

# REGISTRATION REPORT

## Part A

### Risk Management

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

NATIONAL ASSESSMENT POLAND

(authorization)

Applicant: Asahi Chemical Europe s.r.o

Submission date: June 2022

MS Finalisation date: April 2023 (initial National Assessment)

June 2023 (final National Assessment)

## Version history

| When       | What  |
|------------|---|
| June 2022  | Initial version of dRR for submission to zRMS   |
| April 2023 | Initial zRMS assessment<br><br>In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and in the product label (Appendix 2) and Lists of data considered for national authorization (Appendix 4) are highlighted in grey, while not agreed use pattern <del>is struck through and shaded</del> . |
| June 2023  | Final report (National Assessment updated following the commenting period)<br><br>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant <del>is struck through and shaded</del> .   |

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# PART A

## RISK MANAGEMENT

### 1 Details of the application

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 (3g/L), Sodium *o*-nitrophenolate (6g/L), Sodium *p*-nitrophenolate (9g/L).

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

#### 1.1 Application background

The formulation ARY-0469-04 is registered in Europe Southern zone 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. ASAHI MAX containing 3g/L sodium 5-nitroguaiacolate (Na 5-NG), 6 g/L sodium *ortho*-nitrophenolate (Na *o*-NP) and 9 g/L sodium *para*-nitrophenolate (Na *p*-NP) has been previously evaluated at EU level by Greece according to Uniform Principles (for more details, please refer to Confidential Part C).

This document describes the acceptable use conditions required for the re-registration/registration of ASAHI MAX containing the active substances sodium 5-nitroguaiacolate (Na 5-NG), sodium *o*-nitrophenolate (Na *o*NP) and sodium *p*-nitrophenolate (Na *p*NP) in Poland. This evaluation is required subsequent to the inclusion of these active substances on Annex 1.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national re-registration/registration by the EU review. It also includes assessment of data and information relating to ASAHI MAX where that data has not been considered in the EU review. Otherwise, assessments for the safe use of ASAHI MAX have been made using endpoints agreed in the EU review of sodium 5-nitroguaiacolate (Na 5-NG), sodium *o*-nitrophenolate (Na *o*NP) and sodium *p*-nitrophenolate (Na *p*NP).

#### 1.2 Letters of Access

Not necessary: the applicant is the owner of data which support the (renewal of) approval of the active substance.

#### 1.3 Justification for submission of tests and studies

According to the applicant: *“The test and study reports submitted are necessary to support the authorization of the product in accordance with data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.”*

#### 1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

## 2 Details of the authorization decision

### 2.1 Product identity

|   |  |
|---|--|
| Product code  | ARY-0469-04  |
| Product name in MS                                  | ASAHI MAX  |
| Authorization number                                | -  |
| Function  | Plant growth regulator   |
| Applicant   | Asahi Chemical Europe s.r.o.   |
| Active substance(s)<br>(incl. content)              | Sodium 5-nitroguaiacolate 3,0 g/L<br>Sodium <i>o</i> -nitrophenolate 6,0 g/L<br>Sodium <i>p</i> -nitrophenolate 9,0 g/L  |
| Formulation type                                    | Soluble concentrate (SL)   |
| Packaging   | HDPE bottles of 50 ml (cylindrical / approx. 44 mm diameter x 72 mm), 200 ml (type A: cylindrical / approx. 51 mm diameter x 146 mm; type B: cylindrical / approx. 54 mm diameter x 138 mm), 500 mL (type A: cylindrical / approx. 76,2 mm diameter x 168,5 mm; type B: cylindrical / approx. 69 mm diameter x 187 mm) and 1 L (cylindrical / approx. 89 mm diameter x 238 mm)<br>HDPE canister of 5 (round square / approx. 142 mm depth x 193 mm width x 305 mm height) and 10 L (round square / approx. 179 mm depth x 240 mm width x 375 mm height)<br>HDPE canister of 20 L (round square / approx. 245 mm depth x 293 mm width x 400 mm height)<br>professional user |
| Coformulants of concern for national authorizations | not applicable   |
| Mandatory tank mixtures                             | none   |
| Recommended tank mixtures                           | none   |

### 2.2 Conclusion

The evaluation of the application for Asahi Max resulted in the decision to grant the authorization.

### 2.3 Substances of concern for national monitoring

None.

### 2.4 Classification and labelling

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

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

|                               |                |
|-------------------------------|----------------|
| Hazard class(es), categories: | Not classified |
|-------------------------------|----------------|

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label** is **formatted bold**:

|                      |      |
|----------------------|------|
| Hazard pictograms:   | None |
| Signal word:         | None |
| Hazard statement(s): | None |

|                               |   |
|-------------------------------|---|
| Precautionary statement(s):   | P102 - Keep out of reach of children.<br>P261 - Avoid breathing vapours/spray.<br>P270 - Do not eat, drink or smoke when using this product.<br>P271 - Use only outdoors or in a well-ventilated area.<br>P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.     |
|                               | P501 – Dispose of contents / container to an approved waste disposal plant.   |
| Additional labelling phrases: | EUH401 - To avoid risks to human health and the environment, comply with the instructions for use.<br>SP1 - 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). |

|  |   |
|--|---|
| Special rule for labelling of plant protection product (PPP):    |   |
| EUH401   | To avoid risks to man and the environment, comply with the instructions for use.  |
| SP1  | 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). |
| Further labelling statements under Regulation (EC) No 1272/2008: |   |
| None   |   |

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

|      |   |
|------|---|
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
| None |   |

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

None.

## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

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

|   |      |
|---|------|
| Operator protection:                              |      |
|   |      |
| Worker protection:                                |      |
|   |      |
| Integrated pest management (IPM)/sustainable use: |      |
|   |      |
| Environmental protection                          |      |
|   | none |
| Other specific restrictions                       |      |
|   | none |

The authorization of the PPP is linked to the following conditions (voluntary labelling): None.

## **2.5.2            Specific restrictions linked to the intended uses**

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling): None.



## 2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1.0 , date: 2023-03

PPP (product name/code): Asahi SL / ARY-0469-04 Formulation type: SL  
Active substance 1: Sodium 5-nitroguaiacolate Conc. of as 1: 3 g/L  
Active substance 2: Sodium o-nitrophenolate Conc. of as 2: 6 g/L  
Active substance 3: Sodium p-nitrophenolate Conc. of as 3: 9 g/L  
Safener: no Conc. of safener: -  
Synergist: no Conc. of synergist: -  
Applicant: Asahi Chemical Europe s.r.o. Professional use: ☒  
Zone(s): Central Non professional use: ☐  
Verified by MS: yes  
Field of use: Plant growth regulator

| 1   | 2                      | 3   | 4  | 5   | 6                    | 7  | 8  | 9   | 10   | 11   | 12                                | 13            | 14   | 15*             |                    |            |          |             |               |                                |          |
|---|------------------------|---|--|---|----------------------|--|--|---|--|--|-----------------------------------|---------------|--|-----------------|--------------------|------------|----------|-------------|---------------|--------------------------------|----------|
| Use-<br>No.<br>(e)  | Membe<br>r<br>state(s) | Crop and/<br>or<br>situation<br><br>(crop<br>destination<br>/ purpose<br>of crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<br>or<br>I | Pests or<br>Group of<br>pests<br>controlled<br><br>(additionally:<br>developmental<br>stages of the<br>pest or pest<br>group)     | Application          |  |  |   | Application rate   |  |                                   | PHI<br>(days) | Remarks:<br><br>e.g. g<br>safener/syn<br>ergist per<br>ha<br>(i) | zRMS Conclusion |                    |            |          |             |               |                                |          |
|   |                        |   |  |   | Metho<br>d /<br>Kind | Timing /<br>Growth<br>stage of<br>crop &<br>season | Max.<br>number<br>a) per<br>use<br>b) per<br>crop/<br>season | Min.<br>interval<br>between<br>applications<br>(days) | kg or L<br>product / ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | g or kg as/ha<br><br>a) max. rate per<br>appl.<br>b) max. total rate per<br>crop/season            | Water<br>L/ha<br><br>min /<br>max |               |  | Phys-chem       | Analytical methods | Toxicology | Residues | Groundwater | Ecotoxicology | Relevance of<br>metabolites in | Efficacy |
| Zonal uses (field or outdoor uses, certain types of protected crops)a |                        |   |  |   |                      |  |  |   |  |  |                                   |               |  |                 |                    |            |          |             |               |                                |          |
| 1   | Poland                 | Winter<br>oilseed<br>rape   | F  | Plant growth<br>regulator,<br>number of<br>pods per plant,<br>number of<br>seeds per<br>plant, higher<br>lignification of<br>pods | spray                | BBCH<br>29-69<br>(spring)                          | 2  | 7   | 0.2<br>0.4   | a)<br>Na 5NG: 0.6<br>Na oNP: 1.2<br>Na pNP: 1.8<br>b)<br>Na 5NG: 1.2<br>Na oNP: 2.4<br>Na pNP: 3.6 | 200-500                           | 28            |  | A               | A                  | A          | A        | A           | A             | A                              | A        |
| 2   | Poland                 | Winter<br>wheat   | F  | Plant growth<br>regulator,<br>number of<br>tillers and ears,<br>portion above   | spray                | BBCH<br>21-49<br>(spring)                          | 1  | -   | 0.2<br>0.2   | Na 5NG: 0.6<br>Na oNP: 1.2<br>Na pNP: 1.8  | 200-300                           | 28            |  | A               | A                  | A          | A        | A           | A             | A                              | A        |

|   |        |   |   |   |       |                                      |   |   |                           |   |         |    |  |   |   |   |   |   |   |   |      |
|---|--------|---|---|---|-------|--------------------------------------|---|---|---------------------------|---|---------|----|--|---|---|---|---|---|---|---|------|
|   |        |   |   | the sieves,<br>germination<br>energy  |       |                                      |   |   |                           |   |         |    |  |   |   |   |   |   |   |   |      |
| 3   | Poland | Sugar beet  | F | Plant growth<br>regulator,<br>effect on<br>higher yield of<br>sugar, lower<br>content of<br>unwanted<br>Sodium                    | spray | BBCH<br>12-49<br>(spring-<br>summer) | 2 | 7 | 0.2<br><del>0.6</del> 0.4 | a)<br>Na 5NG: 0.6<br>Na oNP: 1.2<br>Na pNP: 1.8<br>b)<br>Na 5NG: <del>1.8</del> 1.2<br>Na oNP: <del>3.6</del> 2.4<br>Na pNP: <del>5.4</del> 3.6 | 200-500 | 15 |  | A | A | A | A | A | A | A | A    |
| Minor crops registered on the base of art 51. |        |   |   |   |       |                                      |   |   |                           |   |         |    |  |   |   |   |   |   |   |   |      |
| 4   | Poland | Mustard,<br>spring rape,<br>turnip rape,<br>camelina,<br><del>garden<br/>radish,</del><br>poppy,<br>linseed,<br>hemp,<br><del>sunflower,</del><br>borage. | F | Plant growth<br>regulator,<br>number of<br>pods per plant,<br>number of<br>seeds per<br>plant, higher<br>lignification of<br>pods | spray | BBCH<br>29-69<br>(spring)            | 2 | 7 | 0.2<br>0.4                | a)<br>Na 5NG: 0.6<br>Na oNP: 1.2<br>Na pNP: 1.8<br>b) Na<br>5NG: 1.2<br>Na oNP: 2.4<br>Na pNP: 3.6  | 200-500 | 28 | Extrapolati<br>on from<br>winter<br>oilseed rape | A | A | A | A | A | A | A | n.r. |
| 5   | Poland | Spring rye,<br>spelt,<br>emmer<br>wheat,<br>small spelt,<br>durum<br>wheat.   | F | Plant growth<br>regulator,<br>number of<br>tillers and ears,<br>portion above<br>the sieves,<br>germination<br>energy             | spray | BBCH<br>21-49<br>(spring)            | 1 | - | 0.2<br>0.2                | Na 5NG: 0.6<br>Na oNP: 1.2<br>Na pNP: 1.8   | 200-300 | 28 | Extrapolati<br>on from<br>winter<br>wheat        | A | A | A | A | A | A | A | n.r. |
| 6   | Poland | Fodder<br>beet,<br>red beet,<br>swede,<br>turnip.   | F | Plant growth<br>regulator,<br>effect on<br>higher yield   | spray | BBCH<br>12-49<br>(spring-<br>summer) | 2 | 7 | 0.2<br><del>0.6</del> 0.4 | a)<br>Na 5NG: 0.6<br>Na oNP: 1.2<br>Na pNP: 1.8<br>b)<br>Na 5NG: <del>1.8</del> 1.2<br>Na oNP: <del>3.6</del> 2.4<br>Na pNP: <del>5.4</del> 3.6 | 200-500 | 15 | Extrapolati<br>on from<br>sugar beet             | A | A | A | A | A | A | A | n.r. |
| 7   | Poland | Garden<br>radish  | F | Plant growth<br>regulator,<br>number of<br>pods per plant,  | Spray | BBCH<br>29-69<br>(spring)            | 2 | 7 | 0.2                       | 0.6<br>1.2<br>1.8   | 200-500 | 28 | Extrapolati<br>on from<br>main crops<br>not      | A | A | A | A | A | A | A | n.r. |

|   |        |           |   |   |       |                     |   |   |     |                   |         |    |   |   |   |   |   |   |   |   |     |
|---|--------|-----------|---|---|-------|---------------------|---|---|-----|-------------------|---------|----|---|---|---|---|---|---|---|---|-----|
|   |        |           |   | number of seeds per plant, higher lignification of pods   |       |                     |   |   |     |                   |         |    | possible, the ground water exposure assessment performed with consideration of cabbage/leafy vegetables as a surrogate crop.                |   |   |   |   |   |   |   |     |
| 8 | 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<br>1.2<br>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 | A | n.r |

**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.

**\* 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                             |

- 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/m<sup>3</sup> 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
- 15 Overall conclusions - explanation for the column 15 is below\*

### **3 Background of authorization decision and risk management**

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

Commercial packaging:

Bottles and cans in HDPE: 0,05; 0,2; 0.5 L; 1 L; 5 L; 10 L; 20 L.

ASAHI MAX is a soluble concentrate (SL). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of homogeneous brown yellow liquid free from visible suspended matter, with a faint chemical not specific odour. It is not explosive, has no oxidising properties. The product is not flammable, contain more than 95% of water. Self-ignition temperature of product was not tested, as product contains more than 95% of water. In 1% aqueous solution, it has a pH value around 8,63 at 21 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE*. Its technical characteristics are acceptable for a *soluble concentrate* formulation. The intended concentration of use is 0,3% Na 5-NG, 0,6% Na *o*-NP and 0,9% Na *p*-NP.

According to the information provided by the applicant the product can be mixed and applied on crops together with other plant protection products or fertilizers. There are no problems with miscibility or phytotoxicity reported from practice for more then 40-year registration in Greece. However, compatibility studies have not been submitted for evaluation. According to the RR Section 1,2,4, point 2.9.1 and 2.9.2 ASAHI MAX is recommended to be used alone.

#### **3.2 Efficacy (Part B, Section 3)**

Considering the data submitted:

The efficacy level of ASAHI MAX is considered satisfactory for all the requested uses according to national authorised conditions of use.

The selectivity level of ASAHI MAX is considered acceptable for all the requested uses according to national authorised conditions of use.

Based on the absence of adverse effects across trials the risks of negative impact on yield, quality, transformation processes and propagation are considered acceptable according to national authorised conditions of use.

The risk of negative impact on succeeding and adjacent crops is considered acceptable. Furthermore, ASAHI MAX is a new formulation providing the same amount of the three active substances as ASAHI SL, currently registered for use as a plant growth regulator in various crops and EU countries, when applied at 0.2 L and 0.6 L product/ha respectively. ASAHI SL has been used for many years in various crops and EU countries, including those relevant for this application for the approval of ASAHI MAX in the EU Central Registration zone, and no adverse impact on succeeding crops has been reported.

#### **3.3 Efficacy data**

ASAHI MAX is applied at the proposed label rate of 0.2 L product/ha compared to that of ASAHI SL applied at the approved label rate of 0.6 L product/ha. Both formulations are applied to field at final rate of active substances of 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha.

The proposed label rate of 0.2 L product/ha for the use of ASAHI MAX, as a plant growth regulator in oilseed rape, sugar beet and winter wheat, is consistent with the approved label rate of 0.6 L product/ha

of the registered ASAHI SL product in terms of amounts and ratio of the three active substances. ASAHI SL at the approved label rate of 0.6 L product/ha and ASAHI MAX at the proposed label rate of 0.2 L product/ha gave comparable efficacy and crop safety. It is therefore considered that the approved ratio of the active substances of ASAHI SL provides full justification of the same ratio of the three active substances in ASAHI MAX. Furthermore, it is considered that data generated with ASAHI SL are fully supportive of the proposed label claim of ASAHI MAX.

Based on the summarized data, it is considered that claims of ASAHI MAX as a plant growth regulator applied according to the proposed GAP in oilseed rape, winter wheat and sugar beet are fully supported.

### **3.3.1 Information on the occurrence or possible occurrence of the development of resistance**

The formulation ASAHI MAX is used as plant growth regulator, and therefore no use towards pest is performed. The resistance of pest is not relevant.

### **3.3.2 Adverse effects on treated crops**

The crop safety of ASAHI MAX and/or ASAHI SL has been tested under a wide range of climatic and agronomic conditions. Based on the absence of effects across trials, it is reasonable to conclude that ASAHI MAX at the proposed label rate of 0.2 L product/ha, and applied according to label recommendations, causes no phytotoxic symptoms or adverse effects to oilseed rape, winter wheat and sugar beet in terms of quality of harvested crop.

Product has no effects on relevant processing procedures and causes no taints on sugar beet, oilseed rape and winter wheat crops.

Product applied according to label recommendations, has no adverse impact on progeny seed in winter wheat and no restrictions are necessary regarding use on crops grown for seed production.

### **3.3.3 Observations on other undesirable or unintended side-effects**

No adverse impact on succeeding crops or no significant risk with regard to adverse impact on other plants, including adjacent crops, has been reported.

## **3.4 Methods of analysis (Part B, Section 5)**

### **3.4.1 Analytical method for the formulation**

Sufficiently sensitive and selective analytical methods are available for the active substance sodium 5-nitroguaiacolate (Na 5-NG), sodium *ortho*-nitrophenolate (Na *o*-NP) and sodium *para*-nitrophenolate (Na *p*-NP) in the plant protection product.

No methods are available for the determination of relevant impurities in ASAHI MAX. There are relevant impurities specified for sodium *o*-nitrophenolate and sodium *p*-nitrophenolate in technical material. Monitoring methods for all relevant impurities are required, regardless if they form during storage or not in the formulation.

Analytical method need to be provided to determine the content of the relevant impurities specified for sodium *o*-nitrophenolate and sodium *p*-nitrophenolate in the PPP in accordance with the data requirements set out in Reg. (EU) 284/2013. The method should be validated in accordance with SANCO/3030/99 rev. 5 (including confirmation of impurity identity) at a level appropriate to the maximum impurity content in the PPP.

### **3.4.2 Analytical methods for residues**

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

In EFSA Scientific Report (2008) 191, 1-130 – “Conclusion on the peer review of sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate” it is stated that *Adequate methods are available to monitor all compounds given in the respective residue definitions in food/feed of plant origin and environmental matrices. The methods available determine the three compounds concurrently.*

*A HPLC-MS/MS method with column switching is available to monitor residues in food/feed of plant origin with LOQ 0.01 mg/kg (sugar beet, oil seed rape, tomatoes) for each individual compound.*

*Since residues in foodstuff of animal origin will not reach a level of significance, no analytical methods are required for the determination of Na 5-NG, Na p-NP and Na o-NP residues in matrices of animal origin.*

*Adequate HPLC-MS/MS methods with column switching are available to monitor residues of Na 5-NG, Na o-NP and Na p-NP in soil with LOQ of 0.01 mg/kg; in drinking, surface and ground water with a LOQ of 0.1 µg/L and in air with a LOQ of 1.25 µg/m<sup>3</sup> for each individual compound.*

*Analytical methods for the determination of residues in body fluids and tissues are not required as Na 5-NG, Na o-NP and Na p-NP are not classified as toxic or highly toxic.*

According to the EFSA Journal 2015;13(12):4356:

*An analytical method using HPLC-MS/MS was validated for the monitoring of sodium 5-nitroguaiacolate, sodium o-phenolate and sodium p-nitrophenolate with, for each compound, a limit of quantification (LOQ) of 0.01 mg/kg in high water content and high oil content commodities (EFSA, 2008). This method is supported by an independent laboratory validation (ILV) and a confirmatory method was not deemed necessary.*

*During the Member States consultation, EURLs indicated to EFSA that a single residue method was validated for enforcement of sodium 5-nitroguaiacolate, sodium o-phenolate and sodium p-nitrophenolate in dry commodities. However, as this statement is not supported by data, it cannot be evaluated in the present assessment.*

*Hence analytical methods for monitoring of sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in high acid content commodities, dry commodities and hops (dried) are still required.*

To address the data gap related to validated analytical enforcement method, the validation data of a method for the determination of sodium nitrocompounds in high acid content commodities, dry commodities and hops (dried) was submitted. The data gap was considered satisfactorily addressed (please refer EFSA Journal 2020;18(3):6060).

#### Body fluids and tissues

According to the SANTE/2020/12830: “Analytical methods for monitoring residues in body fluids and tissues are required for detection of active substances and/or metabolites in humans and animals after possible intoxications or for biomonitoring purposes, regardless of their toxicological classification.”

Therefore, an analytical method for the residues of Na 5-NG, Na o-NP and Na p-NP in body fluids and tissues is required. Applicant has been requested by the zRMS to submit the additional analytical method.

Applicant submitted new analytical method for determination of residues of Na 5-NG, Na o-NP and Na p-NP in body fluids and tissues (Guserle, R., 2020 (P 5263 G (433-001)) – “Development and validation of a method for the determination of 5-nitroguaiacol, ortho-nitrophenol and para-nitrophenol expressed as sodium 5-nitroguaiacolate, sodium ortho-nitrophenolate and sodium para-nitrophenolate, respectively, in blood, urine and meat matrix”.

The limit of quantification was established at 0.1 mg/kg for meat and 0.05 mg/L for blood and urine, but according to the SANTE/2020/12830, Rev.1, 24. February 2021, the LOQ should be lower - 0.01 mg/L for body fluids and 0.01 mg/kg for body tissues.

In our opinion, it is necessary to supply the method for determining the residues of Na 5-NG, Na o-NP and Na p-NP in body fluids and tissues with lower LOQ of 0.01 mg/L at the renewal of the active

substance and/or re-evaluation of plant production product.

### Nectar

At the request of the zRMS, the Applicant submitted a new nectar residue study in the framework of this application.

Analytical method has been validated to determine of residues of sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in nectar by Kugel (2020). The analytical method is acceptable according to SANCO/3029/99 rev. 4 and fits for purpose the requirements of SANTE/2020/12830, Rev.1 for determination of Na 5-NG, Na o-NP and Na p-NP in nectar.

For the detailed description please see Appendix 2 of Part 5.

## 3.5 Mammalian toxicology (Part B, Section 6)

### Endpoints used in the risk assessment

|                                      | Sodium 5-nitroguaiacolate | Sodium o-nitrophenolate | Sodium p-nitrophenolate |
|--------------------------------------|---------------------------|-------------------------|-------------------------|
| Common Name                          | Sodium 5-nitroguaiacolate | Sodium 2-nitrophenolate | Sodium 4-nitrophenolate |
| CAS-No.                              | 67233-85-6                | 824-39-5                | 824-78-2                |
| <b>Agreed EU endpoints (EU 2013)</b> |                           |                         |                         |
| ADI                                  | 0.003 mg/Kg bw/day        |                         |                         |
| ARfD                                 | 0.045 mg/Kg bw            |                         |                         |
| AOEL systemic                        | 0.007 mg/kg bw/d          |                         |                         |
| Oral absorption (%)                  |                           |                         |                         |
| Dermal absorption (%)                |                           |                         |                         |
|                                      | Concentrate               | 8%                      |                         |
|                                      | Spray dilution            | 27%                     |                         |

### 3.5.1 Acute toxicity

Acute toxicity studies for ASAHI MAX were evaluated by zRMS Greece. ASAHI MAX containing Na 5-NG (3 g/L), Na o-NP (6 g/L) and Na p-NP (9 g/L) has a low toxicity in respect to acute oral, dermal and inhalation toxicity and is not irritating to the rabbit skin. Whilst slight irritation was observed in the rabbit eye, this was insufficient to trigger classification. A skin sensitisation test (LLNA) confirmed that ASAHI MAX is not a skin sensitiser. Taking into account all submitted data and the labelling of the active substances, ASAHI MAX does not warrant classification.

### 3.5.2 Operator exposure

The zonal assessment was based on the maximum product application rate of 0.2 kg/ha.

Summary of critical use patterns (worst cases):

| Crop type | F | Equipment<br>Application method      | Maximum application rate kg<br>product/ha (g a.s./ha)                      | Maximum volume<br>water (L/ha) |
|-----------|---|--------------------------------------|--|--------------------------------|
| Oil crops | F | Vehicle-mounted<br>Downward spraying | 0.2 L/ha<br>Na 5-NG (0,6 g/ha)<br>Na o-NP (1,2 g/ha)<br>Na p-NP (1,8 g/ha) | 500                            |

Thus, according to the EFSA Guidance calculations, a safe use could be demonstrated for operators using ARY-0469-04 /ASAHI MAX for proposed uses, even if no PPE is worn.



### **3.5.3 Worker exposure**

Thus, according to the EFSA Guidance calculations and EUROPOEM II calculations, a safe use could be demonstrated for workers using ARY-0469-04 /ASAHI MAX for proposed uses, using only work wear.

### **3.5.4 Bystander and resident exposure**

It is concluded that there is no undue risk to any resident after accidental short-term exposure to ARY-0469-04 /ASAHI MAX even if added are exposures of the three components. This has no labelling implications.

### **3.5.5 Combined exposure**

The product is a mixture of three active substances. For pesticide formulations containing two or more active substances, combined toxicity and their potential relevance for the risk assessments should be considered.

The Hazard Index is  $< 1$ . Thus, combined exposure to both active substances in ARY-0469-04/ASAHI MAX is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

## **3.6 Residues and consumer exposure (Part B, Section 7)**

The proposed use on oilseed rape, winter wheat and sugar beet are covered by the previously evaluated metabolism studies as the metabolism in three diverse crop groups has been assessed and was shown to be similar. The residue definition of 'sum of sodium 5-nitroguaiacolate, sodium *o*-nitrophenolate and sodium *p*-nitrophenolate, expressed as sodium 5-nitroguaiacolate' (EFSA 2008/2015) is therefore considered applicable to oilseed rape, winter wheat and sugar beet. The residue definition for enforcement is also considered in Reg. (EU) 2021/1098.

Further investigation of residues in rotational crops is not required and relevant residues in rotational crops are not expected.

The level of residues in oilseed rape, winter wheat and sugar beet are below the trigger of 0.03 mg/kg, and contribution of the commodity under consideration to the theoretical maximum daily intake (TMDI) is  $< 10\%$  of the ADI and therefore studies on the magnitude of residues in processed commodities are not required.

### **3.6.1 Residues**

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application for oilseed rape (4x), winter wheat (4x) and sugar beet (4x) in North Zone. All trials are considered acceptable as all residues were  $< \text{LOQ}$  (0.01 mg/kg).

According to Commission Regulation (EU) No. 283/2013 animal metabolism studies are required, when a pesticide is to be used in crops whose parts or products are fed to animals and where the intake is expected to exceed 0.004 mg/kg bw/d. The potential total feed residues of the sum of Na 5-NG, Na *o*-NP and Na *p*-NP, expressed as Na 5-NG were calculated for cattle, sheep and swine and poultry. The dietary burden for cattle is slightly above the trigger value and driven by sugar beet ensiled pulp, sugar beet tops and wheat grain for which the input values were the combined LOQ of 0.03 mg/kg. As a no residue situation for sugar beet and wheat grain can be expected based on the 10X overdosed metabolism studies as well as the residue levels are  $< \text{LOQ}$  for Na 5-NG, Na *o*-NP and Na *p*-NP in the residue trials, the input value of 0.03 mg/kg is expected to be overly conservative. As already concluded in the 91/414/EEC review and within the EFSA Article 12 MRL review (EFSA Journal 2015;13(12):4356) confirmed, metabolism studies in animal livestock are not required. Furthermore, a residue definition in animal products is not needed and the setting of MRLs in commodities of animal origin is not necessary.

As residues of sodium nitrocompounds do not exceed the trigger values defined in Reg. (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

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.

### 3.6.2 Consumer exposure

The data available are considered sufficient for risk assessment. A highest estimated chronic intake has been shown for NL toddler and represents 41% of the ADI. Acute consumer risk has been assessed as well. No exceedance of the ARfD was identified for the proposed commodities. The highest contribution for children is potato and melon for unprocessed (10% of ARfD) and Sugar beet (root) / sugar (10 % of ARfD) for processed commodities.

It is concluded that the long-term and short-term intake of residues resulting from the proposed uses of Asahi Max on oilseed rape, cereals and sugar beet are unlikely to present a risk to consumer health.

|  |   |
|--|---|
| TMDI (% ADI) according to EFSA PRIMo 3.1 | - % - oilseed rape – no record<br>7.0% - wheat – GEMS/Food G06<br>8.0% - sugar beet – NL child  |
| IEDI (% ADI) according to EFSA PRIMo 3.1 | 41% - NL toddler  |
| IESTI (% ARfD) according to EFSA PRIMo*  | oilseed rape unprocessed: 0.09% for children<br>oilseed rape processed: 0.0% for children<br><br>wheat unprocessed: 1% for children<br>wheat processed: 0.8% for children<br><br>sugar beet unprocessed: - % for children<br>sugar beet processed: 7.0 % for children |
| NTMDI (% ADI) **                         | -   |
| NEDI (% ADI) **                          | -   |
| NESTI (% ARfD) **                        | -   |

\* include raw and processed commodities if both values are required for PRIMo

\*\* if national model is available

### 3.7 Environmental fate and behaviour (Part B, Section 8)

A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment.

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

ECsoil and PECsw values derived for the active substance and its metabolites are used for the ecotoxicological risk assessment. No unacceptable risk of groundwater contamination is expected for the intended uses.

#### 3.7.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)

The predicted environmental concentrations in soil were assessed in accordance with the recommendations of the respective EU guidance documents on the basis of the EU agreed input parameters and intended use pattern of ASAHI MAX.

The results for PECsoil for the active substances were used for the ecotoxicological risk assessment.

### 3.7.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)

The leaching behaviour of the active ingredients Na 5-NG, Na *o*-NP and Na *p*-NP were calculated using the simulation models FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 for all FOCUS groundwater scenarios on the basis of the EU agreed input parameters and intended use pattern of ASAHI MAX.

The PEC<sub>GW</sub> calculations were performed for appropriate worst-case application scenarios for all relevant crops defined by the GAP.

However, the zRMS is of the opinion that winter OSR is most suitable surrogate crop for mustard, spring rape, turnip rape, camelina, poppy, linseed, hemp and borage. But it is not relevant for garden radish and sunflower for which, based on FOCUS crop scenarios and crop morphology, leafy vegetables (cabbage) and maize, respectively, are more relevant. Therefore, additional modelling was performed by the zRMS for Na 5-NG, Na *o*-NP and Na *p*-NP and metabolite M5 using the models FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 with assumption of two applications with 7 days interval.

The 80<sup>th</sup> percentiles of the predicted annual leachate concentrations of Na 5-NG, Na *o*-NP and Na *p*-NP and their metabolite M5 were clearly lower than 0.1 µg/L in all tested scenarios and models indicating that no unacceptable leaching of these substances is expected after application of ASAHI MAX according to the intended use pattern.

### 3.7.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)

The surface water modelling was performed for the intended use pattern of ASAHI MAX in line with recommendations of respective FOCUS guidance documents using most up-to-date versions of the models.

The PEC calculations in surface water (PEC<sub>sw</sub>) and sediment (PEC<sub>sed</sub>) were performed for appropriate worst-case application scenarios for all relevant crops defined by the GAP.

The zRMS agrees that winter OSR is most suitable surrogate crop for mustard, spring rape, turnip rape, camelina, poppy, linseed, hemp and borage. However, it is not relevant for garden radish and sunflower. Based on FOCUS crop scenarios and crop morphology, leafy vegetables, are in opinion of the zRMS more relevant for garden radish, while for sunflower there is no need to consider surrogate crop as sunflower is available as crop scenario in FOCUS. Additionally, surface water exposure was calculated by the zRMS for the active ingredients Na 5-NG, Na *o*-NP and Na *p*-NP and their metabolites at Step 1-2 with consideration of two applications to sunflower and leafy vegetables with 7 days interval.

Further details on the assessment as well as detailed results are presented in Part B, Section 8 of the Core dossier. The presented PEC<sub>sw</sub> and PEC<sub>sed</sub> values are suitable for subsequent ecotoxicological risk assessment.

### 3.7.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)

Due to the relatively low vapour pressure of each of the active substances in the ASAHI MAX mixture ( $<1.33 \times 10^{-5}$  Pa at 25°C for Na 5-NG and Na *p*-NP and  $7.75 \times 10^{-5}$  Pa at 25°C for Na *o*-NP), the substances are not expected to undergo significant volatilisation in the environment.

The DT<sub>50</sub> of Na 5-NG, Na *o*-NP and Na *p*-NP in air is higher than 2 days, which indicate some potential for long range transport of these active substances. Nevertheless, due to low vapour pressure no significant volatilisation is expected and with DT<sub>50</sub> slightly above, but still close to 2 days no unacceptable contamination of the atmosphere is expected following application of ASAHI MAX.

### **3.8 Ecotoxicology (Part B, Section 9)**

#### **3.8.1 Effects on terrestrial vertebrates**

A safe use for birds and mammals has been concluded at screening step. There is no risk for birds and mammals from drinking water consumption and the risk from secondary poisoning for fish-eating and worm-eating birds and mammals is acceptable.

Therefore, it is concluded that the intended use of ASAHI MAX does not pose any potential risk for birds and mammals.

#### **3.8.2 Effects on aquatic species**

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

An acceptable risk is concluded for aquatic organisms from the use of ASAHI MAX and the intended GAP. No risk mitigation measures are required.

#### **3.8.3 Effects on bees**

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

An acceptable risk is concluded for bees from the use of ASAHI MAX and the intended GAP.

The chronic studies for adult bees and larvae were provided according to EU Reg.284/2009.

No chronic for bees risk is required to bees until EFDSA GD for Bees and other pollinators will be implemented at UE level.

#### **3.8.4 Effects on other arthropod species other than bees**

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

An acceptable risk is concluded for non-target arthropods from the use of ASAHI MAX and the intended GAP.

#### **3.8.5 Effects on soil organisms**

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

An acceptable risk is concluded for soil organisms from the use of ASAHI MAX and the intended GAP.

#### **3.8.6 Effects on non-target terrestrial plants**

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

An acceptable risk is concluded for non-target plants from the use of ASAHI MAX and the intended GAP.

### 3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No further information is required.

### 3.9 Relevance of metabolites (Part B, Section 10)

There are no metabolites that are considered to be of relevance for groundwater assessment. A data gap for identification and further assessment of the unknown soil metabolite M5 in groundwater was identified during the EU review. This issue has been addressed in a separate confirmatory data submission in accordance with current EU regulatory guidance (SANCO/5634/2009 rev. 6.1) and an assessment has been accordingly performed for PEC<sub>gw</sub> for metabolite M5 in the present dRR (refer to Point 8.8)

|   | Assessment step |         | Result of assessment  |  |
|---|-----------------|---------|---|--|
|   | STEP 1          |         | Metabolite of no concern?   | No                                     |
| Quantification of groundwater contamination | STEP 2          |         | Max PEC <sub>gw</sub>   | 0.092737 µg/L                          |
|   |                 |         | Based on  | Sugar beet<br>Jokioinen<br>PEARL 5.5.5 |
| Hazard assessment                           | STEP 3          | Stage 1 | Biological activity comparable to the parent?   | N/A                                    |
|   |                 | Stage 2 | Genotoxic properties of metabolite  | N/A                                    |
|   |                 | Stage 3 | Toxic properties of metabolite;   | N/A                                    |
|   |                 |         | Classification of parent  | N/A                                    |
|   |                 |         | Classification of metabolite  | N/A                                    |
| Consumer health risk assessment             | STEP 4          |         | Estimated consumer exposure via drinking water and other sources; threshold of concern approach | N/A                                    |
|   | STEP 5          |         | Refined risk assessment   | N/A                                    |
|   |                 |         | Predicted exposure (% of ADI)   | N/A                                    |
|   |                 |         |   | ADI based on                           |

## 4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substances are not approved as a candidates for substitution, therefore a comparative assessment is not foreseen.

## 5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Analytical method need to be provided to determine the content of the relevant impurities specified for sodium o-nitrophenolate and sodium p-nitrophenolate in the PPP in accordance with the data requirements set out in Reg. (EU) 284/2013. The method should be validated in accordance with SANCO/3030/99 rev. 5 (including confirmation of impurity identity) at a level appropriate to the maximum impurity content in the PPP.

## **Appendix 1    Copy of the product authorization**

## Appendix 2 Copy of the product label

### **Komentarz oceniających:**

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, toksykologii i istotności toksykologicznej metabolitów, pozostałości, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym podświetleniem tekstu (fragmenty dodane) lub ~~przekreśleniem i jasno-szarym cieniem~~ (fragmenty usunięte).

Zakres zmian jest następujący:

### **Sekcja właściwości fizykochemiczne:**

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodnie z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008 r. nie jest wymagane.
2. Okres ważności: 2 lata w opakowaniach wykonanych z HDPE na podstawie zaakceptowanego 2 letniego badania stabilności. W związku z powyższym, wszystkie opakowania wymienione, w punktach 2.1 dokumentu A i 4.1 Sekcji 1,2,4 można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do punktów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin i opakowania oraz sporządzania cieczy użytkowej.
4. Brak uwag do zapisu nazw substancji czynnych i ich zawartości.
5. Zgodnie z informacjami zawartymi w punktach IIIA 2.9.1 i IIIA 2.9.2 Sekcji 1,2,4 Raportu Rejestracyjnego środek nie jest dedykowany do łącznego stosowania.

### **Sekcja skuteczność:**

1. Na podstawie przedłożonych wyników badań możliwa jest rejestracja środka Asahi Max jako regulatora wzrostu do zastosowania w rzepaku ozimym, pszenicy ozimej i buraku cukrowym w zakresie sekcji skuteczność.
2. Zweryfikowano opis działania środka. W przedłożonych badaniach skuteczności oceniono określone parametry zarówno ilościowe jak i jakościowe roślin. ~~W opisie uwzględnionym przez wnioskodawcę w etykiecie zakres parametrów jest znacznie szerszy, a brak ich potwierdzenia w badaniach uniemożliwia akceptację takiego opisu działania.~~ Pozytywne rezultaty po zastosowaniu środka uzyskano w przypadku: liczby roślin na określonej jednostkę powierzchni, masy sadzonek, ilości plonu i jego parametrów jakościowych (wilgotność, MTZ, HLW, zawartość białka, glutenu, oleju, cukru, potasu, sodu i azotu), energii kiełkowania oraz obszaru wylegania. Ponadto, w ocenie wykorzystano badania prowadzone na zarejestrowanym obecnie środku Asahi SL. W etykiecie tego środka opis działania został ujęty następująco: „Zastosowanie środka jest wskazane w warunkach stresowych, niesprzyjających wzrostowi roślin np. susza, przymrozki i po posadzeniu lub w przypadku uszkodzenia roślin np. środkami ochrony roślin lub nawozami”. Z uwagi na to, że substancje zawarte w obu środkach są takie same i działają stymulująco na wzrost roślin, w opinii eksperta fragment ten pokrywa część opisu zaproponowanego przez wnioskodawcę w etykiecie środka Asahi Max ~~zatem może on pozostać w takiej formie.~~ **Dodatkowo na etapie komentowania wnioskodawca przedłożył informacje na temat sposobu działania nitrozwiązków sodu, co pozwoliło na pozostawienie zaproponowanego opisu działania środka Asahi Max, jakkolwiek w nieco zmienionej formie.**
3. W przedłożonych badaniach prowadzonych na rzepaku ozimym odstęp między poszczególnymi zabiegami wynosił od 10 do 16 dni. Na tej podstawie zweryfikowano zapis w etykiecie środka.

### **Sekcja metody analityczne:**

1. Brak uwag.

### **Sekcja toksykologia i istotność toksykologiczna metabolitów:**

1. W części dotyczącej środków ostrożności dla osób stosujących środek, odpowiedni zapis został zmodyfikowany zgodnie z wymaganiami harmonizacyjnymi oraz odpowiednio do wyniku szacowania NDE.

### **Sekcja pozostałości:**

1. Wprowadzono do etykiety zapis dotyczący roślin uprawianych następnie. „Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie: Nie dotyczy”.
2. Ze względu na to, że okres przechowywania próbek całych roślin zbóż oraz roślin oleistych zebranych z pola (zanim dojrzało ziarno czy nasiona; ang. *whole plant*) był dłuższy niż okres, w trakcie którego wykazano stabilność pozostałości, nie powinno się tych części roślin używać do skarmiania zwierząt.

**Sekcja los i zachowanie w środowisku:**

1. Brak uwag.

**Sekcja ekotoksykologia:**

1. Wprowadzono zapis P501.

Załącznik do zezwolenia MRiRW nr R-xx/2023 z dnia xx.xx.2023 r.

Posiadacz zezwolenia:

Asahi Chemical Europe s.r.o., Lužná 716/2, Vokovice, 160 00 Praha 6, Republika Czeska,  
tel.: +420 212 244 322, faks: +420 212 244 323

1. Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:  
UPL Polska Sp. z o.o., ul. Stawki 40, 01-040 Warszawa, tel.: +48 22 434 00 90, e-mail: sekretariat@upl-ltd.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin: (...)

## Asahi Max

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

para-nitrofenolan sodu (związek z grupy pochodnych nitrofenoli) – 9 g/l (0,9%)

orto-nitrofenolan sodu (związek z grupy pochodnych nitrofenoli) – 6 g/l (0,6%)

5-nitrogwajakolan sodu (związek z grupy pochodnych nitrofenoli) – 3 g/l (0,3%)

**Zezwolenie MRiRW nr R-xx/2023 z dnia xx.xx.2023 r.**

|                           |  |
|---------------------------|--|
| EUH401                    | W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.  |
| P261<br>P271<br>P301+P312 | Unikać wdychania rozpylonej cieczy.<br>Używać wyłącznie na zewnątrz lub w dobrze wentylowanym pomieszczeniu.<br>W PRZYPADKU POŁKNIECIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem. |
| P391<br>P501              | Zebrać wyciek.<br>Zawartość/pojemnik usuwać do recyklingu bądź składowania na składowiskach odpowiednich dla pestycydów lub spalania w odpowiednich instalacjach.  |



## OPIS DZIAŁANIA

Regulator wzrostu, w formie koncentratu do sporządzania roztworu wodnego (SL). Środek pozytywnie wpływa na plon roślin uprawnych, powodując polepszenie jego parametrów ilościowych i jakościowych, metabolizm enzymów, reguluje kwitnienie, zawiązywanie i wzrost owoców. Zwiększa produkcję auksyn w roślinach i pobudza stymuluje przepływ cytoplazmatyczny, promując w ten sposób większe wyższe plony i wyższą jakość zbiorów. Traktowane rośliny Rośliny poddane zabiegowi wykazują lepsze ukorzenienie, wzrost i rozwój generatywny, lepszą akumulację biomasy i wyższą wydajność aparatu fotosyntetycznego, zawartość wody, integralność błony i lignifikację ściany komórkowej. Środek zmniejsza negatywny wpływ stresu biotycznego i abiotycznego. Zabieg profilaktyczny aktywuje systemy obronne roślin i buduje lepszą tolerancję na niekorzystne warunki uprawy (susza, niska temperatura, zasolenie gleby itp.) oraz przyspiesza regenerację roślin po uszkodzeniach (mróz, grad, mniej selektywne herbicydy itp.).

## STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego

### Rzepak ozimy

Maksymalna / zalecana dawka środka dla jednorazowego zastosowania: 0,2 l/ha.

Termin stosowania środka: środek stosować od końca formowania pędów bocznych do końca fazy kwitnienia (BBCH 29-69).

Odstęp między zabiegami: co najmniej 7 10 dni.

Zalecana ilość wody: 200 - 500 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

### Pszenica ozima

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 0,2 l/ha.

Termin stosowania środka: Środek stosować od początku fazy krzewienia do fazy widocznych pierwszych ości (BBCH 21-49).

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie :drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

### Burak cukrowy

Maksymalna / zalecana dawka środka dla jednorazowego zastosowania: 0,2 l/ha.

Termin stosowania środka: Środek stosować od fazy rozwiniętych dwóch liści właściwych do fazy, gdy korzeń osiąga wielkość wymaganą do zbioru (BBCH 12-49).

Odstęp między zabiegami: co najmniej 7 dni.

Zalecana ilość wody: 200 - 500 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

## STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOObszarowych

**Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik**

**Gorczyca biała, gorczyca czarna, gorczyca sarepska, rzepak jary, rzepik ozimy, lnianka siewna, rzodkiew oleista, mak lekarski, len zwyczajny, słonecznik zwyczajny, konopie siewne, ogórecznik lekarski**

Maksymalna / zalecana dawka środka dla jednorazowego zastosowania: 0,2 l/ha.

Termin stosowania środka: środek stosować od końca formowania pędów bocznych do końca fazy kwitnienia (BBCH 29-69).

Odstęp między zabiegami: co najmniej 7 dni.

Zalecana ilość wody: 200 - 500 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

**Pszenica orkisz, pszenica płaskurka, pszenica samopsza, pszenica twarda, żyto jare**

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 0,2 l/ha.

Termin stosowania środka: Środek stosować od początku fazy krzewienia do fazy widocznych pierwszych ości (BBCH 21-49).

Zalecana ilość wody: 200 - 300 l/ha.

Zalecane opryskiwanie :drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

**Burak pastewny, burak ćwikłowy, brukiew, rzepa pastewna**

Maksymalna / zalecana dawka środka dla jednorazowego zastosowania: 0,2 l/ha.

Termin stosowania środka: Środek stosować od fazy rozwiniętych dwóch liści właściwych do fazy, gdy korzeń osiąga wielkość wymaganą do zbioru (BBCH 12-49).

Odstęp między zabiegami: co najmniej 7 dni.

Zalecana ilość wody: 200 - 500 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

**ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA**

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

- Burak cukrowy, burak pastewny, burak ćwikłowy, brukiew, rzepa pastewna - 15 dni,
- Pszenica ozima, pszenica orkisz, pszenica płaskurka, pszenica samopsza, pszenica twarda, żyto jare - 28 dni,
- Rzepak ozimy, gorczyca biała, gorczyca czarna, gorczyca sarepska, rzepak jary, rzepik ozimy, lnianka siewna, rzodkiew oleista, mak lekarski, len zwyczajny, słonecznik zwyczajny, konopie siewne, ogórecznik lekarski - 28 dni.

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

Nie dotyczy

**SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wleciu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.

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

## **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

Resztki cieczy użytkowej należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

## **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

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

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

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

~~Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.~~

Nie wdychać rozpylonej cieczy użytkowej.

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

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

## **ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALEGO.**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

## **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,

- w temperaturze 0 °C-30°C.

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

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów.

Opróżnione opakowania po środku zaleca się zwrócić do sprzedawcy środków ochrony roślin lub można je potraktować, jako odpady komunalne. W razie wątpliwości dotyczących postępowania z opakowaniami poradź się sprzedawcy środków ochrony roślin.

### **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

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

W przypadku połknięcia: w przypadku złego samopoczucia skontaktować się z ośrodkiem zatruc lub lekarzem.

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....

## **Appendix 3   Letter of Access**

Not required.

## Appendix 4 Lists of data considered for national authorization

### List of data submitted by the applicant and relied on

| Data point  | Author(s)       | Year  | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed          | Owner                        |
|---|-----------------|-------|--|-------------------------|--------------------------------|--|------------------------------|
| <b>Section 1, 2, 4</b>  |                 |       |  |                         |                                |  |                              |
| KCP 2.1; KCP 2.1/01;<br>KCP 2.4.2;<br>KCP 2.7.5;<br>KCP 2.8.2;<br>KCP 2.8.4 | Burkhard, A.    | 2011  | Physico-chemical Properties of the Formulation ATONIK PLUS 1.8% over 2 Years at 20°C (Values after 24 Months of Storage)<br>eurofins-Agroscience Services GmbH, Germany<br>ALS Report No. S08-0264<br>GLP, Unpublished | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 2.5.1;<br>KCP 2.5.2   | Betteley, J.    | 1999  | ATONIK (PRODUCT) – Physicochemical properties.<br>Huntingdon Life Sciences Ltd., UK<br>ALS Report No. ASI 118/994155<br>GLP, Unpublished   | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 2.6.1   | Phuong Lien, T. | 2008a | Relative Density of Formulation ATONIK PLUS 1.8%<br>eurofins-GAB GmbH, Germany<br>ALS Report No. S08-0261<br>GLP, Unpublished  | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 2.7.1/01  | Phuong Lien, T. | 2008b | Physico-chemical Properties of the Formulation ATONIK PLUS 1.8% after Accelerated Storage at 54°C for 2 Weeks<br>eurofins-GAB GmbH, Germany<br>ALS Report No. S08-0262<br>GLP, Unpublished                             | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 2.7.1/01a;<br>KCP 2.7.5   | Fau, J.         | 2013  | Statement on packaging<br>ArystaLifeScience SAS, France<br>ALS Report No. not stated<br>GLP, Unpublished   | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 2.7.4   | Phuong Lien, T. | 2008c | Low Temperature Stability of the Formulation ATONIK PLUS 1.8% at 0°C for 7 days<br>eurofins-GAB GmbH, Germany<br>ALS Report No. S08-0263<br>GLP, Unpublished   | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 4.4   | Anon.           | 2014  | Packing material specification - bottle 50 ml (intem nr. 40-001),<br>Polycorp Kft. Hungary<br>Company Report No: not applicatble<br>Source: Polycorp Kft   | N                       | N                              |  | Asahi Chemical Europe s.r.o. |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed | Owner                        |
|------------|-----------|------|--|-------------------------|--------------------------------|---|------------------------------|
|            |           |      | non GLP<br>Unpublished   |                         |                                |   |                              |
| KCP 4.4    | Anon.     | 2014 | Packing material specification - bottle 200 ml (intem nr. 40-0079), Polycorp Kft. Hungary<br>Company Report No: not applicatble<br>Source: Polycorp Kft<br>non GLP<br>Unpublished    | N                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 4.4    | Anon.     | 2014 | Packing material specification - closure Ø 29 mm (intem nr. 54-0012), Polycorp Kft. Hungary<br>Company Report No: not applicatble<br>Source: Polycorp Kft<br>non GLP<br>Unpublished  | N                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 4.4    | Anon.     | 2015 | Packing material specification - bottle 200 ml (intem nr. 40-00809), Polycorp Kft. Hungary<br>Company Report No: not applicatble<br>Source: Polycorp Kft<br>non GLP<br>Unpublished   | N                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 4.4    | Anon.     | 2015 | Packing material specification - closure Ø 42 mm (intem nr. 54-00404), Polycorp Kft. Hungary<br>Company Report No: not applicatble<br>Source: Polycorp Kft<br>non GLP<br>Unpublished | N                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 4.4    | Anon.     | 2016 | Packing material specification - bottle 500 ml (spec. D5A20 GB), Ipackchem France<br>Company Report No: not applicatble<br>Source: Ipackchem<br>non GLP<br>Unpublished               | N                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 4.4    | Anon.     | 2002 | Packing material specification - closure Ø 45 mm (ref.nr. BIO455B-BIO455D), Procap Belgium<br>Company Report No: not applicatble<br>Source: Polycorp Kft<br>non GLP                  | N                       | N                              |   | Asahi Chemical Europe s.r.o. |

| Data point  | Author(s)                   | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed                              | Owner                        |
|---|-----------------------------|------|--|-------------------------|--------------------------------|--|------------------------------|
|   |                             |      | Unpublished  |                         |                                |  |                              |
| <b>Section 3</b>  |                             |      |  |                         |                                |  |                              |
| KCP 6.1/001<br>KCP 6.2/001<br>KCP 6.4.1/001                                   | B. Tiggemann                | 2008 | Selectivity&efficacy/CAL97R01/Anti-stress bioagent/BEAVA/<br>Germany 2008<br>AGROSTAT GmbH, In den Gruben 6, Herrentierbach<br>EUR_MNN_BEAVA_DE_2771<br>GEP<br>Unpublished                 | N                       | Y                              | Data/study report never submitted before to <Poland>                     | Asahi Chemical Europe s.r.o. |
| KCP 6.1/002<br>KCP 6.2/002<br>KCP 6.4.1/002<br>KCP 6.4.2/001<br>KCP 6.4.3/001 | Agnieszka Kukuła-Młynarczyk | 2008 | The influence of biostimulator ASAHI SL (CAL97R01) on sugar beet quantity and quality<br>BIOTEK AGRICULTURE POLSKA SP. Z O.O.<br>EUR_MNN_BEAVA_PL_2997<br>GEP<br>Unpublished               | N                       | Y                              | Data/study report never submitted before to <Poland>                     | Asahi Chemical Europe s.r.o. |
| KCP 6.1/003<br>KCP 6.2/003<br>KCP 6.4.1/003<br>KCP 6.4.2/002<br>KCP 6.4.3/002 | Agnieszka Kukuła-Młynarczyk | 2008 | The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on sugar beet quantity and quality<br>BIOTEK AGRICULTURE POLSKA SP. Z O.O.<br>EUR_MNN_BEAVA_PL_2998<br>GEP<br>Unpublished | N                       | Y                              | Data/study report never submitted before to <Poland>                     | Asahi Chemical Europe s.r.o. |
| KCP 6.1/004<br>KCP 6.2/004<br>KCP 6.4.1/004<br>KCP 6.4.2/003<br>KCP 6.4.3/003 | Wojciech Cieśliski          | 2008 | The influence of Asahi SL (CAL97R01) and ALS08R369 on quality and quantity of sugar beet yielding<br>Uniwersytet Przyrodniczy Poznań<br>EUR_MNN_BEAVA_PL_2999<br>GEP<br>Unpublished        | N                       | Y                              | Data/study report never submitted before to <Poland>                     | Asahi Chemical Europe s.r.o. |
| KCP 6.1/005<br>KCP 6.2/005<br>KCP 6.4.1/005<br>KCP 6.4.2/004<br>KCP 6.4.3/004 | Magdalena Zaremba           | 2008 | Influence of ASAHI SL (CAL97R01), ALS08R369 o yield parameters in BEAVA, Poland 2008<br>AGROSTAT SP. zo.o., Zalesie 12, Jaraczewo, Poland<br>EUR_MNN_BEAVA_PL_3000<br>GEP<br>Unpublished   | N                       | Y                              | Data/study report never submitted before to <Poland>                     | Asahi Chemical Europe s.r.o. |
| KCP 6.1/006<br>KCP 6.2/006<br>KCP 6.4.1/006                                   | Agnieszka Kukuła-Młynarczyk | 2009 | The influence of Asahi SL (CAL97R01) and ALS08R369 on sugar beet quantity and quality<br>BIOTEK AGRICULTURE POLSKA SP. Z O.O.<br>EUR_MNN_BEAVA_PL_3290                                     | N                       | Y                              | Data/study report submitted before to <Poland> for Asahi SL registration | Asahi Chemical Europe s.r.o. |



| Data point                                  | Author(s)                   | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed  | Owner                        |
|---|-----------------------------|------|---|-------------------------|--------------------------------|--|------------------------------|
|   |                             |      | GEP<br>Unpublished  |                         |                                | Protection is claimed for Asahi Max data   |                              |
| KCP 6.1/007<br>KCP 6.2/007<br>KCP 6.4.1/007 | Agnieszka Kukula-Młynarczyk | 2009 | The influence of Asahi SL (CAL97R01) and ALS08R369 on sugar beet quantity and quality<br>BIOTEK AGRICULTURE POLSKA SP. Z O.O.<br>EUR_MNN_BEAVA_PL_3291<br>GEP<br>Unpublished  | N                       | Y                              | Data/study report never submitted before to <Poland>   | Asahi Chemical Europe s.r.o. |
| KCP 6.1/008<br>KCP 6.2/008<br>KCP 6.4.1/008 | Robert Idziak               | 2009 | The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on yield and quality of sugar beet<br>Uniwersytet Przyrodniczy Poznań<br>EUR_MNN_BEAVA_PL_3292<br>GEP<br>Unpublished                                       | N                       | Y                              | Data/study report never submitted before to <Poland>   | Asahi Chemical Europe s.r.o. |
| KCP 6.1/009<br>KCP 6.2/009<br>KCP 6.4.1/009 | Jacek Jatczak               | 2009 | Evaluation of the effect biostimulators Asahi SL (CAL97R01) and ALS08R369 on development, increase of yield and yield quality of sugar beet<br>ANADIAG S.A. Oddział w Polsce<br>EUR_MNN_BEAVA_PL_3293<br>GEP<br>Unpublished | N                       | Y                              | Data/study report submitted before to <Poland> for Asahi SL registration<br><br>Protection is claimed for Asahi Max data | Asahi Chemical Europe s.r.o. |
| KCP 6.1/010<br>KCP 6.2/010<br>KCP 6.4.1/010 | Bernd Tiggemann             | 2008 | Selectivity&efficacy/CAL97R01/Anti-stress bioagent/BRSNW/Germany 2008<br>(EUR_MNN_BRSNW_DE_2780_ALS08R02-01_R7371541)<br>AGROSTAT GmbH, In den Gruben 6, Herrentierbach<br>EUR_MNN_BRSNW_DE_2780<br>GEP<br>Unpublished      | N                       | Y                              | Data/study report never submitted before to <Poland>   | Asahi Chemical Europe s.r.o. |
| KCP 6.1/011<br>KCP 6.2/011<br>KCP 6.4.1/011 | Bernd Tiggemann             | 2008 | Selectivity&efficacy/CAL97R01/Anti-stress bioagent/BRSNW/Germany 2008<br>(EUR_MNN_BRSNW_DE_2781_ALS08R02-02_R7321541)<br>AGROSTAT GmbH, In den Gruben 6, Herrentierbach<br>EUR_MNN_BRSNW_DE_2781<br>GEP<br>Unpublished      | N                       | Y                              | Data/study report never submitted before to <Poland>   | Asahi Chemical Europe s.r.o. |

| Data point  | Author(s)                   | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed          | Owner                        |
|---|-----------------------------|------|--|-------------------------|--------------------------------|--|------------------------------|
| KCP 6.1/012<br>KCP 6.2/012<br>KCP 6.4.1/012                                   | Bernd Tiggemann             | 2008 | Selectivity&efficacy/CAL97R01/Anti-stress bioagent/BRSNW/Germany 2008<br>(EUR_MNN_BRSNW_DE_2782_ALS08R02-03_R7311541)<br>AGROSTAT GmbH, In den Gruben 6, Herrentierbach<br>EUR_MNN_BRSNW_DE_2782<br>GEP<br>Unpublished | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 6.1/013<br>KCP 6.2/013<br>KCP 6.4.1/013<br>KCP 6.4.2/005<br>KCP 6.4.3/005 | Wojciech Cieřlicki          | 2008 | The influence of Asahi SL (CAL97R01) and ALS08R369 on quality and quantity of winter rape yielding<br>Research and Education Center Gorzyń<br>EUR_MNN_BRSNW_PL_3038<br>GEP<br>Unpublished                              | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 6.1/014<br>KCP 6.2/014<br>KCP 6.4.1/014<br>KCP 6.4.2/006<br>KCP 6.4.3/006 | Agnieszka Kukuła-Młynarczyk | 2008 | The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on Oilseed Rape quantity and quality<br>BIOTEK AGRICULTURE POLSKA SP. Z O.O.<br>EUR_MNN_BRSNW_PL_3039<br>GEP<br>Unpublished                           | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 6.1/015<br>KCP 6.2/015<br>KCP 6.4.1/015<br>KCP 6.4.2/007<br>KCP 6.4.3/007 | Agnieszka Kukuła-Młynarczyk | 2008 | The influence of biostimulator ASAHI SL (CAL97R01) ALS08R369 on Oilseed Rape quantity and quality<br>BIOTEK AGRICULTURE POLSKA SP. Z O.O.<br>EUR_MNN_BRSNW_PL_3040<br>GEP<br>Unpublished                               | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 6.1/016<br>KCP 6.2/016<br>KCP 6.4.1/016<br>KCP 6.4.2/008<br>KCP 6.4.3/008 | Agnieszka Kukuła-Młynarczyk | 2008 | The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on Oilseed Rape quantity and quality<br>BIOTEK AGRICULTURE POLSKA SP. Z O.O.<br>(EUR_MNN_BRSNW_PL_3041<br>GEP<br>Unpublished                          | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 6.1/017<br>KCP 6.2/017<br>KCP 6.4.1/017                                   | Wojciech Cieřlicki          | 2009 | The influence of ASAHI SL (CAL97R01) and ALS08R369 on quantity and quality of winter rape yielding<br>Research and Education Center Gorzyń<br>EUR_MNN_BRSNW_PL_3286<br>GEP<br>Unpublished                              | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |

| Data point                                   | Author(s)                   | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed  | Owner                        |
|--|-----------------------------|------|--|-------------------------|--------------------------------|--|------------------------------|
| KCP 6.1/018<br>KCP 6.2/018<br>KCP 6.4.1/0118 | Agnieszka Kukula-Młynarczyk | 2009 | The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on winter Oilseed Rape quantity and quality<br>BIOTEK AGRICULTURE POLSKA SP. Z O.O.<br>EUR_MNN_BRSNW_PL_3287<br>GEP<br>Unpublished                            | N                       | Y                              | Data/study report never submitted before to <Poland>   | Asahi Chemical Europe s.r.o. |
| KCP 6.1/019<br>KCP 6.2/019<br>KCP 6.4.1/019  | Agnieszka Kukula-Młynarczyk | 2009 | The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on Winter Oilseed Rape quantity and quality<br>BIOTEK AGRICULTURE POLSKA SP. Z O.O.<br>EUR_MNN_BRSNW_PL_3288<br>GEP<br>Unpublished                            | N                       | Y                              | Data/study report submitted before to <Poland> for Asahi SL registration<br><br>Protection is claimed for Asahi Max data | Asahi Chemical Europe s.r.o. |
| KCP 6.1/020<br>KCP 6.2/020<br>KCP 6.4.1/020  | Agnieszka Kukula-Młynarczyk | 2009 | The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on Winter Oilseed Rape quantity and quality<br>BIOTEK AGRICULTURE POLSKA SP. Z O.O.<br>EUR_MNN_BRSNW_PL_3289<br>GEP<br>Unpublished                            | N                       | Y                              | Data/study report submitted before to <Poland> for Asahi SL registration<br><br>Protection is claimed for Asahi Max data | Asahi Chemical Europe s.r.o. |
| KCP 6.1/021<br>KCP 6.2/021<br>KCP 6.4.1/021  | Katarzyna Furman-Fratczak   | 2021 | Efficacy of ARY-0469-01 and ARY-0469-01 in winter wheat, 2021<br>AGRECO Sp. z o.o.<br>AE21-WHEAT-01<br>GEP<br>Unpublished  | N                       | Y                              | Data/study report never submitted before to <Poland>   | Asahi Chemical Europe s.r.o. |
| KCP 6.1/022<br>KCP 6.2/022<br>KCP 6.4.1/022  | Katarzyna Furman-Fratczak   | 2021 | Efficacy of ARY-0469-01 and ARY-0469-01 in winter wheat, 2021<br>AGRECO Sp. z o.o.<br>AE21-WHEAT-02<br>GEP<br>Unpublished  | N                       | Y                              | Data/study report never submitted before to <Poland>   | Asahi Chemical Europe s.r.o. |
| KCP 6.1/023<br>KCP 6.2/023<br>KCP 6.4.1/023  | Birgit Veckenstedt          | 2021 | Effect of ARY-0469-01 and ARY-0469-04 on the spring crop regeneration, tillering and supporting effect against lodging and on yield and quality in winter wheat<br>A&W FieldScreen GmbH<br>AE21-WHEAT-03<br>GEP<br>Unpublished | N                       | Y                              | Data/study report never submitted before to <Poland>   | Asahi Chemical Europe s.r.o. |

| Data point  | Author(s)          | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed          | Owner                        |
|---|--------------------|------|---|-------------------------|--------------------------------|--|------------------------------|
| KCP 6.1/024<br>KCP 6.2/024<br>KCP 6.4.1/024<br>KCP 6.4.5/001                  | Jan Ksiazkiewicz   | 2010 | Growth regulator / Quality of harvested product / winter wheat / GEP<br>INF, v.o.s., zkusebni pracoviiste Uhersky Ostroh<br>EUR_MNN_TRZAW_CZ_4103<br>GEP<br>Unpublished | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 6.1/025<br>KCP 6.2/025<br>KCP 6.4.1/025<br>KCP 6.4.5/002                  | Milena Bernardova  | 2010 | Growth regulator / efficacy, growth regulation effect / winter wheat / GEP<br>Zkusebni stanice Kluky<br>EUR_MNN_TRZAW_CZ_4104<br>GEP<br>Unpublished                     | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 6.1/026<br>KCP 6.2/026<br>KCP 6.4.1/026<br>KCP 6.4.5/003                  | Antonin Ruzicka    | 2010 | Growth regulator, winter wheat, GEP<br>Zkusebni stanice Rymarov s.r.o.<br>EUR_MNN_TRZAW_CZ_4105<br>GEP<br>Unpublished   | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 6.1/027<br>KCP 6.2/027<br>KCP 6.4.1/027<br>KCP 3.4.2/009<br>KCP 3.4.3/009 | Birgit Veckenstedt | 2020 | REGULATOR/WINTER WHEAT/ANTI-LODGING/EFFICACY/REGISTRATION<br>A&W FieldScreen GmbH<br>EUR_MNN_TRZAW_DE_4351<br>GEP<br>Unpublished  | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 6.1/028<br>KCP 6.2/028<br>KCP 6.4.1/028<br>KCP 6.4.2/010<br>KCP 6.4.3/010 | Birgit Veckenstedt | 2020 | REGULATOR/WINTER WHEAT/ANTI-LODGING/EFFICACY/REGISTRATION<br>A&W FieldScreen GmbH<br>EUR_MNN_TRZAW_DE_4352<br>GEP<br>Unpublished  | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 6.1/029<br>KCP 6.2/029<br>KCP 6.4.1/029<br>KCP 6.4.2/011<br>KCP 6.4.3/011 | Birgit Veckenstedt | 2020 | REGULATOR/WINTER WHEAT/ANTI-LODGING/EFFICACY/REGISTRATION<br>A&W FieldScreen GmbH<br>EUR_MNN_TRZAW_DE_4353<br>GEP<br>Unpublished  | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |

| Data point  | Author(s)                 | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed          | Owner                        |
|---|---------------------------|------|---|-------------------------|--------------------------------|--|------------------------------|
| KCP 6.1/033<br>KCP 6.2/033<br>KCP 6.4.1/033<br>KCP 6.4.2/015<br>KCP 6.4.3/015 | KATARZYNA FURMAN-FRATCZAK | 2011 | ARY-0469-04/REGULATOR/WINTER WHEAT/ANTI-LODGING/EFFICACY/REGISTRATION<br>BIOTEK AGRICULTURE POLSKA Sp. z o.o.<br>POL_MNN_TRZAW_4608<br>GEP<br>Unpublished   | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 6.1/034<br>KCP 6.2/034<br>KCP 6.4.1/034<br>KCP 6.4.2/016<br>KCP 6.4.3/016 | Krzysztof Wozniak         | 2011 | The evaluation of efficacy and selectivity of ARY-0469-04 on winter wheat<br>Biotek Agriculture Sp. z o.o.<br>POL_MNN_TRZAW_4609<br>GEP<br>Unpublished  | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| <b>Section 5</b>  |                           |      |   |                         |                                |  |                              |
| KCP 5.1.2/01  | Lien, T.P.                | 2008 | Development and Validation of an Analytical Method for Determination of the Content of Sodium 5-nitroguaiacolate, Sodium ortho-nitrophenolate and Sodium para-nitrophenolate in the Formulation ATONIK PLUS 1.8%<br>eurofins-GAB GmbH, Niefern, Germany<br>ALS Report No. S08-02059<br>GLP, Unpublished   | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 5.1.2/02  | Krainz, A                 | 2004 | Development and Validation of a Residue Analytical Method for Sodium 5-Nitroguaiacolate, Sodium o-Nitrophenolate and Sodium p-Nitrophenolate (as Active Ingredients in Atonik Formulated Product) in Tomato (Fruits), Sugar Beet (Roots and Tops with Leaves) and Oil Seed Rape<br>Report No 850917<br>RCC Ltd, Switzerland<br>GLP<br>Unpublished | N                       | N                              |  | Asahi Chemical Europe s.r.o. |
| KCP 5.1.2/03  | Tribolet R                | 2004 | Development and validation of a residue analytical method for sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate (as active ingredients in Atonik formulated product) in soil<br>Report No 815343<br>RCC Ltd, Switzerland<br>GLP<br>Unpublished   | N                       | N                              |  | Asahi Chemical Europe s.r.o. |

| Data point   | Author(s)                 | Year  | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed  | Owner                        |
|--------------|---------------------------|-------|--|-------------------------|--------------------------------|--|------------------------------|
| KCP 5.1.2/04 | Tribolet R                | 2004  | Development and Validation of a Residue Analytical Method for Sodium 5-Nitroguaiacolate, Sodium <i>o</i> -Nitrophenolate and Sodium <i>p</i> -Nitrophenolate (as active Ingredients in Atonik formulated Product) in Drinking, Ground and Surface Water<br>Report No 815321<br>RCC Ltd, Switzerland<br>GLP<br>Unpublished                                | N                       | N                              |  | Asahi Chemical Europe s.r.o. |
| KCP 5.1.2/05 | Krainz, A                 | 2004  | Development and Validation of a Residue Analytical Method for Sodium 5-Nitroguaiacolate, Sodium <i>o</i> -Nitrophenolate and Sodium <i>p</i> -Nitrophenolate (as active Ingredients in Atonik formulated Product) in Air<br>Report No 815332<br>RCC Ltd, Switzerland<br>GLP<br>Unpublished   | N                       | N                              |  | Asahi Chemical Europe s.r.o. |
| KCP 5.1.2/06 | Lefresne, S.              | 2013  | Validation of the analytical method for the determination of sodium 5-nitroguaiacolate, sodium <i>o</i> -nitrophenolate and sodium <i>p</i> -nitrophenolate residues in plants (strawberry, cucumber, split peas, sunflower seeds and hops)<br>GIRPA France<br>Report No. ARYST-VAL-13.01<br>GLP<br>Unpublished  | N                       | Y                              | Data/study report submitted before to <Poland> for Asahi SL registration<br><br>Lex to sunflower granted on 18 <sup>th</sup> December 2015 | Asahi Chemical Europe s.r.o. |
| KCP 5.1.2/07 | Maldonado Ribeiro Lopez N | 2005a | Independent Laboratory Validation of a residue analytical method for Na <i>o</i> -nitrophenolate, Na <i>p</i> -nitrophenolate and Na 5-nitroguaiacolate in tomato fruits samples.<br>Bioagri Laboratorios.<br>Final report PE-2254.034.076.03<br>GLP<br>Unpublished  | N                       | N                              |  | Asahi Chemical Europe s.r.o. |
| KCP 5.1.2/08 | Taoudi, M.                | 2016  | Independent Laboratory Validation study for study ARYST-VAL-13-1' Validation of the analytical method for the determination of sodium 5-nitroguaiacolate, sodium <i>o</i> -nitrophenolate and sodium <i>p</i> -nitrophenolate residues in plants (strawberry, cucumber, split peas, sunflower seeds and hops)<br>GIRPA France Report No. ARYST-VAL-13.1' | N                       | Y                              | Data/study report never submitted before to <Poland>   | Asahi Chemical Europe s.r.o. |

| Data point    | Author(s)                 | Year  | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed  | Owner                        |
|---------------|---------------------------|-------|--|----------------------|-----------------------------|--|------------------------------|
|               |                           |       | Battelle Ltd. UK Report No. MD/15/01<br>GLP<br>Unpublished   |                      |                             |  |                              |
| KCP 5.1.2/09  | Maldonado Ribeiro Lopez N | 2005b | Independent laboratory validation of a residue analytical method for sodium ortho-nitrophenolate, sodium para-nitrophenolate and 5-nitroguaiacolate in tomato fruits samples<br>Bioagri Laboratorios.<br>Final report PE-2254.034.077.03<br>GLP<br>Unpublished   | N                    | N                           |  | Asahi Chemical Europe s.r.o. |
| KCP 5.1.2/10  | Egron, C.                 | 2014  | Independent Laboratory Validation (ILV) of the analytical method RCC Study number 815343 for the determination of sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in soil<br>GIRPA France Report No. B13-A1-NOP-31<br>GLP<br>Unpublished  | N                    | Y                           | Data/study report submitted before to <Poland> for Asahi SL registration<br><br>Lex to sunflower granted on 18 <sup>th</sup> December 2015 | Asahi Chemical Europe s.r.o. |
| KCP 5.1.2/11  | Lefresne, S.              | 2014  | Independent Laboratory Validation (ILV) of the analytical method RCC Study number 815321 for the determination of sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in surface water<br>GIRPA France Report No. B13-A1-NOP-32<br>GLP<br>Unpublished   | N                    | Y                           | Data/study report submitted before to <Poland> for Asahi SL registration<br><br>Lex to sunflower granted on 18 <sup>th</sup> December 2015 | Asahi Chemical Europe s.r.o. |
| CA 4.2 (d)/01 | Guserle, R.               | 2020  | Development and validation of a method for the determination of 5-nitroguaiacol, ortho-nitrophenol and para-nitrophenol expressed as sodium 5-nitroguaiacolate, sodium ortho-nitrophenolate and sodium para-nitrophenolate, respectively, in blood, urine and meat matrix<br>EAG Laboratories GmbH, Ulm, Germany<br>Laboratory report P 5263 G (433-001)<br>GLP<br>Unpublished | N                    | Y                           | Data/study report never submitted before to <Poland>   | Asahi Chemical Europe s.r.o. |
| KCP 5.2       | Kugel, D.                 | 2020  | Determination of Residues of 5-Nitroguaiacol, o-Nitrophenol and p-Nitrophenol in Nectar after four Applications of ATONIK containing Sodium 5-Nitroguaiacolate, Sodium o-Nitrophenolate and Sodium p-Nitrophenolate in <i>Phacelia tanacetifolia</i> at 4 Sites in Central and Southern Europe in 2019. Company Report No S19-   | N                    | Y                           | Data/study report never submitted before to <Poland>   | Asahi Chemical Europe r.s.o. |

| Data point       | Author(s)     | Year  | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed          | Owner                        |
|------------------|---------------|-------|--|-------------------------|--------------------------------|--|------------------------------|
|                  |               |       | 03993 (634-96002)<br>Eurofins Agrosience Services Ecotox GmbH, Niefern-Öschelbronn, Germany<br>GLP, Unpublished  |                         |                                |  |                              |
| <b>Section 6</b> |               |       |  |                         |                                |  |                              |
| KCP 7.1.1/02     | xxxxxx        | 2009a | Acute oral toxicity (acute toxic class method) with Atonik plus (1.8%)<br>xxxxxx   | Y                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 7.1.2/03     | xxxxxx        | 2009b | Acute dermal toxicity (limit) with Atonik plus (1.8%)<br>xxxxxx  | Y                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 7.1.3/02     | xxxxxx        | 2009  | Atonik Plus (1.8%): Acute inhalation toxicity study in rats<br>xxxxxx  | Y                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 7.1.4/02     | xxxxxx        | 2009c | Acute dermal irritation/corrosion with Atonik Plus (1.8%)<br>xxxxxx  | Y                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 7.1.5/02     | xxxxxx        | 2009d | Acute eye irritation/corrosion with Atonik Plus (1.8%)<br>xxxxxx   | Y                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 7.1.6/01     | xxxxxx        | 2010  | Test of Sensitisation (Local Lymph Node Assay – LLNA) with ATONIK PLUS (1.8%)<br>xxxxxx  | Y                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 7.3.1/01     | Craig BSc, S. | 2012  | Sodium p-nitrophenolate: The <i>In Vitro</i> Percutaneous absorption of Radiolabelled Pesticide in the Concentrate and a Single In-Use Spray Dilution Through Human Skin.<br>Charles River<br>Test Facility Study N° 791509, Report no. 33044<br>GPL: Yes<br>Unpublished | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| <b>Section 7</b> |               |       |  |                         |                                |  |                              |
| KCA 6.3.1-1      | Diehl, m.     | 2006  | Determination of residues of sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in oil seed rape (rac seeds) following two treatments with atonik in northern europe, 2005<br>Company report no a06028                                       | N                       | N                              |  | Asahi Chemical Europe s.r.o. |



| Data point  | Author(s)    | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed          | Owner                              |
|-------------|--------------|------|--|-------------------------|--------------------------------|--|------------------------------------|
|             |              |      | Rcc ltd<br>Glp<br>Unpublished  |                         |                                |  |                                    |
| KCA 6.3.1-2 | Oxspring, s. | 2010 | Residues of sodium 5-nitroguaiacolate, sodium ortho-nitrophenolate and sodium para-nitrophenolate after two applications of atonik in oilseed rape at 1 site in northern europe 2008<br>Company report no s08-01067<br>Eurofins<br>Glp<br>Unpublished  | N                       | N                              |  | Asahi<br>Chemical<br>Europe s.r.o. |
| KCA 6.3.1-3 | White, t.    | 2019 | Atonik - study to generate specimens of oilseed rape following two applications of atonik. Three trials in northern europe during 2018 (final report amendment 1)<br>Company report no s18-05054<br>Eurofins<br>Glp<br>Unpublished   | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi<br>Chemical<br>Europe s.r.o. |
| KCA 6.3.1-4 | Guserle, r.  | 2019 | Analysis of residues of sodium 5-nitroguaiacolate, sodium ortho-nitrophenolate and sodium para-nitrophenolate in field samples originating from a field study performed under eas study code s18-05054 with two applications of atonik in oilseed rape at three trials in northern europe during 2018<br>Company report no s18-05054 / laboratory report: p 4928 g<br>Eurofins<br>Glp<br>Unpublished | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi<br>Chemical<br>Europe s.r.o. |
| KCA 6.3.1-5 | White, t.    | 2020 | Atonik - study to generate samples of oilseed rape following two applications of atonik. One trial in northern europe during 2019<br>Company report no s19-00203<br>Eurofins<br>Glp<br>Unpublished   | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi<br>Chemical<br>Europe s.r.o. |
| KCA 6.3.1-6 | Guserle, r.  | 2020 | Analysis of residues of sodium 5-nitroguaiacolate, sodium ortho-nitrophenolate and sodium para-nitrophenolate in field samples originating from a field study performed under eas study code s19-00203 with two applications of atonik in oilseed rape at one trial in northern europe during 2019   | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi<br>Chemical<br>Europe s.r.o. |

| Data point   | Author(s)   | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed          | Owner                        |
|--------------|-------------|------|---|-------------------------|--------------------------------|--|------------------------------|
|              |             |      | Company report no s19-00203/ laboratory report: p 5295 g<br>Eurofins<br>Glp<br>Unpublished  |                         |                                |  |                              |
| KCA 6.3.1-7  | Diehl, m.   | 2006 | Determination of residues of sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in cereals (rac straw and grain) following two treatments with atonik in northern europe 2005<br>Company report no a05995<br>Rcc ltd<br>Glp<br>Unpublished  | N                       | N                              |  | Asahi Chemical Europe s.r.o. |
| KCA 6.3.1-8  | White, t.   | 2018 | Atonik – study to generate specimens of winter wheat following two applications of atonik. Three trials in northern europe during 2018<br>Company report no s18-05052<br>Eurofins<br>Glp<br>Unpublished   | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCA 6.3.1-9  | Guserle, r. | 2019 | Analysis of residues of sodium 5-nitroguaiacolate, sodium ortho-nitrophenolate and sodium para-nitrophenolate in field samples originating from a field study performed under eas study code s18-05052 with two applications of atonik in winter wheat at 3 trials in northern europe during 2018<br>Company report no s18-05052/ laboratory report: p 4930 g<br>Eurofins<br>Glp<br>Unpublished | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCA 6.3.1-10 | White, t.   | 2020 | Atonik – study to generate specimens of winter wheat following two applications of atonik. One trial in northern europe during 2019<br>Company report no s19-00202<br>Eurofins<br>Glp<br>Unpublished  | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCA 6.3.1-11 | Guserle, r. | 2020 | Analysis of residues of sodium 5-nitroguaiacolate, sodium ortho-nitrophenolate and sodium para-nitrophenolate in field samples originating from a field study performed under eas study code s19-00202 with two applications of atonik in winter wheat at 1 trial in  | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |

| Data point       | Author(s)    | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed          | Owner                        |
|------------------|--------------|------|--|-------------------------|--------------------------------|--|------------------------------|
|                  |              |      | northern europe during 2020<br>Company report no s19-00202/ laboratory report: p 5296 g<br>Eurofins<br>Glp<br>Unpublished  |                         |                                |  |                              |
| KCA 6.3.1-12     | Diehl, m.    | 2006 | Determination of residues of sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in sugar beet (rac roots and leaves) following four treatments with atonik in northern europe, 2005<br>Company report no a05973<br>Rcc ltd<br>Glp<br>Unpublished   | N                       | N                              |  | Asahi Chemical Europe s.r.o. |
| KCA 6.3.1-13     | Oxspring, s. | 2014 | Atonik - determination of residues of sodium 5-nitroguaiacolate, sodium ortho-nitrophenolate and sodium para-nitrophenolate after four applications of atonik in sugar beet at 1 site in northern europe 2013<br>Company report no s12-04698<br>Eurofins<br>Glp<br>Unpublished   | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCA 6.3.1-14     | White, t.    | 2020 | Atonik - determination of residues of sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in sugar beet following three applications of atonik under field conditions - three trials in northern europe during 2019<br>Company report no s19-04275<br>Eurofins<br>Glp<br>Unpublished  | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCA 6.10, 6.10.1 | Kugel, D.    | 2020 | Determination of Residues of 5-Nitroguaiacol, o-Nitrophenol and p-Nitrophenol in Nectar after four Applications of ATONIK containing Sodium 5-Nitroguaiacolate, Sodium o-Nitrophenolate and Sodium p-Nitrophenolate in <i>Phacelia tanacetifolia</i> at 4 Sites in Central and Southern Europe in 2019.<br>Report No.: S19-03993 (634-96002)<br>Eurofins Agrosience Services Ecotox GmbH, Niefern-Öschelbronn, Germany | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |

| Data point       | Author(s)    | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed  | Owner                        |
|------------------|--------------|------|---|-------------------------|--------------------------------|--|------------------------------|
|                  |              |      | GLP, unpublished  |                         |                                |  |                              |
| <b>Section 8</b> |              |      |   |                         |                                |  |                              |
| Kcp 9.1.3/01     | Garitano, M. | 2022 | ASAHI MAX: Predicted Environmental Concentrations in soil (PECs)<br>Devreg Consulta SLU, Report No. DR20221020<br>Non GLP / Non GEP (modelling calculation)<br>Unpublished  | N                       | N                              |  | Asahi Chemical Europe s.r.o. |
| Kcp 9.2.4/01     | Garitano, M. | 2022 | ASAHI MAX: Predicted Environmental Concentrations in groundwater (PECgw)<br>Devreg Consulta SLU, Report No. DR20221021<br>Non GLP / Non GEP (modelling calculation)<br>Unpublished  | N                       | N                              |  | Asahi Chemical Europe s.r.o. |
| Kcp 9.2.5/01     | Garitano, M. | 2022 | ASAHI MAX: Predicted Environmental Concentrations in surface water (PECsw) and sediment (PECsed)<br>Devreg Consulta SLU, Report No. DR20221022<br>Non GLP / Non GEP (modelling calculation)<br>Unpublished  | N                       | N                              |  | Asahi Chemical Europe s.r.o. |
| <b>Section 9</b> |              |      |   |                         |                                |  |                              |
| KCP 10.2.1/01    | Hasler, T.   | 2011 | ATONIK: Growth inhibition test with <i>Anabaena flos-aquae</i> under static conditions.<br>Report No. 1094.005.430<br>Arysta Life Science S.A.S<br>GLP, Unpublished   | N                       | Y                              | Data/study report submitted before to <Poland> for Asahi SL registration<br><br>Lex to sunflower granted on 18 <sup>th</sup> December 2015 | Asahi Chemical Europe s.r.o. |
| KCP 10.2.1/02    | Biester, M.  | 2011 | ATONIK: Growth inhibition test with the freshwater duckweed ( <i>Lemna gibba</i> ) under semi static conditions.<br>Report No 1094005410<br>Arysta Life Science S.A.S<br>GLP, Unpublished   | N                       | Y                              | Data/study report submitted before to <Poland> for Asahi SL registration<br><br>Lex to sunflower granted on 18 <sup>th</sup> December 2015 | Asahi Chemical Europe s.r.o. |
| KCP 10.3.1/01    | Harkin, S.   | 2020 | ATONIK: 10 day chronic oral toxicity test (repeated doce) for adult honeybees ( <i>Apis mellifera</i> L.) (Amended Final Report)<br>Report No.: FR/000623<br>Fera Science Ltd., Centre for Chemical Safety & Stewardship, Sand Hutton, United Kingdom<br>GLP, Unpublished | N                       | Y                              | Data/study report never submitted before to <Poland>   | Asahi Chemical Europe s.r.o. |

| Data point        | Author(s)    | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed          | Owner                        |
|-------------------|--------------|------|--|-------------------------|--------------------------------|--|------------------------------|
| KCP 10.3.1/02     | Harkin, S.   | 2016 | ATONIK: in vitro 8 day toxicity test – repeated exposure to larval stage honeybee ( <i>Apis mellifera</i> L.)<br>Report No.: FR/000624<br>Fera Science Ltd., Centre for Chemical Safety & Stewardship, Sand Hutton, United Kingdom<br>GLP, Unpublished   | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 10.3.1/03     | Couture, E.  | 2020 | AMP (ATONIK MUP POWDER) – a laboratory study to determine the chronic effects on the honey bee <i>Apis mellifera</i> L. (Hymenoptera: Apidae) 22-day larval toxicity test with repeated exposure<br>Report No.: 516SRFR18C05<br>SynTech Research France SAS, La Chapelle de Guinchay, France<br>GLP, Unpublished | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| <b>Section 10</b> |              |      |  |                         |                                |  |                              |
| Kcp 9.1.3/01      | Garitano, M. | 2022 | ASAHI MAX: Predicted Environmental Concentrations in soil (PECs)<br>Devreg Consulta SLU, Report No. DR20221020<br>Non GLP / Non GEP (modelling calculation)<br>Unpublished   | N                       | N                              |  | Asahi Chemical Europe s.r.o. |

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

| Data point | Author(s)  | Year  | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed | Owner                        |
|------------|------------|-------|---|-------------------------|--------------------------------|---|------------------------------|
| KCP 4.4    | Anon.      | 2006a | Série Standard AgroChem 500ml<br>Polimoon, France<br>Report No. Not stated<br>Not GLP, Unpublished  | N                       | N                              |   | Asahi Chemical Europe s.r.o. |
|            | Picque, B. | 2007a | Approval certificate of combination packaging N° H090922 / 2, Ministère de l'Ecologie, du Développement et de l'Aménagement durables<br>LNE<br>Certificate No.: H090922/2<br>Not GLP, Unpublished | N                       | N                              |   | Asahi Chemical Europe s.r.o. |

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title<br/>Company Report No.<br/>Source (where different from company)<br/>GLP or GEP status<br/>Published or not</b>  | <b>Vertebrate study<br/>Y/N</b> | <b>Data protection claimed<br/>Y/N</b> | <b>Justification if data protection is claimed</b> | <b>Owner</b>                 |
|-------------------|------------------|-------------|---|---------------------------------|--|--|------------------------------|
|                   | Anon.            | 2006b       | Certificat d'agrément de type d'emballage, Ministère de l'Équipement, des Transports, du Logement, du Tourisme et de la Mer<br>BVT<br>Report No.: 6877<br>Not GLP, Unpublished                    | N                               | N                                      |  | Asahi Chemical Europe s.r.o. |
|                   | Anon.            | 2006c       | Série Standard AgroChem 1 Litre, Polimoon France<br>Report No. Not stated<br>Not GLP, Unpublished   | N                               | N                                      |  | Asahi Chemical Europe s.r.o. |
|                   | Marcel, H.       | 2008        | Approval certificate of combination packaging N° H090922 / 2, Ministère de l'Écologie, du Développement et de l'Aménagement durables<br>Certificate No.: H111030/5<br>Not GLP, Unpublished        | N                               | N                                      |  | Asahi Chemical Europe s.r.o. |
|                   | Anon.            | 2005        | Certificat d'agrément de type d'emballage, Ministère de l'Équipement, des Transports, du Logement, du Tourisme et de la Mer<br>BVT Report No.: 6722<br>Not GLP, Unpublished                       | N                               | N                                      |  | Asahi Chemical Europe s.r.o. |
|                   | Anon.            | 2008a       | 5L Ag-Chem Chesapeake Plastics<br>Report No.: SPEC 5AO-63 GB<br>Not GLP, Unpublished  | N                               | N                                      |  | Asahi Chemical Europe s.r.o. |
|                   | Pique, B.        | 2007b       | Approval certificate of combination packaging N° H090922 / 2, Ministère de l'Écologie, du Développement et de l'Aménagement durables<br>LNE<br>Certificate No.: H061505/4<br>Not GLP, Unpublished | N                               | N                                      |  | Asahi Chemical Europe s.r.o. |
|                   | Anon.            | 2004a       | Certificat d'agrément de type d'emballage, Ministère de l'Équipement, des Transports, du Logement, du Tourisme et de la Mer<br>BVT<br>Report No.: 6434<br>Not GLP, Unpublished                    | N                               | N                                      |  | Asahi Chemical Europe s.r.o. |

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title<br/>Company Report No.<br/>Source (where different from company)<br/>GLP or GEP status<br/>Published or not</b>  | <b>Vertebrate study<br/>Y/N</b> | <b>Data protection claimed<br/>Y/N</b> | <b>Justification if data protection is claimed</b> | <b>Owner</b>                       |
|-------------------|------------------|-------------|---|---------------------------------|--|--|------------------------------------|
|                   | Anon.            | 2009        | 10L Ag-Chem<br>Chesapeake Plastics<br>Report No.: SPEC 10AO GB<br>Not GLP, Unpublished  | N                               | N                                      |  | Asahi<br>Chemical<br>Europe s.r.o. |
|                   | Anon.            | 2004b       | 10L Ag-Chem<br>Boxmore Emballage<br>Report No.: SPEC 10AO FR<br>Not GLP, Unpublished  | N                               | N                                      |  | Asahi<br>Chemical<br>Europe s.r.o. |
|                   | Fragu, E.        | 2004        | Certificat d'agrément de type d'emballage, Ministère de l'Équipement, des Transports, du Logement, du Tourisme et de la Mer<br>BVT<br>Report No. : 6116<br>Not GLP, Unpublished   | N                               | N                                      |  | Asahi<br>Chemical<br>Europe s.r.o. |
|                   | Fragu, E.        | 2005        | Certificat d'agrément de type d'emballage, Ministère de l'Équipement, des Transports, du Logement, du Tourisme et de la Mer<br>BVT<br>Report No. : 4238<br>Not GLP, Unpublished   | N                               | N                                      |  | Asahi<br>Chemical<br>Europe s.r.o. |
|                   | Anon.            | 2008b       | 20L Stackable<br>Chesapeake Plastics<br>Report No.: SPEC 20G0 GB<br>Not GLP, Unpublished  | N                               | N                                      |  | Asahi<br>Chemical<br>Europe s.r.o. |
|                   | Anon.            | 2008c       | Certificat d'agrément de type d'emballage, Ministère de l'Écologie, du Développement et de l'Aménagement durables<br>BVT Report No.: 7384<br>Not GLP, Unpublished   | N                               | N                                      |  | Asahi<br>Chemical<br>Europe s.r.o. |
| KCP 5.1.2/02      | Krainz, A        | 2004        | Development and Validation of a Residue Analytical Method for Sodium 5-Nitroguaiacolate, Sodium o-Nitrophenolate and Sodium p-Nitrophenolate (as Active Ingredients in Atonik Formulated Product) in Tomato (Fruits), Sugar Beet (Roots and Tops with Leaves) and Oil Seed Rape<br>Report No 850917<br>RCC Ltd, Switzerland<br>GLP<br>Unpublished | N                               | N                                      |  | Asahi<br>Chemical<br>Europe s.r.o. |

| Data point   | Author(s)                 | Year  | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed | Owner                        |
|--------------|---------------------------|-------|---|-------------------------|--------------------------------|---|------------------------------|
| KCP 5.1.2/03 | Tribolet R                | 2004  | Development and validation of a residue analytical method for sodium 5-nitroguaiacolate, sodium <i>o</i> -nitrophenolate and sodium <i>p</i> -nitrophenolate (as active ingredients in Atonik formulated product) in soil<br>Report No 815343<br>RCC Ltd, Switzerland<br>GLP<br>Unpublished                               | N                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 5.1.2/04 | Tribolet R                | 2004  | Development and Validation of a Residue Analytical Method for Sodium 5-Nitroguaiacolate, Sodium <i>o</i> -Nitrophenolate and Sodium <i>p</i> -Nitrophenolate (as active Ingredients in Atonik formulated Product) in Drinking, Ground and Surface Water<br>Report No 815321<br>RCC Ltd, Switzerland<br>GLP<br>Unpublished | N                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 5.1.2/05 | Krainz, A                 | 2004  | Development and Validation of a Residue Analytical Method for Sodium 5-Nitroguaiacolate, Sodium <i>o</i> -Nitrophenolate and Sodium <i>p</i> -Nitrophenolate (as active Ingredients in Atonik formulated Product) in Air<br>Report No 815332<br>RCC Ltd, Switzerland<br>GLP<br>Unpublished                                | N                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 5.1.2/07 | Maldonado Ribeiro Lopez N | 2005a | Independent Laboratory Validation of a residue analytical method for Na <i>o</i> -nitrophenolate, Na <i>p</i> -nitrophenolate and Na 5-nitroguaiacolate in tomato fruits samples.<br>Bioagri Laboratorios.<br>Final report PE-2254.034.076.03<br>GLP<br>Unpublished   | N                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 5.1.2/09 | Maldonado Ribeiro Lopez N | 2005b | Independent laboratory validation of a residue analytical method for sodium ortho-nitrophenolate, sodium para-nitrophenolate and 5-nitroguaiacolate in tomato fruits samples<br>Bioagri Laboratorios.<br>Final report PE-2254.034.077.03<br>GLP   | N                       | N                              |   | Asahi Chemical Europe s.r.o. |



| Data point   | Author(s) | Year  | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed | Owner                        |
|--------------|-----------|-------|--|-------------------------|--------------------------------|---|------------------------------|
|              |           |       | Unpublished  |                         |                                |   |                              |
| KCP 7.1.1/01 | XXXXXX    | 1990  | Acute Exposure Oral Toxicity in Rats (Atonik)<br>Pharmakon Research International. Inc.. Waverly. Pennsylvania 1841. USA<br>PH 402-AH-004-90<br>GLP. not published   | Y                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 7.1.2/01 | XXXXXX    | 1985a | Acute dermal toxicity in rats (Atonik).<br>Huntingdon Research Centre Ltd.. P.O. Box 2. Huntingdon. Cambridgeshire. PE18 6ES. England<br>HRC Report No 85433D/ ACM 11/AC<br>GLP. not published                             | Y                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 7.1.2/02 | XXXXXX    | 1985b | Acute dermal toxicity in rabbits (Atonik).<br>Huntingdon Research Centre Ltd.. P.O. Box 2. Huntingdon. Cambridgeshire. PE18 6ES. England<br>HRC Report No 85434D/ ACM 12/AC<br>GLP. not published                          | Y                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 7.1.3/01 | XXXXXX    | 1990  | Atonik solution: Acute Inhalation Toxicity Study in Rats 4-hour Exposure<br>Huntingdon Research Centre Ltd.. P.O. Box 2. Huntingdon. Cambridgeshire. PE18 6ES. England<br>HRC Report No ACM 14/85584<br>GLP. not published | Y                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 7.1.4/01 | XXXXXX    | 1984a | Irritant effects on rabbit skin (Atonik)<br>Huntingdon Research Centre Ltd.. P.O. Box 2. Huntingdon. Cambridgeshire. PE18 6ES. England<br>HRC Report No 84642D/ACM 7/SE<br>GLP. not published                              | Y                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCP 7.1.5/01 | XXXXXX    | 1984b | Irritant effects on the rabbit eye (Atonik)<br>Huntingdon Research Centre Ltd.. P.O. Box 2. Huntingdon. Cambridgeshire. PE18 6ES. England<br>HRC Report No 84696D/ACM 8/SE(G)<br>GLP. not published                        | Y                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCA 6.2.1-1  | Diehl M   | 2004  | 14C-ATONIK: Plant metabolism in sugar beet.<br>RCC Ltd., Report No: 815433<br>GLP<br>Unpublished   | N                       | N                              |   | Asahi Chemical Europe s.r.o. |

| Data point  | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed | Owner                        |
|-------------|-----------|------|---|-------------------------|--------------------------------|---|------------------------------|
| KCA 6.2.1-2 | Diehl M   | 2004 | 14C-ATONIK: Plant metabolism in tomato.<br>RCC Ltd., Report No: 815444<br>GLP<br>Unpublished                  | N                       | N                              |   | Asahi Chemical Europe s.r.o. |
| KCA 6.2.1-3 | Diehl M   | 2004 | 14C-ATONIK: Plant metabolism in rape.<br>RCC Ltd., Report No: 815455<br>GLP<br>Unpublished                    | N                       | N                              |   | Asahi Chemical Europe s.r.o. |

**List of data submitted by the applicant and not relied on**

| Data point  | Author(s)         | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Data protection claimed<br>Y/N | Justification if data protection is claimed          | Owner                        |
|---|-------------------|------|--|-------------------------|--------------------------------|--|------------------------------|
| <b>Section 3</b>  |                   |      |  |                         |                                |  |                              |
| KCP 6.1/030<br>KCP 6.2/030<br>KCP 6.4.1/030<br>KCP 6.4.2/012<br>KCP 6.4.3/012 | Yannis TALLOT     | 2011 | Essai efficacité contre la verse en culture de blé tendre Produit testé : ARY-0469-04<br>SARL PHYLIAE<br>EUR_MNN_TRZAW_FR_4266<br>GEP<br>Unpublished | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 6.1/031<br>KCP 6.2/031<br>KCP 6.4.1/031<br>KCP 6.4.2/013<br>KCP 6.4.3/013 | Yannis TALLOT     | 2011 | GROWTH REGULATOR / LODGING OF CEREALS, WINTER WHEAT, 2011<br>SARL PHYLIAE<br>EUR_MNN_TRZAW_FR_4267<br>GEP<br>Unpublished                             | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |
| KCP 6.1/032<br>KCP 6.2/032<br>KCP 6.4.1/032<br>KCP                            | Jean-Pierre Rivet | 2011 | Essai efficacité contre la verse en culture de blé tendre Produit testé : ARY-0469-04<br>SARL PHYLIAE<br>EUR_MNN_TRZAW_FR_4268                       | N                       | Y                              | Data/study report never submitted before to <Poland> | Asahi Chemical Europe s.r.o. |

| <b>Data point</b>             | <b>Author(s)</b> | <b>Year</b> | <b>Title</b><br><b>Company Report No.</b><br><b>Source (where different from company)</b><br><b>GLP or GEP status</b><br><b>Published or not</b> | <b>Vertebrate study</b><br><b>Y/N</b> | <b>Data protection claimed</b><br><b>Y/N</b> | <b>Justification if data protection is claimed</b> | <b>Owner</b> |
|-------------------------------|------------------|-------------|--|---------------------------------------|--|--|--------------|
| 6.4.2/014<br>KCP<br>6.4.3/014 |                  |             | GEP<br>Unpublished   |                                       |  |  |              |

**List of data relied on and not submitted by the applicant but necessary for evaluation**

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title</b><br><b>Company Report No.</b><br><b>Source (where different from company)</b><br><b>GLP or GEP status</b><br><b>Published or not</b> | <b>Vertebrate study</b><br><b>Y/N</b> | <b>Data protection claimed</b><br><b>Y/N</b> | <b>Justification if data protection is claimed</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--|---------------------------------------|--|--|--------------|
| -                 | -                | -           | -  | -                                     | -  | -  | -            |