FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: SAE053H/01

Product name(s): KAGURA/GENKI

Chemical active substances:

Mesotrione, 80 g/L
Nicosulfuron, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Document number – SAEDoc-00013 CEU

(authorization)

Applicant: Sumi Agro Europe Limited

Submission date: November 2019

MS Finalisation date: 18/02/2022

Version history

When	What
November 2019	dRR submitted by applicant
August 2020	Dossier sent for evaluation to Merit Mark (PL)
October 2021	zRMS finalised evaluation
January 2022	Final version prepared by zRMS after Commenting period
February 2022	Final version prepared by zRMS after Commenting period

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zRMS comments:
The text highlighted in grey was provided by the evaluator.

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application was submitted by Sumi Agro Europe Limited to the proposed zRMS Poland.

The application is submitted for first approval of SAE053/H, an oil dispersion formulation (OD) containing 80 g/L mesotrione and 30 g/L nicosulfuron.

The application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

In addition to the submission of studies as listed in sections B1-2-4, B3, B5, B6, B7 and B9, reference is made to data from Mesotrione and Nicosulfuron that are out of data protection. Reference is also made to data that are still under protection, for which letters of access are available.

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~~ was initially prepared for a maximal application rate of 1.5 L product/ha, and thus all risk and exposure assessments presented ~~have been~~ were 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. Risk assessments in the documents B8, B9 and B10 were updated to 1.2 L product/ha during a subsequent dossier update.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Northern zone	-	-
Central zone	PL: KAGURA	CZ: KAGURA SK: KAGURA HU: KAGURA RO: KAGURA DE: KAGURA BE: GENKI NL: GENKI SI: GENKI AU: GENKI UK: GENKI IE: GENKI
Southern zone	-	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Mesotrione

Table 0.1-2: Summary of regulatory history of CAS No: 104206-82-8

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 2017/725
RMS	UK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.06.2017
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	01.09.2017 (Art. 43)
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	31.05.2032
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must shall pay particular attention to:

- the protection of operators,
- the protection of groundwater in vulnerable regions,
- the protection of mammals, aquatic and non-target plants.

The final renewal report for mesotrione (SANTE/11654/2016 - 23/03/2017) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Conclusion was made available on 07/03/2016.

Table 0.1-3: Information on minimum purity of mesotrione

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report**
920 g/kg	980 g/kg Equivalence report available: Y UK (CRD), ref COP 2017/01072 finalised in July 2017

0.1.3.2 Nicosulfuron

Table 0.1-4: Summary of regulatory history of CAS No: 111991-09-4

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011
RMS	LV

Status	
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.06.2009
Date of final Commission (re-registration) deadline (Step 2)	31.12.2012
Current expiration of approval	31.12.2020
Low risk substance or Candidate for Substitution?	CfS

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the potential exposure of the aquatic environment to metabolite DUDN when nicosulfuron is applied in regions with vulnerable soil conditions,
- the protection of aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones,
- the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field nospray buffer zone,
- the protection of groundwater and surface water under vulnerable soil and climatic conditions.

The SANCO report for nicosulfuron (SANCO/3780/07 – 22/01/2008) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 29/11/2007.

Table 0.1-5: Information on minimum purity of nicosulfuron

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report**
~~930~~ 910 g/kg	~~930~~ 910 g/kg Equivalence report available: not applicable*

*The source of nicosulfuron is ISK Biosciences Europe N.V. and is identical to the source evaluated for the inclusion of nicosulfuron in the EU.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information
Two-year shelf life is accepted.
Based on physicochemical properties the PPP is not classified.

Section 3. Efficacy
The evaluation of the application of Kagura resulted in the decision to grant authorization for use according to the GAP table.

Section 5. Analytical Methods
The analytical methods used for analysing the active substances and relevant impurities in the PPP are accepted.

Section 6. Mammalian Toxicology
Classification of the product: Skin sens. 1B, H317, Repr. 2, H361d (eyes, nervous system).

Exposure assessment:
Operator: Taking into account the classification of the undiluted product, protective gloves and work wear during M&L must be used by the operator.
Worker: 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.
Bystander/resident: 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.

Section 7. Metabolism and Residues
The SAE 053H contains nicosulfuron (30 g/L) and mesotrione (80 g/L). The proposed use according to the GAP is on maize.
Nicosulfuron
EU GAP (EFSA Journal 2012;10(12):3048):
Maize: 1 appl., BBCH 12-20, max appl. rate 0.06 kg a.s./ha
GAP proposed for SAE 053H:
Maize: 1 appl., BBCH 12-19, max appl. rate 0.036 kg a.s./ha (36 g nicosulfuron + 96 g mesotrione)
Critical GAP for SAE053H/01 presented in the Part B, Section 7
Maize: 1 appl., BBCH 12-19, max appl. rate 0.045 kg a.s./ha (45 g nicosulfuron + 120 g mesotrione)
GAP proposed for SAE 053H is covered by EU GAP for nicosulfuron.
According to the EFSA Journal 2012;10(12):3048: *In the framework of the peer review, storage stability of nicosulfuron was demonstrated for a period of 9 months at -20°C in dry commodities (maize grain) and in high water content commodities (maize whole plant) (United Kingdom, 2005). All residues trial samples were stored in compliance with the storage conditions reported above. Degradation of residues during storage of the trial samples is therefore not expected*.
The residue for enforcement and risk assessment in cereals is defined as nicosulfuron only.
The Applicant has not submitted any new studies on the magnitude of residues in plants for the purpose of this application. The use of nicosulfuron proposed in the GAP for SAE053H is covered by GAP already evaluated at EU level. In all studies considered in the evaluation at EU level residues of nicosulfuron in maize grains (n=18) and whole plants (n=18) were below LOQ (0.01 mg/kg). Sufficient residue trials are available to support the use of nicosulfuron on maize at the GAP proposed for SAE053H. Additional studies are not required.
As quantifiable residues of nicosulfuron are not expected in maize and the chronic exposure does not exceed 10% of the ADI, there is no need to investigate the effect of industrial and/or household processing.
Magnitude of residues in representative succeeding crops was evaluated at EU level. The available studies were considered sufficient by EFSA to demonstrate the absence of residues in rotational crops, provided that nicosulfuron is applied in compliance with the GAPs reported in EFSA Journal 2012;10(12):3048. GAP proposed for nicosulfuron in SAE 053H is less critical than GAP evaluated at EU level. Additional studies are not required.
It was not possible to propose residue definitions in animal products however, residues in animal products are not expected to be significant (animal dietary intakes are <0.1 mg/kg diet) (EFSA Scientific Report (2007) 120, 1-91; EFSA Journal 2012;10(12):3048). Studies on the magnitude of residues in livestock are not required.
Studies on the effect on the level of residues in pollen and bee products are not required. According to the Appendix II of *Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey*, SANTE/11956/2016 rev. 9, maize was considered a crop from which it is not possible to produce honey.
TMDI calculation performed using EFSA PRIMo Rev. 3.1 covered all MRLs in force (Reg. (EU) 617/2014). The highest chronic exposure was calculated for NL toddler, representing 0.1 % of the ADI. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.
The use of nicosulfuron on maize according to the GAP proposed for SAE053H did not indicate a risk to consumers.
Mesotrione

EU GAP (EFSA Journal 2016;14(3):4419):
Maize: 1 appl., BBCH 12-18, max appl. rate 150 g a.s./ha
GAP proposed for SAE 053H:
Maize: 1 appl., BBCH 12-19, max appl. rate 96 g a.s./ha (36 g nicosulfuron + 96 g mesotrione)
Critical GAP for SAE053H/01 presented in the Part B, Section 7
Maize: 1 appl., BBCH 12-19, max appl. rate 120 g a.s./ha (36 g nicosulfuron + 120 g mesotrione)

GAP proposed for SAE 053H is covered by EU GAP for mesotrione

The stability of residues for the active substance mesotrione was evaluated at EU level (EFSA Journal 2016;14(3):4419). Sufficient storage stability data are available for mesotrione on maize grain and forage. Mesotrione was considered to be stable at -18°C ± 5°C for 42 months in high starch content products (maize grain) and 31 months in products of high water content (maize forage). MNBA which is a metabolite of mesotrione is stable at the above mentioned temperature for 42 months in high water content product and high starch content products (maize grain and forage).

According to the EFSA Journal 2016;14(3):4419 conclusions: "*Since the absolute concentration of all metabolites was below 0.01 mg/kg in the seeds, the residue definition for enforcement and risk assessment was set as mesotrione only for food commodities. For feed commodities, the potential inclusion of the predominant metabolites MNBA and AMBA (free and conjugated) besides mesotrione in the residue definition for risk assessment was envisaged."*

"MNBA was characterized as non genotoxic and of lower toxicity compared to the parent compound and was never detected in the GAP-compliant residue trials on maize (<0.01 mg/kg). In contrast, a genotoxic potential in vivo could not be excluded for AMBA and repeated dose toxicity profile needs to be addressed (see data gap in section 2). For risk assessment in feed commodities and pending on the toxic logical profile of AMBA conjugates, the residue definition is provisionally proposed as mesotrione and AMBA (including its conjugates). If it can be demonstrated that the conjugates of AMBA are not genotoxic and of no toxicological relevance, additional residue trials on maize where AMBA is analysed for are not needed and only mesotrione has to be included in the residue definition. These residue definitions are valid for conventional crops (cereals, pulses and oilseeds) only. For future uses on genetically modified crops and considering the significant proportions of 4/5-hydroxy mesotrione recovered in soya bean forage and hay, this compound may have to be included in the residue definition for risk assessment pending on its toxicological relevance".

The metabolism of mesotrione in rotational crops was found to be similar to the primary crops.

Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered (mesotrione residue levels in maize grain <0.01 mg/kg). In all studies evaluated at EU level and new studies submitted by the Applicant residues of mesotrione and were below LOQ (0.01 mg/kg).

Livestock metabolism studies are not triggered considering the estimated dietary burden calculation.

Residue trials evaluated on DAR can support the use proposed for SAE053H. BBCH proposed in the GAP for SAE053H – 19 is in principal growth stage 1: leaf development as in the case of the growth phase accepted in the EU GAP (BBCH 18). The residue results can be assumed to be comparable.

In addition the Applicant submitted four new trials conducted on maize during 2015 in Austria, Denmark and the United Kingdom. One application was performed at BBCH 15-18 at a nominal rate of 1.5 L/ha (120 g mesotrione plus 45 g nicosulfurone/ha). The GAP proposed for SAE 063H (Part B, section 0) is less critical: 1 appl., BBCH 12-19, max appl. rate 1.2 L/ha (96 g mesotrione/ha plus 36 g nicosulfurone/ha). Specimen extraction and determination of residues were performed according to multi-residue method QuEChERS. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for mesotrione in maize matrices with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The mean recoveries at each fortification level in all specimens (maize grain, rest of plant and whole plant) were in the range of 70 - 110 % with RSD ≤ 20 % - see Part B, Section 5.

Max. storage time for samples (< -18 °C) was 211 days (sampling to extraction) - it is covered by stability

of mesotione (42 months for grain and 31 days for forage).

No residues of mesotrione above the LOD were detected in any of the untreated specimens. Metabolite AMBA has not been considered.

According to the EFSA Journal 2016;14(3):4419 data gap is set for clarification of the genotoxic potential of AMBA and of its toxicological profile. Pending the outcome of the requested data on the toxicological relevance of this compound, maize residue trials for the determination of the residues of AMBA conjugates in feed items may be needed.

The dossier for SAE053H may need to be re-evaluated after the toxicological data for AMBA has been assessed at Community level. At this stage, the available data are sufficient to confirm that the use proposed for SAE053H on maize is acceptable and an exceedance of current MRL of 0.01 mg/kg (Reg. (EU) 2017/626) is not expected.

At the estimated dietary burden, the transfer of AMBA residues in all matrices was shown to be negligible and residue definitions for animal commodities are provisionally not required for the representative use (maize). This assessment has however to be reconsidered pending the outcome of AMBA toxicity. At this stage, the available data are sufficient to confirm that the use proposed for SAE053H on maize is acceptable and an exceedance of current MRLs for animal products (Reg. (EU) 2017/626) is not expected.

As quantifiable residues of mesotrione are not expected in maize and the chronic exposure does not exceed 10% of the ADI, there is no need to investigate the magnitude of residues in processed commodities.

Magnitude of residues in representative succeeding crops was evaluated at EU level. According to the EFSA Journal 2016;14(3):4419: *Bare soil application of mesotrione labelled respectively on cyclohexane-2-14C and phenyl-U14C at a dose rate of 164 g a.s./ha (1N). At 120 day plant back interval (PBI), TRRs are very low in all crop parts: <0.01 mg/kg in wheat grain and radish root, 0.012 mg/kg in broadleaves endive and up to 0.033 mg/kg in wheat forage and straw. Metabolites' identification at 300 d PBI not further investigated.*

Not triggered considering the very low TRRs in rotational crops after a bare soil application at ca. 1N rate and considering also the low to moderate persistence of mesotrione, MNBA and AMBA.

US rotational crop field trials were conducted on pulses/oilseeds (soya bean), leafy vegetables (endive), root vegetables (radish) and cereals (small grains (wheat)) after bare soil application at 0.34 kg a.s./ha or after bare soil application (0.34 kg a.s./ha) followed by a post-emergence application (0.22 kg a.s./ha). Residues of mesotrione and of MNBA were < 0.01 mg/kg in all crop parts.

Studies on the effect on the level of residues in pollen and bee products are not required. According to the Appendix II of *Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey*, SANTE/11956/2016 rev. 9, maize was considered a crop from which it is not possible to produce honey.

TMDI calculation performed using EFSA PRIMo Rev. 3.0 covered all MRLs in force (Reg. (EU) 2017/626).

The highest chronic exposure was calculated for NL toddler, representing 12 % of the ADI. The highest acute exposure corresponded to 0.3 % ARfD.

The use of mesotrione on maize according to the GAP proposed for SAE053H did not indicate a risk to consumers. Taking into account that clarification on the genotoxic potential of AMBA and of its toxicological profile is requestes, the dossier for SAE053H may need to be re-evaluated after the toxicological data for AMBA has been assessed at Community level.

Section 8. Environmental Fate

In accordance with proposed pattern use, an exposure assessment for the formulation SAE053H/01 was submitted and sufficient. The application in maize is acceptable if the formulation is used every third year.

Section 9. Ecotoxicology:

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of SAE053H/01 as herbicide on maize poses acceptable risk to non-target organisms, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from SAE053H/01 applications are required for: aquatic organisms, non-target terrestrial plants.

Section 10. Assessment of the relevance of metabolites in groundwater
Mesotrione. The maximum PECGW values for its metabolites are below the trigger value of 0.1 µg/L. No further action is required.

Nicosulfuron. For the metabolies AUSN, UCSN, ASDM, HMUD the PECgw values are above the trigger value of 0.1 µg/L if applied every third year.

Uses to be considered safe on the basis of EU methodology:

1-13

Uses to be considered non-safe on the basis of EU methodology:

None

All uses/ GAPs are covered by established MRLs.

Authorization can be granted.

Appendix 1 ALL intended uses

			GAP , date: August 2021
PPP (product name/code):	KAGURA, GENKI / SAE053H/01	Formulation type:	OD (Oil dispersion)
Active substance 1:	Mesotrione	Conc. of as 1:	80 g/L
Active substance 2:	Nicosulfuron	Conc. of as 2:	30 g/L
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Sumi Agro Europe Limited	Professional use:	☒
Zone(s):	central	Non professional use:	☐
Verified by MS:	yes		
Field of use:	herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g 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	CEU risk envelope	Maize (ZEAMX)	F	Broadleaved weeds (TTTDD) and grasses (TTTMM)	foliar spray	~~BBCH 12-19~~ BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron: 36 g/ha	200-300 ~~400~~	n.a.	Zonal GAP is covering the highest GAP for growth stage range, dose rates, water volumes. The GAP applied for is the same in all countries covered in this dossier.
2	AT	Maize (ZEAMX)	F	Broadleaved weeds (TTTDD) and grasses (TTTMM)	foliar spray	~~BBCH 12-19~~ BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron: 36 g/ha	200-300 ~~400~~	n.a.	
3	BE	Maize (ZEAMX)	F	Broadleaved weeds (TTTDD) and grasses (TTTMM)	foliar spray	~~BBCH 12-19~~ BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron: 36 g/ha	200-300 ~~400~~	n.a.	
4	CZ	Maize (ZEAMX)	F	Broadleaved weeds (TTTDD) and grasses (TTTMM)	foliar spray	~~BBCH 12-19~~ BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron: 36 g/ha	200-300 ~~400~~	n.a.	
5	DE	Maize (ZEAMX)	F	~~Broadleaved weeds (TTTDD) and grasses (TTTMM)~~ *Annual broad-leaved weeds* *Annual grasses: ECCHG*	foliar spray	~~BBCH 12-19~~ BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron: 36 g/ha	200-300 ~~400~~	n.a.	
6	HU	Maize (ZEAMX)	F	Broadleaved weeds	foliar	~~BBCH 12-19~~	a, b) 1	-	a, b) 1.2 L/ha	a, b)	200-300 ~~400~~	n.a.	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
				(TTTDD) and grasses (TTTMM)	spray	BBCH 12-18				mesotrione: 96 g/ha nicosulfuron: 36 g/ha			
7	IE	Maize (ZEAMX)	F	Broadleaved weeds (TTTDD) and grasses (TTTMM)	foliar spray	~~BBCH 12-19~~ BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron: 36 g/ha	200-300 ~~400~~	n.a.	
8	NL	Maize (ZEAMX)	F	Broadleaved weeds (TTTDD) and grasses (TTTMM)	foliar spray	~~BBCH 12-19~~ BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron: 36 g/ha	200-300 ~~400~~	n.a.	
9	PL	Maize (ZEAMX)	F	Broadleaved weeds (TTTDD) and grasses (TTTMM)	foliar spray	~~BBCH 12-19~~ BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron: 36 g/ha	200-300 ~~400~~	n.a.	
10	RO	Maize (ZEAMX)	F	Broadleaved weeds (TTTDD) and grasses (TTTMM)	foliar spray	~~BBCH 12-19~~ BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron: 36 g/ha	200-300 ~~400~~	n.a.	
11	SI	Maize (ZEAMX)	F	Broadleaved weeds (TTTDD) and grasses (TTTMM)	foliar spray	~~BBCH 12-19~~ BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron: 36 g/ha	200-300 ~~400~~	n.a.	
12	SK	Maize (ZEAMX)	F	Broadleaved weeds (TTTDD) and grasses (TTTMM)	foliar spray	~~BBCH 12-19~~ BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron:	200-300 ~~400~~	n.a.	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
										36 g/ha			
13	UK	Maize (ZEAMX)	F	Broadleaved weeds (TTTDD) and grasses (TTTMM)	foliar spray	~~BBCH 12-19~~ BBCH 12-18	a, b) 1	-	a, b) 1.2 L/ha	a, b) mesotrione: 96 g/ha nicosulfuron: 36 g/ha	200-300 ~~400~~	n.a.	

The PHI is covered by the period remaining between the application of the plant protection product and harvest.

Remarks table heading:

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

Remarks columns:

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

Fate & behaviour: The formulation application in mazie is acceptable if it is used every third year.