REGISTRATION REPORT

Part A

Risk Management

Product code: ATONIK 123, ARY-0469-01

Product name: ATONIK

Active substances:

sodium 5-nitroguaiacolate, 1 g/L

sodium *o*-nitrophenolate, 2 g/L

sodium *p*-nitrophenolate, 3 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: **Asahi Chemical Europe s.r.o.**

Date: **18/06/2021**

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PART A – Risk Management

The company Asahi Chemical Europe s.r.o. has requested marketing authorisation in France for the product ATONIK (product codes: ATONIK 123, ARY-0469-01), containing 1 g/L sodium 5-nitroguaiacolate, 2 g/L sodium *o*-nitrophenolate and 3 g/L sodium *p*-nitrophenolate, for use as a plant growth regulator, for professional use.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report (RR), Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to ATONIK (ATONIK 123, ARY-0469-01) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of ATONIK (ATONIK 123, ARY-0469-01) have been made using endpoints agreed in the EU peer review) of sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate.

This document describes the specific conditions of use and labelling required for France for the registration of ATONIK (ATONIK 123, ARY-0469-01).

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

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of Asahi Chemical Europe s.r.o.'s application to market ATONIK (ATONIK 123, ARY-0469-01) in France as a plant growth regulator (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Sodium 5-nitroguaiacolate (CAS No 67233-85-6)

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows: PART A Only use as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account.
An EFSA conclusion is available (EFSA Journal 2008 191, 1-130), 1 April 2009. A Review Report is available (SANCO/210/08 rev 2, 2 December 2008).

Sodium* ortho-*nitrophenolate (CAS No 824-39-5)

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows: PART A Only use as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured, which 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. The Member States concerned shall request the submission of further studies to address the risk to groundwater. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2011.
An EFSA conclusion is available (EFSA Journal 2008 191, 1-130), 1 April 2009. A Review Report is available (SANCO/210/08 rev 2, 2 December 2008).

Sodium* para-*nitrophenolate (CAS No 824-78-2)

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows: PART A Only use as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured, which 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. The Member States concerned shall request the submission of further studies to address the risk to groundwater. They

shall ensure that the notifiers provide such studies to the Commission by 31 October 2011.
An EFSA conclusion is available (EFSA Journal 2008 191, 1-130) on the 1 April 2009. A Review Report is available (SANCO/210/08 rev 2, 2 December 2008).

1.3 Regulatory approach

The present application (2015-0435) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4 May 2017[2] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, drift buffer zones may be reduced under some circumstances as explained in Appendix 3 of the above-mentioned French Order.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[3], implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[5] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] is to supply "minor" crops with registered plant protection products.

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1 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

2 Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

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

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

5 http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ATONIK (ATONIK 123, ARY-0469-01), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not necessary: the applicant is the owner of the active substance and ATONIK (ATONIK 123, ARY-0469-01) data.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	ATONIK (ATONIK 123, ARY-0469-01).
Authorisation number	2210262
Function	Plant growth regulator.
Applicant	Asahi Chemical Europe s.r.o.
Composition	1 g/L sodium 5-nitroguaiacolate, 2 g/L sodium *o*-nitrophenolate, 3 g/L sodium *p*-nitrophenolate.
Formulation type (code)	Soluble concentrate (SL).
Packaging	HDPE/EVOH (0.5 L), HDPE (1 L), HDPE (5 L, 10 L, 20 L).

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	Not classified for human health.	
Environmental hazards	Not classified for the environment.	
Hazard pictograms	-	
Signal word	-	
Hazard statements	-	
Precautionary statements –	***For the P phrases, refer to the extant legislation.***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	

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

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

The authorisation of the preparation is linked for professional uses only to the following conditions:

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.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres[7] to surface water bodies

[7] The legal basis for this is **Titre III Article 12** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

SPe 8	To protect bees and other pollinating insects, do not use in presence of bees and other pollinating insects, do not apply to crop plants when in flower, do not apply when flowering weeds are present.re present.

2.2.3 Other phrases linked to the preparation

PPE : refer to the Decision in Appendix 1 for the details The applicant is required to comply with the current applicable standard for clothing-type PPE (NF EN ISO 27065/A1).		
Re-entry period[8]: six hours.		
Pre-harvest interval[9]:	Sugar and fodder beet	15 days (BBCH 12-19)
	Oilseed rape	30 days (BBCH 29-65)
	Apple trees	Seven days (BBCH 55-72)
Other mitigation measures: The product must be protected from frost.		
The label may include the following recommendations: The product efficacy level being variable and partial, specify the optimal conditions of use The label must reflect the conditions of authorisation.		

[8] The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[9] According to the French Order of 4 May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. , date: 2020-09

PPP (product name/code)	ATONIK/ARY-0469-01	Formulation type**:**	SL
Active substance 1	Sodium 5-nitroguaiacolate (Na 5-NG)	Conc. of a.s. 1:	1 g/L
Active substance 2	Sodium *ortho*-nitrophenolate (Na *o*-NP)	Conc. of a.s. 2:	2 g/L
Active substance	Sodium *para*-nitrophenolate (Na *p*-NP)	Conc. of a.s. 3:	3 g/L
Applicant:	Asahi Chemical Europe s.r.o.	Professional use	☒
Zone(s):	Southern EU	Non-professional use	☐
Verified by MS	yes		

1	2	3	4	5	6	7	8	10	11	12	13	14	
Use No.	Member state(s)	Crop and/ or situation (crop destination/ purpose of crop)	F G or 1	Pest or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	**zRMS conclusion**
					Method/ kind	Timing / growth stage of crop & season	Max. number (min interval between applications) a) per use b) per crop/season	L product/ha a) max. per appl. b) max. total per crop/season	g a.s./ha a) max. per appl. b) max. total per crop/season	Water L/ha min/max			
1	FR	Sugar and fodder beet	F	Plant growth regulation, better crop development, sugar yield increase	Spraying	BBCH 12-19	a, b) 2 (7 days)	a) 0.6 b) 1.2	a) Na 5-NG: 0.6 g Na o-NP: 1.2 g Na p-NP: 1.8 g b) Na 5-NG: 1.2 g Na o-NP: 2.4 g Na p-NP: 3.6 g	200 - 500	15	The timing of application should be selected by the farmer with two applications maximum per crop. In general, the recommended application timings are the following, corresponding to the timing of herbicide applications: BBCH 12-13 BBCH 14-16 BBCH 17-19	**Acceptable** Efficacy level is considered partial and variable. Efficacy is shown on yield and sugar content.

1	2	3	4	5	6	7	8	10	11	12	13	14	
Use No.	Member state(s)	Crop and/ or situation (crop destination/ purpose of crop)	F G or I	Pest or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	**zRMS conclusion**
					Method/ kind	Timing / growth stage of crop & season	Max. number (min interval between applications) a) per use b) per crop/season	L product/ha a) max. per appl. b) max. total per crop/season	g a.s./ha a) max. per appl. b) max. total per crop/season	Water L/ha min/max			
2	FR	Oilseed rape	F	Plant growth regulation, higher number of seeds and higher oil content, yield	Spraying	T1: BBCH 29-31 T2: BBCH 51-55	a, b) 2 (14 days)	a) 0.6 b) 1.2	a) Na 5-NG: 0.6 g Na o-NP: 1.2 g Na p-NP: 1.8 g b) Na 5-NG: 1.2 g Na o-NP: 2.4 g Na p-NP: 3.6 g	200 -500	30	The timing of application should be selected by the farmer with a maximum of two applications per crop.	**Acceptable** Efficacy level is considered partial and variable. Efficacy is shown on yield and oil content.
3	FR	Apple trees	F	Plant growth regulation, fruit set, fruit size and weight, yield	Spraying	BBCH 55-72	a, b) 3 (7 days)	a) 0.6 b) 1.8	a) Na 5-NG: 0.6 g Na o-NP: 1.2 g Na p-NP: 1.8 g b) Na 5NG: 1.8 g Na o-NP: 3.6 g Na p-NP: 5.4 g	500	7	Dose rate expression in BE: 0.6 L/ha = 0.4 L/ha Leaf Wall Area (LWA). The timing of application should be selected by the farmer with three applications maximum per year. In general, the recommended application timings are the following: BBCH 55-72	**Acceptable** Efficacy level is considered partial and variable. Efficacy is shown on yield, fruit formation, diameter and mass of fruits.

* As some standards may have undergone changes, it is the responsibility of the applicant to update the references

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

ATONIK (ATONIK 123, ARY-0469-01) is a soluble concentrate (SL). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a homogenous brown-yellow liquid, with faint unspecific chemical odour. It is not explosive, has no oxidising properties and is not auto-flammable. In aqueous solution (1 %), it has a pH value of 8.36 at 21°C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0°C and 14 days at 54°C, neither the active substances' content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE/EVOH. As the stability testing was performed on HDPE/EVOH packaging, the HDPE packaging may be considered acceptable.

The technical characteristics are acceptable for a SL formulation.

The product is not classified for the physico-chemical aspect but must be protected from frost.

3.1.2 Methods of analysis

Analytical methodology for the determination of the active substances in the formulation is available and validated.

As the active substance sodium 5-guaiacolate does not contain relevant impurities, no analytical method is required.

There are relevant impurities specified for sodium *o*-nitrophenolate and sodium *p*-nitrophenolate in technical material but these are unlikely to be formed during storage of the formulation. Therefore, an analytical method for the determination of relevant impurities in the formulation is not necessary.

Analytical methods are available in the Draft Assessment Report and in this dossier. These methods are validated for the determination of residues of sodium 5-guaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate in plants (dry crops, high–acid-content, high–water-content, high-oil-content and difficult matrices), soil, water (surface and drinking) and air.

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

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active substance: sodium para-nitrophenolate</td></tr>
<tr><td>ADI</td><td colspan="2">0.003 mg/kg bw/d</td><td rowspan="4">EU (2009)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.045 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="2">0.007 mg/kg bw/d</td></tr>
<tr><td>AAOEL</td><td colspan="2">-</td></tr>
<tr><td rowspan="2">Dermal absorption</td><td colspan="3">Based on an in vitro human study performed on formulation:</td></tr>
<tr><td></td><td>Concentrate (tested)
3 g/L</td><td>Diluted formulation (tested)
0.0015 g/L</td></tr>
<tr><td></td><td>In vitro (human) %</td><td>6</td><td>26</td></tr>
</table>

		Concentrate (used in formulation) 3 g/L	Spray dilution (used in formulation) 0.0036 g/L*
	Dermal absorption endpoints %	**6**	**26**
Oral absorption (%)	**100**		Efsa (2008)

* Rate of application: 0.6 L/ha with a maximum water volume of 500 L/ha corresponds to 0.0036 g active substance/L.

Active substance: **sodium *ortho*-nitrophenolate**			
ADI	0.003 mg/kg bw/d		EU (2009)
ARfD	0.045 mg/kg bw		
AOEL	0.007 mg/kg bw/d		
AAOEL	-		
Dermal absorption	Default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 2 g/L	Spray dilution (used in formulation) 0.0024 g/L*
	Dermal absorption endpoints %	**75**	**75**
Oral absorption (%)	**100**		Efsa (2008)

* Rate of application: 0.6 L/ha with a maximum water volume of 500 L/ha corresponds to 0.0024 g active substance/L.

Active substance: **sodium 5-nitroguaiacolate**			
ADI	0.003 mg/kg bw/d		EU (2009)
ARfD	0.045 mg/kg bw		
AOEL	0.007 mg/kg bw/d		
AAOEL	-		
Dermal absorption	Default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 1 g/L	Spray dilution (used in formulation) 0.0012 g/L*
	Dermal absorption endpoints %	**75**	**75**
Oral absorption (%)	**100**		Efsa (2008)

* Rate of application: 0.6 L/ha with a maximum water volume of 500 L/ha corresponds to 0.0012 g active substance/L.

3.1.3.1 Acute Toxicity

ATONIK (ATONIK 123, ARY-0469-01) (ARY-0469-01), containing 3 g/L sodium *para*-nitrophenolate, 2 g/L sodium *ortho*-nitrophenolate and 1 g/L sodium 5-nitroguaiacolate, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[10]	Equipment *Application method*	Maximum application rate kg as /ha	Minimum volume water (L/ha)
Oilseeds	F	Vehicle-mounted *Downward spraying*	0.6 L (0.6 g Na 5-NG/ha + 1.2 g Na *o*-NP/ha + 1.8 g Na *p*-NP)	200
Root and tuber vegetables	F	Vehicle-mounted *Downward spraying*		200
Pome fruit	F	Vehicle-mounted *Upward spraying*		500

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model[11]:

Crop	Equipment	PPE and/or working coverall	% AOEL Na 5-NG	% AOEL Na *o*-NP	% AOEL Na *p*-NP
Oilseeds Root and tuber vegetables	Vehicle-mounted *Downward spraying*	Working coverall and gloves during mixing/loading and application	2.61	4.04	1.46
Pome fruit	Vehicle-mounted *Upward spraying*	Working coverall and gloves during mixing/loading and application	2.76	4.83	3.35
		Working coverall during mixing/loading and application	24.22	42.13	10.86

According to the model calculations, it may be concluded that the risk for the operator using ARY-0469-01 is acceptable with a working coverall and gloves during mixing/loading and application for oilseeds, root and tuber vegetables and pome fruit.
For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.1.3.3 Bystander Exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e., no acute operator or bystander exposure assessments can be performed with the AOE model where no AAOEL has been set.

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer*

[10] Open field or glasshouse
[11] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure."

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation or searching, reaching and picking activities. Therefore, estimation of worker exposure was calculated according to the AOE model.

Exposure is estimated to be:

Application scenario (with PPE)	**Active substances**	**% AOEL**
Sugar beet (work wear)	Na 5-NG	1.67
	Na *o*-NP	3.33
	Na *p*-NP	1.73
Oilseeds (work wear)	Na 5-NG	1.55
	Na *o*-NP	3.10
	Na *p*-NP	1.61
Pome fruit (work wear and gloves)	Na 5-NG	14.89
	Na *o*-NP	29.79
	Na *p*-NP	15.49
Pome fruit (work wear)	Na 5-NG	29.79
	Na *o*-NP	59.58
	Na *p*-NP	30.98

It may be concluded that there is no unacceptable risk anticipated for the worker.

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

3.1.3.5 Resident Exposure

Residential exposure was assessed according to the EFSA model. An acceptable risk was determined for residents (adult and/or child) without drift reduction technology and mitigation measures (**buffer zone of 10 metres for pome fruit application/33 metres for oilseed and root and tuber vegetable applications**):

Crop	**Model (AOEM) - All pathways (mean)**	**% AOEL Na 5-NG**	**% AOEL Na *o*-NP**	**% AOEL Na *p*-NP**
Sugar beet	Resident (children)	17.50	19.71	17.61
	Resident (adults)	4.33	5.38	4.37
Oilseed rape	Resident (children)	17.38	19.47	17.48
	Resident (adults)	4.27	5.25	4.31
Pome fruit	Resident (children)	18.97	22.65	19.16
	Resident (adults)	5.29	7.30	5.37

3.1.3.7 Combined exposure

Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches employed up to now make use of the Hazard Index (HI) concept. It is therefore suggested to use this as a first-tier assessment.

A cumulative assessment for operators, bystanders/residents and workers has been performed. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQs) for each active substance and the HI (sum of hazard quotients) are:

Crop: Sugar and fodder beet (root and tuber vegetables)

Population groups and PPE		**Active substance**	**Estimated exposure / AOEL (HQ)**
Operators	Working coverall and gloves during mixing/loading and application	**Na 5-NG**	0.0261
		Na *o*-NP	0.0404
		Na *p*-NP	0.0146
	Cumulative risk operators (HI)		**0.0811**
Bystanders/ Residents	Children - All pathways (mean)	**Na 5-NG**	0.1750
		Na *o*-NP	0.1971
		Na *p*-NP	0.1761
	Cumulative risk bystanders/residents (child) (HI)		**0.5482**
	Adults - All pathways (mean)	**Na 5-NG**	0.0433
		Na *o*-NP	0.0538
		Na *p*-NP	0.0437
	Cumulative risk bystanders/residents (adult) (HI)		**0.1408**
Worker	Working coverall	**Na 5-NG**	0.0167
		Na *o*-NP	0.0333
		Na *p*-NP	0.0173
	Cumulative risk workers (HI)		**0.0673**

Crop: Oilseeds

Population groups and PPE		**Active substance**	**Estimated exposure / AOEL (HQ)**
Operators	Working coverall and gloves during mixing/loading and application	**Na 5-NG**	0.0261
		Na *o*-NP	0.0404
		Na *p*-NP	0.0146
	Cumulative risk operators (HI)		**0.0811**
Bystanders/ Residents	Children - All pathways (mean)	**Na 5-NG**	0.1738
		Na *o*-NP	0.1947
		Na *p*-NP	0.1748
	Cumulative risk bystanders/residents (child) (HI)		**0.5433**
	Adults - All pathways (mean)	**Na 5-NG**	0.0427
		Na *o*-NP	0.0525
		Na *p*-NP	0.0431
	Cumulative risk bystanders/residents (adult) (HI)		**0.1383**
Worker	Working coverall	**Na 5-NG**	0.0155
		Na *o*-NP	0.0310
		Na *p*-NP	0.0161
	Cumulative risk workers (HI)		**0.0626**

Crop: Pome fruits

Population groups and PPE		Active substance	Estimated exposure / AOEL (HQ)
Operators	Working coverall and gloves during mixing/loading and application	**Na 5-NG**	0.0276
		Na *o*-NP	0.0483
		Na *p*-NP	0.0335
	Cumulative risk operators (HI)		**0.1094**
Bystanders/ Residents	Children - All pathways (mean)	**Na 5-NG**	0.1897
		Na *o*-NP	0.2265
		Na *p*-NP	0.1916
	Cumulative risk bystanders/residents (child) (HI)		**0.6078**
	Adults - All pathways (mean)	**Na 5-NG**	0.0529
		Na *o*-NP	0.0730
		Na *p*-NP	0.0537
	Cumulative risk bystanders/residents (adult) (HI)		**0.1796**
Worker	Working coverall and gloves	**Na 5-NG**	0.1489
		Na *o*-NP	0.2979
		Na *p*-NP	0.1549
	Cumulative risk workers (HI)		**0.6017**

The Hazard Index is < 1. Thus combined exposure to all active substances in ARY-0469-01 is not expected to present an unacceptable risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Overall conclusion

The data available are considered sufficient for risk assessment. No exceedance of the current MRLs for the active substances sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate as laid down in Reg. (EU) 396/2005 is expected.

The chronic and short-term intakes of the three active substances' residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France agrees with the authorisation of the intended uses.

According to the available data, no specific mitigation measures should apply.

3.1.4.2 Summary of the evaluation

Summary for the three active substances: sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate:

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 2016/1785	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Sugar beet	Yes	Yes (3 N + 3 S)	Yes	Yes	Yes	No	No	No-residue situation

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 2016/1785	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
2-3	Oilseed rape	Yes	Yes (3 N + 3 S)	Yes	Yes	Yes		No	No-residue situation
4	Apple	Yes	Yes (3 N + 3 S)	Yes	Yes	Yes		No	No-residue situation

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

Considering that a no-residue situation is demonstrated, the effects of processing on the nature and magnitude of "sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate, sodium *p*-nitrophenolate" residues is not required.

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

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

3.1.5 Summary for ATONIK (ARY-0469-01)

Information on ARY-0469-01 (KCA 6.8)

Crop	PHI for ATONIK (ARY-0469-01) requested by applicant	PHI/withholding period* sufficiently supported for sodium nitro compounds: sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate, sodium *p*-nitrophenolate	PHI for ATONIK (ARY-0469-01) proposed by zRMS	zRMS Comments (if different PHI proposed)
Sugar beet	15 days (BBCH 12-19)	Yes	15 days (BBCH 12-19)	
Oilseed rape	30 days (BBCH 29-65)	Yes	30 days (BBCH 29-65)	
Apple	7 days (BBCH 55-72)	Yes	7 days (BBCH 55-72)	

3.1.6 Environmental fate and behaviour

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

The PEC values of the active substances and their metabolite in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECsoil and PECsw values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment.

PECgw values for the active substances and their metabolite do not occur at levels exceeding those mentioned in Regulation (EC) no 1107/2009 and guidance document SANCO 221/2000[12]. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.7 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substances were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals and other non-target arthropods, earthworms, other soil macro- and micro-organisms and terrestrial plants are acceptable for the intended uses.

For aquatic organisms, mitigation measures are required (see 2.2.2).

According to new requirements of Reg. (EU) No. 284/2013, **information on the chronic effects on adult bees and on development of bees should have been submitted,** as exposure of bees to the product cannot be excluded. In the absence of these data, risk mitigation measures are proposed (SPe8).

3.1.8 Efficacy

Considering the data submitted:

- The efficacy level of ATONIK (ATONIK 123, ARY-0469-01) observed on different parameters related to the quality of the crops or fruit is considered partial and variable. However, it is considered acceptable for this kind of product.
- The phytotoxicity level of ATONIK (ATONIK 123, ARY-0469-01) is considered acceptable for all the requested uses.
- The risks of negative impact on yield, quality, transformation and propagating purposes, succeeding and adjacent crops are considered acceptable.

[12] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation **can be granted** as proposed in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Label amendments

The draft label proposed by the applicant in Appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

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

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

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***ATONIK***

de la société *ASAHI CHEMICAL EUROPE S.R.O.*

enregistrée sous le *n°2015-0435*

Vu les conclusions de l'évaluation de l'Anses du 15 décembre 2020,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et son annexe.

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

Avertissement :

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

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Informations générales sur le produit	
Nom du produit	ATONIK
Type de produit	Produit de référence
Titulaire	ASAHI CHEMICAL EUROPE S.R.O. Nam. 14 rijna 1307/2 150 00 Praha 5 République tchèque
Formulation	Concentré soluble (SL)
Contenant	1 g/L - 5-nitroguaiacolate de sodium 2 g/L - ortho-nitrophénolate de sodium 3 g/L - para-nitrophénolate de sodium
Numéro d'intrant	9861-2015.01
Numéro d'AMM	2210262
Fonction	Régulateur de croissance
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 octobre 2023.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

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

A Maisons-Alfort, le 18 JUIN 2021

Charlotte GRASTILLEUR
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Bouteilles en polyéthylène haute densité / éthylène alcool vinylique	500 mL
Bouteilles en polyéthylène haute densité	500 mL ; 1 L
Bidons en polyéthylène haute densité	5 L ; 10 L ; 20 L
Cuves en polyéthylène haute densité	200 L

Classification du produit
La classification retenue est la suivante : Sans classement.
Pour les phrases P se référer à la règlementation en vigueur. **Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.**

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15053802 Betterave industrielle et fourragère* Trt Part.Aer.*Act. Qual. Récolte	**0,6 L/ha**	**2/an**	entre les stades BBCH 12 et BBCH 19	15	5	-	-	-
	Effets observés sur le rendement et la teneur en sucre. Intervalle minimum entre les applications : 7 jours							
15203802 Crucifères oléagineuses* Trt Part.Aer.*Act. Qual. Récolte	**0,6 L/ha**	**1/an**	entre les stades BBCH 29 et BBCH 31	F (BBCH 31)	5	-	-	-
	Effets observés sur le nombre de graines par plante et la teneur en huile. 2 applications maximum par culture et par parcelle avec un intervalle minimum entre les applications de 14 jours.							
	0,6 L/ha	**1/an**	entre les stades BBCH 51 et BBCH 55	F (BBCH 55)	5	-	-	-
	Effets observés sur le nombre de graines par plante et la teneur en huile. 2 applications maximum par culture et par parcelle avec un intervalle minimum entre les applications de 14 jours. L'usage est refusé pour une application entre les stades BBCH 61 et BBCH 65 en raison d'un risque pour les abeilles et autres pollinisateurs.							

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Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
12603813 Fruits à pépins* Trt Part.Aer.*Act. Qual. Fruits	**0,6 L/ha**	**3/an**	entre les stades BBCH 55 et BBCH 72	F (BBCH 72)	5	-	-	-
	Effets observés sur le rendement, la fructification, le diamètre des fruits et le poids des fruits. 3 applications maximum par an et par culture. Intervalle minimum entre les applications : 7 jours							

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
Betterave industrielle et fourragère* Phytostimulant	0,6 L/ha	2/an	15
	Motivation du refus : L'usage est refusé car transformé en l'usage 15053802 mieux adapté à la revendication.		
Crucifères oléagineuses*Phytostimulant	0,6 L/ha	2/an	30
	Motivation du refus : L'usage est refusé car transformé en l'usage 15203802 mieux adapté à la revendication.		
Pommier*Phytostimulant	0,6 L/ha	3/an	7
	Motivation du refus : L'usage est refusé car transformé en l'usage 12603813 mieux adapté à la revendication.		

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Stocker le produit à une température supérieure à 0°C.

Protection de l'opérateur et du travailleur

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

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

Pour l'opérateur, porter

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

- **pendant le mélange/chargement**

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

- **pendant l'application**

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- Combinaison de protection de catégorie III type 4 avec capuche ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

- **pendant le nettoyage du matériel de pulvérisation**

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

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

- **pendant le mélange/chargement**

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

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- **pendant l'application**

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

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

- **pendant le nettoyage du matériel de pulvérisation**

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

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 et, en cas de contact avec la culture traitée, des gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).

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

- 6 heures.

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

Pour les usages sur "Pommier", respecter une distance d'au moins 10 mètres entre le dernier rang traité et :

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

Pour les usages sur "Crucifères oléagineuses" et " Betterave industrielle et fourragère", respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et :

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

Respect des limites maximales de résidus (LMR)

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

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

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

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Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.
- SPe 8 : Pour protéger les abeilles et autres insectes pollinisateurs, ne pas utiliser en présence d'abeilles et autres pollinisateurs, ne pas appliquer durant la période de floraison, ne pas appliquer lorsque des adventices en fleur sont présentes.

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- L'efficacité du produit étant variable et partielle, préciser les conditions optimales d'utilisation.

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

ATONIK

Homologué sous le numéro :	XXX	
Composition :	sodium 5-nitroguaiacolate sodium o-nitrophenolate sodium p-nitrophenolate	1 g/l 2 g/l 3 g/l
Type de formulation :	Concentré soluble (SL)	

Avant d'utiliser ce produit, lire attentivement l'étiquette.
L'utilisation de ce produit est réservée aux professionnels.

Quantité nette :	0,5, 1, 5, 10, 20, 200 L
Fabriqué par :	Asahi Chemical Mfg. Co. Ltd., 500 Oaza Takayasu, Ikaruga-cho, Ikoma-gun, Nara Prefecture 636-0104, Japan
Nom et adresse du détenteur de l'autorisation :	Asahi Chemical Europe s.r.o. Lužná 591/4, 160 00 Praha 6 - Vokovice, Czech Republic
Distribué en France par :	*à préciser*
Usage, type de produit :	Régulateur de croissance des plantes
Date de production (j-m-a): Numéro de lot : Durée de vie du produit :	Voir sur le bidon Dans son bidon original entreposé dans un endroit frais et sec : 2 ans.

Mode d'action :

ATONIK contient des substances nitro-phénoliques jouant un rôle de régulation des processus naturels du métabolisme des plantes.
ATONIK a une action sur de nombreuses enzymes des plantes ce qui permet :
- un transport intracellulaire amélioré et plus rapide,
- une optimisation de l'utilisation de l'eau par la plante, une transpiration plus intense et une absorption de l'eau par les racines plus importante
-une amélioration du processus de photosynthèse grâce à une assimilation par les feuilles plus importante, et une augmentation de la quantité de chlorophylle,
- une augmentation des hormones, protéines, hydrates de carbone, minéraux et lignine de la plante
- une meilleure lignification des parois cellulaires permettant d'augmenter les mécanismes de résistances des tissus (par exemple contre la cécidomyie des siliques des crucifères)
- un meilleur développement et une croissance augmentée du système racinaire permettant un transport optimisé des nutriments assimilés,
- une bonne qualité de pollinisation grâce au meilleur développement du tube pollinique et une haute activité des cellules du stigmate,
- un amélioration du nombre de graines, de la fructification, de la taille et de la régularité des fruits
- une tolérance accrue des plantes vis-à-vis des conditions défavorables à leur croissance : sécheresse, salinité, froid, chaleur, ou dommages causés par des produits phytosanitaires – régénérescence plus rapide des tissus.
En conclusion, grâce à ses effets sur les processus physiologiques de la plante, ATONIK améliore les rendements de manière quantitative et qualitative.

Utilisation et doses d'application :

Cultures	Cible	Dose d'application a) dose max. par appl. b) dose max. totale par culture/saison	Nombre d'application	Stades de croissance	Intervalle de temps entre applications (min, jours)	Volume (l/ha)	DAR (jours)
Betterave	Régulation de la croissance des plantes, régénération plus rapide après un stress dû aux herbicides et meilleur développement des cultures, augmentation des rendements en sucre	a) 0.6 L/ha b) 1,2 L/ha	max. 2 *	T1: 2-3 feuilles (BBCH 12-13) T2: 4-6 feuilles (BBCH 14-16) T3: 7-9 feuilles (BBCH 17-19)	7	200-500	15
Colza	Régulation de la croissance des plantes, régénération plus rapide après l'hiver, nombre supérieur de graines et rendement supérieur en huile, rendement	a) 0.6 L/ha b) 1.2 L/ha	max. 2 *	T1: Sortie d'hiver (BBCH 29-31) T2: Durant les premiers stades de développement des bourgeons floraux (BBCH 51-55) T3: Durant les premiers stades floraux (BBCH 61-65)	14	200-500	30
Pomme	Régulation de la croissance des plantes, mise à fruits, dimension et poids des fruits, rendement.	a) 0.6 L/ha b) 1,8 L/ha	max. 3 **	T1: Durant les premiers stades de développement des bourgeons floraux (BBCH 55-57) T2: Début de floraison (BBCH 61-63) T3: Pleine floraison (BBCH 65-67) T4: Pendant les premiers stades de développement des fruits (BBCH 69-72)	7	500	7

* The timing of application should be selected by the farmer with maximum of 2 applications per crop/season.
** The timing of application should be selected by the farmer with maximum of 3 applications per crop/season.

RECOMMENDATIONS D'APPLICATION

Appliquer avec un pulvérisateur foliaire à la dose recommandée, de manière uniforme (en accord avec les informations dans le tableau ci-dessus). Pour mélanger, remplir la moitié du réservoir du pulvérisateur avec de l'eau, ajouter le produit et remplir en agitant l'eau.

Ne pas appliquer lorsque de la pluie est prévue.

COMPATIBILITES

ATONIK est compatible avec la plupart des fertilisants, des régulateurs de croissance, des insecticides, des fongicides et des herbicides. Cependant, différents facteurs peuvent affecter cette compatibilité entre produits, il est donc recommandé de faire un essai de mélange en utilisant l'eau de pulvérisation prévue.

La pratique de mélanges peut engendrer des risques pour la santé et l'environnement. Respecter la réglementation en vigueur et les recommandations des guides officiels de bonnes pratiques.

MANIPULATION

Le port de chaussures ou de bottes à semelles antidérapantes est recommandé
Ne pas manger, boire ou fumer. Après l'application, se laver avec de l'eau et du savon et prendre une douche.

MESURES DE SECURITE

Etiquetage relatif au Réglement (EC) 1272/2008 "CLP"

Pictogramme(s) de danger	Aucun
Mention(s) d'avertissement	Aucun

Mention(s) de danger

EUH401	Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Mention(s) de précaution

P102	Tenir hors de portée des enfants
P270	Ne pas manger, boire ou fumer en manipulant le produit
P261	Éviter de respirer les aérosols
P301+ 312	EN CAS D'INGESTION: Appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise
P271	Utiliser seulement en plein air ou dans un endroit bien ventilé
Phrase (s) SP	SP1: Ne pas polluer l'eau avec le produit ou son emballage. (Ne pas nettoyer le matériel d'application près des eaux de surface. / Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.)

Conditions de stockage

Conserver ATONIK dans son emballage d'origine, fermé, dans un local fermé, sec et aéré. Conserver entre 0°C et 35 °C. Conserver à l'abri du gel, de l'humidité, des sources de chaleur et du soleil direct.

Elimination des emballages :

Rincer correctement chaque emballage vide en utilisant un dispositif de rinçage intégré ou manuellement en rinçant trois fois, puis verser l'eau dans le réservoir du pulvérisateur.
Il est obligatoire d'envoyer les bidons vides à une entreprise de recyclage responsable de l'élimination des emballages vides (filières de traitement des déchets EcoDDS).

Avertissement:
Les recommandations et les indications d'utilisation de ce produit sont les résultats de nombreuses études et essais mis en place.
Cependant, lors de l'utilisation du produit, de nombreux facteurs peuvent intervenir (comme la préparation des mélanges, l'application, la météo, etc) qui ne sont pas sous notre contrôle. La société garantit la composition, la formulation et le contenu.
L'utilisateur sera responsable des dommages (manque d'efficacité, la toxicité en général, les résidus, etc) résultant d'une non-conformité avec une partie ou le total des instructions données sur l'étiquette.

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Appendix 3 – Letter(s) of Access

Not applicable.