

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SAE053H/01

Product name(s): KAGURA

Chemical active substances:

Mesotrione, 80 g/L

Nicosulfuron, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: Sumi Agro Europe Limited

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MS Finalisation date: 16/05/2022

Version history

When	What
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Table of Contents

1	Details of the application	5
1.1	Application background	5
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorization decision	5
2.1	Product identity	5
2.2	Conclusion	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	7
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	7
2.5	Risk management	7
2.5.1	Restrictions linked to the PPP	7
2.5.2	Specific restrictions linked to the intended uses	8
2.6	Intended uses (only NATIONAL GAP)	9
3	Background of authorization decision and risk management	11
3.1	Physical and chemical properties (Part B, Section 2)	11
3.2	Efficacy (Part B, Section 3)	11
3.2.1	Efficacy data	12
3.2.2	Information on the occurrence or possible occurrence of the development of resistance	13
3.2.3	Adverse effects on treated crops	14
3.2.4	Observations on other undesirable or unintended side-effects	15
3.3	Methods of analysis (Part B, Section 5)	16
3.3.1	Analytical method for the formulation	16
3.3.2	Analytical methods for residues	16
3.4	Mammalian toxicology (Part B, Section 6)	17
3.4.1	Acute toxicity	17
3.4.2	Operator exposure	17
3.4.3	Worker exposure	18
3.4.4	Bystander and resident exposure	18
3.5	Residues and consumer exposure (Part B, Section 7)	18
3.5.1	Residues	19
3.5.2	Consumer exposure	20
3.6	Environmental fate and behaviour (Part B, Section 8)	20
3.6.1	Predicted environmental concentrations in soil (PEC _{soil})	20
3.6.2	Predicted environmental concentrations in groundwater (PEC _{gw})	21
3.6.3	Predicted environmental concentrations in surface water (PEC _{sw})	21
3.6.4	Predicted environmental concentrations in air (PEC _{air})	22
3.7	Ecotoxicology (Part B, Section 9)	22

3.7.1	Effects on terrestrial vertebrates	22
3.7.2	Effects on aquatic species	23
3.7.3	Effects on bees	23
3.7.4	Effects on other arthropod species other than bees.....	23
3.7.5	Effects on soil organisms	23
3.7.6	Effects on non-target terrestrial plants	24
3.7.7	Effects on other terrestrial organisms (Flora and Fauna).....	24
3.8	Relevance of metabolites (Part B, Section 10)	24
Appendix 1	Copy of the product label	25
Appendix 2	Lists of data considered for national authorization.....	29

PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application under article 33 of regulation 1107/2009 submitted by the applicant in March 2019 is for first authorization of the product SAE053H/01, an oil dispersion formulation (OD) containing 80 g/L mesotrione and 30 g/L nicosulfuron., for use in maize, with max. 1.2 L/ha and at latest BBCH of 18.

Please note: The intended maximal application rate to be registered is 1.2 L product/ha, which is equivalent to 96 g mesotrione/ha and 36 g nicosulfuron/ha. Nevertheless, the dossier has been prepared for a maximal application rate of 1.5 L product/ha, and thus all risk and exposure assessments presented have been performed with that exaggerated application rate, unless otherwise stated. An application rate of 1.5 L product/ha is regarded as worst case and is therefore covering the intended rate of 1.2 L product/ha.

The zRMS for this central zone dossier is Poland. The concerned member states (cMS) are CZ, SK, HU, RO, DE, BE, NL, SI, AT, UK and IE.

1.2 Letters of Access

Business Confidential.

1.3 Justification for submission of tests and studies

All reports submitted are needed for the first registration of SAE053H/01 in accordance to the data requirements laid down in Regulation (EC) No. 284/2013.

1.4 Data protection claims

Under Article 59, Regulation 1107/2009/EC, the Applicant claims data protection for the studies submitted with this application. The list of the studies for which the applicant requests data protection are reported in the appendix 4 of Part A. The Applicant confirms that no period of data protection has previously been granted in respect of the study or has been granted and not yet expired.

2 Details of the authorization decision

2.1 Product identity

Product code	SAE053H/01
Product name in MS	KAGURA
Authorization number	New product, not assigned yet
Function	herbicide
Applicant	Sumi Agro Europe Limited
Active substance(s) (incl. content)	mesotrione; 80 g/L nicosulfuron; 30 g/L
Formulation type	Oil Dispersion [Code: OD]
Packaging	1, 5 and 10 L PA/PE-COEX containers, professional user
Coformulants of concern for national authorizations	not applicable
Restrictions related to identity	not applicable
Mandatory tank mixtures	not applicable

Recommended tank mixtures	not applicable
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2.2 Conclusion

2.3 Substances of concern for national monitoring

Not applicable.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Skin Sens. 1 B , Repr. 2 , Aquatic Acute 1, Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS07, GHS08 , GHS09
Signal word:	Warning
Hazard statement(s):	H317, H361d (eyes, nervous system), H410
Precautionary statement(s):	<p>WARNING SECTION OF THE LABEL (first page)</p> <p>P201: Obtain special instructions before use. P261: Avoid breathing spray. P280: Wear protective gloves P302+P352: IF ON SKIN: Wash with plenty of soap and water. P391: Collect spillage.</p> <p>Other section of the label:</p> <p>P201: Do not handle until all safety precautions have been read and understood. P270: Do not eat, drink or smoke when using this product. P272: Contaminated work clothing should not be allowed out of the workplace P363: Wash contaminated clothing before reuse. P391: Collect spillage. P501: Dispose of contents/container to ...</p> <p>And P280 as follows: Operator: <i>„Stosować rękawice ochronne oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu”</i> “Wear protective gloves and work wear (coverall) during mixing/loading and work wear during application”. Worker: <i>„Stosować rękawice ochronne oraz odzież roboczą (długie spodnie, koszula z długim rękawem).”</i> “Wear protective gloves and workwear (long trousers, long-sleeve shirt).”</p> <p>Section First aid: P302+352 P333 + P313.</p>

Additional labelling phrases:	To avoid risks to human health and the environment, comply with the instructions for use. [EUH401]
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Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe2	To protect groundwater do not apply the formulation more often than every third year.
SPe3	To protect aquatic organisms: Respect 5 m no-spray buffer zone and a 5 m vegetated buffer strip. To protect non-target plants: Respect an unsprayed buffer zone of 10 m to non-agricultural land. OR Respect an unsprayed buffer zone of 5 m associated with a 50% drift reducing nozzles to non-agricultural land. OR Respect an unsprayed buffer zone of 1 m associated with a 90% drift reducing nozzles to non-agricultural land.

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

Refer to national product label.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
respective code if available	Exposure: none Classification: Gloves (due to sensitizing potential of SAE053H/01)
Worker protection:	
respective code if available	Exposure: none Classification: none (diluted product), gloves: recommendation (due to sensitizing potential of SAE053H/01)
Integrated pest management (IPM)/sustainable use:	
respective code if available	none
Environmental protection	
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).
SPe2	To protect groundwater do not apply the formulation more often than every third year.
respective code if available	buffer zones or other national risk mitigation

available	
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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):

Integrated pest management (IPM)/sustainable use:	Relevant for use no.
Environmental protection:	Relevant for use no.

2.6 Intended uses (only NATIONAL GAP)

GAP , date: November 2019

PPP (product name/code): SAE053H/01
Active substance 1: Mesotrione
Active substance 2: Nicosulfuron
Safener: -
Synergist: -
Applicant: Sumi Agro Europe Limited
Zone(s): central
Verified by MS: yes

Formulation type: OD)
Conc. of as 1: 80
Conc. of as 2: 30)
Conc. of safener: -
Conc. of synergist: -
Professional use: X
Non professional use: ☐

Field of use: herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergis per ha (i)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Maize	F	North East and South Eastern broadleaved weeds and grasses	foliar spray	BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron: 36 g/ha	200-300	n.a.	

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

Fate & behaviour: To protect groundwater do not apply the formulation more often than every third year.

3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of an off-white opaque free-flowing liquid of medium viscosity with no foreign matter present. It is not explosive, has no oxidising properties. The product has no flash point below 100 °C. It has a self-ignition temperature of 335 °C. The pH value of the neat formulation is 3.3 at 23.4 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 12 weeks at 35 °C, neither the content of the two active ingredients, the amount of impurities nor the technical properties were changed. The 2 years shelf life study is accepted. Based on the ambient storage stability study, the data confirms the high quality of the formulation and the shelf life is expected to be at least 2 years when stored at ambient temperature in PE/PA commercial containers. Its technical characteristics are acceptable for an OD formulation. The intended concentration of use is 0.3% to 0.6%.

The product will not be used in tank mixtures.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Experimental results on the product SAE053H/01 with regard to product classification and labelling:

Studies	Method	Findings	Classification acc. to Regulation (EC) No. 1272/2008
Explosive properties	Calculation	Not explosive	None
Oxidising properties	Calculation	Not oxidizing	None
Flammability	--	Not applicable for OD-formulation	--
Flash point	ASTM D93	> 100°C	None
Auto-flammability	EEC A.15	Self-ignition temperature = 335°C	None
pH	CIPAC MT 75.3	3.3	None
Acidity	CIPAC MT 191	1.69 %m/m H ₂ SO ₄	None
Viscosity	CIPAC MT 192	Kinematic viscosity > 20.5 mm ² /s at 40°C	None
Surface tension	EEC A.5	32.5 mN/m for neat formulation 30.8 mN/m for 0.75 % in water	None
Relative density	EEC A.3	0.980 (neat formulation)	None

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No precautionary statements according to Regulation (EC) No. 1272/2008 are needed with regard to the physical/chemical data of the product.

Compliance with FAO specifications:

The product SAE053H/01 complies with FAO specifications.

3.2 Efficacy (Part B, Section 3)

SAE053H/01, an oil dispersion (OD) formulation containing 80 g/L mesotrione and 30 g/L nicosulfuron, is intended to be applied at rates within the range of 1.0-1.2 L product/ha, with one application per crop made when the growth stage of the crop is within range of 12-19 (BBCH) and in water volumes of 200-400 L/ha. The actual application rate to be used is dependent on the weeds to be controlled, with the lowest rate of 1.0 L product/ha sufficient to give effective control of some more susceptible annual broad-

leaved weed species and the higher rate of 1.2 L product/ha needed to control other susceptible annual broad-leaved weed species, annual grass weed species and perennial broad-leaved and grass weed species.

The minimum effective rate of SAE053H/01 required to consistently give optimum control is shown to be between 1.0 L and 1.2 L product/ha. This included annual broad-leaved weed species (CAPBP, CHERS, DATST, HIBTR, LAMPU, MATIN, SINAR, VERPE), a perennial broad-leaved weed species (CIRAR) and perennial grass weed species (CYNDA, SORHA).

For other weed species, the minimum effective rate of SAE053H/01 required to consistently give optimum control is shown to be between 1.2 L and 1.5 L product/ha. This included annual broad-leaved weed species (AMASS, GALAP, GERSS, POLAV, POLCO, POLPE, POLLA, POLLM, POROL, VERHE, VIOAR), annual grass weed species (DIGSA, ECHCG, SETSS) and a perennial grass weed species (AGRRE).

3.2.1 Efficacy data

Preliminary tests

The combination of mesotrione and nicosulfuron in SAE053H/01 is justified on the basis of the complementary and overlapping selective herbicidal activities of the two active substances giving effective broad spectrum control of a wide range of annual and perennial broad-leaved and grass weed species.

The ratio of the two active substances in SAE053H/01 is justified on the basis that it is almost identical to the content and ratio of the same active substances in a product that is currently authorised for use as a herbicide in maize in the majority of EU countries, including those relevant to this application for the approval of SAE053H/01 in the EU Central Registration zone.

Minimum effective dose

A total of 59 trials carried out across countries in the Maritime, North-east and South-east climatic zones that generated data on the efficacy of SAE053H/01 against broad-leaved and grass weeds in maize included a comparison of ranges of different rates.

Data from these trials demonstrate that rates within the range of 1.0-1.2 L product/ha are fully justified as the minimum effective doses required to give consistent control of many of the main susceptible annual and perennial broad-leaved and grass weeds for which label claims for control are supported for SAE053H/01 in maize, with the 1.0 L product/ha rate sufficient to give effective control of more susceptible species, whilst rates of up to 1.2 L product/ha rate are needed to give optimum control of other species.

Efficacy tests

A total of 60 trials conducted within the Maritime (23 trials), North-east (16 trials) and South-east (21 trials) EPPO climatic zones between 2014 and 2018 generated data on the efficacy of SAE053H/01 applied the lowest and/or highest rates in the range of 0.75-1.85 L product/ha against a wide range of annual and perennial broad-leaved and grass weed species in maize.

Across these trials, the efficacy of SAE053H/01 has been evaluated under a wide range of climatic conditions and agronomic practices fully representing those in maize growing regions of EU Central Registration zone countries relevant to this submission.

A single post-emergence application of SAE053H/01 at either the lowest or highest rate in the proposed label range of 1.0-1.2 L product/ha gave consistently effective post-emergence control of susceptible weed species across trials that were either similar or superior to those given by standard reference products applied at authorised national label rates.

Based on submitted data, label claims for control of susceptible annual and perennial broad-leaved and grass weed species are fully supported for SAE053H/01 applied post-emergence (crop growth stage 12-19 BBCH) at rates within the range of 1.0-1.2 L product/ha and according to label recommendations in maize.

For NE EPPO climatic zone the following target weed species were categorized as:

- susceptible (S)

for dose rate 1,0 l/ha: CAPBP, CHEAL, GASPA, MATIN, SINAR, THLAR,

for dose rate 1,2 l/ha: CAPBP, CHEAL, GASPA, MATIN, SINAR, STEME, THLAR, VERHE, VIOAR, ECHCG, AGRRE

- moderately susceptible (MS)

for dose rate 1,0 l/ha: VIOAR, ECHCG, AGRRE

for dose rate 1,2 l/ha: POLCO

- moderately tolerant (MT)

for dose rate 1,0 l/ha: POLCO

for dose rate 1,2 l/ha: GERPU

SAE053H/01 caused insufficient (tolerant) susceptibility for GERPU at dose rate 1,0 l/ha. On the dose rate 1,2 l/ha the weed appeared only moderately tolerant.

It might be concluded that in the NE EPPO climatic zone the application of SAE053H/01 at 1,0 l/ha and 1,2 l/ha dose rates (spray volume 200 - 300 l/ha), post-emergence provides benefit against weeds in maize comparable or better with standard products: Elumis, Calisto 100 SC. The dose rate 1,2 l/ha gave better and more consistent control of AGREE, ECHCG and POLCO.

For the Maritime and the SE EPPO climatic zones the Applicant presented for some weeds too few number of trials and took under consideration also trials from other EPPO climatic zones explaining that SAE053H/01 gave similar levels of control of weed species between trials carried out in the Maritime, North-East and South-East climatic zones. Additionally in some trials number of weeds per m² were below the threshold of 5 weeds per m². Appropriateness of such an approach is for decision of CMS whether above mentioned trials and results should be taken under consideration to prove efficacy of SAE053H/01.

3.2.2 Information on the occurrence or possible occurrence of the development of resistance

SAE053H/01 contains mesotrione, a 4-HPPD inhibitor herbicide (HRAC mode of action group F2) and nicosulfuron, an ALS-inhibitor herbicide (HRAC mode of action group B) and therefore combines two active substances with different modes of action.

The calculated overall risk of resistance arising from the use of SAE053H/01 with an unrestricted use pattern ranges from **low-medium risk (1-3)**, dependent on the risk associated with the individual weed species.

The risk management strategy to reduce the risk of resistance developing to mesotrione or nicosulfuron from the use of SAE053H/01 is based on Good Agricultural Practices (GAP), current measures advocated by HRAC and in particular:

- The combination of mesotrione and nicosulfuron, both with different herbicidal modes of action
- Maximum of one application per season
- Maintaining the recommended label rates as those shown to give effective control
- Application to be made when weeds are at the most susceptible stages of development
- Use in sequences with herbicides with different modes of action
- Use of herbicides with different modes of action in subsequent seasons

- Good agronomical practices: crop rotations, soil management work, etc.

This should ensure there is no adverse shift in the sensitivity of weed populations to the product.

On this basis, the overall risk of resistance arising from the proposed uses of SAE053H/01 applied according to label recommendations for broad spectrum control of broad-leaved and grass weeds in maize is low and therefore acceptable.

3.2.3 Adverse effects on treated crops

Phytotoxicity to host crop

In addition to assessments for phytotoxicity and other adverse effects on the crop having been carried out on all 60 efficacy trials, 23 crop selectivity trials were conducted in maize specifically to evaluate the crop safety and potential for adverse effects on crop yield and quality of SAE053H/01 applied at the highest rate in the label range of 1.0-1.5 L product/ha or at the slightly higher rate of 1.85 L product/ha, and also at twice these rates, in the absence of weeds. Crop selectivity trials were conducted within the Maritime (10 trials), North-east (5 trials) and South-east (8 trials) EPPO climatic zones between 2014 and 2018.

Across efficacy and crop selectivity trials, the crop safety of SAE053H/01 has been tested under a wide range of climatic conditions and agronomic practices that are considered to be fully representative of those under which maize are grown across EU Central Registration zone countries relevant to this submission. Trials were carried out on a range of different commercially representative and commonly grown cultivars.

On the overall majority of trials, SAE053H/01 applied from the proposed label rates up to 1.85 L product/ha, and also at twice these rates in crop selectivity trials, caused either no phytotoxicity or relatively low and transient levels of symptoms. In the few trials where more persistent phytotoxicity occurred, this was attributable to the crop being under stress at application.

Based on submitted data, a single application of SAE053H/01 at up to the highest rate in label range of 1.0-1.2 L product/ha, and applied according to label recommendations (including not to apply to crops under stress), is crop safe on maize.

Effects on yield of treated plants or plant products

Evaluations of crop yield carried out on 22 crop selectivity trials demonstrate that SAE053H/01 has no consistent or pronounced adverse impact on yield when applied at the highest rate in the label range of 1.0-1.2 L product/ha (or at the highest efficacy tested rate of 1.85 L product/ha) or at twice these rates.

Effects on quality of plants and plant products

Evaluations of quality parameters of the harvested produce carried out on 22 crop selectivity trials demonstrate that SAE053H/01 has no consistent or pronounced adverse impact on moisture content, thousand grain weight or starch content (as relevant to maize for grain production), plant dry matter and moisture content (as relevant to maize for silage production) or plant moisture content (as relevant to maize for ethanol production) when applied at the highest rate in the label range of 1.0-1.2 L product/ha or at the highest efficacy tested rate of 1.85 L product/ha, and also at twice these rates.

Effects on transformation processes

Whilst there are no major transformation processes applicable to forage or grain maize, products containing mesotrione and/or nicosulfuron have been approved and extensively used as herbicides in maize across EU countries for many years and are well proven to have no negative impact on any relevant

processing procedures. It can therefore be concluded that SAE053H/01 applied at up to the highest rate in the label range of 1.0-1.2 L product/ha on maize has no effects on relevant processing procedures.

Impact on treated plants or plant parts to be used for propagation

Products containing mesotrione and/or nicosulfuron have been approved and extensively used as herbicides in maize across EU countries for many years and are well proven to have no negative impact on the viability of progeny seed. It can therefore be concluded that SAE053H/01 applied at up to the highest rate in the label range of 1.0-1.2 L product/ha can be used on maize for seed production without risk of adverse impact on germination of the seed.

3.2.4 Observations on other undesirable or unintended side-effects

Impact on succeeding crops

One greenhouse pot study conducted according to the OECD 208 test method in 2016 generated data on the impact of SAE053H/01 on a representative range of monocotyledonous and dicotyledonous crop types sown following application to the soil at a range of rates.

Based on TERs calculated from end points (NOER) determined in this study and PEC_{soil} values for mesotrione and nicosulfuron, after commercial harvest of a maize crop on which SAE053H/01 has been applied at up to the highest rate in the label range of 1.0-1.2 L product/ha in the spring, only winter cereals can safely be sown as succeeding crops in the same year as application and **cereals and maize** ~~and all crop types~~ can safely be sown without restriction in the year following application. In the event of crop failure of a maize crop following the application of SAE053H/01 at up to the highest rate in the proposed range of 1.0-1.2 L product/ha no crop types other than maize should be sown as a replacement crop.

Impact on other plants including adjacent crops

Both mesotrione and nicosulfuron have low volatility and therefore the risk to other plants including adjacent crops from volatilisation and air movement away from the area of application can be considered to be negligible when SAE053H/01 is applied at up to the highest rate in the proposed range of 1.0-1.5 L product/ha and risk is therefore primarily that associated with spray drift.

Two greenhouse pot studies conducted according to OECD 208 and 227 test methods in 2016 generated data on the safety of SAE053H/01 applied at a range of rates to the soil prior to sowing or at early post-emergence on a representative range of monocotyledonous and dicotyledonous crop types.

Based on the data generated on pre- and post-emergence sensitivity of the range of different crop types to SAE053H/01 in these tests, TER values calculated from ER_{50} values for the most sensitive crop type tested (LACSA for post-emergence sensitivity) were below the trigger value of 1.0 up to a distance of 5 m from the area of application. Based on TER values for the most sensitive crop species, the risk of adverse impact resulting from the post-emergence application of SAE053H/01 at the highest rate in the label range of 1.0-1.2 L product/ha is acceptably low when a 5 m buffer zone is observed, with a buffer zone of 3 m when 50% drift reduction nozzles are used or without a buffer zone when 90% drift reduction nozzles are used.

Effects on beneficial and other non-target organisms

Based on studies on effects on beneficial and other non-target organisms, SAE053H/01 poses no unacceptable risk to beneficial and other non-target organisms.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

The analysis of mesotrione and nicosulfuron in the plant protection product SAE053H/01 was done by high performance liquid chromatograph (HPLC) with UV detection at 255 nm (nicosulfuron) and 290 nm (mesotrione). Quantitation was performed by external standard calibration.

3.3.2 Analytical methods for residues

Validated methods for the generation of post-authorisation data

Mesotrione

Component of residue definition: Mesotrione				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
High water content (Maize forage), High acid content (Whole orange), High oil content (Oilseed rape seed), High protein/high starch content (dry) (Maize kernel)	Primary	0.01 mg/kg	QuEChERS HPLC-MS/MS m/z 338 → 291 m/z 338 → 212	Watson G., 2013a, RAR 2015
	ILV (High water content and High protein/high starch content (dry))	0.01 mg/kg	QuEChERS HPLC-MS/MS m/z 338 → 291 m/z 338 → 212	Tessier V., 2013 RAR 2015
	Confirmatory (if required)	0.01 mg/kg	see above (Watson G., 2013a)	

The following equivalent study reports are available as matching studies to the validation method from Watson G. (2013a) presented in the RAR 2015:

- Report No. S15-04204 by Schernikau N., Colorado, C.S. (2016)
- Report No. S16-04650 by Giesau A., Bruhn F. (2016)
- Report No. S17-00739 by Giesau A., Schneider B., Giesler W. (2017)

The following equivalent study reports are available as matching studies to the ILV method from Tessier V. (2013) presented in the RAR 2015:

- Report No. S15-04205 by Meseguer C. (2016)
- Report No. S16-05123 by Lesot C. (2017)
- Report No. S16-06606 by Lesot C. (2017)

Nicosulfuron

Component of residue definition: Nicosulfuron				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
High water content (maize forage), High protein/high starch content (dry) (maize corn)	Primary	0.01 mg/kg	HPLC-MS/MS m/z 411.2 → 182.1 m/z 411.2 → 213.0	Gemrot F., 2013 AIR dossier 2016
	ILV	0.01 mg/kg	HPLC-MS/MS	Richter S., 2013 AIR dossier 2016

Component of residue definition: Nicosulfuron				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
			m/z 411 → 182 m/z 411 → 213	
	Confirmatory (if required)	0.01 mg/kg	see above (Gemrot, 2013)	
High water content (cherry), High protein/high starch content (dry) (corn), High acid content (lemon) High oil content (soybean seed)	Primary	0.01 mg/kg	HPLC-MS/MS m/z 411 → 182 m/z 411 → 213	Cabusas, M. E. Y. and Pentz A., 2012 (Rev. 2) and McInerney K. 2016b AIR dossier 2016
High water content (corn silage), High protein/high starch content (dry) (corn grain)	ILV	0.01 mg/kg	HPLC-MS/MS m/z 411 → 182 m/z 411 → 213	Ducat, N. and Pigeon, O. 2004 AIR dossier 2016
High water content (cherry), High protein/high starch content (dry) (corn), High acid content (lemon) High oil content (soybean seed)	Confirmatory (if required)	0.01 mg/kg	see above (Cabusas, M. E. Y. and Pentz A., 2012 (Rev. 2) and McInerney K. 2016b)	

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

Following studies with SAE053H/01 were performed: acute oral, acute dermal, skin irritation, eye irritation (*in vitro* and *in vivo*) and skin sensitisation (LLNA) study. All of them are considered acceptable. SAE053H/01 is not acutely toxic with respect to oral and dermal application. No skin and no eye irritation are found, but the potential for skin sensitisation have been identified. Taking into account the composition of the product / additivity formula, the classification regarding acute inhalation toxicity is not required but the formulation **exhibits reproductive toxicity**. Consequently, classification as Skin Sens. 1, H317 and **Repr.2, H361d is required**, according to CLP Regulation (EC) 1272/2008.

3.4.2 Operator exposure

According to the estimation based on AOEM, the use of SAE053H/01/Kagura, Genki containing mesotrione (80 g/kg) and nicosulfuron (30 g/L) **causes acceptable health risk for unprotected operator**. The potential exposure to the active substances amounts to the values lower than AOEL set for both active ingredients. Taking into account the classification of the undiluted product, protective gloves and work wear during M&L must be used by the operator.

Thus, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label:

„Stosować rękawice ochronne oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu”

“Wear protective gloves and work wear (coverall) during mixing/loading and work wear during application”.

3.4.3 Worker exposure

According to the estimation results, the use of SAE053H/01/Kagura, Genki containing mesotrione (80 g/kg) and nicosulfuron (30 g/L) **does not cause unacceptable health risk for a worker wearing work wear** during field inspection if the exposure amounts to 2h.

Nevertheless, it is forbidden to re-enter area treated with SAE053H/01/Kagura, Genki until spray deposit on plant surfaces has dried.

The sensitization potential of SAE053H/01 (Skin Sens 1, H317) is confirmed for undiluted product. However, bearing in minds the risk for the most sensitive individuals and no dose-effect relationship in case of sensitization, the protective gloves and work wear is recommended for the worker.

Following sentence regarding the use of PPE is recommended by the evaluator to be placed in the **section of precautions for the workers**:

„Stosować rękawice ochronne oraz odzież roboczą (długie spodnie, koszula z długim rękawem).”

“Wear protective gloves and workwear (long trousers, long-sleeve shirt)”

3.4.4 Bystander and resident exposure

The estimations performed according to AOEM indicate that the systemic exposure to mesotrione (80 g/L) and nicosulfuron (30 g/L), contained in the formulation SAE053H/01/Kagura, Genki does not exceed the values of AOEL for the active substances.

The **incidental short-time exposure of bystander and resident (children and adult)** to the formulation SAE053H/01/Kagura, Genki **causes no risk** to human health if the product is used in accordance to the intended uses listed in the GAP Table.

Combined exposure

The estimations performed according to AOEM and EUROPOEM II indicate that the concurrent systemic exposure to mesotrione (80 g/L) and nicosulfuron (30 g/L) contained in the formulation SAE053H/01/Kagura, Genki does not cause unacceptable risk for the health of operators, workers, bystanders and residents (adults and children) because the HI values remain below 1.

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

This dossier is presented to support the product SAE053H/01 for the use in maize. The supported uses are all within the critical GAP evaluation on EU-level (refer to EFSA Journal 2007;120:1-91 and EFSA Journal 2016;14(3):4419).

The summary for the individual substances is given hereafter:

Mesotrione

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?
1	Maize	Yes	Yes	Not applicable. The PHI is covered	Yes	Yes	No	No

Use- No.*	Crop	Plant metab- olism cov- ered?	Sufficient residue trials?	PHI suffi- ciently sup- ported?	Sample storage covered by stabil- ity data?	MRL com- pliance	Chronic risk for consumers identified?	Acute risk for con- sumers identified?
				by the time remaining between application and harvest.				

Nicosulfuron

Use- No.*	Crop	Plant metab- olism cov- ered?	Sufficient residue trials?	PHI suffi- ciently sup- ported?	Sample storage covered by stabil- ity data?	MRL com- pliance	Chronic risk for consumers identified?	Acute risk for con- sumers identified?
1	Maize	Yes	Yes	Not applica- ble. The PHI is covered by the time remaining between application and harvest.	Yes	Yes	No	No

3.5.1 Residues

Mesotrione

New field residue trials (4) were performed with mesotrione as OD formulation in the Northern zone. Trials were conducted during the 2015 growing season. Mesotrione was applied once at a dose rate of *ca.* 120 g/ha at BBCH 12-15-18. Residues of mesotrione in maize (whole plant, forage, silage, grain and rest of plant) were always below the LOQ (0.01 mg/kg) except for whole plant sampled immediately after application. As no residues in grain were found above the LOQ, these trials can be taken into account for the assessment of SAE053H/01.

Based on the available data, the intended use of SAE053H/01 on maize is considered acceptable and it is not expected to have residues of mesotrione above the EU MRL of 0.01 mg/kg (set at the LOQ) for maize, when SAE053H/01 is applied according to the critical GAP (1×0.120 kg/ha mesotrione, BBCH 12-19). No additional field trials are required to support the intended use since no residues above the LOQ are expected in maize grains.

Nicosulfuron

No new data are submitted in the framework of this application. According to the available data as relied on for Annex I approval, residues of nicosulfuron in maize (forage/silage and grain) were always below the LOQ (0.01 mg/kg) when nicosulfuron was applied once at an exaggerated dose rate of *ca.* 60-80 g/ha at BBCH 13-19.

The intended use of SAE053H/01 on maize is considered acceptable and it is not expected to have residues of nicosulfuron above the EU MRL of 0.01 mg/kg (set at the LOQ) for maize, when SAE053H/01 is applied according to the critical GAP (1×0.045 kg/ha nicosulfuron, BBCH 12-19). No additional field trials are required to support the intended use since no residues above the LOQ are expected in maize

grains.

Taking into account that clarification on the genotoxic potential of AMBA and of its toxicological profile is requested, the dossier for SAE053H may need to be re-evaluated after the toxicological data for AMBA has been assessed at Community level.

3.5.2 Consumer exposure

Dietary risk assessments for the active substances mesotrione and nicosulfuron were carried out using EFSA PRIMo revision 3. As a first approach, the EU MRL of each active was taken into account. The results are presented in Point 7.2.8 for mesotrione and 7.3.8 for nicosulfuron. Calculations were performed taking into account all categories of crops for the chronic risk assessment and only the intended use for acute risk assessment (where applicable).

Mesotrione

The calculated chronic exposure was up to 12 % of the ADI. The diet with the highest TMDI is NL toddler where the highest contributor is cattle milk with 6 % of the ADI. The estimated chronic consumer intake levels do not exceed the EU agreed ADI of 0.01 mg/kg bw per day for mesotrione, including a safety factor of 200. It can therefore be concluded that acceptable margins of safety exist for consumers.

The results of the IESTI calculations demonstrate that in no case the IESTI is above the acute reference dose (ARfD) of 0.02 mg/kg bw, including a safety factor of 100. Thus, the acute risk to the consumer based on the short-term intake of residues of the active substance mesotrione is considered to be acceptable.

Nicosulfuron

The calculated chronic exposure was up to 0.1 % of the ADI. The diet with the highest TMDI is NL toddler where the highest contributor is cattle milk with 0.1 % of the ADI. The estimated chronic consumer intake levels do not exceed the EU agreed ADI of 2 mg/kg bw per day for nicosulfuron, including a safety factor of 100. It can therefore be concluded that acceptable margins of safety exist for consumers.

No acute risk assessment was calculated because no ARfD was allocated for nicosulfuron.

The proposed use of the formulation SAE053H/01 does not represent unacceptable chronic and acute risks for the consumer.

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

The product is a mixture of two active substances, but for only one of them has an acute reference dose been allocated. Therefore, combined acute exposure can be considered as irrelevant. The uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues and currently no specific consideration is warranted in the scope of this evaluation. Combined exposure to all active substances in SAE053H/01 is not expected to present a consumer risk.

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

For the active substance mesotrione and its metabolites, calculations of predicted environmental concentrations were based on the EFSA conclusion for mesotrione. For the active substance nicosulfuron, calculations were based on the endpoints presented in EFSA conclusion, 2007.

3.6.1 Predicted environmental concentrations in soil (PEC_{soil})

For the calculation of predicted environmental concentrations in soil for the product, the active substances and their metabolites, the commonly used assumptions of 5 cm initial mixing depth and a soil bulk density of 1.5 kg/L were used, as well as a crop interception of 25%.

As for some metabolites accumulation over the years could not be excluded, accumulation PECs were

calculated, assuming annual application and a tillage depth of 20 cm. For degradation in soil, non-normalised worst-case DT₅₀ values were used in these calculations.

3.6.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The PEC of mesotrione, nicosulfuron and their soil metabolites in groundwater has been assessed with standard FOCUS scenarios and FOCUS-PEARL 4.4.4, FOCUS-PELMO 5.5.3 and FOCUS-MACRO 5.5.4 models. Applications were specified to take place 7 days post emergence, directly to soil at BBCH 12 and assuming 25% crop interception.

For mesotrione and its metabolite AMBA, a pH dependence of soil degradation and soil sorption was established in the EU review. Consequently, three different soil pH scenarios were calculated to cover the maize cultivation area in the European Union, specifically acidic soils (pH 5.1), basic soils (pH 7.9) and soils with an intermediate pH of 6.5.

Predicted environmental concentrations in groundwater evaluated according to the FOCUS methodology were below 0.1 µg/L for mesotrione and its soil metabolites MNBA and AMBA in all simulations.

~~For nicosulfuron, clay dependent sorption to soil was established during Annex I inclusion. A refined parameterisation of this clay dependent sorption was developed for Annex I renewal by the Nicosulfuron Task force. The latter was used for this dossier. At tier 1, degradation rates and formation fractions were based on laboratory data. At tier 2, they were based on the available field data.~~

Predicted environmental concentrations in groundwater determined according to the FOCUS guidance were below 0.6 µg/L for nicosulfuron at Tier 1.

At Tier 2 and application every third year, PEC_{gw} values were below 0.1 µg/L for nicosulfuron and for its metabolites ADMP and MU466.

PEC groundwater values for ASDM and AUSN were below 10 µg/L. For HMUD, and UCSN they were below 0.75 µg/L.

To protect groundwater do not apply the formulation more often than every third year.

The results are summarized in Part B Section 8.

Toxicological assessment:

Taking into account the toxicological data, the groundwater metabolites of nicosulfuron are considered toxicologically non-relevant. The results of consumer risk calculations indicate that the use of SAE053H/01 (Kagura/Genki) according to the list of intended uses presented in GAP Table, causes no risk for health for the adults, toddlers and infants.

3.6.3 Predicted environmental concentrations in surface water (PEC_{sw})

The initial, short-term and long-term (actual and average time-weighted) values of PEC_{sw} and PEC_{sed} were calculated for both active substances and appropriate metabolites using STEPS 1-2 in FOCUS v.3.2, FOCUS SWASH v.5.3, FOCUS PRZM v.4.3.1, FOCUS MACRO v.5.5.4, FOCUS TOXSWA v.5.5.3 and SWAN v.5.0.1 with VFSmod.

PEC_{sw} for the formulated product SAE053H/01 based on drift entry were calculated using the FOCUS drift calculator for buffer distances up to 20 m.

FOCUS Step 1 calculations were performed for both active substances and their aquatic and soil metabolites.

FOCUS surface water calculations at Steps 2 up to Step 4, considering vegetated and non-sprayed buffer strips were performed for both active substances.

At Step 3, the highest maximum surface water PEC values were obtained in the runoff stream scenarios. These maximum PEC values were effectively reduced in Step 4 when considering a 10 m or 20 m runoff buffer parameterised using the percentages given in the FOCUS Landscape and Mitigation Report and 4

m or 3 m 5 m and 10 m vegetated and non-sprayed buffer strip using VFSmod. In order to support the ecotoxicological risk assessment, additional Step 4 calculations with a reduced application rate were performed as well.

The relevant mitigation measures will be proposed in Section 9.

3.6.4 Predicted environmental concentrations in air (PEC_{air})

Both active compounds possess a very low vapour pressure (below $1 \cdot 10^{-9}$ Pa at 25°C) and their photochemical half-life as estimated by Atkinson calculations is smaller than 2 days. Therefore, significant long-range transport or accumulation in the atmosphere is unlikely.

3.7 Ecotoxicology (Part B, Section 9)

The risk for non-target organisms from the exposure to SAE053H/01 for the intended use in maize was assessed. The risk was considered acceptable for terrestrial vertebrates, bees, non-target arthropods other than bees and soil meso- and macrofauna as well as soil microflora without the necessity to apply risk mitigation measures. For aquatic organisms, the risk was considered acceptable based on FOCUS Step 4 PEC_{SW} including 20 m vegetated and 5 non-spray buffer zone or 5 m non-spray, vegetated filter strip (based on VFSmod). For non-target plants, the risk was considered acceptable based on the probabilistic approach including risk mitigation measures such as either 10 m drift buffer OR 5 m drift buffer + 50% drift-reducing nozzles OR 90 % drift-reducing nozzles.

3.7.1 Effects on terrestrial vertebrates

The risk assessment for birds and mammals was carried out according to the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

Birds

An acceptable acute and reproductive risk is presented for dietary exposure of birds to the individual active substances as well as to the mixture of both actives applied as SAE053H/01 in maize based on Tier 1 assessments. Detailed drinking water assessments and secondary poisoning assessments were not triggered.

Terrestrial vertebrates (other than birds)

An acceptable acute risk is presented for dietary exposure of mammals to the individual active substances and the mixture applied as SAE053H/01 in based on screening step risk assessments. The reproductive risk from dietary exposure is indicated to be acceptable for nicosulfuron based on a screening risk assessment and based on higher tier risk assessment for mesotrione.

A higher tier risk assessment was based on the following refinement parameters: focal species, foliage residue dissipation (DT₅₀) and ecological data on PT value.

The residue trials reported by Bakker (2016) and van de Sandt (2019) were assessed and accepted. The mesotrione modelling DT₅₀ values ranged from 0.13 to 0.92 days. The geometric mean was 0.46 days (zRMS calculations: taking to consideration all data (8 trials) the geomean is 0.45828; using data from central zone (5 trials) the geomean is 0.45887). Taking to consideration very good quality of the residue decline data, specific DT₅₀ value for mesotrione was calculated according to best practice in environmental modelling. Thus, the DT₅₀ of 0.46 days proposed by applicant was accepted and use in the risk assessment (f_{TWA} for grasses and cereal shoots is 0.031).

The risk from drinking water was indicated to be acceptable for nicosulfuron. For mesotrione, a detailed assessment was required which then indicated an acceptable risk. Secondary poisoning assessments were not triggered.

3.7.2 Effects on aquatic species

The risk assessment for aquatic organisms was carried out according to the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290).

Effects on aquatic organisms of SAE053H/01 were not evaluated as part of the EU assessment of mesotrione or nicosulfuron. SAE053H/01 was tested on rainbow trout, *Daphnia* (acute and reproduction study), *Raphidocelis subcapitata*, *Navicula pelliculosa*, *Lemna gibba* and *Myriophyllum spicatum*. Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

The risk from exposure to mesotrione and nicosulfuron applied as SAE053H/01 in maize at the actual application rate of 1 x 1.2 L product/ha was indicated to be acceptable for the individual active substances and for the mixture based. For aquatic organisms, the risk was considered acceptable based on FOCUS Step 4 PEC_{SW} including 20 m vegetated and 5 non-spray buffer zone or 5 m non-spray, vegetated filter strip (based on VFSmod). The risk from metabolites of mesotrione and nicosulfuron was indicated to be acceptable based on Tier 1 data and FOCUS Step 1 calculations.

3.7.3 Effects on bees

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

Effects on bees of SAE053H/01 were not evaluated as part of the EU assessment of mesotrione or nicosulfuron. SAE053H/01 was tested in acute (oral and contact exposure) and chronic studies (oral exposure of adults and larvae). Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

The risk from oral and contact exposure to mesotrione and nicosulfuron applied as SAE053H/01 in maize (risk envelope: 1 x 1.5 L product/ha, i.e. 120 g a.s./ha mesotrione and 45 g a.s./ha nicosulfuron) was indicated to be acceptable for bees based on active substance and product data.

3.7.4 Effects on other arthropod species other than bees

The evaluation of the risk for non-target arthropods was principally performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

Effects on non-target arthropods other than bees of SAE053H/01 were not evaluated as part of the EU assessment of mesotrione or nicosulfuron. SAE053H/01 was tested on *Aphidius rhopalosiphii* (Tier 1 and Tier 2 data), *Typhlodromus pyri* (Tier 1) and *Aleochara bilineata* (Tier 2 data). Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

The in-field and off-field risk from exposure to mesotrione and nicosulfuron applied as SAE053H/01 in maize (risk envelope: 1 x 1.5 L product/ha, i.e. 120 g a.s./ha mesotrione and 45 g a.s./ha nicosulfuron) was indicated to be acceptable for non-target arthropods other than bees based on Tier 2 data.

3.7.5 Effects on soil organisms

The risk assessment was conducted according to the Guidance Document on Terrestrial Ecotoxicology (2002).

Meso- and macrofauna

Effects on soil meso- and macrofauna of SAE053H/01 were not evaluated as part of the EU assessment of mesotrione or nicosulfuron. SAE053H/01 was tested on earthworms, *Folsomia* and *Hypoaspis*. Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

The risk from exposure to mesotrione and nicosulfuron applied as SAE053H/01 in maize was indicated to be acceptable for earthworms and the soil macro- and mesofauna. The risk from the product itself and from relevant soil degradation products was indicated to be acceptable as well.

Microbial activity

Effects on soil microorganisms of SAE053H/01 were not evaluated as part of the EU assessment of mesotrione or nicosulfuron. Effects of SAE053H/01 on the nitrification of soil microorganisms have been determined. Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

The risk from exposure to mesotrione and nicosulfuron applied as SAE053H/01 in maize was indicated to be acceptable for the soil microflora. The risk from the product itself and from relevant soil degradation products was indicated to be acceptable as well.

3.7.6 Effects on non-target terrestrial plants

The risk assessment was based on the “Guidance Document on Terrestrial Ecotoxicology” (SANCO/10329/2002 rev.2 final, 2002).

The risk from exposure to mesotrione and nicosulfuron applied as SAE053H/01 in maize (risk envelope: 1 x 1.5 L product/ha; i.e. 120 g a.s./ha mesotrione and 45 g a.s./ha nicosulfuron) was indicated to be acceptable for non-target plants based on Tier 2 data using the probabilistic approach with either a drift buffer zone of 10 m OR a combination of 5 m drift buffer and 50% drift-reducing nozzles OR 90% drift-reducing nozzles.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

No further relevant data available and considered necessary.

3.8 Relevance of metabolites (Part B, Section 10)

Predicted environmental concentrations in groundwater evaluated according to the FOCUS methodology were clearly below 0.1 µg/L for mesotrione and its soil metabolites MNBA and AMBA in all simulations (see dRR Part B Section 8 Point 8.8). Therefore, there is no need to further address the relevance of the metabolites of mesotrione.

The nicosulfuron metabolites ASDM, AUSN, HMUD, MU-466 and UCSN are predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR Part B Section 8 Point 8.8). The relevance of these groundwater metabolites has already been assessed and the assessment agreed at EU level (see EFSA Conclusion for nicosulfuron (EFSA Scientific Report (2007) 120, 1-91)). These relevance assessments are applicable as well for the GAP and groundwater scenarios considered in this dRR also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR.

These groundwater metabolites are not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

Metabolites which have not been identified as being relevant according to the hazard screening should be further tested in an exposure assessment to make sure that any contamination of groundwater will not lead to unacceptable exposure of consumers via their drinking water. Based on the calculations, no risk for the consumer could be identified.

Appendix 1 Copy of the product label

Uwagi do etykiety:

Fizykochemia – brak uwag do etykiety.

Toksykologia – zmieniono treść etykiety w zakresie toksykologii. **Zaktualizowano klasyfikację środka.**

Pozostałości – brak uwag do etykiety.

Los i zachowanie w środowisku – dodano zapis, że w uprawie kukurydzy dopuszcza się stosowanie środka raz na trzy lata. Dodano zwrot P501.

Ekotoksykologia – wyznaczono strefy ochronne w celu ochrony organizmów wodnych, roślin oraz stawonogów.

Skuteczność działania – zmieniono treść etykiety w zakresach: „Działanie na chwasty”, „Stosowanie środka”, „Następstwo roślin”, „Środki ostrożności i zalecenia stosowania związane z dobrą praktyką rolniczą”.

Posiadacz zezwolenia:

Sumi Agro Europe Ltd.; Vintners' Place, 68 Upper Thames Street; Londyn; EC4V 3 BJ; Zjednoczone Królestwo Wielkiej Brytanii i Irlandii Północnej, tel.: + 4420 7246 3697; fax: + 4420 7246 3799

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

Sumi Agro Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa; tel.: +48 22 637 32 37, fax: +48 22 637 32 38, e-mail: biuro@sumiagro.pl, www.sumiagro.pl

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

.....

KAGURA

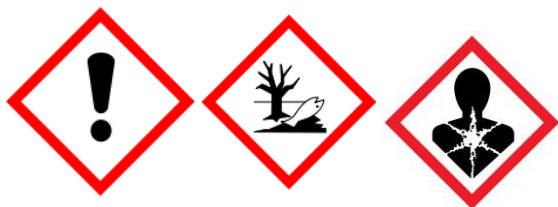
Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

mezotrion (związek z grupy trójketonów) – **80 g/l** (8 %),

nikosulfuron (związek z grupy pochodnych sulfonilomocznika) – **30 g/l** (3 %).

Zezwolenie MRiRW nr R - z dnia



UWAGA

H 317 Może powodować reakcję alergiczną skóry.

H 410 Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.

H 361d Podejrzewa się, że działa szkodliwie na dziecko w łonie matki (oczy, układ nerwowy).

EUH 401 W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

P201 Przed użyciem zapoznać się ze specjalnymi środkami ostrożności

P261 Unikać wdychania rozpylonej cieczy.

P280 Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.

P302+P352 W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody.

P391 Zebrać wyciek.

P501 Zawartość/pojemnik usuwać do podmiotu uprawnionego do utylizacji.

OPIS DZIAŁANIA

Kagura jest środkiem chwastobójczym, koncentratem w postaci zawiesiny olejowej do rozcieńczania wodą, stosowanym nalistnie, przeznaczonym do powschodowego zwalczania perzu właściwego i innych chwastów jednoliściennych oraz chwastów dwuliściennych w uprawie kukurydzy. Środek przeznaczony do stosowania przy użyciu opryskiwaczy polowych.

Kagura zawiera w swoim składzie dwie substancje czynne.

Mezotrion, który głównie działa na jednoroczne chwasty jedno-i dwuliścienne i jest pobierany przez liście jak również przez łodygi i korzenie chwastów. W klasyfikacji HRAC należy do grupy F2, czyli jest inhibitorem biosyntezy karotenoidów doprowadzając do zaniku ich wytwarzania, powodując tym samym zanik chlorofilu. Typowym charakterystycznym objawem dla takiego mechanizmu działania widocznym na roślinach zwalczanych jest całkowite ich bielenie.

Nikosulfuron należy do grupy herbicydów sulfonilomocznikowych. Jest selektywną substancją o działaniu układowym szybko przemieszczającą się w roślinie. Głównie jest pobierany przez liście hamując ich wzrost i rozwój. Według klasyfikacji HRAC nikosulfuron należy do grupy B jako Inhibitor biosyntezy aminokwasów (inhibitor funkcjonowania syntazy acetolaktanowej). Charakterystycznymi objawami po zastosowaniu środka są:

- bielenie roślin,
- zahamowanie wzrostu, zwłaszcza merystemów korzeniowych, które obserwuje się już w kilka godzin po zastosowaniu,
- podłużne chlorozy liści - różowe bądź czerwone zabarwienie nerwów,
- obumieranie tkanek w okolicy merystemów i w efekcie zamieranie całych roślin; objawy widoczne są dopiero po kilkunastu dniach (czasami w przypadku niekorzystnych warunków pogodowych po 3 tygodniach).

DZIAŁANIE NA CHWASTY

Chwasty wrażliwe:

- chwasty dwuliścienne:

- tasznik pospolity, komosa biała, żóltlica drobnokwiatowa, rumian polny, gorczyca polna, tobołki polne, gwiazdnica pospolita (w dawce 1,2 l/ha), przetacznik bluszczykowy (w dawce 1,2 l/ha)

- Chwasty średniowrażliwe:

- chwasty dwuliścienne:

- fiołek polny, rdestówka powojowata (w dawce 1,2 l/ha)

- chwasty jednoliścienne:

- chwastnica jednostronna, perz właściwy

STOSOWANIE ŚRODKA

Kukurydza na ziarno, **na paszę i na kiszonkę.**

W UPRAWIE KUKURYDZY DOPUSZCZA SIĘ STOSOWANIE ŚRODKA RAZ NA TRZY LATA.

Maksymalna dawka dla jednorazowego zastosowania: 1,2 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha – 1,2 l/ha.

Termin stosowania: zabieg można wykonać po wschodach kukurydzy (od fazy 2 liści do fazy 9 liści rośliny uprawnej, BBCH 12-18).

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

W zwalczaniu perzu właściwego, chwastnicy jednostronnej oraz fiołka polnego, jak też w zaawansowanych fazach rozwojowych chwastów stosować wyższą z zalecanych dawek.

NASTĘPSTWO ROŚLIN

W przypadku konieczności wcześniejszego zaorania plantacji potraktowanej środkiem Kagura (w wyniku uszkodzenia kukurydzy przez grad, choroby, szkodniki lub przymrozki) na polu można uprawiać kukurydzę. Po wykonaniu głębokiej orki można także uprawiać życie trwałą i soję.

Po zbiorze kukurydzy uprawianej w normalnych warunkach wegetacji, odchwaszczonej środkiem Kagura do 1 lipca oraz po wykonaniu głębokiej orki można wysiewać zboża.

Wiosną można wysiewać zboża i kukurydzę.

Wiosną można wysiewać wszystkie rośliny uprawne. W przypadku uprawy roślin wrażliwych tj. buraka, strączkowych, rzepaku ozimego, słonecznika i warzyw oraz wcześniej sianych zbóż ozimych możliwe jest wystąpienie uszkodzeń.

W skrajnie niekorzystnych warunkach (gleby piaszczyste, gleby łatwo przesuszające, gleby o niskim pH [<6.0], gleby o wysokiej zawartości substancji organicznej [$>4.0\%$], niskiej aktywności biologicznej, wyjątkowo niskich temperaturach w okresie zimowym, wyjątkowo niskiej wilgotności gleby latem i/lub jesienią i/lub zimą, nakładania się powierzchni opryskanej preparatem, gleby nadmiernie ugniecionej) mogą wystąpić tymczasowe wybielenia, zahamowanie wzrostu, zmniejszenie obsady w roślinach wrażliwych (buraki, strączkowe, słonecznik i warzywa). Dlatego też uprawa w/w roślin jako roślin następczych nie jest zalecana, gdy pH gleby jest znacznie poniżej 6.0 lub jeśli po zastosowaniu środka w poprzednim sezonie, wystąpił długotrwały okres posuchy. Głęboka orka po uprawie kukurydzy i pH gleby ponad 6.0 znacząco zmniejszają ryzyko uszkodzeń tych roślin.

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

Po zastosowaniu środka mogą czasami wystąpić przejściowe objawy fitotoksyczności takie jak chloroza, martwica, bielenie, przebarwienia, redukcja biomasy, karłowatość, bez wpływu na plonowanie kukurydzy.

Należy unikać aplikacji środka na uprawy cierpiące na stres spowodowany ekstremalnymi temperaturami, zalaniem wodą, suszą, uszkodzeniami fizycznymi, jak również unikać nakładania się oprysku na rośliny.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym miesza-dłem) i uzupełnić wodą do potrzebnej ilości. Opryskiwać z włączonym miesza-dłem. Po wlaściu środka do zbiornika opryskiwacza niewyposażonego w miesza-dło hydrauliczne, ciecz w zbiorniku mechanicznie wymieszać. Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy należy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów. Prawa wodnego oraz skażenia gruntu, tj. – po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe lub – unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub – unieszkodliwić w inny sposób, zgodny z przepisami o

odpadach. Po pracy aparaturę dokładnie wymyć. Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy roboczej i które zwróciły się o taką informację.

Środki ostrożności dla osób stosujących środek:

Nie jeść, nie pić ani nie palić podczas używania produktu.

Zanieczyszczonej odzieży ochronnej nie wnosić poza miejsce pracy.

Wyprać zanieczyszczoną odzież przed ponownym użyciem.

Operator: Stosować rękawice ochronne oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Pracownik polowy: Stosować rękawice ochronne oraz odzież roboczą (długie spodnie, koszula z długim rękawem).

Środki ostrożności związane z ochroną środowiska naturalnego:

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony wód podziemnych środek można stosować raz na trzy lata.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie nieopryskiwanej, zadarnio-nej strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 10 m od terenów nieużytkownych rolniczo lub strefy ochronnej o szerokości 5 m od terenów nieużytkownych rolniczo z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50 %, lub 1m i redukcji znosu chmury oprysku na poziomie 90%.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta:

nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie dotyczy.

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia, w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz):

Nie dotyczy.

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

Należy uwzględnić NASTĘPSTWO ROŚLIN.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą
- w temperaturze nieprzekraczającej zakresu 0 - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych. Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody.

W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii-

Appendix 2 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Please refer to the reference list.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Please refer to the reference list.