

REGISTRATION REPORT

Part A

Risk Management

Product code: SL-160 25% WG

Product name: KATANA 25 WG

Chemical active substance:

Flazasulfuron, 250 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(label extension)

Applicant: ISK Biosciences Europe N.V.

Date: 01/08/2024

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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 25 WG (product code: SL-160 25% WG), containing 250 g/kg flazasulfuron¹ as an 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 18/11/2022 to market KATANA 25 WG (SL-160 25% WG) 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 label extension of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2022-3311) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², 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")³. 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 25 WG (SL-160 25% WG) has been made using endpoints agreed in the EU peer review of flazasulfuron. It also includes assessment of data and information related to KATANA 25 WG (SL-160 25% WG) 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 546/2011⁴, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

¹ Commission Implementing Regulation (EU) 2017/805 of 11 May 2017 renewing the approval of the active substance flazasulfuron 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 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

³ 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](#)

⁴ 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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This document also describes the specific conditions of use and labelling required for France for the registration of KATANA 25 WG (SL-160 25% WG).

1.2 Letters of Access

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

1.3 Justification for submission of tests and studies

According to the applicant: “*All submitted studies are necessary for evaluation and authorisation of KATANA 25 WG (SL-160 25% WG).*”

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of KATANA 25 WG (product code: SL-160 25% WG), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	SL-160 25% WG
Product name in MS	KATANA 25 WG
Authorisation number	9700070
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	ISK Biosciences Europe N.V.
Active substance(s) (incl. content)	Flazasulfuron; 250 g/kg
Formulation type	Water-dispersible granule [WG]
Packaging	Not relevant for extension of authorisation
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 25 WG (SL-160 25% WG) resulted in the decision **to grant** 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

Not relevant for extension of authorisation.

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 2017⁵ 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.

Moreover, the French Order of 12 April 2021⁶ provides that:

⁵ 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>

⁶ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

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- 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 extrapolation⁷ 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.

Finally, the French Order of 20 November 2021⁸ on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop⁹ when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order

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	
Application on the entire field surface	
SPe 1	To protect groundwater, following application on the entire field surface, do not apply this or any other product containing flazasulfuron more than once every other year on pome fruits and hazelnuts orchards.
SPe 2	To protect aquatic organisms, do not apply to soil with pH, H ₂ O > 6 for the uses on pome fruits and hazelnuts orchards on the entire field surface.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 m with a 20 m permanent planted buffer strip to surface water bodies for uses on pome fruits and hazelnuts orchards on the entire field surface on soils with pH, H ₂ O < 6

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

⁸ Arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques - Légifrance (legifrance.gouv.fr)

⁹ List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

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Application under the row, 33% of the surface	
SPe 2	To protect groundwater, only apply under the row and do not apply on more than 33% of the surface for a yearly application on pome fruits and hazelnuts orchards.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies for uses on pome fruits and hazelnuts orchards under the row (33% of the surface) on soils with pH, H ₂ O < 6.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 m with a 5 m permanent planted buffer strip to surface water bodies for uses pome fruits and hazelnuts orchards under the row (33% of the surface) on soil with pH, H ₂ O > 6
SPe 3	To protect non-target plants, maintain an untreated zone 5 metres from the adjacent uncultivated area.
Other specific restrictions	
Re-entry period	Not changed
Storage	-
SPa 1	-
Risk mitigation measures	
Agricultural recommendations	-

The other conditions of use specified in the previous evaluations are not changed.

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” or 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: 2024-08-01

PPP (product name/code): KATANA 25 WG / SL-160 25% WG
Active substance 1: flazasulfuron
Safener: -
Synergist: -
Applicant: ISK Biosciences Europe N.V.
Zone(s): Southern Zone ^(d)
Verified by MS: Yes
Field of use: Herbicide

Formulation type: WG ^(a, b)
Conc. of a.s. 1: 250 g/kg ^(c)
Conc. of safener: - ^(c)
Conc. of synergist: - ^(c)
Professional use:
Non-professional use:

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, 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/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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/ma x		
Zonal uses (field or outdoor uses, certain types of protected crops)													

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or and/ situation (crop destination/purpose of crop)	F, Fn, 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/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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/ma x		
1	FR	Pome fruit orchards	F	Annual grassweeds Annual broadleaf weeds	Broadcast spray Only treat under the row; max. 1 m width (max. 33% of the field surface).	February-June	a) 1 (under the row) b) 1 (under the row)	-	a) 0.08 b) 0.08	a) 20 b) 20	200- 400	60	Acceptable
1a	FR	Pome fruit orchards	F	Annual grassweeds Annual broadleaf weeds	Broadcast spray Biennial application	February-June	a) 1 (every other year) b) 1 (every other year)	730	a) 0.08 b) 0.08	a) 20 b) 20	200- 400	60	Acceptable
2	FR	Stone fruit orchards	F	Annual grassweeds Annual broadleaf weeds	Broadcast spray Only treat under the row; max. 1 m width (max. 33% of the field surface).	February-June	a) 1 (under the row) b) 1 (under the row)	-	a) 0.08 b) 0.08	a) 20 b) 20	200- 400	60	Not acceptable (selectivity)
2a	FR	Stone fruit orchards	F	Annual grassweeds Annual broadleaf weeds	Broadcast spray Biennial application	February-June	a) 1 (every other year) b) 1 (every other year)	730	a) 0.08 b) 0.08	a) 20 b) 20	200- 400	60	Not acceptable (selectivity)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop 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/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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/ma x		
3	FR	Hazlenut groves	F	Annual grassweeds Annual broadleaf weeds	Broadcast spray Only treat under the row; max. 1 m width (max. 33% of the field surface).	February-June	a) 1 (under the row) b) 1 (under the row)	-	a) 0.08 b) 0.08	a) 20 b) 20	200- 400	120	Acceptable
3a	FR	Hazlenut groves	F	Annual grassweeds Annual broadleaf weeds	Broadcast spray Biennial application	February-June	a) 1 (every other year) b) 1 (every other year)	730	a) 0.08 b) 0.08	a) 20 b) 20	200- 400	120	Acceptable

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, 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 Background of authorisation decision and risk management

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

The claimed concentrations of use for the new claimed uses are covered by the authorization dossier. No new study on physical or chemical properties is necessary.

3.2 Efficacy (Part B, Section 3)

From the submitted data, it can be concluded that:

- Effectiveness of the product

- 0.08 kg/ha is the minimum effective dose regarding 0.06 kg/ha.

- the effectiveness of the product KATANA 25 WG (SL-160 25% WG) applied according to the intended GAP is acceptable on all the intended uses.

- Resistance

The risk of development of resistance to the active substance in the product KATANA 25 WG (SL-160 25% WG) is moderately high. A survey of resistance should be carried out.

- Selectivity of the product

On pome fruit and nut trees, the level of phytotoxicity can be considered acceptable for an application at 0.08 kg/ha every year. The risk of negative impact on yield and quality is acceptable on pome fruit and nut trees.

On stone fruit, not enough selectivity data (including multi years applications trials submitted during commenting round) were submitted for each main crop. The assessment of phytotoxicity can't be finalized.

The risk of negative effect on yield and quality is considered as acceptable on apple trees, pear trees and by extrapolation to hazelnuts trees (minor crop). **Insufficient selectivity data were submitted on stone fruit.**

The risk of negative effect on the production of cider is considered acceptable.

- Other effects

The risk of negative effect on adjacent crops is acceptable.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

An analytical method for the determination of flazasulfuron in the formulation is available and validated during the first authorization.

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3.3.2 Analytical methods for residues

Validated analytical methods are available for the determination of flazasulfuron residues in matrices of vegetal and animal matrices, soil, water (surface and drinkable), air and body fluids. As no residue above 0.01 mg/kg is quantify in metabolism study available in the RAR, no data on extraction efficiency are required.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints	
Active substance	Fluazasulfuron
AOEL systemic	0.02 mg/kg bw/day
AAOEL	1 mg/kg bw/day
Oral absorption	90%
Reference	EFSA Journal 2016;14(8):4575
Dermal absorption	Concentrate: 10% Dilution: 17%

3.4.1 Acute toxicity

KATANA 25 WG (SL-160 25% WG) containing 250 g/L flazasulfuron has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model¹⁰:

Model data	flazasulfuron		
	Level of PPE	% AOEL	% AAOEL
Application : Tractor / down spraying Outdoor Orchards			
Application rate: 0.08 kg KATANA 25 WG/ha (SL-160 25% WG)		0.02 kg flazasulfuron / ha	
Spray ap- plication (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	2.47	0.46

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

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According to the model calculations, it can be concluded that operator exposure using KATANA 25 WG (SL-160 25% WG) is below the AOEL and AAOEL of a.s 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 worker exposure was calculated according to AOEM model.

Model data		Flazasulfuron
	Level of PPE	%AOEL
Activity: inspectopn/irrigation Outdoor Work rate: 2 hours/day Number of applications : 1 Interval between treatments: 365 days		
DT50:		30 days
DFR:		3 µg/cm ² /kg a.s./ha
Application rate (kg as/ha)		0.02 kg flazasulfuron/ha
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	2.38

Worker exposure re-entering into treated crops with KATANA 25 WG (SL-160 25% WG) is estimated to be below the AOEL of the active substance.

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

3.4.4 Bystander exposure

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

Model data		Flazasulfuron
		% AAOEL
Scenario: Buffer zone: 2-3 (m) Drift reduction technology: no Number of applications : 1 Interval between treatments: 365 days		
DT ₅₀		30 days
DFR		3 µg/cm ² /kg a.s./ha
Bystander (children) Body weight: 10 kg	Spray drift (95th percentile)	0.10
	Vapour (95th percentile)	0.11
	Surface deposits (95th percentile)	0.07

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	Entry into treated crops (95th percentile)	0.06
Bystander (adults) Body weight: 60 kg	Spray drift (95th percentile)	0.03
	Vapour (95th percentile)	0.02
	Surface deposits (95th percentile)	0.02
	Entry into treated crops (95th percentile)	0.03

Bystander exposure has been estimated to be below the AAOEL of active substance.

3.4.5 Resident exposure

Resident exposure was assessed according to EFSA model without mitigation measures, a distance of 3 metres from the spray boom and no drift reduction technology was considered.

Model data	Flazasulfuron	
	% AOEL	
Scenario: Buffer zone: 2-3 (m) Drift reduction technology: no Number of applications : 1 Interval between treatments: 365 days		
DT ₅₀	30 days	
DFR	3 µg/cm ² /kg a.s./ha	
Resident (children) Body weight: 10 kg	Spray drift (75th percentile)	2.29
	Vapour (75th percentile)	5.53
	Surface deposits (75th percentile)	1.41
	Entry into treated crops (75th percentile)	2.87
	All pathways (mean)	10.1
Resident (adults) Body weight: 60 kg	Spray drift (75th percentile)	0.55
	Vapour (75th percentile)	1.15
	Surface deposits (75th percentile)	0.50
	Entry into treated crops (75th percentile)	1.59
	All pathways (mean)	3.07

Resident exposure has been estimated to be below the AOEL of the active substance.

3.4.6 Combined exposure

Not relevant. The product contains only one active substance.

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 flazasulfuron as laid down in Reg. (EU) 396/2005 is not expected.

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The chronic and the short-term intakes of flazasulfuron 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, Anses, France agrees with the authorization of the intended uses.

Summary for KATANA 25 WG (SL-160 25% WG)

Table : Information on KATANA 25 WG (KCA 6.8) (SL-160 25% WG)

Crop	PHI for KATANA 25 WG (SL-160 25% WG) proposed by applicant	PHI sufficiently supported for	PHI for KATANA 25 WG (SL-160 25% WG) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Flazasulfuron		
Pome fruits (whole group)	60	Yes		
Stone fruits (whole group)	60	Yes		
Hazelnuts	120	Yes		

Waiting periods before planting succeeding crops

Table : Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for KATANA 25 WG (SL-160 25% WG)
Crop group	Flazasulfuron	
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 flazasulfuron and its 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 PEC_{sw} derived for the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC_{gw} for flazasulfuron and its metabolites do not occur at levels exceeding those mentioned in regulation EU No 546/2011 and guidance document SANCO 221/2000¹¹, with mitigation measures as reported hereafter.

¹¹ Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev.11, 21 October 2021

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 review for active substances and 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 and other soil macro-organisms, micro-organisms and non-target plants are acceptable for the intended uses.

For aquatic organisms, the risks are acceptable when mitigation measures indicated in point 2.5.1 Restrictions linked to the PPP are applied.

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)

The active substance flazasulfuron is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

Set up a resistance monitoring to the active substance flazasulfuron. Any new information which would change the resistance risk analysis must be provided to the competent authorities immediately for the whole uses.

5.1.2 Post-authorisation data requirements

None.

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Appendix 1 Copy of the product authorisation

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Décision relative à une demande d'extension d'usages 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 réglementaire,

*Vu la demande d'extension d'usages majeurs du produit phytopharmaceutique **KATANA 25 WG***

de la société ISK BIOSCIENCES EUROPE N.V

enregistrée sous le n° 2022-3311

Vu les conclusions de l'évaluation de l'Anses du 5 avril 2024,

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** aux usages décrits dans la présente décision.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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Informations générales sur le produit	
Noms du produit	KATANA 25 WG KATANA MISSION DEIMOS HINOKI
Type de produit	Produit de référence
Titulaire	ISK BIOSCIENCES EUROPE N.V De Kleetlaan 12 B Box 9 Pegasus Park B-1831 DIEGEM Belgique
Formulation	Granulé dispersable (WG)
Contenant	250 g/kg - flazasulfuron
Numéro d'intrant	9700070
Numéro d'AMM	9700070
Fonction	Herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

La présente décision peut être retirée ou modifiée si des éléments le justifient.

A Maisons-Alfort, le 01/08/2024

DocuSigned by:
Charlotte Grastilleur
AE281A955A42454...

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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ANNEXE : Modalités d'autorisation du produit

Liste des nouveaux usages autorisés								
En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ. En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.								
Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
12455901 Fruits à coque*Désherbage*Cult. Installées	0,08 kg/ha	1/an	-	120	20 (dont DVP 20)	-	5	Non concerné
	Application de février à juin. Uniquement sur sol à pH inférieur à 6. 1 application tous les 2 ans en respectant un intervalle minimum entre les applications de 730 jours.							
	0,08 kg/ha	1/an	-	120	20 (dont DVP 5)	-	5	Non concerné
	Application de février à juin. Application sous le rang : ne pas appliquer sur plus de 33 % de la surface de la parcelle. Uniquement sur sol à pH supérieur à 6.							
	0,08 kg/ha	1/an	-	120	20	-	5	Non concerné
Application de février à juin. Application sous le rang : ne pas appliquer sur plus de 33 % de la surface de la parcelle. Uniquement sur sol à pH inférieur à 6.								
12605905 Fruits à pépins*Désherbage*Cult. Installées	0,08 kg/ha	1/an	-	60	20 (dont DVP 20)	-	5	Non concerné
	Application de février à juin. Uniquement sur sol à pH inférieur à 6. 1 application en plein tous les 2 ans en respectant un intervalle minimum entre les applications de 730 jours.							

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Liste des nouveaux usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
	0,08 kg/ha	1/an	-	60	20 (dont DVP 5)	-	5	Non concerné
Application de février à juin. Application sous le rang : ne pas appliquer sur plus de 33 % de la surface de la parcelle. Uniquement sur sol à pH supérieur à 6.								
	0,08 kg/ha	1/an	-	60	20	-	5	Non concerné
Application de février à juin. Application sous le rang : ne pas appliquer sur plus de 33 % de la surface de la parcelle. Uniquement sur sol à pH inférieur à 6.								

DVP : Dispositif Végétalisé Permanent.

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12555902 Fruits à noyau*Désherbage*Cult. Installées	0,08 kg/ha	1/an	60
Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas de démontrer la sélectivité du produit.			



Conditions d'emploi du produit

Stockage et manipulation du produit :

- Application avec un pulvérisateur à rampe uniquement.

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles ;
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage) ;
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

• pendant l'application

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) 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

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1.

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Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 6 heures.

Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013)

Respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et :

- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

Respect des limites maximales de résidus (LMR)

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SPe 1 : Pour protéger les eaux souterraines, ne pas appliquer ce produit ou tout autre produit contenant du flazasulfuron, en plein, plus d'une année sur deux.
- SPe 2 : Pour protéger les eaux souterraines, dans le cas d'une application localisée, appliquer ce produit uniquement sur le rang sans dépasser 33 % de la surface de la parcelle.

Protection de la faune

- SPe 2 : Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur sol à $pH_{H_2O} > 6$ pour une application en plein.
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau pour une application en plein sur sol à $pH_{H_2O} < 6$.
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau pour une application localisée sur sol à $pH_{H_2O} < 6$.
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau pour une application localisée sur sol à $pH_{H_2O} > 6$.

Protection de la flore

- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

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Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Réurrence (mois)
Mettre en place un suivi de la résistance au flazasulfuron. Fournir, aux autorités compétentes, toute nouvelle information susceptible de modifier l'analyse du risque de résistance.	-	-

Les autres modalités d'autorisation du produit restent inchangées.

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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® – MA N°9700070 – Contains 250 g/kg (25% w/w) flazasulfuron in water dispersible granules (WG)
UFI: 5MJ2-KQ54-0V0U-SUP9

H410 Very toxic to aquatic life with long lasting effects.

Warning



PRECAUTIONARY STATEMENTS
P273 Avoid release into the environment.
P391 Collect spillage.
P501 Dispose of contents and/or container in accordance with the applicable local/national regulations concerning hazardous waste.
SP1 Do not contaminate water with the product or container. (Do not clean the product application equipment near surface water / Avoid contamination via drainage systems from farmyards or roads.)
SPe3 To protect aquatic organisms respect an unsprayed buffer zone of 20 metres to surface water bodies where applied to permanent vegetated systems. SPe3 To protect non-target plants respect an unsprayed buffer zone of 10 metres to adjacent non-agricultural land.
Re-entry interval: 6 hours after treatment.
EUH401 To avoid risks to human health and the environment, comply with the instructions for use.

Distributed by: **Belchim Crop Protection France SA**
Parc Tertiaire de Bois Dieu - 3 allée des Chevreuils - 69380 LISSIEU

IN CASE OF EMERGENCY: Notify the emergency services by dialling 15 or 112 or contact the nearest poison centre

then report your symptoms to the Phyt'Attitude network. Freephone number: 0 800 887 887 (Calls are free from a landline). 24-hour emergency contact number: 0032 14 58 45 45

FIRST-AID MEASURES:

Move away from the hazard.

In case of contact with skin: take off all contaminated clothing, rinse skin immediately with plenty of water. In case of irritation or rash, consult a specialist.

In case of contact with eye: rinse immediately for 15 to 20 minutes under a continuous stream of water with both eyes open.

Do not use neutralising products. Consult a specialist.

In case of inhalation of product: Remove person to fresh air. If experiencing respiratory symptoms, seek emergency medical help immediately: call 15, 112 or the nearest poison centre.

In case of ingestion of product: rinse mouth immediately with water. Do not induce vomiting without seeking medical advice. Seek emergency medical help immediately: call 15, 112 or nearest poison centre.

In all cases, if the symptoms persist or if you feel unwell, consult a doctor and show them the label and/or the safety data sheet.

In case of animal consumption, contact your nearest veterinarian.

Safety data sheet can be accessed on the following website www.quickfds.com

21_03030704_38 | 02150-FR | 7-3207-631-195-14/22 | label approved: 09/2021

PRODUCT DESCRIPTION

Mode of action: Flazasulfuron (the active ingredient in Katana®) belongs to the sulfonylureas chemical group (HRAC 2 group, formerly group B). The product penetrates the targeted plants through both foliar and root channels. As such the product moves up and down the targeted plants. The product acts on the weeds meristems and inhibits the ALS (acetolactate synthase) enzyme.

When applied as part of a pre-emergence treatment, the weed may emerge, however the development is blocked between the cotyledon and 2-leaf stages before the weed is killed entirely.

Table of authorised uses: Katana® is used to control weeds in established crops (over 4 years old): grapevines, olive trees, citrus, pome and stone fruits and hazelnuts. For each of the above crops, the authorised uses are as stated below for each crop.

Crop	Target	Maximum dosage	Maximum number of applications/year	Pre-harvest interval (PHI)	Aquatic buffer zone (non-treatment area) (metres)	Non-target plants buffer zone (non-treatment area) (metres)
Grapevines	annual and biennial broadleaf weeds, annual grassweeds	0.2 kg/ha	1	75 days	20, including DVP*	10
Olive trees		0.2 kg/ha	1	45 days	20, including DVP*	10
Citrus		0.2 kg/ha	1	45 days	20, including DVP*	10
Pome fruits	annual broadleaf weeds, annual grassweeds	0.08 kg/ha	1	60 days	20, including DVP*	10
Stone fruits		0.08 kg/ha	1	60 days	20, including DVP*	10
Hazelnuts		0.08 kg/ha	1	120 days	20, including DVP*	10

* Permanent vegetated systems (Dispositif Végétalisé Permanent)

Belchim Crop Protection strongly recommend that the product be used solely on the crops outlined above as a protective treatment and, as such, shall not be liable for any other use not described in the applicable catalogue of uses in force at the time of application.

Maximum Residue Limits: refer to the MRLs defined at the European Union level, available at: <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database>

Efficacy spectrum

List of weeds susceptible to Katana®

Susceptible weeds	Pre-emergence of weeds		Post-emergence on young weeds(**)	
	Katana® 0.2 kg/ha	Katana® 0.08 kg/ha	Katana® 0.2 kg/ha	Katana® 0.08 kg/ha
Poverty brome, <i>Bromus sterilis</i>	HS	-	S	L
Hairy finger-grass, <i>Digitaria sanguinalis</i>	S	-	-	MS-L

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Italian ryegrass, <i>Lolium multiflorum</i>	HS	-	S	MS
Annual meadow grass, <i>Poa annua</i>	MS	HS	L	MS
Rough bristle-grass, <i>Setaria verticillata</i>	S	-	-	-
Green bristle-grass, <i>Setaria viridis</i>	S	HS	-	MS-L

Red-root amaranth, <i>Amaranthus retroflexus</i>	HS	-	L	S
Shepherd's purse, <i>Capsella bursa-pastoris</i>	HS	-	S	S
White goosefoot, <i>Chenopodium album</i>	HS	-	-	MS
Canadian horseweed, <i>Conyza canadensis</i>	S-MS*	-	MS*	S-MS*
Sacred hawksbeard, <i>Crepis sancta</i>	S	-	L	-
Wild carrot, <i>Daucus carota</i>	S	-	S	-
Square stalked willow herb, <i>Epilobium tetragonum</i>	HS	MS	HS	MS
Common stork's-bill, <i>Erodium cicutarium</i>	HS	-	S	-
Geranium (soft, dissected, round-leaved), <i>Geranium sp. (G. mole, G. dissectum, G. rotundifolium)</i>	S	-	HS	L
Prickly lettuce, <i>Lactuca serriola</i>	MS	-	L	-
Mallow, <i>Malva sp.</i>	S	-	HS	HS-L
Bristly ox-tongue, <i>Picris echioides</i>	HS	-	L	-
Annual mercury, <i>Mercurialis annua</i>	S	S	-	S
Common groundsel, <i>Senecio vulgaris</i>	S-L*	MS-L*	S-L*	S-L*
Black nightshade, <i>Solanum nigrum</i>	L	-	-	-
Sow thistles, <i>Sonchus sp. (S. asper, S. oleraceus)</i>	MS	L	MS	S-MS
Common chickweed, <i>Stellaria media</i>	HS	-	HS	S-MS
Common Dandelion, <i>Taraxacum officinalis</i>	S	S	S	L
Veronica (Speedwell), <i>Veronica sp.</i>	L	L	L	L

HS: Highly susceptible (efficacy $\geq 95\%$) — S: Susceptible ($95\% > \text{efficacy} \geq 85\%$) — MS: Moderately susceptible ($85\% > \text{efficacy} \geq 70\%$) — L: Low to no susceptibility (efficacy $< 70\%$)

* known cases of resistance; efficacy $< 70\%$

(**) grasses: before tillering, broadleaves: before 3-leaf stage.

GENERAL INSTRUCTIONS FOR USE

Conditions for application: Do not apply if there is a risk of rain within 6 hours.

When spraying, ensure that the green portions of the crop (burst buds, leaves, bunches, non-lignified stems, pruning cuts, base shoots, etc.) are not directly or indirectly affected.

Katana® may be used with a mounted, trailed or backpack sprayer. Apply under low pressure (< 2 bar), with nozzles suitable for the spraying of herbicides; production of large droplets without misting. Katana® should be applied with water volumes of between 150 to 400 l/ha.

Be careful when applying on heavily blown or cloddy soil as the effectiveness of Katana® may be affected. Apply in a controlled manner when there is no wind (in accordance with regulations in force).

In vineyards: do not treat vines in a poor state of health (parasitic infestation; wood diseases such as Eutypiosis, Esca (a grapevine trunk disease); root asphyxia, frost, waterlogged soil etc.).

In pome fruits, stone fruits and hazelnut: only treat under the row; max. 1 m width (max. 33% of

the field surface).

In stone fruits: do not use in soils with pH above 7.5 and/or more than 20% CaCO₃ or in stony soils.

For all crops: do not use under drip or sprinkler irrigation.

Do not treat the current crop. Protect all plants less than 4 years old with waterproof covers.

When Katana® is used in accordance with these recommendations there is no effect on the quantity or quality of the crop. The product has no effect on the fermentation process or on the quality of the wine.

Precautions for use

- Conduct regular checks on all application equipment to ensure that the equipment is kept in a good condition and correctly calibrated. Also check that the equipment is compliant with current legislation.
- Monitor the spray tank during filling operations and adjust the volume of the product accordingly (use of non-return valve, overflow protection device).
- Do not blow directly into spray nozzles to clear them of blockages.
- Avoid contact with skin and eyes.
- Do not breathe in any product-related vapours or mist from the sprayer operation.
- Do not spray the product near water (ponds, streams, ditches, etc.). Avoid discharging any spray or boom overflow over or into water sources, ponds, ditches, rivers, etc.
- Do not spray the product during windy conditions.
- Do not store the product in the spray tank for periods greater than 10 hours.

Extemporaneous mixtures (Tank mixes): Extemporaneous mixtures (tank mixes) must be prepared and used in accordance with the regulations in force at the time of preparation.

Note: it is necessary to carry out physical and biological compatibility testing to ensure the mixture is compatible. This should be undertaken by spraying a significant area of the crop concerned.

Preparation of the spray mixture: No filling operations should be undertaken on the spray tank unless the spray mixture has been prepared accordingly. It is also necessary to verify that the spray mixture does not contain any

liquid or solid residue from a previous treatment. Weigh out the exact amount of Katana® for each preparation of spray mixture.

Fill the spray tank to 50% of the required volume with clean water. Start the agitation or intake system and gradually add the mixture to the tank. Finally, add the remaining volume of water required for the spraying operation. The spray mixture must be kept in a state of agitation until all spraying operations are completed. Under no circumstances should excess spray mixture be prepared; only prepare the amount required for the intended operation.

When using equipment that is not equipped with an agitation system, prepare the product solution beforehand.

Subsequent crops: If the perennial crops where a treatment was conducted are uprooted, cereals (wheat, barley, rye) or maize may be planted one year after the last application of Katana®.

RESISTANCE PREVENTION AND MANAGEMENT

Repeated use of preparations that are based on active substances of the same chemical group or that use the same mode of action on the same plot of land may lead to the appearance of resistant organisms.

To mitigate this risk, the user should consider best agronomic practices and respect the conditions of use of the product. For applications on the same plot of land it is advisable to alternate or combine chemical preparations based on active substances that belong to different chemical groups or that have different modes of action, both during a crop season and during crop rotation.

Notwithstanding compliance with the aforementioned usage conditions, it is not possible to wholly exclude the possibility that the effectiveness of the herbicide may alter due to the appearance of resistant organisms. As a result of this BELCHIM CROP PROTECTION and ISK Biosciences Europe N.V. do not accept any liability for any consequences that may arise from such resistance.

Please consult your nearest specialist adviser or distributor to find out more information about cases of resistance in your region.

REGULATORY COMPLIANCE AND GOOD PRACTICE

Storage of the product

- The product must only be stored in the original packaging and placed in a room suitable for the storage of plant protection products. The room must comply with the regulations in force and ensure that the product is stored away from humid conditions or freezing temperatures. The product should be kept cool and ventilated, away from food and drink including those intended for animals.
- Keep the product out of the reach of children and unauthorised persons.

Operator and Worker Protection

Wash hands after handling/using/operating on a previously treated plot.

Do not eat, drink, use the telephone or smoke whilst using the product.

Using appropriate well-maintained equipment and implementing general protection measures remain the primary preventive measure against occupational risks. The implementation of additional protection measures such as personal protection equipment is the secondary preventive measure.

In any case, the wearing of dedicated work overalls or PPE must be combined with established sanitation protocols (e.g., Washing hands, showering at the end of each treatment) and consistent risk mitigation routine (e.g., dressing/undressing procedure). The cleaning and storage procedures for reusable work overalls and PPE must comply with their respective instructions for use.

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Part A - National Assessment
FRANCE

The following work clothing and Personal Protective Equipment (PPE) should be worn:

PPE Characteristics	PROTECTION OF THE OPERATOR DURING THE FOLLOWING PHASES:					PROTECTION OF THE WORKER
	PREPARATION/UNLOADING	APPLICATION WITH:			CLEANING	
		BOOM SPRAYER MOUNTED OR TRAILED	BACKPACK SPRAYER			
	REACTION WITH CLOSED CAB	REACTION WITHOUT CAB				
NITRILE GLOVES - NF EN ISO 374-1:01 <small>reusable NF EN 18252-1:01 (type A) or single-use NF EN ISO 374-2 (types A, B or C)</small>	Reusable	Single-use*	Single-use	Reusable	Reusable	Reusable
PPE CLOTHING <small>compliant with NF EN ISO 27065A1 standard</small>	PPE clothing AND partial PPE				PPE clothing AND partial PPE	
PARTIAL PPE <small>long-sleeved gown or apron category III (type P60)</small>						
CHEMICAL PROTECTIVE OVERALL category III type 3 or 4	Type 3 or 4			Type 4 with hood	Type 3 or 4	
BOOTS <small>EN 13 622-3 certified</small>						

* these gloves must only be worn outside the cab and must be stored outside the cab after use

Return used personal protective equipment (PPE) in a translucent bag to your nearest ECO PPE partner distributor or use a company authorised to collect and dispose of hazardous materials.

Immediately after application, clean all protective equipment, wash hands with soap and water, shower and change clothes.

Sprayer cleaning procedure and tank bottom management: At the end of the application period, the entire application equipment (tank, boom, track, nozzles, etc.) must be cleaned carefully with a suitable product (such as Phytnet) and rinsed with clean water. In order to eliminate all traces of the product it is imperative to clean the equipment thoroughly with Phytnet® cleaner and follow the procedures stated on the label and product packaging. Failure to do so may cause damage to crops when the spraying equipment is next used.

The rinsing of the sprayer, the spraying operation itself and the emptying of the tank bottom including the removal of effluents must be carried out in accordance with the regulations in force.

Disposal of product, packaging: Re-use of the packaging is prohibited.

When using the product, empty and rinse the container thoroughly with clear water (manual rinsing 3 times while shaking the container when filled to 1/3 or mechanical rinsing for a minimum of 30 seconds), taking care to pour the rinse water into the sprayer tank. Take the opened, rinsed and drained packaging to your A.D.I.VALOR partner (waste management service) or to another specific collection service.

Unused products may only be disposed of in the original packaging. Contact your A.D.I.VALOR partner (waste management service) or use a company authorised to collect and dispose of hazardous waste.



In case of accidental spillage: Protect yourself (with suitable PPE) and secure the affected area. Call the fire brigade (18 or 112) in the event that the spillage presents an immediate danger to the environment that you cannot control using your own resources. Collect anything that may have come into contact with the product,

including any contaminated ground. Clean the area and equipment used, taking care to contain the effluents generated by the cleaning operation. Dispose of all waste in accordance with the regulations in force.

THE RIGHT WAY TO SPRAY IN COMPLETE SAFETY

- Use plant protection products only if necessary.
- Protect water sources.
- Protect your health and the health of those around you.
- Protect pollinators.
- Monitor weather conditions.
- Preserve wildlife.

MORE INFO - [HTTP://WWW.UIPP.ORG/PHYTOPRATIQUE/](http://www.uipp.org/phytopratique/) : SCAN ME



DISCLAIMER

Any reproduction whether in full or part of this label is strictly prohibited.

Ensure compliance with all uses, doses, conditions and precautions related to use stated on the packaging. The instructions relate specifically to the product and take into account the characteristics of the product and the applications for which it is recommended.

On this basis all cultivation and treatments should be carried out in accordance with good agricultural practice and the recommendations of your adviser taking into account the operator's sole responsibility to consider all the specific factors relating to their land, such as the nature of the soil, the weather conditions, the cultivation methods, the plant varieties, the resistance of the species etc.

The manufacturer guarantee is limited in scope to a quality guarantee where the product is sole in its original packaging and stored in accordance with the recommended storage conditions. The manufacturer also guarantees that the product supplied complies with the Marketing Authorisation issued by the Competent Authorities in France.

For foodstuffs derived from crops protected with this product and intended for export, the exporter is solely responsible for ensuring compliance with the regulations in force in the country of import.


WARRANTY - The manufacturer makes no warranty, expressed or implied, regarding the use of the product in any manner other than those indicated on the label. The operator shall be responsible for any and all risks associated with the use and/or handling and/or storage of this product in circumstances where they have failed to comply with the recommendations stated on the label.

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Katana® – MA N°9700070 – Contains 250 g/kg (25% w/w) flazasulfuron in water dispersible granules (WG)
 UFI: 5MJ2-KQ54-0V0U-SUP9

H410 Very toxic to aquatic life with long lasting effects.

Warning



PRECAUTIONARY STATEMENTS
 P273 Avoid release into the environment.
 P391 Collect spillage.
 P501 Dispose of contents and/or container in accordance with the applicable local/national regulations concerning hazardous waste.
 SP1 Do not contaminate water with the product or container. (Do not clean the product application equipment near surface water / Avoid contamination via drainage systems from farmyards or roads.)
 SPe3 To protect aquatic organisms respect an unsprayed buffer zone of 20 metres to surface water bodies where applied to permanent vegetated systems. SPe3 To protect non-target plants respect an unsprayed buffer zone of 10 metres to adjacent non-agricultural land.
 Re-entry interval: 6 hours after treatment.
 EUH401 To avoid risks to human health and the environment, comply with the instructions for use.

Distributed by: **Belchim Crop Protection France SA**
 Parc Tertiaire de Bois Dieu - 3 allée des Chevreuils - 69380 LISSIEU

IN CASE OF EMERGENCY: Notify the emergency services by dialling 15 or 112 or contact the nearest poison centre

then report your symptoms to the Phyt'Attitude network, Freephone number: 0 800 887 887 (Calls are free from a landline). 24-hour emergency contact number: 0032 14 58 45 45

FIRST-AID MEASURES:

Move away from the hazard.

In case of contact with skin: take off all contaminated clothing, rinse skin immediately with plenty of water. In case of irritation or rash, consult a specialist.

In case of contact with eye: rinse immediately for 15 to 20 minutes under a continuous stream of water with both eyes open.

Do not use neutralising products. Consult a specialist.

In case of inhalation of product: Remove person to fresh air. If experiencing respiratory symptoms, seek emergency medical help immediately: call 15, 112 or the nearest poison centre.

In case of ingestion of product: rinse mouth immediately with water. Do not induce vomiting without seeking medical advice. Seek emergency medical help immediately: call 15, 112 or nearest poison centre.

In all cases, if the symptoms persist or if you feel unwell, consult a doctor and show them the label and/or the safety data sheet.

In case of animal consumption, contact your nearest veterinarian.

Safety data sheet can be accessed on the following website www.quickfds.com