

European Commission



**Draft Assessment Report prepared according to the Commission
Regulation (EU) N° 1107/2009**

Napropamide-M

List of Endpoints

Rapporteur Member State: United Kingdom

List of end points

| Rapporteur Member State | Month and year | Active Substance |
|-------------------------|----------------|------------------|
| UK | June 2017 | Napropamide-M |

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

Version History

| When | What |
|-----------|-------------|
| June 2017 | Initial DAR |
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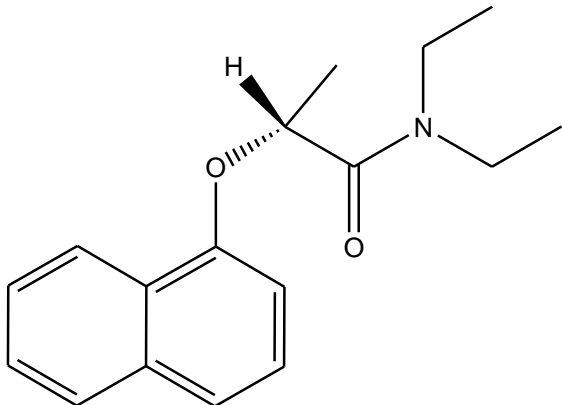
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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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) | Napropamide-M |
| Function (<i>e.g.</i> fungicide) | Herbicide |
| Rapporteur Member State | United Kingdom |
| Co-rapporteur Member State | n/a |

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

| | |
|---|---|
| Chemical name (IUPAC) | (R)-(-)-N,N-diethyl-2-(1-naphthyloxy)propionamide |
| Chemical name (CA) | (-)-N,N-diethyl-2-(1-naphthalenyloxy)propanamide |
| CIPAC No | 976 (assigned by CIPAC January 2015) |
| CAS No | 41643-35-0 |
| EC No (EINECS or ELINCS) | Not assigned |
| FAO Specification (including year of publication) | Not applicable |
| Minimum purity of the active substance as manufactured | 930 g/kg (napropamide-M (D-isomer)) 965 g/kg (napropamide-M (sum of D- +L-isomer)) |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | None |
| Molecular formula | C ₁₇ H ₂₁ NO ₂ |
| Molar mass | 271.35 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) | 92.2 °C (99.85 % (total D- + L-isomer)) |
| Boiling point (state purity) | 319.4 °C (99.85 % (total D- + L-isomer)) |
| Temperature of decomposition (state purity) | Not ascertained (see boiling point) |
| Appearance (state purity) | Beige crystalline solid with no discernible odour (99.85 % (total D- + L-isomer)) |
| Vapour pressure (state temperature, state purity) | 3.80 x 10 ⁻⁶ Pa at 25°C (99.85 % (total D- + L-isomer)) |
| Henry's law constant (state temperature) | 2.644 x 10 ⁻⁵ Pa m ³ mol ⁻¹ |
| Solubility in water (state temperature, state purity and pH) | 0.039 g/L at 20°C ('neutral' pH) (99.85 % (total D- + L-isomer)) |
| Solubility in organic solvents (state temperature, state purity) | At 21°C (97.26 % (total D- + L-isomer)) In n-heptane <10 g/L In p-xylene >200 g/L In 1,2 -dichloroethane >250 g/L In methanol >250 g/L In acetone >250 g/L In ethyl acetate >250 g/L |
| Surface tension (state concentration and temperature, state purity) | <u>Surface tension at 20°C:</u> 56.9 mN/m <u>Surface tension at 40°C:</u> 56.2 mN/m (90 % saturated solution) (99.85 % (total D- + L-isomer)) |
| Partition coefficient (state temperature, pH and purity) | log P _{OW} = 3.27 at 22 °C (pH) (99.85 % (total D- + L-isomer)) |
| Dissociation constant (state purity) | no measurable dissociation constant (tested at 20°C). |

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UV/VIS absorption (max.) incl. ϵ
(state purity, pH)

| | |
|--|---|
| (99.85 % (total D- + L-isomer)) | |
| <u>Acidic media (pH 1.98):</u> | |
| λ_{max} (nm) | ϵ (L.mol ⁻¹ .cm ⁻¹) |
| 217 | 4.8139 x 10 ⁴ |
| 289 | 4.987 x 10 ³ |
| <u>Neutral media (pH 7.10):</u> | |
| λ_{max} (nm) | ϵ (L.mol ⁻¹ .cm ⁻¹) |
| 217 | 5.2385 x 10 ⁴ |
| 290 | 5.579 x 10 ³ |
| <u>Basic/ alkali media (pH 10.14):</u> | |
| λ_{max} (nm) | ϵ (L.mol ⁻¹ .cm ⁻¹) |
| 217 | 1.3123 x 10 ⁵ |
| 291 | 2.271 x 10 ³ |
| Not highly flammable (97.26 % (total D- + L-isomer)) | |
| Not explosive (97.26 % (total D- + L-isomer)) | |
| Not oxidising (97.26 % (total D- + L-isomer)) | |

Flammability (state purity)

Explosive properties (state purity)

Oxidising properties (state purity)

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

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*name of active substance or the respective variant*) (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

| Crop and/or situation (a) | Member State | Product Name | F G I (b) | Pests or group of pests controlled (c) | Formulation | | Application | | | | Application rate per treatment | | | PHI (days) (l) | Remarks (m) |
|---------------------------|--------------|--------------|-----------|--|-------------|-----------------------|---|--|--------------------|-------------------------------------|--------------------------------|--------------------|-------------------------------|----------------|---|
| | | | | | Type (d-f) | Conc of a.i. g/kg (i) | Method kind (f-h) | Growth stage and season (j) | Number min max (k) | Interval between applications (min) | Kg a.i./hl min max (g/hl) | Water l/ha min max | Lk a.i./ha min max (*) (g/ha) | | |
| Winter oilseed rape | All zones | HBW03 | F | Annual grasses and broad-leaved weeds | SC | 450 g/L | Broadcast soil spray and incorporation | Pre-sowing, summer-autumn | 1 | na | 0.255-0.3825 | 200-300 | 0.765 | na | |
| Winter oilseed rape | All zones | HBW03 | F | Annual grasses and broad-leaved weeds | SC | 450 g/L | Broadcast soil spray only, no incorporation | Pre-sowing, summer-autumn | 1 | na | 0.255-0.3825 | 200-300 | 0.765 | na | |
| Brassica vegetable crops | All zones | HBW03 | F | Annual grasses and broad-leaved weeds | SC | 450 g/L | Broadcast soil spray and incorporation | Pre-planting / pre-sowing, spring-summer | 1 | na | 0.1275-0.3825 | 200-600 | 0.765 | na | Treatment is made to soil prior to sowing or transplanting of crops |
| Brassica vegetable crops | All zones | HBW03 | F | Annual grasses and broad-leaved weeds | SC | 450 g/L | Broadcast soil spray only, no incorporation | Pre-planting / pre-sowing, spring-summer | 1 | na | 0.1275-0.3825 | 200-600 | 0.765 | na | Treatment is made to soil prior to sowing or transplanting of crops |
| Winter oilseed rape | All zones | HBW03 | F | Annual grasses and broad-leaved weeds | SC | 450 g/L | Broadcast soil spray only, no incorporation | Post-sowing, pre-emergence / BBCH 00-08, summer-autumn | 1 | na | 0.255-0.3825 | 200-300 | 0.765 | na | |
| Brassica vegetable crops | All zones | HBW03 | F | Annual grasses and broad-leaved weeds | SC | 450 g/L | Broadcast soil spray only, no incorporation | Post-sowing, pre-emergence | 1 | na | 0.1275-0.3825 | 200-600 | 0.765 | na | Treatment is made to soil post-sowing but not post- |

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| | | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|---------------------------------------|--|--|--|--|--|--|---------------------------|
| | | | | | | | | / BBCH 00-08, spring- summer | | | | | | | transplanting of crops |
|--|--|--|--|--|--|--|--|---------------------------------------|--|--|--|--|--|--|---------------------------|

| | |
|---|--|
| <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. fluoroxypry). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialvalicarb-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> |
|---|--|

Note: Brassica vegetable crops covered by the GAP include (According to Commission Regulation (EU) No 212/2013 of 11 March 2013 replacing Annex I to Regulation (EC) No 396/2005): Broccoli (calabrese, Broccoli raab, Chinese broccoli), cauliflower, brussels sprout, Head cabbage (pointed head cabbage, red cabbage, savoy cabbage, white cabbage) Chinese cabbage (Indian or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi, choi sum, Peking cabbage/pe-tsa) kale (Borecole/curly kale, collards, Portuguese Kale, Portuguese cabbage, cow cabbage) and kohl rabi

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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 (*Napropamide-M*)

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

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

| Crop and/or situation (a) | Member State or Country | Product name | F 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) | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
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| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |

- (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
- (j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) Indicate the minimum and maximum number of applications possible under practical conditions of use
- (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)
- (m) PHI - minimum pre-harvest interval

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Further information, Efficacy

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

The representative uses/ GAPs are supported.

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

The representative uses/ GAPs are supported.

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

The representative uses/ GAPs are supported.

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

Activity against target organism

Not required, as there are no metabolites that are considered to be of relevance for groundwater assessment

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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) | Validated methods: GC-MS ('total napropamide' sum of D- isomer and L-isomer) Reverse phase (C18) HPLC-UV ('total napropamide'). Normal phase chiral HPLC (UV) for determination of napropamide-M (D-isomer) and L-isomer of napropamide. |
| Impurities in technical a.s. (analytical technique) | Validated methods: GC-MS, GC-FID, IC |
| Plant protection product (analytical technique) | Reverse phase HPLC-UV (C18) [determination of ('total napropamide' sum of D- isomer and L-isomer); validated Normal phase chiral HPLC (UV) for determination of napropamide-M (D-isomer) and L-isomer of napropamide , not fully validated in the formulated product. Reverse phase (chiral column) HPLC-UV napropamide-M (D-isomer). Validated in the formulated product. |

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 | Napropamide (sum of the <i>R</i> - and <i>S</i> - isomers at any ratio) |
| Food of animal origin | Not required residues intakes by livestock are <0.004 mg/kg bw/day |
| Soil | |
| Sediment | |
| Water surface | |
| drinking/ground | |
| Air | |
| Body fluids and tissues | |

Monitoring/Enforcement methods

| | |
|--|--|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | Napropamide (sum of the <i>R</i> - and <i>S</i> - isomers at any ratio) LC-MS/MS method (QuEChERS approach) LOQ = 0.01 mg/kg (for high water, high acid, high oil and dry matrices). |
|--|--|

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| | |
|---|--|
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Not required residues intakes by livestock are <0.004 mg/kg bw/day |
| Soil (analytical technique and LOQ) | GC-MS (DFG S19 multi-residue method) LOQ = 0.01 mg/kg N.B. The method is capable of determining the total napropamide (racemate), but validation has not been provided for the individual isomers. |
| Water (analytical technique and LOQ) | LC-MS/MS LOQ = 0.05 µg/L (drinking water) and 0.1 µg/L (surface water) N.B. The method has been validated for napropamide-M. |
| Air (analytical technique and LOQ) | LC-UV (215 nm) LOQ = 3.33 x10 ⁻³ mg/m ³ N.B. The method is capable of determining the total napropamide (racemate), but validation has not been provided for the individual isomers. |
| Body fluids and tissues (analytical technique and LOQ) | GC/MS (DFG S19), LOQ = 0.02 mg/kg (muscle, kidney and liver – detection of total napropamide racemate only) LC-MS/MS, LOQ = 50 ng/mL (rat plasma – validated for napropamide-M only) |

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

| | |
|--|---|
| Substance | Napropamide-M |
| 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 : | No current harmonised classification |
| Peer review proposal ² for harmonised classification according to Regulation (EC) No 1272/2008: | No classification (with reference to physical and chemical properties data) |

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 | >90 % based on urinary (15 %) and biliary (78 %) excretion within 24 h following single dose administration. Value of 100 % suitable for AOEL. |
| Toxicokinetics | 30 mg/kg bw: plasma C _{max} 4.12 µg equiv/mL, T _{max} 6 h, T _{1/2} 14.8 h 300 mg/kg bw: plasma C _{max} 37.2 µg equiv/mL, T _{max} 6 h, T _{1/2} 18.6 h |
| Distribution | Uniformly distributed; highest levels in blood, liver, spleen and kidney. |
| Potential for bioaccumulation | No evidence for accumulation. |
| Rate and extent of excretion | Rapid and extensive (approx. 90%) within 72 h. Majority excreted within 24 hours via urine (37-60%) and faeces (29-55%); 78 % of administered dose excreted via bile within 24 h, indicating extensive enterohepatic circulation |
| Metabolism in animals | Extensively metabolised (>92 %); >15 metabolites in urine and faeces; metabolic pathway: N-dealkylation, oxidation, followed by conjugation |
| <i>In vitro</i> metabolism | Not investigated; biotransformation pathways in rats likely to be conserved across species, including humans |
| Toxicologically relevant compounds (animals and plants) | Parent compound |
| 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 LD ₅₀ dermal | >2000 mg/kg bw | |
| Rat LC ₅₀ inhalation | >4.8 mg/L/4h (nose-only) / test not feasible | |
| Skin irritation | Non-irritant | |
| Eye irritation | Non-irritant | |
| Skin sensitisation | Non-sensitiser | |
| Phototoxicity | Not required | |

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

| | | |
|--------------------------------|---|--|
| Target organ / critical effect | Rat = liver (increased weight, hepatotoxicity), blood system (mild anaemia), spleen (increased weight, extramedullary haematopoiesis), body-weight decrease Dog = liver (increased weight, hepatotoxicity), body-weight decrease | |
| Relevant oral NOAEL | 90-day rat: 46 mg/kg bw/day for males and 50 mg/kg bw/day for females 90-day dog: 40 mg/kg bw/d | |
| Relevant dermal NOAEL | 30-day rat: 1000 mg/kg bw/day | |
| Relevant inhalation NOAEL | No study | |

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

| | | |
|----------------------------|--|--|
| <i>In vitro</i> studies | Bacterial (Ames) gene mutation: negative (+/-S9) Mammalian (L5178Y <i>tk</i> ^{+/+}) gene mutation: negative (-S9), positive (+S9) Mammalian (human peripheral blood lymphocytes) chromosome aberration: negative (+/-S9) | |
| <i>In vivo</i> studies | Mouse bone marrow micronucleus: negative Rat liver comet: negative | |
| Photomutagenicity | Not required | |
| Potential for genotoxicity | Napropamide-M 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) | Rats: body-weight decreases Mice: liver (increased weight), kidney (increased weight), body weight decreases | |
| Relevant long-term NOAEL | 2-year, rat: 30 mg/kg bw/day 18-month, mouse: 55 mg/kg bw/day | |
| Carcinogenicity (target organ, tumour type) | Rat: no tumours Mouse: no tumours Napropamide-M is unlikely to pose a carcinogenic hazard to humans | |
| Relevant NOAEL for carcinogenicity | 2-year, rat: 522 mg/kg bw/day; 18-month, mouse: 455 mg/kg bw/day | |

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

Reproduction toxicity

| | | |
|---------------------------------------|--|--|
| Reproduction target / critical effect | Parental toxicity: decreased body weight Reproductive toxicity: no adverse effect observed in rat 3-generation study Offspring toxicity: decreased body weight | |
| Relevant parental NOAEL | 30 mg/kg bw/day | |
| Relevant reproductive NOAEL | >100 mg/kg bw/day | |
| Relevant offspring NOAEL | 30 mg/kg bw/day | |

Developmental toxicity

| | | |
|--|---|--|
| Developmental target / critical effect | <u>Rat:</u> Maternal toxicity: decreased body weight and food consumption Developmental toxicity: no adverse developmental effects <u>Rabbit:</u> Maternal toxicity: decreased body weight and food consumption Developmental toxicity: no adverse developmental effects | |
| Relevant maternal NOAEL | Rat: 110 mg/kg bw/day Rabbit: 300 mg/kg bw/day | |
| Relevant developmental NOAEL | Rat: 400 mg/kg bw/day Rabbit: 1000 mg/kg bw/day | |

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

| | | |
|--|----------|--|
| Acute neurotoxicity | No study | |
| Repeated neurotoxicity | No study | |
| Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) | No study | |

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

| | |
|---|----------|
| Supplementary studies on the active substance | No study |
| Endocrine disrupting properties | No study |

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Section 2 Mammalian Toxicology

Studies performed on metabolites or impurities

For napropamide-M there were no relevant metabolites in groundwater, surface water, soil or air observed in environmental fate and behaviour studies that needed to be considered from a toxicological point of view.

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

Limited; new active substance, no detrimental effects on health in manufacturing personnel

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) | 0.3 | rat, 2-year | 100 |
| Acute Reference Dose (ARfD) | Not set – not necessary | | |
| Acceptable Operator Exposure Level (AOEL) | 0.5 | dog, 1 year | 100 |
| Acute Acceptable Operator Exposure Level (AAOEL) | Not set – not necessary | | |

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: 0.6 % (450 g/L)
Spray dilution: 18% (1.3 g/L)
Based on an *in vitro* human skin study with D-Devrinol 450 SC

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

Operators

Use: Brassica vegetables and oil seed rape, tractor mounted equipment, application rate 0.765 kg a.s./ha
Exposure estimates (model): % of AOEL
UK POEM
Without PPE: 100
PPE (gloves during mixing and loading): 96
German model
Without PPE: 17

Workers

Pre-emergence herbicide therefore worker exposure is considered negligible.

³ If available include also reference values for metabolites

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| UK | June 2017 | Napropamide-M |

Section 2 Mammalian Toxicology

Bystanders and residents

| | |
|--|-----------------------|
| <u>Modelling Approach: UK</u> | <u>% of AOEL</u> |
| • Bystander exposure to vapour (surrogate value derived from Californian Environmental Protection Agency studies) | 2% child <1% adult |
| • Bystander exposure to spray drift (measurements of simulated bystander exposure for field crop sprayers in a UK study) | <1% adult |
| • Bystander exposure to fallout (children model) | <1% child |
| <u>Modelling Approach: German (BfR)</u> | <u>% of AOEL</u> |
| • Exposure to adult bystander | <1% |
| • Exposure to child bystander | <1% |
| • Exposure to adult resident | <1% |
| • Exposure to child resident | <1% |

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

| | |
|--|--------------------------------------|
| Substance : | Napropamide-M |
| 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 : | No current harmonised classification |
| Peer review proposal ⁵ for harmonised classification according to Regulation (EC) No 1272/2008: | No classification |

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.

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.

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| UK | June 2017 | Napropamide-M |

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) | Crop groups | Crop(s) | Application(s) | | DAT (days) |
| | Fruit crops | Tomato | 2.5 kg as [∞] /ha – preplanting | | Harvested once ripe |
| | | Apple | 9.15 kg as/ha – to soil | | 35, 550 |
| | Root crops | Potato | 2 kg as/ha soil incorporated | | 61 |
| | Leafy crops | Cabbage | 2.5 kg as/ha soil incorporated | | 55-60 |
| | Cereals/grass crops | - | - | | - |
| | Pulses/Oilseeds | Oilseed rape | 2 kg as/ha 0.72 kg as [*] /ha | | 124, 195, 256, 292 Forage at BBCH 15, 22 and 51, pods and foliage at GS 76 and pods, straw and seed at BBCH 84. |
| | Miscellaneous | | | | |
| ∞Napropamide *Napropamide-M | | | | | |
| Rotational crops (metabolic pattern) | Crop groups | Crop(s) | PBI (days) | Comments | |
| | Root/tuber crops | Carrot | 60, 180, 360 | | |
| | Leafy crops | Lettuce | 60, 180, 360 | | |
| | Cereal (small grain) | Wheat | 60, 180, 360 | | |
| | Other | - | - | | |
| | Rotational crop and primary crop metabolism similar? | Yes | | | |
| Processed commodities (standard hydrolysis study) | Conditions | | | | |
| | 20 min, 90°C, pH 4 | - | | | |
| | 60 min, 100°C, pH 5 | - | | | |
| | 20 min, 120°C, pH 6 | - | | | |
| | | | | | |

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| UK | June 2017 | Napropamide-M |

Section 3 Residues

| | |
|---|---|
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | - |
| Plant residue definition for monitoring (RD-Mo) | Napropamide (sum of the <i>R</i> - and <i>S</i> - isomers at any ratio) |
| Plant residue definition for risk assessment (RD-RA) | Napropamide (sum of the <i>R</i> - and <i>S</i> - isomers at any ratio) |
| Conversion factor (monitoring to risk assessment) | - |

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)

| | Animal | Dose (mg/kg bw/d) | Duration (days) | N rate/comment |
|--|--|----------------------|--------------------|----------------|
| Animals covered | Laying hen | 0.57 | 10 | See below |
| | Goat/Cow | 0.29 | 4 | See below |
| | Pig | - | | |
| | Fish | - | | |
| | | | | |
| Time needed to reach a plateau concentration in milk and eggs (days) | 2-4 days | | | |
| Animal residue definition for monitoring (RD-Mo) | Not required residues intakes by livestock are <0.004 mg/kg bw/day | | | |
| Animal residue definition for risk assessment (RD-RA) | Not required residues intakes by livestock are <0.004 mg/kg bw/day | | | |
| Conversion factor (monitoring to risk assessment) | - | | | |
| Metabolism in rat and ruminant similar (Yes/No) | Yes | | | |
| Fat soluble residues (Yes/No) | Yes | | | |

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

| | |
|---|---|
| Confined rotational crop study (Quantitative aspect) | Lettuce, carrot (top and root) and wheat. residues <0.01 mg/kg for 180 DAT. |
|---|---|

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| UK | June 2017 | Napropamide-M |

Section 3 Residues

Field rotational crop study

Residues of napropamide in immature wheat and mature grain and straw (589-717 days after planting) were below the LOQ (0.01 mg/kg) in all samples with the exception of one immature wheat sample that contained 0.04 mg/kg napropamide.

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|--------------------------------|-----------------------|--------------------------------|
| UK | June 2017 | Napropamide-M |

Section 3 Residues

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

| Plant products (Category) | Commodity | T (°C) | Stability (Month/Year) | | | |
|--------------------------------------|-----------------------------|-------------------|-------------------------------|--|--|--|
| | | | | | | |
| High water content | Cabbage | -18 | 341 day | | | |
| High oil content | Oilseed rape | -18 | 1 year | | | |
| High protein content | - | | | | | |
| High starch content | - | | | | | |
| High acid content | - | | | | | |
| | | | | | | |
| | | | | | | |
| Animal | Animal commodity | T (°C) | Stability (Month/Year) | | | |
| | | | | | | |
| | Muscle | | | | | |
| | Liver | | | | | |
| | Kidney | | | | | |
| | Milk | | | | | |
| | Egg | | | | | |
| | | | | | | |
| Not required. | | | | | | |

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| UK | June 2017 | Napropamide-M |

Section 3 Residues

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3)

| 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 | | | | | | |
| Brassica vegetables (flowering and head brassicas) | NEU | 7 x <0.1, 8 x <0.01 | | 0.02 | 0.02 | 0.02 |
| | SEU | 4 x <0.01 | | 0.02 | 0.02 | 0.02 |
| Oilseed rape | NEU | 6 x < 0.01, 0.01 | | 0.01 | 0.01 | 0.01 |
| | SEU | 4 x <0.01 | | 0.01 | 0.01 | 0.01 |
| Summary of the data on formulation equivalence | | | | | | |
| Crop | Region | Residue data (mg/kg) | Recommendations/comments | | | |
| - | - | - | | | | |
| | | | | | | |
| | | | | | | |
| Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1) | | | | | | |
| Product(s) | Region | Residue data (mg/kg) | Recommendations/comments | | | |
| - | - | - | | | | |

(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) |
|--------------------------------|-----------------------|--------------------------------|
| UK | June 2017 | Napropamide-M |

Section 3 Residues**Inputs for animal burden calculations**

| Feed commodity | Median dietary burden | | Maximum dietary burden | |
|----------------------------|------------------------------|----------------------|-------------------------------|----------------------|
| | (mg/kg) | Comment | (mg/kg) | Comment |
| Representative uses | | | | |
| Brassica vegetables | 0.02 | STM _R | 0.02 | HR |
| Oilseed rape | 0.02 | STM _R *PF | 0.02 | STM _R *PF |

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| UK | June 2017 | Napropamide-M |

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)

| 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 | 0.0004 | Broiler | 0.0003 | Carp | - |
| | Dairy cattle | 0.001 | Lamb | 0.001 | Finishing | 0.0001 | Layer | 0.001 | Trout | - |
| | | | | | | | Turkey | 0.0003 | Fish intake >0.1 mg/kg DM | |
| Intake >0.004 mg/kg bw | No | | No | | No | | No | | N/A | |
| Feeding study submitted | No | | No | | No | | No | | No | |
| 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 (Name) |
|-------------------------|----------------|-------------------------|
| UK | June 2017 | Napropamide-M |

Section 3 Residues

| STMR calculations | Ruminant | | | | Pig/Swine | | Poultry | | Fish | |
|---|-----------------------------------|---|-----------------------------------|---|-----------------------------------|---|-----------------------------------|---|-----------------------------------|---|
| Median expected intake (mg/kg bw/d) (mg/kg DM for fish) | Beef cattle | 0.001 | Ram/Ewe | 0.001 | Breeding | 0.0004 | Broiler | 0.0003 | Carp | |
| | Dairy cattle | 0.001 | Lamb | 0.001 | Finishing | 0.0001 | Layer | 0.001 | Trout | |
| | | | | | | | Turkey | 0.0003 | | |
| 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 |
| | Mean level in feeding level | Estimated STMR ^(b) at 1N | Mean level in feeding level | Estimated STMR ^(b) at 1N | Mean level in feeding level | Estimated STMR ^(b) at 1N | Mean level in feeding level | Estimated STMR ^(b) at 1N | Mean level in feeding level | Estimated STMR ^(b) at 1N |
| Muscle | | | | | | | | | | |
| Fat | | | | | | | | | | |
| Meat ^(a) | | | | | | | | | | |
| Liver | | | | | | | | | | |
| Kidney | | | | | | | | | | |
| Milk | | | | | | | | | | |
| Eggs | | | | | | | | | | |
| Method of calculation ^(c) | | | | | | | | | | |

^(a): STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

^(b): When the mean level is set at the LOQ, the STMR is set at the LOQ.

^(c): The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by interpolation (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 (Name) |
|-------------------------|----------------|-------------------------|
| UK | June 2017 | Napropamide-M |

Section 3 Residues

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

| 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 | | | | |
| Not required. | | | | |
| | | | | |

^(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 | 0.3 mg/kg bw per day |
| TMDI according to EFSA PRIMo | Highest TMDI: 0.02% ADI (PT, general population) |
| NTMDI, according to (to be specified) | Highest NTMDI: <1 % ADI (UK, all consumer groups) |
| IEDI (% ADI), according to EFSA PRIMo | Highest IEDI: 0.01 % ADI (WHO Cluster diet E) |
| NEDI (% ADI), according to (to be specified) | Highest NEDI: 0.02 % ADI PT, general population) |
| Factors included in the calculations | - |
| ARfD | n.n. |
| IENTI (% ARfD), according to EFSA PRIMo | - |
| NESTI (% ARfD), according to (to be specified) | - |
| Factors included in IESTI and NESTI | - |

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

| Code ^(a) | Commodity/Group | MRL/Import tolerance ^(b) (mg/kg) and Comments | |
|---------------------|--------------------------|---|--|
| Plant commodities | | | |
| Representative uses | | | |
| 0241010 | Broccoli | 0.02* | |
| 0241020 | Cauliflowers | 0.02* | |
| 0242010 | Brussels sprouts | 0.02* | |
| 0242020 | Head cabbages | 0.02* | |
| 0243010 | Chinese cabbages/pe-tsai | 0.02* | |
| 0243020 | Kales | 0.02* | |
| 0244000 | kohlrabies | 0.02* | |
| 0401060 | Rapeseeds/canola seeds | 0.01* | |
| Animal commodities | | | |

List of end points

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| UK | June 2017 | Napropamide-M |

Section 3 Residues

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

(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 |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

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)

| | |
|---|--|
| Mineralisation after 100 days | 0.1-1.2 % RR (recovered radioactivity) (mean) after 120d, [¹⁴ C-naphthyl-1]-label (n ⁶ = 5) |
| Non-extractable residues after 100 days | 13.0- 28.4 % RR (mean) after 120 d, [¹⁴ C- naphthyl-1]-label (n= 5) |
| Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) | N/A |

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

| | |
|---|---|
| Mineralisation after 100 days | 7.20% RR (mean) CO ₂ /volatiles at 100 d, [¹⁴ C-naphthyl-1]-label (n= 1) |
| Non-extractable residues after 100 days | 24.4% RR (mean) at 100 d, [¹⁴ C-naphthyl-1]-label (n= 1) |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | N/A |

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

| | |
|---|--|
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | N/A |
| Mineralisation at study end | 7.70 % AR after 30d, [¹⁴ C-naphthyl-1]-label (n= 1) |
| Non-extractable residues at study end | 5.35 % AR (mean) after 30d, [¹⁴ C-naphthyl-1]-label (n= 1) |

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Persistence endpoints

⁶ n corresponds to the number of soils.

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 4 Environmental fate and behaviour

| Parent | Dark aerobic conditions- laboratory studies | | | | | |
|--------------------------------------|---|----------------|--|--|-----------------------|-----------------------|
| Soil type | pH ^{a)} | t. °C / % MWHC | DT ₅₀ /DT ₉₀ (d) | DT ₅₀ (d) 20 °C pF2/10kPa ^{b)} | St. (χ ²) | Method of calculation |
| Clay | 7.3 | 20 ±2; 35.4 | 727; 2820 | - | 1.89 | DFOP |
| Loamy Sand | 7.5 | 20 ±2; 10.5 | 636; 2200 | - | 0.598 | HS |
| Sandy Loam | 6.6 | 20 ±2; 16.3 | 408; 1690 | - | 2.34 | HS |
| Clay Loam | 7.6 | 20 ±2; 27.3 | 1150; 5250 | - | 2.92 | HS |
| Loam | 7.4 | 20 ±2; 28.6 | 382; 1270 | - | 1.19 | SFO |
| Geometric mean (if not pH dependent) | | | 608; 2338 | | | |
| pH dependent: No | | | | | | |

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Laboratory studies were performed at 20 °C and pF2

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Metabolite | N/A | | | | | | | |
|--------------------------------------|-----|------------------|----------------|---|--|--|-----------------------|-----------------------|
| Soil type | | pH ^{a)} | t. °C / % MWHC | DT ₅₀ / DT ₉₀ (d) | f. f. k _f / k _{dp} | DT ₅₀ (d) 20 °C pF2/10kPa ^{b)} | St. (χ ²) | Method of calculation |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| Geometric mean (if not pH dependent) | | | | | | | | |
| Arithmetic mean | | | | | | | | |
| pH dependence, | | | | | | | | |

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Persistence endpoints

| Parent | Aerobic conditions- field dissipation trials | | | | | | | | |
|--|--|--------|------------------|------------|-----------------------------|-----------------------------|-----------------------|---|-----------------------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | Plot | pH ^{a)} | Depth (cm) | DT ₅₀ (d) actual | DT ₉₀ (d) actual | St. (χ ²) | DT ₅₀ (d) Norm ^{b)} . | Method of calculation |
| Sandy Loam | Italy | spring | 5.5 | 0-30 | 6.91 | 138.0 | 14.4 | - | FOMC |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 4 Environmental fate and behaviour

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Persistence endpoints

| Parent | Aerobic conditions- field dissipation trials | | | | | | | | |
|--|--|--------|------------------|------------|-----------------------------|-----------------------------|------------------|---|-----------------------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | Plot | pH ^{a)} | Depth (cm) | DT ₅₀ (d) actual | DT ₉₀ (d) actual | St. (χ^2) | DT ₅₀ (d) Norm ^{b)} . | Method of calculation |
| Sandy Loam | Italy | autumn | 5.5 | 0-30 | 94.4 | 313.0 | 17.9 | - | SFO |
| Sandy Clay Loam | Spain | spring | 8.7 | 0-30 | 5.31 | 605.0 | 8.86 | - | HS |
| Sandy Clay Loam | Spain | autumn | 8.7 | 0-30 | 101.0 | 900.0 | 10.5 | - | HS |
| Sand | Germany | spring | 7.3 | 0-30 | 57.9 | 192.0 | 17.7 | - | SFO |
| Sand | Germany | autumn | 7.3 | 0-30 | 49.0 | 163.0 | 18.2 | - | SFO |
| Sandy Loam | UK | spring | 6.8 | 0-30 | 40.7 | 135.0 | 12.1 | - | SFO |
| Sandy Loam | UK | autumn | 6.8 | 0-30 | 73.7 | 245.0 | 7.43 | - | SFO |
| Geometric mean (if not pH dependent) | | | | | 36.24 | 265.03 | - | - | - |
| pH dependent: No | | | | | | | | | |

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

Persistence endpoints were calculated using non-normalised field data

| Metabolite | N/A | | | | | | | | | |
|--------------------------------------|----------|--|------------------|------------|-----------------------------|-----------------------------|------------------|---|--|-----------------------|
| Soil type | Location | | pH ^{a)} | Depth (cm) | DT ₅₀ (d) actual | DT ₉₀ (d) actual | St. (χ^2) | DT ₅₀ (d) Norm ^{b)} . | f. f. k _f / k _{dp} | Method of calculation |
| | | | | | | | | | | |
| Geometric mean (if not pH dependent) | | | | | | | | | | |
| Arithmetic mean | | | | | | | | | | |
| pH dependence, Yes or No | | | | | | | | | | |

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 values are DegT50matrix

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 4 Environmental fate and behaviour

Modelling endpoints

There was uncertainty over the degradation rates in the aerobic soil laboratory conditions, with DT50 values extrapolated well beyond the study duration. Therefore, the risk assessment was based on data from the field dissipation trials.

| Parent | Aerobic conditions- field dissipation trials | | | | | | | | |
|--|--|--------|------------------|------------|-----------------------------|-----------------------------|------------------|---|-----------------------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | Plot | pH ^{a)} | Depth (cm) | DT ₅₀ (d) actual | DT ₉₀ (d) actual | St. (χ^2) | DT ₅₀ (d) Norm ^{b)} . | Method of calculation |
| Sandy Loam (bare soil) | Italy | spring | 5.5 | 0-30 | 6.91 | 34.2 | 14.6 | 3.34 | FOMC |
| Sandy Loam (bare soil) | Italy | autumn | 5.5 | 0-30 | 73.5 | 244 | 16.0 | 28.6 | SFO |
| Sandy Clay Loam (bare soil) | Spain | spring | 8.7 | 0-30 | 5.61 | >1000 | 13.5 | 440 | DFOP |
| Sandy Clay Loam (bare soil) | Spain | autumn | 8.7 | 0-30 | 201 | 667 | 16.9 | 89.6 | SFO |
| Sand (bare soil) | Germany | spring | 7.3 | 0-30 | 62.4 | 207 | 14.1 | 24.0 | SFO |
| Sand (bare soil) | Germany | autumn | 7.3 | 0-30 | 49 | 163 | 20.2 | 15.3 | SFO |
| Sandy Loam (bare soil) | UK | spring | 6.8 | 0-30 | 40.7 | 135 | 10.7 | 12.8 | SFO |
| Sandy Loam (bare soil) | UK | autumn | 6.8 | 0-30 | 73.7 | 245 | 7.35 | 24.0 | SFO |
| Geometric mean (if not pH dependent) | | | | | | | | 28.41 | |
| pH dependent: No | | | | | | | | | |

a) Measured in water

b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT₅₀ matrix. Longer phase K2 DT₅₀ shown for DFOP derived value, the K1 DT₅₀ value for the DFOP model was 1.7 days.

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)

Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)

Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean

| |
|-----|
| N/A |
| |
| |

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration

Plateau concentration of 1.5979 mg/kg reached after 6 years (based on calculation)

List of end points

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Section 4 Environmental fate and behaviour

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Parent | Dark anaerobic conditions | | | | | | |
|--------------------------------------|---------------------------|------------------|---|---|--|-----------------------|-----------------------|
| Soil type | | pH ^{a)} | t. °C / moisture content at 1/3 bar (%) | DT ₅₀ / DT ₉₀ (d) | DT ₅₀ (d) 20 °C ^{b)} | St. (χ ²) | Method of calculation |
| Clay | | 7.3 | 20 ±2; 35.4 | 241; 799 | - | 3.39 | SFO |
| Geometric mean (if not pH dependent) | | | | | | | |

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58

List of end points

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

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

| | | | | | | | | |
|--------------------------------------|-----|------------------|----------------|---|--|---|-----------------------|-----------------------|
| Metabolite | N/A | | | | | | | |
| Soil type | | pH ^{a)} | t. °C / % MWHC | DT ₅₀ / DT ₉₀ (d) | f. f. k _f / k _{dp} | DT ₅₀ (d) 20°C ^{b)} | St. (χ ²) | Method of calculation |
| | | | | | | | | |
| Geometric mean (if not pH dependent) | | | | | | | | |
| Arithmetic mean | | | | | | | | |

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Normalised using a Q10 of 2.58

| | | | | | | |
|-----------|------------------|--------------------------------------|--|--|-----------------------|-----------------------|
| Parent | Soil photolysis | | | | | |
| Soil type | pH ^{a)} | t. °C / moisture content 1/3 bar (%) | Experimental DT ₅₀ / DT ₉₀ (d) | DT ₅₀ / DT ₉₀ (d) calculated at 37°N ^{b)} | St. (χ ²) | Method of calculation |
| Loam | 7.4 | 16-19; 28.6 | 174; 580 | ca 488-519 | 3.63 | SFO |

^{a)} Measured in water

^{b)} Using the conversion factor of either 2.8 or 2.98

List of end points

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

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Napropamide-M | | | | | | | |
|---------------------------------------|------|-----------------------|--------------------------|---------------------------|--------------------------|----------------------------|-------|
| Soil Type | OC % | Soil pH ^{a)} | K _d (mL/g) | K _{oc} (mL/g) | K _F (mL/g) | K _{Foc} (mL/g) | 1/n |
| Loam | 1.0 | 7.6 | 7.076 | 707.6 | 5.390 | 539 | 0.917 |
| Loamy Sand | 1.1 | 7.5 | 5.461 | 496.45 | 3.444 | 313.09 | 0.857 |
| Clay | 2.0 | 7.5 | 21.47 | 1073.5 | 10.567 | 528.35 | 0.843 |
| Clay Loam | 1.3 | 7.8 | 16.71 | 1285.39 | 9.707 | 746.69 | 0.868 |
| Sandy Loam | 0.93 | 6.6 | 5.536 | 595.27 | 3.309 | 355.81 | 0.843 |
| Geometric mean (if not pH dependent)* | | | | | 5.747 | 472.61 | 0.865 |
| Arithmetic mean (if not pH dependent) | | | | | 6.48 | 496.30 | 0.865 |
| pH dependent: No | | | | | | | |

^{a)} Measured in water

* Only relevant after implementation of the published EFSA guidance.

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Metabolite N/A | | | | | | | |
|---------------------------------------|------|-----------------------|--------------------------|----------------------------|--------------------------|----------------------------|-----|
| Soil Type | OC % | Soil pH ^{a)} | K _d (mL/g) | K _{doc} (mL/g) | K _F (mL/g) | K _{Foc} (mL/g) | 1/n |
| | | | | | | | |
| Geometric mean (if not pH dependent)* | | | | | | | |
| Arithmetic mean (if not pH dependent) | | | | | | | |
| pH dependence, | | | | | | | |

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

* Only relevant after implementation of the published EFSA guidance.

List of end points

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

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching: not required

| |
|-----|
| N/A |
| |

Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching: not required

| |
|-----|
| N/A |
| |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
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Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies: not required

N/A

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Section 4 Environmental fate and behaviour

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)

Hydrolytic degradation of the active substance and metabolites < 10 %

Hydrolytically stable at pH 4 at 50 ±0.5 °C, no DT₅₀ calculated.

Hydrolytically stable at pH 7 at 50 ±0.5 °C, no DT₅₀ calculated.

Hydrolytically stable at pH 9 at 50 ±0.5 °C, no DT₅₀ calculated.

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

DT₅₀: 6.56 mins (experimental)

Isomer-I: max. 37.03 %AR (mean) at 60 minutes

Isomer-II: max. 57.1 %AR (mean) at 30 minutes

1-naphthol: max 23.31 %AR (mean) at 120 minutes

Estimated DT₅₀ 6.13 minutes

Isomer-I: 54.4 minutes

Isomer-II: 75.5 minutes

1-naphthol: 90.5 minutes

Quantum yield of direct phototransformation in water at Σ > 290 nm

0.475 and 0.474 mol⁻¹ · Einstein⁻¹ based on actinometer and absorbance respectively

‘Ready biodegradability’ (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable: no

Biodegradation <10%, not readily biodegradable

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
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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)

| Parent | | | | | | | | | | |
|--|----------------------|-------------------------|------------------------|---|--|--------------------------|---|---|--------------------------|--------------------------|
| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed ^{a)} | t. °C ^{b)} | DT ₅₀ /DT ₉₀ whole sys. (suspended sediment test) | | St. (χ ²) | DT ₅₀ /DT ₉₀ Water (pelagic test) | | St. (χ ²) | Method of calculation |
| | | | | At study temp | Normalise d to <i>x</i> °C ^{c)} | | At study temp | Norma lised to <i>x</i> °C ^{c)} | | |
| Fresh surface water (PA, USA) | 8.1 | N/A | 20 ±2°C | N/A | N/A | N/A | 1840- 2320 | | 3.36- 4.02 | SFO |

^{a)} Measured in water

^{b)} Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C

^{c)} Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

| Metabolite | N/A | | | | | | | | | |
|--|----------------|----------------------|---------------------|---|----------------------------------|-----------------------|---|----------------------------------|-----------------------|-----------------------|
| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed ^{a)} | t. °C ^{b)} | DT ₅₀ /DT ₉₀ whole sys. (suspended sediment test) | | St. (χ ²) | DT ₅₀ /DT ₉₀ Water (pelagic test) | | St. (χ ²) | Method of calculation |
| | | | | At study temp | Normalised to x °C ^{c)} | | At study temp | Normalised to x °C ^{c)} | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C

^{c)} Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

List of end points

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Section 4 Environmental fate and behaviour

| Mineralisation and non extractable residues (for parent dosed experiments) | | | | | |
|--|----------------|--------|--------------------|--|--|
| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed | Mineralisation | Non-extractable residues (suspended sediment test) | Non-extractable residues. (end of the study) (suspended sediment test) |
| Fresh surface water (PA, USA) | 8.1 | N/A | <20% after 90 days | N/A | N/A |
| | | | | | |
| | | | | | |

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)

| Parent | Distribution (max. 95.91 %AR in water after 0 d; max. 85.20 %AR in sediment after 30 d) | | | | | | | | | |
|--------------------------------------|---|----------------------|--------|---|-----------------------|--|-----------------------|--|-----------------------|------------------------------|
| Water / sediment system | pH water phase | pH sed ^{a)} | t. °C | DT ₅₀ /DT ₉₀ whole sys. | St. (χ ²) | DT ₅₀ /DT ₉₀ water | St. (χ ²) | DT ₅₀ /DT ₉₀ sed | St. (χ ²) | Method of calculation |
| Sandy loam (Cary, N. Carolina, USA) | 7.4 | 5.7 | 20 ± 2 | 301; 1000 | 1.9 | 2.96; 57.4 | 4.8 7 | - | - | SFO-whole system; FOMC-water |
| Clay loam (Lucana, N. Carolina, USA) | 7.3 | 5.8 | 20 ± 2 | 333; 1110 | 1.4 3 | 5.53; 68.9 | 5.2 4 | - | - | SFO-whole system; FOMC-water |
| Geometric mean at 20°C ^{b)} | | | | 316.6; 1053.57 | | 4.05; 62.89 | | | | |

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Normalised using a Q10 of 2.58

| Metabolite | N/A | | | | | | | | | |
|--------------------------------------|----------------|----------------------|-------|---|-----------------------|--|-----------------------|--|-----------------------|-----------------------|
| Water / sediment system | pH water phase | pH sed ^{a)} | t. °C | DT ₅₀ /DT ₉₀ whole sys. | St. (χ ²) | DT ₅₀ /DT ₉₀ water | St. (χ ²) | DT ₅₀ /DT ₉₀ sed | St. (χ ²) | Method of calculation |
| | | | | | | | | | | |
| Geometric mean at 20°C ^{b)} | | | | | | | | | | |

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Normalised using a Q10 of 2.58

| Mineralisation and non extractable residues (from parent dosed experiments) | | | | | |
|---|----------------|--------|----------------|---------------------------------|--|
| Water / sediment system | pH water phase | pH sed | Mineralisation | Non-extractable residues in sed | Non-extractable residues in sed. max (study end) |

List of end points

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| | | | | | |
|--|-----|-----|--------------------------|--|--|
| Sandy loam (Cary, N. Carolina, USA) | 7.4 | 5.7 | <0.1 % AR at 100 days | Max. 5.99 % AR (mean) after 60 days | Max. 4.10% AR (mean) after 100 days (study end) |
| Clay loam (Lucana, N. Carolina, USA) | 7.3 | 5.8 | <0.1 % AR at 100 days | Max. 12.22 % AR after 60 days | Max. 5.29 % AR after 100 days |

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

| | |
|--|--|
| Direct photolysis in air | No study submitted or required |
| Photochemical oxidative degradation in air | DT ₅₀ of 0.552 hours (0.046 days) derived by the AOPWIN model. OH (12 h) concentration assumed = 1.5 x10 ⁶ OH/ cm ³ |
| Volatilisation | No study submitted or required |
| Metabolites | No study submitted or required |

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

| | |
|--|--|
| Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure | Soil: Napropamide-M Surface water: Napropamide-M, isomer-I, isomer-II and 1-naphthol Sediment: Napropamide-M Groundwater: Napropamide-M Air: None |
|--|--|

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

See section 5, Ecotoxicology

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

| | |
|---|---------------------------------|
| Soil (indicate location and type of study) | No data available not required. |
| Surface water (indicate location and type of study) | No data available not required. |
| Ground water (indicate location and type of study) | No data available not required. |
| Air (indicate location and type of study) | No data available not required. |

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Section 4 Environmental fate and behaviour

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

| | |
|-----------------------|--|
| Parent | DT ₅₀ (d): 101 days |
| Method of calculation | Kinetics: HS Worst case field DT ₅₀ used (non-normalised data) |
| Application data | Crop: winter oilseed rape and brassicas Depth of soil layer: 5cm Soil bulk density: 1.5g/cm ³ % plant interception: Pre-emergence therefore no crop interception Number of applications: 1 Interval (d): N/A Application rate(s): 765 g a.s./ha |

| PEC _(soil) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|----------------------------------|------------------------------|--|--------------------------------|--|
| Initial | 1.0200 | | N/A | |
| Short term 24h | 0.9833 | 1.0016 | | |
| 2d | 0.9479 | 0.9836 | | |
| 4d | 0.8808 | 0.9488 | | |
| Long term 7d | 0.7891 | 0.8997 | | |
| 28d | 0.5934 | 0.6999 | | |
| 50d | 0.5677 | 0.6473 | | |
| 100d | 0.5134 | 0.5937 | | |
| Plateau concentration | 1.5979 mg/kg after 6 yr | | | |

| | |
|-----------------------|-----|
| Metabolite I | N/A |
| Method of calculation | |
| Application data | |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
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PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)

Model(s) used: PEARL v.4.4.4., PELMO v.5.5.3 and MACRO v.5.5.4.
 Crop(s): winter oilseed rape and brassicas
 Crop uptake factor: 0
 Water solubility (mg/L): 39 at pH 7 and 20°C
 Vapour pressure: 0 Pa at 20°C
 Geometric mean parent field DT₅₀ 14.19 (fast phase)
 28.41 (slow phase)
 K_{FOC}: 472.61 mL/g (geometric mean, n=5)
 496.30 mL/g (arithmetic mean, n=5)
 Metabolites: No major metabolites for groundwater modelling
 Crop interception estimated: application to bare soil, no crop interception assumed
 Number of applications: 1 per trial, 1 per plot
 Duration: 0- 365±4 (slight variation between trial locations)
 Average annual leachate volume (mm): no data

Application rate

Gross application rate: 765 g/ha.
 Crop growth stage: application to bare soil, pre-emergence application
 Canopy interception %: application to bare soil, no crop interception
 Application rate net of interception: N/A
 No. of applications: 1 per crop
 Time of application (relative application dates): 7 days pre-emergence (winter oilseed rape); day of transplantation, i.e. 0 days (brassicas)

* Only relevant after implementation of the published EFSA guidance.

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
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| UK | June 2017 | Napropamide-M D-Devrinol |

Section 4 Environmental fate and behaviour

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

| PEARL v4.4.4 / winter oilseed rape | Scenario | Parent (µg/L) | Metabolites N/A | | |
|------------------------------------|--------------|------------------|-----------------|--|--|
| | Chateaudun | <0.001 | | | |
| | Hamburg | <0.001 | | | |
| | Jokioinen | N/A | | | |
| | Kremsmunster | <0.001 | | | |
| | Okehampton | <0.001 | | | |
| | Piacenza | <0.001 | | | |
| | Porto | <0.001 | | | |
| | Sevilla | N/A | | | |
| | Thiva | N/A | | | |

| PEARL v4.4.4 / brassicas | Scenario | Parent (µg/L) 1 st brassica crop | Parent (µg/L) 2 nd brassica crop | Metabolites N/A | |
|--------------------------|--------------|---|---|-----------------|--|
| | Chateaudun | <0.001 | <0.001 | | |
| | Hamburg | <0.001 | <0.001 | | |
| | Jokioinen | <0.001 | N/A | | |
| | Kremsmunster | <0.001 | <0.001 | | |
| | Okehampton | N/A | N/A | | |
| | Piacenza | N/A | N/A | | |
| | Porto | <0.001 | <0.001 | | |
| | Sevilla | <0.001 | <0.001 | | |
| | Thiva | <0.001 | N/A | | |

List of end points

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| PELMO v5.5.3 / winter oilseed rape | Scenario | Parent (µg/L) | Metabolites N/A | |
|------------------------------------|--------------|---------------|-----------------|--|
| | Chateaudun | <0.001 | | |
| | Hamburg | <0.001 | | |
| | Jokioinen | N/A | | |
| | Kremsmunster | <0.001 | | |
| | Okehampton | <0.001 | | |
| | Piacenza | <0.001 | | |
| | Porto | <0.001 | | |
| | Sevilla | N/A | | |
| | Thiva | N/A | | |

| PELMO v5.5.3 / brassicas | Scenario | Parent (µg/L) 1 st brassica crop | Parent (µg/L) 2 nd brassica crop | Metabolites N/A | |
|--------------------------|--------------|--|--|-----------------|--|
| | Chateaudun | <0.001 | <0.001 | | |
| | Hamburg | <0.001 | <0.001 | | |
| | Jokioinen | <0.001 | N/A | | |
| | Kremsmunster | <0.001 | <0.001 | | |
| | Okehampton | N/A | N/A | | |
| | Piacenza | N/A | N/A | | |
| | Porto | <0.001 | <0.001 | | |
| | Sevilla | <0.001 | <0.001 | | |
| | Thiva | <0.001 | N/A | | |

PEC_(gw) From lysimeter / field studies N/A

| Parent | 1 st year | 2 nd year | 3 rd year |
|-----------------------|----------------------|----------------------|----------------------|
| Annual average (µg/L) | | | |

| Metabolite N/A | 1 st year | 2 nd year | 3 rd year |
|-----------------------|----------------------|----------------------|----------------------|
| Annual average (µg/L) | | | |

List of end points

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

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

Parent

Parameters used in FOCUSsw step 1 and 2

Version control no. of FOCUS calculator: 3.2
Molecular weight (g/mol): 271.35
 K_{FOC}/K_{FOM} (mL/g): 472.61; 272.25
DT₅₀ soil (d): 28.41 (geomean, field)
DT₅₀ water/sediment system (d): 316.6 (geomean, n=2)
DT₅₀ water (d): 316.6 (geomean, n=2)
DT₅₀ sediment (d): 316.6 (geomean, n=2)
Crop interception (%): none, application to bare soil

Parameters used in FOCUSsw step 3

Version control no.'s of FOCUS software: FOCUS SWASH v5.3 (MACRO 5.5.4, PRZM 4.3.1 and TOXSWA v4.4.3)
Water solubility (mg/L): 39
Vapour pressure: 0 Pa at 20°C
 K_{FOC}/K_{FOM} (mL/g): 472.61; 272.25
1/n: 0.865 (Freundlich exponent, soil adsorption study, arithmetic mean, n=5)
Q10=2.58, Walker equation coefficient 0.7
Crop uptake factor: 0

Application rate

Crop and growth stage: pre-emergent use on bare soil for winter oilseed rape and brassica crops.
Number of applications: 1 per season (2 possible growing seasons for brassicas)
Interval (d): N/A
Application rate(s): 765 g a.s./ha
Application window: relative dates were used in surface water modelling and were set as 7 days pre-emergence to winter oilseed rape and as 0 d pre-emergence to brassicas i.e. day of transplantation
winter oilseed rape: Aug/Sept- Sept/Oct
Brassicas: 1st crop Feb/Aug- May/ June
2nd crop June/July- July/August

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 4 Environmental fate and behaviour

| FOCUS STEP 1 Parent All GAP uses | Day after overall maximum | PEC _{sw} (µg/L) | | PEC _{sed} (µg/kg) | |
|--|---------------------------------|--------------------------|---------|----------------------------|---------|
| | | Actual | TWA | Actual | TWA |
| | 0 h | 163.463 | | 739.293 | |
| | 1 d | 160.392 | 161.928 | 758.028 | 748.661 |
| | 2 d | 160.0412 | 161.072 | 756.371 | 752.930 |
| | 4 d | 159.342 | 160.382 | 753.066 | 753.823 |
| | 7 d | 158.299 | 159.712 | 748.136 | 752.441 |
| | 14 d | 155.891 | 158.402 | 736.758 | 747.437 |
| | 21 d | 153.520 | 157.169 | 725.553 | 742.005 |
| | 28 d | 151.186 | 155.964 | 714.518 | 736.509 |
| | 42 d | 146.622 | 153.607 | 692.950 | 725.566 |

| FOCUS STEP 2 Parent Winter oilseed rape | Day after overall maximum | PEC _{sw} (µg/L) | | PEC _{sed} (µg/kg) | |
|--|---------------------------------|--------------------------|--------|----------------------------|---------|
| | | Actual | TWA | Actual | TWA |
| Northern EU (June-Sept) | 0 h | 33.288 | | 153.992 | |
| | 24 h | 32.583 | 32.936 | 153.655 | 153.824 |
| | 2 d | 32.512 | 32.742 | 153.319 | 153.656 |
| | 4 d | 32.370 | 32.591 | 152.650 | 153.320 |
| | 7 d | 32.158 | 32.451 | 151.650 | 152.818 |
| | 14 d | 31.669 | 32.182 | 149.344 | 151.656 |
| | 21 d | 31.187 | 31.931 | 147.073 | 150.506 |
| | 28 d | 30.713 | 31.685 | 144.836 | 149.367 |
| | 42 d | 29.786 | 31.206 | 140.464 | 147.124 |
| Southern EU (June-Sept) | 0 h | 47.476 | | 220.901 | |
| | 24 h | 46.741 | 47.109 | 220.418 | 220.659 |
| | 2 d | 46.638 | 46.899 | 219.936 | 220.418 |
| | 4 d | 46.435 | 46.718 | 218.975 | 219.937 |
| | 7 d | 46.131 | 46.531 | 217.541 | 219.217 |
| | 14 d | 45.429 | 46.155 | 214.233 | 217.550 |
| | 21 d | 44.738 | 45.798 | 210.975 | 215.900 |
| | 28 d | 44.058 | 45.448 | 207.766 | 214.266 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 4 Environmental fate and behaviour

| FOCUS STEP 2 Parent Winter oilseed rape | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--|---------------------------------|--------------------------|--------|----------------------------|---------|
| | | Actual | TWA | Actual | TWA |
| | 42 d | 42.728 | 44.762 | 201.494 | 211.049 |

| FOCUS STEP 2 Parent Winter oilseed rape | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--|---------------------------------|--------------------------|--------|----------------------------|---------|
| | | Actual | TWA | Actual | TWA |
| | | Actual | TWA | Actual | TWA |
| Northern EU (Oct- Feb) | 0 h | 75.853 | | 354.718 | --- |
| | 24 h | 75.055 | 75.454 | 353.942 | 354.330 |
| | 2 d | 74.891 | 75.214 | 353.168 | 353.943 |
| | 4 d | 74.564 | 74.970 | 351.625 | 353.170 |
| | 7 d | 74.076 | 74.691 | 349.323 | 352.014 |
| | 14 d | 72.949 | 74.101 | 344.011 | 349.337 |
| | 21 d | 71.840 | 73.532 | 338.779 | 346.687 |
| | 28 d | 70.747 | 72.972 | 333.626 | 344.065 |
| | 42 d | 68.612 | 71.873 | 323.556 | 338.898 |
| Southern EU (Oct- Feb) | 0 h | 61.665 | --- | 287.809 | --- |
| | 24 h | 60.898 | 61.281 | 287.180 | 287.495 |
| | 2 d | 60.765 | 61.056 | 286.552 | 287.180 |
| | 4 d | 60.499 | 60.844 | 285.300 | 286.553 |
| | 7 d | 60.103 | 60.611 | 283.432 | 285.615 |
| | 14 d | 59.189 | 60.128 | 279.122 | 283.443 |
| | 21 d | 58.289 | 59.665 | 274.877 | 281.294 |
| | 28 d | 57.402 | 59.210 | 270.696 | 279.165 |
| | 42 d | 55.670 | 58.317 | 262.525 | 274.974 |

| FOCUS STEP 2 Parent Brassicas | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|-------------------------------------|---------------------------------|--------------------------|--------|----------------------------|---------|
| | | Actual | TWA | Actual | TWA |
| | | Actual | TWA | Actual | TWA |
| Northern EU (March- May) | 0 h | 33.288 | --- | 153.992 | --- |
| | 1 d | 32.583 | 32.936 | 153.655 | 153.824 |
| | 2 d | 32.512 | 32.742 | 153.319 | 153.656 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 4 Environmental fate and behaviour

| FOCUS STEP 2 Parent Brassicas | Day after overall maximum | PEC _{sw} (µg/L) | | PEC _{sed} (µg/kg) | |
|-------------------------------------|---------------------------------|--------------------------|--------|----------------------------|---------|
| | | Actual | TWA | Actual | TWA |
| | 4 d | 32.370 | 32.591 | 152.650 | 153.320 |
| | 7 d | 32.158 | 32.451 | 151.650 | 152.818 |
| | 14 d | 31.669 | 32.182 | 149.344 | 151.656 |
| | 21 d | 31.187 | 31.931 | 147.073 | 150.506 |
| | 28 d | 30.713 | 31.685 | 144.836 | 149.367 |
| | 42 d | 29.786 | 31.206 | 140.464 | 147.124 |
| Southern EU (March- May) | 0 h | 61.665 | --- | 287.809 | --- |
| | 1 d | 60.898 | 61.281 | 287.180 | 287.495 |
| | 2 d | 60.765 | 61.056 | 286.552 | 287.180 |
| | 4 d | 60.499 | 60.844 | 285.300 | 286.553 |
| | 7 d | 60.103 | 60.611 | 283.432 | 285.615 |
| | 14 d | 59.189 | 60.128 | 279.122 | 283.443 |
| | 21 d | 58.289 | 59.665 | 274.877 | 281.294 |
| | 28 d | 57.402 | 59.210 | 270.696 | 279.165 |
| | 42 d | 55.670 | 58.317 | 262.525 | 274.974 |

| FOCUS STEP 2 Parent Brassicas | Day after overall maximum | PEC _{sw} (µg/L) | | PEC _{sed} (µg/kg) | |
|-------------------------------------|---------------------------------|--------------------------|--------|----------------------------|---------|
| | | Actual | TWA | Actual | TWA |
| Northern EU (June –Sept) | 0 h | 33.288 | --- | 153.992 | --- |
| | 1 d | 32.583 | 32.936 | 153.655 | 153.824 |
| | 2 d | 32.512 | 32.742 | 153.319 | 153.656 |
| | 4 d | 32.370 | 32.591 | 152.650 | 153.320 |
| | 7 d | 32.158 | 32.451 | 151.650 | 152.818 |
| | 14 d | 31.669 | 32.182 | 149.344 | 151.656 |
| | 21 d | 31.187 | 31.931 | 147.073 | 150.506 |
| | 28 d | 30.713 | 31.685 | 144.836 | 149.367 |
| | 42 d | 29.786 | 31.206 | 140.464 | 147.124 |
| Southern EU (June –Sept) | 0 h | 47.476 | --- | 220.901 | --- |
| | 1 d | 46.741 | 47.109 | 220.418 | 220.659 |
| | 2 d | 46.638 | 46.899 | 219.936 | 220.418 |
| | 4 d | 46.435 | 46.718 | 218.975 | 219.937 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 4 Environmental fate and behaviour

| FOCUS STEP 2 Parent Brassicas | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|-------------------------------------|---------------------------------|--------------------------|--------|----------------------------|---------|
| | | Actual | TWA | Actual | TWA |
| | 7 d | 46.131 | 46.531 | 217.541 | 219.217 |
| | 14 d | 45.429 | 46.155 | 214.233 | 217.550 |
| | 21 d | 44.738 | 45.798 | 210.975 | 215.900 |
| | 28 d | 44.058 | 45.448 | 207.766 | 214.266 |
| | 42 d | 42.728 | 44.762 | 201.494 | 211.049 |

| FOCUS STEP 2 Parent Brassicas | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|-------------------------------------|---------------------------------|--------------------------|--------|----------------------------|---------|
| | | Actual | TWA | Actual | TWA |
| Northern EU (Oct-Feb) | 0 h | 75.853 | --- | 354.718 | --- |
| | 1 d | 75.055 | 75.454 | 353.942 | 354.330 |
| | 2 d | 74.891 | 75.214 | 353.168 | 353.943 |
| | 4 d | 74.564 | 74.970 | 351.625 | 353.170 |
| | 7 d | 74.076 | 74.691 | 349.323 | 352.014 |
| | 14 d | 72.949 | 74.101 | 344.011 | 349.337 |
| | 21 d | 71.840 | 73.532 | 338.779 | 346.687 |
| | 28 d | 70.747 | 72.972 | 333.626 | 344.065 |
| | 42 d | 68.612 | 71.873 | 323.556 | 338.898 |
| Southern EU (Oct-Feb) | 0 h | 61.665 | --- | 287.809 | --- |
| | 1 d | 60.898 | 61.281 | 287.180 | 287.495 |
| | 2 d | 60.765 | 61.056 | 286.552 | 287.180 |
| | 4 d | 60.499 | 60.844 | 285.300 | 286.553 |
| | 7 d | 60.103 | 60.611 | 283.432 | 285.615 |
| | 14 d | 59.189 | 60.128 | 279.122 | 283.443 |
| | 21 d | 58.289 | 59.665 | 274.877 | 281.294 |
| | 28 d | 57.402 | 59.210 | 270.696 | 279.165 |
| | 42 d | 55.670 | 58.317 | 262.525 | 274.974 |

| FOCUS STEP 3 Parent winter oilseed rape | Application date | Surface water | | Sediment | | Main route of entry into water body |
|---|-------------------------|-------------------------------------|-------------------------|---------------------------------------|------------------------|---|
| | | Max. PEC _{SW} (µg/L) | on | Max. PEC _{SED} (µg/kg) | on | |
| D2 ditch | 8 th Sept 86 | 23.400 | 20 th Nov 86 | 57.580 | 7 th Apr 87 | Drainage |
| D2 stream | 8 th Sept 86 | 14.670 | 20 th Nov 86 | 34.240 | 8 th Apr 87 | Drainage |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 4 Environmental fate and behaviour

| | | | | | | |
|-----------|--------------------------|--------------|--------------------------|-------|--------------------------|-----------------|
| D3 ditch | 26 th Aug 92 | 4.902 | 26 th Aug 92 | 9.101 | 9 th Sept 92 | Drift |
| D4 pond | 27 th Aug 85 | 1.101 | 1 st Jan 86 | 7.446 | 1 st May 86 | Drainage |
| D4 stream | 27 th Aug 85 | 4.190 | 27 th Aug 85 | 2.700 | 30 th Dec 85 | Drift |
| D5 pond | 13 th Sept 78 | 0.328 | 13 th Feb 79 | 2.884 | 1 st May 79 | Drainage |
| D5 stream | 13 th Sept 78 | 4.521 | 13 th Sept 78 | 1.100 | 13 th Sept 78 | Drift |
| R1 pond | 17 th Sept 78 | 0.200 | 31 st Dec 78 | 1.566 | 17 th Mar 79 | Run-off/erosion |
| R1 stream | 17 th Sept 78 | 3.896 | 25 th Oct 78 | 1.122 | 25 th Nov 78 | Run-off/erosion |
| R3 stream | 22 nd Oct 75 | 7.424 | 13 th Nov 75 | 3.563 | 17 th Nov 75 | Run-off/erosion |

Values in bold indicate PEC_{SW} which exceed the RAC of 4.33 µg/L

| FOCUS Parent STEP 3 brassicas | Application date | Surface water | | Sediment | | Main route of entry into water body |
|-------------------------------|--------------------------|-------------------------------|--------------------------|---------------------------------|--------------------------|-------------------------------------|
| | | Max. PEC _{SW} (µg/L) | on | Max. PEC _{SED} (µg/kg) | on | |
| D3 ditch 1 st | 4 th May 92 | 4.848 | 4 th May 92 | 2.364 | 5 th May 92 | Drift |
| D3 ditch 2 nd | 18 th Aug 92 | 4.853 | 18 th Aug 92 | 2.529 | 19 th Aug 92 | Drift |
| D4 pond | 16 th May 85 | 0.271 | 31 Dec 85 | 1.391 | 1 st May 86 | Drainage |
| D4 stream | 16 th May 85 | 3.803 | 16 th May 85 | 0.752 | 29 th Dec 85 | Drift |
| D6 ditch | 19 th Aug 86 | 4.747 | 19 th Aug 86 | 1.831 | 6 th Nov 86 | Drift |
| R1 pond 1 st | 26 th Apr 84 | 0.630 | 30 th May 84 | 3.675 | 4 th Sept 84 | Runoff/ erosion |
| R1 pond 2 nd | 20 th Aug 78 | 0.513 | 17 th Sept 78 | 4.284 | 4 th Mar 79 | Runoff/ erosion |
| R1 stream 1 st | 26 th Apr 84 | 6.750 | 20 th May 84 | 2.500 | 20 th May 84 | Runoff/ erosion |
| R1 stream 2 nd | 20 th Aug 78 | 6.279 | 17 th Sept 78 | 3.097 | 17 th Sept 78 | Runoff/ erosion |
| R2 stream 1 st | 6 th Mar 78 | 4.190 | 6 th Mar 78 | 1.734 | 4 th May 78 | Drift |
| R2 stream 2 nd | 5 th Aug 89 | 4.297 | 5 th Aug 89 | 2.084 | 24 th Oct 89 | Drift |
| R3 stream 1 st | 1 st Mar 80 | 13.820 | 8 th Mar 80 | 5.533 | 8 th Mar 80 | Runoff/ erosion |
| R3 stream 2 nd | 15 th June 75 | 9.024 | 23 rd June 75 | 6.321 | 23 rd June 75 | Runoff/ erosion |
| R4 stream 1 st | 5 th Mar 84 | 4.474 | 12 th Apr 84 | 2.116 | 12 th Apr 84 | Runoff/ erosion |
| R4 stream 2 nd | 23 rd June 85 | 16.360 | 28 th June 85 | 7.794 | 28 th June 85 | Runoff/ erosion |

Values in bold indicate PEC_{SW} which exceed the RAC of 4.33 µg/L

RMS Summary STEP 3 and STEP 4 maximum PEC_{SW} winter oilseed rape

| FOCUS Scenario | Application date | STEP 3 | STEP 4- 10 m BZ | STEP 4- 20 M BZ | STEP 4-20 m BZ + VFS 10-12m |
|---------------------|--------------------------|---------------|-----------------|-----------------|-----------------------------|
| Winter oilseed rape | | | | | |
| D2 ditch | 8 th Sept 86 | 23.400 | 23.400 | 23.400 | 23.400 |
| D2 stream | 8 th Sept 86 | 14.670 | 14.670 | 14.670 | 14.67 |
| D3 ditch | 26 th Aug 92 | 4.902 | 0.705 | 0.366 | 0.366 |
| D4 pond | 27 th Aug 85 | 1.101 | 1.082 | 1.072 | 1.072 |
| D4 stream | 27 th Aug 85 | 4.190 | 1.722 | 1.722 | 1.722 |
| D5 pond | 13 th Sept 78 | 0.328 | 0.313 | 0.305 | 0.305 |
| D5 stream | 13 th Sept 78 | 4.521 | 0.876 | 0.858 | 0.858 |
| R1 pond | 17 th Sept 78 | 0.1996 | 0.178 | 0.167 | 0.082 |
| R1 stream | 17 th Sept 78 | 3.896 | 3.896 | 3.896 | 1.708 |
| R3 stream | 22 nd Oct 75 | 7.424 | 7.424 | 7.424 | 3.375 |

BZ= buffer zone; VFS= vegetative filter strip (not recommended for EU level assessment, reported for transparency for consideration in other MS national addenda)

Values in bold indicate PEC_{SW} which exceed the RAC of 4.33 µg/L

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 4 Environmental fate and behaviour

RMS Summary STEP 3 and STEP 4 maximum PEC_{sw} brassicas

| FOCUS Scenario Brassicas | Application date | STEP 3 | STEP 4-10 m BZ | STEP 4-20 m BZ | STEP 4-20 m BZ + 10-12m VFS | STEP 4-20 m BZ + 18-20 m VFS |
|---------------------------|--------------------------|---------------|----------------|----------------|-----------------------------|------------------------------|
| D3 ditch 1 st | 4 th May 92 | 4.848 | 0.697 | 0.362 | 0.362 | 0.362 |
| D3 ditch 2 nd | 18 th Aug 92 | 4.853 | 4.853 | 0.362 | 0.362 | 0.362 |
| D4 pond | 16 th May 85 | 0.271 | 0.271 | 0.261 | 0.261 | 0.261 |
| D4 stream | 16 th May 85 | 3.803 | 3.803 | 0.386 | 0.386 | 0.386 |
| D6 ditch | 19 th Aug 86 | 4.747 | 4.747 | 1.837 | 1.837 | 1.837 |
| R1 pond 1 st | 26 th Apr 84 | 0.630 | 0.630 | 0.568 | 0.255 | 0.15 |
| R1 pond 2 nd | 20 th Aug 78 | 0.513 | 0.496 | 0.487 | 0.218 | 0.127 |
| R1 stream 1 st | 26 th Apr 84 | 6.750 | 6.750 | 6.750 | 3.061 | 1.601 |
| R1 stream 2 nd | 20 th Aug 78 | 6.279 | 6.279 | 6.279 | 2.856 | 1.496 |
| R2 stream 1 st | 6 th Mar 78 | 4.190 | 4.190 | 3.498 | 1.555 | 0.807 |
| R2 stream 2 nd | 5 th Aug 89 | 4.297 | 0.833 | 0.725 | 0.433 | 0.433 |
| R3 stream 1 st | 1 st Mar 80 | 13.820 | 13.820 | 13.820 | 6.251 | 3.264 |
| R3 stream 2 nd | 15 th June 75 | 9.024 | 9.024 | 9.024 | 4.111 | 2.158 |
| R4 stream 1 st | 5 th Mar 84 | 4.474 | 4.474 | 4.474 | 2.034 | 1.066 |
| R4 stream 2 nd | 23 rd June 85 | 16.360 | 16.360 | 16.360 | 7.427 | 3.890 |

BZ= buffer zone; VFS= vegetative filter strip (not recommended for EU level assessment, reported for transparency for consideration in other MS national addenda)

Values in bold indicate PEC_{sw} which exceed the RAC of 4.33 µg/L

Metabolites observed in the aqueous photolysis study >10% AR (isomer-I, isomer-II and 1-naphthol)

Parameters used in FOCUSsw step 1 and 2

Parameters used in FOCUSsw step 3 and 4

Application rate

Main routes of entry

Not performed at STEPs 1 and 2

Metabolite PEC_{sw} values calculated from parent PEC_{sw} at STEPs 3 and 4 based on the maximum percentage formed. This was accepted as a conservative alternative method as formation fractions were unknown. See section 3CP B.8.5 for full explanation.

As above

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product**

| | | |
|-----------|------------------|-------------------------------------|
| UK | June 2017 | Napropamide-M D-Devrinol |
|-----------|------------------|-------------------------------------|

Section 4 Environmental fate and behaviour

| FOCUS STEP 3 metabolites winter oilseed rape | Max. PEC _{SW} | | | | Max. PEC _{SED} | | | |
|---|------------------------|----------|-----------|------------|-------------------------|----------|-----------|------------|
| | parent STEP3 | Isomer-I | Isomer-II | 1-naphthol | parent STEP3 | Isomer-I | Isomer-II | 1-naphthol |
| D2 ditch | 23.40 | 8.658 | 13.361 | 2.902 | 57.580 | 21.305 | 32.878 | 7.140 |
| D2 stream | 14.670 | 5.428 | 8.377 | 1.819 | 34.240 | 12.669 | 19.551 | 4.246 |
| D3 ditch | 4.902 | 1.814 | 2.799 | 0.608 | 9.101 | 3.367 | 5.196 | 1.129 |
| D4 pond | 1.101 | 0.407 | 0.629 | 0.137 | 7.446 | 2.755 | 4.252 | 0.923 |
| D4 stream | 4.190 | 1.550 | 2.392 | 0.520 | 2.700 | 0.999 | 1.542 | 0.335 |
| D5 pond | 0.326 | 0.121 | 0.187 | 0.041 | 2.884 | 1.067 | 1.647 | 0.358 |
| D5 stream | 4.521 | 1.673 | 2.581 | 0.561 | 1.100 | 0.407 | 0.628 | 0.136 |
| R1 pond | 0.200 | 0.074 | 0.114 | 0.025 | 1.566 | 0.579 | 0.894 | 0.194 |
| R1 stream | 3.896 | 1.441 | 2.225 | 0.483 | 1.122 | 0.415 | 0.641 | 0.139 |
| R3 stream | 7.424 | 2.747 | 4.239 | 0.921 | 3.563 | 1.318 | 2.034 | 0.441 |

RAC values for isomer-I and isomer-II were 501 and 32 µg/L respectively. No ecotoxicological data has been provided for the metabolite 1-naphthol.

| FOCUS STEP 3 metabolites brassicac | Max PEC _{SW} | | | | Max PEC _{SED} | | | |
|--|-----------------------|----------|-----------|------------|------------------------|----------|-----------|------------|
| | parent STEP3 | Isomer-I | Isomer-II | 1-naphthol | parent STEP3 | Isomer-I | Isomer-II | 1-naphthol |
| D3 ditch 1st | 4.848 | 1.794 | 2.768 | 0.601 | 2.364 | 0.875 | 1.350 | 0.293 |
| D3 ditch 2nd | 4.853 | 1.796 | 2.771 | 0.602 | 2.529 | 0.936 | 1.444 | 0.314 |
| D4 pond | 0.2714 | 0.100 | 0.155 | 0.0337 | 1.391 | 0.515 | 0.794 | 0.172 |
| D4 stream | 3.803 | 1.407 | 2.172 | 0.472 | 0.752 | 0.278 | 0.429 | 0.093 |
| D6 ditch | 4.747 | 1.756 | 2.711 | 0.589 | 1.831 | 0.677 | 1.046 | 0.227 |
| R1 pond 1st | 0.6302 | 0.233 | 0.360 | 0.078 | 3.675 | 1.360 | 2.098 | 0.456 |
| R1 pond 2nd | 0.5129 | 0.190 | 0.293 | 0.064 | 4.284 | 1.585 | 2.446 | 0.531 |
| R1 stream 1st | 6.75 | 2.498 | 3.854 | 0.837 | 2.500 | 0.925 | 1.428 | 0.310 |
| R1 stream 2nd | 6.279 | 2.323 | 3.585 | 0.779 | 3.097 | 1.146 | 1.768 | 0.384 |
| R2 stream 1st | 4.19 | 1.550 | 2.392 | 0.520 | 1.734 | 0.642 | 0.990 | 0.215 |
| R2 stream 2nd | 4.297 | 1.590 | 2.454 | 0.533 | 2.084 | 0.771 | 1.190 | 0.258 |
| R3 stream 1st | 13.82 | 5.113 | 7.891 | 1.714 | 5.533 | 2.047 | 3.159 | 0.686 |
| R3 stream 2nd | 9.024 | 3.339 | 5.153 | 1.119 | 6.321 | 2.339 | 3.609 | 0.784 |
| R4 stream 1st | 4.474 | 1.655 | 2.555 | 0.555 | 2.116 | 0.783 | 1.208 | 0.262 |
| R4 stream 2nd | 16.36 | 6.053 | 9.341 | 2.0286 | 7.794 | 2.884 | 4.450 | 0.966 |

RAC values for isomer-I and isomer-II were 501 and 32 µg/L respectively. No ecotoxicological data has been provided for the metabolite 1-naphthol.

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 4 Environmental fate and behaviour

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

No data submitted; not required

PEC

Maximum concentration

N/A

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

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 a.s./kg bw per day) | Reference |
|---|----------------|--------------------------------|------------------|---|----------------------|
| Birds | | | | | |
| Japanese quail (<i>Coturnix coturnix japonica</i>) | Napropamide-M | Acute | LD ₅₀ | >2000 | [REDACTED] (2013) |
| | | | NOAEL | not stated | |
| Bobwhite quail (<i>Colinus virginianus</i>) | Napropamide | Long-term | NOAEL | 309 | [REDACTED] (1991) |
| Mammals | | | | | |
| Rat | Napropamide-M | Acute | LD ₅₀ | >2000 | [REDACTED] (2010) |
| Rat | Napropamide | ADI | NOAEL | 30 | [REDACTED] (1978) |
| Rat | Napropamide | Long term (3 generation) | NOAEL | 30 | [REDACTED] (1978) |
| Endocrine disrupting properties (Annex Part A, points 8.1.5) | | | | | |
| Currently, discussions are ongoing within the European Commission on how to address the issue of endocrine disruption. Until these discussions have concluded and a clear approach has been agreed with the Commission and the Member States, the RMS proposes no further consideration | | | | | |
| Additional higher tier studies (Annex Part A, points 10.1.1.2): | | | | | |
| No higher tier data on mammals is required as the risk assessment presented above indicates an acceptable risk from the supported GAP uses. | | | | | |
| Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): | | | | | |
| Endpoints based on relevant available data presented below. | | | | | |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Winer oilseed rape and brassica vegetable crops pre-planting/sowing - BBCH 00-08 at 765 g a.s./ha x 1 application

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---|----------------------------|--------------|---------------------------|-------|---------|
| Screening Step (Birds) | | | | | |
| All | Small granivorous bird | Acute | 19.0 | 105 | 10 |
| All | Small granivorous bird | Long-term | 4.62 | 43 | 5 |
| Tier 1 (Birds): Not needed. | | | | | |
| Higher tier (birds): Not needed. | | | | | |
| Screening Step (Mammals) | | | | | |
| All | Small granivorous mammal | Acute | 11.0 | 181 | 10 |
| All | Small granivorous mammal | Long-term | 2.68 | 11 | 5 |
| Tier 1 (Mammals): Not needed. | | | | | |
| Higher tier (Mammals): Not needed. | | | | | |
| Risk from bioaccumulation and food chain behaviour | | | | | |
| Indicator or focal species | | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
| Napropamide-M | | | | | |
| Earthworm-eating birds | | Long-term | 5.67 | 35.2 | 5 |
| Earthworm-eating mammals | | Long-term | 4.9 | 6.1 | 5 |
| Fish-eating birds | | Long-term | 0.365 | 547.9 | 5 |
| Fish-eating mammals | | Long-term | 0.325 | 93.73 | 5 |
| Relevant metabolites (Napropamide isomer I and Napropamide isomer II) | | | | | |
| Earthworm-eating birds | | Not required | | | |
| Earthworm-eating mammals | | Not required | | | |
| Fish-eating birds | | Long-term | 0.365 | 54.79 | 5 |
| Fish-eating mammals | | Long-term | 0.325 | 9.75 | 5 |
| Higher tier : <i>[in higher tier refinement provide brief details of any refinements used]</i> | | | | | |
| Risk from consumption of contaminated water | | | | | |
| Scenarios | Indicator or focal species | Time scale | PEC _{dw} xDWR | TER | Trigger |
| Leaf scenario | Birds | acute | Not relevant | | - |
| Puddle scenario, Screening step | | | | | |
| 1)Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| Puddle scenario | Birds | acute | Not needed | | (<50) |
| Puddle scenario | Mammals | acute | Not needed | | (<50) |
| Puddle scenario | Birds | Long-term | Not needed | | (<50) |
| Puddle scenario | Mammals | Long-term | Not needed | | (<50) |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

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 | Reference |
|---|-------------------|---|---|---|-----------------------|
| Laboratory tests | | | | | |
| Fish | | | | | |
| Rainbow trout (<i>Oncorhynchus mykiss</i>) | D-Napropamide | Acute 96 hr (Static) | Mortality, LC ₅₀ | 11.2 mg a.s./L (mm) | ██████████ (2011a) |
| Rainbow trout (<i>Oncorhynchus mykiss</i>) | D-Devrinol 450 SC | Acute 96 hr (Static) | Mortality, LC ₅₀ | 30 mg/L 12.3 mg a.s./L (nom) | ██████████ (2011b) |
| Zebrafish (<i>Danio rerio</i>) | Napropamide-M | Early life stage (flow-through)- 30 day | Reproduction NOEC | >0.4 mg a.s./L (nom) | ██████████ (2015) |
| Aquatic invertebrates | | | | | |
| <i>Daphnia magna</i> | D-Napropamide | 48 h (static) | Mortality, EC ₅₀ | 19 mg a.s./L (mm) | Liedtke, A (2011c) |
| <i>Daphnia magna</i> | D-Devrinol 450 SC | 48 h (static) | Mortality, EC ₅₀ | 52 mg/L 21.32 mg a.s./L (nom) | Liedtke, A (2011d) |
| <i>Daphnia magna</i> | Napropamide-M | 21 d (semi-static) | NOEC | 0.3 mg a.s./L (nom) | Kamile,M.K (2014) |
| Algae | | | | | |
| Algae (<i>Pseudokirchneriella</i>) | Napropamide-M | 72 h (static) | Growth rate: E _r C ₅₀ Biomass: E _b C ₅₀ Yield: E _y C ₅₀ (NOEC) | 28.18 mg a.s./L (nom) 7.74 mg a.s./L (nom) 7.56 mg a.s./L (nom) 0.8 mg a.s./L (nom) | Kamle, M (2014) |
| Algae (<i>Pseudokirchneriella</i>) | D-Devrinol 450 SC | 72 h (static) | Growth rate: E _r C ₅₀ Biomass: E _b C ₅₀ Yield: E _y C ₅₀ (NOEC) | 30 mg/L ^a >12.45 mg a.s./L ^a 6.13 mg/L 2.51 mg a.s./L (nom) 6.93 mg/L 2.84 mg a.s./L (nom) 0.09 mg/L 0.037 mg a.s./L (nom) | Kamile,M.K (2014) |

List of end points

Rapporteur Member State Month and year Active substance and Plant Protection Product

| | | |
|----|-----------|-----------------------------|
| UK | June 2017 | Napropamide-M D-Devrinol |
|----|-----------|-----------------------------|

Section 5 Ecotoxicology

| Group | Test substance | Time-scale (Test type) | End point | Toxicity ¹ | Reference |
|---|-------------------|---------------------------|--|--|-------------------------|
| <i>Algae (Anabena)</i> | Napropamide | 72 h (static) | Growth rate: E _r C ₅₀ Biomass: E _b C ₅₀ (NOEC) | 55.0 mg a.s./L (mm) 14.2 mg a.s./L (mm) 5.05 mg a.s./L (mm) | Jenkins, C.A. (2002) |
| Aquatic macrophytes | | | | | |
| <i>Lemna gibba</i> | Napropamide-M | 7 day (semi-static) | E _r C ₅₀ (frond count) E _y C ₅₀ (dry weight) E _r C ₁₀ (dry weight) E _y C ₁₀ (dry weight) NOEC (frond count) NOEC (dry weight) | 0.08 mg a.s./L (mm) 0.0194 mg a.s./L (mm) 0.0030 mg a.s./L (mm) 0.0035 mg a.s./L (mm) 0.016 mg a.s./L (mm) 0.0030 mg a.s./L (mm) | Ramsden, C (2015) |
| <i>Lemna minor</i> | Isomer I | 7 day (semi-static) | E _r C ₅₀ (frond no. & biomass) E _y C ₅₀ (biomass) E _r C ₁₀ (biomass) E _y C ₁₀ (biomass) NOEC (both) | >5.81 mg a.s./L (mm) 0.729 mg a.s./L (mm) 0.060 mg a.s./L (mm) 0.010 mg a.s./L (mm) 0.006 mg a.s./L (mm) | Juckeland, (2012a) |
| <i>Lemna minor</i> | Isomer II | 7 day (semi-static) | E _r C ₅₀ (frond no. & biomass) E _y C ₅₀ (frond number) E _r C ₁₀ (frond number) E _y C ₁₀ (frond number) NOEC (both) | >0.321 mg a.s./L (mm) 0.244 mg a.s./L (mm) 0.072 mg a.s./L (mm) 0.035 mg a.s./L (mm) 0.038 mg a.s./L (mm) | Juckeland, (2012b) |
| <i>Lemna gibba</i> | D-Devrinol 450 SC | 14 day (semi-static) | E _r C ₅₀ (frond count) E _y C ₅₀ (frond count) E _r C ₁₀ (dry weight) E _y C ₁₀ (dry weight) NOEC (dry weight) | 0.096 mg/L 0.044 mg a.s./L (mm) 0.076 mg/L 0.035 mg a.s./L (mm) 0.004 mg/L 0.002 mg a.s./L (mm) 0.007 mg/L 0.003 mg a.s./L (mm) 0.004 mg/L 0.002 mg a.s./L (mm) | Ramsden, C (2015) |
| <i>Myriophyllum spicatum</i> | Napropamide-M | 7 day (semi-static) | E _r C ₅₀ (shoot length) E _y C ₅₀ (wet weight) E _r C ₁₀ (wet weight) E _y C ₁₀ (dry weight) NOEC (wet weight) | >2.35 mg a.s./L (mm) 0.904 mg a.s./L (mm) 0.112 mg a.s./L (mm) 0.097 mg a.s./L (mm) 0.108 mg a.s./L (mm) | Hermes, H (2015) |
| Further testing on aquatic organisms: Not needed. | | | | | |
| Potential endocrine disrupting properties (Annex Part A, point 8.2.3) | | | | | |
| There is no risk assessment or endocrine disruption issues for fish which require further investigation. | | | | | |

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

^a As effects of >50 % were not reported in the study, an extrapolated E_rC₅₀ was calculated using regression analysis to be 69.43 mg product/L (equivalent to 28.81 mg a.s./L) however to provide a conservative assessment

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

the maximum concentration tested of 30 mg product/L (equivalent to 12.45 mg a.s/L) is used in the risk assessment

- = Could not be calculated.

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

| | Active substance | Isomer I | Isomer II | 1-Naphthol |
|--|-----------------------------------|----------|-----------|------------|
| logP _{O/W} | 3.27 | 3.08 | - | 2.83 |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) | 98 | - | - | - |
| Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content) | 39.2 (K1)/ 0.420 (K2) | - | - | - |
| Annex VI Trigger for the bioconcentration factor | 100 | - | - | - |
| Clearance time (days) (CT ₅₀) | Not reported | - | - | - |
| (CT ₉₀) | ~ 7 days | - | - | - |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | <5% (measured as ¹⁴ C) | - | - | - |
| Higher tier study: Not required. | | | | |
| | | | | |

* based on total ¹⁴C or on specific compounds

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|-------------------------|----------------|--|
| UK | June 2017 | Napropamide-M D-Devrinol |

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 Napropamide-M – Winter Oilseed Rape at 765 g a.s./ha x one application

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|----------------------|-------------------------------|----------------------------|--------------------------------|-----------------------|---------------------------------|--|--------------------|------------------------|----------------------|
| | | <i>Oncorhynchus mykiss</i> | <i>Zebrafish (Danio rerio)</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Pseudokirchneriella subcapitata</i> | <i>Lemna gibba</i> | Not triggered | Not triggered |
| | | LC ₅₀ | NOEC | EC ₅₀ | NOEC | EC ₅₀ | EC ₅₀ | NOEC | NOEC |
| | | 11,200 µg/L | 400 µg/L | 19,000 µg/L | 300 µg/L | 12450 µg/L | 43.3 µg/L | | |
| FOCUS Step 1 | N/A | - | - | - | - | - | - | - | - |
| FOCUS Step 2 | N/A | - | - | - | - | - | - | - | - |
| North Europe | | - | - | - | - | - | | | |
| South Europe | | - | - | - | - | - | | | |
| FOCUS Step 3* | PEC _{sw} (µg a.s./L) | TER | TER | TER | TER | TER | TER | | |
| D2 Ditch | 23.40 | 478.63 | 17.09 | 811.97 | 12.82 | 532.05 | 1.85 | - | - |
| D2 Stream | 14.67 | 763.46 | 27.27 | 1295.16 | 20.45 | 848.67 | 2.95 | - | - |
| D4 Pond | 1.10 | 10181.82 | 363.64 | 17272.73 | 272.73 | 11318.18 | 39.36 | - | - |
| D5 Pond | 0.33 | 33939.39 | 1212.12 | 57575.76 | 909.09 | 37727.27 | 131.21 | - | - |
| R1 Pond | 0.20 | 56000.00 | 2000.00 | 95000.00 | 1500.00 | 62250.00 | 216.50 | - | - |
| R1 Stream | 3.90 | 2871.79 | 102.56 | 4871.79 | 76.92 | 136.42 | 11.10 | - | - |
| R3 Stream | 7.42 | 1509.43 | 53.91 | 2560.65 | 40.43 | 1677.90 | 5.84 | - | - |
| D3 Ditch | 4.90 | 2285.71 | 81.63 | 3877.55 | 61.22 | 2540.82 | 8.84 | - | - |
| D4 stream | 4.19 | 2673.03 | 95.47 | 4534.61 | 71.60 | 2971.36 | 10.33 | - | - |
| D5 stream | 4.52 | 2477.88 | 88.50 | 4203.54 | 66.37 | 2754.42 | 9.58 | - | - |
| Trigger** | | 100 | 10 | 100 | 10 | 10 | 10 | 10 | |

NOTE: TERs in bold indicate unresolved risks (TER < Trigger)

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|-------------------------|----------------|--|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

TERs presented to 3 s.f.**

FOCUS_{sw} step 1-3 - TERs for Napropamide-M – Brassica Vegetable Crops at 765 g a.s./ha x one application

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|----------------------|-------------------------------|----------------------------|--------------------------------|-----------------------|---------------------------------|--|--------------------|------------------------|----------------------|
| | | <i>Oncorhynchus mykiss</i> | <i>Zebrafish (Danio rerio)</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Pseudokirchneriella subcapitata</i> | <i>Lemna gibba</i> | Not triggered | Not triggered |
| | | LC ₅₀ | NOEC | EC ₅₀ | NOEC | ErC ₅₀ | ErC ₅₀ | NOEC | NOEC |
| | | 11,200 µg/L | 400 µg/L | 19,000 µg/L | 300 µg/L | 12450 µg/L | 43.3 µg/L | | |
| FOCUS Step 1 | N/A | - | - | - | - | - | - | - | - |
| FOCUS Step 2 | N/A | - | - | - | - | - | - | - | - |
| North Europe | | | | | | | | | |
| South Europe | | | | | | | | | |
| FOCUS Step 3* | PEC _{sw} (µg a.s./L) | TER | TER | TER | TER | TER | TER | | |
| D4 pond | 0.27 | 41481.48 | 1481.48 | 70370.37 | 1111.11 | 46111.11 | 160.37 | - | - |
| R1 pond 1st | 0.63 | 17777.78 | 634.92 | 30158.73 | 476.19 | 19761.90 | 68.73 | - | - |
| R1 pond 2nd | 0.51 | 21960.78 | 784.31 | 37254.90 | 588.24 | 24411.76 | 84.90 | - | - |
| R1 stream 1st | 6.75 | 1659.26 | 59.26 | 2814.81 | 44.44 | 1844.44 | 6.41 | - | - |
| R1 stream 2nd | 6.28 | 1783.44 | 63.69 | 3025.48 | 47.77 | 1982.48 | 6.89 | - | - |
| R3 stream 1st | 13.82 | 810.42 | 28.94 | 1374.82 | 21.71 | 3336.55 | 3.13 | - | - |
| R3 stream 2nd | 9.02 | 1241.69 | 44.35 | 2106.43 | 33.26 | 1380.27 | 4.80 | - | - |
| R4 stream 1st | 4.47 | 2505.59 | 89.49 | 4250.56 | 67.11 | 2785.23 | 9.69 | - | - |
| R4 stream 2nd | 16.36 | 684.60 | 24.45 | 1161.37 | 18.34 | 761.00 | 2.65 | - | - |
| D3 ditch 1st | 4.85 | 2309.28 | 82.47 | 3917.53 | 61.86 | 2567.01 | 8.93 | - | - |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|-------------------------|----------------|--|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

| | | | | | | | | | |
|---------------|------|---------|--------|---------|-------|---------|-------------|----|---|
| D3 ditch 2nd | 4.85 | 2309.28 | 82.47 | 3917.53 | 61.86 | 2567.01 | 8.93 | - | - |
| D4 stream | 3.80 | 2947.37 | 105.26 | 5000.00 | 78.95 | 3276.32 | 11.39 | - | - |
| D6 ditch | 4.75 | 2357.89 | 84.21 | 4000.00 | 63.16 | 2621.05 | 9.12 | - | - |
| R2 stream 1st | 4.19 | 2673.03 | 95.47 | 4534.61 | 71.60 | 2971.36 | 10.33 | - | - |
| R2 stream 2nd | 4.30 | 2604.65 | 93.02 | 4418.61 | 69.77 | 2895.35 | 10.07 | - | - |
| Trigger** | 100 | 10 | 100 | 10 | 10 | 10 | 10 | 10 | |

NOTE: TERs in bold indicate unresolved risks (TER < Trigger)

TERs presented to 3 s.f.**

FOCUS_{sw} step 4 - TERs Napropamide-M – Winter Oilseed Rape at 765 g a.s./ha x 1 application

Organisms: *Lemna gibba*

Toxicity endpoint: 43.3 µg a.s./L

| Mitigation options | [x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction) | [x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction) | PEC _{sw} (µg/L) | TER | Trigger |
|----------------------|--|---|-----------------------------|-------------|---------|
| FOCUS Step 4* | | | | | |
| D2 Ditch | 20m buffer zone | - | 23.40 | 3.41 | 10 |
| D2 Stream | 20m buffer zone | - | 14.67 | 5.45 | 10 |
| R3 Stream | 20m buffer zone | 10-12m vegetated buffer strip | 3.38 | 12.8 | 10 |
| D3 Ditch | 10m buffer zone | - | 0.71 | 60.98 | 10 |
| D5 stream | 10m buffer zone | - | 0.88 | 49.20 | 10 |

NOTE: TERs in bold indicate unresolved risks (TER < Trigger)

FOCUS_{sw} step 4 - TERs Napropamide-M – Brassica Vegetable crops at 765 g a.s./ha x 1 application

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|-------------------------|----------------|--|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

Organisms: *Lemna gibba*

Toxicity endpoint:

43.3 µg a.s./L

| Mitigation options | [x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction) | [x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction) | PEC _{sw} (µg/L) | TER | Trigger |
|----------------------|--|---|-----------------------------|--------|---------|
| FOCUS Step 4* | | | | | |
| R1 stream 1st | 20m buffer zone | 10-12m vegetated buffer strip | 2.03 | 21.33 | 10 |
| R1 stream 2nd | 20m buffer zone | 10-12m vegetated buffer strip | 2.86 | 15.13 | 10 |
| R3 stream 1st | 20m buffer zone | 18-20m vegetated buffer strip | 3.26 | 13.28 | 10 |
| R3 stream 2nd | 20m buffer zone | 10-12m vegetated buffer strip | 4.11 | 10.53 | 10 |
| R4 stream 1st | 20m buffer zone | 18-20m vegetated buffer strip | 2.03 | 21.33 | 10 |
| R4 stream 2nd | 20m buffer zone | 10-12m vegetated buffer strip | 3.89 | 11.13 | 10 |
| D3 ditch 2nd | 20m buffer zone | - | 0.36 | 120.28 | 10 |
| D6 ditch | 20m buffer zone | - | 1.84 | 23.53 | 10 |

Napropamide-M Metabolites

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

FOCUS_{sw} Risk Assessment - TERs for Isomer I – Winter Oilseed Rape at 765 g a.s./ha x one application

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|----------|-----------------------------|------------|--------------|--------------------------|---------------------------------------|-------|--------------|---------------------------|-------------------------|
|----------|-----------------------------|------------|--------------|--------------------------|---------------------------------------|-------|--------------|---------------------------|-------------------------|

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|-------------------------|----------------|--|
| UK | June 2017 | Napropamide-M D-Devrinol |

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| | | <i>O. mykiss</i> | <i>O. mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Pseudokirchneriella subcapitata</i> | <i>Lemna minor</i> | Not triggered | Not triggered |
|---------------------|------|------------------|------------------|----------------------|----------------------|--|--------------------|---------------|---------------|
| | | LC ₅₀ | NOEC | EC ₅₀ | NOEC | ErC ₅₀ | ErC ₅₀ | | |
| | | 11200 µg/L | 400 µg/L | 19000 µg/L | 300 µg/L | 12450 µg/L | 5810 µg/L | | |
| FOCUS Step 1 | N/A | - | - | - | - | - | - | - | - |
| FOCUS Step 2 | N/A | - | - | - | - | - | - | - | - |
| North Europe | | | | | | | | | |
| South Europe | | | | | | | | | |
| FOCUS PECs | | | | | | | | | |
| D2 ditch | 8.66 | 1293.30 | 46.19 | 2194.00 | 34.64 | 1437.64 | 670.90 | - | - |
| D2 stream | 5.43 | 2062.62 | 73.66 | 3499.08 | 55.25 | 2292.82 | 1069.98 | - | - |
| D3 ditch | 1.81 | 6187.85 | 220.99 | 10497.24 | 165.75 | 6878.45 | 3209.94 | - | - |
| D4 pond | 0.41 | 27317.07 | 975.61 | 46341.46 | 731.71 | 30365.85 | 14170.73 | - | - |
| D4 stream | 1.55 | 7225.81 | 258.06 | 12258.06 | 193.55 | 8032.26 | 3748.39 | - | - |
| D5 pond | 0.12 | 93333.33 | 3333.33 | 158333.33 | 2500.00 | 11980.37 | 48416.67 | - | - |
| D5 stream | 1.67 | 6706.59 | 239.52 | 11377.25 | 179.64 | 7455.09 | 3479.04 | - | - |
| R1 pond | 0.07 | 160000.00 | 5714.29 | 271428.57 | 4285.71 | 177857.14 | 83000.00 | - | - |
| R1 stream | 1.44 | 7777.78 | 277.78 | 13194.44 | 208.33 | 8645.83 | 4034.72 | - | - |
| R3 stream | 275 | 4072.73 | 145.45 | 6909.09 | 109.09 | 4527.27 | 2112.73 | - | - |
| Trigger** | | 100 | 10 | 100 | 10 | 10 | 10 | 10 | |

NOTE: TERs in bold indicate unresolved risks (TER < Trigger)

TERs presented to 3 s.f.**

FOCUS_{sw} Risk Assessment - TERs for Isomer II – Winter Oilseed Rape at 765 g a.s./ha x one application

| PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|--------------------------|------------|--------------|--------------------------|---------------------------------------|-------|--------------|---------------------------|-------------------------|
|--------------------------|------------|--------------|--------------------------|---------------------------------------|-------|--------------|---------------------------|-------------------------|

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|-------------------------|----------------|--|
| UK | June 2017 | Napropamide-M D-Devrinol |

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| | <i>O. mykiss</i> | <i>O. mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Pseudokirchneriella subcapitata</i> | <i>Lemna minor</i> | Not triggered | Not triggered |
|---------------------|----------------------------------|------------------|----------------------|----------------------|--|--------------------|---------------|---------------|
| | LC ₅₀ | NOEC | EC ₅₀ | NOEC | ErC ₅₀ | ErC ₅₀ | | |
| | 11200 µg/L | 400 µg/L | 19000 µg/L | 300 µg/L | 12450 µg/L | 321 µg/L | | |
| FOCUS Step 1 | N/A | - | - | - | - | - | - | - |
| FOCUS Step 2 | N/A | - | - | - | - | - | - | - |
| North Europe | | | | | | | | |
| South Europe | | | | | | | | |
| FOCUS PECs | PEC _{sw} (µg a.s./L) | TER | TER | TER | TER | TER | TER | |
| D2 ditch | 13.36 | 838.32 | 29.94 | 1422.16 | 22.46 | 931.89 | 24.03 | - |
| D2 stream | 8.38 | 1336.52 | 47.73 | 2267.30 | 35.80 | 1485.68 | 38.31 | - |
| D3 ditch | 2.80 | 4000.00 | 142.86 | 6785.71 | 107.14 | 4446.43 | 114.64 | - |
| D4 pond | 0.63 | 17777.78 | 634.92 | 30158.73 | 476.19 | 19761.90 | 509.52 | - |
| D4 stream | 2.39 | 4686.19 | 167.36 | 7949.79 | 125.52 | 5209.21 | 134.31 | - |
| D5 pond | 0.19 | 58947.37 | 2105.26 | 100000.00 | 1578.95 | 4904.66 | 1689.47 | - |
| D5 stream | 2.58 | 4341.09 | 155.04 | 7364.34 | 116.28 | 4825.58 | 124.42 | - |
| R1 pond | 0.12 | 93333.33 | 3333.33 | 158333.33 | 2500.00 | 103750.00 | 2675.00 | - |
| R1 stream | 2.22 | 5045.05 | 180.18 | 8558.56 | 135.14 | 5608.11 | 144.59 | - |
| R3 stream | 4.24 | 2641.51 | 94.34 | 4481.13 | 70.75 | 2936.32 | 75.71 | - |
| Trigger** | | 100 | 10 | 100 | 10 | 10 | 10 | 10 |

NOTE: TERs in bold indicate unresolved risks (TER < Trigger)

TERs presented to 3 s.f.**

FOCUS_{sw} Risk Assessment - TERs for 1-naphthol - Winter Oilseed Rape at 765 g a.s./ha x one application

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|----------|-----------------------------|------------|--------------|--------------------------|---------------------------------------|-------|--------------|---------------------------|-------------------------|
|----------|-----------------------------|------------|--------------|--------------------------|---------------------------------------|-------|--------------|---------------------------|-------------------------|

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|-------------------------|----------------|--|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

| | | <i>O. mykiss</i> | <i>O. mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Pseudokirchneriella subcapitata</i> | <i>Lemna gibba</i> | Not triggered | Not triggered |
|---------------------|-------------------------------|------------------|------------------|----------------------|----------------------|--|--------------------|---------------|---------------|
| | | LC ₅₀ | NOEC | EC ₅₀ | NOEC | ErC ₅₀ | ErC ₅₀ | | |
| | | 11200 µg/L | 400 µg/L | 19000 µg/L | 300 µg/L | 12450 µg/L | 43.3 µg/L | | |
| FOCUS Step 1 | N/A | - | - | - | - | - | - | - | - |
| FOCUS Step 2 | N/A | - | - | - | - | - | - | - | - |
| North Europe | | | | | | | | | |
| South Europe | | | | | | | | | |
| FOCUS PECs | PEC _{sw} (µg a.s./L) | TER | TER | TER | TER | TER | TER | | |
| D2 ditch | 2.9 | 3862.07 | 137.93 | 6551.72 | 103.45 | 4293.10 | 14.93 | - | - |
| D2 stream | 1.82 | 6153.85 | 219.78 | 10439.56 | 164.84 | 6840.66 | 23.79 | - | - |
| D3 ditch | 0.61 | 18360.66 | 655.74 | 31147.54 | 491.80 | 20409.84 | 70.98 | - | - |
| D4 pond | 0.14 | 80000.00 | 2857.14 | 135714.29 | 2142.86 | 88928.57 | 309.29 | - | - |
| D4 stream | 0.52 | 21538.46 | 769.23 | 36538.46 | 576.92 | 23942.31 | 83.27 | - | - |
| D5 pond | 0.04 | 280000.00 | 10000.00 | 475000.00 | 7500.00 | 107327.59 | 1082.50 | - | - |
| D5 stream | 0.56 | 20000.00 | 714.29 | 33928.57 | 535.71 | 22232.14 | 77.32 | - | - |
| R1 pond | 0.02 | 560000.00 | 20000.00 | 950000.00 | 15000.00 | 622500.00 | 2165.00 | - | - |
| R1 stream | 0.48 | 23333.33 | 833.33 | 39583.33 | 625.00 | 25937.50 | 90.21 | - | - |
| R3 stream | 0.92 | 12173.91 | 434.78 | 20652.17 | 326.09 | 13532.61 | 47.07 | - | - |
| Trigger** | | 100 | 10 | 100 | 10 | 10 | 10 | 10 | |

NOTE: TERs in bold indicate unresolved risks (TER < Trigger)

TERs presented to 3 s.f.**

FOCUS_{sw} Risk Assessment - TERs for Isomer I – Brassica Vegetable Crops at 765 g a.s./ha x one application

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|----------|-----------------------|------------|--------------|-----------------------|---------------------------------|-------|--------------|------------------------|----------------------|
|----------|-----------------------|------------|--------------|-----------------------|---------------------------------|-------|--------------|------------------------|----------------------|

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|-------------------------|----------------|--|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

| | | <i>O. mykiss</i> | <i>O. mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Pseudokirchneriella subcapitata</i> | <i>Lemna minor</i> | Not triggered | Not triggered |
|----------------------|-------------------------------|------------------|------------------|----------------------|----------------------|--|--------------------|---------------|---------------|
| | | LC ₅₀ | NOEC | EC ₅₀ | NOEC | ErC ₅₀ | ErC ₅₀ | NOEC | NOEC |
| | | 11200 µg/L | 400 µg/L | 19000 µg/L | 300 µg/L | 12450 µg/L | 5810 µg/L | | |
| FOCUS Step 1 | N/A | - | - | - | - | - | - | - | - |
| FOCUS Step 2 | N/A | - | - | - | - | - | - | - | - |
| North Europe | | | | | | | | | |
| South Europe | | | | | | | | | |
| FOCUS Step 3* | PEC _{sw} (µg a.s./L) | TER | TER | TER | TER | TER | TER | | |
| D3 ditch 1st | 1.79 | 6256.98 | 223.46 | 10614.53 | 167.60 | 6955.31 | 3245.81 | - | - |
| D3 ditch 2nd | 1.80 | 6222.22 | 222.22 | 10555.56 | 166.67 | 6916.67 | 3227.78 | - | - |
| D4 pond | 0.10 | 112000.00 | 4000.00 | 190000.00 | 3000.00 | 124500.00 | 58100.00 | - | - |
| D4 stream | 1.41 | 7943.26 | 283.69 | 13475.18 | 212.77 | 8829.79 | 4120.57 | - | - |
| D6 ditch | 1.76 | 6363.64 | 227.27 | 10795.45 | 170.45 | 7073.86 | 3301.14 | - | - |
| R1 pond 1st | 0.23 | 48695.65 | 1739.13 | 82608.70 | 1304.35 | 30240.47 | 25260.87 | - | - |
| R1 pond 2nd | 0.19 | 58947.37 | 2105.26 | 100000.00 | 1578.95 | 65526.32 | 30578.95 | - | - |
| R1 stream 1st | 2.50 | 4480.00 | 160.00 | 7600.00 | 120.00 | 4980.00 | 2324.00 | - | - |
| R1 stream 2nd | 2.32 | 4827.59 | 172.41 | 8189.66 | 129.31 | 5366.38 | 2504.31 | - | - |
| R2 stream 1st | 1.55 | 7225.81 | 258.06 | 12258.06 | 193.55 | 8032.26 | 3748.39 | - | - |
| R2 stream 2nd | 1.59 | 7044.03 | 251.57 | 11949.69 | 188.68 | 7830.19 | 3654.088 | - | - |
| R3 stream 1st | 5.11 | 2191.78 | 78.28 | 3718.20 | 58.71 | 2436.40 | 1136.986 | - | - |
| R3 stream 2nd | 3.34 | 3353.29 | 119.76 | 5688.62 | 89.82 | 3727.54 | 1739.521 | - | - |
| R4 stream 1st | 1.66 | 6746.99 | 240.96 | 11445.78 | 180.72 | 7500.00 | 3500 | - | - |
| R4 stream 2nd | 6.05 | 1851.24 | 66.12 | 3140.50 | 49.59 | 2057.85 | 960.33 | - | - |
| Trigger** | | 100 | 10 | 100 | 10 | 10 | 10 | 10 | |

NOTE: TERs in bold indicate unresolved risks (TER < Trigger)

FOCUS_{sw} Risk Assessment - TERs for Isomer II – Brassica Vegetable Crops at 765 g a.s./ha x one application

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|-------------------------|----------------|--|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|---------------------|-------------------------------|------------------|------------------|-----------------------|---------------------------------|--|--------------------|------------------------|----------------------|
| | | <i>O. mykiss</i> | <i>O. mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Pseudokirchneriella subcapitata</i> | <i>Lemna minor</i> | Not triggered | Not triggered |
| | | LC ₅₀ | NOEC | EC ₅₀ | NOEC | ErC ₅₀ | ErC ₅₀ | NOEC | NOEC |
| | | 11200 µg/L | 400 µg/L | 19000 µg/L | 300 µg/L | 12450 µg/L | 321 µg/L | | |
| FOCUS Step 1 | N/A | - | - | - | - | - | - | - | - |
| FOCUS Step 2 | N/A | - | - | - | - | - | - | - | - |
| North Europe | | | | | | | | | |
| South Europe | | | | | | | | | |
| FOCUS Step 3* | PEC _{sw} (µg a.s./L) | TER | TER | TER | TER | TER | TER | | |
| D3 ditch 1st | 2.77 | 4043.32 | 144.40 | 6859.21 | 108.30 | 4494.58 | 115.88 | - | - |
| D3 ditch 2nd | 2.77 | 4043.32 | 144.40 | 6859.21 | 108.30 | 4494.58 | 115.88 | - | - |
| D4 pond | 0.15 | 74666.67 | 2666.67 | 126666.67 | 2000.00 | 83000.00 | 2140.00 | - | - |
| D4 stream | 2.17 | 5161.29 | 184.33 | 8755.76 | 138.25 | 5737.33 | 147.93 | - | - |
| D6 ditch | 2.71 | 4132.84 | 147.60 | 7011.07 | 110.70 | 4594.10 | 118.45 | - | - |
| R1 pond 1st | 0.36 | 31111.11 | 1111.11 | 52777.78 | 833.33 | 12484.96 | 891.67 | - | - |
| R1 pond 2nd | 0.29 | 38620.69 | 1379.31 | 65517.24 | 1034.48 | 42931.03 | 1106.90 | - | - |
| R1 stream 1st | 3.85 | 2909.09 | 103.90 | 4935.06 | 77.92 | 3233.77 | 83.38 | - | - |
| R1 stream 2nd | 3.59 | 3119.78 | 111.42 | 5292.48 | 83.57 | 3467.97 | 89.42 | - | - |
| R2 stream 1st | 2.39 | 4686.19 | 167.36 | 7949.79 | 125.52 | 5209.21 | 134.31 | - | - |
| R2 stream 2nd | 2.45 | 4571.43 | 163.27 | 7755.10 | 122.45 | 5081.63 | 131.02 | - | - |
| R3 stream 1st | 7.89 | 1419.52 | 50.70 | 2408.11 | 38.02 | 1577.95 | 40.68 | - | - |
| R3 stream 2nd | 5.15 | 2174.76 | 77.67 | 3689.32 | 58.25 | 2417.48 | 62.33 | - | - |
| R4 stream 1st | 2.55 | 4392.16 | 156.86 | 7450.98 | 117.65 | 4882.35 | 125.88 | - | - |
| R4 stream 2nd | 9.34 | 1199.14 | 42.83 | 2034.26 | 32.12 | 1332.98 | 34.37 | - | - |
| Trigger** | | 100 | 10 | 100 | 10 | 10 | 10 | 10 | |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|-------------------------|----------------|--|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

NOTE: TERs in bold indicate unresolved risks (TER < Trigger)

FOCUS_{sw} Risk Assessment - TERs for 1-napthol – Brassica Vegetable Crops at 765 g a.s./ha x one application

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|---------------------|-------------------------------|------------------|------------------|-----------------------|---------------------------------|--|--------------------|------------------------|----------------------|
| | - | <i>O. mykiss</i> | <i>O. mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Pseudokirchneriella subcapitata</i> | <i>Lemna gibba</i> | Not triggered | Not triggered |
| | | LC ₅₀ | NOEC | EC ₅₀ | NOEC | ErC ₅₀ | ErC ₅₀ | NOEC | NOEC |
| | | 11200 µg/L | 400 µg/L | 19000 µg/L | 300 µg/L | 12450 µg/L | 43.3 µg/L | | |
| FOCUS Step 1 | N/A | - | - | - | - | - | - | - | - |
| FOCUS Step 2 | N/A | - | - | - | - | - | - | - | - |
| North Europe | | | | | | | | | |
| South Europe | | | | | | | | | |
| FOCUS Step 3* | PEC _{sw} (µg a.s./L) | TER | TER | TER | TER | TER | TER | | |
| D3 ditch 1st | 0.60 | 18666.67 | 666.67 | 31666.67 | 500.00 | 20750.00 | 72.17 | - | - |
| D3 ditch 2nd | 0.60 | 18666.67 | 666.67 | 31666.67 | 500.00 | 20750.00 | 72.17 | - | - |
| D4 pond | 0.03 | 373333.33 | 13333.33 | 633333.33 | 10000.00 | 415000.00 | 1443.33 | - | - |
| D4 stream | 0.47 | 23829.79 | 851.06 | 40425.53 | 638.30 | 26489.36 | 92.13 | - | - |
| D6 ditch | 0.59 | 18983.05 | 677.97 | 32203.39 | 508.47 | 21101.69 | 73.39 | - | - |
| R1 pond 1st | 0.08 | 140000.00 | 5000.00 | 237500.00 | 3750.00 | 259375.00 | 541.25 | - | - |
| R1 pond 2nd | 0.06 | 186666.67 | 6666.67 | 316666.67 | 5000.00 | 207500.00 | 721.67 | - | - |
| R1 stream 1st | 0.84 | 13333.33 | 476.19 | 22619.05 | 357.14 | 14821.43 | 51.55 | - | - |
| R1 stream 2nd | 0.78 | 14358.97 | 512.82 | 24358.97 | 384.62 | 15961.54 | 55.51 | - | - |
| R2 stream 1st | 0.52 | 21538.46 | 769.23 | 36538.46 | 576.92 | 23942.31 | 83.27 | - | - |
| R2 stream 2nd | 0.53 | 21132.08 | 754.72 | 35849.06 | 566.04 | 23490.57 | 81.70 | - | - |
| R3 stream 1st | 1.71 | 6549.71 | 233.92 | 11111.11 | 175.44 | 7280.70 | 25.32 | - | - |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product (Name) |
|-------------------------|----------------|--|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

| | | | | | | | | | |
|---------------|------|----------|--------|----------|--------|----------|-------|----|---|
| R3 stream 2nd | 1.12 | 10000.00 | 357.14 | 16964.29 | 267.86 | 11116.07 | 38.66 | - | - |
| R4 stream 1st | 0.55 | 20363.64 | 727.27 | 34545.45 | 545.45 | 22636.36 | 78.73 | - | - |
| R4 stream 2nd | 2.03 | 5517.24 | 197.04 | 9359.61 | 147.78 | 6133.00 | 21.33 | - | - |
| Trigger** | | 100 | 10 | 100 | 10 | 10 | 10 | 10 | |

NOTE: TERs in bold indicate unresolved risks (TER < Trigger)
to 3 s.f.*

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | December 2016 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 84/2013 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 | Reference |
|--------------------------------------|-------------------|-----------------------------|------------------|-------------------------------------|-------------------|
| Honey bee, (<i>Apis mellifera</i>) | D-Devrinol 450 SC | Acute (oral) | LD ₅₀ | >264.9 µg/bee (>110 µg a.s./bee) | Rana, J.R (2014a) |
| Honey bee, (<i>Apis mellifera</i>) | D-Devrinol 450 SC | Acute (contact) | LD ₅₀ | >264.9 µg/bee (>110 µg a.s./bee) | Rana, J.R (2014b) |

Potential for accumulative toxicity: Not assessed

Semi-field test (Cage and tunnel test).

The risk to bees from the intended use of Napropamide-M is considered to be low and so higher tier studies on the sub-lethal effects on bees are not required.

Field tests

The risk to bees from the intended use of Napropamide-M is considered to be low and so higher tier studies on the sub-lethal effects on bees are not required.

Risk assessment for winter oilseed rape and brassica vegetable crops pre-planting/sowing - BBCH 00-08 at 765 g a.s./ha x 1 application

| Species | Test substance | Risk quotient | HQ/ETR | Trigger |
|-----------------------|-------------------|-----------------------|--------|---------|
| <i>Apis mellifera</i> | D-Devrinol 450 SC | HQ _{oral} | <7 | 50 |
| <i>Apis mellifera</i> | D-Devrinol 450 SC | HQ _{contact} | <7 | 50 |

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 | Reference |
|-------------------------------|-------------------|-----------------------------|---|---------------------|
| <i>Typhlodromus pyri</i> | D-Devrinol 450 SC | Mortality, LR ₅₀ | > 9.0 L/ha (equivalent to >4140 g a.s./ha) | Cockroft, R. (2014) |
| | | NOER | - | |
| <i>Aphidius rhopalosiphii</i> | D-Devrinol 450 SC | Mortality, LR ₅₀ | > 9.0 L/ha (equivalent to >4140 g a.s./ha) | Gamblin, C. (2014) |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

| Species | Test Substance | End point | Toxicity | Reference |
|--------------------------|----------------|-----------|--|-----------|
| | | NOER | 1.0 L/ha (equivalent to >460 g a.s./ha) | |
| Additional species. None | | | | |

Key - = could not be determined.

First tier risk assessment for winter oilseed rape and brassica vegetable crops pre-planting/sowing - BBCH 00-08 at 765 g a.s./ha x 1 application

| Test substance | Species | Effect (LR ₅₀ g a.s./ha) | HQ in-field | HQ off-field ¹ | Trigger |
|-------------------|-------------------------------|-------------------------------------|-------------|---------------------------|---------|
| D-Devrinol 450 SC | <i>Typhlodromus pyri</i> | >4140 | <0.18 | <0.0051 | 2 |
| D-Devrinol 450 SC | <i>Aphidius rhopalosiphii</i> | >4140 | <0.18 | <0.0051 | 2 |

¹indicate distance assumed to calculate the drift rate

Extended laboratory tests, aged residue tests

| Species | Life stage | Test substance, substrate | Time scale | Dose (g/ha) ^{1,2} | End point | % effect ³ | ER ₅₀ |
|-------------------|------------|---------------------------|------------|----------------------------|-----------|-----------------------|------------------|
| No data submitted | | | | | N/A | | |

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 for winter oilseed rape and brassica vegetable crops pre-planting/sowing - BBCH 00-08 at 765 g a.s./ha x 1 application

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

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

| |
|--------------------------|
| Semi-field tests |
| N/A |
| Field studies |
| N/A |
| Additional specific test |
| N/A |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

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 | Application method of test a.s./ OM ¹ | Time scale | End point | Toxicity* | Reference |
|-----------------------------------|-------------------|--|-------------------|--|--|-------------------|
| Earthworms | | | | | | |
| <i>Eisenia foetida</i> | D-Devrinol 450 SC | Mixed with soil as a solution / 10 % | Chronic (56 days) | LC ₅₀ EC ₅₀ NOEC | 122.02 mg/kg (50.01 mg a.s/kg) 80.72 mg/kg (33.48 mg a.s/kg) 41.7 mg/kg (17.3 mg a.s/kg) | Rana J.R (2014c) |
| Other soil macro-organisms | | | | | | |
| <i>Folsomia candida</i> | Napropamide-M | Mixed with soil as a solution / 10 % | Chronic (28 days) | EC ₅₀ NOEC | >500 mg a.s/kg >47. mg a.s/kg | Vinall, S. (2014) |
| <i>Hypoaspis aculeifer</i> | Napropamide-M | Mixed with soil as a solution / 10 % | Chronic (14 days) | EC ₅₀ NOEC | >500 mg a.s/kg 500 mg a.s/kg | Vinall, S. (2014) |

* a Endpoint corrected by a factor of 2 to account for the high organic matter content of the study soil log K_{ow} >2

Higher tier testing (e.g. modelling or field studies) – **Non undertaken**

| | | | | |
|-------------------------|-------------------|--|---|--------------------|
| Nitrogen transformation | D-Devrinol 450 SC | Maximum tested rate 32.40mg a.s./kg d.w. soil. | 9% effect at day 28 at 32.40 mg a.s./kg d.w.soil (79.12 mg/kg d.w.soil) | Shrimali A. (2013) |
|-------------------------|-------------------|--|---|--------------------|

Toxicity/exposure ratios for soil organisms

Winer oilseed rape and brassica vegetable crops pre-planting/sowing - BBCH 00-08 at 765 g a.s./ha x 1 application

| Test organism | Test substance | Time scale | Soil PEC ¹ mg a.s./kg soil dw) | TER* | Trigger |
|------------------------|-------------------|------------|--|-------|---------|
| Earthworms | | | | | |
| <i>Eisenia foetida</i> | D-Devrinol 450 SC | Chronic | 1.5979 | 10.95 | 5 |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

Section 5 Ecotoxicology

| Test organism | Test substance | Time scale | Soil PEC ¹ mg a.s./kg soil dw) | TER* | Trigger |
|-----------------------------------|----------------|-------------------|---|-------|---------|
| Other soil macro-organisms | | | | | |
| <i>Hypoaspis aculeifer</i> | a.s. | Chronic (14 days) | 1.5979 | 316.6 | 5 |
| <i>Folsomia candida</i> | a.s. | Chronic (28 days) | 1.5979 | 30.20 | 5 |

¹Accumulation PEC_{soil}

* ^a Endpoint corrected by a factor of 2 to account for the high organic matter content of the study soil log K_{ow} >2

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 a.s./ha) ² vegetative vigour (fresh weight) | ER ₅₀ (g a.s./ha) ² emergence (fresh weight) |
|---|-------------------|--|--|
| Maize (<i>Zea mays</i>) | D-Devrinol 450 SC | 1408 | 321 |
| Oat (<i>Avena sativa</i>) | D-Devrinol 450 SC | 521 | 368 |
| Onion (<i>Allium cepa</i>) | D-Devrinol 450 SC | 1631 | 244 |
| Ryegrass (<i>Lolium perenne</i>) | D-Devrinol 450 SC | 1159 | 76.6 |
| Radish (<i>Raphanus sativus</i>) | D-Devrinol 450 SC | >2430 | 2430 |
| Sugar beet (<i>Beta vulgaris</i>) | D-Devrinol 450 SC | >2430 | >2430 |
| Carrot (<i>Daucus carota</i>) | D-Devrinol 450 SC | >2430 | 1776 |
| Cucumber (<i>Cucumis sativus</i>) | D-Devrinol 450 SC | >2430 | >2430 |
| Soybean (<i>Glycine max</i>) | D-Devrinol 450 SC | >2430 | 1506 |
| Tomato (<i>Lycopersicon esculentum</i>) | D-Devrinol 450 SC | >2430 | >2430 |

Extended laboratory studies : No studies were submitted with the representative product as an acceptable risk was demonstrated in a tier 2 risk assessment with appropriate risk mitigation

Semi-field and field test: not required.

List of end points

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Section 5 Ecotoxicology

Toxicity/exposure ratios for non-target plants

Winer oilseed rape and brassica vegetable crops pre-planting/sowing - BBCH 00-08 at 765 g a.s./ha x 1 application

| Effect | Test organism | Test substance | Time scale | Toxicity endpoint ER ₅₀ (g a.s./ha) | PER _{off-field} | TER | Trigger |
|---------------------|-----------------------|----------------|------------|---|--------------------------|-------|---------|
| Distance: 1m | | | | | | | |
| Seedling emergence | <i>Lolium perenne</i> | preparation | 21-day | 76.6 | 21.19 | 3.6 | 5 |
| Vegetative vigour | <i>Avena sativa</i> | preparation | 21-day | 521 | 21.19 | 25 | 5 |
| Distance: 5m | | | | | | | |
| Seedling emergence | <i>Lolium perenne</i> | preparation | 21-day | 76.6 | 4.36 | 17.56 | 5 |
| Vegetative vigour | <i>Avena sativa</i> | preparation | 21-day | 521 | 4.36 | 119.5 | 5 |

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

| Test type/organism | Test substance | end point |
|--------------------|----------------|--|
| Activated sludge | Napropamide | Respiration inhibition, 3 hours, EC ₅₀ >1000 mg as/L |
| | | NOEC 1000 mg as/L |

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s.

No data submitted

Available monitoring data concerning effect of the PPP.

No data submitted

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

| Compartment | Compound |
|-------------|----------|
| soil | |

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Section 5 Ecotoxicology

| | |
|-------------|--|
| water | |
| sediment | |
| groundwater | |

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

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Section 5 Ecotoxicology

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

| | |
|--|---|
| Substance | Napropamide-M |
| 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] ⁷ : | No current harmonised classification |
| Peer review proposal ⁸ for harmonised classification according to Regulation (EC) No 1272/2008: | H400; Very toxic to aquatic life; H410; Very toxic to aquatic life with long lasting effects |

⁷ 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.

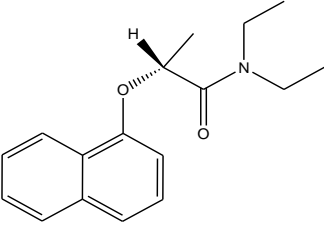
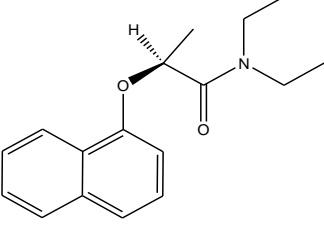
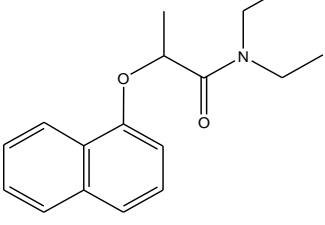
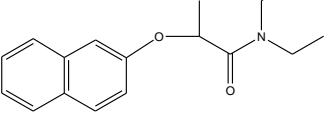
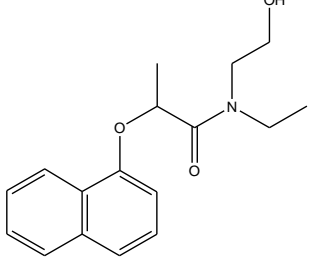
⁸ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
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Section 5 Ecotoxicology

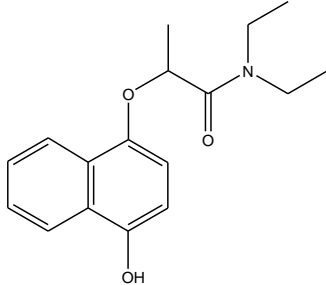
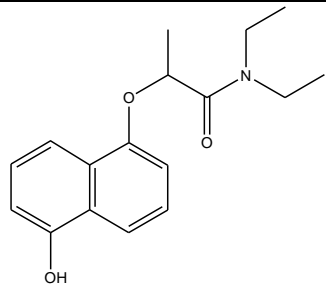
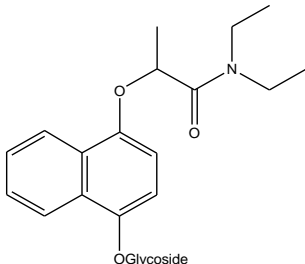
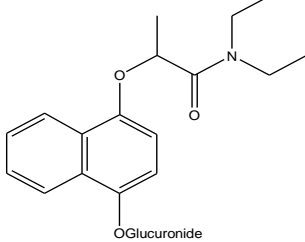
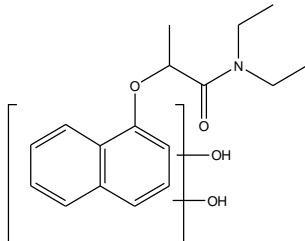
Used compounds code(s)

| Code/Trivial name* | IUPAC name/SMILES notation | Structural formula |
|--|---|---|
| a.s Napropamide-M | (-)-N,N-diethyl-2-(1-naphthalenyloxy) propanamide |  |
| L-napropamide | (+)-N,N-diethyl-2-(1-naphthalenyloxy) propanamide |  |
| Napropamide (racemate) | N,N-diethyl-2-(1-naphthalenyloxy) propanamide |  |
| β-Devrinol β-Napropamide Compound IX | N,N-diethyl-2-(naphthalen-2-yloxy) propanamide |  |
| E-OH-NPAM Hydroxyethyl devrinol Compound XIV | N-ethyl-N-(2-hydroxyethyl)-2-(naphthalen-1-yloxy) propanamide |  |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
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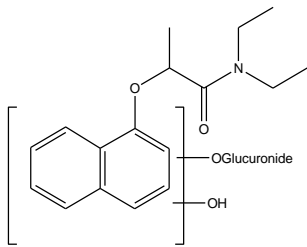
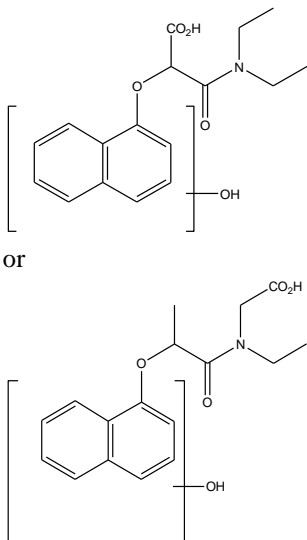
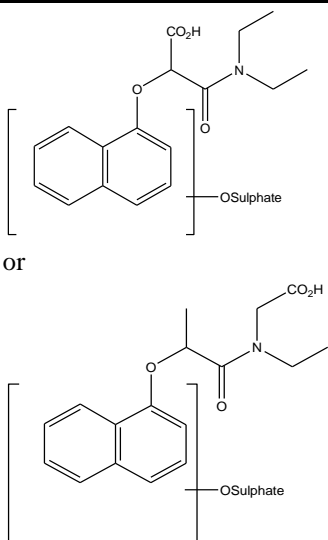
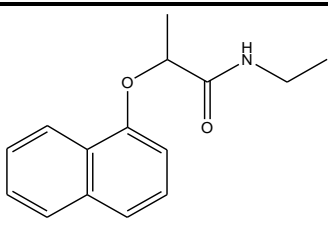
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| | | |
|--|---|---|
| 4-OH-NPAM R7465/05 4-Hydroxy-napropamide 4-Hydroxy devrinol Compound 5 Compound VI U6 | N,N-diethyl-2-(4-hydroxy naphthalen-1-yloxy) propanamide |  |
| 5-OH-NPAM R7465/04 5-Hydroxy-napropamide 5-Hydroxy devrinol Compound 4 Compound IV U13 | N,N-diethyl-2-(5-hydroxynaphthalen-1-yloxy) propanamide |  |
| 4-O- β-Glucosidyl devrinol 4-O- β-Glucosidyl napropamide | O-glycoside conjugate of: N,N-diethyl-2-(4-hydroxy naphthalen-1-yloxy) propanamide |  |
| Hydroxy-NPAM glucuronide U1 B1 (U3 B3 - position of hydroxylation not confirmed) | O-glucuronide conjugate of: N,N-diethyl-2-(4-hydroxy naphthalen-1-yloxy) propanamide |  |
| Dihydroxy-NPAM | 2-(dihydroxynaphthalen-1-yloxy)-N,N-diethylpropanamide |  |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

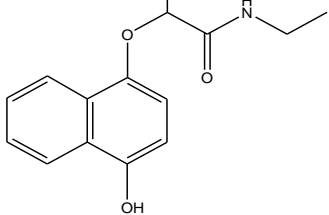
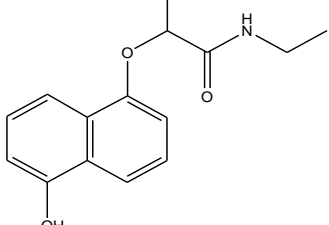
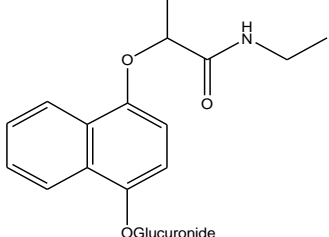
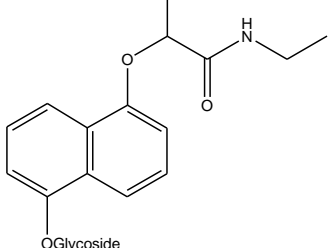
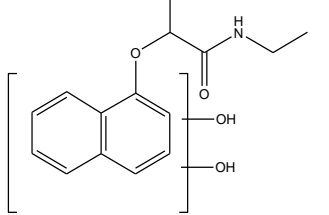
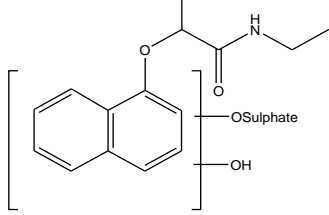
Section 5 Ecotoxicology

| | | |
|---|---|---|
| Dihydroxy-NPAM glucuronide | O-glucuronide conjugate of: 2-(dihydroxynaphthalen-1-yloxy)- <i>N,N</i> -diethylpropanamide |  |
| Hydroxy acid napropamide | 3-(diethylamino)-2-(hydroxynaphthalen-1-yloxy)-3-oxopropanoic acid Or 2-(<i>N</i> -ethyl-2-(hydroxynaphthalen-1-yloxy)propanamido)acetic acid |  |
| Hydroxy acid napropamide sulphate | O-sulphate conjugate of: 3-(diethylamino)-2-(hydroxyl naphthalen-1-yloxy)-3-oxo propanoic acid or 2-(<i>N</i> -ethyl-2-(hydroxynaphthalen-1-yloxy)propanamido)acetic acid |  |
| DE-NPAM R7465/07 Desethyl-napropamide DE napropamide Desethyl-devrinol Compound 7 Compound III U10 | <i>N</i> -ethyl-2-(naphthalen-1-yloxy)propanamide |  |

List of end points

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|-------------------------|----------------|---|
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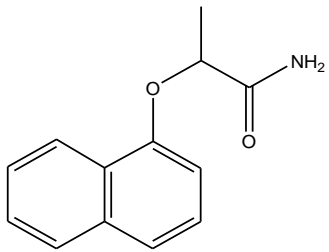
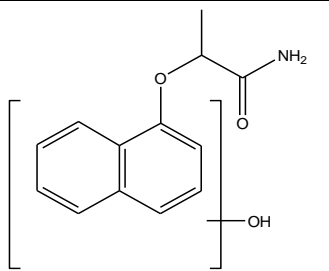
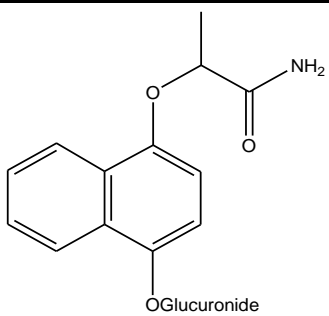
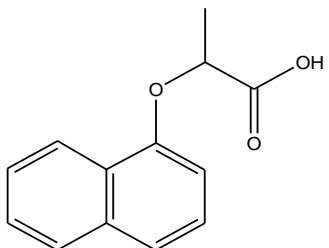
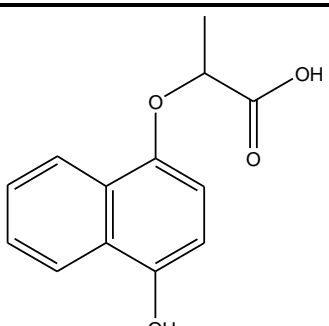
Section 5 Ecotoxicology

| | | |
|--|---|---|
| 4-OH-DE-NPAM R7465/08 4- Hydroxy-desethyl- napropamide Compound 8 U7 | <i>N</i> -ethyl-2-(4-hydroxynaphthalen-1-yloxy) propanamide |  |
| 5-OH-DE-NPAM R7465/10 5-Hydroxy-desethyl- napropamide Compound 10 Compound V U14 | <i>N</i> -ethyl-2-(5-hydroxynaphthalen-1-yloxy) propanamide |  |
| DE-NPAM glucuronide U2, B2 | O-glucuronide conjugate of: <i>N</i> -ethyl-2-(4-hydroxynaphthalen-1-yloxy) propanamide |  |
| 5-O-β-Glucosidyl- desethyl-devrinol 5-O-β-Glucosidyl- desethyl-napropamide | O-glycoside conjugate of: <i>N</i> -ethyl-2-(5-hydroxynaphthalen-1- yloxy)propanamide |  |
| Dihydroxy-DE-NPAM | 2-(dihydroxynaphthalen-1-yloxy)- <i>N</i> - ethylpropanamide |  |
| Dihydroxy-DE-NPAM sulphate | O-sulphate conjugate of: 2-(dihydroxynaphthalen-1-yloxy)- <i>N</i> - ethylpropanamide |  |

List of end points

| Rapporteur Member State | Month and year | Active substance and Plant Protection Product |
|-------------------------|----------------|---|
| UK | June 2017 | Napropamide-M D-Devrinol |

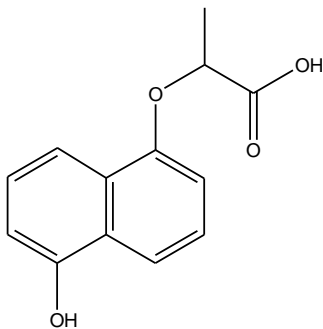
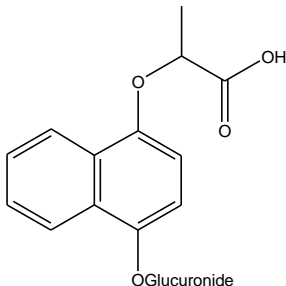
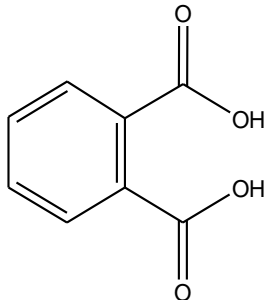
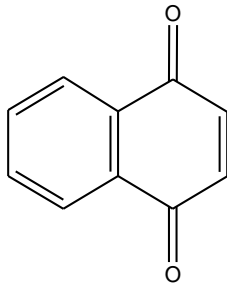
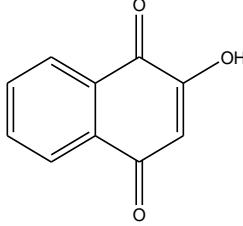
Section 5 Ecotoxicology

| | | |
|--|---|---|
| NOPAM R7465/06 Naphthoxy-propionamide Compound 6 U11 | 2-(naphthalen-1-yloxy) propanamide |  |
| OH-NOPAM R7465/27 or 28 U8 | 2-(hydroxynaphthalen-1-yloxy) propanamide |  |
| 4-OGlu-NOPAM U3, B3 | O-glucuronide conjugate of: 2-(4-hydroxynaphthalen-1-yloxy)propanamide |  |
| NOPA R7465/15 Compound 15 Compound VIII U12 | 2-(naphthalen-1-yloxy) propanoic acid |  |
| 4-OH-NOPA R7465/22 Compound 22 U9 | 2-(4-hydroxynaphthalen-1-yloxy) propanoic acid |  |

List of end points

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|-------------------------|----------------|---|
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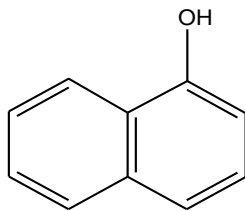
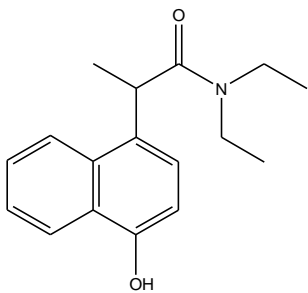
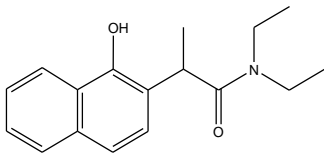
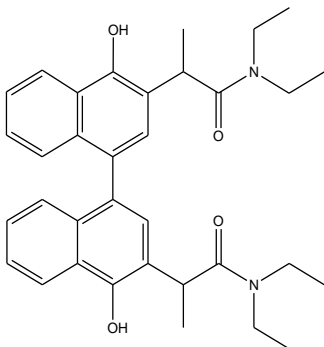
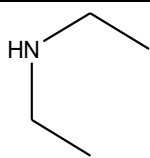
Section 5 Ecotoxicology

| | | |
|--|---|---|
| 5-OH-NOPA R7465/21 Compound 21 B5 | 2-(5-hydroxynaphthalen-1-yloxy) propanoic acid |  |
| 4-OGlu-NOPA U4, B4 | O-glucuronide of: 2-(4-hydroxynaphthalen-1-yloxy) propanoic acid |  |
| PA R7465/11 Compound 11 Compound XII | phthalic acid |  |
| NQ R7465/13 1,4-NQ Compound 13 Compound I U15 | naphthalene-1,4-dione |  |
| 2-OH-NQ Compound XIII | 2-hydroxynaphthalene-1,4-dione |  |

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| | | |
|---------------------------|---|---|
| 1-Naphthol Compound XI | naphthalene-1-ol |  |
| Isomer I | <i>N,N</i> -diethyl-2-(4-hydroxy naphthalen-1-yl) propanamide |  |
| Isomer II | <i>N,N</i> -diethyl-2-(1-hydroxy naphthalen-2-yl) propanamide |  |
| Dimer | - |  |
| Diethylamine | diethylamine |  |