulfuron has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin but is an eye irritant and is a skin sensitizer.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases)

Crop	F/G	Equipment	Application rate L product/ha	Spray dilution (L/ha)	Model
Maize	F	Tractor boom trailed sprayer-hydrolic nozzles	3L product/ha (0,45 kg sulcotrione/ha ;0,06 kg nicosulfuron /ha	80-400	BBA

Considering proposed uses, operator systemic exposure was estimated using the German BBA model and/or UK-POEM model / French study from UPJ 2009-2010[12] dedicated to non-agricultural areas / French study 2005 dedicated to amateur use:

Crop	Equipment	PPE and/or working coverall	% AOEL Sulcotrione	% AOEL nicosulfuron
Maize	Tractor boom trailed sprayer-hydrolic nozzles	Working coverall and gloves during mixing/loading and application	671	0.8

According to the model calculations, it can be concluded that **the risk for the operator** using ILLUMINA (AG-NS3-170) **is unacceptable** with a working coverall (90% protection factor) and gloves during mixing/loading and application.
For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to 75% of the AOEL of sulcotrione and 0.1% of the AOEL of nicosulfuron.
It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to ILLUMINA (AG-NS3-170-OD).

3.1.3.4 Worker Exposure

The product ILLUMINA (AG-NS3-170-OD) is used as herbicidal treatment on several crops where there is no need to re-enter the treated area after application. Worker exposure is considered not relevant.

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

3.1.3.5 Relevance of metabolites

Foreseeable estimated concentrations in groundwater exceed the threshold of 0.1 µg/L for HMUD, UCSN, AUSN, ASDM, ADMP, MU-466 and CMBA metabolites of active substances nicosulfuron and sulcotrione.
Given the available information, the metabolites HMUD, UCSN, AUSN, ASDM, ADMP, MU-466 and CMBA are considered not relevant according to the guideline SANCO/221/2000.

3.1.4 Residues and Consumer Exposure

Overall conclusion

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

[12] Studies and models that can be used to estimate operator exposure during the use of plant protection products in non- agricultural areas. Report from expert group « produits phytosanitaires : substances et préparations chimiques » Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011

The chronic intakes of sulcotrione, its metabolite CMBA[13] and nicosulfuron residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.
As far as consumer health protection is concerned, France agrees with the authorization of the intended uses.
According to available data, the following specific mitigation measures are recommended:

- In the framework of a crop failure only maize can be sown.

Data gaps : None
Data required in post-authorization : None**Summary for sulcotrione**

Use-No.	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg 2016/1822	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Maize	Yes	Yes (14 NEU and 14 SEU)	Yes	Yes	Yes	No	Not relevant	

As residues of sulcotrione and CMBA do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary. **Summary for nicosulfuron**

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg 617/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Maize	Yes	Yes (26 NEU and 19 SEU)	Yes	Yes	Yes	No	Not relevant	

As residues of nicosulfuron do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the GAP uses being considered here. It is very unlikely that residues will be present in succeeding crops. Nevertheless in the framework of a crop failure only maize can be sown.

[13] 2-chloro-4-(methylsulfonyl)benzoic acid

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary. **Summary for ILLUMINA (AG-NS3-170 OD)**

Crop	PHI for ILLUMINA (AG-NS3-170 OD) proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for ILLUMINA (AG-NS3-170 OD) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Sulcotrione	Nicosulfuron		
Maize	BBCH 12-19	Yes	Yes	F** - BBCH 12-19	

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops:

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for ILLUMINA (AG-NS3-170 OD)
Crop group	Led by sulcotrione	Led by nicosulfuron	
/	Not relevant	In case of a crop failure, only maize can be sown	In case of a crop failure, only maize can be sown

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substances and their metabolites 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.

The PEC of nicosulfuron, sulcotrione 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 or agreed in the assessment based on new data provided.

PEC soil and PECsw derived for nicosulfuron, sulcotrione and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for nicosulfuron, sulcotrione and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[14]. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

Effect on birds

All acute and chronic TER exceed the trigger value for birds considering refinement proposal for the intended use on maize.

Effect on aquatic organisms

The acute and long-term TERs using the worst case Step 1 - 3 PECsw showed there was no potential risk to fish, aquatic invertebrates and algae (but not higher aquatic plants) without risk mitigation measures using agreed

[14] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

sulcotrione and nicosulfuron endpoints. For the higher aquatic plants, a 20 meters vegetative buffer zone associated with a 20 meters vegetated filter strip was necessary to show an acceptable risk.

Effects on terrestrial vertebrates other than birds

All acute and chronic TER exceed the trigger value for mammals for the intended use on maize. Higher tier risk characterization for the relevant focal species with refinement of fTWA, PD as well as PT, however, shows a safe use for uses in maize.

Effects on bees

Bee hazard quotients (oral and contact) for ILLUMINA (AG-NS3-170 OD), sulcotrione and nicosulfuron were well below the trigger value of 50. Therefore, the risk of exposure to honeybees foraging in maize is acceptably acceptable when ILLUMINA (AG-NS3-170 OD) is applied according to the recommended label instructions.

Effects on arthropods other than bees

It is concluded that the recommended use of ILLUMINA (AG-NS3-170 OD) will not result in any unacceptable effects on non-target arthropod populations occurring in either in-field or off-field habitats. Any effects occurring in-field will be of limited duration and this will allow rapid re-colonisation of the in-field area. The risk to off-field non-target arthropod is assessed as low.

Effects on earthworms and other soil non-target macro-organisms

It is concluded that the recommended use of ILLUMINA (AG-NS3-170 OD) will not result in any unacceptable effects on earthworms and other soil non-target macro-organisms.

Effects on soil non-target micro-organisms

It can be concluded that sulcotrione, nicosulfuron and their degradation products pose no risk to soil non-target micro-organisms when ILLUMINA (AG-NS3-170 OD) is used in accordance with the label recommendations.

Effects on Non-target plants

Studies on the effects of ILLUMINA (AG-NS3-170 OD) on non-target terrestrial plants was investigated under two study types: seedling emergence and growth and vegetative vigour. The TER is above the trigger level of 1 at a distance of 15 m.

3.1.7 Efficacy

Considering the data submitted:

- The efficacy of ILLUMINA (AG-NS3-170 OD) is considered as satisfying for the control of grass and broadleaved weeds in maize post-emergence.
- The selectivity of ILLUMINA (AG-NS3-170 OD) is considered as acceptable.
- The risk of negative impact (yield, quality, succeeding crops, and adjacent crops) is considered as acceptable. However, specific attention should be payed to the settlement conditions of succeeding crops and to the application conditions considering adjacent crops.
- There is a risk of resistance development or appearance to nicosulfuron which requires the set-up of a monitoring program for *Setaria* spp.. The risk of resistance development or appearance to sulcotrione does not require the set-up of a monitoring program.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation cannot be granted (operator risk).** A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

A monitoring of resistance to nicosulfuron should be put in place on *Setaria spp.*. Any new information which would change the resistance risk analysis should immediately be provided to Anses. In all cases a report on the results of the monitoring put in place should be provided at the time of the renewal of ILLUMINA (AG-NS3-170 OD).

3.4.2 Post-authorisation data requirements

The following data would have been required to update the dossier:

- Analytical methods for the determination of revelant impurities from sulcotrione with a LOQ=0.001 % for hydrogen cyanide and with LOQ=0.063 % for toluene in the preparation ILLUMINA (AG-NS3-170 OD).

3.4.3 Label amendments

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique ***ILLUMINA***

de la société *NUFARM S.A.S.*

enregistrées sous les *n°2014-3661, 2015-0141*

Vu les conclusions de l'évaluation de l'Anses du 13 avril 2018,

Considérant que l'estimation de l'exposition de l'opérateur est supérieure au niveau acceptable d'exposition à la sulcotrione dans les conditions d'emploi évaluées,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

ILLUMINA
AMM n°-

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Informations générales sur le produit	
Noms du produit	ILLUMINA KAN-DOO
Type de produit	Produit de référence
Titulaire	NUFARM S.A.S. 28 Boulevard Camélinat, BP 75, 92230 GENNEVILLIERS CEDEX, FRANCE
Formulation	Suspension concentrée huileuse (OD)
Contenant	150 g/L - sulcotrione 20 g/L - nicosulfuron
Numéro d'intrant	9653-2014.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usages	Professionnel

A Maisons-Alfort, le 08 AOUT 2018

Françoise WEBER
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

ILLUMINA
AMM n°-

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15555901 Maïs*Désherbage	3 L/ha	1/an	F (BBCH 19)

Motivation du refus :
L'usage est refusé en raison, pour l'opérateur, d'une exposition estimée supérieure au niveau acceptable d'exposition à la sulcotrione.

ILLUMINA
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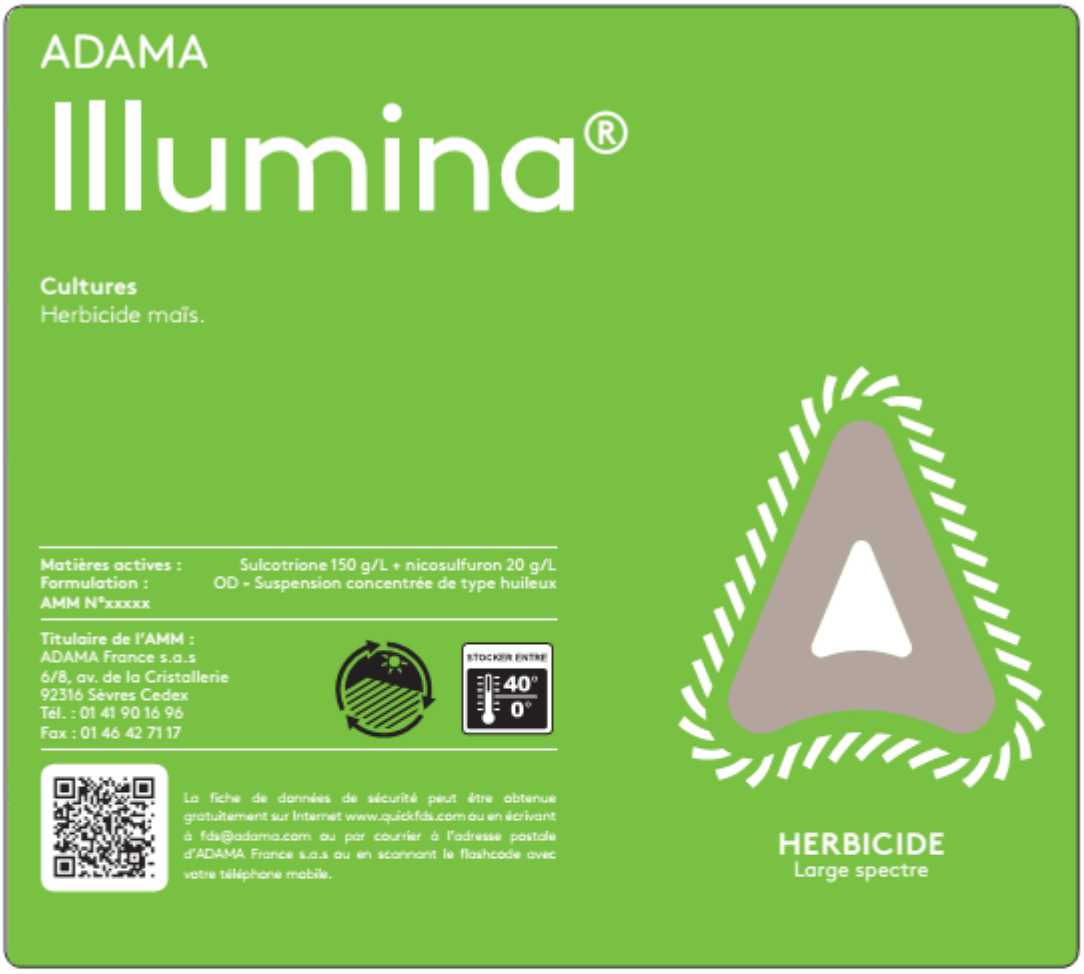
Appendix 2 – Copy of the draft product label as proposed by the applicant



MODE D'ACTION - PROPRIÉTÉS

Illumina® est un herbicide à base de sulcotrione, de la famille des tricétones et de nicosulfuron de la famille des sulfonylurées. **Illumina®** est un désherbant sélectif du maïs. Illumina est efficace sur graminées et dicotylédones annuelles classiques du maïs (chénopode blanc, amaranthe réfléchie, morelle noire...).

Illumina® est absorbé par les mauvaises herbes principalement par voie foliaire. Toutefois, il est également partiellement absorbé par les racines, particulièrement en conditions humides, si la dose appliquée est au moins égale à 1 L/ha. Grâce à cette action racinaire, **Illumina®** assure le contrôle des relevées de certaines adventices pendant 2 à 3 semaines (chénopode blanc, morelle, digitaire sanguine, renouée persicaire). Une fois traitées, les mauvaises herbes sensibles blanchissent dans les 3 à 4 jours après l'application puis disparaissent progressivement.

MODE D'EMPLOI

Usages et doses homologués :

Libellé de l'usage	Cultures associées pour le produit	Dose et nombre d'applications max	Stade d'application	Délai avant récolte
Maïs*Désherbage	Maïs	3 L/ha max/an fractionnable en 2 applications max/an	BBCH 12-18	Couvert par les conditions d'application.

ADAMA France ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées dans le tableau ci-dessus et, à ce titre, décline toute responsabilité concernant l'élargissement de son utilisation à d'autres cultures et cibles telles que prévues par le catalogue des usages fixé par l'arrêté du 26 mars 2014.

Ainsi, l'attention de l'utilisateur est attirée sur les risques éventuels de non-conformité de cet élargissement permis par ce catalogue.

Délai de rentrée des travailleurs sur la parcelle : 6 heures après traitement conformément à l'arrêté du 12 septembre 2006 relatif à la mise sur le marché et à l'utilisation des produits visés à l'article L.253-1 du code rural.

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur selon l'arrêté du 7 avril 2010.

Les Limites Maximales de Résidus sont consultables sur le site Internet de la Commission - Direction Générale Santé et protection du Consommateur à l'adresse suivante :
http://ec.europa.eu/sanco_pesticides/public/index.cfm

Préconisations d'emploi :

Illumina® s'utilise aux volumes/ha de bouillies habituellement employés en désherbage (80 à 400 l/ha).
Illumina® s'utilise sur maïs grain et maïs fourrage, du stade 2 feuilles au stade 8 feuilles.
La culture doit être poussante et en bon état végétatif au moment de l'application. Ne pas traiter sur une culture mal implantée, en mauvais état sanitaire ou souffrant du froid, de l'excès d'eau, de la sécheresse. Eviter également de traiter une culture susceptible de subir de grands écarts thermiques.
Illumina® est recommandé en applications sur adventices jeunes (graminées jusqu'à 3 feuilles, dicotylédones jusqu'à 4 feuilles) pour bénéficier à la fois d'une efficacité optimale et de la persistance d'action.
En pratique, **Illumina®** s'utilise en rattrapage après une prélevée (généralement vers 4-6 feuilles du maïs) ou en programme tout en post (premier traitement généralement vers 2-4 feuilles du maïs, puis en cas de relevée, second traitement vers 6-8 feuilles du maïs).

Précautions d'emploi :

- Appliquer **Illumina®** sur des cultures poussantes en bon état végétatif.
- Eviter de traiter des cultures souffrant de froid, d'un d'excès d'eau, ou de la sécheresse.
- Température optimale : 15 à 25°C.
- Délai sans pluie ou sans irrigation après application : 4 heures.
- Il est recommandé de traiter avec une l'humidité relative est supérieure à 60%.

Cultures de remplacement :

Cultures suivantes dans la rotation : Dans le cas d'une rotation normale, après une application de **Illumina®** les cultures possibles sont : blé tendre d'hiver et de printemps, blé dur, orge d'hiver et de printemps, ray-grass, lin, pomme de terre, scorsonère, sorgho, maïs.
En raison des phénomènes de blanchiment occasionnellement rencontrés sur certaines cultures suivantes, nous déconseillons l'implantation des cultures telles qu'épinard, pois (notamment pois de conserve), haricots, trèfle violet, betteraves. Cette recommandation s'applique tout particulièrement dans des sols à faible activité microbienne, battants ou compactés.
Cultures de remplacement : En cas d'accident nécessitant le remplacement d'une culture désherbée avec **Illumina®**, il est possible d'implanter maïs, sorgho, ray-grass. Nous déconseillons alors l'implantation de cultures de soja, haricot, luzerne, trèfle violet, épinard, choux, colza.

Conditions d'emploi :

Agiter avant emploi. Verser la quantité nécessaire de **Illumina®** dans la cuve du pulvérisateur remplie à moitié du volume d'eau nécessaire, le système d'agitation étant en marche, puis compléter avec la quantité d'eau nécessaire à l'application. Rincer trois fois les emballages et verser l'eau de rinçage dans la cuve du pulvérisateur.
Appliquer immédiatement la bouillie après sa préparation, et maintenir l'agitation pendant toutes les opérations de traitement.
Pulvériser les eaux de rinçage de la cuve sur la parcelle.
Bien nettoyer le pulvérisateur (cuve et circuits de pulvérisation) à l'aide d'un détergent et bien rincer pour éviter toute conséquence néfaste lors de l'utilisation de l'appareil sur d'autres cultures. L'emploi de All Clear Extra (marque déposée Du Pont De Nemours) est recommandé pour ce nettoyage. Bien suivre les recommandations d'emploi de ce produit.

PRÉCAUTIONS GÉNÉRALES

Equipements de protection individuels (EPI)

Pour protéger l'opérateur, porter :

Pendant le mélange/chargement :

- Combinaison Polyester 65%/coton 35% (230 g/m² ou supérieur) avec traitement déperlant
- Tablier de catégorie III/type PB (3) à longues manches et porté au-dessus de la combinaison pré-citée
- Gants en nitrile certifiés EN 374-3

Pendant l'application avec un tracteur à cabine :

- Combinaison Polyester 65%/coton 35% (230 g/m² ou supérieur) avec traitement déperlant.
- Gants en nitrile certifiés EN 374-2 (à disposition en cas d'intervention sur le matériel pendant l'application ; les gants ne doivent être portés que pendant l'intervention sur le matériel et stockés après utilisation à l'extérieur de la cabine).

Pendant le nettoyage du materiel de pulvérisation :

- Combinaison Polyester 65%/coton 35% (230 g/m² ou supérieur) avec traitement déperlant.
- Tablier de catégorie III/type PB (3) à longues manches et portés au-dessus de la combinaison pré-citée.
- Gants en nitrile certifiés EN 374-3.

Gestion du risque d'apparition de résistance :

L'utilisation répétée, sur une même parcelle, de préparations a base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire a l'apparition d'organismes résistants. Pour réduire ce risque, il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations a base de substances actives de familles chimiques différentes ou a modes d'action différents, tant au cours d'une saison culturale que dans la rotation.

Dans le cadre des bonnes pratiques agricoles

Emballages vides : Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et l'éliminer via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR ou tout autre service de collecte spécifique. Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Nettoyage de l'équipement : Ne pas laisser de bouillie prête à l'emploi dans le pulvérisateur. Eliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur. Eviter toute contamination des mares, puisards, ruisseaux, eaux souterraines ou de distribution ou de tout autre point d'eau par la produit, la bouillie de pulvérisation et les eaux de rinçage des emballages et des équipements de traitement.

Premiers secours :

Inhalation : Transporter la victime à l'air frais. En cas de respiration irrégulière ou d'absence de respiration, pratiquer la respiration artificielle. Consulter un médecin.

Contact avec la peau : Rincer immédiatement au savon et à grande eau en retirant les chaussures et vêtements contaminés. Consulter un médecin si nécessaire.

Contact avec les yeux : Rincer immédiatement et abondamment avec de l'eau. Après le rinçage initial, retirer les éventuelles lentilles des contact et continuer à rincer pendant au moins 15 minutes. Maintenir l'œil grand ouvert pendant le rinçage. Si les symptômes persistent, consulter un médecin.

Ingestion : Rincer la bouche. Boire beaucoup d'eau. Si les symptômes persistent, consulter un médecin.

Mesures d'urgence :

En cas d'urgence, contacter le centre antipoison le plus proche de votre domicile ou appeler le 15. Présentez aux secours la fiche de données de sécurité. Puis signalez vos symptômes au réseau Phyt'attitude : tél. 0 800 887 887 (numéro vert).

IMPORTANT : Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces, la pression parasitaire... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture. Compte-tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées protégées ou issues de cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. ADAMA France s.a.s ne saurait être tenu en aucun cas responsable des conséquences inhérentes à toute copie (totale ou partielle) de cette étiquette, à sa diffusion ou son utilisation non autorisée.

Illumina®

AMM N°xxxxx
OD - Suspension concentrée de type huileux
Sulcotrione 150 g/L (14,91%) + nicosulfuron 20 g/L (1,98%)

Attention

H361 d : Susceptible de nuire au fœtus.
H373 : Risque présumé d'effets graves pour les reins à la suite d'expositions répétées ou d'une exposition prolongée.
H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH208 : Contient de la sulcotrione. Peut produire une réaction allergique.
EUH401 : Respecter les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Délai de rentrée des travailleurs sur la parcelle : 6 h après traitement
P102 : Tenir hors de portée des enfants.
P201 : Se procurer les instructions avant utilisation.
P260 : Ne pas respirer les brouillards ou vapeurs.
P280 : Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage.
P501 : Eliminer le contenu / récipient dans un centre de collecte des déchets dangereux ou spéciaux.

SP1 : Ne pas polluer l'eau avec le produit ou son emballage.
Spe 3 : pour protéger les organismes aquatiques, respecter une zone non traitée de 5 m comprenant un dispositif végétalisé permanent de 5 m, en bordures des points d'eau
Spe 3 : pour protéger les plantes non-cibles, respecter une zone non traitée de 20 m par rapport à la zone non cultivée adjacente.

PRODUIT POUR LES PROFESSIONNELS : RESPECTER LES CONDITIONS D'EMPLOI.
Lire les instructions ci-jointes avant emploi.

Titulaire de l'AMM : ADAMA France s.a.s - 6/8, avenue de la Cristallerie
92316 Sèvres Cedex - Tél. : 01 41 90 16 96 - Fax : 01 46 42 71 17

Produit fabriqué en Israël

N° de lot	VOIR SUR L'EMBALLAGE
Date de fabrication	

Appendix 3 – Letter(s) of Access

Not applicable.