

# REGISTRATION REPORT

## Part B

### Section 0

Product Background, Regulatory Context and  
GAP information

Product code: ARY-0469-04

Product name(s): ASAHI MAX

Chemical active substance(s):

Sodium 5-nitroguaiacolate, 3g/L

Sodium o-nitrophenolate, 6g/L

Sodium p-nitrophenolate, 9g/L

Central zone

Zonal Rapporteur Member State: POLAND

## CORE ASSESSMENT

Applicant: Asahi Chemical Europe s.r.o

Submission date: June 2022

Finalisation date: March 2023 (initial Core Assessment)

June 2023 (final Core Assessment)

### Version history

When	What
June 2022	Initial version of dRR for submission to zRMS
March 2023	Initial zRMS assessment  The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and <b>highlighted in grey</b> . Not agreed or not relevant information are <del>struck through and shaded for transparency</del> .
June 2023	Final report (Core Assessment updated following the commenting period)  No additional information or assessments after the commenting period.

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## 0 Product background, regulatory context and GAP information

### 0.1 Introduction

#### 0.1.1 Reason for application

The formulation ARY-0469-04 is registered in Europe under several trade names, which includes ATONIK SL, LITOTEN PLUS, MIGOTO, IKARUGA. Here and after in this document the formulation is stated as ASAHI MAX.

The purpose of this application is to present the data in support of the authorization in the Central zone of ASAHI MAX as a plant growth regulator of winter wheat, oilseed rape and sugar beet. This document summarizes the information related to the plant regulation product ASAHI MAX containing Sodium 5-nitroguaiacolate (3 g/L), Sodium *o*-nitrophenolate (6 g/L), Sodium *p*-nitrophenolate (9 g/L).

#### 0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

Zone	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Southern Central zone	zRMS Poland	-

#### 0.1.3 Regulatory history of the active(s)

##### 0.1.3.1 Sodium 5-nitroguaiacolate, Sodium *o*-nitrophenolate, Sodium *p*-nitrophenolate

Sodium 5-nitroguaiacolate (Na 5-NG), sodium *ortho*-nitrophenolate or sodium *o*-nitrophenolate (Na *o*-NP) and sodium *para*-nitrophenolate or sodium *p*-nitrophenolate (Na *p*-NP) were included into Annex I of Directive 91/414 (2009/11/EC). The SANCO report for Sodium 5-nitroguaiacolate (1 g/L), Sodium *o*-nitrophenolate (2 g/L), Sodium *p*-nitrophenolate (3 g/L) (SANCO/210-08 rev. 02) is considered to provide the relevant review information or a reference to where such information can be found. The EU MRLs for sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate are established in Annex II of Regulation (EC) No 396/2005. Since the entry into force of this regulation no modification of MRLs for sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate has been considered. The data gap provided for the confirmatory data following the Article 12 MRL review was considered satisfactory addressed, the new information provided does not require a revision of the existing MRLs; the risk assessment performed for the three active substances sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate in the framework of the MRL review remains valid (EFSA, 2020)<sup>1</sup>.

The existing active substances sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate are due for renewal of approval and a respective dossier was submitted in April 2020 by Asahi Chemical Europe s.r.o., the European subsidiary of OAT Agrio.

<sup>1</sup> EFSA (European Food Safety Authority), 2020. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate (sodium nitrocompounds). EFSA Journal 2020;18(4):6060, 14 pp.

**Table 0.1-2: Summary of regulatory history of sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate**

name (ISO)	Sodium 5- nitroguaiacolate (No ISO common name is allocated)	Sodium o-nitrophenolate (No ISO common name is allocated)	Sodium p-nitrophenolate (No ISO common name is allocated)
<b>Chemical name (IUPAC)</b>	Sodium 2-methoxy-5-nitrophenolate	Sodium 2- nitrophenolate; sodium o-nitrophenolate	Sodium 4- nitrophenolate; sodium p-nitrophenolate
<b>Chemical name (CA)</b>	3-hydroxy-4-methoxynitrobenzene sodium salt	Sodium o-nitrophenolate	Sodium p-nitrophenolate
<b>CIPAC No</b>	Not allocated	Not allocated	Not allocated
<b>CAS No</b>	67233-85-6	824-39-5	824-78-2
<b>EEC No</b>	Not allocated	Not allocated	Not allocated
<b>FAO SPECIFICATION</b>	Not allocated		
<b>Status</b>			
Approved in EU	Y		
Original Inclusion Directive or Commission Implementing Regulation	SANCO/210/08 – rev. 2, 2 December 2008, 17 May 2013  Date of (01/11/2009) and reference to decision (Commission Directive 2009/11/EC of 18 February 2009 amending Council Directive 91/414/EEC) - <a href="http://data.europa.eu/eli/dir/2009/11/oj">http://data.europa.eu/eli/dir/2009/11/oj</a> Reg 540/2011		
RMS	Poland		
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.11.2009		
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.10.2019		
Date of final Commission (re-registration) deadline (Step 2)	AIR IV – postponed to 31.10.2022		
Current expiration of approval	31.10.2022 2023		
Low risk substance or Candidate for Substitution?	-		

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 specification of the technical materials as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material;
- the protection of the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure;
- the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate.

**Table 0.1-3: Information on minimum purity of sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate**

Active substance	EU agreed minimum purity from Inclusion Directive or Implementing regulation
Sodium 5-nitroguaiacolate	≥980g/kg
Sodium <i>o</i> -nitrophenolate	≥980g/kg
Sodium <i>p</i> -nitrophenolate	≥998g/kg

#### 0.1.4 Regulatory history of the product

ATONIK as the representative formulation in the EU review of the active substances (Na 5-NG, Na *o*-NP and Na *p*-NP) was evaluated by Poland according to Uniform Principles.

Product name and code	ARY-0469-04/ASAHI MAX
Formulation type	SL
Active substance(s) (incl. content)	Sodium 5-nitroguaiacolate 3,0 g/L Sodium <i>o</i> -nitrophenolate 6,0 g/L Sodium <i>p</i> -nitrophenolate 9,0 g/L
Function	Plant growth regulator
Product already evaluated as the ‘representative formulation’ during the approval of the active substance(s)	As a representative formulation for approval of active substances was evaluated product ARY-0469-01 / ATONIK (in PL registered as ASAHI SL): Sodium 5-nitroguaiacolate 1,0 g/L Sodium <i>o</i> -nitrophenolate 2,0 g/L Sodium <i>p</i> -nitrophenolate 3,0 g/L Product ASAHI MAX is 3 time more concentrated product ATONIK. There is no other difference.
Product previously evaluated in another MS according to Uniform Principles	ATONIK / ASAHI SL (ARY-0469-01) Yes (Greece, auth. number 8227 under the name ASAHI SL, date of approval 23.07.2014)  ATONIK PLUS / ASAHI MAX (ARY-0469-04) (Greece, auth. number 8226 under the name ATONIK SL, date of approval 23.07.2014)

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

**Table 0.1-4: Summary of regulatory history of the product ARY-0469-01 / Asahi SL**

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
ARY-0469-04	MIGOTO	Bulgaria	01658 – PRZ	23.1.2019	-
ARY-0469-04	ATONIK SL	Cyprus	2084	15.10.2014	-
ARY-0469-04	ATONIK SL Litosen PLUS	Greece	271/77 8230	1977 2010	23.7.2014 29.12.2014
ARY-0469-04	IKARUGA	Portugal	1981	2.5.2022	-

#### 0.2 zRMS conclusion

For the overview of accepted uses see the Complete GAP table in Appendix 1 of this document.  
For detailed information see the GAP tables in the individual relevant sections.

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

See column 15 of the Complete GAP table presented in Appendix 1 of this document.

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

See column 15 of the Complete GAP table presented in Appendix 1 of this document.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

See column 15 of the Complete GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs.

## Appendix 1 ALL intended uses

GAP rev. 1.0, date:  
2023-03

PPP (product name/code): Asahi SL / ARY-0469-04  
Active substance 1: Sodium 5-nitroguaiacolate  
Active substance 2: Sodium o-nitrophenolate  
Active substance 3: Sodium p-nitrophenolate  
Safener: no  
Synergist: no  
Applicant: Asahi Chemical Europe s.r.o.  
Zone(s): Central  
Verified by MS: no  
Field of use: Plant growth regulator

Formulation type: SL  
Conc. of as 1: 3 g/L  
Conc. of as 2: 6 g/L  
Conc. of as 3: 9 g/L  
Conc. of safener: -  
Conc. of synergist: -  
Professional use: ☒  
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15*							
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop desti- nation / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled  (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g saf- ener/syner- gist per ha (f)	zRMS Conclusion							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applications (days)	kg or L prod- uct / 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			Phys-chem	Analytical methods	Toxicology	Residues	Groundwater	Ecotoxicology	Relevance of metabolites in	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	Poland	Winter oilseed rape	F	Plant growth regulator, num- ber of pods per plant, number of seeds per plant, higher lignification of pods	spray	BBCH 29-69 (spring)	2	7	0.2 0.4	a) Na 5NG: 0.6 Na oNP: 1.2 Na pNP: 1.8 b) Na 5NG: 1.2 Na oNP: 2.4 Na pNP: 3.6	200- 500	28		A	A	A	A	A	A	A	A
2	Poland	Winter wheat	F	Plant growth regulator, num- ber of tillers and ears, portion	spray	BBCH 21-49 (spring)	1	-	0.2 0.2	Na 5NG: 0.6 Na oNP: 1.2 Na pNP: 1.8	200- 300	28		A	A	A	A	A	A	A	A



				above the sieves, germination energy																
3	Poland	Sugar beet	F	Plant growth regulator, effect on higher yield of sugar, lower content of unwanted Sodium	spray	BBCH 12-49 (spring- summer)	2	7	0.2 <del>0.4</del> 0.6	a) Na 5NG: 0.6 Na oNP: 1.2 Na pNP: 1.8 b) Na 5NG: <del>1.8</del> <del>1.2</del> Na oNP: <del>3.6</del> <del>2.4</del> Na pNP: <del>5.4</del> <del>3.6</del>	200- 500	15		A	A	A	A	A	A	A
Minor uses according to Article 51 (field uses)																				
1	Poland	Mustard, spring rape, turnip rape, camelina, <del>garden-rad- ish</del> poppy, linseed, hemp, <del>sun- flower</del> bor- age.	F	Plant growth regulator, num- ber of pods per plant, number of seeds per plant, higher lignification of pods.	spray	BBCH 29-69 (spring)	2	7	0.2 0.4	a) Na 5NG: 0.6 Na oNP: 1.2 Na pNP: 1.8 b) Na 5NG: 1.2 Na oNP: 2.4 Na pNP: 3.6	200- 500	28	Extrapolation from winter osr.	A	A	A	A	A	A	n.r.
2	Poland	Spring rye, spelt, emmer wheat, small spelt, durum wheat.	F	Plant growth regulator, number of tillers and ears, portion above the sieves, germination energy.	spray	BBCH 21-49 (spring)	1	-	0.2 0.2	Na 5NG: 0.6 Na oNP: 1.2 Na pNP: 1.8	200- 300	28	Extrapolation from winter wheat.	A	A	A	A	A	A	n.r.

3	Poland	Fodder beet, red beet, swede, turnip.	F	Plant growth regulator, effect on higher yield.	spray	BBCH 12-49 (spring-summer)	2	7	0.2 <del>0.6</del> 0.4	a) Na 5NG: 0.6 Na oNP: 1.2 Na pNP: 1.8 b) Na 5NG: <del>1.8</del> 1.2 Na oNP: <del>3.6</del> 2.4 Na pNP: <del>5.4</del> 3.6	200-500	15	Extrapolation from sugar beet	A	A	A	A	A	A	A	n.r.
4	Poland	Garden radish	F	Plant growth regulator, number of pods per plant, number of seeds per plant, higher lignification of pods	Spray	BBCH 29-69 (spring)	2	7	0.2	0.6 1.2 1.8	200-500	28	Extrapolation from main crops not possible, the ground water exposure assessment performed with consideration of cabbage/leafy vegetables as a surrogate crop.	A	A	A	A	A	A	A	n.r.
5	Poland	Sunflower	F	Plant growth regulator, number of pods per plant, number of seeds per plant, higher lignification of pods	Spray	BBCH 29-69 (spring)	2	7	0.2	0.6 1.2 1.8	200-500	28	Extrapolation from main crops not possible, the ground water exposure assessment performed with consideration of maize as a surrogate crop.	A	A	A	A	A	A		n.r.

<b>Remarks table heading:</b>	(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.
<b>Remarks columns:</b>	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 <sup>3</sup> 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 Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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
			15	Overall conclusions - explanation for the column 15 is below *

\* Explanation for column 15 “Overall conclusions”

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant