REGISTRATION REPORT

Part A

Risk Management

Product code: SL 162 (IBE-4036)

Product name: CHIKARA DUO

Active Substance(s):

Flazasulfuron, 6.7 g/kg

Glyphosate, 288 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing extension of use)

Applicant: ISK BIOSCIENCES EUROPE N.V.

Date: 15/11/2016

Table of Contents

PART A – Risk Management

The company ISK Biosciences Europe N.V. has requested label extension in France for the product CHIKARA DUO (SL 162 (IBE-4036)), containing 6.7 g/kg flazasulfuron and 288 g/kg glyphosate for use as an herbicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to CHIKARA DUO (SL 162 (IBE-4036)) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of CHIKARA DUO (SL 162 (IBE-4036)) have been made using endpoints agreed in the EU peer reviews of flazasulfuron and glyphosate.

This document describes the specific conditions of use and labelling required for France for the registration of CHIKARA DUO (SL 162 (IBE-4036)).

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

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of ISK Biosciences Europe's application to market CHIKARA DUO (SL 162 (IBE-4036)) in France as an herbicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the label extension of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Flazasulfuron

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. Commission Regulation (EU) No 823/2012 of 14 September 2012 derogating from Implementing Regulation (EU) No 540/2011 as regards the expiry dates of the approval of the active substances 2,4-DB, benzoic acid, beta-cyfluthrin, carfentrazone ethyl, Coniothyrium minitans Strain CON/M/91-08 (DSM 9660), cyazofamid, cyfluthrin, deltamethrin, dimethenamid-P, ethofumesate, ethoxysulfuron, fenamidone, flazasulfuron, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mecoprop, mecoprop-P, mesosulfuron, mesotrione, oxadiargyl, oxasulfuron, pendimethalin, picoxystrobin, propiconazole, propineb, propoxycarbazone, propyzamide, pyraclostrobin, silthiofam, trifloxystrobin, warfarin and zoxamide.
Specific provisions of regulation were as follows : PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flazasulfuron, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 November 2003 shall be taken into account. In this overall assessment Member States. —should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions,

—should pay particular attention to the protection of aquatic plants. Risk mitigation measures should be applied where appropriate. The Member States shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.
There is no definitive EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance. A Review Report is available (SANCO/3051/99/-final, 27 November 2003).

Glyphosate

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. Commission Implementing Regulation (EU) 2015/1885 of 20 October 2015 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-D, acibenzolar-s-methyl, amitrole, bentazone, cyhalofop butyl, diquat, esfenvalerate, famoxadone, flumioxazine, DPX KE 459 (flupyrsulfuron-methyl), glyphosate, iprovalicarb, isoproturon, lambda-cyhalothrin, metalaxyl-M, metsulfuron methyl, picolinafen, prosulfuron, pymetrozine, pyraflufen-ethyl, thiabendazole, thifensulfuron-methyl and triasulfuron.
Specific provisions of the Regulation were as follows : PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on glyphosate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 29 June 2001 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses.
There is no definitive EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. A Review Report is available (SANCO/6511/VI/99-final, 21 January 2002).

1.3 Regulatory approach

The present application (2013-0741) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 12 September 2006[3] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally 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, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

[1] French Food Safety Agency, Afssa, before 1 July 2010
[2] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5
[3] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570

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

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

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

- an authorization granted for a « reference » crop applies also for "linked" crops unless formally stated in the decision
- the "reference" and "linked crops are defined in appendix 1 of this French order.

Then, at FR level, possible extrapolation of submitted data and corresponding assessment from "reference" crops to linked ones are assessed even if not clearly intended by applicant in the dRR, and a conclusion is reached on acceptability of intended uses on those linked crops. The aim of this order, mainly based on EU document on residue data extrapolation [7] is to supply minor crops with registered PPP.

Then, GAPs table (§2.3.) and decision may include uses on crops not clearly intended by applicant.

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CHIKARA DUO, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of access

The applicant has provided the supporting data in Document K; the ownership of the data for glyphosate is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	SL 162 (IBE-4036) CHIKARA DUO
Authorisation number	2140086
Function	Herbicide
Applicant	ISK Biosciences Europe N.V.
Composition	6.7 g/kg flazasulfuron and 288 g/kg glyphosate
Formulation type (code)	Water dispersible granule formulation [Code: WG]

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

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

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

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

Packaging	PEHD (0.3 kg, 3 kg and 12 kg) Papier/Al/PE (30, 60 and 120 g)

The preparation does not contain tallowamine (n° CAS 61791-26-2).

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	No classification required	
Health hazards	Serious eye damage/eye irritation, Hazard Category 2	
Environmental hazards	Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H319	Causes serious eye irritation
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long lasting effects
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

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

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

N/A : no use extension granted:

2.2.4 Other phrases linked to the preparation

N/A : no use extension granted:

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 march 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2016-November-15

PPP (product name/code)	**CHIKARA DUO (SL 162 (IBE-4036))**	**Formulation type:**	**WG**
active substance 1	**Flazasulfuron**	**Conc. of as 1:**	**6.7 g/kg**
active substance 2	**Glyphosate**	**Conc. of as 2:**	**288 g/kg**
Applicant:	**ISK Biosciences Europe N.V.**	**professional use**	☒
Zone(s):	**Southern**	**non professional use**	☐

Verified by MS: yes

Crop and/ or situation	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
			Type	Conc. of as	method kind	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
(a)	(b)	(c)	(d-f)	(i)	(f-h)							(l)	(m)
Pome fruit (apple/pear)	F	Weeds (Annual grass weeds and dicotyledonous weeds)	WG	Flazasulfuron 6.7 g/kg + Glyphosate 288 g/kg	Soil directed spray; application under the row (max. 30% of field surface is treated)	Post emergence on young weeds up to 5-10cm (March till mid of July)	1	n.a.	0.005 – 0.010 (Flazasulfuron) + 0.216 – 0.432 (Glyphosate)	200 - 400	0.020 (Flazasulfuron) + 0.864 (Glyphosate)	60	3 kg product/ha **Not acceptable (aquatic organisms exposure not acceptable)**

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at 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
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The product CHIKARA DUO (SL 162 (IBE-4036)) is a white homogeneous solid. All studies have been performed in accordance with the current requirements. It is not explosive and has no oxidising properties. It is not highly flammable or autoflammable. In aqueous solution at 1% its pH is 5.2 at ambient temperature. Stability data indicate a shelf life of at least 2 years at ambient temperature (in paper/aluminium/PE bag and HDPE bottle). Its technical characteristics are acceptable for a WG formulation.

The product is not classified for the physico-chemical aspect.

The product must be stored at a temperature below 40°C.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of active substances in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Reports and in this dossier and validated for the determination of residues of flazasulfuron and glyphosate in plants (matrices with high water content), food of animal origin, soil, water (surface and drinking) and air.

Analytical methods for the determination of residues of flazasulfuron in foodstuff of animal origin are not necessary.

To update the dossier, the following analytical methods will be required after the re-evaluation of glyphosate:
- a confirmatory method for the determination of glyphosate in high water content commodities
- a fully validated method with ILV for the determination of glyphosate residue in foodstuffs of animal origin
- a confirmatory method for the determination of glyphosate residue in soil and a fully validated method in surface water

The active substances are neither toxic nor very toxic hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

CHIKARA DUO (SL 162 (IBE-4036)), containing 6.7g/kg flazasulfuron and 288g/kg glyphosate, has a low acute toxicity with respect to acute oral (LD50 > 5000 mg/kg bw), dermal (LD50 > 2000 mg/kg bw), and inhalation toxicity (LC50 > 3.38 mg/L/4 hours (maximum achieve concentration)). The product was not irritating to the rabbit skin and eye and did not reveal skin sensitising properties in the guinea pig.

Taking into account all submitted data and the labelling of the active substances flazasulfuron and glyphosate, SL 162 (IBE-4036) classification and labelling are proposed in part 2.2.

3.1.3.3 Operator Exposure

For flazasulfuron, the dermal absorption value of 10% for the non-diluted formulation and diluted formulation has been determined based on physical and chemical properties.

Data on dermal absorption of SL 162 was derived from the EU peer review of glyphosate (max. rate of 3 %) and considered acceptable.

Operator exposure was modelled using the German BBA model and UK POEM.

According to the German model calculations, the risk for the operator using SL 162 with a boom sprayer represents 1% of AOEL of flazasulfuron and 2% of AOEL of glyphosate with working coverall and gloves during mixing/loading and application.

According to UK POEM calculations, the risk for the operator using SL 162 with a hand-held sprayer represents 9% of AOEL of flazasulfuron and 13% of AOEL of glyphosate with working coverall and gloves during mixing/loading and application.

(evaluation was performed with the models with similar entry parameters in the model as presented in the RR; however taking into account a protection factor of 90% for the working coverall).

3.1.3.4 Bystander Exposure

The exposure of bystanders present at the time of spraying was calculated using data presented in the report on EURO-POEM II[8]. Exposure is calculated as 0.1% of the AOEL of flazasulfuron and 0.2% of AOEL of glyphosate, for a 60 kg person situated seven meters away from the spraying operation and exposed for five minutes. The health risk to bystanders is therefore considered acceptable.

3.1.3.5 Worker Exposure

The formulation CHIKARA DUO (SL 162 (IBE-4036)) is an herbicide that is applied to weeds at early stage of growth. It is not necessary to enter treated areas shortly after application.

Moreover, CHIKARA DUO (SL 162 (IBE-4036)) is an herbicide applied at ground level (approx 10-15 cm in vineyard and orchards, and up 50 cm in intercrop application) in order to target weeds and it is never applied directly on the crop (due to the glyphosate non selective action). Worker exposure is likely to be very low, therefore the measurement of worker exposure is not relevant. As a consequence, even if re-entry occurs after application, no exposure is expected.

3.1.4 Residues and Consumer Exposure

Selection of critical uses and justification

The GAPs with respect to consumer intake and risk assessment for the preparation CHIKARA DUO are presented in table 2.3.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedence of the current MRL for glyphosate and flazasulfuron as laid down in Reg. (EU) 396/2005 is not expected.

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

As far as consumer health protection is concerned, France agrees with the authorization of the intended use(s).

Post- registration demands: none

Mitigation measures

Additionally in the framework of this dossier it is proposed to add a mitigation measure for intended uses in all orchards. Indeed, considering that commodities can be present during treatment, the following mitigation measure is proposed to avoid any fruits contamination: “Use application material or agricultural practices to avoid fruits contact with active substance or with soil treated with active substance”.

[8] EURO-POEM II - Bystander Working group Report.

Summary for glyphosate

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
	Orchards treatments * Pome fruits	Yes	Yes	Yes	Yes	Yes with mitigation measures	No	No

Additionally in the framework of this dossier it is proposed to add a mitigation measure for intended uses in all orchards. Indeed, considering that commodities can be present during treatment, the following mitigation measure is proposed to avoid any fruits contamination: "Use application material or agricultural practices to avoid fruits contact with active substance or with soil treated with active substance".

The effects of processing on the nature of glyphosate residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary for flazasulfuron

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
	Orchards treatments * Pome fruits	Yes	Yes	Yes	Yes	Yes with mitigation measures	No	No

Additionally in the framework of this dossier it is proposed to add a mitigation measure for intended uses in all orchards. Indeed, considering that commodities can be present during treatment, the following mitigation measure is proposed to avoid any fruits contamination: "Use application material or agricultural practices to avoid fruits contact with active substance or with soil treated with active substance".

As residues of active substance do not exceed the trigger value of 0.1 mg/kg in treated crops, and the overall chronic exposure did not exceed 10% of the ADI, there is no need to investigate the effect of industrial and/or household processing.

All crops evaluated in the framework of this dossier are not considered relevant with regard to the potential occurrence of residues in rotational crops, thus there was no need to investigate the occurrence of flazasulfuron residues in rotational crops

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary for CHIKARA DUO

Crop	PHI for Product code CHIKARA DUO proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for Product code proposed by zRMS	zRMS Comments (if different PHI proposed)
		glyphosate	carfentrazone		
Orchards treatments Pome fruit	60	Yes	Yes		mitigation measures proposed

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Not necessary.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU peer review were used to calculate PECs for the active substances and their metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of flazasulfuron and glyphosate and their metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU peer review or agreed in the assessment based on new data provided.

PEC soil and PECsw derived for flazasulfuron and glyphosate and their metabolites are used for the eco-toxicological risk assessment and mitigation measures are proposed.

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

Based on vapour pressure, information on volatilisation from plants and soil, and DT50 calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU peer reviews 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 and micro-organisms are acceptable for the intended uses.

For aquatic organisms, since STEP 3-4 PECsw from the applicant are not considered as acceptable by zRMS (see section 5), no acceptable risk to aquatic organisms can be demonstrated for an application of SL162 (IBE-4036).

For all uses, a 5-metre spray distance to terrestrial off-field habitats is required to protect non-target terrestrial plants.

3.1.7 Efficacy

The product complies with the Uniform Principles.

Considering the data submitted:

The efficacy of CHIKARA DUO is considered satisfactory.

The selectivity of CHIKARA DUO is considered satisfactory.

The risk of negative impact (yield, quality, transformation processes, propagation, adjacent crops) is considered negligible.

The risk of resistance of SL-162 is considered acceptable for the control of weeds susceptible to both active ingredients in perennial crops when the product is applied once per year. On *Ambrosia artemisiifolia*, *Conyza bonariensis*, *Conyza canadensis*, *Conyza sumatrensis*, *Lolium multiflorum*, and *Lolium rigidum*, the risk of resistance to glyphosate is still considered to be high as the efficacy of flazasulfuron at 20 g a.s./ha is not demonstrated on these weeds. In case there will be emergences of new weeds during the season that require chemical control by the grower, the application of herbicides with different modes of action than those of flazasulfuron or glyphosate are recommended.

The applicant should put in place a monitoring of resistance cases on weeds, especially on:
- rye grass (*Lolium multiflorum, Lolium perenne* et *Lolium rigidum*),
- fleabanes (*Conyza sp.*),
- common ragweed (*Ambrosia artemisiifolia*).

All new data (that may modify the risks) should be communicated to the authorities.

3.2 Conclusions arising from French assessment

An acceptable risk to aquatic organisms cannot be demonstrated for an application of CHIKARA DUO (SL 162 (IBE-4036)) on pome fruit (apple/pear).

Taking into account the above assessment, an authorisation of label extension cannot be granted. A copy of the Decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

N/A : no use extension granted:

3.4.2 Post-authorisation data requirements

N/A : no use extension granted:

3.4.3 Label amendments (see label in Appendix 2):

N/A : no use extension granted:

Appendix 1 – Copy of the French decision

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Décision relative à une demande d'extension d'usage d'un produit phytopharmaceutique

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

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

Vu la demande d'extension d'usage majeur du produit phytopharmaceutique ***CHIKARA DUO***

de la société *ISK BIOSCIENCES EUROPE N.V.*

enregistrée sous le *n°2013-0741*

Vu les conclusions de l'évaluation du 26 mai 2016,

Considérant que l'utilisation de la préparation entraîne un risque inacceptable pour les organismes aquatiques,

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

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

CHIKARA DUO
AMM n°2140086

Page 1 sur 3

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Informations générales sur le produit	
Noms du produit	CHIKARA DUO LONGRUN
Type de produit	Produit de référence
Titulaire	ISK BIOSCIENCES EUROPE N.V. Pegasus Park De Kleetlaan 12B-Bus 9 B-1831 Diegem BELGIQUE
Formulation	Granulés dispersables (WG)
Contenant	6,7 g/kg - flazasulfuron 288 g/kg - glyphosate (exprimé en équivalent acide)
Numéro d'intrant	2140137
Numéro d'AMM	2140086
Fonction	Herbicide
Gamme d'usages	Professionnel

A Maisons-Alfort, le 15 NOV. 2016

Françoise WEBER
Directrice générale adjointe des produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

CHIKARA DUO
AMM n°2140086

Page 2 sur 3

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12605905 Pommier*Désherbage*Cult. Installées	3 kg/ha	1/an	60
Motivation du refus : L'usage est refusé au motif que l'utilisation de la préparation entraîne un risque inacceptable pour les organismes aquatiques.			

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

Proposed commercial name: Chikara duo

- ORCHARD HERBICIDE –

SL 162 is a wettable granule formulation (WG) containing
0.67 % flazasulfuron and 28.8% glyphosate acid
for control of annual and some perennial grasses, annual and biannual broadleaved weeds in pome fruit orchards.
The (COSHH) Control of Substances Hazardous to Health Regulations may apply to the use of this product at work.

SL162

R52 Harmful to aquatic organisms.
R53 May cause long-term adverse effects in the aquatic environment

Use appropriate containment to avoid environmental contamination.
This material and its container must be disposed of in a safe way.
To avoid risks to man and the environment, comply with the instructions for use.

Registered by:
ISK Biosciences Europe N.V.
De Kleetlaan 12 ; box 9B
B-1831 Diegem
BELGIUM
BATCH N°.....
Date of manufacturing:
® Trademark of ISK

SAFETY PRECAUTIONS
Precautions marked * are a legal requirement

Operator Protection:
WASH CONCENTRATE from skin or eyes immediately DO NOT BREATHE SPRAY WASH HANDS AND EXPOSED SKIN before eating and drinking and after work.

Environmental Protection:
Do not contaminate surface water with the product or its container
To protect non-target plants respect an unsprayed buffer zone of 5 m to non-agricultural land.

Storage and Disposal:
S2: KEEP OUT OF REACH OF CHILDREN.
S13: KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDING STUFFS.
S35: THIS MATERIAL AND ITS CONTAINER MUST BE DISPOSED OF IN A SAFE WAY
S60: THIS MATERIAL AND ITS CONTAINER MUST BE DISPOSED OF AS HARDOUS WASTE
S61: AVOID RELEASE IN THE ENVIRONMENT

Crop:	Apple and Pear orchard
Maximum individual dose:	3.0 kg product per hectare
Maximum number of treatments:	One
Time of application:	Period covering spring till summer, post emergence application on young weeds up to 5-10 cm Application period starts in March till mid of July

OTHER SPECIFIC RESTRICTIONS:
Application is recommended at early post-emergence of weeds, at maximum 10 cm height.
Ground directed under the row application on orchards of 4 years old minimum with no contact on any green part of the trees.

READ ALL OTHER SAFETY PRECAUTIONS AND DIRECTIONS FOR USE BEFORE USE

DIRECTIONS FOR USE

IMPORTANT: This information is approved as part of the Product Label. All instructions within this section must be read carefully in order to obtain safe and successful use of this product.

Restrictions

Do not spray SL162, directly or indirectly, on green parts of orchard trees (opened bud, leaves, bunches, branches not wooded, wounds of pruning, rejections of the base).
Apply SL 162 using (to check) hydraulic tracted or backpack (before using, proceed to the calibration of equipment). Apply under low pressure (< 2 bars), with adapted nozzles to herbicide spray, generating droplets of median to coarse size.

Apply SL 162 in water volumes varying between 200 and 400 l/ha. Application must be regular and homogenous.
Avoid application on lumping or blown soil.
Apply in directed spray, without wind, in weather conditions totally avoiding drift spray on adjacent crops or even on the treated crop.
SL 162 must not be applied to any crop suffering from stress as a result of drought, waterlogging, low temperatures, pest or disease attack, nutrient or lime deficiency or other factors reducing crop growth.
Protect all plants of less than 4 years old with waterproof tool (protection shield) or do not spray in the vicinity of these young plants.
In case of digging out treated crop, cereals (wheat, barley, rye) or maize can be sown in a minimum delay of one year after the last application of SL 162

Weed control

SL 162 contains flazasulfuron and glyphosate, two active substances, in a co-formulation which on one hand boosts the post-emergent action of this foliar herbicide and on the other hand allows keeping a sufficient pre-emergent activity.
Flazasulfuron belongs to Sulfonylurea's family; it is rapidly absorbed into the weed leaves and can also be absorbed by the roots. It is translocated through the xylem and the phloem towards the meristematic zones. Sulfonylurea herbicides are applied at pre-emergence and at early post-emergence of weeds. Glyphosate belongs to Glycine's family; its use is limited to foliar applications only, since glyphosate is rapidly inactivated in the soil. **Glyphosate** is absorbed through foliage and translocated to growing points. Because of this mode of action, it is only effective on actively growing plants; it is not effective as a pre-emergence herbicide.
SL 162 is readily translocated within the weed plant, inhibiting growth within hours of treatment, thus preventing competition with the crop. Many weeds show marked colour changes as they die back after treatment, but the time taken for these symptoms to appear and death to occur may vary according to weed species and weather conditions. The full effect of the treatment may not be apparent for up to four weeks. Plants not completely killed are often severely stunted and much less competitive with the crop.
SL 162 is most effective when applied to young and small (< 10 cm height), actively growing weeds. As larger weeds may become less susceptible, it is important to note the size of each weed species so that application is made at the optimum time. Good spray cover of the weeds must be obtained. Weed control may be reduced when soil conditions are very dry. Residual effects may be reduced by heavy rain or extreme dryness. The susceptibility rating of weeds in the following table refer to good spray cover and good growing conditions.

Weed Resistance

When herbicides with the same mode of action are used repeatedly over several years in the same field, selection of resistant biotypes or less susceptible weed species can take place. These can propagate and may become dominating. A weed species is considered resistant to a herbicide if it survives a correctly applied treatment at the recommended dose. Development of resistance with a weed species can be avoided or delayed by alternating (or tank mixing) with suitable products having a different mode of action. A strategy for preventing and managing resistance should be adopted. The Weed Resistance Action Group has produced guidelines and copies are available from the HGCA, CPA, your distributor, crop advisor or product manufacturer.
As some weeds normally controlled by SL 162 have been identified as resistant to sulfonylurea (ALS inhibitors) or glycines (EPSPS inhibitors) herbicides, it is

recommended to alternate, plant protection products based on active substances belonging to different chemical families, or with different modes of action.

Susceptible Weeds

The susceptibility rating of weeds in the following table refer to good spray cover and good growing conditions.

	Pre-emergence application	Post-emergence application
Weed Sensitivity	**SL 162 at 3kg/ha**	
Bromus sterilis	HS	S
Digitaria sanguinalis	S	
Lolium multiflorum	HS	HS
Poa annua	MS	HS
Setaria verticillata	S	HS
Setaria viridis	S	HS
Amaranthus retroflexus	HS	HS
Capsella bursa-pastoris	HS	HS
Chenopodium album	HS	MS
Conyza canadensis	HS	HS
Crepis sancta	S	
Daucus carota	S	
Epilobium tetragonum	HS	
Erodium cicutarium	HS	
Geranium molle, G.dissectum, G.rotondifolium	S	S
Lactuca serriola	MS	S
Malva sp	S	S
Picris echioïdes	HS	HS
Mercurialis annua	S	
Senecio vulgaris	MS	TS
Solanum nigrum	L	
Sonchus asper, S. oleraceus	MS	HS
Stellaria media	HS	HS
Taraxacum officinalis	S	HS
Veronica sp	L	HS

HS : Highly susceptible (control ≥ 95%)
S : Susceptible (control ≥ 85% to 95%)
MS : Moderately susceptible (control ≥ 65% to 85%)
L : Low sensitive (control < 65%)

Growth stages of crops or plants to be protected

SL 162 can be/must be applied independently on the growth stage of the crop (applied by soil directed sprays; mainly under the row treatments with merely no contact of spraying solution with the crops to be protected.

SL 162 will be used as a post-emergence foliar applied herbicide to the weeds. Flazasulfuron will express its pre-emergence activity (soil uptake by existing weeds and control of germination of seeds) due to its presence in the soil over a certain period of time. The application will be done against small weeds (5-10 cm of height); germination of new weeds will be delayed by minimal 1-2 months (depending on specific conditions of use (timing; temperature and moisture content in the soil).

Remark: Avoid application of SL** 162 **in climatic conditions that may result in reduced absorption of the herbicide by the weeds; these include severe drought, water logging, frost and strong, cold or dry winds.

Development stages of the harmful organism concerned

For best results, apply SL 162 when all annual weeds have germinated/emerged.
The product provides the best activity when applied in an early stage of development of the weed population and against germinating seeds (via soil uptake by germinating seeds).

Apple and Pear orchards: SL 162 can be used in spring to summer (March till mid of July) following the emergence of the weeds after the rains; this period is indicated for improving harvesting preparations by cleaning the soil under the trees prior to harvest. The pre-harvest interval (PHI) to be respected is 60 days.

Rate of use, water volume and time of spraying
Apply up to 3kg of SL 162 per hectare. Apply using a water volume of 200 to 400 L/ha. Use the higher water volume where weed populations are dense. Best results will be obtained from applications made when weeds have sufficient leaf area for herbicide uptake and are actively growing but they are not too developed (not above 15 cm).

For best results, apply the product to well emerged and growing weeds of 5-10cm of height; a pre-emergence effect can be observed up to about 2 months (depending the sensitivity of the weed species).

SL 162 will not control all perennial weeds and sedges and might not fully control Horsetail (*Equisetum arvense)* and some other strong rooted and developed weeds.

SL 162 will give short-term control only (1-2 months) of Creeping thistle (*Cirsium arvense)*, Smooth Hawks beard (*Crepis capillaris)*, Hairy rocket (*Erucastrum gallicum*), Smooth cat's ear (*Hypochoeris glabra*), Scentless mayweed (*Matricaria inodora*) and Common dandelion (*Taraxacum officinalis)*.

Spray solution preparations Practical recommendations:
Half fill the spray tank with water. Add the recommended quantity of SL 162 to water. Agitate thoroughly and top up the tank with water. Do not store the spray solution overnight in the spray tank.

Application Equipment
Apply using a hydraulic sprayer or a dedicated knapsack sprayer, choosing a nozzle type to obtain the stated water volume and giving a MEDIUM spray quality (BCPC definition). Use a

spray pattern that enables good coverage of the weeds to be controlled. Ensure that all sprayers used are well maintained and free of leaks.

Subsequent plantings/rotational crops*
DO NOT plant desirable plant species within the same season following application of SL 162 except where used as a pre-plant, site preparation treatment for the conifer species *Chamaecyparis lawsoniana*, *Thuja plicata* and *Thuja occidentalis*.
In case of digging out treated crop, cereals (wheat, barley, rye) or maize can be sown in a minimum delay of one year after the last application of SL 162.

Adjacent Plants
Avoid all spray drift onto leaves of non-target plants, trees or shrubs; all plants with green parts (green shoots & leaves are susceptible to damage).

PROCEDURE FOR CLEANING HYDRAULIC APPLICATION EQUIPMENT

1. Immediately after spraying, drain tank completely. Any contamination on the outside of the spraying equipment should be removed by washing with clean water.
2. Rinse inside of tank with a volume of clean water equivalent to at least 20% of the sprayer tank capacity for several minutes and flush through booms and hoses. Drain tank completely.
3. Half fill tank with clean water and add chlorine bleach/sodium hypochlorite to make a 0.25% solution (250ml of a 10% containing bleach solution per 100l of water). Agitate for 10 minutes and then flush the boom and hoses with the cleaning solution. Tank-washings should be disposed of safely and by approved means.
4. Nozzles and filters should be removed and cleaned separately with chlorine bleach/sodium hypochlorite solution at the same concentration as used in the sprayer.
5. Rinse the tank with a volume of clean water equivalent to at least half of the sprayer tank capacity and flush through the boom and hoses. Drain tank completely.
6. For the disposal of washings, follow Code of Practice for the Safe Use of Pesticides on Farms and Holdings. Do not spray onto sensitive crops or land intended for cropping with sensitive crops.

PROCEDURE FOR CLEANING KNAPSACK APPLICATION EQUIPMENT

1. Immediately after spraying, empty tank completely. Any contamination on the outside of the spraying equipment should be removed by washing with clean water.
2. Rinse inside of tank with a volume of clean water equivalent to at least 20% of the sprayer tank capacity for several minutes and flush through the lance and nozzles. Empty tank completely.
3. Half fill tank with clean water and add chlorine bleach/sodium hypochlorite to make a 0.25% solution (25ml of a 10% containing bleach solution per 10l of water). Shake vigorously and leave to stand for 10 minutes. Then empty tank by spraying through lance and nozzles with the cleaning solution. Tank-washings should be disposed of safely and by approved means.
4. Nozzles and filters should be removed and cleaned separately with chlorine bleach/sodium hypochlorite solution at the same concentration as used in the sprayer.
5. Rinse the tank with a volume of clean water equivalent to at least half of the sprayer tank capacity and flush through the lance and nozzles. Empty tank completely.
6. For the disposal of washings, follow Code of Practice for the Safe Use of Pesticides on Farms and Holdings. Do not spray onto sensitive crops or land intended for cropping with sensitive crops.

PRECAUTIONS

SL 162 is a non-selective herbicide which is active on most plant species. **Avoid overdosing.**
EXTREME CARE must be taken to **spraying** onto target crops to prevent damages by reaching the foliage with the herbicide.
Do NOT apply SL 162 in windy conditions or using a high pressure which produces a fine spray prone to drifting. Do not apply the product when wind can derive spray solution to neighbouring crops.

RESISTANCE

SL 162 contains a sulfonyl urea herbicide in a mixture with glyphosate. The mode of action is respectively as an ALS inhibitor and as a systemic (up and downward transport) total herbicide.

Glyphosate its mode of action is to inhibit an enzyme involved in the synthesis of the aromatic amino acids: tyrosine, tryptophan and phenylalanine. It is absorbed through foliage and translocated to growing points. Because of this mode of action, it is only effective on actively growing plants; glyphosate alone is not effective as a pre-emergence herbicide.

Cases of weed resistance against ALS inhibitors (like flazasulfuron) in combination with glyphosate are not expected. Whilst no cases of resistance have been reported so far for SL 162, application of SL 162 should nevertheless form part of an integrated weed management strategy. This would include the following measures:

- Only one application of SL 162 may be made per year.
- Rotational use with herbicides with differing modes of action, (e.g. Diuron oxyfluorfen, flumioxazin, terbuthylazine, ammonium gluphosinate, MCPA, etc.) is recommended.

SUSCEPTIBILITY OF NON-TARGET SPECIES

SL 162 should not enter into contact with green parts of the crop to be protected; this can be obtained by soil directed sprays under the row. Adequate application equipment with low pressure and flat fan nozzles is recommended to increase the application safety.

As the product SL 162 contains glyphosate, a total herbicide that is absorbed by green parts of plants and trees/shrubs, extreme care should be taken not to spray on the crops to be protected and to avoid all kind of drift towards green plants in the vicinity of the treated areas.
When applying near sensitive plant species, large areas should **NOT** be treated until a small area has been test sprayed to show the variety to be safe for treatment with SL 162.

TRADEMARK ACKNOWLEDGEMENTS

SL 162 is a trademark of ISK Ltd.

NOTICE TO BUYER

All goods supplied by us are of a high grade and we believe them to be suitable for any purpose for which we expressly supply them, but as we cannot exercise control over their mixing or use, all conditions and warranties, statutory or otherwise, as to the quality or fitness for any purpose of our goods are excluded and no responsibility will be accepted by us for any damage or injury whatsoever arising from their storage, handling, application or use.

Appendix 3 – Letter(s) of access

HELM AG

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
(BVL)
Abteilung 2, Pflanzenschutzmittel
Messeweg 11/12
38104 Braunschweig

HAMBURG, 24.04.2012
DEPARTMENT: Regulatory Affairs Europe CB/CB

YOUR REFERENCE: DATED:

TELEPHONE DIRECT-NO.: +49 40/2375
E-MAIL: C.Bleschke@helmag.com

LETTER OF ACCESS

Glyphosate

We, HELM AG, Nordkanalstraße 28, 20097 Hamburg, Germany hereby authorise the German authority to access Helm's Glyphosate Technical Equivalence Dossier submitted under the reference number ZA1 007385 00/00 in order to grant the authorisation of the below listed product for the applicant and future authorisation holder:

Company: **ISK Biosciences Europe N.V.**
Pegasus Park
De Kleetlaan 12B, bus 9
1831 Diegem
Belgium

Product: Product name: **CHIKARA DUO**
Formulation type: **Wettable granules (WG)**
Composition: **Glyphosate 30,32 % w/w +**
Flazasulfuron 0,71 % w/w
Reference number / Trial Code: **ISK-162-H-0-WG**

HELM AG

Dr. Nikolaus Wilhelm
Head of Regulatory Affairs Europe

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HELM AG

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TO WHOM IT MAY CONCERN

HAMBURG, 06.08.2012

DEPARTMENT Regulatory Affairs Europe
CB/CB

YOUR REFERENCE DATED

TELEPHONE-DIRECT-NO.: +49-40/2375-
E-MAIL C.Blaschke@helmag.com

LETTER OF ACCESS

Glyphosate

We, HELM AG, Nordkanalstraße 28, 20097 Hamburg, Germany hereby authorise the authorities in the following countries:
Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Poland, Romania, Slovakia, Slovenia and the *UK*
to access Helm's Glyphosate Technical Equivalence Dossier in order to grant the authorisation of the below listed product for the applicant and future authorisation holder:

Company	**ISK Biosciences Europe N.V.** **Pegasus Park** **De Kleetlaan 12B, bus 9** **1831 Diegem** **Belgium**	
Product	Product name:	**CHIKARA DUO**
	Formulation type:	**Waterdispersable granules (WG)**
	Composition:	**Glyphosate 30,32 % w/w +** **Flazasulfuron 0,71 % w/w**

1. The right of referral to the **Proprietary Data** is only valid in support of the above registration in Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Poland, Romania, Slovakia, Slovenia and the UK. The use of the registration obtained thanks to this letter of access is limited to Agricultural Uses in the Austria, **Belgium**, Czech Republic, Hungary, Ireland, Luxembourg, Poland, Romania, Slovakia, Slovenia and the UK.
2. The right of referral is expressly **limited to the Technical Equivalence Dossier** mentioned above. No access to any further studies is granted by this letter of access.
3. The right of referral is subject to the fulfilling by ISK of all other registration requirements.

HELM AG

page 2

date 06.08.2012

4. The right of referral to the Proprietary Data is neither transferable nor sub-licensable to any further companies or other legal or natural entities or its employees, advisors or customers. The right of referral expires in case of transferral of the above mentioned Registration to a new Registration holder.
5. The right of referral applies only to the above mentioned Product and the registered uses and must not be used for any other application, registration extension or amendment without the express written confirmation of HELM AG.
6. ISK or any of its affiliates, its employees, its advisors or its customers are not authorized to receive any copies of the Proprietary Data nor are they authorized to inspect or view the Proprietary Data or any specific document in whole or in part, provided this is consistent with the laws of the territories concerned.
7. This letter of access is valid until this permission is withdrawn by HELM AG in writing at any time.

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Dr. Felix Thürwächter

Senior Executive Manager
Business Development Crop Protection