REGISTRATION REPORT

Part A

Risk Management

Product code: SL-163

Product name: KATANA DUO

Chemical active substance(s):

glyphosate, 288 g/kg
flazasulfuron, 13.3 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Autorisation renewal according to Art. 43)

Applicant: ISK BIOSCIENCES EUROPE N.V.

Date: 29/11/2019

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PART A
RISK MANAGEMENT

1 Details of the application

The company ISK BIOSCIENCES EUROPE N.V. has requested a marketing authorisation in France for the product KATANA DUO (formulation code: SL-163), containing 288 g/kg glyphosate[1] and 13.3 g/kg flazasulfuron[2] 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 ISK BIOSCIENCES EUROPE N.V.'s application submitted on 02/11/2017 to market KATANA DUO (SL-163) in France (product uses described under point 2.6). France acted as zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the re-registration of authorisation after the renewal of approval of the actives substances glyphosate and flazasulfuron of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2017-3123 & 2018-3230) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[3], 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 KATANA DUO (SL-163) have been made using endpoints agreed in the EU peer reviews of glyphosate and flazasulfuron. It also includes assessment of data and information related to KATANA DUO (SL-163) 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)

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1 COMMISSION IMPLEMENTING REGULATION (EU) 2017/2324 of 12 December 2017, renewing the approval of the active substance glyphosate in accordance with Regulation (EC) N°1107/2009 of teh European Parliament and the Council concerning the placing of plant protection products on the market, and amending the Annex to commission Implementing Regulation (EU) N°540/2011.

2 COMMISSION IMPLEMENTING REGULATION (EU) 2017/805 of 11 May 2017, renewing the approval of the active substance flazasulfuron in accordance with Regulation (EC) N°1107/2009 of teh European Parliament and the Council concerning the placing of plant protection products on the market, and amending the Annex to commission Implementing Regulation (EU) N°540/2011.

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

No 546/2011[5], 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 KATANA DUO (SL-163).

1.2 Letters of Access

Not necessary for flazasulfuron: the applicant is the owner of data which support the renewal of approval of the active substance.

The applicant has provided letters of access for glyphosate data. These letters of access are available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « All submitted studies are necessary for evaluation and authorisation of KATANA DUO (SL-163). ».

1.4 Data protection claims

2 Where protection for data is being claimed for information supporting registration of KATANA DUO (SL-163), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.Details of the authorisation decision

2.1 Product identity

Product code	SL-163
Product name in MS	KATANA DUO
Authorisation number	2140164
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	ISK BIOSCIENCES EUROPE N.V.
Active substance(s) (incl. content)	glyphosate, 288 g/kg flazasulfuron, 13.3 g/kg
Formulation type	Water-dispersible granule [WG]
Packaging	HDPE (0.1 kg, 0.3 kg, 1 kg, 3 kg, 9 kg, 12 kg) HDPE/PA (0.1 kg, 0.3 kg, 1 kg, 3 kg, 9 kg, 12 kg)Paper/Al/PE (30 g, 60 g, 120 g)

[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

Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for KATANA DUO (SL-163) resulted in the **decision to withdraw 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

N/A : marketing authorisation withdrawn.

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

N/A : marketing authorisation withdrawn.

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

N/A : marketing authorisation withdrawn.

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 2017[6] 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

[6] 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

appendix 3 of the above-mentioned French Order.

Moreover, for glyphosate-based products, the official statement[7] of 8 October 2004 provides specific restrictions (applied doses and/or conditions of use) for uses on crops, in non-agricultural or industrial areas or in forestry.

Finally, the French Order of 26 March 2014[8] 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 extrapolation[9] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.6) 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

N/A : marketing authorisation withdrawn.

2.5.2 Specific restrictions linked to the intended uses

N/A : marketing authorisation withdrawn.

[7] Avis du 8 octobre 2004 à tous les détenteurs d'autorisations de mise sur le marché pour des spécialités commerciales à base de glyphosate, https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000000445445

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

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

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant.
When the conclusion is "not acceptable" the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date: 2019/11/29

PPP (product name/code):	KATANA DUO / SL-163	Formulation type:	WG [a, b]
Active substance 1:	glyphosate	Conc. of a.s. 1:	288 g/kg [c]
Active substance 2:	flazasulfuron	Conc. of a.s. 2:	13.3 g/kg [c]
Applicant:	ISK BIOSCIENCES EUROPE N.V.	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/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)	kg or 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	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)	kg or 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		
1	FR	Grapes (table & wine grapes) (0151000, FB 0269)	F	Weeds (Annual grasses and dicotyledonous weeds; Perennial grasses and dicotyledonous weeds)	**Tractor mounted sprayer** Soil directed spray application under the row (50% of surface treated)	End of winter/ beginning of spring at post-emergence on young weeds up to 10 cm	a) 1 b) 1	not relevant	a) 3 b) 3	a) 40 (flazasulfuron) & 864 (glyphosate) b) 40 (flazasulfuron) & 864 (glyphosate)	150-300	**75**	**Not acceptable** (genotoxic potential, relevant impurity, operator for manual application, groundwater contamination, (*))

(*) Risk to diversity and abundance of non-target terrestrial arthropods (other than bees) and vertebrates *via* trophic interactions.

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 authorisation possible for uses where the line is highlighted in grey.

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 Background of authorisation decision and risk management

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

KATANA DUO (SL-163) is a water dispersible granule formulation (WG). 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 a white homogeneous solid. It is not explosive and has no oxidising properties. The product is not flammable and it is not self-ignitable. In aqueous solution (1%), it has a pH value of 5.3 at 20°C ± 1 °C. Its technical characteristics are acceptable for a water dispersible granule formulation. There is no effect of low and 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.

The active substance glyphosate contains two relevant impurities, formaldehyde and N-nitrosoglyphosate. The relevant impurity formaldehyde is considered as a by-product of the manufacturing process for glyphosate and as such cannot be formed by storage of the formulation. The monitoring of this impurity in the storage studies is not necessary.

Concerning the relevant impurity N-nitrosoglyphosate, based on the conditions of formation of this impurity, it is unlikely that this impurity is formed during the formulation of the preparation. **No monitoring of the concentration of this impurity during storage of the preparation was provided.**

The product KATANA DUO (SL-163) does not contain POE-tallowamines (CAS n° 61791-26-2).

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of KATANA DUO (SL-163) is considered satisfactory for the claimed use.

- Glyphosate having an herbicidal activity on all types of plants (known as “total weed control”), the preparation KATANA DUO (SL-163) cannot therefore be considered as selective. Given the foliar penetration of glyphosate, the preparation should not be directed to the green parts of crops.

- For the claimed use, the risks of negative impact on yield, quality and propagation are considered negligible.

- The risk of negative impact on adjacent crops is considered acceptable, as long as the preparation does not reach the green parts of adjacent crops. Specific attention should be paid to the spraying conditions close to adjacent crops.

- There is a risk of resistance development or appearance to flazasulfuron for fleabanes (*Conyza* sp.) and *Senecio vulgaris* requiring a survey of resistance.

- There is a risk of resistance development or appearance to glyphosate for ryegrass (*Lolium multiflorum*, *Lolium perenne* and *Lolium rigidum*), fleabanes (*Conyza* sp.), and common ragweed (*Ambrosia artemisiifolia*) requiring a survey of resistance.

3.3 Methods of analysis (Part B, Section 5)

Analytical methods for the determination of active substances flazasulfuron and glyphosate and the relevant impurity formaldehyde in the formulation are available and validated.

The method of Pomeroy D. 2013 for the determination of NNG in formulation SL-162 is considered as acceptable according to SANCO guidance 3030/99 rev.4 with a LOQ at 0.72 mg NNG/kg formulation SL-162. This LOQ is above the maximum allowed limit for NNG in SL-163 (0.297 mg/kg NNG/formulation),
Analytical methods are available in this dossier or in the RAR and validated for the determination of residues of flazasulfuron in plants (acidic, high water content, oily), soil, water (surface and drinking), air and body fluids. Analytical methods for foodstuff of animal origin are not necessary since residues in claimed crops are low.
Analytical methods are available in this dossier or in the RAR and validated for the determination of residues of glyphosate in plants, food of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active Substance: Flazasulfuron</td></tr>
<tr><td>ADI</td><td colspan="2">0.013 mg kg bw/d</td><td rowspan="4">EU (2017)</td></tr>
<tr><td>ARfD</td><td colspan="2">1 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="2">0.02 mg/kg bw/d</td></tr>
<tr><td>AAOEL</td><td colspan="2">1 mg/kg bw</td></tr>
<tr><td rowspan="5">Dermal absorp-tion</td><td colspan="3">Based on an in vitro human study performed on a similar formulation (CHIKARA DUO, SL 162)*:</td></tr>
<tr><td></td><td>Concentrate (tested)
6.7 g/L</td><td>Diluted formulation (tested)
0.026 g/L</td></tr>
<tr><td>In vitro (human) %</td><td>0.9</td><td>20</td></tr>
<tr><td></td><td>Concentrate (used in formulation)
13.3 g/L</td><td>Spray dilution (used in formulation)
0.133 g/L</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>0.9</td><td>20</td></tr>
<tr><td>Oral absorption</td><td colspan="2">100%</td><td>UE (2017)</td></tr>
</table>

* Proposed dermal absorption rates for flazasulfuron are based on a dermal absorption study on a formulation comparable to the product SL-163, *i.e*. the product SL-162.
In the dermal absorption study on the product SL-162, the dermal absorption of flazasulfuron was determined to be 0.9 % for the undiluted product SL-162 and 20 % for the diluted product SL-162, indicating a clear concentration related absorption. As the concentration of flazasulfuron was lower in the product SL-162 (6.7 g/kg) than in the product SL-163 (13.3 g/kg) and the tested flazasulfuron concentration in the field dilution of SL-162 (0.026 g/L) was lower than in the applied field dilutions of the product SL-163 (0.133 g/L) the use of the flazasulfuron results from the dermal absorption study on the product SL-162 represents a worst case approach for the product SL-163. It is therefore considered appropriate to use the dermal absorption determined with the product SL-162 for the product SL-163.

<table>
<tr><td colspan="4">Active Substance: glyphosate</td></tr>
<tr><td>ADI</td><td colspan="2">0.5 mg kg bw/d</td><td rowspan="4">EU (2017)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.5 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="2">0.1 mg/kg bw/d</td></tr>
<tr><td>AAOEL</td><td colspan="2">none</td></tr>
<tr><td rowspan="5">Dermal absorp-tion</td><td colspan="3">Based on an in vitro human study performed on a similar formulation (CHIKARA DUO, SL 162)**:</td></tr>
<tr><td></td><td>Concentrate (tested) 288 g/L</td><td>Diluted formulation (tested) 1.152 g/L</td></tr>
<tr><td>In vitro (human) %</td><td>0.3</td><td>0.3</td></tr>
<tr><td></td><td>Concentrate (used in formulation) 288 g/L</td><td>Spray dilution (used in formulation) min: 2.88 g/L</td></tr>
<tr><td>Dermal absorption endpoints %*</td><td>0.3</td><td>0.3</td></tr>
<tr><td>Oral absorption</td><td colspan="2">20%</td><td>UE 2017</td></tr>
</table>

** In the dermal absorption study on the product SL-162, the dermal absorption of glyphosate was determined to be 0.23 % for the undiluted product SL-162 and 0.30 % for the diluted product SL-162, indicating a very low dermal absorption, irrespective of the glyphosate concentration. As the product SL-162 and the product SL-163 contain the same amount of glyphosate (288 g/kg), and the tested dilution of the product SL-162 (1.152 g/L) was lower than the maximum applied dilution of the product SL-163 (2.88 g/L), it is considered appropriate to use the dermal absorption determined with the productSL162 for the product SL-163.

3.4.1 Acute toxicity

KATANA DUO, containing 288 g/kg glyphosate and 13.3 g/kg flazasulfuron, has a low toxicity in respect of acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin, is irritating to the rabbit eye and is not a skin sensitiser.

3.4.2 Genotoxic potential

In the EC review report for glyphosate (SANTE/10441/2017 Rev 2), the following toxicity studies were requested (see page 6 of the review report):
"As outlined in the EFSA conclusion on glyphosate, the peer review recognised that some genotoxicity studies on formulations presented positive results, and therefore, that the genotoxic potential of formulations should be addressed during renewal or first authorisation of plant protection products."

According to EFSA scientific opinion on genotoxicity testing strategies (EFSA Journal 2011; 9(9):2379), a combination of two tests is needed to "*[fulfil] the basic requirements to cover the three genetic endpoints: the bacterial reverse mutation assay covers gene mutations and the in vitro micronucleus test covers both structural and numerical chromosome aberrations*".

The genotoxicity tests were not provided for the formulation KATANA DUO. Hence the genotoxic potential of KATANA DUO (SL-163) cannot be finalised.

3.4.3 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[10]	Equipment *Application method*	Maximum application rate kg as /ha	Minimum volume water (L/ha)
Grapes	F	Vehicle mounted downward spraying. Manual Knapsack downward spraying Manual Hand held downward spraying	3 kg product/ha 0.04 kg flazasulfuron/ha 0.864 kg glyphosate/ha	150

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[11] :

Crop	**Equipment**	**PPE and/or working coverall**	% AOEL **flazasulfuron**	% AOEL **glyphosate**
Grapes	Vehicle mounted downward spraying.	Working coverall and gloves during mixing/loading and application	3.2	1.5
	Manual Knapsack downward spraying		**153**	1.3
	Manual Hand held downward spraying		**153**	2.9

According to the model calculations, it can be concluded that the risk for the operator using KATANA DUO (SL-163) is:

- Acceptable on vineyards with a vehicle mounted boom sprayer with a working coverall and gloves during mixing/loading and application.
- **Unacceptable on vineyards with manual hand held sprayer or manual knapsack sprayer with a working coverall and gloves during mixing/loading and application.**

3.4.4 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation activities. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is estimated to 1.68% of the AOEL of flazasulfuron and 0.04% of the AOEL of glyphosate with PPE (work wear).
It is concluded that there is no unacceptable risk anticipated for the worker.

[10] Open field or glasshouse
[11] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

3.4.5 Bystander and resident exposure

Bystander exposure was assessed for the active substance flazasulfuron according to EFSA model taking into consideration grapes treatment as a risk envelope. An acceptable risk was determined for bystanders (adult and/or child):

Bystander	**Pathways**	**% of systemic AOEL flazasulfuron**
Bystander (child)	Spray drift (95th percentile)	0.33
	Vapour (95th percentile)	0.11
	Surface deposits (95th percentile)	0.04
	Entry into treated crops (95th percentile)	0.14
Bystander (adult)	Spray drift (95th percentile)	0.09
	Vapour (95th percentile)	0.02
	Surface deposits (95th percentile)	0.02
	Entry into treated crops (95th percentile)	0.08

For the active substance glyphosate, 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 set[12].
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.*"

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and/or child) when mitigation measures such as a buffer zone of 3 meters are taken.

Model (AOEM) - All pathways (mean)	**% AOEL flazasulfuron**	**% AOEL glyphosate**
Resident (children)	15	1.9
Resident (adults)	5.2	0.5

3.4.6 Combined exposure

Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches employed up to now make use of the Hazard Index (HI) concept. It is therefore suggested to use this as a first tier assessment.

[12] 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).

A cumulative assessment for operators, bystanders/residents and workers has been performed. At the first tier, combined exposure is 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 active substance and the HI (sum of hazard quotients) are:

Population groups and PPE	Active ingredient		Estimated exposure / AOEL (HQ)
Operators (LCTM spraying)	Potential	flazasulfuron	0.29
		glyphosate	0.037
	Cumulative risk operators (HI)		**0.327**
Worker	Work wear	flazasulfuron	0.0168
		glyphosate	0.0004
	Cumulative risk workers (HI)		**0.0172**
Residents	Children - All pathways (mean)	flazasulfuron	0.15
		glyphosate	0.019
	Cumulative risk residents (child) (HI)		**0.169**
	Adults - All pathways (mean)	flazasulfuron	0.052
		glyphosate	0.005
	Cumulative risk residents (adult) (HI)		**0.057**

The Hazard Index is < 1 for all subjects. Thus, combined exposure to all active substances in KATANA DUO (SL-163) for accepted uses in the previous sections is not expected to present a risk for operators, workers, bystanders and residents. No further refinement of the assessment is required.

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 of 0.01* mg/kg for flazasulfuron and 0.5 mg/kg for glyphosate as laid down in Reg. (EU) 396/2005 is not expected, providing the application of the mitigation measures.

The chronic and the short-term intakes of flazasulfuron and glyphosate residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, the zRMS France agrees with the authorization of the intended use on grapes.

According to available data, the following specific mitigation measure is recommended:
- “Use application material or agricultural practices to avoid edible parts contact with soil treated with active substance”.

Data gaps

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Information on KATANA DUO

Crop	PHI for SL-163 proposed by applicant	PHI/ Withholding period sufficiently supported for		PHI for SL-163 proposed by zRMS	zRMS Comments (if different PHI proposed)
		flazasulfuron	glyphosate		
Grapes	75 days	Yes	Yes	75 days	

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).

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. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substances and its/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 glyphosate, flazasulfuron and their metabolites in soil and surface water 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. PECgw for glyphosate and metabolites have also been assessed according to FOCUS guidance documents.

PEC soil and PECsw derived for glyphosate, flazasulfuron and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.
Due to significant deviation in the application mode used for modelling, contamination *via* drainage is not considered as covered by the PECsw calculations and a mitigation measure is considered as needed.
PECgw for glyphosate and its metabolite do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[13] with mitigation measure. No acceptable PECgw calculations were provided for flazasulfuron and its metabolites. **Therefore the groundwater contamination for flazasulfuron and its metabolites cannot be finalised 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 use.

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 and its 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.

[13] 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.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses.

Risk mitigation measures are required in order to protect aquatic organisms, soil macroorganisms and non-target plants.

Concerning the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions (Regulation (EU) 2017/2324), no information has been provided by the notifier to assess this risk.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the Steps described in SANCO/221/2000 guidance document. For flazasulfuron, since PECgw calculations (Step 2 of SANCO/221/2000) were not acceptable (see 3.6), Steps 3 to 5 described in SANCO/221/2000 were not performed.

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

N/A : marketing authorisation withdrawn.

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

N/A : marketing authorisation withdrawn.

5.1.2 Post-authorisation data requirements

N/A : marketing authorisation withdrawn.

Appendix 1 Copy of the product authorisation

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Décision relative à une demande de renouvellement de l'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 règlement d'exécution (UE) 2017/2324 de la Commission du 12 décembre 2017 renouvelant l'approbation de la substance active « glyphosate » conformément au règlement (CE) n°1107/2009 du Parlement européen et du Conseil concernant la mise sur le marché des produits phytopharmaceutiques et modifiant l'annexe du règlement d'exécution (UE) no 540/2011 de la Commission,

Vu le règlement d'exécution (UE) 2017/805 de la commission du 11 mai 2017 renouvelant l'approbation de la substance active « flazasulfuron » conformément au règlement (CE) n°1107/2009 du Parlement européen et du Conseil concernant la mise sur le marché des produits phytopharmaceutiques et modifiant l'annexe du règlement d'exécution (UE) no 540/2011 de la Commission,

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 de renouvellement de l'autorisation de mise sur le marché, suite aux renouvellements des approbations des substances actives glyphosate et flazasulfuron, et d'autorisation de nouveaux emballages du produit phytopharmaceutique **KATANA DUO***

de la société	*ISK BIOSCIENCES EUROPE N.V*
enregistrées sous les	*n°2017-3123 et 2018-3230*

Vu les conclusions de l'évaluation de l'Anses du 18 octobre 2019,

Considérant que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit,

Considérant qu'un effet génotoxique ne peut être exclu,

Considérant que les conditions mentionnées à l'article 29 du règlement (CE) n°1107/2009 ne sont donc pas respectées,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas renouvelée** en France.

KATANA DUO
AMM n°2140164

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Informations générales sur le produit	
Noms du produit	KATANA DUO MANTIS KOUDAI
Type de produit	Produit de référence
Titulaire	ISK BIOSCIENCES EUROPE N.V Pegasus Park De Kleetlaan 12B - Box 9 B-1831 Diegem Belgique
Formulation	Granulé dispersable (WG)
Contenant	288 g/kg – glyphosate (sous forme de sel de sodium) 13,3 g/kg - flazasulfuron
Numéro d'intrant	2140268
Numéro d'AMM	2140164
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 29 NOV. 2019

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

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Liste des usages retirés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'écouler utilisation les stocks
12705902 Vigne*Désherbage* Cult. Installées	3 kg/ha	1/an	F (BBCH 69)	6 mois à compter de la présente décision	12 mois à compter de la présente décision
	Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit, ni d'exclure la formation de l'impureté pertinente N-nitrosoglyphosate (NNG) au cours du stockage. L'usage est également retiré en raison d'un risque d'effet nocif lié au flazasulfuron pour les opérateurs pour des applications manuelles. L'usage avec un délai avant récolte inférieur à 75 jours est également retiré conformément aux données résidu fournies.				

KATANA DUO
AMM n°2140164

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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.

Katana Duo® - AMM n°2140164 - Contient 1.33% de flazasulfuron et 28.8% de Glyphosate sous forme de granulés dispersables dans l'eau (WG)

ATTENTION

H319 **Provoque une sévère irritation des yeux.**
H410 **Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.**

CONSEILS DE PRUDENCE

P273 Éviter le rejet dans l'environnement.
P280 Porter des gants de protection / des vêtements de protection / un équipement de protection des yeux / du visage.
P305+P351+P338 EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer.
P337+P313 Si l'irritation oculaire persiste : consulter un médecin.
P391 Recueillir le produit répandu.
P501 Éliminer le contenu / récipient selon la réglementation en vigueur.

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 via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.]
SPe3 Pour Protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.
SPe3 Pour protéger les organismes aquatiques, respecter une zone non traitée comportant un dispositif végétalisé permanent de 20 mètres par rapport aux points d'eau.
Délai de rentrée: 24 heures.
EUH401 **Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.**

Distribué par : **Belchim Crop Protection France SA**
Parc Tertiaire de Bois Dieu - 3 allée des Chavraults - 69380 LISSIEU

Fiche de données de sécurité disponible sur le site www.quickfds.com

EN CAS D'URGENCE :
Prévenir les secours en composant le 15 ou le 112 ou contacter le centre anti poison le plus proche

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. Ne pas utiliser de produits neutralisants. Consulter un spécialiste.

puis signalez vos symptômes au réseau PhytAttitude, N° vert : 0 800 887 887 (Appel gratuit depuis un poste fixe). 24h/24 Numéro d'appel d'urgence : 0032 14 58 45 45

En cas d'inhalation : Emmener la victime à l'air frais. En cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

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

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, contactez votre vétérinaire.

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