Appendix to:
EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance zoxamide. EFSA Journal 2017;15(9):4980, 79 pp. doi:10.2903/j.efsa.2017.4980
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Appendix A – List of end points for the active substance and the representative formulation

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

| Active substance (ISO Common Name) | Zoxamide |
|-----------------------------------|----------|
| Function (e.g. fungicide)         | Fungicide|
| Rapporteur Member State           | Latvia   |
| Co-rapporteur Member State        | France   |

Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

| Chemical name (IUPAC)             | (RS)-3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-p-toluidine |
| Chemical name (CA)                | 3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide |
| CIPAC No                          | 640 |
| CAS No                           | 156052-68-5 |
| EC No (EINECS or ELINCS)          | Not allocated |
| FAO Specification (including year of publication) | A FAO specification has not yet been established. |
| Minimum purity of the active substance as manufactured | 953 g/kg |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | Open |
| Molecular formula                 | C_{14}H_{16}NO_{2}Cl_{3} |
| Molar mass                        | 336.65 g/mol |
| Structural formula                | ![Structural formula image] |
### Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

| Property                                             | Value/Description                                                                 |
|------------------------------------------------------|-----------------------------------------------------------------------------------|
| Melting point (state purity)                         | 159.5 – 161 °C (97.7%)                                                           |
| Boiling point (state purity)                         | Not determined, as decomposition begins at the melting point.                      |
| Temperature of decomposition (state purity)          | Irreversible chemical decomposition occurs at the melting point. (97.7%)          |
| Appearance (state purity)                            | Lumpy white powder (98.8%)                                                       |
| Vapour pressure (state temperature, state purity)    | <1.3 x 10^{-5} Pa at 25, 35 and 45 °C (98.8%)                                     |
| Henry’s law constant (state temperature)             | <6.59 x 10^{-3} Pa m^3 mol^{-1} (20 to 25 °C)                                    |
| Solubility in water (state temperature, state purity and pH) | 0.681 ± 0.017 mg/L at 20 °C (98.7%)                                               |
| Zoxamide does not protonate or ionise at pH values between 3 and 11. |
| Solubility in organic solvents (state temperature, state purity) | ethyl acetate: 20.0 g/L at 20°C (97.7%)                                             |
| acetone: 55.7 g/L at 20°C (97.7%)                     |
| xylene: 1.56 g/L at 20°C (97.7%)                       |
| 1-octanol: 6.49 g/L at 20°C (97.7%)                    |
| heptane: 0.038 g/L at 20°C (97.7%)                     |
| 1,2-dichloroethane: 12.5 g/L at 20°C (97.7%)          |
| Surface tension (state concentration and temperature, state purity) | Not determined, as solubility in water is < 1 mg/L.                             |
| Partition coefficient (state temperature, pH and purity) | log Pow = 3.76 ± 0.04 (98.7%)                                                   |
| Zoxamide contains no acid or base functionality - Kow is not dependent on pH. |
| Dissociation constant (state purity)                  | Does not dissociate. (98.8%)                                                      |
| UV/VIS absorption (max.) incl. \( \varepsilon \) (state purity, pH) |                                                                  |
| pH | Absorbance \( \lambda \) (nm) | Molar extinction coefficient (\( \varepsilon \)) | Bandwidth |
|-----|-----------------------------|---------------------------------|-----------|
| neutral | 241.2 | 10034 | 36 |
| acid | 241.4 | 11549 | 40 |
| alkaline | 244.8 | 13300 | 40 |
| neutral | 212.0 | 46330 | 20 |
| acid | 212.4 | 49596 | 20 |
| alkaline | 218.2 | 29899 | 16 |
| Flammability (state purity)                          | Not flammable or auto-flammable. (97.7%)                                          |
| Explosive properties (state purity)                  | Not explosive (97.7%)                                                            |
| Oxidising properties (state purity)                  | Not oxidising (97.7%)                                                             |
## Summary of representative uses evaluated, for which all risk assessments needed to be completed
(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

| Crop and/or situation (a) | Member State or Country (b) | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|--------------------------|-----------------------------|--------------|-------------|---------------------------------|-------------|------------|------------------------------|------------|---------|
| Grapes (Wine, Table)     | CEU, SEU                    | Zoxium 240 SC | F           | grape downy mildew *Plasmodara viticola* | SC 240 g/L | BBCH 15-79 | 0.018 kg a.s./ha | 28 |         |
| Potato                   | NEU, CEU, SEU               | Zoxium 240 SC | F           | potato late blight *Phytophthora infestans* | SC 240 g/L | BBCH 20-80 | 0.018 kg a.s./ha | 7 |         |

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) kg/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).

(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of applications possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha

(m) PHI - minimum pre-harvest interval
Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment

Regulation (EC) N° 1107/2009 Article 8.1(g))

Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses

| Crop and/or situation (a) | Member State or Country | Product name | F or G or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|--------------------------|-------------------------|--------------|----------------|---------------------------------------|-------------|------------|-------------------------------|----------------|---------|
|                          |                         |              |                |                                       | Type (d-f)  | Conc. a.s. (i) | method kind (f-h) | range of growth stages & season (j) | number min-max (k) | Interval between application (min) | kg a.s. /L.min-max (l) | Water L/ha min-max (l) | kg a.s./ha min-max (l) |                |
|                          |                         |              |                |                                       |             |             |                  |                                  |                    |                        |                      |                    |                    |                |
| MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009) | Not Applicable |

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval
Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

|   |   |   |   |
|---|---|---|---|
|   |   |   |   |

The active ingredient acts against fungus from the class of Oomycetes, especially against downy mildews (e.g. *Phytophtora infestans*). It works protective and needs to be applied before the disease attack.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

|   |   |   |
|---|---|---|
|   |   |   |

No adverse effects on treated crops have been observed. Zoxamide based products have been registered in many EU countries based on detailed national assessments of the efficacy package. More detailed consideration will be fully assessed in the context of subsequent applications for products authorisation.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

|   |   |   |
|---|---|---|
|   |   |   |

No undesirable or unintended side-effects have ever been reported or observed. Zoxamide based products have been registered in many EU countries based on detailed national assessments of the efficacy package. More detailed consideration will be fully assessed in the context of subsequent applications for products authorisation.

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

| Activity against target organism |
|---------------------------------|
| RH -141455 | RH-24549 | RH-163353 | RH-127450 |
| No | Not applicable, PEC<sub>GW</sub> << 0.1 μg/L |
Methods of Analysis

**Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)**

| Method Type                                | Technique Details                                                                 |
|--------------------------------------------|-----------------------------------------------------------------------------------|
| Technical a.s. (analytical technique)       | Reversed-phase HPLC with UV detection                                             |
| Impurities in technical a.s. (analytical technique) | Reversed-phase HPLC with UV detection, For some more volatile impurities GC with FID detection. |
| Plant protection product (analytical technique) | Reversed-phase HPLC with UV detection                                             |

**Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)**

**Residue definitions for monitoring purposes**

| Food Type                           | Residue Details                                                                 |
|-------------------------------------|---------------------------------------------------------------------------------|
| Food of plant origin                | Zoxamide (fruit crops and pulses and oilseed) sum of metabolites RH-141455 and RH-141452 (root crops) |
| Food of animal origin               | Open                                                                            |
| Soil                                | At least zoxamide but open regarding metabolites RH-163353 and RH-141455        |
| Sediment                            | At least zoxamide but open regarding metabolites RH-127450 and RH-163353        |
| Water surface                       | At least zoxamide but open regarding RH-127450, RH-24549, RH-163353 & RH-141455 |
| drinking/ground                     | At least zoxamide but open regarding RH -141455                                |
| Air                                 | Zoxamide                                                                        |
| Body fluids and tissues             | Zoxamide                                                                        |

**Monitoring/Enforcement methods**

| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | Zoxamide in potato (tuber, chips and flakes), grapes (berries, juice, wine and raisins), lettuce, dry bean and oilseed rape seed: QuEChERS multi-residue method, LC-MS/MS. LOQ: 0.01 mg/kg ILV: Potato tuber, grape vine and lettuce – LOQ 0.01 mg/kg RH-141455 and RH-141452 in potato: LC-MS/MS LOQ: 0.01 mg/kg in potato tubers and 0.05 mg/kg in potato chips and flakes for both metabolites ILV: data gap |
|------------------------------------------|----------------------------------------------------------------------------------|
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Pending, data gaps identified                                                    |
| Soil (analytical technique and LOQ)      | LC-MS/MS, LOQ: 0.05 mg/kg determining zoxamide                                    |
Water (analytical technique and LOQ)

- Drinking and surface water: LC-MS/MS, LOQ: 0.1 µg/L determining zoxamide
- ILV: Drinking water, LOQ: 0.1 µg/L for determining zoxamide

Air (analytical technique and LOQ)

- LC-MS/MS, LOQ: 90 µg/m³

Body fluids and tissues (analytical technique and LOQ)

- Data gap

### Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

| Substance | Zoxamide |
|-----------|----------|
| -         | -        |

Peer review proposal 2 for harmonised classification according to Regulation (EC) No 1272/2008:

- -

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1 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

2 It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
### Impact on Human and Animal Health

#### Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) No 283/2013, Annex Part A, point 5.1)

| Parameter                                      | Description                                                                                                                                 |
|------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| Rate and extent of oral absorption/systemic   | 60% based on the recovery of radioactivity from the bile, blood, urine, tissues and carcasses, of the administered oral dose (rat, single dose, 10 mg/kg bw per day) |
| bioavailability                               |                                                                                                                                              |
| Toxicokinetics                                 | The maximum concentrations of radioactivity in plasma were observed at 8 hours postdose (Cmax in plasma = 8 hrs; ½ Cmax = 22 hrs).                      |
| Distribution                                   | Wide distribution. The highest concentrations of residues were observed in liver, intestinal tract and carcass.                                 |
| Potential for bioaccumulation                  | No evidence for accumulation.                                                                                                              |
| Rate and extent of excretion                   | Rapid and almost completely eliminated (over 85% of the administered radioactivity was excreted during the first 24 - 48 hours after dosing) via the bile. |
| Metabolism in animals                          | Extensive, 32 metabolites identified (mainly by hydrolysis, oxidation, reductive dehalogenation and conjugation).                           |
| In vitro metabolism                            | No unique human metabolite expected.                                                                                                         |
| Toxicologically relevant compounds             | Parent compound                                                                                                                           |
| (animals and plants)                           |                                                                                                                                              |
| Toxicologically relevant compounds             | Parent compound                                                                                                                           |
| (environment)                                  |                                                                                                                                              |

#### Acute toxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.2)

| Parameter          | Description                          |
|--------------------|--------------------------------------|
| Rat LD₅₀ oral      | > 5000 mg/kg bw (rat)                |
|                    | > 5000 mg/kg bw (mouse)              |
| Rat LD₅₀ dermal    | > 2000 mg/kg bw                      |
| Rat LC₅₀ inhalation| > 5.3 mg/L air /4h (nose only)       |
| Skin irritation    | Non-irritant                         |
| Eye irritation     | Irritant                             |
|                    | H319                                 |
| Skin sensitisation| Sensitising (M&K and Buehler)        |
|                    | H317 cat 1                           |
| Phototoxicity      | Not phototoxic                       |

#### Short-term toxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.3)

| Parameter                                      | Description                                                                                                                                 |
|------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| Target organ / critical effect                 | Dog: liver (increased weight). Reduction in body weight gain at higher dose levels. Rat: none. Mouse: reduction in body weight gain and in overall body weight in female mice |
Relevant oral NOAEL

- **Dog**: 50 mg/kg bw/ per day (90-day & 1-year dog)
- **Rat**: 1509 mg/kg bw per day (highest dose) (90-day rat)
- **Mouse**: 574 mg/kg bw per day (90-day mouse)

Relevant dermal NOAEL

- **28-day rat**:
  - NOAEL for systemic effects: 1000 mg/kg bw per day
  - LOAEL for local effects: 150 mg/kg bw per day
  - Due to the dose-related increase in skin scabbing and reddening as well as histopathological changes in dermis.

Relevant inhalation NOAEL

- No data - not required

**Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)**

**In vitro studies**

- Bacterial mutation assay (Ames): **negative**
- Mammalian chromosome aberration test in Chinese hamster ovary cells: **positive (aneugenic)**
- Gene mutation at the HGPT locus in cultured CHO cells: **negative**

**In vivo studies**

- Micronucleus assay in CD-1 mouse bone marrow cells: **negative**
- Mammalian erythrocyte test with the kinetochore analyses: **negative**

**Photomutagenicity**

- Not provided. Absorption was <1000 L/mol/cm, hence photomutagenicity studies are not required.

**Potential for genotoxicity**

- Zoxamide is genotoxic *in vitro* (i.e. aneugenic) and not *in vivo*.

**Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)**

**Long-term effects (target organ/critical effect)**

- **Rat**: Liver (increased relative liver weight)
- **Mice**: None.

**Relevant long-term NOAEL**

- 2-year, rat: 50 mg/kg bw/ per day,
- 18-month, mouse: 1021 mg/kg bw/ per day (highest dose)

**Carcinogenicity (target organ, tumour type)**

- Not carcinogenic in rat and in mouse.

**Relevant NOAEL for carcinogenicity**

- 2-year, rat: 1058 mg/kg bw per day (highest dose),
- 18-month, mouse: 1021 mg/kg bw per day (highest dose)
Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

**Reproduction toxicity**

| Reproduction target / critical effect | Parental toxicity: reduced bodyweight and liver toxicity effects  
Reproductive toxicity: no adverse effects on reproduction.  
Offspring’s toxicity: reduced body weight gain |
|--------------------------------------|------------------------------------------------------------------|
| Relevant parental NOAEL              | 360 mg/kg bw per day                                              |
| Relevant reproductive NOAEL          | 1474 mg/kg bw per day (highest dose)                             |
| Relevant offspring NOAEL             | 360 mg/kg bw per day                                              |

**Developmental toxicity**

| Developmental target / critical effect | Rat and rabbit: no evidence of maternal nor developmental toxicity in developmental toxicity studies. |
|---------------------------------------|----------------------------------------------------------------------------------------------------|
| Relevant maternal NOAEL               | Rat: 1000 mg/kg bw per day (highest dose)  
Rabbit: 1000 mg/kg bw per day (highest dose) |
| Relevant developmental NOAEL          | Rat: 1000 mg/kg bw per day (highest dose)  
Rabbit: 1000 mg/kg bw per day (highest dose) |

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

| Neurotoxicity | Rat: 2000 mg/kg bw |
|---------------|--------------------|
| Acute neurotoxicity | Rat: 1509 mg/kg bw per day |
| Repeated neurotoxicity | No data – not required. |
| Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) | No data – not required. |

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

| Supplementary studies on the active substance | Mechanism of action on Phytophthora capsici, tobacco, mouse lymphoma cells and isolated bovine tubulin:  
Zoxamide was comparable in potency to carbendazim in inhibiting microtubule assembly and the growth of mouse lymphoma cells, and was considerably less active than colchicine and vinblastine.  
**Immunotoxicity:**  
zoxamide has no immunotoxic potential based on the available standard toxicity studies. |
|-----------------------------------------------|------------------------------------------------------------------|
| Endocrine disrupting properties | Zoxamide is unlikely to have endocrine disrupting properties. |
Studies performed on metabolites or impurities

| RH-141455: | Rat metabolism study: Greater than 96 % radioactivity excreted from faeces and urine was identified to be unchanged RH-141455. |
| Acute oral toxicity in mice: LD₅₀: > 5000 mg/kg bw |
| In vitro micronucleus test in human lymphocytes: negative |
| In vitro mutation test in mouse lymphoma L5178Y cells: negative |
| Ames test: negative |

| RH-150721: |
| Ames test: negative |

| RH-141452: |
| Rat metabolism study: Majority was eliminated unchanged through urine. |
| Acute oral toxicity: > 5000 mg/kg bw |
| Ames test: negative |

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

| Value (mg/kg bw (per day)) | Study | Uncertainty factor |
|-----------------------------|-------|-------------------|
| 0.5                         | dog, 1-year | 100 |
| Not allocated - not necessary |
| 0.3                         | dog, 90-day | 100 |
| Not allocated - not necessary |

* same as in the first peer review (European Commission, 2004)

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Zoxium 240 SC: suspension concentrate (SC) formulation containing a nominal 240 g/L of zoxamide

| Concentrate: 4 % |
| Spray dilution (0.15 g/l): 10 % |
| Based on an in vitro human study with Zoxium 240SC |

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators

| Zoxium 240 SC |
| Use: potatoes, tractor mounted equipment, application rate, 0.18 kg a.s./ha |
| Exposure estimates (model): % of AOEL |
**UK POEM**  
Without PPE: 15  
German model  
Without PPE: 5

### Zoxium 240 SC

**Use:** grapevines, tractor mounted equipment broadcast air-assisted sprayer, application rate 0.18 kg a.s./ha  
**Exposure estimates (model):** % of AOEL

| Scenario               | Exposure % of AOEL |
|------------------------|--------------------|
| **UK POEM** Without PPE| 18                 |
| German model           | 9                  |

### Zoxium 240 SC

**Use:** Hand-held sprayer application outdoors to low crops, application rate 0.18 kg a.s./ha  
**Exposure estimates (model):** % of AOEL

| Scenario               | Exposure % of AOEL |
|------------------------|--------------------|
| **UK POEM** Without PPE| 82                 |

### Zoxium 240 SC

**Use:** Hand-held sprayer application outdoors to low crops, application rate 0.18 kg a.s./ha  
**Exposure estimates (model):** % of AOEL

| Scenario               | Exposure % of AOEL |
|------------------------|--------------------|
| **German model** Without PPE| 37                 |

### Workers

**Zoxium 240 SC**  
**Exposure estimates (model):** % of AOEL  
**Use:** potatoes - 7.5% (scouting), 30% (hand harvesting)  
**Use:** grapevines - 54%

### Bystanders and residents

**Zoxium 240 SC**  
**Exposure estimates (model):** % of AOEL  
**Bystander:**  
1.1% of AOEL (EUROPOEM II)  
Adult 0.13% of AOEL (Martin et al., 2008)  
Child 0.10% of AOEL (Martin et al., 2008)  
**Residents:**  
Adult 0.1% of AOEL (Martin et al., 2008)  
Child 0.3% of AOEL (Martin et al., 2008)
Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

| Substance: Zoxamide |
|--------------------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]: |
| Skin Sens.1 H317 “May cause an allergic skin reaction” |
| Eye Irrit. 2 H319 “Causes serious eye irritation” |
| EUH066: “Repeated exposure may cause skin dryness or cracking” |

3 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

4 It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) No 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

| Primary crops (Plant groups covered) | Crop groups | Crop(s) | Application(s) | DAT (days) |
|--------------------------------------|-------------|---------|----------------|------------|
| OECD Guideline 501                   | Fruit crops | Grapes  | Foliar application, outdoor, 3 x 1867 g as/ha | 1          |
|                                      |             |         | Foliar application, outdoor, 3 x 500 g as/ha | 28         |
|                                      |             | Tomato  | Foliar application, greenhouse 3 x 860 g as/ha | 1          |
|                                      |             | Cucumber| Foliar application, greenhouse 3 x 1344 g as/ha | 1          |
|                                      | Root crops  | Potato  | Foliar application, outdoor, 3 x 900 g as/ha | 14         |
|                                      | Leafy crops | -       | -              | -          |
|                                      | Cereals/grass crops | - | - | - |
|                                      | Pulses/Oilseeds | Peas | Foliar application, outdoor, 2 x 145 g as/ha | 7/13/30 |
|                                      | Miscellaneous | - | - | - |

Following foliar application to crops, most of the applied material remains on the surface of the plants. In the metabolism studies conducted in grapes, tomato, cucumber and peas, the major component of the residue is unchanged zoxamide (RH-7281). No parent zoxamide was found in potato tubers. The main components of the residue in potato tubers were the metabolites RH-141452 and RH-141455.

| Rotational crops (metabolic pattern) | Crop groups | Crop(s) | PBI (days) | Comments |
|--------------------------------------|-------------|---------|------------|----------|
| OECD Guideline 502                   | Root/tuber crops | Radish, turnip | 30;137;210;365 |          |
|                                      | Leafy crops | Mustard | 30;145;210;365 |          |
|                                      | Cereal (small grain) | Sorghum | 30;137;210;365 |          |
|                                      | Other | Soybean | 30;137;210;365 |          |

Rotational crop and primary crop metabolism similar?

Yes. Very little uptake of residues from soil. Parent zoxamide not detected in following crops. The crop metabolite RH-141452 was found at trace levels in following crops. No detectable residues of zoxamide or related metabolites are expected in rotational crops.

Processed commodities (standard hydrolysis)

| Conditions |
|------------|
| 20 min, 90°C, pH 4 |
study)

**OECD Guideline 507**

| Residue pattern in processed commodities similar to residue pattern in raw commodities? |
|-----------------------------------------------|
| Stability of zoxamide under standard hydrolytical conditions is not addressed, studies are not submitted (data gap). Radiolabelled vinification study showed that the major residue in wine is metabolite RH-150721. |

| Plant residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31 | Zoxamide (fruit, pulses and oilseeds) Metabolites RH-141455 and RH-141452 (root crops) pending data gap for RH-141455 and RH-141452 |
|-----------------------------------------------|
| Plant residue definition for risk assessment (RD-RA) | Zoxamide and RH 141452 (fruit) pending data gap on RH-141452 Zoxamide (Pulses and oilseeds) Metabolites RH-141455 and RH-141452 (root crops) pending data gap for RH-141455 and RH-141452 |

**Conversion factor (monitoring to risk assessment)**

1

**Metabolism in livestock (Regulation (EU) No 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)**

| OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish) | Animal | Dose (mg/kg bw/d) | Duration (days) | N rate/comment |
|-----------------------------------------------------|--------|-----------------|----------------|----------------|
| Animals covered                                     | Laying hen | - | - | - |
|                                                     | Goat | 2.82 | 7 | - |
|                                                     | Pig | - | - | - |
|                                                     | Fish | - | - | - |

Goat metabolism study was submitted. Poultry metabolism study is required according to provisional dietary burdain calculation (for turkey expected exposure level 0.008 mg/kg bw/day).

| Time needed to reach a plateau concentration in milk and eggs (days) | 4 days in milk |
|---------------------------------------------------------------------|----------------|
| Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31 | Pending (data gap) |
| Animal residue definition for risk assessment (RD-RA)                | Pending (data gap) |
| Conversion factor (monitoring to risk assessment)                     | - |

**Metabolism in rat and ruminant similar (Yes/No)**

Yes

**Fat soluble residues (Yes/No) (FAO, 2009)**

Yes, log $P_{ow}$ 3.76 for zoxamide (data gap for for RH-141288 and RH-127450)
Residues in succeeding crops (Regulation (EU) No 283/2013, Annex Part A, point 6.6.2)

| **Confined rotational crop study** (Quantitative aspect) | In the confined rotational crop metabolism study, the only crops to contain total radioactive residues greater than 0.1 mg/kg were immature radish (0.127 mg/kg) and soybean hay (0.189 mg/kg). Both crops were planted 30 days after bare soil was treated (4 applications at 18 day intervals) at a rate of 500 g/ha. |
|---|---|
| OECD Guideline 502 | |

| **Field rotational crop study** | Low residues were found in the rotational crop metabolism study using an exaggerated application rate. Residues are not expected to exceed the LOQ in practice. |
|---|---|
| OECD Guideline 504 | |
## Stability of residues (Regulation (EU) No 283/2013, Annex Part A, point 6.1)

**OECD Guideline 506**

| Plant products (Category) | Commodity | T (°C) | Stability (Month) |
|--------------------------|-----------|--------|-------------------|
| High water content       |           |        |                   |
| High oil content         |           |        |                   |
| High protein content     |           |        |                   |
| High starch content      | Potato    | Frozen /-20°C | 24 | - | 24 | 24 |
| High acid content        | Grapes    | -20°C  | 18 | 18 | - | - |
|                         | Wine      |         | 24 | 24 | - | - |
|                         | Grape juice |       | 24 | - | - | - |
|                         | Raisins   |         | 24 | - | - | - |

| Animal | Animal commodity | T (°C) | Stability (Month/Year) |
|--------|------------------|--------|------------------------|
| -      | Muscle           | -      | -                      |
| -      | Liver            | -      | -                      |
| -      | Kidney           | -      | -                      |
| -      | Milk             | -      | -                      |
| -      | Egg              | -      | -                      |

No data provided. Open
Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

| Crop          | Region/Indoor (a) | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) (c) | STMR (mg/kg) (d) |
|---------------|------------------|------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|----------------|------------------|
|               | NEU              |                                                                                               | Insufficient number of valid field trials (data gap) |                      |                |                  |
|               | SEU              |                                                                                               |                                             |                      |                |                  |
| Potato        | NEU              |                                                                                               | Insufficient number of valid field trials (data gap) |                      |                |                  |
|               | SEU              |                                                                                               |                                             |                      |                |                  |
| Grapes        | NEU              |                                                                                               | Insufficient number of valid field trials (data gap) |                      |                |                  |
|               | SEU              |                                                                                               |                                             |                      |                |                  |

(a): NEU or SEU for northern or southern outdoor trials in EU member states (N+SEU if both zones), Indoor for glasshouse/protected crops, Country if non-EU location.

(b): Residue levels in trials conducted according to GAP reported in ascending order (e.g. 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use Mo/RA to differentiate data expressed according to the residue definition for Monitoring and Risk Assessment.

(c): HR: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).

(d): STMR: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMR_{Mo}).
### Inputs for animal burden calculations

| Feed commodity                  | Median dietary burden (mg/kg) | Comment          | Maximum dietary burden (mg/kg) | Comment          |
|---------------------------------|------------------------------|------------------|------------------------------|------------------|
| Potato                          | 0.04                         | STMR (<0.04mg/kg)| 0.11                         | HR 0.11mg/kg     |

Provisional calculation, residue definition for root crops sum of RH-141452 and RH-141455
### Residues from livestock feeding studies (Regulation (EU) No 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

#### MRL calculations

| Highest expected intake (mg/kg bw/d) | Ruminant | Pig/Swine | Poultry | Fish |
|-------------------------------------|----------|-----------|---------|------|
| Beef cattle                         | 0.004    | 0.006     | Breeding | 0.006 | Broiler | 0.004 |
| Dairy cattle                        | 0.006    | 0.005     | Finishing| 0.008 | Layer   | 0.004 |
| Intake >0.004 mg/kg bw              | Yes      | Yes       | Yes     | Yes   | No       |
| Feeding study submitted             | No       | No        | No      | No    |          |

| Highest expected intake (mg/kg DM for fish) | Ruminant | Pig/Swine | Poultry | Fish |
|---------------------------------------------|----------|-----------|---------|------|
| Beef cattle                                 | 0.004    | 0.006     | Breeding | 0.006 | Broiler | 0.004 |
| Dairy cattle                                | 0.006    | 0.005     | Finishing| 0.008 | Layer   | 0.004 |
| Intake >0.1 mg/kg DM                       | Turkey   | 0.008     |         |       |

| Representative feeding level (mg/kg/bw, mg/kg DM for fish) | Ruminant | Pig/Swine | Poultry | Fish |
|------------------------------------------------------------|----------|-----------|---------|------|
| Level Beef: N Dairy: N                                      | MRL proposals | Estimated HR\(^{(a)}\) at 1N | Level Lamb: N Ewe: N | MRL proposals | Estimated HR\(^{(a)}\) at 1N | Level N rate Breed/Finish | Level B or T: N Layer: N | MRL proposals | Estimated HR\(^{(a)}\) at 1N | MRL proposals |
| Muscle                                                     |          |          |         |      |
| Fat                                                       |          |          |         |      |
| Meat\(^{(b)}\)                                             |          |          |         |      |
| Liver                                                     |          |          |         |      |
| Kidney                                                    |          |          |         |      |
| Milk\(^{(a)}\)                                             |          |          |         |      |
| Eggs                                                      |          |          |         |      |

Method of calculation\(^{(c)}\)

\(^{(a)}\): Estimated HR calculated at 1N level (estimated mean level for milk).

\(^{(b)}\): HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

\(^{(c)}\): The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.
Conversion Factors (CF) for monitoring to risk assessment

Not relevant (RD-Mo = RD-RA)

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

| Crop (RAC)/Edible part or Crop (RAC)/Processed product | Number of studies\(^{(a)}\) | Processing Factor (PF) | Conversion Factor (CF\(_P\)) for RA\(^{(b)}\) |
|--------------------------------------------------------|-----------------------------|------------------------|---------------------------------|
|                                                        | Individual values           | Median PF              |                                  |
| **Representative uses**                                 |                             |                        |                                 |
| Potato                                                 | -                           | -                      | -                               |
| Grapes/unclarified juice                               | -                           | -                      | -                               |
| Grapes/raisins                                         | -                           | -                      | -                               |
| Grapes/aged wine                                       | -                           | -                      | -                               |

\(^{(a)}\): Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)
\(^{(b)}\): When the residue definition for risk assessment differs from the residue definition for monitoring

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

Including all uses (representative uses and uses related to an MRL application).

**ADI**

TMDI according to EFSA PRIMo

0.5 mg/kg bw per day

Highest TMDI:

Since the toxicity profile of metabolites RH 141452 and RH 141455 is not known and considering the outstanding data on the nature of residues in processed commodities, the consumer risk assessment cannot be finalised.

NTMDI, according to (to be specified)

Not applicable; see representative uses below

IEDI (% ADI), according to EFSA PRIMo

Not applicable; see representative uses below

NEDI (% ADI), according to (to be specified)

Not applicable; see representative uses below

Factors included in the calculations

**ARfD**

IESTI (% ARfD), according to EFSA PRIMo

No ARfD

NESTI (% ARfD), according to (to be specified)

Not applicable;

Factors included in IESTI and NESTI

Consumer risk assessment limited to the representative uses

TMDI (% ADI), according to EFSA PRIMo

Highest TMDI:

Since the toxicity profile of metabolites RH 141452 and RH 141455 is not known and considering the outstanding data on the nature of residues in processed commodities, the consumer risk assessment cannot be finalised.

NTMDI (% ADI), according to (to be specified)

Not required.

IEDI (% ADI), according to EFSA PRIMo

Not required.
| Factor                        | Calculation                |
|------------------------------|----------------------------|
| NEDI (% ADI, according to (to be specified)) | Not required.              |
| Factors included in the calculations | -                           |
| IESTI (% ARfD, according to EFSA PRIMo) | Not applicable.            |
| NESTI (% ARfD, according to (to be specified)) | Not applicable.            |
| Factors included in IESTI and NESTI | -                           |
Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

| Code\(^{(a)}\) | Commodity/Group | MRL/Import tolerance\(^{(b)}\) (mg/kg) and Comments |
|----------------|-----------------|--------------------------------------------------|
|                | Plant commodities |                                                  |
|                | Representative uses |                                                |
| 0151010        | Table grapes     | MRL could not be proposed as trials are missing. |
| 0151020        | Wine grapes      | MRL could not be proposed as trials are missing. |
| 0211000        | Potatoes         | MRL could not be proposed as trials are missing. |

\(^{(a)}\): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

\(^{(b)}\): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.
### Environmental fate and behaviour

#### Route of degradation (aerobic) in soil
(Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

| Mineralization after 100 days | 34.4-57.8% by days 120-122, [\(^{14}\text{C}\)-phenyl-U]-zoxamide (n=4 at 20°C, n=2 at 25°C and n=1 at 10°C) |
|------------------------------|---------------------------------------------------------------------------------------------------|
| Non-extractable residues after 100 days | 23.8-38.43% by days 120-122, [\(^{14}\text{C}\)-phenyl-U]-zoxamide (n=4 at 20°C, n=2 at 25°C and n=1 at 10°C). |
| Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) | RH-127450 (de-chlorinated product, Max of 15.1% AR after 7 days)  
RH-24549 (benzoic acid derivative, Max of 33.8% AR after 7 days)  
RH-163353 (acid, Max of 15% AR after 3 days).  
RH-141455 (Max of 8.4% AR after 14 days) |

#### Route of degradation (anaerobic and photolysis) in soil
(Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2 and 7.1.1.3)

**Anaerobic degradation**

| Mineralization after 100 days | Mineralisation: <0.1% throughout study (n=1). |
|------------------------------|-----------------------------------------------|
| Non-extractable residues after 100 days | Non-extractable residues: 26.4%, day 120, (n=1). |
| Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) | RH-127450: Maximum of 30.2% AR (day 28), declining slowly to 23.7% AR by day 120.  
RH-24549: Maximum of 23.7% AR (day 120).  
RH-141288: Maximum of 5.5% AR (day 14).  
M25: Maximum of 6.3% AR (day 7).  
M15: Maximum of 6.6% AR (day 120). |

**Soil photolysis**

Irradiation does not affect the route and rate of degradation of zoxamide.  
Mineralisation: 0.32% AR after 30 days.  
Similar levels evolved in dark control samples.  
Non-extractable residues: 30.8% AR after 30 days. Similar levels in dark control samples.  
Metabolites:  
RH-127450: Maximum of 10.9% AR, day 14  
RH-24549: Maximum of 22.2% AR, day 30.  
Levels of metabolites in control samples were similar
**Rate of degradation in soil (aerobic)** (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1, 7.1.2.1.2, 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1 and 9.1.1.2.1)

Method of calculation

Laboratory studies (range or median, with n value, with r² value)

FOCUS (2006, 2011)

DT₅₀ for zoxamide and its metabolites are given below. Geometric mean modelling DT₅₀ were calculated for the soils incubated at 20/25°C; DT₅₀ values at three different incubation conditions are presented for German sandy loam, however only the DT₅₀ value derived from soil with standard incubation conditions (20°C, 100%FC) were used for calculation of geometric mean.

### Zoxamide

| Soil                     | DT₅₀ (days) | DT₉₀ (days) | Temp | Model | Kinetic parameters | Moist Corr. | T-Corr. | DT₅₀ normalised to 20°C & pF2 |
|--------------------------|-------------|-------------|------|-------|-------------------|-------------|---------|-------------------------------|
| England silt loam 20°C 50%MWHC | 3.9         | 13          | 20°C | SFO   | k: 0.1779         | 5.68        | 1.00    | 0.84                          |
| France loam 20°C 50%MWHC | 1.99        | 6.62        | 20°C | SFO   | k: 0.3479         | 7.02        | 1.00    | 0.94                          |
| Italy clay loam 20°C 50%MWHC | 2.37        | 7.87        | 20°C | SFO   | k: 0.2927         | 6.06        | 1.00    | 0.83                          |
| Germany sandy loam 20°C 50%MWHC | 2.71        | 9.01        | 20°C | SFO   | k: 0.2556         | 4.65        | 1.00    | 0.99                          |
| Germany sandy loam 20°C 100%FC | 2.22        | 7.38        | 20°C | SFO   | k: 0.3119         | 6.72        | 1.00    | 1.00                          |
| Germany sandy loam 10°C 50%MWHC | 7.29        | 24.2        | 10°C | SFO   | k: 0.0951         | 6.78        | 0.39    | 0.99                          |
| Pennsylvania silt loam 25°C 75%FC | 7.75        | 98.1        | 25°C | DFOP (persistence) | k1:0.635   | 9.2             | 1.57   | 0.74                          |
|                            | 29.5²       |             |      | DFOP (modelling)  | k2:0.01774 | 13.5          | 1.57   | 0.71                          |
|                            |             |             |      | SFO (modelling)   | g:0.4299  | 28.4          | 1.57   | 0.71                          |
| Ohio loamy sand 25°C 75%FC | 13.6        | 115         | 25°C | DFOP (persistence) | k1:0.1581 | 31.66         | 13.5   | 1.57                          |
|                            | 28.4        |             |      | SFO (modelling)   | k2:0.01477 |              |        |                               |
|                            |             |             |      |                  | g:0.4531  |              |        |                               |

Geometric mean

5.5

¹ values which were not used for calculation of geometric mean DT₅₀ ² DT₉₀/3.32
### RH-127450

| Soil                  | DT$_{50}$ (days) | Temp | Model | $\chi^2$ error (%) | T-Corr. | Moist Corr. | DT$_{50}$ normalised to 20°C & pF2 | FF$^*$ |
|-----------------------|------------------|------|-------|--------------------|---------|-------------|-----------------------------------|-------|
| England silt loam 20°C 50%MWHC | 14.9             | 20°C | SFO-SFO | 9.61               | 1.00    | 0.84        | 12.52                             | 0.22  |
| France loam 20°C 50%MWHC   | 3.8              | 20°C | SFO-SFO | 8.63               | 1.00    | 0.94        | 3.57                              | 0.21  |
| Italy clay loam 20°C 50%MWHC | 1.99             | 20°C | SFO-SFO | 20.1               | 1.00    | 0.83        | 1.65                              | 0.21  |
| Germany sandy loam 20°C 50%MWHC | 6.66             | 20°C | SFO-SFO | 19.3               | 1.00    | 0.99        | 6.59$^3$                          | 0.18$^3$ |
| Germany sandy loam 20°C 100%FC  | 5.79             | 20°C | SFO-SFO | 23.9               | 1.00    | 1.00        | 5.79                              | 0.19  |
| Germany sandy loam 10°C 50%MWHC | 18.7             | 10°C | SFO-SFO  | 16.9               | 0.39    | 0.99        | 7.22$^3$                          | 0.17$^3$ |
| Ohio loam sand 25°C 75%FC    | 8.27             | 25°C | SFO-SFO | 17.7               | 1.57    | 0.71        | 9.22                              | 0.38  |
| **Geometric mean**          |                  |      |        |                    |         |             | 5.2                               |       |
| **Arithmetic mean**         |                  |      |        |                    |         |             | -                                 | 0.24  |

* formation fraction from zoxamide; $^1$ values which were not used for calculation of geometric/arithmetic mean values

### RH-24549

| Soil                  | DT$_{50}$ (days) | Temp | Model | $\chi^2$ error (%) | T-Corr. | Moist Corr. | DT$_{50}$ normalised to 20°C & pF2 | FF$^*$ |
|-----------------------|------------------|------|-------|--------------------|---------|-------------|-----------------------------------|-------|
| France loam 20°C 50%MWHC | 6.32             | 20°C | SFO-SFO | 23.2               | 1.00    | 0.94        | 5.94                              | 0.19  |
| Italy clay loam 20°C 50%MWHC | 8.45             | 20°C | SFO-SFO | 24.2               | 1.00    | 0.83        | 7.01                              | 0.47  |
| Germany sandy loam 20°C 50%MWHC | 5.78             | 20°C | SFO-SFO | 30.7               | 1.00    | 0.99        | 5.72$^3$                          | 0.17$^3$ |
| Germany sandy loam 20°C 100%FC  | 3.07             | 20°C | SFO-SFO | 16                 | 1.00    | 1.00        | 3.07                              | 0.27  |
| Ohio loamy sand 25°C 75%FC    | 6.13             | 25°C | SFO-SFO | 16.1               | 1.57    | 0.71        | 6.83                              | 0.57  |
| **Geometric mean**          |                  |      |        |                    |         |             | 5.4                               |       |
| **Arithmetic mean**         |                  |      |        |                    |         |             | -                                 | 0.38  |

* formation fraction from zoxamide; $^1$ values which were not used for calculation of geometric/arithmetic mean values
RH-163353

| Soil                        | DT₅₀ (days) | Temp | Model  | χ² error (%) | T-Corr. | Moist Corr. | DT₅₀ normalised to 20°C & pF2 | FF* |
|-----------------------------|-------------|------|--------|--------------|---------|-------------|-------------------------------|-----|
| England silt loam 20°C 50%MWHC | 49.7        | 20°C | SFO-SFO | 7.38          | 1.00    | 0.84        | 41.75                        | 0.10|
| France loam 20°C 50%MWHC    | 6.65        | 20°C | SFO-SFO | 25.2          | 1.00    | 0.94        | 6.25                         | 0.20|
| Italy clay loam 20°C 50%MWHC | 6.4         | 20°C | SFO-SFO | 7.2           | 1.00    | 0.83        | 5.31                         | 0.23|
| Germany sandy loam 20°C 50%MWHC | 5.62       | 20°C | SFO-SFO | 17.2          | 1.00    | 0.99        | 5.56*                        | 0.29|
| Germany sandy loam 20°C 100%FC | 9.96       | 20°C | SFO-SFO | 13.8          | 1.00    | 1.00        | 9.96                         | 0.18|
| Germany sandy loam 10°C 50%MWHC | 55.6        | 10°C | SFO-SFO | 17.5          | 0.39    | 0.99        | 21.47*                       | 0.15|
| Geometric mean              |             |      |        |              |         |             |                               | 10.8|
| Arithmetic mean             |             |      |        |              |         |             |                               | -   |

* formation fraction from zoxamide; ¹ values which were not used for calculation of geometric/arithmetic mean values

RH-141455

| Soil                        | DT₅₀ (days) | Temp | Model  | χ² error (%) | T-Corr. | Moist Corr. | DT₅₀ normalised to 20°C & pF2 | FF |
|-----------------------------|-------------|------|--------|--------------|---------|-------------|-------------------------------|----|
| Germany sandy loam 20°C 50%MWHC | 88.5        | 20°C | SFO-SFO | 18.2          | 1.00    | 0.99        | 87.62                        | ¹   |
| Speyer 2.2                  | 12          | 20°C | SFO    | 6.95          | 1.00    | 1.00        | 12.00                        | ²  |
| Speyer 2.3                  | 11.1        | 20°C | SFO    | 5.77          | 1.00    | 0.86        | 9.54                         | ²  |
| Speyer 6S                   | 31.7        | 20°C | SFO    | 6.8           | 1.00    | 0.46        | 14.72                        | ²  |
| Geometric mean              |             |      |        |              |         |             |                               | 19.6|

¹ from RH-24549 ² study conducted with metabolite (RH-141455)

Field studies (state location, range or median with n value)

- DT₅₀:
- DT₅₀ of zoxamide and metabolites are <60 days therefore field studies are not necessary

Soil accumulation and plateau concentration

- DT₉₀:
- DT₉₀ of zoxamide is 6<365 days, therefore risk of accumulation is negligible and soil accumulation and plateau concentrations are not required

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)
### Soil adsorption/desorption

(Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1, 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Soil                                    | % oc | pH  | $K_F$ | $1/n$ | $K_{Foc}$ | Kom  |
|-----------------------------------------|------|-----|-------|-------|-----------|------|
| Loam, Huntsburg, Ohio, USA              | 1.27 | 7.2 | 10.35 | 0.896 | 815       | 473  |
| Silty clay loam, Concord, Ohio, USA     | 1.77 | 4.8 | 25.33 | 0.963 | 1431      | 830  |
| Sandy loam, Madison, Ohio, USA          | 1.1  | 6.7 | 15.23 | 0.953 | 1385      | 803  |
| Silty loam, Newtown, Pennsylvania, USA  | 1.04 | 6.8 | 12.44 | 1.067 | 1196      | 694  |
| Mean / Geometric mean                   | 0.97 |     |       |       | 1207 / 1179 | 700 / 684 |

### RH-127450

| Soil                                    | % oc | pH  | $K_F$ | $1/n$ | $K_{Foc}$ | Kom  |
|-----------------------------------------|------|-----|-------|-------|-----------|------|
| Loamy sand, Borstel/Germany             | 1.05 | 6.1 | 12.14 | -     | 1156      | 671  |
| Clay, Egerkingen/ Switzerland           | 2.82 | 5.0 | 11.4  | 0.603 | 404       | 234  |
| Silt loam, Vetroz/Switzerland           | 4.05 | 7.3 | 18.12 | 0.448 | 447       | 259  |
| Mean / Geometric mean                   | 0.9* |     |       |       | 669 / 593 | 388 / 344 |

* no reliable mean value of $1/n$ could be achieved therefore a value of 0.9 is considered appropriate for the modelling

### RH-24549

| Soil                                    | % oc | pH  | $K_F$ | $1/n$ | $K_{Foc}$ | Kom  |
|-----------------------------------------|------|-----|-------|-------|-----------|------|
| Sandy loam, Iowa/USA                    | 1.3  | 5.2 | 4.0   | 0.791 | 307.43    | 178  |
| Silty clay loam, Illinois/USA           | 2.4  | 7.3 | 3.6   | 0.833 | 150.16    | 87   |
| Silt loam, Ohio/USA                     | 2.0  | 7.6 | 1.8   | 0.811 | 90.55**   | 53   |
| Mean / Geometric mean                   | *    |     |       |       | *         | *    |

*a desorption of RH-24549 is pH dependent **the worst case $K_{foc}$ is considered appropriate for modelling
### RH-163353

| Soil                        | %oc | pH  | KF  | 1/n | Koc  | Kom |
|-----------------------------|-----|-----|-----|-----|------|-----|
| Loamy sand, Borstel/Germany | 1.22| 6.1 | 0.6 | 1.0*| 50*  | 29  |
| Clay, Egerkingen/ Switzerland| 3.17| 5.4 | 2.4 | 0.833| 75   | 44  |
| Silt loam, Vetroz/Switzerland| 4.79| 7.2 | 3.8 | 0.844| 79   | 46  |
| **Mean / Geometric mean**   |     |     |     | **0.892**| **68 / 67**| **39 / 39** |

*Koc derived from a Kd from the screening study therefore a default 1/n value of 1.0 is assumed.

### RH-141455

| Soil                        | %oc | pH  | Kd  | 1/n | Koc  | Kom |
|-----------------------------|-----|-----|-----|-----|------|-----|
| Speyer 2.2, loamy sand      | 1.87| 5.5 | 0.06| 1.0*| 3.1* | 1.8 |
| Speyer 2.3, sandy loam      | 0.94| 6.8 | 0.03| 1.0*| 3.3* | 1.9 |
| Speyer 6S, clay             | 1.64| 7.1 | 0.03| 1.0*| 2.1* | 1.2 |
| **Mean / Geometric mean**   |     |     |     | **1.0**| **2.8 / 2.8**| **1.6 / 1.6** |

*Koc derived from a Kd from the screening study therefore a default 1/n value of 1.0 is assumed.

### Mobility in soil

(Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1, 7.1.4.1.2, 7.1.4.2, 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1, 9.1.2.2 and 9.1.2.3)

#### Aged residues leaching

| Guideline ‘SETAC’ | Aged for 3 days | Study time period 2 days | Leachate: 1.8-2.3% AR |
|-------------------|-----------------|--------------------------|----------------------|

#### Lysimeter/field leaching studies

| RH-127450: 6.9-11.9 %AR in 0-5 cm, ≤0.3 %AR in 5 - 10 cm, undetectable in 10-20 cm layer |
|---------------------------------------------------------------|

| RH-24549: 5.6-8.8% AR in 0-5 cm layer, 0.3-1.9% AR in 15-20 cm layer |
|---------------------------------------------------------------|

| RH-163353: 4-6.7% AR in 0-5 cm layer, 0.5-0.7% AR in 15-20 cm layer |
|---------------------------------------------------------------|

| No studies required |
|--------------------|
Peer review of the pesticide risk assessment of the active substance zoxamide

Route and rate of degradation in water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1 to 7.2.1.3 and 7.2.2.1)

Hydrolysis of active substance and relevant metabolites > 10% (DT₅₀) (state pH and temperature)

| pH 4: Parent | 25°C DT₅₀ 16 days (1ˢᵗ order, r² 1.0) |
|--------------|--------------------------------------|
| RH-129151    | 0.67% AR, day 3                       |
| RH-150721    | 25°C DT₅₀ 18.3 days * (37.6% AR, day 21) |
| RH-24549     | stable (30.9% AR, day 30)             |
| RH 141288    | 0.6% AR, day 30                       |

* kinetics: linear and non-linear compartmental regression analysis (SAS JMP Version 3.2).

| pH 7: Parent | 25°C DT₅₀ 16 days (1ˢᵗ order, r² 1.0) |
|--------------|--------------------------------------|
| RH-129151    | 25°C DT₅₀ 9.1 days * (24.5% AR, day 21) |
| RH-150721    | 1.5% AR, day 30                       |
| RH-24549     | stable (20.75% AR, day 30)            |
| RH 141288    | stable (21.9% AR, day 30)             |

* kinetics: linear and non-linear compartmental regression analysis (SAS JMP Version 3.2).

| pH 9: Parent | 25°C DT₅₀ 8 days (1ˢᵗ order, r² 1.0) |
|--------------|--------------------------------------|
| RH-129151    | 25°C DT₅₀ 2.4 days * (16.4% AR, day 7) |
| RH-150721    | (0.13% AR, day 30)                   |
| RH-24549     | stable (11.5% AR, day 30)            |
| RH 141288    | stable (50.2% AR, day 30)            |

* kinetics: linear and non-linear compartmental regression analysis (SAS JMP Version 3.2).

Photolytic degradation of active substance and relevant metabolite above 10%

| pH 4: Xenon lamp (equivalent to light intensity of New Jersey summer sunlight, 42° N) | DT₅₀ 8 days (12-hour photo-period) and 22 days in dark control (1ˢᵗ order, r² 0.99 – 1.0). |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| Metabolites >10% AR: RH-24549 (27.69% AR, day 30), RH-150721 (15.10% AR, day 10) not photoproducts, similar levels in dark controls & RH-139432, stable (42.4% AR day 30, also a minor hydrolysis product). |

Readily biodegradable (yes/no) No
Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Method of study

Metabolites

\[^{14}\text{C}-\text{zoxamide was incubated at two test concentrations (10 \mu g/L and 50 \mu g/L) in surface water at 20 \pm 2 ^{\circ} \text{C in the dark for 58 days.}\]

RH-141455, RH-139432, RH-141288, RH-163353 and RH-24549 were detected at >5% on two consecutive occasions at respective maximums of 10.5% AR (day 44), 21.4% AR (day 28), 22.1% AR (day 58), 47.9% AR (day 28) and 22.7% AR (day 58).

M-7 was detected at a maximum of 9.1% AR (day 58) but was multicomponent, consisting of 2-3 different substances which individually did not exceed 5% AR.

### Rates of degradation of zoxamide in the systems

| System         | pH (water phase) | T. °C | Model | Parameter estimates | DT\(_{50}\)/ DT\(_{90}\) water (pelagic test) | \(\chi^2, \%\) error | P- value |
|----------------|------------------|-------|-------|--------------------|---------------------------------|---------------------|----------|
| High dose      | 7.1\(^1\)/8.2-8.4\(^2\) | 20\(^2\) | SFO   | \(M_0 = 97.6 \pm 4.7\) k = 0.09078 ± 0.0117 \(\text{d}^{-1}\) | 7.6/25.4 24.9/83.1 16.1/54 | 12.1 <0.05 |
| Low dose       |                  |       | SFO   | \(M_0 = 111.2 \pm 8.5\) k = 0.0823 ± 0.0171 \(\text{d}^{-1}\) | 8.4/28.0 27.5/91.6 17.8/59.5 | 21.9 <0.05 |

\(^1\) pH and temperature at sampling \(^2\) pH and temperature during incubation. Q10 used for normalisation 2.58 days.
**Water / sediment study** (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

**Zoxamide**

| Parent | Max in sediment 30.2% AR at day 7 (pond, 10°C ). At 20°C max in sediment 23.1% AR at day 7 (pond). |
|---|---|
| Water / sediment system | pH water phase | pH sed | T. °C | DT₅₀-DT₉₀ whole sys. | x² err | DT₅₀-DT₉₀ water | x² err | DT₅₀-DT₉₀ sed | x² err | Method of calculation |
| River | 8.39 | 7.4 | 20 | 6.4/21.1 | 5.921 | FOCUS SFO |
| Pond | 8.09 | 7.0 | 20 | 6.3/20.9 | 6.044 | FOCUS SFO |
| River | 8.34 | 7.4 | 10 | 10.4/34.7 | 2.59 | FOCUS SFO |
| Pond | 8.12 | 7.0 | 10 | 19.4/64.6 | 3.424 | FOCUS SFO |
| **Mean (of 20°C systems)** | | | | | | 6.4/- |

**RH-127450**

| RH-127450 | Max in water 17.1% AR at day 28 (river, 10°C), max in sediment 23.1 % AR at day 56 (river, 10°C) and max in total system 39.3% AR at day 56 (river, 10°C). At 20°C max in water 12.8% AR at day 14 (river), max in sediment 22.1% AR at day 56 (pond) and max in total system 30.0% AR at day 28 (river). |
|---|---|
| Water / sediment system | pH water phase | pH sed | T. °C | DT₅₀-DT₉₀ whole sys. | x² err | DT₅₀-DT₉₀ water | x² err | DT₅₀-DT₉₀ sed | x² err | Method of calculation |
| River | 8.39 | 7.4 | 20 | 148.4/493.1 | 16.271 | FOCUS SFO |
| Pond | 8.09 | 7.0 | 20 | 326.1/1083 | 7.265 | FOCUS SFO |
| River | 8.34 | 7.4 | 10 | - | - | FOCUS SFO |
| Pond | 8.12 | 7.0 | 10 | 123/408.7 | 20.12 | FOCUS SFO |
| **Mean (of 20°C systems)** | | | | | | 237/- | Formation fraction 0.24 to 0.33 from parent |

Other metabolites detected at >10% AR:
RH-163353 – max in water 15.8% AR at day 28 (river, 20°C), max in sediment 13.8% AR at day 106 (pond, 10°C) and max in total system 28.0% AR at day 106 (river, 10°C). At 20°C max in sediment 7.4% AR at day 106 (river) and max in total system 20.6% AR at day 56 (river).
Mineralisation and non-extractable residues

| Water / sediment system | pH water phase | pH sed | Mineralisation at end of study | Non-extractable residues in sed. (Max) | Non-extractable residues in sed. (end of the study) |
|-------------------------|---------------|--------|-------------------------------|----------------------------------------|-----------------------------------------------|
| River (20°C)            | 8.39          | 7.4    | 21.9                          | 36.6                                   | 36.6                                          |
| Pond (20°C)             | 8.09          | 7.0    | 19.7                          | 39.9                                   | 39.0                                          |
| River (10°C)            | 8.34          | 7.4    | 6.5                           | 33.5                                   | 33.5                                          |
| Pond (10°C)             | 8.12          | 7.0    | 4.0                           | 37.3                                   | 37.3                                          |

**Fate and behaviour in air** (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

**Direct photolysis in air**

Quantum yield of direct phototransformation

\( \Phi = 0.0225 \) (\( \lambda > 290 \text{ nm} \))

**Photochemical oxidative degradation in air**

DT\(_{50}\) of 7.5 hours (Atkinson method), assuming hydroxyl radical concentration of \( 1.5 \times 10^6 \text{ OH/cm}^3 \) and a 12 hour day. Rate constant for reaction with hydroxyl radicals: \( 17.1 \times 10^{-12} \text{ cm}^3/\text{molecule-sec.} \).

**Volatilization**

From plant surfaces: 5.1% AR after 24 hours.
From soil: 3.9% AR after 24 hours.

**Metabolites**

Not applicable

**PEC (air)**

Method of calculation

Not applicable

**PEC\((a)\)**

Maximum concentration

Not applicable
Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure

| Component         | Soil             | Surface water | Sediment          | Ground water | Air          |
|-------------------|------------------|---------------|-------------------|--------------|--------------|
|                    | Zoxamide, RH-127450, RH-24549, RH-163353, RH-141455, RH-141288*, unknown M25* and unknown M15* | Zoxamide, RH-127450, RH-163353, RH-24549, RH-141455 and RH-139432 | Zoxamide, RH-127450, RH-163353 | Zoxamide, RH-127450, RH-24549, RH-163353 and RH-141455 | Zoxamide |
|                   | *- metabolites formed under anaerobic conditions |

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

| Component               | Soil (indicate location and type of study) | Surface water (indicate location and type of study) | Ground water (indicate location and type of study) | Air (indicate location and type of study) |
|-------------------------|------------------------------------------|---------------------------------------------------|---------------------------------------------------|------------------------------------------|
|                         | No data submitted                        | No data submitted                                 | No data submitted                                 | No data submitted                        |

PEC (soil) (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent
Method of calculation

FOCUS (1997), Crop interception as defined by FOCUS (2012).
Maximum laboratory DT$_{50}$ in soil of 13.6 days (DFOP, $k_1 = 0.1581$, $k_2 = 0.01477$, $g = 0.4531$) was used.
Soil density: 1.5 kg/L Soil depth: 5 cm

Application rate

5 x 180 g a.s./ha to grapevines and potatoes, 8 day interval.
Potatoes crop interception of 50% assumed.
Grapevines crop interception of 60% assumed.

| PEC$_{soil}$ | Potatoes | Potatoes | Grapevines | Grapevines |
|--------------|----------|----------|------------|------------|
|              | Multiple application | Multiple application | Actual | Multiple application | Actual |
|              | Actual | Time weighted average | | Actual | Time weighted average |
| Initial      | 0.3825 | - | 0.3060 | - |
| Short term   | 24h | 0.3707 | 0.3766 | 0.2966 | 0.3013 |
|              | 2d | 0.3598 | 0.3710 | 0.2879 | 0.2968 |
|              | 4d | 0.3404 | 0.3604 | 0.2723 | 0.2884 |
| Long term    | 7d | 0.3160 | 0.3473 | 0.2528 | 0.2779 |
|              | 21d | 0.2471 | 0.3150 | 0.1977 | 0.2520 |
|              | 28d | 0.2263 | 0.3031 | 0.1810 | 0.2425 |
|              | 50d | 0.1805 | 0.2731 | 0.1444 | 0.2185 |
|              | 100d | 0.1135 | 0.2242 | 0.0908 | 0.1794 |

RH-127450

FOCUS (1997), Crop interception as defined by FOCUS (2012).
Maximum laboratory DT$_{50}$ in soil of 14.9 days (SFO) was used.*
Formation at maximum of 15.1% assumed.
PEC$_{soil}$ also corrected for molecular weight.
Method of calculation

| Soil density: 1.5 kg/L Soil depth: 5 cm |

Application rate

| 5 x 24.5 g a.s./ha to grapevines and potatoes, 8 day interval. |
| Potatoes crop interception of 50% assumed. |
| Grapevines crop interception of 60% assumed. |

*longer DT$_{so}$ – 18.7 days was obtained at 10°C

### PEC$_{(s)}$

|          | Potatoes Multiple application Actual | Potatoes Multiple application Time weighted average | Grapevines Multiple application Actual | Grapevines Multiple application Time weighted average |
|----------|-------------------------------------|---------------------------------------------------|---------------------------------------|-------------------------------------------------------|
| Initial  | 0.0542                              | -                                                 | 0.0433                                | -                                                     |
| Short term | 24h                                  | 0.0526                                            | 0.0534                                | 0.0421                                                |
|          | 2d                                   | 0.0511                                            | 0.0526                                | 0.0409                                                |
|          | 4d                                   | 0.0483                                            | 0.0512                                | 0.0386                                                |
| Long term | 7d                                   | 0.0442                                            | 0.0493                                | 0.0354                                                |
|          | 21d                                  | 0.0295                                            | 0.0447                                | 0.0236                                                |
|          | 28d                                  | 0.0241                                            | 0.0425                                | 0.0193                                                |
|          | 50d                                  | 0.0127                                            | 0.0369                                | 0.0102                                                |
|          | 100d                                 | 0.0030                                            | 0.0259                                | 0.0024                                                |

FOCUS (1997), Crop interception as defined by FOCUS (2012). Maximum laboratory DT$_{so}$ in soil of 8.45 days (SFO) was used. Formation at maximum of 33.8% assumed. PEC$_{soil}$ also corrected for molecular weight.
### RH-24549

**Method of calculation**

5 x 37.1 g a.s./ha to grapevines and potatoes, 8 day interval.
Potatoes crop interception of 50% assumed.
Grapevines crop interception of 60% assumed.

| PEC<sub>c</sub> | Potatoes Multiple application | Potatoes Multiple application | Grapevines Multiple application | Grapevines Multiple application |
|----------------|-------------------------------|-------------------------------|---------------------------------|---------------------------------|
|                | Actual                        | Time weighted average         | Actual                          | Time weighted average           |
| Initial        | 0.0642                        | -                             | 0.0513                          | -                               |
| Short term     |                               |                               |                                 |                                 |
| 24h            | 0.0610                        | 0.0626                        | 0.0488                          | 0.0501                          |
| 2d             | 0.0580                        | 0.0610                        | 0.0464                          | 0.0488                          |
| 4d             | 0.0523                        | 0.0581                        | 0.0419                          | 0.0465                          |
| Long term      |                               |                               |                                 |                                 |
| 7d             | 0.0449                        | 0.0549                        | 0.0359                          | 0.0440                          |
| 21d            | 0.0220                        | 0.0495                        | 0.0176                          | 0.0396                          |
| 28d            | 0.0154                        | 0.0478                        | 0.0123                          | 0.0382                          |
| 50d            | 0.0050                        | 0.0395                        | 0.0040                          | 0.0316                          |
| 100d           | 0.0004                        | 0.0243                        | 0.0003                          | 0.0195                          |

FOCUS (1997), Crop interception as defined by FOCUS (2012).
Maximum laboratory DT<sub>50</sub> in soil of 49.7 days (SFO) was used.*
Formation at maximum of 15% assumed.
PEC<sub>soil</sub> also corrected for molecular weight.
Soil density: 1.5 kg/L Soil depth: 5 cm
Method of calculation

Application rate

* longer DT<sub>50</sub> - 55.6 days was obtained at 10°C

| PEC<sub>50</sub> | Potatoes Multiple application | Potatoes Multiple application | Grapevines Multiple application | Grapevines Multiple application |
|-----------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
|                 | Actual                        | Time weighted average         | Actual                          | Time weighted average          |
| Initial         | 0.0775                        | -                              | 0.0620                          | -                               |
| Short term      | 24h                           | 0.0769                         | 0.0772                          | 0.0615                          | 0.0618                          |
|                 | 2d                            | 0.0762                         | 0.0769                          | 0.0610                          | 0.0615                          |
|                 | 4d                            | 0.0749                         | 0.0762                          | 0.0599                          | 0.0610                          |
| Long term       | 7d                            | 0.0730                         | 0.0752                          | 0.0584                          | 0.0602                          |
|                 | 21d                           | 0.0646                         | 0.0711                          | 0.0517                          | 0.0569                          |
|                 | 28d                           | 0.0608                         | 0.0691                          | 0.0486                          | 0.0553                          |
|                 | 50d                           | 0.0502                         | 0.0647                          | 0.0402                          | 0.0518                          |
|                 | 100d                          | 0.0325                         | 0.0552                          | 0.0260                          | 0.0442                          |
Method of calculation

FOCUS (1997), Crop interception as defined by FOCUS (2012).
Maximum laboratory DT_{50} in soil of 88.5 days (SFO) was used.
Formation at maximum of 8.4% assumed.
PEC_{soil} also corrected for molecular weight.
Soil density: 1.5 kg/L Soil depth: 5 cm

Application rate

5 x 10.6 g a.s./ha to grapevines and potatoes, 8 day interval.
Potatoes crop interception of 50% assumed.
Grapevines crop interception of 60% assumed.

| PEC\((s)\) | Potatoes Multiple application Actual | Potatoes Multiple application Time weighted average | Grapevines Multiple application Actual | Grapevines Multiple application Time weighted average |
|-----------|-------------------------------------|-----------------------------------------------|-------------------------------------|-----------------------------------------------|
| Initial   | 0.0327                              | -                                             | 0.0262                              | -                                             |
| Short term| 24h                                 | 0.0326                                        | 0.0327                              | 0.0261                                        | 0.0261                                        |
|           | 2d                                  | 0.0324                                        | 0.0326                              | 0.0259                                        | 0.0261                                        |
|           | 4d                                  | 0.0321                                        | 0.0324                              | 0.0257                                        | 0.0257                                        |
| Long term | 7d                                  | 0.0316                                        | 0.0322                              | 0.0253                                        | 0.0257                                        |
|           | 21d                                 | 0.0295                                        | 0.0311                              | 0.0236                                        | 0.0249                                        |
|           | 28d                                 | 0.0286                                        | 0.0306                              | 0.0228                                        | 0.0245                                        |
|           | 50d                                 | 0.0256                                        | 0.0291                              | 0.0205                                        | 0.0233                                        |
|           | 100d                                | 0.0201                                        | 0.0264                              | 0.0161                                        | 0.0211                                        |

PEC (ground water) (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (eg. modelling, monitoring, lysimeter)

FOCUS (2000, 2014)
FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4
Input parameters used for zoxamide and its metabolites are given below:

Input parameters used in the FOCUS groundwater modelling
### End-Point

| End-Point                        | Zoxamide | RH-127450 | RH-24549 | RH-163353 | RH-141455 |
|---------------------------------|----------|-----------|----------|-----------|-----------|
| Molecular Weight (g/mol)        | 336.65   | 302.15    | 205      | 332.15    | 235.02    |
| Water Solubility, 20°C (mg/L)   | 0.681    | 1000      | 1000     | 1000      | 1000      |
| Vapour pressure, 20°C (Pa)      | $1.3 \times 10^{-5}$ | 0         | 0        | 0         | 0         |
| $K_{oc} / K_{om}$ (L/kg) – arith. mean | 1207/700 | 669/388   | 90.5/52.5* | 68/39     | 2.8/1.6   |
| Freundlich exponent, $1/n$ – arith. mean | 0.969    | 0.9†      | 0.811    | 0.892     | 1.0**     |
| DT$_{soil}$ in Soil (days) – geom. mean | 5.5      | 5.2       | 5.4      | 10.8      | 19.6      |
| Crop uptake factor               | 0        | 0         | 0        | 0         | 0         |
| Formation fraction – arith. mean | -        | 0.24 (from zoxamide) | 0.38 (from zoxamide) | 0.18 (from zoxamide) | 1 (from RH-24549) |

* worst case as adsorption is pH dependent  
** Adsorption of RH-141455 on soil was very low and therefore no desorption kinetics and desorption/desorption isotherms were determined; hence a Freundlich exponent of 1 was used.  
† The measured Freundlich exponent of 0.523 was considered unreliable so the default value was used.

### Application rate

- **Crop**: Potato  
  - FOCUS Crop: Potato  
  - Application Rate: 5 x 180 g a.s./ha (8 days interval)  
  - Application timing: First application 28 days after emergence  
  - Crop Interception: First/Second/Third application: 60%  
    Fourth/Fifth application: 85%  
  - Application every year and every three years were simulated.

- **Crop**: Vines  
  - FOCUS Crop: Vines  
  - Application Rate: 5 x 180 g a.s./ha (8 days interval)  
  - Application timing: First application 28 days after emergence  
  - Crop Interception: All application: 60%

### PEC$_{(pw)}$

| Crop                              | Potatoes | Vines |
|-----------------------------------|----------|-------|
| **Model**                         | PEARL [µg/l] | PELMO [µg/l] | PEARL [µg/l] | PELMO [µg/l] |
| **Application Scenario**          | every year | every 3 years | every year | every 3 years | every year |
| Châteaudun                        | < 0.001  | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Hamburg                           | < 0.001  | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Jokioinen                         | < 0.001  | < 0.001 | < 0.001 | < 0.001 | - | - |
| Kremsmünster                      | < 0.001  | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Crop      | RH-24549 | RH-163353 |
|-----------|-----------|-----------|
|           | PEARL [µg/l] | PELMO [µg/l] | PEARL [µg/l] | PELMO [µg/l] | PEARL [µg/l] | PELMO [µg/l] |
|           |            |            |            |            |            |            |
| **Model** |            |            |            |            |            |            |
| **Application Scenario** | every year | every 3 years | every year | every 3 years | every year | every year |
| Châteaudun | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   |
| Hamburg   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   |
| Jokioinen | < 0.001   | < 0.001   | < 0.001   | < 0.001   | -         | -         |
| Kremsmünster | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Okehampton | < 0.001   | < 0.001   | < 0.001   | < 0.001   | -         | -         |
| Piacenza  | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   |
| Porto     | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   |
| Sevilla   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   |
| Thiva     | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   |
|           |            |            |            |            |            |            |
| **Crop**  |            |            |            |            |            |            |
| **Potatoes** | PEARL [µg/l] | PELMO [µg/l] |  |  |  |  |
|           |            |            |            |            |            |            |
| **Model** |            |            |            |            |            |            |
| **Application Scenario** | every year | every 3 years | every year | every 3 years | every year | every year |
| Châteaudun | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   |
| Hamburg   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   |
| Jokioinen | < 0.001   | < 0.001   | < 0.001   | < 0.001   | -         | -         |
| Kremsmünster | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Okehampton | < 0.001   | < 0.001   | < 0.001   | < 0.001   | -         | -         |
| Piacenza  | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   |
| Porto     | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   |
| Sevilla   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   | < 0.001   |
### RH-127450

| Crop  | Potatoes | Vines |
|-------|----------|-------|
|       | PEARL [µg/l] | PELMO [µg/l] | PEARL [µg/l] | PELMO [µg/l] |
| Model |           |       |           |       |
| Application Scenario | every year | every 3 years | every year | every 3 years | every year |
| Châteaudun | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Hamburg | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Jokioinen | < 0.001 | < 0.001 | < 0.001 | < 0.001 | - | - |
| Kremsmünster | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Okehampton | < 0.001 | < 0.001 | < 0.001 | < 0.001 | - | - |
| Piacenza | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Porto | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Sevilla | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Thiva | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |

### RH-141455

| Crop  | Potatoes | Vines |
|-------|----------|-------|
|       | PEARL [µg/l] | PELMO [µg/l] | PEARL [µg/l] | PELMO [µg/l] |
| Model |           |       |           |       |
| Application Scenario | every year | every 3 years | every year | every 3 years | every year |
| Châteaudun | 1.469 | 0.594 | 1.159 | 0.416 | 3.033 | 2.420 |
| Hamburg | 5.489 | 1.727 | 3.092 | 1.114 | 5.493 | 4.753 |
| Jokioinen | 8.369 | 2.803 | 7.531 | 2.457 | - | - |
| Kremsmünster | 2.338 | 0.897 | 2.322 | 0.892 | 2.819 | 3.559 |
| Okehampton | 2.204 | 0.828 | 1.897 | 0.741 | - | - |
| Piacenza | 0.668 | 0.247 | 0.669 | 0.204 | 1.189 | 1.483 |
| Porto | 0.206 | 0.072 | 0.449 | 0.153 | 0.552 | 0.977 |
| Sevilla | 0.046 | 0.022 | 0.088 | 0.041 | 1.162 | 0.516 |
| Thiva | 0.359 | 0.142 | 0.280 | 0.111 | 0.659 | 0.583 |

**PEC (surface water and sediment)** (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 and 9.3.1)

Parameters used in FOCUS<sub>sw</sub> step 1 and 2. FOCUS Step 1 &2 version 2.1 used for calculations
### End-Point | Zoxamide | RH-127450 | RH-24549 | RH-163353 | RH-141455 | RH-139432
--- | --- | --- | --- | --- | --- | ---
Molecular Weight (g/mol) | 336.65 | 302.15 | 205 | 332.15 | 235.02 | 204.06
Water Solubility, 20°C (mg/L) | 0.681 | 1000⁺ | 1000⁺ | 1000⁺ | 1000⁺ | 1000⁺
Koc / Kom (L/kg) – arith. mean | 1207/700 | 669/388 | 90.55/53 | 68/39 | 2.8/1.6 | 10⁺
DT50 in Soil (days) – geom. mean | 5.5 | 5.2 | 5.4 | 10.8 | 19.6 | 1000⁺
DT50 whole system (days) – arithmetic. mean* | 6.4 | 237 | 1000⁺ | 1000⁺ | 1000⁺ | 1000⁺
DT50 water (days) | 6.4⁻⁻ | 237⁻⁻ | 1000⁺ | 1000⁺ | 1000⁺ | 1000⁺
DT50 sed (days) | 6.4⁻⁻ | 237⁻⁻ | 1000⁺ | 1000⁺ | 1000⁺ | 1000⁺
Max. occurrence in soil (%) | - | 15.1 | 33.8 | 15 | 8.4 | 4.9
Max. occurrence in water/sed system or aqueous photolysis(%) | - | 39.3*** | 22.7**** | 47.9**** | 10.5**** | 42.4

* Arithmetic mean is used as is more conservative than the respective geometric mean
** Following the Generic guidance for FOCUS surface water Scenarios (2012) and SANCO/10058/2005, DT₅₀ whole system must be assigned to both compartments in STEP 2
*** As worst case scenario, the higher value obtained when the system was incubated at 10°C is used for the simulations
**** Value from OECD 309 study erroneously used correct water sediment values are RH24549 5%, RH-163353 20.6%, RH-141455 2.1%
+ worst case default in absence of measured value

### Parent

Parameters used in FOCUS<sub>sw</sub> step 3 (if performed)

Step 3-4 simulations were performed for zoxamide alone.

In addition to the parameters above, the following parameters were used in the FOCUS Step 3-4 simulations for zoxamide using FOCUS SWASH v3.1 MACROv5.5.4 PRZMs w v3.1.1 and TOXSWAv3.3.1:

- Vapour Pressure (Pa, 25°C) < 1.3x10⁻³
- 1/n – arith. mean 0.973
- DT₅₀ in water(days) at 20°C* 1000 (default) / 6.4
- DT₅₀ in sediment (days) at 20°C* 6.4 / 1000 (default)
- Plant Uptake Factor 0 (conservative value)
- Exponent for the effect of water content 0.49(MACRO) 0.7 (PRZM)

* Two combinations of DT₅₀s were assumed:
  - combination # 1: DT₅₀water 1000 d & DT₅₀sed 6.4 d
  - combination # 2: DT₅₀water 6.4 d & DT₅₀sed 1000 d
### Step 1-2 assumptions:
5 applications of 180 g a.s./ha to potatoes and grapevines at an interval of 8 days

| Crop type                          | Potatoes, Grapevines (early application), Grapevines (late application) |
|------------------------------------|------------------------------------------------------------------------|
| Crop interception                  | Potatoes – average crop cover for both crops                           |
|                                    | Grapevines (early application) – minimal crop cover                    |
|                                    | Grapevines (late application) – full crop cover                        |
| Region and season of application   | Potatoes - N & S EU June-Sept                                           |
|                                    | Grapevines (early application) – N & S EU Mar-May                       |
|                                    | Grapevines (late application) – N & S EU June-Sept                      |

### Step 3-4 assumptions:

#### FOCUS Crop: Potato
- **Application Rate:** 1 x 180 g a.s./ha
- **Application Rate:** 5 x 180 g a.s./ha (8 days interval)

**Application timing:**
- 37 days before harvest to 7 days before harvest for single application and 69 days before harvest to 7 days before harvest for multiple application (Actual dates set by PAT)

**Crop Interception:** Calculated internally by MACRO or PRZM (foliar application defined in SWASH)

**Appropriate Scenarios:** D3, D4, D6, R1, R2 and R3

#### FOCUS Crop: Vines (early application)
- **Application Rate:** 1 x 180 g a.s./ha
- **Application Rate:** 5 x 180 g a.s./ha (8 days interval)

**Application timing:**
- 28 days after emergence to 58 days after emergence for single application and 28 days after emergence to 90 days after emergence for multiple application (Actual dates set by PAT)

**Crop Interception:** Calculated internally by MACRO or PRZM (foliar application defined in SWASH)

**Appropriate Scenarios:** D6, R1, R2, R3 and R4

#### FOCUS Crop: Vines (late application)
- **Application Rate:** 1 x 180 g a.s./ha
- **Application Rate:** 5 x 180 g a.s./ha (8 days interval)

**Application timing:**
- 58 days before harvest to 28 days before harvest for single application and 90 days before harvest to 28 days before harvest for multiple application (Actual dates set by PAT)

**Crop Interception:** Calculated internally by MACRO or PRZM (foliar application defined in SWASH)

**Appropriate Scenarios:** D6, R1, R2, R3 and R4

### Drift, run-off
Main routes of entry
Summary of FOCUS Step 1 and 2 PECsw and PECsed for zoxamide and its metabolites

| Crop              | Step | Region | Zoxamide | RH-127450 | RH-24549 | RH-163353 | RH-141455 | RH-139432 |
|-------------------|------|--------|----------|-----------|----------|-----------|-----------|-----------|
| **PECsw**         |      |        |          |           |          |           |           |           |
| Potatoes          | Step 1 | -      | 123.2489 | 24.4087   | 56.2390  | 44.6193   | 18.1338   | 10.92     |
|                   | Step 2 | N EU   | 2.7467   | 1.5062    | 1.7003   | 3.8136    | 1.3229    | 2.22      |
|                   |       | S EU   | 3.8331   | 1.6975    | 2.2110   | 4.5376    | 1.7903    | 2.65      |
| Vines - early     | Step 1 | -      | 123.0689 | 24.3453   | 56.2141  | 44.5343   | 18.1206   | 10.87     |
|                   | Step 2 | N EU   | 3.3745   | 1.9610    | 2.1332   | 4.8997    | 1.6405    | 2.85      |
|                   |       | S EU   | 5.9819   | 2.4202    | 3.3587   | 6.6373    | 2.7623    | 3.89      |
| Vines - late      | Step 1 | -      | 139.0559 | 29.9843   | 58.4240  | 52.0897   | 19.2924   | 14.98     |
|                   | Step 2 | N EU   | 5.3315   | 4.7282    | 3.1246   | 9.6191    | 1.9965    | 5.52      |
|                   |       | S EU   | 5.3315   | 4.7282    | 3.4310   | 10.0535   | 2.2770    | 5.78      |
| **PECsed**        |      |        |          |           |          |           |           |           |
| Potatoes          | Step 1 | -      | 1.39E+03 | 153.6362  | 50.7776  | 30.0992   | 0.5073    | 0.88      |
|                   | Step 2 | N EU   | 30.8338  | 8.8688    | 1.5165   | 2.5469    | 0.0370    | 0.22      |
|                   |       | S EU   | 43.9464  | 10.1452   | 1.9786   | 3.0389    | 0.0501    | 0.26      |
| Vines - early     | Step 1 | -      | 1.39E+03 | 153.4124  | 50.7575  | 30.0462   | 0.5070    | 0.88      |
|                   | Step 2 | N EU   | 37.6305  | 11.5059   | 1.9008   | 3.2699    | 0.0459    | 0.28      |
|                   |       | S EU   | 69.1007  | 14.5691   | 3.0097   | 4.4507    | 0.0773    | 0.39      |
| Vines - late      | Step 1 | -      | 1.39E+03 | 173.2934  | 52.5417  | 34.7535   | 0.5396    | 0.88      |
|                   | Step 2 | N EU   | 32.7826  | 24.8949   | 2.7458   | 6.3717    | 0.0558    | 0.55      |
|                   |       | S EU   | 40.6502  | 25.6607   | 3.0230   | 6.6669    | 0.0637    | 0.58      |

Initial FOCUS Step 3 and 4 PECsw and PECsed for zoxamide, potatoes (single application)

| Scenario | PECsw [µg/L] | PECsed [µg/kg] | Main |
|----------|--------------|----------------|------|

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Initial FOCUS Step 3 and 4 PECsw and PECsed for zoxamide, potatoes (multiple application)

| Scenario | PECsw [µg/L] | PECsed [µg/kg] | Main route of entry |
|----------|--------------|----------------|-------------------|
| Step 3   | Step 4       | Step 3         | Step 4            |
| D3 Ditch | 0.943        | 0.164          | 0.487             | 0.093           | Drift |
| D4 Pond  | 0.038        | -              | 0.086             | -               | Drift |
| D4 Stream| 0.709        | 0.159          | 0.018             | 0.004           | Drift |
| D6 Ditch (1st) | 0.937     | 0.163          | 0.311             | 0.058           | Drift |
| D6 Ditch (2nd) | 0.938     | 0.380          | 0.353             | 0.062           | Drift |
| R1 Pond  | 0.038        | -              | 0.081             | -               | Drift |
| R1 Stream| 0.654        | 0.146          | 0.095             | 0.045           | Drift |
| R2 Stream| 0.877        | 0.312          | 0.385             | 0.379           | Drift |
| R3 Stream| 0.922        | 0.618†         | 0.282             | 0.967           | Drift |

* Mitigation: 10 m spray drift; ** Mitigation: 10 m spray drift and 10 m vegetative strip (manual); † Run-off is the main route of entry when this mitigation is considered; Figures in bold are those obtained for the simulations using a DT_{50water} of 1000 days and a DT_{50sed} of 6.4 days.
Peer review of the pesticide risk assessment of the active substance zoxamide

Initial FOCUS Step 3 and 4 PECsw and PECsed for zoxamide, vines (early application, single application)

| Scenario   | PECsw [µg/L] | PECsed [µg/kg] | Main route of entry into water body at Step 3 |
|------------|--------------|----------------|-----------------------------------------------|
|            | Step 3       | Step 4         | Step 3                                       | Step 4                               |
|            | 10 m*        | 10 m**         | 10 m*                                        | 10 m**                               |

* Spray drift and run-off mitigation was considered for the run-off scenarios (manual); † No mitigation can be performed for drainage within the programme
### Initial FOCUS Step 3 and 4 PECsw and PECsed for zoxamide, vines (early application, multiple application)

| Scenario | **PEC<sub>SW</sub> [µg/L]** | **PEC<sub>SED</sub> [µg/kg]** | Main route of entry into water body at Step 3 |
|----------|-----------------------------|-------------------------------|-----------------------------------------------|
|          | **Step 3**                  | **Step 4**                   |                                               |
|          | Step 3                      | Step 4                       |                                               |
|          | 10 m*                       | 10 m**                       | 10 m*                                        |
|          | 10 m**                      | 20 m**                       | 10 m**                                       |
|          | 20 m**                      |                               | 20 m**                                       |
Initial FOCUS Step 3 and 4 PEC_{sw} and PEC_{sed} for zoxamide, vines (late application, single application)

| Scenario | PEC_{SW} [µg/L] | PEC_{SED} [µg/kg] | Main route of entry into water body at Step 3 |
|----------|-----------------|------------------|---------------------------------------------|
|          | Step 3          | Step 4           | Step 3   | Step 4   |                                  |
|          | 10 m*           | 20 m**           | 10 m*    | 20 m**   |                                  |
| D6 Ditch | 3.086           | 0.676            | 0.237    | 3.819    | 0.890  | 0.326  | Drift |
| R1 Pond  | 0.110           | -                | -        | 0.265    | -   | -   | Drift |
| R1 Stream| 2.264           | 0.597            | 0.209    | 0.327    | 0.087  | 0.0305  | Drift |

* Mitigation: 10 m spray drift; ** Spray drift and run-off mitigation was considered (manual); † Run-off is the main route of entry when this mitigation is considered; ‡ Spray drift is the main route of entry when this mitigation is considered.
Initial FOCUS Step 3 PECsw and PECsed for zoxamide, vines (late application, multiple application)

| Scenario          | PECsw [µg/L] | PECsed [µg/kg] | Main route of entry into water body at Step 3 |
|-------------------|--------------|----------------|---------------------------------------------|
|                   | Step 3       | Step 3         |                                             |
| D6 Ditch          | 3.546        | 8.442          | Drift                                       |
| R1 Pond           | 0.308        | 0.600          | Drift                                       |
| R1 Stream         | 1.857        | 0.421          | Drift                                       |
| R2 Stream         | 2.489        | 0.315          | Drift                                       |
| R3 Stream         | 2.622        | 1.823          | Drift                                       |
| R4 Stream         | 2.128        | 1.485          | Run-off                                     |

* Mitigation: 10 m spray drift; ** Mitigation: 20 m spray drift

Initial FOCUS 4 PECsw for zoxamide, vines (late application, multiple application)

| Scenario          | PECsw [µg/L] |
|-------------------|--------------|
|                   | Step 4       |
|                   | 10 m (drift) | 10 m* | 20 m (drift) | 20 m* |
| D6 Ditch          | 0.776        | -     | 0.272        | -     |
| R1 Pond           | -            | -     | -            | -     |
| R1 Stream         | 0.482        | -     | 0.167        | -     |
| R2 Stream         | 0.647        | -     | 0.224        | -     |
| R3 Stream         | 1.579†       | 0.707†| 1.579†       | 0.368†|
| R4 Stream         | -            | 0.950†| -            | 0.494†|

* Spray drift and run-off mitigation was considered (manual); † Run-off is the main route of entry when this mitigation is considered; ‡ Spray drift is the main route of entry when this mitigation is considered

Initial FOCUS Step 4 PECsed for zoxamide, vines (late application, multiple application)
### Table 1: PEC_{SED} [µg/kg]

| Scenario       | 10 m (drift) | 10 m* | 20 m (drift) | 20 m* |
|----------------|-------------|--------|--------------|-------|
| D6 Ditch       | 2.005       | -      | 0.738        | -     |
| R1 Pond        | -           | -      | -            | -     |
| R1 Stream      | 0.114       | -      | 0.063        | -     |
| R2 Stream      | 0.085       | -      | 0.030        | -     |
| R3 Stream      | 1.504       | 0.711  | 1.423        | 0.348 |
| R4 Stream      | -           | 0.605  | -            | 0.304 |

* Spray drift and run-off mitigation was considered (manual);
Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

| Species          | Test substance | Time scale | End point | Toxicity (mg/kg bw per day) |
|------------------|----------------|------------|-----------|----------------------------|
| **Birds**        |                |            |           |                            |
| Bobwhite quail   | a.s.           | Acute      | LD₅₀      | >2000                      |
| *Colinus virginianus* |             |            |           |                            |
| Bobwhite quail   | a.s.           | Short-term | LD₅₀      | 1889.3                     |
| *Colinus virginianus* |          |            |           |                            |
| Mallard duck     | a.s.           | Short-term | LD₅₀      | 1597.7                     |
| *Anas plathyrrhynchos* |          |            |           |                            |
| Mallard duck     | a.s.           | Reproduction | NOEC   | 122.8                      |
| *Anas plathyrrhynchos* |          |            |           |                            |
| Bobwhite quail   | a.s.           | Reproduction | NOEC   | 170.9                      |
| *Colinus virginianus* |          |            |           |                            |
| **Mammals**      |                |            |           |                            |
| Rat              | a.s.           | Acute      | LD₅₀      | >5000                      |
| Rat              | a.s.           | Long term  | NOAEL     | 360                        |
| (parental)       |                |            |           |                            |
| Rat              | a.s.           | Reproductive | NOAEL | 1474                       |
| Rat              | a.s.           | Long term  | NOAEL     | 360                        |
| (offspring)      |                |            |           |                            |
| Rabbit           | a.s.           | Long term  | NOAEL     | 1000                       |
| (development)    |                |            |           |                            |
| Rat              | a.s.           | Long term  | NOAEL     | 1000                       |
| (development)    |                |            |           |                            |
| Rat              | a.s.           |            |           | 71*                        |

Endocrine disrupting properties (Annex Part A, points 8.1.5)

With regard to the endocrine disruption potential, as discussed in Section 2, it is unlikely that zoxamide is an endocrine disruptor for mammals. No firm conclusion could be drawn regarding fish and birds.

Additional higher tier studies (Annex Part A, points 10.1.1.2)

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):

* Value agreed in the Peer review meeting 160 by experts
Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) No 284/2013, Part A, Annex point 10.1)

**Zoxium 240 SC: Potatoes at 180 g a.s./ha [5 applications]**

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|----------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | | | | | |
| All | Small omnivorous bird | Acute | 48.59 | 41.2 | 10 |
| All | Small omnivorous bird | Long-term | 13.60 | 9.0 | 5 |
| Tier 1 (Birds): | | | | | |
| | | | | | |
| Higher tier (birds): | | | | | |
| | | | | | |
| Screening Step (Mammals) | | | | | |
| All | Small herbivorous mammal | Acute | 36.23 | 138.0 | 10 |
| All | Small herbivorous mammal | Long-term | 10.14 | 7.00 | 5 |
| Tier 1 (Mammals) | | | | | |
| | | | | | |
| Higher tier (Mammals): | | | | | |
| | | | | | |

**Zoxium 240 SC: grapevines at 180 g a.s./ha [5 applications]**

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|----------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | | | | | |
| All | Small omnivorous bird | Acute | 29.16 | 68.6 | 10 |
| All | Small omnivorous bird | Long-term | 8.16 | 15.0 | 5 |
| Tier 1 (Birds): | | | | | |
| | | | | | |
| Higher tier (birds): | | | | | |
| | | | | | |
| Screening Step (Mammals) | | | | | |
| All | Small herbivorous mammal | Acute | 41.74 | 119.8 | 10 |
| All | Small herbivorous mammal | Long-term | 15.17 | 4.68 | 5 |
| Tier 1 (Mammals) | | | | | |

BBCH 10-19 Large herbivorous mammal "lagomorph" Long-term 1.4 50.7 5
BBCH 20 - 39 Large herbivorous mammal "lagomorph" Long-term 1.1 61.8 5
BBCH ≥ 40 Large herbivorous mammal "lagomorph" Long-term 0.7 103.0 5
BBCH 10 - 19 Small insectivorous mammal "shrew" Long-term 0.9 80.9 5
BBCH ≥ 20 Small insectivorous mammal "shrew" Long-term 0.4 178.9 5
| Growth stage | Indicator or focal species                          | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------------------------------|------------|------------------------|-----|---------|
| BBCH ≥ 40    | Small herbivorous mammal “voles”                  | Long-term  | 4.5                    | 15.7| 5       |
| BBCH ≥ 40    | Small omnivorous mammal “mouse”                   | Long-term  | 0.5                    | 147.8| 5       |

**Higher tier (Mammals):**

Not required.

### Risk from bioaccumulation and food chain behaviour

| Indicator or focal species                          | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------------------------------|------------|------------------------|-----|---------|
| zoxamide                                          |            |                        |     |         |
| Earthworm-eating birds                            | Long-term  | 1.15                   | 107.1| 5       |
| Earthworm-eating mammals                          | Long-term  | 1.40                   | 257.54| 5       |
| Fish-eating birds                                 | Long-term  | 0.15                   | 787.44| 5       |
| Fish-eating mammals                               | Long-term  | 0.13                   | 2777.05| 5       |

**RH-127450***

| Indicator or focal species                          | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds                            | Long-term  | 1.36                   | 8.38 | 5       |
| Earthworm-eating mammals                          | Long-term  | 1.36                   | 3.67 | 5       |
| Earthworm-eating mammals (use on grapes)          | Long-term  | 0.11                   | 46   | 5       |
| Fish-eating birds                                 | Long-term  | 0.12                   | 20.84| 5       |
| Fish-eating mammals                               | Long-term  | 0.48                   | 10.4 | 5       |

**RH-24549***

| Indicator or focal species                          | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds                            | Long-term  | 2.35                   | 4.84 | 5       |
| Earthworm-eating birds (use on grapes)            | Long-term  | 1.88                   | 6.05 | 5       |
| Earthworm-eating mammals                          | Long-term  | 2.9                    | 12.55| 5       |
| Fish-eating birds                                 | Long-term  | 1.2                    | 9.14 | 5       |
| Fish-eating mammals                               | Long-term  | 1.2                    | 28.88| 5       |

**Higher tier:**

Not required.

### Risk from consumption of contaminated water

| Scenarios                                      | Indicator or focal species | Time scale | PEC_{dw}xDWR | TER | Trigger |
|------------------------------------------------|---------------------------|------------|--------------|-----|---------|
| Leaf scenario                                  | Birds                     | Not required for the intended uses |              | 5   |         |

**Puddle scenario, Screening step**

Application rate (180 g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed

* In the absence of toxicity data the metabolites were considered as 10 times more toxic than the parent compound.

**Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)**

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.
| Group                      | Test substance | Time-scale (Test type) | End point | Toxicity^1 |
|---------------------------|----------------|------------------------|-----------|------------|
| Laboratory tests          |                |                        |           |            |
| Fish                      |                |                        |           |            |
| *Oncorhynchus mykiss*     | a.s.           | Acute 96 hr (flow-through) | Mortality, LC$_{50}$ | 0.16 mg a.s./L (mm) |
| *Lepomis macrochirus*     | a.s.           | Acute 96 hr (flow-through) | Mortality, LC$_{50}$ | >0.79 mg a.s./L (mm) |
| *Pimephales promelas*     | a.s.           | Acute 96 hr (flow-through) | Mortality, LC$_{50}$ | >208 mg a.s./L (mm) |
| *Brachydanio rerio*       | a.s.           | Acute 96 hr (flow-through) | Mortality, LC$_{50}$ | >0.73 mg a.s./L (mm) |
| *Cyprinodon variegatus*   | a.s.           | Acute 96 hr (flow-through) | Mortality, LC$_{50}$ | >0.85 mg a.s./L (mm) |
| *Danio rerio*             | Preparation    | Acute 96 hr (static)    | Mortality, LC$_{50}$ | 0.865 mg prep./L (0.184 mg a.s./L) |
| *Oncorhynchus mykiss*     | RH-139 432     | Acute 96 hr (flow-through) | Mortality, LC$_{50}$ | 2 mg/L (nom) (mm) |
| *Oncorhynchus mykiss*     | RH-24549       | 48h-semi static         | Mortality, LC$_{50}$ | 23 mg/L (mm) |
| *Oncorhynchus mykiss*     | a.s.           | 95 d (flow-through, ELS) | NOEC      | 0.00348 mg a.s./L (mm) |
| *Pimephales promelas*     | a.s.           | 202 d (flow-through, FLC) | NOEC      | 0.06 mg a.s./L (mm) |
| *Lepomis macrochirus*     | a.s.           | 28 day (flow-through, bioaccumulation) | BCF       | 95-136 mg a.s./L |
| *Danio rerio*             | a.s.           | 30 days - post-hatch under flow-through conditions, ELS | NOEC      | ≥0.12 mg a.s./L (mm) |
| Aquatic invertebrates     |                |                        |           |            |
| *Daphnia magna*           | a.s.           | 48 h (flow-through)     | Mortality, EC$_{50}$ | >0.78 mg a.s./L (mm) |
| Group                   | Test substance     | Time-scale (Test type) | End point            | Toxicity                                      |
|------------------------|--------------------|------------------------|----------------------|-----------------------------------------------|
| *Mysisidopsis bahia*   | a.s.               | 96h (flow-through)     | Mortality, LC<sub>50</sub> | 0.076 mg a.s./L (mm)                          |
| *Daphnia magna*        | Preparation        | 48 h (static)          | Mortality, EC<sub>50</sub> | >3.0 mg prep./L (>0.69 mg a.s./L)              |
| *Daphnia magna*        | a.s.               | 21d (flow-through)     | NOEC                 | 0.039 mg a.s./L (mm)                          |
| *Chironomus riparius*  | a.s.               | 28d (flow-through)     | NOEC                 | 0.45 mg a.s./L (nom)                          |
|                        |                    |                        | EC<sub>10</sub> (development rate) | 0.38 mg a.s./L (geomean)                      |
|                        |                    |                        | EC<sub>10</sub> (emergence rate) | 0.223 mg a.s./L                              |
| *Mysisidopsis bahia*   | a.s.               | 27 d (flow-through)    | NOEC                 | 0.0072 mg a.s./L (mm)                         |
| *Daphnia magna*        | RH-139432          | 48h (semi-static)      | Mortality, EC<sub>50</sub> | 17 mg/L (mm)                                  |
| *Daphnia magna*        | RH-24549           | 48h - static           | Mortality, EC<sub>50</sub> | 40 mg/L (mm)                                  |
| **Algae**              |                    |                        |                      |                                               |
| *Selenastrum capricornutum* | Preparation   | 96h (static)          | Growth rate: E<sub>i</sub>C<sub>50</sub> (NOEC) | 0.274 mg prep./L (0.0582 mg a.s./L) *          |
|                        |                    |                        |                      |                                               |
|                        |                    |                        | Biomass: E<sub>i</sub>C<sub>50</sub> (NOEC) | 0.24 mg prep./L (0.0514 mg a.s./L) *           |
| *Desmodesmus subspicatus* | RH-24549          | 72h static             | E<sub>i</sub>C<sub>50</sub> | >60 mg/L (nom)                                |
|                        |                    |                        | Growth rate: E<sub>i</sub>C<sub>50</sub> | >60 mg/L (nom)                                |
| *Pseudokirchneriella subcapitata* | RH-141455   | 72 static             | EC<sub>50</sub>      | >100 mg/L (nom)                               |
|                        |                    |                        | EC<sub>10</sub> yield | 96.3 mg/L (nom)                               |
|                        |                    |                        | EC<sub>10</sub> growth rate | >100 mg/L (nom)                              |
| Group          | Test substance | Time-scale (Test type) | End point | Toxicity $^{1}$ |
|---------------|----------------|------------------------|-----------|-----------------|
| Aquatic plant |                |                        |           |                 |
| *Lemna gibba* | a.s.           | 14 d (static renewal)  | 7 d-EC$_{50}$ | >0.018 mg a.s./L(mm) |
|               |                |                        | 14 d-EC$_{50}$ | 0.017 mg a.s./L(mm) |
|               |                |                        | NOEC      | 0.009 mg a.s/L   |

Further testing on aquatic organisms

- 

Potential endocrine disrupting properties (Annex Part A, point 8.2.3)

With regard to the endocrine disruption potential, as discussed in Section 2, it is unlikely that zoxamide has endocrine disrupting properties in mammals. No firm conclusion could be drawn regarding fish and birds.

$^{1}$ (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance

*Endpoints expressed as mg formulation/L are converted to mg a.s./L considering the purity of the formulation (21.24%)

** Study was performed with RH-117,281 2F, a very similar formulation to Zoxium 240 SC. Refer to Document J-CP for details of both formulations.

Values in bold are used for TER calculation

### Bioconcentration in fish (Annex Part A, point 8.2.2.3)

| Log Pow     | 3.76 ± 0.04 (98.7%) |
|-------------|---------------------|
| Bioconcentration factor (BCF) | 95-136 mg a.s./L |
| Risk assessment trigger for the bioconcentration factor | - |
| Clearance time (CT50) | - |
| (CT90) | - |
| Level of residues (%) in organisms after the 14 day depuration phase | - |
Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

**FOCUS<sub>n</sub> step 1-3 - TERs for zoxamide – Zoxium 240 SC at potatoes at 180 g a.s./ha [5 applications]**

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Higher plant | Sed. dweller prolonged |
|----------|-----------------------|------------|--------------|-----------------------|-------------------------------|--------------|------------------------|
|          |                       | Oncorhynchus mykiss | Oncorhynchus mykiss | Mysisopsis bahia | Mysisopsis bahia | Lemma sp. | Chironomus riparius |
|          |                       | LC<sub>50</sub> | NOEC | EC<sub>50</sub> | NOEC | EC<sub>50</sub> | NOEC |
| FOCUS Step 1 | 160 µg/L | 3.48 µg/L | 76 µg/L | 7.2 µg/L | 9µg/L | 380 µg/L |
| FOCUS Step 2 | 123.2489 | 1.29 | 0.028 | 0.62 | 0.058 | 0.07 | 3.08 |
| North Europe | 2.7467 | 58.25 | 1.27 | 27.67 | 2.62 | 3.28 | 138.3 |
| South Europe | 3.8331 | 41.75 | 0.91 | 19.83 | 1.88 | 2.35 | 99.1 |
| FOCUS Step 3 | | | | | | | |
| D3 / ditch | 0.943<sup>1</sup> | 170 | 3.69 | 80.6 | 7.64 | 9.5 | Not required |
| D4 / pond | 0.047<sup>2</sup> | 3404 | 74.0 | 1617 | 153 | 190.7 | Not required |
| D4 / stream | 0.709<sup>1</sup> | 226 | 4.91 | 107 | 10.1 | 12.7 | Not required |
| D6 / ditch (1<sup>st</sup>) | 0.937<sup>1</sup> | 171 | 3.71 | 81.1 | 7.68 | 9.6 | Not required |
| D6 / ditch (2<sup>nd</sup>) | 1.370<sup>1</sup> | 116.8 | 2.54 | 55.5 | 5.26 | 6.6 | Not required |
| R1 / pond | 0.534<sup>2</sup> | 300 | 6.52 | 142 | 13.5 | 16.8 | Not required |
| R1 / stream | 2.415<sup>2</sup> | 66.3 | 1.44 | 31.5 | 2.98 | 3.7 | Not required |
| R2 / stream | 0.877<sup>1</sup> | 182 | 3.97 | 86.7 | 8.21 | 10.3 | Not required |
| R3 / stream | 0.961<sup>2</sup> | 166 | 3.62 | 79.1 | 7.49 | 9.4 | Not required |
| Trigger<sup>#</sup> | 100 | 10 | 100 | 10 | 10 | 10 |

<sup>1</sup> single application
<sup>2</sup> multiple application
<sup>#</sup>[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
<sup>**</sup>[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

# Values are in bold when an high risk could not be excluded
Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)  
FOCUS<sub>sw</sub> step 1-3 - TERs for zoxamide – Zoxium 240 SC at grapevines (late application) at 180 g a.s./ha [5 applications]

| Scenario | PEC global max (µg L<sup>-1</sup>) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Higher plant | Sed. dweller prolonged |
|----------|----------------------------------|------------|--------------|-----------------------|---------------------------------|--------------|------------------------|
|          |                                  | Oncorhynchus mykiss | Oncorhynchus mykiss | Mysisopsis bahia | Mysisopsis bahia | Lemma sp. | Chironomus riparius |
|          |                                  | LC<sub>50</sub> | NOEC | EC<sub>30</sub> | NOEC | EC<sub>50</sub> | NOEC |
| FOCUS Step 1 | 160 µg/L                         | 3.48 µg/L | 76 µg/L | 7.2 µg/L | 9µg/L | 380 µg/L |
| FOCUS Step 2 |                                  | 139.0559 | 1.15 | 0.025 | 0.55 | 0.052 | 0.06 | 2.73 |
| North Europe | 5.3315                      | 30.01 | 0.65 | 14.25 | 1.35 | 1.69 | 71.3 |
| South Europe | 5.3315                     | 30.01 | 0.65 | 14.25 | 1.35 | 1.69 | 71.3 |
| FOCUS Step 3 |                                  | 3.546<sup>2</sup> | 45.1 | 0.98 | 21.4 | 2.03 | 2.5 | Not required |
| D6 / ditch | 3.08<sup>2</sup> | 5.19 | 11.3 | 247 | 23.4 | 29.2 | Not required |
| R1 / pond | 2.264<sup>1</sup> | 70.7 | 1.54 | 33.6 | 3.18 | 4 | Not required |
| R1 / stream | 3.034<sup>1</sup> | 52.7 | 1.15 | 25.0 | 2.37 | 3 | Not required |
| R2 / stream | 3.190<sup>1</sup> | 50.1 | 1.09 | 23.8 | 2.26 | 2.8 | Not required |
| R3 / stream | 2.263<sup>1</sup> | 70.7 | 1.54 | 33.6 | 3.18 | 4 | Not required |
| R4 / stream | 100 | 10 | 100 | 10 | 10 | 10 | Not required |
| Trigger<sup>**</sup> | 100 | 10 | 10 | 10 | 10 | 10 | 10 |

1<sup>single application</sup>  
2<sup>multiple application</sup>  
3<sup>[Only scenarios where the trigger is not met at FOCUS<sub>sw</sub> step 1-2 should be included in step 3.]</sup>  
4<sup>[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]</sup>  
# Values are in bold when an high risk could not be excluded

FOCUS<sub>sw</sub> step 4 - TERs zoxamide – Zoxium 240 SC at 180 g a.s./ha [5 applications]
Organisms
*Oncorhynchus mykiss*

**Toxicity endpoint:**
160 µg/L

| Mitigation options | 10 m non-spray buffer zone (corresponding to ≤ 95 % drift reduction) | 10 m non-spray buffer zone and 10 m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction) | TER | Trigger |
|--------------------|---------------------------------------------------------------|---------------------------------------------------------------|------|---------|
| **FOCUS Step 4**   |                                                              |                                                              |      |         |
| **Potatoes**       |                                                              |                                                              |      |         |
| R1 / stream        | 1.028                                                         | 0.368                                                         | 156  | 100     |
| **Grapevines (late application)** |                                                             |                                                              |      |         |
| D6 / ditch         | 0.776                                                         | -                                                            | 206  | 100     |
| R1 / stream        | 0.597                                                         | -                                                            | 268  | 100     |
| R2 / stream        | 0.801                                                         | -                                                            | 200  | 100     |
| R3 / stream        | 1.564                                                         | -                                                            | 102  | 100     |
| R4 / stream        | 0.950                                                         | 0.950                                                        | 168  | 100     |

*Only scenarios where the trigger is not met at FOCUS sw step 3 should be included in step 4.
# Values are in bold when an high risk could not be excluded
FOCUS\textsubscript{sw} step 4 - TERs zoxamide – Zoxium 240 SC at 180 g a.s./ha [5 applications]

**Organisms**
*Oncorhynchus mykiss*

**Toxicity endpoint:**
3.48 µg/L

| Mitigation options | 10 m non-spray buffer zone | 10 m non-spray buffer zone and 10m vegetated buffer strip | 20 m non-spray buffer zone | 20 m non-spray buffer zone and 20m vegetated buffer strip | TER | Trigger |
|--------------------|-----------------------------|----------------------------------------------------------|-----------------------------|----------------------------------------------------------|-----|---------|
| **FOCUS Step 4\*** |                             |                                                          |                             |                                                          |     |         |
| **Potatoes**       |                             |                                                          |                             |                                                          |     |         |
| D3 / ditch         | 0.164                       | -                                                        | -                           | -                                                        | 21.2| 10      |
| D4 / stream        | 0.159                       | -                                                        | -                           | -                                                        | 21.9| 10      |
| D6 / ditch (1\*\*) | 0.163                       | -                                                        | -                           | -                                                        | 21.3| 10      |
| D6 / ditch (2\*\*) | 1.370                       | -                                                        | -                           | -                                                        | 2.54| 10      |
| R1 / pond          | 0.235                       | -                                                        | -                           | -                                                        | 14.81| 10     |
| R1 / stream        | 1.028                       | 0.368                                                    | 0.539                       | 0.0477                                                   | 6.47| 10      |
| R2 / stream        | 0.312                       | -                                                        | -                           | -                                                        | 11.1 | 10      |
| R3 / stream        | 0.618                       | 0.282                                                    | -                           | -                                                        | 12.3 | 10      |

| **Grapevines (late application)** | | | | | |
|-----------------------------------|-----------------------------|----------------------------------------------------------|-----------------------------|----------------------------------------------------------|-----|---------|
| D6 / ditch                        | 0.776                       | -                                                        | 0.272                       | -                                                        | 12.8| 10      |
| R1 / stream                       | 0.597                       | -                                                        | -                           | 0.209                                                   | 16.6| 10      |
| R2 / stream                       | 0.801                       | -                                                        | -                           | 0.281                                                   | 12.4| 10      |
| R3 / stream                       | 1.579                       | 0.707                                                    | 1.579                       | 0.368                                                   | 9.46 | 10      |
| R4 / stream                       | -                           | 0.950                                                    | -                           | 0.494                                                   | 7.04 | 10      |

\*Only scenarios where the trigger is not met at FOCUS\textsubscript{sw} step 3 should be included in step 4.

# Values are in bold when an high risk could not be excluded

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**FOCUS\textsubscript{sw} step 4 - TERs zoxamide – Zoxium 240 SC at 180 g a.s./ha [5 applications]**

**Organisms**
*Mysidopsis bahia*
Toxicity endpoint: 76 µg/L

Mitigation options

| Mitigation options | 10 m non-spray buffer zone | 10 m non-spray buffer zone and 10m vegetated buffer strip | 20 m non-spray buffer zone and 20m vegetated buffer strip | TER | Trigger |
|--------------------|-----------------------------|----------------------------------------------------------|----------------------------------------------------------|-----|---------|
| FOCUS Step 4*      |                             |                                                          |                                                          |     |         |
| Potatoes           |                             |                                                          |                                                          |     |         |
| D3 / ditch         | 0.164                       | -                                                       | -                                                        | 463 | 100     |
| D6 / ditch (1ˢᵗ)   | 0.163                       | -                                                       | -                                                        | 466 | 100     |
| D6 / ditch (2ⁿᵈ)   | 1.370                       | -                                                       | -                                                        | 55.5| 100     |
| R1 / stream        | -                           | 1.027                                                   | 0.539                                                    | 141 | 100     |
| R2 / stream        | 0.312                       | -                                                       | -                                                        | 243 | 100     |
| R3 / stream        | 0.618                       | -                                                       | -                                                        | 123 | 100     |
| Grapevines (late application) |      |                                                          |                                                          |     |         |
| D6 / ditch         | 0.776                       | -                                                       | 0.272                                                    | 279 | 100     |
| R1 / stream        | 0.597                       | -                                                       | -                                                        | 127 | 100     |
| R2 / stream        | 0.801                       | -                                                       | 0.281                                                    | 270 | 100     |
| R3 / stream        | 1.579                       | 0.707                                                   | -                                                        | 108 | 100     |
| R4 / stream        | -                           | 0.950                                                   | 0.494                                                    | 154 | 100     |

* [Only scenarios where the trigger is not met at FOCUSsw step 3 should be included in step 4].
# Values are in bold when a high risk could not be excluded

FOCUSsw step 3 - TERs zoxamide – Zoxium 240 SC at 180 g a.s./ha [5 applications] using refined LC₅₀ value for aquatic invertebrates

| Scenario      | Main route of entry into water body at Step 3 | Maximum initial Step 3 PECsw (µg a.s./L) | Acute endpoint (µg a.s./L) | TER | Trigger value |
|---------------|-----------------------------------------------|-----------------------------------------|-----------------------------|-----|----------------|
| Potatoes:     |                                               |                                         |                             |     |                |
| D3 Ditch      | Drift                                        | 0.943¹                                 | 229                         | 242.8| 100            |
| D4 Pond       | Drift                                        | 0.047²                                 | 4.872                       |     |                |
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### Scenario

| Scenario                  | Main route of entry into water body at Step 3 | Maximum initial Step 3 PEC\textsubscript{sw} (µg a.s./L) | Acute endpoint (µg a.s./L) | TER | Trigger value |
|--------------------------|-----------------------------------------------|--------------------------------------------------------|-----------------------------|-----|---------------|
| D4 Stream                | Drift                                         | 0.709\textsuperscript{1}                                |                             | 323 |               |
| D6 Ditch (1\textsuperscript{st}) | Drift                                         | 0.937\textsuperscript{1}                                |                             | 244.3 |               |
| D6 Ditch (2\textsuperscript{nd}) | Drainage                                      | 1.370\textsuperscript{2}                                |                             | 167.2 |               |
| R1 Pond                  | Run-off                                       | 0.534\textsuperscript{2}                                |                             | 428.8 |               |
| R1 Stream                | Run-off                                       | 2.415\textsuperscript{2}                                |                             | 94.8 |               |
| R2 Stream                | Drift                                         | 0.877\textsuperscript{1}                                |                             | 261.1 |               |
| R3 Stream                | Run-off                                       | 0.961\textsuperscript{2}                                |                             | 238.3 |               |
| **Grapevines (early application):** |                                              |                                                      |                             |     |               |
| D6 Ditch                 | Drift                                         | 1.471\textsuperscript{2}                                |                             | 155.7 |               |
| R1 Pond                  | Drift                                         | 0.126\textsuperscript{2}                                |                             | 1.817 |               |
| R1 Stream                | Drift                                         | 1.666\textsuperscript{2}                                |                             | 137.5 |               |
| R2 Stream                | Drift                                         | 0.984\textsuperscript{1}                                |                             | 232.7 |               |
| R3 Stream                | Drift                                         | 1.043\textsuperscript{1}                                |                             | 219.6 |               |
| R4 Stream                | Run-off                                       | 3.145\textsuperscript{2}                                |                             | 72.8 |               |
| **Grapevines (late application):** |                                              |                                                      |                             |     |               |
| D6 Ditch                 | Drift                                         | 3.546\textsuperscript{2}                                |                             | 64.6 |               |
| R1 Pond                  | Drift                                         | 0.308\textsuperscript{2}                                |                             | 743.5 |               |
| R1 Stream                | Drift                                         | 2.264\textsuperscript{1}                                |                             | 101.1 |               |
| R2 Stream                | Drift                                         | 3.034\textsuperscript{1}                                |                             | 75.5 |               |
| R3 Stream                | Drift                                         | 3.190\textsuperscript{1}                                |                             | 71.8 |               |
| R4 Stream                | Run-off                                       | 2.263\textsuperscript{1}                                |                             | 101.2 |               |

# Values are in bold when an high risk could not be excluded

**FOCUS\textsubscript{sw} step 4 - TERs zoxamide – Zoxium 240 SC at 180 g a.s./ha [5 applications] using refined LC\textsubscript{50} value**

### Organisms

Aquatic invertebrates

### Toxicity endpoint: 229 µg/L

### Mitigation options

| Mitigation options | 10 m non-spray buffer zone | 10 m non-spray buffer zone and 20 m non-spray buffer zone | TER | Trigger |
|--------------------|---------------------------|----------------------------------------------------------|-----|---------|

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| FOCUS Step 4* | 10m vegetated buffer strip | and 20m vegetated buffer strip |
|--------------|-----------------------------|-----------------------------|
| **Potatoes** |                             |                             |
| R1 / stream  | -                           | 1.027                       |
|              |                             | 0.539                       |
|              |                             | 223                         |
|              |                             | 100                         |
| **Grapevines (late application)** |                             |                             |
| D6 / ditch   | 0.776                       | -                           |
|              |                             | 0.272                       |
|              |                             | 295                         |
|              |                             | 100                         |
| R2 / stream  | 0.801                       | 0.281                       |
|              |                             | 0.281                       |
|              |                             | 285                         |
|              |                             | 100                         |
| R3 / stream  | 1.579                       | 0.707                       |
|              |                             | -                           |
|              |                             | 145                         |
|              |                             | 100                         |

*Only scenarios where the trigger is not met at FOCUSsw step 3 should be included in step 4.*

# Values are in bold when an high risk could not be excluded

FOCUSsw step 4 - TERs zoxamide – Zoxium 240 SC at 180 g a.s./ha [5 applications]

| Organisms | Mysidopsis bahia |
|-----------|------------------|
| **Toxicity endpoint:** | 7.2 µg/L |

| Mitigation options | 10 m non-spray buffer zone | 10 m non-spray buffer zone and 10m vegetated buffer strip | 20 m non-spray buffer zone | 20 m non-spray buffer zone and 20m vegetated buffer strip | TER | Trigger |
|--------------------|---------------------------|-------------------------------------------------------|---------------------------|-------------------------------------------------------|-----|---------|
| FOCUS Step 4*      |                           |                                                       |                           |                                                       |     |         |
| **Potatoes**       |                           |                                                       |                           |                                                       |     |         |
| D3 / ditch         | 0.164                     | -                                                     | -                         | -                                                     | 43.9| 10      |
| D6 / ditch (1<sup>st</sup>) | 0.163                     | -                                                     | -                         | -                                                     | 44.1| 10      |
| D6 / ditch (2<sup>nd</sup>) | 1.370                     | -                                                     | 0.539                     |                                                      | 5.26| 10      |
| R1 / stream        | -                         | 1.028                                                 | -                         | 0.539                                                 | 13.4| 10      |
| R2 / stream        | 0.312                     | -                                                     | -                         | -                                                     | 23.1| 10      |
| R3 / stream        | 0.618                     | -                                                     | -                         | -                                                     | 11.7| 10      |
| **Grapevines (late application)** |                                                   |                                                       |                           |                                                       |     |         |
| D6 / ditch         | 0.776                     | -                                                     | 0.272                     | -                                                     | 26.8| 10      |
| R1 / stream        | 0.597                     | -                                                     | -                         | -                                                     | 12.1| 10      |
| R2 / stream        | 0.801                     | -                                                     | 0.281                     | -                                                     | 26.6| 10      |
| R3 / stream        | 1.579                     | 0.707                                                 | 1.579                     | -                                                     | 10.2| 10      |
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![Table](data:image/png;base64,iVBORw0KGgoAAAANSUhEUgAAAIgAAAgCAIAAACsDcAAAAA1BMVEX///8AAABJRU5ErkJggg==)

| R4 / stream | 0.950 | - | 0.494 | 14.6 | 10 |
|-------------|-------|---|-------|------|----|

*Only scenarios where the trigger is not met at FOCUSsw step 3 should be included in step 4.*

# Values are in bold when an high risk could not be excluded
FOCUS<sub>sw</sub> step 4 - TERs zoxamide – Zoxium 240 SC at 180 g a.s./ha [5 applications]

**Organisms**

*Lemna sp.*

**Toxicity endpoint:** 9µg/L

| Mitigation options | 10 m non-spray buffer zone (corresponding to ≤ 95 % drift reduction) | 10 m non-spray buffer zone and 10 m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction) | TER | Trigger |
|--------------------|--------------------------------------------------|------------------------------------------------------|-----|---------|
| **FOCUS Step 4*** |
| **Potatoes**       |
| D3/ ditch          | 0.164                                            | -                                                    | 54.9| 10      |
| D6 Ditch (1st)     | 0.163                                            | -                                                    | 55.2| 10      |
| D6 Ditch (2nd)     | 0.380                                            | -                                                    | 23.7| 10      |
| R1 / stream        | -                                                | 1.028                                                | 8.8 | 10      |
| R3 / stream        | 0.618                                            | -                                                    | 14.7| 10      |

| **Grapevines (late application)** |
| D6 / ditch          | 0.776                                            | -                                                    | 11.6| 10      |
| R1 / stream         | 0.597                                            | -                                                    | 15.1| 10      |
| R2 / stream         | 0.801                                            | -                                                    | 11.2| 10      |
| R3 / stream         | 1.579                                            | -                                                    | 5.7 | 10      |
| R4 / stream         | -                                                | 0.950                                                | 9.5 | 10      |

*Only scenarios where the trigger is not met at FOCUS<sub>sw</sub> step 3 should be included in step 4."

# Values are in bold when an high risk could not be excluded
FOCUS\textsubscript{sw} Step 1-2 - TERs for zoxamide metabolite RH-127450 – Zoxium 240 SC at 180 g a.s./ha [5 applications]\#

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates |
|----------|------------------------|------------|-----------------------|
|          |                        | Oncorhynchus mykiss | Mysis bahia |
|          |                        | LC\textsubscript{50} | EC\textsubscript{50} |
|          |                        | 16***µg/L | 7.6***µg/L |
|          |                        | TER        | TER                   |

| Potatoes | FOCUS Step 1 | 24.4087 | 0.66 | 0.31 |
|          | FOCUS Step 2 | North Europe | 1.5062 | 10.6 | 5.0 |
|          | South Europe | 1.6975 | 9.4 | 4.5 |

| Grapevines (late applications) | FOCUS Step 1 | 29.9843 | 0.53 | 0.25 |
|                                | FOCUS Step 2 | North Europe | 4.7282 | 3.4 | 1.6 |
|                                | South Europe | 4.7282 | 3.4 | 1.6 |
| Trigger**                       | 100          | 100       |

*Only scenarios where the trigger is not met at FOCUS\textsubscript{sw} step 1-2 should be included in step 3.*

**If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.*

***Risk assessment of the metabolite done assuming a toxicity ten times higher than the active substance.*

# Values are in bold when an high risk could not be excluded

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FOCUS\textsubscript{sw} Step 1-2 - TERs for zoxamide metabolite RH-139432 – Zoxium 240 SC at 180 g a.s./ha [5 applications]\#

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates |
|----------|------------------------|------------|-----------------------|
|          |                        | Oncorhynchus mykiss | Daphnia magna |

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LC₅₀ | EC₅₀
---|---
2000 µg/L | 7.6*** µg/L

| TER | TER |
---|---|

## Potatoes

**FOCUS Step 1**

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|---|---|---|---|---|
| Onchorhynchus mykiss | Oncorhynchus mykiss | Mysispora bahia | Desmodesmus subspicatus |
| LC₅₀ | EC₅₀ | EC₅₀ |
|---|---|---|
| 10.92 | 183.2 | 0.7 |

**FOCUS Step 2**

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|---|---|---|---|---|
| North Europe | 2.22 | not required | 3.4 |
| South Europe | 2.65 | not required | 2.9 |

## Grapevines (late applications)

**FOCUS Step 1**

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|---|---|---|---|---|
| Onchorhynchus mykiss | Oncorhynchus mykiss | Mysispora bahia | Desmodesmus subspicatus |
| LC₅₀ | EC₅₀ | EC₅₀ |
|---|---|---|
| 14.98 | 133.5 | 0.5 |

**FOCUS Step 2**

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|---|---|---|---|---|
| North Europe | 5.52 | not required | 1.4 |
| South Europe | 5.78 | not required | 1.3 |

**Trigger**

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|---|---|---|---|---|
| Onchorhynchus mykiss | Oncorhynchus mykiss | Mysispora bahia | Desmodesmus subspicatus |
| LC₅₀ | EC₅₀ | EC₅₀ |
|---|---|---|
| 100 | 100 |

*Only scenarios where the trigger is not met at FOCUS sw step 1-2 should be included in step 3.
**If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.
***Risk assessment of the metabolite done assuming a toxicity ten times higher than the active substance.
# Values are in bold when an high risk was identified
### FOCUS sw Step 1-2 - TERs for zoxamide metabolite RH-163353 – Zoxium 240 SC at 180 g a.s./ha [5 applications]#

| Scenario          | PEC global max (µg L) | fish acute | Aquatic invertebrates |
|-------------------|-----------------------|------------|-----------------------|
|                   |                       | Oncorhynchus mykiss | Mysidopsis bahia |
|                   |                       | LC₅₀        | EC₅₀                  |
|                   |                       | 16*** µg/L  | 7.6*** µg/L           |
|                   |                       | TER        | TER                   |

| Potatoes          | FOCUS Step 1          | 56.2390    | 408                   | 0.14 | >1066 |
|                   | FOCUS Step 2          | North Europe | 1.7003  | not required | 4.5   | not required |
|                   |                       | South Europe | 2.2110  | not required | 3.4   | not required |

| Grapevines (late applications) | FOCUS Step 1 | 58.4240 | 393 | 0.13 | >1026 |
|                                | FOCUS Step 2  | North Europe | 3.1246 | not required | 2.4 | not required |
|                                |                       | South Europe | 3.4310  | not required | 2.2 | not required |

*Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.*

**If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.*

***Risk assessment of the metabolite done assuming a toxicity ten times higher than the active substance.*

# Values are in bold when an high risk was identified.
### FOCUS\textsubscript{sw} Step 1 - TERs for zoxamide metabolite RH-141455 – Zoxium 240 SC at 180 g a.s./ha [5 applications]#

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|----------|------------------------|------------|-----------------------|-------|
|          |                        | Oncorhynchus mykiss | Mysisopsis bahia | Pseudokirchneriella subspicata |
|          |                        | LC\textsubscript{50} | EC\textsubscript{50} | EC\textsubscript{10} |
|          |                        | 16*** µg/L | 7.6*** µg/L | > 100 000 µg/L |

|             | FOCUS Step 1            | FOCUS Step 2     |
|-------------|-------------------------|------------------|
|             |                         |                  |
| Potatoes    |                         |                  |
|             | 18.1338                 | 0.88             | 0.42               | >5 514 |
| North Europe| 1.3229                 | 12.1             | 5.7                | not required |
| South Europe| 1.7903                 | 8.9              | 4.2                | not required |
| Grapevines (late) | 19.2924             | 0.83             | 0.39               | >5183 |

*Only scenarios where the trigger is not met at FOCUS\textsubscript{sw} step 1-2 should be included in step 3.*

**If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.**

***Risk assessment of the metabolite done assuming a toxicity ten times higher than the active substance.***

# Values are in bold when an high risk was identified.
applications) | FOCUS Step 2 | | | |
| --- | --- | --- | --- |
| North Europe | 1.9965 | 8.0 | 3.8 | not required |
| South Europe | 2.2770 | 7.0 | 3.3 | not required |

**Trigger**

| | 100 | 100 | 10 |

* [Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]

** [If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

*** [Risk assessment of the metabolite done assuming a toxicity ten times higher than the active substance.]

# Values are in bold when an high risk was identified
Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

| Species          | Test substance       | Time scale/type of endpoint | End point               | toxicity                                                                 |
|------------------|----------------------|-----------------------------|-------------------------|--------------------------------------------------------------------------|
| Apis mellifera   | RH-117,281 2F        | Acute                       | Oral toxicity (LD_{50}) | >147 µg formulation/bee (corresponding to >33 µg a.s./bee)               |
| Apis mellifera   | a.s.                 | Acute                       | Contact toxicity (LD_{50}) | > 100 µg a.s./bee<sup>1</sup>                                             |
| Apis mellifera   | RH-117,281 2F        | Acute                       | Contact toxicity (LD_{50}) | >200 µg formulation/bee (corresponding to >43.2 µg a.s./bee)             |
| Apis mellifera   | Zoxium 240 SC        | Chronic                     | 10 d-LC_{50}            | >5000 mg a.s./kg feed                                               174.8 µg a.s./bee/day |
| Apis mellifera   | Zoxium 240 SC        | Semi-field bee brood test   | -                       | No effects on bee brood development up to 3.47 g Zoxium 240 SC/L feeding solution corresponding to 0.75 g a.s./L feeding solution |

<sup>1</sup>endpoint derived from a study not providing a toxicity standard, the study was considered valid as the endpoint was in the toxicity range of similar studies.

Potential for accumulative toxicity: yes/no

| Semi-field test (Cage and tunnel test) | - |
|---------------------------------------|---|
| Field tests                          | - |

**Risk assessment** for – Zoxium 240 SC at 180 g a.s./ha [5 applications]

First tier contact risk assessment for honey bees

| scenario          | BBCH  | Honeybee |
|-------------------|-------|----------|
|                   |       | HQ       | trigger |
| treated crop      | < 40  | 0.0      | 42      |
| treated crop      | ≥ 40  | 0.0      | 42      |
| treated crop      | < 10  | 0.0      | 85      |
| treated crop      | 10 - 19 | 0.0  | 85      |
| treated crop      | 20 - 39 | 0.0  | 85      |
| treated crop      | ≥ 40  | 0.0      | 85      |
| weeds              | < 40  | 4.2      | 42      |
| weeds              | ≥ 40  | 1.3      | 42      |
| weeds              | < 10  | 4.2      | 42      |
First tier oral risk assessment for honey bees

| Crop          | Category         | Scenario            | BBCH   | ETR  | Trigger |
|---------------|------------------|---------------------|--------|------|---------|
| Potatoes      | acute            | treated crop        | < 10   | 0.00 | 0.2     |
|               | acute            | treated crop        | 10 - 39| 0.01 | 0.2     |
|               | acute            | treated crop        | 40 - 69| 0.01 | 0.2     |
|               | acute            | weeds                | < 10   | 0.02 | 0.2     |
|               | acute            | weeds                | 10 - 39| 0.02 | 0.2     |
|               | acute            | weeds                | ≥ 70   | 0.00 | 0.2     |
|               | acute            | field margin         | < 10   | 0.00 | 0.2     |
|               | acute            | field margin         | 10 - 39| 0.00 | 0.2     |
|               | acute            | field margin         | 40 - 69| 0.00 | 0.2     |
|               | acute            | field margin         | ≥ 70   | 0.00 | 0.2     |
|               | acute            | adjacent crop        | < 10   | 0.00 | 0.2     |
|               | acute            | adjacent crop        | 10 - 39| 0.00 | 0.2     |
|               | acute            | adjacent crop        | 40 - 69| 0.00 | 0.2     |
|               | acute            | next crop            | < 10   | 0.00 | 0.2     |
|               | acute            | next crop            | 10 - 39| 0.00 | 0.2     |
|               | acute            | next crop            | 40 - 69| 0.00 | 0.2     |
|               | acute            | next crop            | ≥ 70   | 0.00 | 0.2     |
|               | chronic          | treated crop         | < 10   | 0.00 | 0.03    |
|               | chronic          | treated crop         | 10 - 39| 0.00 | 0.03    |
|               | chronic          | treated crop         | 40 - 69| 0.00 | 0.03    |
|               | chronic          | treated crop         | ≥ 70   | 0.00 | 0.03    |
|               | chronic          | weeds                | < 10   | 0.00 | 0.03    |
|               | chronic          | weeds                | 10 - 39| 0.00 | 0.03    |
|               | chronic          | weeds                | 40 - 69| 0.00 | 0.03    |
|               | chronic          | field margin         | < 10   | 0.00 | 0.03    |
|               | chronic          | field margin         | 10 - 39| 0.00 | 0.03    |
|               | chronic          | field margin         | 40 - 69| 0.00 | 0.03    |
|               | chronic          | field margin         | ≥ 70   | 0.00 | 0.03    |
|               | chronic          | adjacent crop        | < 10   | 0.00 | 0.03    |
|               | chronic          | adjacent crop        | 10 - 39| 0.00 | 0.03    |
|               | chronic          | adjacent crop        | 40 - 69| 0.00 | 0.03    |
| Wine grapes | | | |
| --- | --- | --- | |
| chronic | adjacent crop | ≥ 70 | 0.00 | 0.03 |
| chronic | next crop | < 10 | 0.00 | 0.03 |
| chronic | next crop | 10 - 39 | 0.00 | 0.03 |
| chronic | next crop | 40 - 69 | 0.00 | 0.03 |
| chronic | next crop | ≥ 70 | 0.00 | 0.03 |
| acute | treated crop | < 10 | 0.00 | 0.2 |
| acute | treated crop | 10 - 19 | 0.06 | 0.2 |
| acute | treated crop | 20 - 39 | 0.06 | 0.2 |
| acute | treated crop | 40 - 69 | 0.06 | 0.2 |
| acute | treated crop | ≥ 70 | 0.00 | 0.2 |
| acute | weeds | < 10 | 0.02 | 0.2 |
| acute | weeds | 10 - 19 | 0.01 | 0.2 |
| acute | weeds | 20 - 39 | 0.01 | 0.2 |
| acute | weeds | 40 - 69 | 0.01 | 0.2 |
| acute | weeds | ≥ 70 | 0.01 | 0.2 |
| acute | field margin | < 10 | 0.00 | 0.2 |
| acute | field margin | 10 - 19 | 0.00 | 0.2 |
| acute | field margin | 20 - 39 | 0.00 | 0.2 |
| acute | field margin | 40 - 69 | 0.00 | 0.2 |
| acute | field margin | ≥ 70 | 0.00 | 0.2 |
| acute | adjacent crop | < 10 | 0.00 | 0.2 |
| acute | adjacent crop | 10 - 19 | 0.00 | 0.2 |
| acute | adjacent crop | 20 - 39 | 0.00 | 0.2 |
| acute | adjacent crop | 40 - 69 | 0.00 | 0.2 |
| acute | adjacent crop | ≥ 70 | 0.00 | 0.2 |
| acute | next crop | < 10 | 0.00 | 0.2 |
| acute | next crop | 10 - 19 | 0.00 | 0.2 |
| acute | next crop | 20 - 39 | 0.00 | 0.2 |
| acute | next crop | 40 - 69 | 0.00 | 0.2 |
| acute | next crop | ≥ 70 | 0.00 | 0.2 |
| chronic | treated crop | < 10 | 0.00 | 0.03 |
| chronic | treated crop | 10 - 19 | 0.01 | 0.03 |
| chronic | treated crop | 20 - 39 | 0.01 | 0.03 |
| chronic | treated crop | 40 - 69 | 0.01 | 0.03 |
| chronic | treated crop | ≥ 70 | 0.00 | 0.03 |
| chronic | weeds | < 10 | 0.00 | 0.03 |
| chronic | weeds | 10 - 19 | 0.00 | 0.03 |
| chronic | weeds | 20 - 39 | 0.00 | 0.03 |
| chronic | weeds | 40 - 69 | 0.00 | 0.03 |
| chronic | weeds | ≥ 70 | 0.00 | 0.03 |
| chronic | field margin | < 10 | 0.00 | 0.03 |
| chronic | field margin | 10 - 19 | 0.00 | 0.03 |
| chronic | field margin | 20 - 39 | 0.00 | 0.03 |
| chronic | field margin | 40 - 69 | 0.00 | 0.03 |
| chronic | field margin | ≥ 70 | 0.00 | 0.03 |
| chronic | adjacent crop | < 10 | 0.00 | 0.03 |
| chronic | adjacent crop | 10 - 19 | 0.00 | 0.03 |
| chronic | adjacent crop | 20 - 39 | 0.00 | 0.03 |
| chronic | adjacent crop | 40 - 69 | 0.00 | 0.03 |
| chronic | adjacent crop | ≥ 70 | 0.00 | 0.03 |
Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

| laboratory tests with standard sensitive species |
|-----------------------------------------------|
| Species                         | Test Substance | End point               | Toxicity               |
| Typhlodromus pyri               | preparation    | Mortality, LR<sub>50</sub> | >300 g a.s./ha         |
|                                |                | Reproduction, ER<sub>50</sub> | >300 g a.s./ha         |
| Aphidius rhopalosiphi           | preparation    | Mortality, LR<sub>50</sub> | >300 g a.s./ha         |
|                                |                | Reproduction, ER<sub>50</sub> | >300 g a.s./ha         |
| Additional species              |                |                         |                        |
| Amblyseius andersoni            | preparation    | Mortality, LR<sub>50</sub> | >300 g a.s./ha         |
|                                |                | Reproduction, ER<sub>50</sub> | >300 g a.s./ha         |
| Pardosa sp.                    | preparation    | Mortality, LR<sub>50</sub> | >300 g a.s./ha         |
|                                |                | Feeding, ER<sub>50</sub>   | >300 g a.s./ha         |
| Chrysoperla carnea             | preparation    | Mortality, LR<sub>50</sub> | >300 g a.s./ha         |
|                                |                | Reproduction, ER<sub>50</sub> | >300 g a.s./ha         |
| Orius insidiosus               | preparation    | Mortality, LR<sub>50</sub> | >300 g a.s./ha         |
|                                |                | Reproduction, ER<sub>50</sub> | >300 g a.s./ha         |

First tier risk assessment for potatoes at 180 g a.s./ha [5 applications]

| Test substance | Species            | Effect (LR<sub>50</sub> g/ha) | HQ in-field | HQ off-field<sup>1</sup> | Trigger |
|----------------|--------------------|--------------------------------|-------------|--------------------------|---------|
| Zoxium 240 SC  | Typhlodromus pyri  | >300 g a.s./ha                 | <1.8        | <0.0315                  | 2       |
| Zoxium 240 SC  | Aphidius rhopalosiphi | >300 g a.s./ha              | <1.8        | <0.0315                  | 2       |

<sup>1</sup>indicate distance assumed to calculate the drift rate

First tier risk assessment for grapevines at 180 g a.s./ha [5 applications]
### Test substance, Species, Effect

| Test substance | Species                  | Effect (LR₅₀ g/ha) | HQ in-field | HQ off-field¹ | Trigger |
|----------------|--------------------------|--------------------|-------------|---------------|---------|
| Zoxium 240 SC  | *Typhlodromus pyri*     | >300 g a.s./ha      | <1.8        | <0.119        | 2       |
| Zoxium 240 SC  | *Aphidius rhopalosiphi* | >300 g a.s./ha      | <1.8        | <0.119        | 2       |

¹Indicate distance assumed to calculate the drift rate

### Extended laboratory tests, aged residue tests

- Not performed

| Species | Life stage | Test substance, substrate | Time scale | Dose (g/ha)¹,² | End point | % effect³ | ER₅₀ |
|---------|------------|---------------------------|------------|----------------|-----------|-----------|------|
|         |            |                           |            |                | Mortality, reproduction |         |       |

¹Indicate whether initial or aged residues

²For preparations indicate whether dose is expressed in units of a.s. or preparation

³Indicate if positive percentages relate to adverse effects or not

### Risk assessment

Based on extended lab test or aged residue tests

- Not performed

| Species | ER₅₀ (g/ha) | In-field rate | Off-field rate¹ |
|---------|------------|---------------|-----------------|
|         |            |               |                 |

¹Indicate distance assumed to calculate the drift rate and if 3D or 2D.

### Semi-field tests

- Field studies

- Additional specific test

### Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

| Test organism | Test substance | Test system | End point |
|---------------|----------------|-------------|-----------|
| *Eisenia fetida* | a.s.         | 14d – artificial soil | 14d-LC₅₀: >1070 mg a.s./kg soil dw 14d-NOEC (mortality): 66.7 mg a.s./kg soil dw |
|               | RH-127450     | 14d – artificial soil | 14d-LC₅₀: >1000 mg a.s./kg soil dw 14d-NOEC (mortality): 1000 mg a.s./kg soil dw |
|               | RH-141455     | 56d – artificial soil | NOEC = 5 mg/kg soil dw LOEC = 10 mg/kg soil dw. The EC₅₀ > 10 mg/kg soil dw |

¹To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).
Higher tier testing (e.g. modelling or field studies) -

| Nitrogen transformation | a.s. | <25% after 42 days at 2 mg a.s./kg soil |
|-------------------------|------|----------------------------------------|
| Carbon transformation   | a.s. | <25% after 28 days at 2 mg a.s./kg soil |
| Nitrogen transformation  | RH-141455 | <25% after 28 days at 0.2-1 mg a.s./kg soil |

**Toxicity/exposure ratios for earthworms**  
Zoxium 240 SC at 180 g a.s./ha [5 applications]

| Test organism      | Test substance | Time scale | Soil PEC*** | TER  | Trigger |
|--------------------|----------------|------------|-------------|------|---------|
|                    | a.s.           | Acute      | LD$_{50}$, corr. >535* | 0.3825 | 1146 |
| RH-127450          | Acute          |            |             | 0.0542 | 9225 |
| RH-24549**         | Acute          |            |             | 0.0642 | 833 |
| RH-163353**        | Acute          |            |             | 0.0775 | 690 |
| RH-141455**        | Acute          |            |             | 0.0327 | 1636 |

| Test organism      | Test substance | Time scale | Soil PEC*** | TER  | Trigger |
|--------------------|----------------|------------|-------------|------|---------|
|                    | RH-141455      | PEC soil accumulation (mg/kg soil dw) |            |      |         |
|                    | >53.5**        | no tillage – potatoe 0.0902 |             | 593  |         |
|                    | >53.5**        | no tillage – vineyard 0.0722 |             | 741  |         |
|                    | >53.5**        | tillage – potatoe 0.0799 |             | 670  |         |
|                    | >53.5**        | tillage – vineyard 0.0639 |             | 837  |         |

**Eisenia fetida**

| Test organism      | Test substance | Time scale | Soil PEC*** | TER  | Trigger |
|--------------------|----------------|------------|-------------|------|---------|
|                    | Chronic NOEC corr. 2.5* | no tillage – potatoe 0.0902 |             | 27.7 |         |
|                    | Chronic NOEC corr. 2.5* | no tillage – vineyard 0.0722 |             | 34.6 |         |
|                    | Chronic NOEC corr. 2.5* | tillage – potatoe 0.0799 |             | 31.3 |         |
Test organism | Test substance | Time scale | Soil PEC***<sup>1</sup> | TER | Trigger
---|---|---|---|---|---
RH-141455**<sup>2</sup> | Chronic NOEC corr. 2.5* | tillage – vineyard 0.0639 | 39.1 |

<sup>1</sup>indicate which PEC soil was used (e.g. plateau PEC)<br><sup>2</sup> Since zoxamide has a log P<sub>ow</sub> of 3.76 (>2) it is necessary to reduce the LC<sub>50</sub> and NOEC values by a factor of 2 for the studies conducted using artificial soil in line with EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 of October 2002). A correction factor of 2 is used for endpoints from study with natural soil.<br><sup>3</sup> Acute and chronic toxicity endpoints used for metabolites assuming that each metabolite is 10 fold more toxic than the parent to earthworms<br><sup>***</sup> All maximum initial PEC<sub>soil</sub> values were calculated for application in potatoes

**Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)**

Given the nature of the proposed uses, it is unlikely that zoxamide will reach sewage treatment plants.

**Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)**

Ecotoxicologically relevant compounds<sup>1</sup>

| Compartment | Ecotoxicologically relevant compounds |
|---|---|
| soil | zoxamide, RH-163353 (pending), RH-141455 (pending) |
| water | zoxamide, RH-127450 (pending), RH-24549 (pending), RH-163353 (pending), RH-141455 (pending) |
| sediment | zoxamide, RH-127450 (pending), RH-163353 (pending) |
| groundwater | At least zoxamide but open regarding RH -141455 |

<sup>1</sup> metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent
Classification and labelling with regard to ecotoxicological data (Regulation (EU) No 283/2013, Annex Part A, Section 10)

| Substance      | Zoxamide                                                                 |
|----------------|---------------------------------------------------------------------------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]⁵: | Aquatic acute 1, H400: Very toxic to aquatic life Aquatic chronic 1, H410: Very toxic to aquatic life with long lasting effects |
| Peer review proposal⁶ for harmonised classification according to Regulation (EC) No 1272/2008: | Aquatic acute 1, H400: Very toxic to aquatic life Aquatic chronic 1, H410: Very toxic to aquatic life with long lasting effects |

⁵ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

⁶ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.