

Renewal Assessment Report

under Regulation (EC) 1107/2009



Zoxamide

List of End Points

Rapporteur Member State: Latvia
Co-Rapporteur Member State: France

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
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| RMS – Latvia Co-RMS – France | July 2016 | Zoxamide |

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Version history

| Date | Subject |
|-----------|-------------|
| July 2016 | Initial RAR |
| | |
| | |

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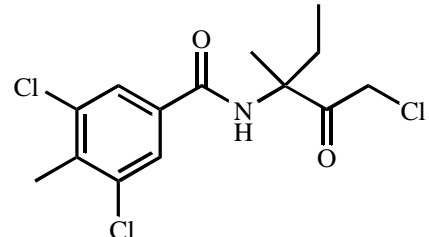
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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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 (<i>e.g.</i> 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-methylacetonyl)-p-toluamide |
| Chemical name (CA) | (RS)-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) | An FAO specification has not yet been established. |
| Minimum purity of the active substance as manufactured | 950 g/kg |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | None of the impurities are of toxicological or environmental significance. |
| Molecular formula | C ₁₄ H ₁₆ NO ₂ Cl ₃ |
| Molar mass | 336.65 g/mol |
| Structural formula |  |

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Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

| | |
|---|--|
| Melting point (state purity) | 159.5 – 160.5 °C (98.8%) |
| Boiling point (state purity) | Not required the substance is solid. |
| Temperature of decomposition (state purity) | Irreversible chemical decomposition occurs at the melting point. |
| Appearance (state purity) | Lumpy white powder (98.8%) |
| Vapour pressure (state temperature, state purity) | $<1.3 \times 10^{-5}$ Pa at 25, 35 and 45 °C (98.8%) |
| Henry's law constant (state temperature) | $<6.59 \times 10^{-3}$ Pa m ³ mol ⁻¹ (98.8%) |
| Solubility in water (state temperature, state purity and pH) | 0.681 ± 0.017 mg/l at 20 °C (98.7%) RH-7281 does not protonate or ionise at pH values between 3 and 11. |
| Solubility in organic solvents (state temperature, state purity) | Determined in g/L at 20°C (97.7%) Ethyl acetate – 20.0 Acetone – 55.7 Xylene – 1.56 n-octanol – 6.49 n-heptane – 0.038 1,2-dichloroethane – 12.5 |
| Surface tension (state concentration and temperature, state purity) | Not determined. |
| Partition coefficient (state temperature, pH and purity) | Log Pow = 3.76 ± 0.04 (98.7%) RH-117281 contains no acid or base functionality - Kow is not dependent on pH. |
| Dissociation constant (state purity) | Does not dissociate. |
| UV/VIS absorption (max.) incl. ε (state purity, pH) | UV/Vis: λ max =212 nm (ε = 46330). No absorbance above 290 nm. (98.8%) |
| 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%) |

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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 | Product name | F 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./ha min-max (l) | Water L/ha min-max | kg a.s./ha min-max (l) | | |
| Grapes (Wine, Table) | CEU, SEU | Zoxium 240 SC | F | grape downy mildew <i>Plasmopara viticola</i> | SC | 240 g/L | 3-d broadcast with mist blower | BBCH 15-79 | 5 | 8 | 0.018 | 1000 | 0.180 | 28 | |
| Potato | NEU, CEU, SEU | Zoxium 240 SC | F | potato late blight <i>Phytophthora infestans</i> | SC | 240 g/L | broadcast with spray boom | BBCH 20-80 | 5 | 8 | 0.018 | 1000 | 0.180 | 28 | |

| | |
|---|--|
| <p>(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)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> | <p>(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. benthialdicarb-isopropyl).</p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
|---|--|

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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

| Important Note: Entries on this column that are left to remain by exporters other than the ones that have not been assessed for these uses | | | | | | | | | | | | | | | |
|--|-------------------------|--------------|-----------------|---|-------------|----------------|-------------------|-------------------------------------|--------------------|------------------------------------|--------------------------------|--------------------|------------------------|-------------------|---------|
| Crop and/or situation (a) | Member State or Country | Product name | F 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 /hL min-max (l) | Water L/ha min-max | kg a.s./ha min-max (l) | | |
| MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009) | | | | | | | | | | | | | | | |
| Not Applicable | | | | | | | | | | | | | | | |

| | |
|---|--|
| <p>(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)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> | <p>(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. fluoroxypr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
|---|--|

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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. *Phytophthora 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)

The applicant informs that 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 authorization.

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

The applicant informs that 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 authorization.

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, $PEC_{GW} \ll 0.1 \mu\text{g/L}$ | | |

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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)

| | |
|---|--------------------------------------|
| Technical a.s. (analytical technique) | Reverse phase HPLC with UV detection |
| Impurities in technical a.s. (analytical technique) | Reverse phase HPLC with UV detection |
| Plant protection product (analytical technique) | Reverse 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 of plant origin | Zoxamide only |
| Food of animal origin | Zoxamide only |
| Soil | Zoxamide only |
| Sediment | Zoxamide only |
| Water surface | Zoxamide only |
| drinking/ground | Zoxamide only |
| Air | Zoxamide only |
| Body fluids and tissues | - |

Monitoring/Enforcement methods

| | |
|---|--|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | 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 |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Not required |
| Soil (analytical technique and LOQ) | LC-MS/MS, LOQ: 0.05 mg/kg |
| Water (analytical technique and LOQ) | Drinking and surface water: LC-MS/MS, LOQ: 0.1 µg/L ILV: Drinking water, LOQ: 0.1 µg/L |
| Air (analytical technique and LOQ) | LC-MS/MS, LOQ: 90 µg/m ³ |

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Body fluids and tissues (analytical technique and LOQ)

Not required

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 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]¹:

-

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

-

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. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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Section 2 Mammalian Toxicology

Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

| | |
|---|---|
| Rate and extent of oral absorption/systemic bioavailability | 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/day) |
| Toxicokinetics | In pharmacokinetic studies, ¹⁴ C-RH 7281 was observed to be rapidly absorbed by rats. The maximum concentrations of radioactivity in plasma were observed at 8 hours postdose (C _{max} in plasma = 8 hrs; ½ C _{max} = 22 hrs). |
| Distribution | Wide distribution between tissues was reported, highest concentrations of residues were observed in blood. |
| 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) |
| Metabolism in animals | Extensive, 32 metabolites identified (mainly by hydrolysis, oxidation, reductive dehalogenation and conjugation) |
| <i>In vitro</i> metabolism | All metabolites detected in human, were also seen in other species apart from (C10) seen at trace levels in the Human 60 min incubation by Radio-HPLC. All samples analysed at a later date than the Radio-HPLC analysis revealed the presence of C10. |
| Toxicologically relevant compounds (animals and plants) | Parent compound (state name; toxicity of individual metabolites not known) |
| Toxicologically relevant compounds (environment) | Parent compound |

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

| | | |
|---------------------------------|--|----------------|
| Rat LD ₅₀ oral | > 2000 mg/kg bw (rat) > 5000 mg/kg bw (mouse) | |
| Rat LD ₅₀ dermal | > 2000 mg/kg bw | |
| Rat LC ₅₀ inhalation | > 5.3 mg/L air /4h (nose only) | |
| Skin irritation | Non-irritant | |
| Eye irritation | Irritant | H319 |
| Skin sensitisation | Sensitising (<i>M & K and Buehler</i>) | H317 1A |

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| | | |
|---------------|-----------------------|--|
| Phototoxicity | <i>Not phototoxic</i> | |
|---------------|-----------------------|--|

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

| | | |
|--------------------------------|---|--|
| Target organ / critical effect | Liver (increased weight and hypertrophy). Reduction in body weight gain at higher dose levels. | |
| Relevant oral NOAEL | 50 mg/kg bw/day (90-day & 1-year dog) | |
| Relevant dermal NOAEL | 1000 mg/kg bw/day (28-day rat) | |
| Relevant inhalation NOAEL | No data - not required | |

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

| | | |
|----------------------------|--|--|
| <i>In vitro</i> studies | Bacterial mutation assay (Ames): negative Mammalian chromosome aberration test in Chinese hamster ovary cells: positive Gene mutation at the HGPT locus in cultured CHO cells: negative | |
| <i>In vivo</i> studies | Micronucleus assay in CD-1 mouse bone marrow cells: negative Mammalian erythrocyte test with the kinetochore analyses: negative | |
| Photomutagenicity | Not provided because of no existing agreed EU guidelines or validated test method for the conduct of the study. | |
| Potential for genotoxicity | Zoxamide is unlikely to be genotoxic | |

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

| | | |
|--|---|--|
| Long-term effects (target organ/critical effect) | Liver (increased relative liver weight) | |
| Relevant long-term NOAEL | 50 mg/kg bw/day (1000ppm), 2-year rat 1021 mg/kg bw/day (7000 ppm), 18-month | |
| 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; 18-month, mouse: 1021 mg/kg bw per day | |

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Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

| | | |
|---------------------------------------|---|--|
| Reproduction target / critical effect | No adverse effects on reproduction. Offspring's toxicity: reduced body weight gain, feed consumption | |
| Relevant parental NOAEL | 360 mg/kg bw per day | |
| Relevant reproductive NOAEL | 1474 mg/kg bw per day | |
| Relevant offspring NOAEL | 360 mg/kg bw per day | |

Developmental toxicity

| | | |
|--|--|--|
| Developmental target / critical effect | No evidence of toxicity in the rat or rabbit in developmental toxicity studies | |
| Relevant maternal NOAEL | Rat: 1000 mg/kg bw per day Rabbit: 1000 mg/kg bw per day | |
| Relevant developmental NOAEL | Rat: 1000 mg/kg bw per day Rabbit: 1000 mg/kg bw per day | |

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

| | | |
|--|-------------------------|--|
| Acute neurotoxicity | Rat: 2000 mg/kg bw | |
| Repeated neurotoxicity | Rat : 1509 mg/kg bw/day | |
| 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 of RH-117,281 on <i>Phytophthora capsici</i>, 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. |
| Endocrine disrupting properties | Zoxamide is unlikely to have endocrine disrupting properties. |

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Studies performed on metabolites or impurities

Studies were originally performed with 3 metabolites:
RH-141,455:
Rat metabolism study: Greater than 96 % radioactivity excreted from faeces and urine was unchanged
Acute oral toxicity in mice: LD50: > 5000 mg/kg bw
In vitro micronucleus test in human lymphocytes: do not show evidence of causing an increase in the induction of micronuclei.
In vitro mutation test in mouse lymphoma L5178Y cells: do not demonstrate mutagenic potential
RH-150,721:
Ames test: negative
RH-141,452:
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)

No detrimental effects on health in manufacturing personnel reported.
 No clinical cases or incidents of poisoning in humans.
 No epidemiological study.

Summary³ (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

| | Value (mg/kg bw (per day)) | Study | Uncertainty factor |
|--|-------------------------------|-------------|--------------------|
| Acceptable Daily Intake (ADI) | 0.5 | dog, 1-year | 100 |
| Acute Reference Dose (ARfD) | Not allocated - not necessary | | |
| Acceptable Operator Exposure Level (AOEL) | 0.3 | dog, 90-day | 100 |
| Acute Acceptable Operator Exposure Level (AAOEL) | Not allocated - not necessary | | |

* Including correction for limited oral absorption (60 %).

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

Representative formulation (*indicate name, type e.g. EC and concentration of active substance*)

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

³ If available include also reference values for metabolites

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

Operators

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

| | |
|--|------------------|
| Zoxium 240 SC | |
| <u>Use:</u> grapewines, tractor mounted equipment broadcast air- assisted sprayer, application rate_ 0.18 kg a.s./ha | |
| <u>Exposure estimates</u> (model): | <u>% of AOEL</u> |
| <u>UK POEM</u> | |
| Without PPE: | 18 |
| <u>German model</u> | |
| Without PPE: | 9 |

Workers

| | |
|------------------------------------|------------------|
| Zoxium 240 SC | |
| <u>Exposure estimates</u> (model): | <u>% of AOEL</u> |
| <u>Use:</u> potatoes - 7.5 % | |
| <u>Use:</u> grapevines - 54 % | |

Bystanders and residents

| | |
|-------------------------------------|-----------|
| Zoxium 240 SC | |
| Bystander: | |
| Exposure estimates (model): | % of AOEL |
| 1.1 % of AOEL (EUROPOEM II) | |
| Residents: | |
| Adult 0.1 % of AOEL (Martin, 2008)) | |
| Child 0.3 % of AOEL (Martin (2008)) | |

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :

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]⁴ :

| |
|---|
| Zoxamide |
| Skin Sens.1 H317 “May cause an allergic skin reaction” |
| Eye Irrit. 2 H319 “Causes serious eye irritation” |

⁴ 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.

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Peer review proposal ⁵ for harmonised classification according to Regulation (EC) No 1272/2008:

Skin Sens.1 H317 “May cause an allergic skin reaction”
Eye Irrit. 2 H319 “Causes serious eye irritation”

⁵ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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|---------------------------------|----------------|-------------------------|
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Section 3 Residues

Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

| Primary crops (Plant groups covered) OECD Guideline 501 | Crop groups | Crop(s) | Application(s) | DAT (days) |
|--|----------------------|----------------|---|------------|
| | 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, outdoor, 3 x 860 g as/ha | 1 |
| | | Cucumber | Foliar application, outdoor, 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 |
| | | | Foliar application, outdoor, 2 x 725 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) OECD Guideline 502 | Crop groups | Crop(s) | PBI (days) | Comments |
| | Root/tuber crops | Radish, turnip | 30;137;210;365 | |
| | Leafy crops | Mustard | 30;137;210;365 | |
| | Cereal (small grain) | Sorghum | 30;137;210;365 | |
| | Other | Soybean | 30;137;210;365 | |

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|---------------------------------|----------------|-------------------------|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide |

Section 3 Residues

| | | | | | |
|---|---|--|--|--|--|
| 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 study) OECD Guideline 507 | Conditions | | | | |
| | 20 min, 90°C, pH 4 | | | | |
| | 60 min, 100°C, pH 5 | | | | |
| | 20 min, 120°C, pH 6 | | | | |
| | | | | | |
| 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. Radiolabelled vinification study showed that parent zoxamide is generally not present (<0.01mg/kg) in wine, 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) Zoxamide and its metabolites RH-141455 and RH-141452 (potato) | | | | |
| Plant residue definition for risk assessment (RD-RA) | Zoxamide (fruit, pulses and oilseeds) Zoxamide and its metabolites RH-141455 and RH-141452 (potato) | | | | |
| Conversion factor (monitoring to risk assessment) | 1 | | | | |

Metabolism in livestock (Regulation (EU) N° 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/Cow | 60.7 | 7 | - |
| | Pig | - | - | - |
| | Fish | - | - | - |
| | Although not required as trigger value of 0.004 mg/kg bw/day is not reached in any specie, one metabolism study was conducted. | | | |

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|---------------------------------|----------------|-------------------------|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide |

Section 3 Residues

| | |
|---|--------------------------------|
| 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 | Not required for intended uses |
| Animal residue definition for risk assessment (RD-RA) | Not required for intended uses |
| 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 |

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

| | |
|--|---|
| Confined rotational crop study (Quantitative aspect) OECD Guideline 502 | 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. |
| Field rotational crop study OECD Guideline 504 | 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. |

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|---------------------------------|----------------|-------------------------|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide |

Section 3 Residues

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1) OECD Guideline 506

| Plant products (Category) | Commodity | T (°C) | Stability (Month) | | | |
|---|---------------------|------------------|------------------------|-----------|-----------|-----------|
| | | | Zoxamide | RH-150721 | RH-141452 | RH-141455 |
| 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 | - | - |
| | | | | | | |
| Animal | Animal commodity | T (°C) | Stability (Month/Year) | | | |
| | | | - | - | - | - |
| - | Muscle | - | - | - | - | - |
| - | Liver | - | - | - | - | - |
| - | Kidney | - | - | - | - | - |
| - | Milk | - | - | - | - | - |
| - | Egg | - | - | - | - | - |
| No data provided and not required as no residue expected in foods of animal origin. | | | | | | |

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|---------------------------------|----------------|-------------------------|
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Section 3 Residues

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) |
|---|--------------------------|---|---|-----------------------------|----------------------|------------------------|
| Representative uses (row to be deleted if not relevant) Residue definition for monitoring and enforcement (Mo): zoxamide Residue definition for risk assessment (RA): zoxamide | | | | | | |
| Potato | NEU | 8 x <0.02; | Residues in Northern and Southern Europe are equivalent. MRL _{OECD} : 0.02 | 0.02* | 0.02 | 0.02 |
| | SEU | 8 x <0.02 | | | | |
| Grapes | NEU | 0.47, 0.50, 0.51, 0.55, 0.67, 0.76, 0.78, 0.81, 0.83, 1.02, 1.37, 1.51, 1.67, 2.65. | MRL _{OECD} : 4 | 5 | 2.65 | 0.80 |
| | SEU | 0.22, 0.24, 0.30, 0.32, 0.46, 0.48, 0.56, 0.63, 0.64, 0.64, 0.66, 0.82, 1.11, 1.21, 1.37, 1.42, 1.53, 1.86. | MRL _{OECD} : 3 | 5 | 1.86 | 0.64 |

(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}).

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|---------------------------------|----------------|-------------------------|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide |

Section 3 Residues

Inputs for animal burden calculations

| Feed commodity | Median dietary burden | | Maximum dietary burden | |
|---|-----------------------|-------------------|------------------------|-----------------|
| | (mg/kg) | Comment | (mg/kg) | Comment |
| Representative uses (row to be deleted if not relevant) | | | | |
| Potato | 0.02 | STMR (<0.02mg/kg) | 0.02 | HR (<0.02mg/kg) |

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|---------------------------------|----------------|-------------------------|
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Section 3 Residues

Residues from livestock feeding studies (Regulation (EU) N° 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 | Ruminant | | | | Pig/Swine | | Poultry | | Fish | |
|--|---|---------------------|---|-------------------|---|------------------------|---|-----------------------|-----------------------------------|----------------------|
| Highest expected intake (mg/kg bw/d) (mg/kg DM for fish) | Beef cattle | 0.001 | Ram/Ewe | 0.001 | Breeding | 0.001 | Broiler | 0.001 | Carp | - |
| | Dairy cattle | 0.001 | Lamb | 0.001 | Finishing | 0.002 | Layer | 0.001 | Trout | - |
| | | | | | | | Turkey | | Fish intake >0.1 mg/kg DM | |
| Intake >0.004 mg/kg bw | No | | No | | No | | No | | No | |
| Feeding study submitted | Not required as trigger value of 0.004 mg/kg bw/d | | Not required as trigger value of 0.004 mg/kg bw/d | | Not required as trigger value of 0.004 mg/kg bw/d | | Not required as trigger value of 0.004 mg/kg bw/d | | | |
| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | Level | Beef: N Dairy: N | Level | Lamb: N Ewe: N | Level | N rate Breed/Finish | Level | B or T: N Layer: N | Level | N rate Carp/Trout |
| | Estimated HR ^(a) at 1N | MRL proposals | Estimated HR ^(a) at 1N | MRL proposals | Estimated HR ^(a) at 1N | MRL proposals | Estimated HR ^(a) at 1N | 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.

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 3 Residues

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 (row to be deleted if not relevant) | | | | |
| 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

NTMDI, according to (to be specified)

IEDI (% ADI), according to EFSA PRIMo

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

Factors included in the calculations

0.5 mg/kg bw per day

Not applicable; see representative uses below

Not applicable; see representative uses below

Not applicable; see representative uses below

Not applicable; see representative uses below

ARfD

IENTI (% ARfD), according to EFSA PRIMo

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

Factors included in IESTI and NESTI

No ARfD

Not applicable;

Not applicable;

Consumer risk assessment limited to the representative uses

TMDI (% ADI), according to EFSA PRIMo

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

IEDI (% ADI), according to EFSA PRIMo

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

Factors included in the calculations

Highest TMDI: 4.1 % ADI (FR, all population)

Not required.

Not required.

Not required.

-

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---|-----------------------|---|
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Section 3 Residues

IESTI (% ARfD, according to EFSA PRIMo)

Not applicable;

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

Not applicable;

Factors included in IESTI and NESTI

-

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---|-----------------------|---|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 3 Residues**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 | 5.0 | Current MRL (Reg 520/2011) |
| 0151020 | Wine grapes | 5.0 | Current MRL (Reg 520/2011) |
| 0211000 | Potatoes | 0.02* | Current MRL (Reg 520/2011) |

(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.

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
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Section 4 Environmental fate and behaviour

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 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 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 8.0% AR after 28 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). |

Soil photolysis

| | |
|--|--|
| Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) | 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 |
|--|--|

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
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Section 4 Environmental fate and behaviour

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

FOCUS (2006, 2011)

Laboratory studies (range or median, with n value, with r^2 value)

DT₅₀s for zoxamide and its metabolites are given below. Geometric mean modelling DT₅₀s were calculated for the soils incubated at 20/25°C; where a number of DT₅₀s were obtained from the same soil (German sandy loam), the arithmetic mean DT₅₀ was first calculated for this soil before calculating the geometric mean for all the soils

Zoxamide

| Soil | DT ₅₀ (days) | Temp | Model | χ ² error (%) | T- Corr. | Moist Corr. | DT ₅₀ normalised to 20°C & pF2 |
|-----------------------------------|----------------------------|------|-----------------------|--------------------------------|-------------|----------------|---|
| England silt loam 20°C 50%MWHC | 4.16 | 20°C | SFO | 5.28 | 1.00 | 0.84 | 3.51 |
| France loam 20°C 50%MWHC | 2.03 | 20°C | SFO | 6.98 | 1.00 | 0.94 | 1.90 |
| Italy clay loam 20°C 50%MWHC | 2.38 | 20°C | SFO | 6.06 | 1.00 | 0.83 | 1.97 |
| Germany sandy loam 20°C 50%MWHC | 2.7 | 20°C | SFO | 4.65 | 1.00 | 0.99 | 2.67 |
| Germany sandy loam 20°C 100%FC | 2.27 | 20°C | SFO | 6.67 | 1.00 | 1.00 | 2.27 |
| Germany sandy loam 10°C 50%MWHC | 7.73 | 10°C | SFO | 6.58 | 0.39 | 0.99 | 2.96 |
| Pennsylvania silt loam 25°C 75%FC | 7.75 | 25°C | DFOP (persistence) | | | | |
| | 39.2 | | DFOP (modelling) | 8.74 | 1.57 | 0.74 | 45.60 |
| Ohio loamy sand 25°C 75%FC | 13.75 | 25°C | DFOP (persistence) | | | | |
| | 41.3 | | DFOP (modelling) | 2.80 | 1.57 | 0.71 | 45.99 |
| Geometric mean | | | | | | | 6.4 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

RH-127450

| Soil | DT ₅₀ (days) | Temp | Model | χ^2 error (%) | T- Corr. | Moist Corr. | DT ₅₀ normalised to 20°C & pF2 | FF* |
|---------------------------------|----------------------------|------|-------|--------------------------|-------------|----------------|---|------|
| England silt loam 20°C 50%MWHC | 11.69 | 20°C | SFO | 10.16 | 1.00 | 0.84 | 9.86 | 0.26 |
| France loam 20°C 50%MWHC | 3.78 | 20°C | SFO | 8.10 | 1.00 | 0.94 | 3.54 | 0.21 |
| Italy clay loam 20°C 50%MWHC | 1.99 | 20°C | SFO | 16.76 | 1.00 | 0.83 | 1.64 | 0.18 |
| Germany sandy loam 20°C 50%MWHC | 6.66 | 20°C | SFO | 18.09 | 1.00 | 0.99 | 6.59 | 0.21 |
| Germany sandy loam 20°C 100%FC | 5.76 | 20°C | SFO | 22.43 | 1.00 | 1.00 | 5.76 | 0.17 |
| Germany sandy loam 10°C 50%MWHC | 17.8 | 10°C | SFO | 11.95 | 0.39 | 0.99 | 6.81 | 0.20 |
| Geometric mean | | | | | | | 4.3 | |

* formation fraction

RH-24549

| Soil | DT ₅₀ (days) | Temp | Model | χ^2 error (%) | T- Corr. | Moist Corr. | DT ₅₀ normalised to 20°C & pF2 | FF |
|---------------------------------|----------------------------|------|-------|--------------------------|-------------|----------------|---|------|
| France loam 20°C 50%MWHC | 6.29 | 20°C | SFO | 21.76 | 1.00 | 0.94 | 5.90 | 0.19 |
| Italy clay loam 20°C 50%MWHC | 8.44 | 20°C | SFO | 22.71 | 1.00 | 0.83 | 6.97 | 0.17 |
| Germany sandy loam 20°C 50%MWHC | 5.35 | 20°C | SFO | 30.77 | 1.00 | 0.99 | 5.29 | 0.47 |
| Germany sandy loam 20°C 100%FC | 3.05 | 20°C | SFO | 15.05 | 1.00 | 1.00 | 3.05 | 0.28 |
| Ohio loamy sand 25°C 75%FC | 16.23 | 25°C | SFO | 21.05 | 1.57 | 0.71 | 18.07 | 0.17 |
| Geometric mean | | | | | | | 7.5 | |

RH-163353

| Soil | DT ₅₀ (days) | Temp | Model | χ^2 error (%) | T- Corr. | Moist Corr. | DT ₅₀ normalised to 20°C & pF2 | FF |
|---------------------------------|----------------------------|------|-------|--------------------------|-------------|----------------|---|-------|
| England silt loam 20°C 50%MWHC | 53.65 | 20°C | SFO | 19.39 | 1.00 | 0.84 | 45.27 | 0.09 |
| France loam 20°C 50%MWHC | 6.62 | 20°C | SFO | 23.63 | 1.00 | 0.94 | 6.21 | 0.20 |
| Italy clay loam 20°C 50%MWHC | 6.39 | 20°C | SFO | 6.75 | 1.00 | 0.83 | 5.28 | 0.29 |
| Germany sandy loam 20°C 50%MWHC | 5.62 | 20°C | SFO | 16.14 | 1.00 | 0.99 | 5.56 | 0.23 |
| Germany sandy loam 20°C 100%FC | 9.9 | 20°C | SFO | 12.97 | 1.00 | 1.00 | 9.90 | 0.15 |
| Germany sandy loam 10°C 50%MWHC | 55.5 | 10°C | SFO | 16.46 | 0.39 | 0.99 | 21.24 | 0.185 |
| Geometric mean | | | | | | | 10.3 | |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

RH-141455

| Soil | DT ₅₀ (days) | Temp | Model | χ^2 error (%) | T- Corr | Moist Corr | DT ₅₀ normalised to 20°C & pF2 | FF |
|---|----------------------------|------|-------|--------------------------|------------|---------------|---|-------------------|
| Germany sandy loam 20°C 50%MWHC | 195.2 | 20°C | SFO | 14.27 | 1.00 | 0.99 | 193.04 ¹ | 0.50 ² |
| Speyer 2.2 | 12 | 20°C | SFO | 6.95 | 1.00 | 1.00 | 12.00 | - ³ |
| Speyer 2.3 | 11.1 | 20°C | SFO | 5.77 | 1.00 | 0.86 | 9.54 | - ³ |
| Speyer 6S | 31.7 | 20°C | SFO | 6.8 | 1.00 | 0.46 | 14.72 | - ³ |
| Geometric mean of soils at 20/25°C | | | | | | | 23.9 | |

¹ calculated from the parent study and length of DT₅₀ mainly due to the low detections ² from RH-24549 ³ study conducted with metabolite (RH-141455)

| | |
|--|---|
| Field studies (state location, range or median with n value) | degradation in the saturated zone: no data submitted and none necessary |
| | DT _{50f} : DT _{50s} of zoxamide and metabolites are <60 days therefore field studies are not necessary |
| Soil accumulation and plateau concentration | DT _{90f} : DT ₉₀ of zoxamide is <<365 days, therefore risk of accumulation is negligible and soil accumulation and plateau concentrations are not required |

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)

| | |
|--|---|
| K _f /K _{oc} | K _f and K _{oc} s for zoxamide and its metabolites are detailed below. |
| K _d | Where relevant, K _d s are given below |
| pH dependence (yes / no) (if yes type of dependence) | Zoxamide, RH-127450, RH-163353 and RH-141455 – No RH-24549 - Yes |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

Zoxamide

| Soil | %oc | pH | Kf | 1/n | Kfoc | Kom |
|--|------|-----|-------|--------------|--------------------|------------------|
| Loam, Huntsburg, Ohio, USA | 1.27 | 7.2 | 10.35 | 0.896 | 815 | 473 |
| Sandy loam, Madera, CA., USA | 0.26 | 5.6 | 3.36 | 0.986 | 1294 | 751 |
| 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 | | | | 0.973 | 1224 / 1201 | 710 / 697 |

RH-127450

| Soil | %oc | pH | Kf | 1/n | Kfoc | Kom |
|-------------------------------|------|-----|-------|---------------|------------------|------------------|
| Loamy sand, Borstel/Germany | 1.05 | 6.1 | 12.14 | 0.519 | 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 | | | | 0.523* | 669 / 593 | 388 / 344 |

*low value not considered reliable therefore a value of 0.9 is considered appropriate for the modelling

RH-24549

| Soil | %oc | pH | Kf | 1/n | Kfoc | 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 | | | | 0.811 | 183 / 161 | 106 / 94 |

*Adsorption of RH-24549 is pH dependent, therefore the worst case Kfoc is considered appropriate for modelling

RH-163353

| Soil | %oc | pH | Kf | 1/n | Kfoc | 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 |

*Kfoc derived from a Kf from the screening study therefore a default 1/n value of 1.0 is assumed

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

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)

Column leaching

See below

Aged residues leaching

Guideline ‘SETAC’
Aged for 3 days
Study time period 2 days
Leachate: 1.8-2.3% AR
68.6-74.4 % AR retained in the top 0-5 cm layer zoxamide:
12.3-16.5% in top 0-5 cm, undetectable in 5-20 cm layer

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.

Lysimeter/field leaching studies

No studies required

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

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)
Slow phase laboratory DT₅₀ in soil of 41.3 days (DFOP, k1 = 0.22, k2 = 0.0168, g = 0.39) was used

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_(s)

| | | Potatoes Multiple application Actual | Potatoes Multiple application Time weighted average | Grapevines Multiple application Actual | Grapevines Multiple application Time weighted average |
|------------|------|---|--|---|---|
| Initial | | 0.467 | - | 0.374 | - |
| Short term | 24h | 0.459 | 0.463 | 0.367 | 0.370 |
| | 2d | 0.452 | 0.459 | 0.361 | 0.367 |
| | 4d | 0.437 | 0.452 | 0.349 | 0.361 |
| Long term | 7d | 0.415 | 0.441 | 0.332 | 0.352 |
| | 28d | 0.292 | 0.373 | 0.234 | 0.298 |
| | 50d | 0.202 | 0.316 | 0.161 | 0.253 |
| | 100d | 0.087 | 0.226 | 0.070 | 0.181 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

RH-127450

Method of calculation

FOCUS (1997), Crop interception as defined by FOCUS (2012) maximum laboratory DT₅₀ in soil of 11.69 days (SFO) was used*

Formation at maximum of 15.1% assumed.

Application rate

PECsoil also corrected for molecular weight

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 DT₅₀ - 17.8 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 | | 0.039 | - | 0.031 | - |
| Short term | 24h | 0.037 | 0.038 | 0.030 | 0.031 |
| | 2d | 0.035 | 0.037 | 0.028 | 0.030 |
| | 4d | 0.031 | 0.035 | 0.025 | 0.028 |
| Long term | 7d | 0.026 | 0.033 | 0.021 | 0.026 |
| | 28d | 0.007 | 0.029 | 0.006 | 0.023 |
| | 50d | 0.002 | 0.024 | 0.002 | 0.019 |
| | 100d | 0.000 | 0.014 | 0.000 | 0.011 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

RH-24549

Method of calculation

FOCUS (1997), Crop interception as defined by FOCUS (2012)
Maximum laboratory DT₅₀ in soil of 16.23 days (SFO) was used
Formation at maximum of 33.8% assumed
PECsoil also corrected for molecular weight

Application rate

5 x 37.1 g a.s./ha to grapevines and potatoes at 8 day intervals
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 | 0.070 | - | 0.056 | - |
| Short term | | | | |
| 24h | 0.067 | 0.069 | 0.054 | 0.055 |
| 2d | 0.064 | 0.067 | 0.051 | 0.054 |
| 4d | 0.059 | 0.064 | 0.047 | 0.052 |
| Long term | | | | |
| 7d | 0.052 | 0.061 | 0.042 | 0.049 |
| 28d | 0.021 | 0.053 | 0.017 | 0.042 |
| 50d | 0.008 | 0.045 | 0.007 | 0.036 |
| 100d | 0.001 | 0.029 | 0.001 | 0.023 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

RH-163353

Method of calculation

FOCUS (1997), Crop interception as defined by FOCUS (2012)
Maximum laboratory DT₅₀ in soil of 53.65 days (SFO) was used*

Application rate

Formation at maximum of 15% assumed
PECsoil also corrected for molecular weight

5 x 26.6 g a.s./ha to grapevines and potatoes.
Potatoes crop interception of 50% assumed.
Grapevines crop interception of 60% assumed

* longer DT₅₀ - 55.5 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 | 0.073 | - | 0.058 | - |
| Short term | | | | |
| 24h | 0.072 | 0.072 | 0.058 | 0.058 |
| 2d | 0.071 | 0.072 | 0.057 | 0.058 |
| 4d | 0.069 | 0.071 | 0.055 | 0.057 |
| Long term | | | | |
| 7d | 0.067 | 0.070 | 0.053 | 0.056 |
| 28d | 0.051 | 0.063 | 0.041 | 0.050 |
| 50d | 0.038 | 0.057 | 0.031 | 0.046 |
| 100d | 0.020 | 0.046 | 0.016 | 0.037 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

RH-141455

Method of calculation

FOCUS (1997), Crop interception as defined by FOCUS (2012)
Maximum laboratory DT₅₀ in soil of 195.2 days (SFO) was used
Formation at maximum of 8% assumed*
PEC_{soil} also corrected for molecular weight

Application rate

5 x 10.1 g a.s./ha to grapevines and potatoes at 8 day intervals
Potatoes crop interception of 50% assumed.
Grapevines crop interception of 60% assumed

* maximum in soil (%) of RH-141455 is 8.4 % (day 14) instead of 8 %, however updated PEC_{SOIL} for this metabolite are deemed not necessary since no significant impact on the risk assessment is expected

PEC_(s)

| | Potatoes Multiple application Actual | Potatoes Multiple application Time weighted average | Grapevines Multiple application Actual | Grapevines Multiple application Time weighted average |
|------------|---|--|---|---|
| Initial | 0.032 | - | 0.025 | - |
| Short term | | | | |
| 24h | 0.032 | 0.032 | 0.025 | 0.025 |
| 2d | 0.032 | 0.032 | 0.025 | 0.025 |
| 4d | 0.031 | 0.032 | 0.025 | 0.025 |
| Long term | | | | |
| 7d | 0.031 | 0.031 | 0.025 | 0.025 |
| 28d | 0.029 | 0.030 | 0.023 | 0.024 |
| 50d | 0.027 | 0.029 | 0.021 | 0.023 |
| 100d | 0.022 | 0.027 | 0.018 | 0.022 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

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

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

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

¹⁴C-zoxamide was incubated at two test concentrations (10 µg/L and 50 µg/L) in surface water at 20 ± 2 °C in the dark for 58 days.

Metabolites

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.

| System | Model | DT ₅₀ | DT ₉₀ | χ ² % error | P/confidence interval acceptable? |
|-----------|-------|------------------|------------------|------------------------|-----------------------------------|
| High dose | SFO | 7.6 | 25.4 | 12.1 | Y |
| | FOMC | 7.6 | 25.5 | 14.0 | N |
| Low dose | SFO | 8.4 | 28.0 | 21.9 | Y |
| | FOMC | 8.3 | 28.3 | 25.3 | N |

Rates of degradation of zoxamide in the systems

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 | Parent max in sediment 30.2% AR at day 7 (pond, 10°C). | | | | | | | | | |
|-------------------------|---|--------|-------|---|--------------------|--|--------------------|--|--------------------|-----------------------|
| Water / sediment system | pH water phase | pH sed | T. °C | DT ₅₀ -DT ₉₀ whole sys. | x ² err | DT ₅₀ -DT ₉₀ water | x ² err | DT ₅₀ -DT ₉₀ sed | x ² err | Method of calculation |
| River | 8.39 | 7.4 | 20 | 6.4/21.1 | 5.921 | FOCUS P-II calculations not performed | | | | 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 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

| | | |
|------------------------|-------|--|
| Mean (of 20°C systems) | 6.4/- | |
|------------------------|-------|--|

RH-127450

| | | | | | | | | | | |
|-------------------------|--|--------|-------|---|---|--|--------------------|--|--------------------|-----------------------|
| RH-127450 | Max 17.1% AR in water (day 28, river, 10°C) and 23.1 % AR in sediment (day 56, river, 10°C). Maximum in total system 39.3% AR (day 56, river, 10°C). | | | | | | | | | |
| Water / sediment system | pH water phase | pH sed | T. °C | DT ₅₀ -DT ₉₀ whole sys. | x ² err | DT ₅₀ -DT ₉₀ water | x ² err | DT ₅₀ -DT ₉₀ sed | x ² err | Method of calculation |
| River | 8.39 | 7.4 | 20 | 148.4/493.1 | 16.271 | FOCUS P-II calculations not performed | | | | 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 at a maximum of 28.0% AR in the total system (max 15.8% AR (day 28, river, 20°C) and 13.8% AR (day 106, pond, 10°C) in water and sediment respectively).

| 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 (20°C) | 8.34 | 7.4 | 6.5 | 33.5 | 33.5 |
| Pond (20°C) | 8.12 | 7.0 | 4.0 | 37.3 | 37.3 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

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

Parent

Parameters used in FOCUS_{SW} step 1 and 2.

| End-Point | Zoxamide | RH-127450 | RH-24549 | RH-163353 | RH-141455 | RH-141288 | RH-139432 |
|---|----------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Molecular Weight (g/mol) | 336.65 | 302.15 | 205 | 332.15 | 235.02 | 318.19 | 204.06 |
| Water Solubility, 20°C (mg/L) | 0.681 | 1000 ⁺ | 1000 ⁺ | 1000 ⁺ | 1000 ⁺ | 1000 ⁺ | 1000 ⁺ |
| Koc / Kom (L/kg) – arith. mean | 1224/710 | 669/388 | 183/106 | 68/39 | 2.8/1.6 | 10 ⁺ | 10 ⁺ |
| DT50 in Soil (days) – geom. mean | 6.4 | 4.3 | 7.5 | 10.3 | 23.9 | 1000 ⁺ | 1000 ⁺ |
| DT50 whole system (days) – arithmetic. mean* | 6.4 | 237 | 1000 ⁺ | 1000 ⁺ | 1000 ⁺ | 1000 ⁺ | 1000 ⁺ |
| DT50 water (days) | 6.4** | 237** | 1000 ⁺ | 1000 ⁺ | 1000 ⁺ | 1000 ⁺ | 1000 ⁺ |
| DT50 sed (days) | 6.4** | 237** | 1000 ⁺ | 1000 ⁺ | 1000 ⁺ | 1000 ⁺ | 1000 ⁺ |
| Max. occurrence in soil (%) | - | 15.1 | 33.8 | 15 | 8.0 | - | 4.9 |
| Max. occurrence in water/sed system (%) or OECD 309 study | - | 39.3*** | 22.7 | 47.9 | 10.5 | 22.1 | 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 values obtained when the system was incubated at 10 C are used for the simulations

+ worst case default in absence of measured value

Parameters used in FOCUS_{SW} 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: | |
| Vapour Pressure (Pa, 25°C) | < 1.3x10 ⁻⁵ |
| 1/n – arith. mean | 0.973 |
| DT ₅₀ in water(days) at 20°C* | 1000 (default) / 6.4 |
| DT ₅₀ 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 DT ₅₀ s were assumed: | |
| combination # 1: DT _{50water} 1000 d & DT _{50sed} 6.4 d | |
| combination # 2: DT _{50water} 6.4 d & DT _{50sed} 1000 d | |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

| | |
|---|---|
| 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 MarMay Grapevines (late application) - N & S EU June-Sept |
| Step 3-4 assumptions: | |
| FOCUS Crop: | Potato |
| Application Rate: | 1 x 180 g a.s./ha 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 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 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 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
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Section 4 Environmental fate and behaviour

Main routes of entry

Summary of FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for zoxamide and its metabolites

| Crop | Step | Region | Zoxamide | RH-127450 | RH-24549 | RH-163353 | RH-141455 | RH-141288 | RH-139432 |
|---------------|--------|--------|----------|-----------|----------|-----------|-----------|-----------|-----------|
| PECsw | | | | | | | | | |
| Potatoes | Step 1 | - | 122.3 | 24.4 | 50.8 | 44.6 | 17.3 | 1.73 | 10.92 |
| | Step 2 | N EU | 3.09 | 1.43 | 1.91 | 3.76 | 1.37 | 1.1 | 2.22 |
| | | S EU | 4.35 | 1.59 | 2.55 | 4.46 | 1.87 | 1.1 | 2.65 |
| Vines - early | Step 1 | - | 122.1 | 24.3 | 50.8 | 44.5 | 17.3 | 1.69 | 10.87 |
| | Step 2 | N EU | 3.78 | 1.87 | 2.38 | 4.83 | 1.70 | 1.5 | 2.85 |
| | | S EU | 6.8 | 2.25 | 3.92 | 6.51 | 2.88 | 1.5 | 3.89 |
| Vines - late | Step 1 | - | 138.1 | 30.0 | 53.0 | 52.1 | 18.5 | 5.03 | 14.98 |
| | Step 2 | N EU | 5.32 | 4.73 | 3.10 | 9.59 | 2.03 | 4.08 | 5.52 |
| | | S EU | 5.32 | 4.73 | 3.49 | 10.0 | 2.32 | 4.08 | 5.78 |
| PECsed | | | | | | | | | |
| Potatoes | Step 1 | - | 1.4E03 | 153.6 | 90.8 | 30.1 | 0.47 | 0.17 | 0.88 |
| | Step 2 | N EU | 35.4 | 8.39 | 3.42 | 2.51 | 0.04 | 0.11 | 0.22 |
| | | S EU | 50.9 | 9.43 | 4.59 | 2.98 | 0.05 | 0.11 | 0.26 |
| Vines - early | Step 1 | - | 1.4E03 | 153.4 | 90.8 | 30.0 | 0.47 | 0.17 | 0.88 |
| | Step 2 | N EU | 43.2 | 10.9 | 4.25 | 3.23 | 0.05 | 0.15 | 0.28 |
| | | S EU | 80.1 | 13.4 | 7.06 | 4.36 | 0.08 | 0.15 | 0.39 |
| Vines - late | Step 1 | - | 1.4E03 | 173.3 | 90.8 | 34.8 | 0.47 | 0.50 | 0.88 |
| | Step 2 | N EU | 35.6 | 24.6 | 5.39 | 6.35 | 0.06 | 0.40 | 0.55 |
| | | S EU | 44.9 | 25.2 | 6.10 | 6.63 | 0.06 | 0.40 | 0.58 |

List of end points

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Section 4 Environmental fate and behaviour

Initial FOCUS Step 3 and 4 PEC_{sw} and PEC_{sed} for potatoes (single application)

| Potatoes - Single application – 1 x 180 g/ha | | | | | | | |
|--|--------------------------|----------------|---------|----------------------------|--------------|---------|---|
| 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 * | 10 m ** | | 10 m * | 10 m ** | |
| 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 (1 st) | 0.937 | 0.163 | - | 0.311 | 0.058 | - | Drift |
| D6 Ditch (2 nd) | 0.938 | 0.309 | - | 0.353 | 0.219 | - | 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 | 0.918 | 0.244 | 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.

Initial FOCUS Step 3 and 4 PEC_{sw} and PEC_{sed} for potatoes (multiple application)

| Potatoes - Multiple application – 5 x 180 g/ha (8 days interval) | | | | | | | |
|--|--------------------------|--------|-------|----------------------------|--------------|-------|---|
| 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* | |
| D3 Ditch | 0.609 | 0.103 | - | 0.563 | 0.110 | - | Drift |
| D4 Pond | 0.047 | - | - | 0.223 | - | - | Drift |
| D4 Stream | 0.507 | 0.111 | - | 0.0335 | 0.028 | - | Drift |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
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| | | | | | | | |
|-----------------------------|--------------|--------------|--------------|--------------|--------------|-------|----------|
| D6 Ditch (1 st) | 0.605 | 0.102 | - | 0.321 | 0.061 | - | Drift |
| D6 Ditch (2 nd) | 1.370 | 1.370‡ | - | 0.367 | 0.280 | - | Drainage |
| R1 Pond | 0.534 | 0.235 | - | 1.248 | 0.558 | - | Run-off |
| R1 Stream | 2.415 | 1.028 | 0.539 | 9.184 | 1.754 | 0.693 | Run-off |
| R2 Stream | 0.650 | 0.289 | - | 2.847 | 0.540 | - | Run-off |
| R3 Stream | 0.961 | 0.439 | 0.230 | 4.120 | 0.871 | 0.365 | Run-off |

* 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 PEC_{sw} and PEC_{sed} for vines (early application, single application)

| Vines (early application) - Single application – 1 x 180 g/ha | | | | | | | |
|---|--------------------------|---------------|--------------|----------------------------|--------|---------|---|
| 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 * | 10 m ** | | 10 m * | 10 m ** | |
| D6 Ditch | 1.015 | 0.213 | - | 0.518 | 0.124 | - | Drift |
| R1 Pond | 0.035 | - | - | 0.090 | - | - | Drift |
| R1 Stream | 0.731 | 0.460† | 0.194 | 0.183 | 0.172 | 0.069 | Drift |
| R2 Stream | 0.984 | 0.250 | - | 0.059 | 0.022 | - | Drift |
| R3 Stream | 1.043 | 0.265 | - | 0.177 | 0.046 | - | Drift |
| R4 Stream | 0.733 | 0.674† | 0.305 | 0.646 | 0.638 | 0.273 | 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

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
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Initial FOCUS Step 3 and 4 PEC_{sw} and PEC_{sed} for vines (early application, multiple application)

| Vines (early application) - Multiple application – 5 x 180 g/ha (8 days interval) | | | | | | | | | |
|---|--------------------------|--------|--------|--------|----------------------------|--------|--------|--------|---|
| 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* | 10 m** | 20 m** | | 10 m* | 10 m** | 20 m** | |
| D6 Ditch | 1.471 | 0.303 | - | - | 2.137 | 0.495 | - | - | Drift |
| R1 Pond | 0.126 | - | - | - | 0.302 | - | - | - | Drift |
| R1 Stream | 1.666 | - | 0.733† | 0.379 | 0.990 | - | 0.386 | 0.194 | Run-off |
| R2 Stream | 0.854 | 0.403† | 0.199‡ | - | 0.638 | 0.611 | 0.179 | - | Drift |
| R3 Stream | 0.901 | 0.210 | - | - | 0.301 | 0.076 | - | - | Drift |
| R4 Stream | 3.145 | - | 1.428† | 0.748 | 2.900 | - | 1.199 | 0.617 | Run-off |

* 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 and 4 PEC_{sw} and PEC_{sed} for vines (late application, single application)

| Vines (late application) - Single application – 1x 180 g/ha | | | | | | | |
|---|--------------------------|--------|---------|----------------------------|--------------|--------------|---|
| 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 |
| R2 Stream | 3.034 | 0.801 | 0.281 | 0.234 | 0.062 | 0.0217 | Drift |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
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| | | | | | | | |
|-----------|-------|-------|-------|-------|-------|--------|-------|
| R3 Stream | 3.190 | 0.842 | 0.325 | 0.734 | 0.550 | 0.527 | Drift |
| R4 Stream | 2.263 | 0.597 | 0.209 | 0.323 | 0.086 | 0.0679 | Drift |

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

Initial FOCUS Step 3 PEC_{sw} and PEC_{sed} for vines (late application, multiple application)

| Vines (late application) - Multiple application – 5 x 180 g/ha (8 days interval) | | | |
|--|--------------------------|----------------------------|---|
| Scenario | PEC _{sw} [µg/L] | PEC _{sed} [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 |

Initial FOCUS 4 PEC_{sw} for vines (late application, multiple application)

| Vines (late application) - Multiple application – 5 x 180 g/ha (8 days interval) | | | | |
|--|--------------------------|---------------|---------------|---------------|
| Scenario | PEC _{sw} [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

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
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Initial FOCUS Step 4 PECsed for vines (late application, multiple application)

| Vines (late application) - Multiple application – 5 x 180 g/ha (8 days interval) | | | | |
|--|----------------------------|-------|--------------|-------|
| Scenario | PEC _{SED} [µg/kg] | | | |
| | Step 4 | | | |
| | 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);

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 | 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 x 10 ⁻⁵ | 0 | 0 | 0 | 0 |
| K _{oc} / K _{om} (L/kg) – arith. mean | 1224/710 | 669/388 | 90.5/52.5* | 68/39 | 2.8/1.6 |
| Freundlich exponent, 1/n – arith. mean | 0.973 | 0.9† | 0.811 | 0.892 | 1.0** |
| DT ₅₀ in Soil (days) – geom. mean | 6.4 | 4.3 | 7.5 | 10.3 | 23.9 |
| Crop uptake factor | 0 | 0 | 0 | 0 | 0 |
| Formation fraction – arith. mean | - | 0.20 (from zoxamide) | 0.26 (from zoxamide) | 0.19 (from zoxamide) | 0.50 (from RH-24549) |

List of end points

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* 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_(gw)

| Zoxamide | | | | | | |
|----------------------|--------------|---------------|--------------|---------------|--------------|--------------|
| 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 |
| 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 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
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| RH-24549 | | | | | | |
|----------------------|--------------|---------------|--------------|---------------|--------------|--------------|
| 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 |
| 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-163353 | | | | | | |
|----------------------|--------------|---------------|--------------|---------------|--------------|--------------|
| 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 |
| 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 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
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| RH-127450 | | | | | | |
|----------------------|--------------|---------------|--------------|---------------|--------------|--------------|
| 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 |
| 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 | |
| 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 | 0.822 | 0.317 | 0.647 | 0.225 | 1.641 | 1.244 |
| Hamburg | 2.772 | 0.820 | 1.613 | 0.558 | 2.596 | 2.331 |
| Jokioinen | 3.478 | 1.201 | 3.164 | 1.014 | - | - |
| Kremsmünster | 1.203 | 0.433 | 1.169 | 0.437 | 1.350 | 1.632 |
| Okehampton | 1.136 | 0.417 | 0.899 | 0.341 | - | - |
| Piacenza | 0.402 | 0.151 | 0.421 | 0.119 | 0.667 | 0.747 |
| Porto | 0.157 | 0.047 | 0.308 | 0.096 | 0.368 | 0.522 |
| Sevilla | 0.041 | 0.022 | 0.071 | 0.032 | 0.662 | 0.356 |
| Thiva | 0.259 | 0.101 | 0.187 | 0.079 | 0.464 | 0.399 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---|-----------------------|---|
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Section 4 Environmental fate and behaviour**Fate and behaviour in air** (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

| | |
|---|--|
| Direct photolysis in air | Not studied no data necessary |
| Quantum yield of direct phototransformation | (Φ) = 0.0225 ($\lambda > 290$ nm) |
| Photochemical oxidative degradation in air | DT ₅₀ of 7.5 hours, derived by Atkinson calculation method |
| 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 |
|-----------------------|----------------|

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 4 Environmental fate and behaviour

Definition of the Residue (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1 and 7.4.2)

| | |
|---|---|
| Soil (risk assessment & monitoring): | Risk Assessment: Zoxamide, RH-127450, RH-24549, RH-163353 and RH-141455. Monitoring: Zoxamide |
| Surface water (risk assessment & monitoring): | Risk Assessment: Zoxamide, RH-127450, RH-163353, RH-141288, RH-24549, RH-141455 and RH-139432 Monitoring: Zoxamide |
| Groundwater (risk assessment & monitoring): | Risk Assessment: Zoxamide, RH-127450, RH-24549, RH-163353 and RH-141455 Monitoring: Zoxamide |
| Air (risk assessment & monitoring): | Zoxamide |

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

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

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

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 <i>Colinus virginianus</i> | a.s. | Acute | LD ₅₀ | >2000 |
| Bobwhite quail <i>Colinus virginianus</i> | a.s. | Short-term | LD ₅₀ | >1415.9 |
| Mallard duck <i>Anas platyrhynchos</i> | a.s. | Short-term | LD ₅₀ | >1167 |
| Mallard duck <i>Anas platyrhynchos</i> | a.s. | Reproduction | NOEC | 114.3 |
| Bobwhite quail <i>Colinus virginianus</i> | a.s. | Reproduction | NOEC | 158.2 |
| Mammals | | | | |
| Rat | a.s. | Acute | LD ₅₀ | >5000 |
| Rat | a.s. | Long term (parental) | NOAEL | 360 |
| Rat | a.s. | Reproductive | NOAEL | 1474 |
| Rat | a.s. | Long term (offspring) | NOAEL | 360 |
| Rabbit | a.s. | Long term (development) | NOAEL | 1000 |
| Rat | a.s. | Long term (development) | NOAEL | 1000 |
| Endocrine disrupting properties (Annex Part A, points 8.1.5) | | | | |
| 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): | | | | |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 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 | | Long-term | 13.60 | 8.4 | 5 |
| Tier 1 (Birds): | | | | | |
| Not required. | | | | | |
| Higher tier (birds): | | | | | |
| Not required. | | | | | |
| Screening Step (Mammals) | | | | | |
| All | Small herbivorous mammal | Acute | 36.23 | 138.0 | 10 |
| All | | Long-term | 10.14 | 35.51 | 5 |
| Tier 1 (Mammals) | | | | | |
| Not required. | | | | | |
| Higher tier (Mammals): | | | | | |
| Not required. | | | | | |

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 | | Long-term | 8.16 | 14.0 | 5 |
| Tier 1 (Birds) | | | | | |
| Not required. | | | | | |
| Higher tier (birds): | | | | | |
| Not required. | | | | | |
| Screening Step (Mammals) | | | | | |
| All | Small herbivorous mammal | Acute | 41.74 | 119.8 | 10 |
| All | | Long-term | 15.17 | 23.72 | 5 |
| Tier 1 (Mammals) | | | | | |
| Not required. | | | | | |
| Higher tier (Mammals): | | | | | |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---|----------------------------|------------------------------------|---------------------------|-----------|---------|
| Not required. | | | | | |
| Risk from bioaccumulation and food chain behaviour | | | | | |
| Indicator or focal species | | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
| Earthworm-eating birds | | Long-term | 0.02 | 6446.9 | 5 |
| Earthworm-eating mammals | | Long-term | 0.02 | 16 656.54 | 5 |
| Fish-eating birds | | Long-term | 0.15 | 787.44 | 5 |
| Fish-eating mammals | | Long-term | 0.13 | 2777.05 | 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 | | | | | |

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 | | | | |
| <i>Oncorhynchus mykiss</i> | a.s. | Acute 96 hr (flow-through) | Mortality, LC ₅₀ | 0.16 mg a.s./L (mm) |
| <i>Lepomis macrochirus</i> | a.s. | Acute 96 hr (flow-through) | Mortality, LC ₅₀ | >0.79 mg a.s./L (mm) |
| <i>Pimephales promelas</i> | a.s. | Acute 96 hr (flow-through) | Mortality, LC ₅₀ | >208 mg a.s./L (mm) |
| <i>Brachydanio rerio</i> | a.s. | Acute 96 hr (flow-through) | Mortality, LC ₅₀ | >0.73 mg a.s./L (mm) |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

| Group | Test substance | Time-scale (Test type) | End point | Toxicity ¹ |
|------------------------------|----------------|--|-----------------------------|---|
| <i>Cyprinodon variegatus</i> | a.s. | Acute 96 hr (flow-through) | Mortality, LC ₅₀ | >0.85 mg a.s./L (mm) |
| <i>Danio rerio</i> | Preparation | Acute 96 hr (static) | Mortality, LC ₅₀ | 0.865 mg prep./L (0.184 mg a.s./L) |
| <i>Oncorhynchus mykiss</i> | RH-127 450 | Acute 96 hr (static) | Mortality, LC ₅₀ | >5 mg/L (nom) |
| <i>Oncorhynchus mykiss</i> | RH-139 432 | Acute 96 hr (flow-through) | Mortality, LC ₅₀ | 2 mg/L |
| <i>Oncorhynchus mykiss</i> | a.s. | 95 d (flow-through, ELS) | NOEC | 0.00348 mg a.s./L (mm) |
| <i>Pimephales promelas</i> | a.s. | 202 d (flow-through, FLC) | NOEC | 0.06 mg a.s./L (mm) |
| <i>Lepomis macrochirus</i> | a.s. | 28 day (flow-through, bioaccumulation) | BCF | 95-136 mg a.s./L |
| Aquatic invertebrates | | | | |
| <i>Daphnia magna</i> | a.s. | 48 h (flow-through) | Mortality, EC ₅₀ | >0.78 mg a.s./L (mm) |
| <i>Mysidopsis bahia</i> | a.s. | 96h (flow-through) | Mortality, LC ₅₀ | 0.076 mg a.s./L (mm) |
| <i>Daphnia magna</i> | Preparation | 48 h (static) | Mortality, EC ₅₀ | >3.0 mg prep./L (>0.69 mg a.s./L) |
| <i>Daphnia magna</i> | a.s. | 21d (flow-through) | NOEC | 0.039 mg a.s./L (mm) |
| <i>Chironomus riparius</i> | a.s. | 28d (flow-through) | NOEC | 0.45 mg a.s./L (nom) |
| <i>Mysidopsis bahia</i> | a.s. | 27 d (flow-through) | NOEC | 0.0072 mg a.s./L (mm) |
| <i>Daphnia magna</i> | RH-127450 | 48 h (semi-static) | Mortality, EC ₅₀ | >5 mg/L (nom) |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

| Group | Test substance | Time-scale (Test type) | End point | Toxicity ¹ |
|----------------------------------|----------------|---------------------------|--|---|
| <i>Daphnia magna</i> | RH-139432 | 48h (semi-static) | Mortality, EC ₅₀ | 17 mg/L _(nom) |
| Algae | | | | |
| <i>Selenastrum capricornutum</i> | a.s. | 120 h (static) | Growth rate: E _r C ₅₀ (NOEC) Biomass: E _b C ₅₀ (NOEC) | 0.048 mg a.s./L (mm) 0.023 mg a.s./L (mm) |
| <i>Anabaena flos-aquae</i> | a.s. | 96h (static) | Growth rate: E _r C ₅₀ (NOEC) Biomass: E _b C ₅₀ (NOEC) | >0.86 mg a.s./L (mm) >0.86 mg a.s./L (mm) |
| <i>Scenedesmus subspicatus</i> | a.s. | 96h (static) | Growth rate: E _r C ₅₀ (NOEC) Biomass: E _b C ₅₀ (NOEC) | 0.018 mg a.s./L (mm) 0.011 mg a.s./L (mm) |
| <i>Navicula pelliculosa</i> | a.s. | 96h (static) | Growth rate: E _r C ₅₀ (NOEC) Biomass: E _b C ₅₀ (NOEC) | >0.93 mg a.s./L (mm) >0.93 mg a.s./L (mm) |
| <i>Skeletonema costatum</i> | a.s. | 96h (static) | Growth rate: E _r C ₅₀ (NOEC) Biomass: E _b C ₅₀ (NOEC) | >0.91 mg a.s./L (mm) >0.91 mg a.s./L (mm) |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

| Group | Test substance | Time-scale (Test type) | End point | Toxicity ¹ |
|---|----------------|---------------------------|--|--|
| <i>Selenastrum capricornutum</i> ** | Preparation | 96h (static) | Growth rate: E _r C ₅₀ (NOEC) | 0.274 mg prep./L (0.0582 mg a.s./L) * |
| | | | Biomass: E _b C ₅₀ (NOEC) | 0.24 mg prep./L (0.0514 mg a.s./L) * |
| <i>Selenastrum capricornutum</i> | RH-127450 | 96 h (static) | EC ₅₀ : | 3.2 mg/L _(mm) |
| | | | Growth rate: E _r C ₅₀ (NOEC) | 4.1 mg/L _(mm) |
| | | | Biomass: E _b C ₅₀ (NOEC) | 2.8 mg/L _(mm) |
| <i>Scenedesmus subspicatus</i> | RH-139432 | 96 h (static) | EC ₅₀ : | 21 mg/L _(mm) |
| | | | Growth rate: 72 h-E _r C ₅₀ (NOEC) | >30 mg/L _(mm) |
| | | | Biomass: 72 h-E _b C ₅₀ (NOEC) | 26 mg/L _(mm) |
| <i>Selenastrum capricornutum</i> | RH-163353 | 96 h (static) | Growth rate: E _r C ₅₀ (NOEC) | >23 mg/L _(mm) |
| | | | Biomass: E _b C ₅₀ (NOEC) | >23 mg/L _(mm) |
| Aquatic plant | | | | |
| <i>Lemna gibba</i> | 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) |
| Further testing on aquatic organisms | | | | |
| - | | | | |
| Potential endocrine disrupting properties (Annex Part A, point 8.2.3) | | | | |
| - | | | | |

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

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---|-----------------------|---|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology**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 | - |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

FOCUS_{sw} 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 | Algae | Higher plant | Sed. dweller prolonged |
|-------------------------------|--------------------------|----------------------------|----------------------------|--------------------------|---------------------------------------|--------------------------------|------------------|----------------------------|
| | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Mysidopsis bahia</i> | <i>Mysidopsis bahia</i> | <i>Scenedesmus subspicatus</i> | <i>Lemna sp.</i> | <i>Chironomus riparius</i> |
| | | LC ₅₀ | NOEC | EC ₅₀ | NOEC | EC ₅₀ | EC ₅₀ | NOEC |
| | | 160 µg/L | 3.48 µg/L | 76 µg/L | 7.2 µg/L | 11 µg/L | 17 µg/L | 450 µg/L |
| FOCUS Step 1 | | | | | | | | |
| | 122.3 | 1.31 | 0.03 | 0.62 | 0.06 | 0.09 | 0.14 | 3.68 |
| FOCUS Step 2 | | | | | | | | |
| North Europe | 3.09 | 51.78 | 1.13 | 24.6 | 2.33 | 3.56 | 5.50 | 145.6 |
| South Europe | 4.35 | 36.78 | 0.8 | 17.47 | 1.66 | 2.53 | 3.91 | 103.4 |
| FOCUS Step 3* | | | | | | | | |
| D3 / ditch | 0.943 | 170 | 3.69 | 80.6 | 7.64 | 11.7 | 18.0 | 477 |
| D4 / pond | 0.047 | 3404 | 74.0 | 1617 | 153 | 234 | 362 | 9574 |
| D4 / stream | 0.709 | 226 | 4.91 | 107 | 10.1 | 15.5 | 24.0 | 634 |
| D6 / ditch (1 st) | 0.937 | 171 | 3.71 | 81.1 | 7.68 | 11.7 | 18.1 | 480 |
| D6 / ditch (2 nd) | 1.370 | 116.8 | 2.54 | 55.5 | 5.26 | 8.03 | 12.4 | 328.5 |
| R1 / pond | 0.534 | 300 | 6.52 | 142 | 13.5 | 20.6 | 32 | 843 |
| R1 / stream | 2.415 | 66.3 | 1.44 | 31.5 | 2.98 | 4.55 | 7.04 | 186 |
| R2 / stream | 0.877 | 182 | 3.97 | 86.7 | 8.21 | 12.5 | 19.4 | 513 |
| R3 / stream | 0.961 | 166 | 3.62 | 79.1 | 7.49 | 11.4 | 17.7 | 468 |
| Trigger** | | | | | | | | |
| | | 100 | 10 | 100 | 10 | 10 | 10 | 10 |

*[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.]

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

FOCUS_{sw} step 1-3 - TERs for zoxamide – Zoxium 240 SC at grapevines (early application) at 180 g a.s./ha [5 applications]

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged |
|----------------------|-----------------------------|--------------------------------|--------------------------------|-----------------------------|---------------------------------------|------------------------------------|------------------|--------------------------------|
| | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Mysidopsis bahia</i> | <i>Mysidopsis bahia</i> | <i>Scenedesmus subspicatus</i> | <i>Lemna sp.</i> | <i>Chironomus riparius</i> |
| | | LC ₅₀ | NOEC | EC ₅₀ | NOEC | EC ₅₀ | EC ₅₀ | NOEC |
| | | 160 µg/L | 3.48 µg/L | 76 µg/L | 7.2 µg/L | 11 µg/L | 17 µg/L | 450 µg/L |
| FOCUS Step 1 | | | | | | | | |
| | 122.1 | 1.31 | 0.03 | 0.62 | 0.06 | 0.09 | 0.14 | 3.68 |
| FOCUS Step 2 | | | | | | | | |
| North Europe | 3.78 | 42.33 | 0.92 | 20.11 | 1.90 | 2.91 | 4.5 | 119 |
| South Europe | 6.8 | 23.53 | 0.51 | 11.18 | 1.06 | 1.62 | 2.5 | 66.18 |
| FOCUS Step 3* | | | | | | | | |
| D6 / ditch | 1.471 | 109 | 2.37 | 51.7 | 4.89 | 7.48 | 11.6 | 306 |
| R1 / pond | 0.126 | 1270 | 28 | 603.2 | 57 | 87 | 135 | 3571 |
| R1 / stream | 1.666 | 96 | 2.1 | 45.6 | 4.32 | 6.60 | 10.2 | 270 |
| R2 / stream | 0.984 | 163 | 3.54 | 77.2 | 7.32 | 11.2 | 17.3 | 457 |
| R3 / stream | 1.043 | 153 | 3.34 | 72.9 | 6.90 | 10.5 | 16.3 | 431 |
| R4 / stream | 3.145 | 50.9 | 1.11 | 24.2 | 2.29 | 3.5 | 5.40 | 143 |
| Trigger** | | 100 | 10 | 100 | 10 | 10 | 10 | 10 |

*[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.]

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

FOCUS_{sw} 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) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged |
|----------------------|-----------------------------|--------------------------------|--------------------------------|-----------------------------|---------------------------------------|------------------------------------|------------------|--------------------------------|
| | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Mysidopsis bahia</i> | <i>Mysidopsis bahia</i> | <i>Scenedesmus subspicatus</i> | <i>Lemna sp.</i> | <i>Chironomus riparius</i> |
| | | LC ₅₀ | NOEC | EC ₅₀ | NOEC | EC ₅₀ | EC ₅₀ | NOEC |
| | | 160 µg/L | 3.48 µg/L | 76 µg/L | 7.2 µg/L | 11 µg/L | 17 µg/L | 450 µg/L |
| FOCUS Step 1 | | | | | | | | |
| | 138.1 | 1.16 | 0.03 | 0.55 | 0.05 | 0.08 | 0.12 | 3.26 |
| FOCUS Step 2 | | | | | | | | |
| North Europe | 5.32 | 30.08 | 0.65 | 14.29 | 1.35 | 2.07 | 3.2 | 84.59 |
| South Europe | 5.32 | 30.08 | 0.65 | 14.29 | 1.35 | 2.07 | 3.2 | 84.59 |
| FOCUS Step 3* | | | | | | | | |
| D6 / ditch | 3.546 | 45.1 | 0.98 | 21.4 | 2.03 | 3.10 | 4.8 | 127 |
| R1 / pond | 0.308 | 519 | 11.3 | 247 | 23.4 | 35.7 | 55.2 | 1461 |
| R1 / stream | 2.264 | 70.7 | 1.54 | 33.6 | 3.18 | 4.86 | 7.51 | 199 |
| R2 / stream | 3.034 | 52.7 | 1.15 | 25.0 | 2.37 | 3.62 | 5.60 | 148 |
| R3 / stream | 3.190 | 50.1 | 1.09 | 23.8 | 2.26 | 3.45 | 5.33 | 141 |
| R4 / stream | 2.263 | 70.7 | 1.54 | 33.6 | 3.18 | 4.86 | 7.51 | 199 |
| Trigger** | | 100 | 10 | 100 | 10 | 10 | 10 | 10 |

*[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.]

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

FOCUS_{sw} 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 (early application) | | | | |
| R1 / stream | - | 0.733 | 218 | 100 |
| R4 / stream | - | 1.428 | 112 | 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 | - | 168 | 100 |

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 3 should be included in step 4].

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

FOCUS_{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 st) | 0.163 | - | - | - | 21.3 | 10 |
| D6 / ditch (2 nd) | - | 1.370 | - | - | 2.54 | 10 |
| R1 / pond | 0.235 | 0.103 | - | - | 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 | - | 0.230 | 15.1 | 10 |
| Grapevines (early application) | | | | | | |
| D6 / ditch | 0.303 | - | - | - | 11.5 | 10 |
| R1 / stream | - | 0.733 | - | 0.397 | 8.77 | 10 |
| R2 / stream | 0.403 | 0.199 | - | - | 8.64 | 10 |
| R3 / stream | 0.265 | - | - | - | 13.1 | 10 |
| R4 / stream | 0.647 | 0.305 | - | - | 5.16 | 10 |
| Grapevines (late application) | | | | | | |
| D6 / ditch | 0.776 | - | 0.272 | - | 12.8 | 10 |
| R1 / stream | 0.597 | - | 0.209 | - | 16.6 | 10 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

| | | | | | | |
|-------------|-------|-------|-------|-------|-------------|----|
| R2 / stream | 0.801 | - | 0.281 | - | 12.4 | 10 |
| R3 / stream | 1.579 | 0.707 | 0.368 | 0.235 | 9.46 | 10 |
| R4 / stream | 0.950 | 0.482 | - | 0.494 | 7.04 | 10 |

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 3 should be included in step 4].

Further calculations are included in Volume 1 and Volume 3.

FOCUS_{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 | 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 (1 st) | 0.163 | - | - | 466 | 100 |
| D6 / ditch (2 nd) | | 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 (early application) | | | | | |
| D6 / ditch | 0.213 | - | - | 375 | 100 |
| R1 / stream | 0.733 | - | - | 103.7 | 100 |
| R2 / stream | 0.403 | - | - | 189 | 100 |
| R3 / stream | 0.265 | - | - | 287 | 100 |
| R4 / stream | 0.674 | - | - | 113 | 100 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

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 | 0.700 | - | 108 | 100 |
| R4 / stream | - | 0.950 | 0.494 | 154 | 100 |

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 3 should be included in step 4].

Further calculations are included in Volume 1 and Volume 3.

FOCUS_{sw} 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 st) | 0.163 | - | - | - | 44.1 | 10 |
| D6 / ditch (2 nd) | | 1.370 | | | 5.26 | 10 |
| R1 / stream | - | 1.028 | - | 0.539 | 13.4 | 10 |

List of end points

| Rapporteur Member State | Month and year | | Active substance and Plant Protection Product (Name) | | | |
|---------------------------------|----------------|--|--|--|--|--|
| RMS – Latvia Co-RMS - France | March 2016 | | Zoxamide/ Zoxium 240 SC | | | |

Section 5 Ecotoxicology

| | | | | | | |
|-------------|-------|---|---|---|------|----|
| R2 / stream | 0.312 | - | - | - | 23.1 | 10 |
| R3 / stream | 0.618 | - | - | - | 11.7 | 10 |

Grapevines (early application)

| | | | | | | |
|-------------|-------|---|-------|---|------|----|
| D6 / ditch | 0.303 | - | - | - | 23.8 | 10 |
| R1 / stream | 0.733 | - | 0.379 | - | 19 | 10 |
| R2 / stream | 0.403 | - | - | - | 17.9 | 10 |
| R3 / stream | 0.265 | - | - | - | 27.2 | 10 |
| R4 / stream | 0.674 | - | - | - | 10.7 | 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 |
| 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].

Further calculations are included in Volume 1 and Volume 3.

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

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

Organisms

Scenedesmus subspicatus

Toxicity endpoint:

11 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 | | | | |
| D6 / ditch (2 nd) | | 1.370 | 8.03 | 10 |
| R1 / stream | - | 1.028 | 10.7 | 10 |
| Grapevines (early application) | | | | |
| R4 / stream | 0.647 | - | 16.3 | 10 |
| D6 / ditch | 0.303 | - | 36.3 | 10 |
| Grapevines (late application) | | | | |
| D6 / ditch | 0.776 | - | 14.2 | 10 |
| R1 / stream | 0.597 | - | 18.4 | 10 |
| R2 / stream | 0.801 | - | 13.7 | 10 |
| R3 / stream | 1.579 | 0.707 | 15.6 | 10 |
| R4 / stream | - | 0.950 | 11.6 | 10 |

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 3 should be included in step 4].

Further calculations are included in Volume 1 and Volume 3.

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

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

Organisms

Lemna sp.

Toxicity endpoint:

17 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 | 16.5 | 10 |
| Grapevines (early application) | | | | |
| R4 / stream | 0.647 | 0.305 | 25.2 | 10 |
| Grapevines (late application) | | | | |
| D6 / ditch | 0.776 | - | 21.9 | 10 |
| R1 / stream | 0.597 | - | 28.5 | 10 |
| R2 / stream | 0.801 | - | 21.2 | 10 |
| R3 / stream | 1.579 | - | 10.8 | 10 |
| R4 / stream | - | 0.950 | 17.9 | 10 |

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 3 should be included in step 4].

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

FOCUS_{sw} step 1-3 - TERs for zoxamide metabolite RH-127,450 – Zoxium 240 SC at potatoes at 180 g a.s./ha [5 applications]

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|---------------------|--------------------------|----------------------------|--------------------------|----------------------------------|
| | | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Selenastrum capricornutum</i> |
| | | LC ₅₀ | EC ₅₀ | E _b C ₅₀ |
| | | >5000 µg/L | >5000 µg/L | 2800 µg/L |
| FOCUS Step 1 | | | | |
| | 24.4 | >204.91 | >204.91 | 114.75 |
| FOCUS Step 2 | | | | |
| North Europe | 1.43 | not required | not required | not required |
| South Europe | 1.59 | not required | not required | not required |
| Trigger** | | 100 | 100 | 10 |

*[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.]

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

FOCUS_{sw} step 1-3 - TERs for zoxamide metabolite RH-127,450 – Zoxium 240 SC at grapevines (early application) at 180 g a.s./ha [5 applications]

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|---------------------|-----------------------------|--------------------------------|--------------------------|--------------------------------------|
| | | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Selenastrum capricornutum</i> |
| | | LC ₅₀ | EC ₅₀ | E _b C ₅₀ |
| | | >5000 µg/L | >5000 µg/L | 2800 µg/L |
| FOCUS Step 1 | | | | |
| | 24.3 | >206 | >206 | 115.2 |
| FOCUS Step 2 | | | | |
| North Europe | 1.87 | not required | not required | not required |
| South Europe | 2.25 | not required | not required | not required |
| Trigger** | | 100 | 100 | 10 |

*[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.]

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

FOCUS_{sw} step 1-3 - TERs for zoxamide metabolite RH-127,450 – Zoxium 240 SC at grapevines (late application) at 180 g a.s./ha [5 applications]

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|---------------------|-----------------------------|--------------------------------|--------------------------|--------------------------------------|
| | | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Selenastrum capricornutum</i> |
| | | LC ₅₀ | EC ₅₀ | E _b C ₅₀ |
| | | >5000 µg/L | >5000 µg/L | 2800 µg/L |
| FOCUS Step 1 | | | | |
| | 30.0 | >166.7 | >166.7 | 93.3 |
| FOCUS Step 2 | | | | |
| North Europe | 4.73 | not required | not required | not required |
| South Europe | 4.73 | not required | not required | not required |
| Trigger** | | 100 | 100 | 10 |

*[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.]

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

FOCUS_{sw} step 1-3 - TERs for zoxamide metabolite RH-139,432 – Zoxium 240 SC at potatoes at 180 g a.s./ha [5 applications]

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|---------------------|--------------------------|----------------------------|--------------------------|----------------------------------|
| | | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Selenastrum capricornutum</i> |
| | | LC ₅₀ | EC ₅₀ | E _p C ₅₀ |
| | | 2000 µg/L | 17000 µg/L | 21000 µg/L |
| FOCUS Step 1 | | | | |
| | 10.92 | 183 | 1556.8 | 1923.1 |
| FOCUS Step 2 | | | | |
| North Europe | 2.22 | not required | not required | not required |
| South Europe | 2.65 | not required | not required | not required |
| Trigger** | | 100 | 100 | 10 |

*[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.]

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

FOCUS_{sw} step 1-3 - TERs for zoxamide metabolite RH-139,432 – Zoxium 240 SC at grapevines (early application) at 180 g a.s./ha [5 applications]

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|---------------------|-----------------------------|--------------------------------|--------------------------|--------------------------------------|
| | | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Selenastrum capricornutum</i> |
| | | LC ₅₀ | EC ₅₀ | E _b C ₅₀ |
| | | 2000 µg/L | 17000 µg/L | 21000 µg/L |
| FOCUS Step 1 | | | | |
| | 10.87 | 184 | 15634 | 1932 |
| FOCUS Step 2 | | | | |
| North Europe | 2.85 | not required | not required | not required |
| South Europe | 3.89 | not required | not required | not required |
| Trigger** | | 100 | 100 | 10 |

*[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.]

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

FOCUS_{sw} step 1-3 - TERs for zoxamide metabolite RH-139,432 – Zoxium 240 SC at grapevines (late application) at 180 g a.s./ha [5 applications]

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|---------------------|-----------------------------|--------------------------------|--------------------------|--------------------------------------|
| | | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Selenastrum capricornutum</i> |
| | | LC ₅₀ | EC ₅₀ | E _b C ₅₀ |
| | | 2000 µg/L | 17000 µg/L | 21000 µg/L |
| FOCUS Step 1 | | | | |
| | 14.98 | 133.5 | 1135 | 1335 |
| FOCUS Step 2 | | | | |
| North Europe | 5.52 | not required | not required | not required |
| South Europe | 5.78 | not required | not required | not required |
| Trigger** | | 100 | 100 | 10 |

*[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.]

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

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 |
|-----------------------|----------------|-----------------------------|--------------------------------------|---|
| <i>Apis mellifera</i> | RH-117,281 2F | Acute | Oral toxicity (LD ₅₀) | >147 µg formulation/bee (corresponding to >33 µg a.s./bee) |
| <i>Apis mellifera</i> | a.s. | Acute | Contact toxicity (LD ₅₀) | > 100 µg a.s./bee |
| <i>Apis mellifera</i> | RH-117,281 2F | Acute | Contact toxicity (LD ₅₀) | >200 µg formulation/bee (corresponding to >43.2 µg a.s./bee) |
| <i>Apis mellifera</i> | Zoxium 240 SC | Chronic | 10 d-LC ₅₀ | >5000 mg a.s./kg feed 174.8 µg a.s./bee/day |
| <i>Apis mellifera</i> | 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 |

| |
|---|
| 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]

| Species | Test substance | Risk quotient | HQ/ETR | Trigger |
|-----------------------|----------------|---------------|--------|---------|
| <i>Apis mellifera</i> | Zoxium 240 SC | HQ contact | <4.2 | 50 |
| <i>Apis mellifera</i> | Zoxium 240 SC | HQ oral | <5.4 | |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

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 |
|------------------------------|----------------|--------------------------------|----------------|
| <i>Typhlodromus pyri</i> | preparation | Mortality, LR ₅₀ | >300 g a.s./ha |
| | | Reproduction, ER ₅₀ | >300 g a.s./ha |
| <i>Aphidius rhopalosiphi</i> | preparation | Mortality, LR ₅₀ | >300 g a.s./ha |
| | | Reproduction, ER ₅₀ | >300 g a.s./ha |
| Additional species | | | |
| <i>Amblyseius andersoni</i> | preparation | Mortality, LR ₅₀ | >300 g a.s./ha |
| | | Reproduction, ER ₅₀ | >300 g a.s./ha |
| <i>Pardosa</i> sp. | preparation | Mortality, LR ₅₀ | >300 g a.s./ha |
| | | Feeding, ER ₅₀ | >300 g a.s./ha |
| <i>Chrysoperla carnea</i> | preparation | Mortality, LR ₅₀ | >300 g a.s./ha |
| | | Reproduction, ER ₅₀ | >300 g a.s./ha |
| <i>Orius insidiosus</i> | preparation | Mortality, LR ₅₀ | >300 g a.s./ha |
| | | Reproduction, ER ₅₀ | >300 g a.s./ha |

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

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

¹ indicate distance assumed to calculate the drift rate

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

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

| Test substance | Species | Effect (LR ₅₀ g/ha) | HQ in-field | HQ off-field ¹ | Trigger |
|----------------|------------------------------|--------------------------------|-------------|---------------------------|---------|
| Zoxium 240 SC | <i>Typhlodromus pyri</i> | >300 g a.s./ha | <1.8 | <0.119 | 2 |
| Zoxium 240 SC | <i>Aphidius rhopalosiphi</i> | >300 g a.s./ha | <1.8 | <0.119 | 2 |

¹ indicate 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 | % effect ³ | ER ₅₀ |
|---------|------------|---------------------------|------------|----------------------------|-------------------------|-----------------------|------------------|
| | | | | | Mortality, reproduction | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

¹ indicate whether initial or aged residues

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

³ indicate if positive percentages relate to adverse effects or not

Risk assessment based on extended lab test or aged residue tests

- Not performed

| Species | ER ₅₀ (g/ha) | In-field rate | Off-field rate ¹ |
|---------|-------------------------|---------------|-----------------------------|
| - | - | - | - |
| - | - | - | - |

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

| |
|--------------------------|
| Semi-field tests |
| - |
| Field studies |
| - |
| Additional specific test |
| - |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

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 |
|------------------------|----------------|-----------------------|--|
| <i>Eisenia foetida</i> | a.s. | 14d – artificial soil | 14d-LC ₅₀ : >1070 mg a.s./kg soil dw 14d-NOEC (mortality): 66.7 mg a.s./kg soil dw |
| | a.s. | 56d – artificial soil | 28d-LD50: >20 mg a.s./kg soil dw 28d – NOEC (mortality): 20 mg a.s./kg soil dw 56d-NOEC (reproduction): 1.0 mg a.s./kg soil dw |
| | a.s. | 56d – natural soil | 28d-LD50: >10 mg a.s./kg soil dw 28d-NOEC (mortality, growth, cocoons laid): 10 mg a.s./kg soil dw 56d-NOEC (reproduction): 7.0 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 |

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 |

Toxicity/exposure ratios for earthworms

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

| Test organism | Test substance | Time scale | Soil PEC*** ₁ | TER | Trigger |
|---------------|----------------|------------|---------------------------------------|-------|---------|
| | a.s. | Acute | 0.467 | 1146 | 10 |
| | RH-127450 | Acute | 0.039 | 12820 | |
| | RH-24549** | Acute | 0.070 | 764 | |
| | RH-163353** | Acute | 0.073 | 733 | |
| | RH-141455** | Acute | 0.032 | 1672 | |
| | | | PEC soil accumulation (mg/kg soil dw) | | |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
| RMS – Latvia Co-RMS - France | March 2016 | Zoxamide/ Zoxium 240 SC |

Section 5 Ecotoxicology

| Test organism | Test substance | Time scale | Soil PEC*** ¹ | TER | Trigger |
|------------------------|----------------------------|------------|---|-------------|---------|
| <i>Eisenia foetida</i> | RH-141455 | >53.5** | no tillage – potatoe 0.0505 | 1059.4 | |
| | | >53.5** | no tillage – vineyard 0.0404 | 1324.3 | |
| | | >53.5** | tillage – potatoe 0.0366 | 1461.7 | |
| | | >53.5** | tillage – vineyard 0.0293 | 1825.9 | |
| | a.s. (artificial soil)* | Chronic | 0.467 | 1.07 | 5 |
| | a.s. (natural soil)* | Chronic | 0.467 | 15 | |
| | RH-127450** | Chronic | 0.039 | 17.9 | |
| | RH-24549** | Chronic | 0.070 | 10.0 | |
| | RH-163353** | Chronic | 0.073 | 9.60 | |
| | RH-141455** | Chronic | 0.032 | 21.9 | |
| | RH-141455** | | PEC soil accumulation (mg/kg soil dw) | | |
| | | Chronic | no tillage – potatoe 0.0505 | 13.9 | |
| | | Chronic | no tillage – vineyard 0.0404 | 17.3 | |
| | | Chronic | tillage – potatoe 0.0366 | 19.1 | |
| | | Chronic | tillage – vineyard 0.0293 | 23.9 | |

¹indicate which PEC soil was used (e.g. plateau PEC)

* Since zoxamide has a log P_{ow} of 3.76 (>2) it is necessary to reduce the LC₅₀ 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). For the natural soil study, no adjustment of the toxicity value is required because the natural soil used in this study is typical of agricultural soils and contained only 2.7% organic carbon.

** Acute and chronic toxicity endpoints used for metabolites assuming that each metabolite is 10 fold more toxic than the parent to earthworms

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
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*** All maximum initial PEC_{soil} values were calculated for application in potatoes

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

| |
|---|
| Not required for herbicides or plant growth regulators as ER ₅₀ tests should be provided |
|---|

Laboratory dose response tests

| Species | Test substance | ER ₅₀ (g/ha) ² vegetative vigour | ER ₅₀ (g/ha) ² emergence | Exposure ¹ (g/ha) ² | TER | Trigger |
|---|----------------|--|---|--|-----|---------|
| - | - | - | - | - | - | - |
| - | - | - | - | - | - | - |
| Extended laboratory studies : Not performed Semi-field and field test: Not performed | | | | | | |

¹ explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

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

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

| Test type/organism | end point |
|-----------------------|-----------|
| Activated sludge | - |
| <i>Pseudomonas sp</i> | - |

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds¹

| Compartment | |
|-------------|--|
| soil | Parent (zoxamide), Metabolite 1 (RH-127450), Metabolite 2 (RH-24549), Metabolite 3 (RH-163353), Metabolite 4 (RH-141455) |
| water | Parent (zoxamide), Metabolite 1 (RH-127450), Metabolite 2 (RH-24549), Metabolite 3 (RH-163353), Metabolite 4 (RH-141455) |
| sediment | - |
| groundwater | - |

¹ metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
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Classification and labelling with regard to ecotoxicological 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] ⁶ : | Aquatic acute 1, H400: Very toxic to aquatic life Aquatic chronic 1, H410: Very toxic to aquatic life with long lasting effects |
| Peer review proposal ⁷ 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 |

⁶ 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.

⁷ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|--|
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Appendix

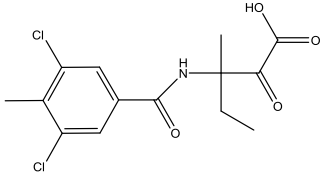
Used compounds code(s)

| Code/Trivial name* | IUPAC name/SMILES notation | Structural formula |
|-------------------------------------|---|--------------------|
| Zoxamide RH-117281 RH-7281 | 3,5-Dichloro-N-(3-chloro-1-ethyl-1-methylacetyl)-p-toluamide | |
| RH-24549 RH-4549 | 3,5-dichloro-4-methylbenzoic acid | |
| RH-127450 RH-7450 | 3,5-dichloro-4-methyl-N-(3-methyl-2-oxopentan-3-yl)benzamide | |
| RH-139432 | 3,5-dichloro-4-methylbenzamide | |
| RH-141452 RH-1452 M-17 in rat | 3,5-dichloro-4-hydroxymethyl benzoic acid | |
| RH-141455 RH-1455 | 3,5-dichloro-4-carboxybenzoic acid 2,6-dichloro-1,4-benzenedicarboxylic acid | |
| RH-141288 | 3,5-dichloro-N-(1-hydroxy-3-methyl-2-oxopentan-3-yl)-4-methylbenzamide | |
| RH-150721 | 3-amino-3-methyl-2-oxopentyl-3,5-dichloro-p-toluate | |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|---------------------------------|----------------|---|
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| | | |
|--------------------------|--|---|
| RH-163353 M-23 in rat | 3,5-dichloro-4-methyl-N-(1-carboxy-3-methyl-2-oxopentan-3-yl)benzamide |  |
|--------------------------|--|---|

* The compound code / trivial name in bold is the name used in the list of endpoints.

