Appendix to:

EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance trinexapac. EFSA Journal 2018;16(3):5229, 34 pp. doi:10.2903/j.efsa.2018.5229
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Appendix A – List of end points for the active substance and the representative formulation

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) | Trinexapac-ethyl derivative of trinexapac
--- | ---
Function (e.g. fungicide) | Plant growth regulator
Rapporteur Member State | Lithuania
Co-rapporteur Member State | Latvia

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

Chemical name (IUPAC) | trinexapac-ethyl: ethyl (1R,5,4E)-4-cyclopropyl(hydroxy)methylene-3,5-dioxocyclohexanecarboxylate
trinexapac: (1R,5,4E)-4-cyclopropyl(hydroxy)methylene-3,5-dioxocyclohexanecarboxylic acid
--- | ---
Chemical name (CA) | trinexapac-ethyl: ethyl 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylate
trinexapac: 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylic acid
CIPAC No | 732.202 (trinexapac-ethyl)
732 (trinexapac)
CAS No | 95266-40-3 (trinexapac-ethyl, enol form)
104273-73-6 (trinexapac, keto form)
143294-89-7 (trinexapac, enol form)
EC No (EINECS or ELINCS) | none allocated
FAO Specification (including year of publication) | none
Minimum purity of the active substance as manufactured | 950 g/kg. Syngenta
960 g/kg and 977 g/kg. Cheminova
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured

| Identity of relevant impurities | Amount |
|--------------------------------|--------|
| toluene                        | 3 g/kg |
| ethyl (1RS)-ethyl 3-hydroxy-5-oxocyclohex-3-ene-1-carboxylate (CGA158377) | 6 g/kg |
| Other potentially relevant impurities | Open |

Molecular formula

C₁₃H₁₆O₅

Molar mass

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

| Property                                      | Value                                             |
|-----------------------------------------------|---------------------------------------------------|
| **Melting point (state purity)**             | 36.1 – 36.6°C (996 g/kg)                          |
| **Boiling point (state purity)**             | Thermal decomposition starts at about 310 °C       |
|                                               | boiling point at 4.2 Pa is 99.8 °C (996 g/kg)     |
| **Temperature of decomposition (state purity)** | Thermal decomposition starts at about 310 °C       |
| **Appearance (state purity)**                | Red-brown solidified melt (968 g/kg)              |
|                                               | White powder (996 g/kg)                            |
| **Vapour pressure (state temperature, state purity)** | 2.16 x 10^-3 Pa at 25 °C                         |
| **Henry’s law constant (state temperature)** | 5.4 x 10^-4 Pa.m^3/mol^-1 at 25°C                  |
| **Solubility in water (state temperature, state purity and pH)** | All values at 25 °C:                             |
|                                               | 1.1 g/L at pH 3.5 distilled water                 |
|                                               | 2.8 g/L at pH 4.9 buffer solution                 |
|                                               | 10.2 g/L at pH 5.5 buffer solution                |
|                                               | 21.1 g/L at pH 8.2 buffer solution mg or g/L at °C (pH ) |
| **Solubility in organic solvents (state temperature, state purity)** | At 25 °C:                                        |
|                                               | acetone > 500 g/L                                 |
|                                               | methanol > 500 g/L                                |
|                                               | n-octanol 420 g/L                                 |
|                                               | toluene > 500 g/L                                 |
|                                               | dichloromethane > 500 g/L                         |
|                                               | ethyl acetate > 500 g/L                           |
|                                               | hexane 45 g/L                                     |
| **Surface tension (state concentration and temperature, state purity)** | The surface tension of pure trinexapac-ethyl in water was determined to be 58.3 mN/m at 22.5 ± 0.5 °C (99.6 % w/w). Pure trinexapac-ethyl demonstrates marginal surface active behaviour in respect of surface tension. |
| **Partition coefficient (state temperature, pH and purity)** | at purity 996 g/kg                                |
|                                               | log P_{OW} = 1.5 at 25°C (pH 5)                   |
|                                               | log P_{OW} = -0.29.5 at 25°C (pH 6.9)            |
|                                               | log P_{OW} = -2.1 at 25°C (pH 8.9)               |
| **Dissociation constant (state purity)**     | pKa = 4.57 at 20°C                                |
| **UV/VIS absorption (max.) incl. ε (state purity, pH)** | Molar extinctions coefficients:                   |
|                                               | neutral: 240.2 nm 9335 L mol^-1 cm^-1             |
|                                               | 277.4 nm 13976 L mol^-1 cm^-1                    |
|                                               | acidic 240.0 nm 11712 L mol^-1 cm^-1             |
|                                               | 280.4 nm 12368 L mol^-1 cm^-1                    |
|                                               | basic 270.8 nm 21320 L mol^-2 cm^-1              |
|                                               | ε = 11134 L mol^-1 cm^-1 (99.6%) at λ 290 nm     |
| Property                        | Description                                      |
|--------------------------------|--------------------------------------------------|
| **Flammability (state purity)**| Trinexapac-ethyl is not classified in terms of its burning characteristics. The flash point is above 60°C.  |
|                                | Auto-ignition temperature: 330 +/- 35°C          |
|                                | Flash Point : 156 +/- 8°C                        |
| **Explosive properties (state purity)** | Trinexapac-ethyl is not considered an explosive substance. |
| **Oxidising properties (state purity)**   | Trinexapac-ethyl is not considered an oxidizing substance. |
Summary of representative uses evaluated, for which all risk assessments needed to be completed *(trinexapac-ethyl)*  
*(Regulation (EU) No 284/2013, Annex Part A, points 3, 4)*

| Crop and/or situation (a) | Member State or Country | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|--------------------------|-------------------------|--------------|--------------|----------------------------------------|-------------|-------------|-------------------------------|-----------------|---------|
| Barley, Winter EU        | Moddus ME               | F            | Prevention of lodging               | ME           | 250 g/L     | foliar spray       | 25-49             | 1                       | 0.8 | 100-400 | 0.2 | Application rate refers to trinexapac-ethyl |
| Barley, Spring EU        | Moddus ME               | F            | Prevention of lodging               | ME           | 250 g/L     | foliar spray       | 25-37             | 1                       | 0.6 | 100-400 | 0.15 | Application rate refers to trinexapac-ethyl |
| Wheat, Winter EU         | Moddus ME               | F            | Prevention of lodging               | ME           | 250 g/L     | foliar spray       | 25-49             | 1                       | 0.5 | 100-400 | 0.125 | Application rate refers to trinexapac-ethyl |

*(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
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 (name of active substance or the respective variant)

Regulation (EC) No 1107/2009 Article 8.1(g))

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

| Crop and/or situation (a) | Member State or Country | Product name | F or G or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|--------------------------|-------------------------|--------------|----------------|-------------------------------------|-------------|-----------|--------------------------|---------------|---------|
| Rye                      | EU                      | Modulus Evo  | F              | Prevention of lodging                | DC          | 250 g/L   | foliar spray              | 25-49         | 0.5     |
|                          |                         |              |                |                                     |             |           |                          |               | 0.125   |

DC – dispersible concentrate formulation

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

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

Trinexapac-ethyl containing products are used in agriculture as plant growth regulators to prevent lodging and brackling (crop leaning) of crops. Trinexapac-ethyl is taken up by plants almost exclusively through the green portions of the plant. Uptake by the plant is rapid and quickly followed by transport into the active meristem tissues. The growth regulatory activity is expressed in these tissues as an inhibition of internode elongation. A more detailed assessment will be performed for products authorization applications.

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

No information has been provided. A more detailed assessment will be performed for products authorization applications.

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

Given the very short half-life of the active ingredient and its primary metabolite in soil, coupled with the lack of significant root uptake, no effect on succeeding crops is to be expected. A more detailed assessment will be performed for products authorization applications.

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

Activity against target organism

| Not relevant |
|--------------|
|              |
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) | HPLC-UV (*Column: Nucleodur 100-5 C18*) |
|--------------------------------------|----------------------------------------|
| Impurities in technical a.s. (analytical technique) | HPLC-UV (*Column: Nucleodur 100-5 C18*); GC-FID (*Column: wide-bore fused silica*) |
| Plant protection product (analytical technique) | HPLC-UV (*Column: Nucleosil C18*); GC-FID Toluene: GC-FID; Data gap for CGA158377 in the formulation |

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 | Sum of trinexapac and its salts, expressed as trinexapac |
|----------------------|--------------------------------------------------------|
| Food of animal origin| Sum of trinexapac and its salts, expressed as trinexapac |
| Soil                 | Trinexapac-ethyl                                        |
| Sediment             | Trinexapac-ethyl                                        |
| Water                | Trinexapac-ethyl                                        |
| Air                  | Trinexapac-ethyl                                        |
| Body fluids and tissues | Sum of trinexapac and its salts, expressed as trinexapac |

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)

| Multi residue method (QuEChERS) |
|----------------------------------|
| LC-MS/MS (LOQ 0.01 mg/kg)        |
| Lettuce (high water), orange (high acid), dry broad bean, wheat grain (high protein/high starch), oilseed rape (high oil). |
| Single residue method (GRM020.05A) |
| LC-MS/MS (LOQ 0.01 mg/kg)        |
| Tomato, apple (high water), dry broad bean, barley grain (high protein/high starch), sunflower seed (high oil), barley hay and straw (no group). |

Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)

| Multi residue method (QuEChERS) |
|----------------------------------|
| LC-MS/MS (LOQ 0.01 mg/kg)        |
| Milk, eggs, muscle/meat, fat, liver. |
| Single residue method (AGR/MOA/TRIN-06) |
| LC-MS/MS (LOQ 0.01 mg/kg)        |
| Milk, eggs, muscle/meat, fat, liver, kidney. |
Soil (analytical technique and LOQ)

| LC-MS/MS |
|----------|
| GRM020.03A (analyte: trinexapac-ethyl) |
| GRM020.04A (analyte: CGA179500) and |
| GRM020.10A (analyte: CGA300405) |
| LOQ: 0.01 mg/kg for trinexapac-ethyl, CGA179500 and CGA300405 |

Water (analytical technique and LOQ)

| LC-MS/MS |
|----------|
| GRM020.02A (analytes: trinexapac-ethyl and trinexapac (CGA179500) in surface, ground and drinking water; ILV for drinking (tap) water); |
| GRM020.11A (analyte: CGA300405 in surface and ground water) |
| LOQ: 0.05 μg /L for trinexapac-ethyl and CGA179500; |
| LOQ: 0.05 μg /L for CGA300405 in surface and ground water |

Air (analytical technique and LOQ)

| LC-MS |
|-------|
| LOQ: 10 μg/m³ |
| Method code: GRM020.12A |

Body fluids and tissues (analytical technique and LOQ)

| Multi residue method (QuEChERS) |
|---------------------------------|
| LC-MS/MS (LOQ 0.01 mg/kg) |
| Trinexapac (CGA 179500) determination in blood (bovine) |

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

| Substance | Trinexapac-ethyl |
|-----------|------------------|
| 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: | None |
| Peer review proposal ² for harmonised classification according to Regulation (EC) No 1272/2008: | No classification proposed |

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

² It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
### Section 2 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 | ≥ 96% (based on urine (95%), cage wash, carcass and tissues within 168 h; irrespective of dose and sex) |
|-------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Toxicokinetics                                             | Low dose- $C_{max}$ 0.5-1.3, $T_{max}$ 0.25 h, Blood $T_{1/2}$ <0.6 h; $AUC_{0.25-48h}$ 1 µg h equiv/g; tissues slow phase $T_{1/2}$ ≤3.2 h |
| High dose- $C_{max}$ 73-85, $T_{max}$ 0.25 h, Blood $T_{1/2}$ <0.8 h; $AUC_{0.25-48h}$ 170 µg h equiv/g; tissues slow phase $T_{1/2}$ ≤12 h |
| Distribution                                               | Widely distributed with the highest concentrations in kidneys, liver and plasma |
| Potential for bioaccumulation                              | No evidence for accumulation |
| Rate and extent of excretion                               | Rapid (≥ 92 % within 24 h) and extensive mainly via urine (95 - 97%, via faeces 0.9-2.4%) within 168 h, irrespective of dose and sex |
| Metabolism in animals                                      | Extensively metabolised; major metabolite trinexapac (CGA179500) (92% in urine, ~50% in faeces) and an unidentified metabolite (probably a conjugate of either parent or CGA 179500) (8% of the urine, 94% of the biliary radiolabel) after low dose administration |
| Hydrolysis                                                  | The metabolism of [14C]-TXP by human liver microsomes was qualitatively comparable but was slower to that seen in rat. All the human metabolites formed were detected in rat. Data gap identified for a comparative in vitro metabolism study between dog and human |
| **In vitro metabolism**                                    | Trinexapac-ethyl /metabolite CGA179500 |
| **Toxicologically relevant compounds**                     | Trinexapac-ethyl /metabolite CGA179500 |

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

| Rat LD$_{50}$ oral                             | 4210 mg/kg bw |
| Rat LD$_{50}$ dermal                          | > 4000 mg/kg bw |
| Rat LC$_{50}$ inhalation                      | > 5.3 mg/L air/4h (nose only, liquid aerosol) |
| Skin irritation                               | Non-irritant |
| Eye irritation                                | Non-irritant |
| Skin sensitisation                            | Sensitisising (LLNA) |
| Phototoxicity                                 | Not phototoxic |
|                                             | H317, Skin Sens. 1B |
### Short-term toxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.3)

| Target organ / critical effect | Rat (male): kidney (histopathological changes)  
Dog: clinical signs, decreased terminal body weight, haematotoxicity, changes in oestrus cyclicity & decreased absolute uterus weight, cerebral vacuolation |
| Relevant oral NOAEL | 90-day rat: 34 mg/kg bw per day  
1-year, dog: 32 mg/kg bw per day |
| Relevant dermal NOAEL | 22-day, rabbit: ≥ 1000 mg/kg bw per day |
| Relevant inhalation NOAEL | No data - not required |

### Genotoxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.4)

| In vitro studies | Nine Bacterial Reverse Mutation assays: negative  
Two Mammalian Chromosome Aberrations assays (CHO K5 and human lymphocytes) negative, one assay (human lymphocytes) equivocal  
Two Mammalian Cell Gene Mutation assays (Chinese hamster V79 cells, HPRT and mouse lymphoma cells L5178Y, TK) negative, one assay (mouse lymphoma cells L5178Y) and one assay (Chinese hamster ovary, Batch fortified) equivocal  
Two (one supplementary) DNA Damage and Repair assays (rat hepatocytes and human fibroblasts): negative |
| In vivo studies | Two (one supplementary) Mouse (Tif: MAGF, SPF) Micronucleus BM assays: negative  
Rat (Sprague Dawley) Micronucleus BM assay: negative |
| Photomutagenicity | Considered covered by negative photoxicity testing |
| Potential for genotoxicity | Trinexapac-ethyl is unlikely to be genotoxic in vivo |

### Long-term toxicity and carcinogenicity (Regulation (EU) No 283/2013, Annex Part A, point 5.5)

| Long-term effects (target organ/critical effect) | Rat: kidney histopathological changes (males), bile duct hyperplasia in the liver (male), galactoceles in mammary skin  
Mouse: no adverse effects |
| Relevant long-term NOAEL | 2-year, rat: 116 mg/kg bw per day  
18-month, mouse: ≥ 911.8 mg/kg bw per day |
| Carcinogenicity (target organ, tumour type) | Rat: no evidence of carcinogenicity  
Mouse: no evidence of carcinogenicity  
Trinexapac-ethyl is unlikely to be a hazard to |
Relevant NOAEL for carcinogenicity: 2-year, rat: ≥ 805.7 mg/kg bw per day; 18-month, mouse: ≥ 911.8 mg/kg bw per day

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

Reproduction toxicity

Reproduction target / critical effect
- Parental toxicity: bw gain reduction in F0, F1 males (~10%) and F0 females (~15%); FC reduction in F1 males
- Reproductive toxicity: no adverse effect observed in rat 2-generation study
- Offspring’s toxicity: reduced survival index in F1 pups (4-21 days), F2 pups (0-4 days) and bw reduction in F1 pups (20%) and F2 pups (24%)

Relevant parental NOAEL: 106.2 mg/kg bw per day
Relevant reproductive NOAEL: ≥ 1293 mg/kg bw per day
Relevant offspring NOAEL: 662.9 mg/kg bw per day

Developmental toxicity

Developmental target / critical effect
- Rat: Maternal toxicity: no adverse effect observed at highest tested dose
- Developmental toxicity: increase in the litter incidence of asymmetrically shaped sternebrae
- Rabbit: Maternal toxicity: mortality, retarded bw gain
- Developmental toxicity: increased post-implantation loss, reduced live foetuses

Relevant maternal NOAEL: Rat: ≥ 1000 mg/kg bw per day; Rabbit: 60 mg/kg bw per day
Relevant developmental NOAEL: Rat: 200 mg/kg bw per day; Rabbit: 60 mg/kg bw per day

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

Acute neurotoxicity
- Systemic NOAEL: ≥ 2000 mg/kg bw
- Neurotoxicity NOAEL: ≥ 2000 mg/kg bw

Repeated neurotoxicity
- Systemic NOAEL: ≥ 948 mg/kg bw per day
- Neurotoxicity NOAEL: ≥ 948 mg/kg bw per day
- Cerebral vacuolation was reported in a 1-year dog study at 357.1 and 726.7 mg/kg bw per day, reflecting a probable interference of metabolic origin.

Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)
- None
Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance

| Study Description | NOAEL (mg/kg bw per day) |
|-------------------|--------------------------|
| 28 day dietary immunotoxicity study in mice: | Systemic NOAEL: ≥ 1530.5 mg/kg bw per day Immunotoxicity NOAEL ≥ 1530.5 mg/kg bw per day |

Endocrine disrupting properties

- No final conclusion on the endocrine disruption potential could be drawn based on the effects observed in 1-year dog study (uterus weight, oestrus cyclicity) and lack of evaluation of endocrine sensitive parameters in two-generation toxicity study

- Data gap

Studies performed on metabolites or impurities

| Substance | Study Description | Outcome |
|-----------|-------------------|---------|
| CGA179500 | Bacterial Reverse Mutation assay: negative | negative |
| | In vitro Mammalian Cell Gene Mutation assay (Chinese hamster V79 cells, HPRT): negative | negative |
| | In vitro Mammalian Cell Micronucleus assay (human lymphocytes): negative | negative |
| SYN54584 | : considered covered by CGA179500 |
| CGA275537 | Genotoxicity: QSAR analyses according to DEREK Nexus negative |
| CGA329773 | LD₅₀ oral rat: >300 mg/kg bw and <2000 mg/kg bw H302 Bacterial Reverse Mutation assay: negative |
| | CGA300405 | Bacterial Reverse Mutation assay: negative |
| | In vitro Mammalian Cell Gene Mutation assays (mouse lymphoma cells L5178Y, TK): negative | negative |
| | In vitro Mammalian Cell Micronucleus assay (human lymphocytes): negative | negative |
| CGA313458 | LD₅₀ oral rat: >2000 mg/kg bw |
| LD₅₀ oral rat: >2000 mg/kg bw | 28 d oral rat: NOAEL ≥12000 ppm (1021 mg/kg bw per day) (highest dose tested) Bacterial Reverse Mutation assay: negative |
| | In vitro Mammalian Cell Gene Mutation assay (Chinese hamster V79 cells, HPRT): negative | negative |
| CGA158377 | LD₅₀ oral rat: >2000 mg/kg bw |
| | LD₅₀ dermal rat: > 2000 mg/kg bw |
| | LC₅₀ inhalation: > 5.226 mg/L air/4h (nose only, aerosol) Acute eye irritation – irreversible effects H318 Skin sensitisation (M & K) – sensitising H317 28 d oral rat (gavage): NOAEL 100 mg/kg bw per day Bacterial Reverse Mutation assay: negative | |
| | In vitro Mammalian Chromosome Aberrations assay (CHO): negative | negative |
| CGA313458 | LD₅₀ oral rat: >2000 mg/kg bw |
Bacterial Reverse Mutation assay: negative
In vitro Mammalian Cell Gene Mutation assay (Chinese hamster V79 cells, HPRT): negative
In vitro Mammalian Chromosome Aberrations assay (human lymphocytes): negative

CGA224439
Bacterial Reverse Mutation assay: negative
In vitro Mammalian Cell Gene Mutation assay (Chinese hamster V79 cells, HPRT): negative
In vitro Mammalian Chromosome Aberrations assay (human lymphocytes): negative

Data gap identified for the repeated exposure toxicity (available 90-day rat study to JMPR) and updated literature search.

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

No detrimental effects on health in manufacturing personnel
Occupational/accidental/intentional exposures - 35 cases in total with none to moderate severity for human health effects. One case of ingestion was leading to minor symptoms of temporary nature.

Summary\(^3\) (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

| Value (mg/kg bw (per day)) | Study | Uncertainty factor |
|---------------------------|-------|-------------------|
| 0.32                      | dog , 1-year | 100 |
| NA                        |       |                   |
| 0.34                      | rat, 90-day | 100 |
| NA                        |       |                   |

| * same as in the first peer review (European Commission, 2006) |

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

Trinexapac-ethyl 250 g/L ME (A8587F)
No proper study on the formulation available.
Concentrate: 25 % (default value)
Spray dilution 75% (default value)

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

Operators

| Use: winter barley, tractor mounted equipment, 1 application, rate 0.2 kg a.s./ha (0.8 L PPP/ha) |
| Exposure estimates (model): % of AOEL |
| UK POEM |
| Without PPE: | 367.4 |
| PPE (gloves during mixing/loading & application): | 54.1 |
| German model (geometric mean) |
| Without PPE: | 35.9 |

\(^3\) If available include also reference values for metabolites
### Classification with regard to toxicological data (Regulation (EU) No 283/2013, Annex Part A, Section 10)

| Substance          | Classification |
|--------------------|----------------|
| Trinexapac-ethyl   | None           |

#### Workers
- Crop inspection (without PPE): 11.0% (*German and EUROPOEM II worker re-entry model*)

#### Bystanders
- *German guidance paper, Martin et al, 2008:*
  - Adults: 2.0% of AOEL (1 meter)
  - Children: 1.6% of AOEL (1 meter)

#### Residents
- *German guidance paper, Martin et al, 2008:*
  - Adults: 0.2% of AOEL (1 meter)
  - Children: 0.4% of AOEL (1 meter)

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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.
Section 3 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) |
|--------------------------------------|-------------|---------|----------------|------------|
| OECD Guideline 501                   |             |         |                |            |
| Fruit crops                          |             |         |                |            |
| Root crops                           |             |         |                |            |
| Leafy crops                          |             |         |                |            |
| Cereals/grass crops                  | Wheat       | 0.211 kg/ha | 7, 34, 62 |            |
|                                      | Wheat       | 0.150 kg/ha | 0.5 h, 4 h, 1, 7, 14, 21 |            |
|                                      | Wheat       | 0.150 kg/ha | 0, 25, 48, 71 | Supplementary |
|                                      | Rice        | 0.040 kg/ha | 1 h, 7, 21, 82 |            |
|                                      | Grass       | 0.560 kg/ha | 60 |            |
| Pulses/Oilseeds                      | Oilseed rape | 0.393 kg/ha | 22, 46, 102 |            |
|                                      | Oilseed rape | 0.400 kg/ha | 0.5 h, 14, 65 | Supplementary |
| Miscellaneous                        |             |         |                |            |

All studies with $^{14}$C-cyclohexyl-trinexapac ethyl.
(a): Only seed analysed.

Metabolic pathways in all studies were comparable. Trinexapac ethyl is rapidly and extensively metabolised via hydrolysis to trinexapac.

A data gap identified for a plant metabolism study with the cyclopropyl label.

| Rotational crops (metabolic pattern) | Crop groups | Crop(s) | PBI (days) | Comments |
|-------------------------------------|-------------|---------|------------|----------|
| OECD Guideline 502                  |             |         |            |          |
| Root/tuber crops                    | Sugar beet  | 343, 407, 496$^{(a)}$ | Two studies with single bare soil application at 0.150 kg/ha (a) and 0.330 kg/ha (b) |
|                                     | Radish      | 30, 120, 309$^{(b)}$ |           |
| Leafy crops                         | Lettuce     | 99, 119$^{(a)}$ |           |
|                                     |             | 30, 120, 270$^{(b)}$ |           |
| Cereal (small grain)                | Wheat       | 173, 299, 343, 407$^{(a)}$ |           |
|                                     | Maize       | 369, 407, 496$^{(a)}$ |           |

Rotational crop and primary crop metabolism similar?

All studies with $^{14}$C-cyclohexyl-trinexapac ethyl.

A data gap identified to address the potential for uptake of residues bearing the cyclopropyl moiety in rotational crops.

| Processed commodities (standard hydrolysis study) | Conditions | Trinexapac-ethyl | CGA 179500 (trinexapac) | CGA 313458 | CGA 224439 | CGA 113745 |
|--------------------------------------------------|------------|------------------|------------------------|------------|------------|------------|
| 14C-cyclohexyl-trinexapac-ethyl                   | 20 min, 90°C, pH 4 | 99% | - | - | - | - |
|                                                  | 60 min, 100°C, pH 5 | 99% | - | - | - | - |
Residue pattern in processed commodities similar to residue pattern in raw commodities?

No. Nature of residues in processed commodities is different to the one in raw agricultural commodities.

A data gap was identified for further clarification to explain the contradictory findings (stability vs. instability) in the standardised hydrolysis experiments.

| Residue pattern in processed commodities | Nature of residues in processed commodities |
|-----------------------------------------|---------------------------------------------|
| Similar                                  | Different                                   |

Plant residue definition for monitoring (RD-Mo)

OECD Guidance, series on pesticides No 31

Plant residue definition for risk assessment (RD-RA)

- Trinexapac, free and conjugated (cereal grain) (provisional)
- Trinexapac, free and conjugated plus CGA300405 (cereal fodder items/grass) (expressed as trinexapac or separate, pending its toxicological relevance) (provisional)

Processed products: open

Conversion factor (monitoring to risk assessment)

| Cereal grain | 1.8 (median) |
|--------------|--------------|
| Cereal straw | open         |

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

| OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish) | Animal | Dose (mg/kg bw/d) | Duration (days) | N rate/comment |
|-------------------------------------------------------|--------|-------------------|-----------------|---------------|
| Animals covered                                       | Laying hen | 0.4 | 4 | Supplementary |
|                                                      |        | 20 | | |
|                                                      |        | 0.85 | 10 | 59 N |
|                                                      | Goat/Cow | 0.2 | 4 | Supplementary |
|                                                      |        | 20 | | |
|                                                      |        | 3 | 4 | 293 N |
|                                                      | Pig | | | |
|                                                      | Fish | | | |
|                                                      | | mg/kg DM | | |
All studies with $^{14}$C-cyclohexyl-trinexapac ethyl. Trinexapac ethyl is rapidly hydrolysed to trinexapac. CGA113745 was the only other metabolite identified in goat tissues (liver, kidney and fat). A data gap to address the nature of residues in livestock with regard to the cyclopropyl moiety was identified during the expert meeting.

| Time needed to reach a plateau concentration in milk and eggs (days) | Milk: 2-3 | Eggs: 2-8 |
|---|---|---|
| Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31 | Trinexapac and its salts, expressed as trinexapac. |
| Animal residue definition for risk assessment (RD-RA) | Poultry: trinexapac | Ruminant: trinexapac + metabolite CGA 113745, expressed as trinexapac (Provisional, pending the outcome of the cyclopropyl label metabolism study proposed in the expert meeting) |
| Conversion factor (monitoring to risk assessment) | Ruminants: provisional (based on the metabolism study): 1.25 (liver), 1.07 (kidney), 1.03 (muscle), 1.13 (fat), 1 (milk) | Poultry: n.a. |
| Metabolism in rat and ruminant similar (Yes/No) | Yes |
| Fat soluble residues (Yes/No) (FAO, 2009) | No |

**Residues in succeeding crops (Regulation (EU) No 283/2013, Annex Part A, point 6.6.2)**

| Confined rotational crop study | No individual extractable $^{14}$C-residue was found to be ≥ 0.01 mg/kg at any PBI, except at 30 days PBI for wheat foliage and hay and immature and mature lettuce (0.02 mg/kg) from the metabolism studies in rotational crops with $^{14}$C-cyclohexyl-trinexapac ethyl (1.65N the highest application rate under consideration). A data gap to address the potential for uptake of residues bearing the cyclopropyl moiety in rotational crops. |
|---|---|
| (Quantitative aspect) OECD Guideline 502 | |
| Field rotational crop study OECD Guideline 504 | Pending metabolism in rotational crops with cyclopropyl- radiolabelled compound. |
### Stability of residues (Regulation (EU) No 283/2013, Annex Part A, point 6.1)

**OECD Guideline 506**

| Plant products (Category) | Commodity       | T (°C) | Stability (Month) |
|--------------------------|-----------------|--------|------------------|
|                          |                 |        | Trinexapac  | CGA 313458 | CGA 113745 | CGA 224439 |
| High water content       |                 |        |              |           |           |           |
| High oil content         | Rapeseed seeds  | -18    |              | 24        |           |           |
| High protein content     |                 |        |              |           |           |           |
| High starch content      | Wheat grain     | -18    | 24           | 12        | 1         | 12        |
| High acid content        |                 |        |              |           |           |           |
| Processed products       | Beer            | -18    |              | 12        | 1         | 12        |
|                          | Bran            | -18    |              | 6         | 1         | 12        |
|                          | Flour           | -18    |              | 3         | 1         | 12        |
|                          | Bread           | -18    |              | 6         | 1         | 12        |

The stability of trinexapac in wheat straw at -18°C was 12 months.

CGA113475 was unstable in the presence of crop matrices - degrading to only 20% of the initial amount over 30 days.

| Animal | Animal commodity | T (°C) | Stability (Month/Year) |
|--------|------------------|--------|------------------------|
| Bovine | Muscle           | -18    | 3 months               |
| Bovine | Liver            | -18    | 3 months               |
| Bovine | Kidney           | -18    | 3 months               |
| Bovine | Milk             | -18    | 4 months               |
|        | Egg              |        |                        |
## Summary of residues data from the supervised residue trials (Regulation (EU) No 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

| Crop          | Region/Indoor | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) (c) | STMR (mg/kg) (d) |
|---------------|---------------|------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|----------------|-----------------|
| **Representative uses** |               |                                                                                               |                                             |                      |                |                 |
| Barley grain  | NEU           | **Mo**: 2 x<0.01; 0.04; 2 x 0.12  
**RA**: 0.01; 0.02; 0.13; 0.26; 0.27 | A total of 5 GAP-compliant acceptable trials (two trials giving residues of 0.03 mg/kg not sufficiently covered by storage stability data were excluded from the calculations). Number not sufficient to derive a MRL proposal. |                      |                |                 |
|               | SEU           | **Mo**: 0.01; 0.03; 0.06; 0.14; 0.16; 0.47; 0.49  
**RA**: 0.02; 0.06; 0.14; 0.17; 0.32; 0.90 | A total of 5 GAP-compliant plus 2 overdosed acceptable trials (one trial giving RA scaled residue of 0.72 mg/kg not sufficiently covered by storage stability data was excluded from the calculations). Complete dataset adjusted to 1N application rate. Scaled values are double-underlined. Number not sufficient to derive a MRL proposal. |                      |                |                 |
| Wheat grain   | NEU           | **Mo**: 0.03; 2x0.05; 0.06; 0.07; 0.08; 0.09; 0.11; 0.22; 0.24; 0.37  
**RA**: 0.01; 0.04; 4x0.06; 0.07; 0.10; 0.17; 0.23; 0.36 | A total of 11 GAP-compliant acceptable trials.  
MRL\textsubscript{OECD}: 0.55 (unrounded) | 0.6 | 0.36 (HR\textsubscript{Mo}: 0.37) | 0.06 (STMR\textsubscript{Mo}: 0.08) |
|               | SEU           | **Mo**: 3x0.03; 2x0.05; 2x0.06; 0.08; 0.15; 0.27  
**RA**: 0.03; 0.04; 3x0.08; 0.09; 0.11; 0.12; 0.19; 0.43 | A total of 8 GAP-compliant plus 2 overdosed acceptable trials. Complete dataset adjusted to 1N application rate. Scaled values are double-underlined.  
MRL\textsubscript{OECD}: 0.38 (unrounded) | 0.4 | 0.43 (HR\textsubscript{Mo}: 0.27) | 0.09 (STMR\textsubscript{Mo}: 0.06) |
| NEU/SEU       |               | **Mo**: 4x0.03; 4x0.05; 3x0.06; 0.07; 2x0.08; 0.09; 0.12; 0.15; 0.22; 0.23; 0.27; 0.39  
**RA**: 0.01; 0.03; 2x0.04; 4x0.06; 0.07; 3 x 0.08; 0.09; 0.11; 0.11; 0.12; 0.18; 0.19; 0.23; 0.35; 0.43 | Combined datasets (U-test, 5%). Complete NEU and SEU datasets adjusted to 1N application rate. Scaled values are double-underlined. | 0.5 | 0.43 (HR\textsubscript{Mo}: 0.39) | 0.08 (STMR\textsubscript{Mo}: 0.06) |
### Crop Residue Levels and Recommendations/Comments

| Crop             | Region/Indoor | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) | STMR (mg/kg) |
|------------------|---------------|-----------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|------------|-------------|
| Barley straw     | NEU           | Mo: 0.01; 0.01; 0.02; 2 x 0.04 RA: - trinexapac (free & conj): 3 x <0.05; 0.07; 0.09 <br>CGA300405: not analysed for | Number of trials not sufficient to derive input values for the dietary burden calculation. Values in straw for which storage stability was not demonstrated are underlined | -                     | -          | -           |
|                  | SEU           | Mo: 2 x<0.01; 0.02; 0.03; 0.04; 0.08; 0.32 RA: - trinexapac (free & conj): 2 x 0.05; 0.07; 0.07; 0.25; 0.26; 0.28 <br>CGA300405: not analysed for | Number of trials not sufficient to derive input values for the dietary burden calculation. Values in straw for which storage stability was not demonstrated are underlined | -                     | -          | -           |
| Wheat straw      | NEU           | Mo: 4 x<0.01; 3 x 0.01; 2 x 0.02; 0.03; 0.07 RA: - trinexapac (free & conj): 4 x <0.05; 7 x <0.05 <br>CGA300405: not analysed for | STMR/HR tentative. Calculated only for trinexapac (free & conjugated) including also residue levels from trials not fully covered by demonstrated storage stability (underlined) | -                     | 0.05       | 0.05 (STMR<sub>Mo</sub>: 0.01) |
|                  | SEU           | Mo: 5x<0.01; 0.01; 0.03; 0.05; 0.08; 0.09 RA: - trinexapac (free & conj): 6 x <0.05; 0.05; 0.03; 0.09; 0.18 <br>CGA300405: not analysed for | STMR/HR tentative. Calculated only for trinexapac (free & conjugated) including also residue levels from trials not fully covered by demonstrated storage stability (underlined). Adjusted to 1N application rate. Scaled values are double-underlined. | 0.18 (HR<sub>Mo</sub>: 0.09) | 0.05 (STMR<sub>Mo</sub>: 0.01) |
|                  | NEU/SEU       | Mo: 9 x <0.01; 4 x 0.01; 2 x 0.02; 2 x 0.03; 0.05; 0.07; 0.08; 0.09 RA: - trinexapac (free & conj): 4 x <0.05; 13 x <0.05; 0.05; 0.03; 0.09; 0.17 | STMR/HR tentative. Calculated only for trinexapac (free & conjugated) and including also residue levels from trials not fully covered by demonstrated storage stability (underlined). Combined datasets adjusted to 1N application rate. Scaled values are double-underlined. | 0.17 (HR<sub>Mo</sub>: 0.09) | 0.05 (STMR<sub>Mo</sub>: 0.01) |

### MRL application

| MRL application | Rye grain | NEU + SEU | No data provided | Extrapolation from wheat possible | 0.5 | 0.43 | 0.08 |
| Crop            | Region/Indoor | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) | STMR (mg/kg) |
|-----------------|---------------|---------------------------------------------------------------------------------------------|-----------------------------------------------|-----------------------|------------|-------------|
| Rye straw       | NEU + SEU     | No data provided                                                                            | See wheat results and calculations            |                       | 0.17       | 0.05        |

**Summary of the data on formulation equivalence OECD Guideline 509**

| 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)*.

**Confirmatory data MRL review**

| Beans dry | Region | Residue levels (mg/kg) | Recommendations/comments |
|-----------|--------|------------------------|-------------------------|

Residue trials compliant with the GAP *(n 7)*. In italics, trials already assessed *(EFSA, 2012)*. Number of trials not sufficient to derive a MRL proposal.
Inputs for animal burden calculations

| Feed commodity       | Median dietary burden (mg/kg) | Comment | Maximum dietary burden (mg/kg) | Comment |
|----------------------|-------------------------------|---------|-------------------------------|---------|

### Residue definition for risk assessment in plants
- Trinexapac, free and conjugated (cereal grain, provisional)
- Trinexapac, free and conjugated, plus CGA300405 (cereal/grass feed items, provisional)

### Representative uses

| Feed commodity          | Median dietary burden (mg/kg) | Comment                          | Maximum dietary burden (mg/kg) | Comment                          |
|-------------------------|-------------------------------|----------------------------------|-------------------------------|----------------------------------|
| Wheat, straw            | 0.05                          | Median residue (tentative)       | 0.17                          | Highest residue (tentative)      |
| Wheat, grain            | 0.08                          | Median residue                   | 0.08                          | Median residue                   |
| Distillers’ grain       | 0.26                          | Median residue × default PF (3.3) | 0.26                          | Median residue × default PF (3.3) |
| Wheat gluten, meal      | 0.14                          | Median residue × default PF (1.8) | 0.14                          | Median residue × default PF (1.8) |
| Wheat, milled by-products | 0.56                         | Median residue × default PF (7)  | 0.56                          | Median residue × default PF (7)  |

### MRL application

| Feed commodity          | Median dietary burden (mg/kg) | Comment                          | Maximum dietary burden (mg/kg) | Comment                          |
|-------------------------|-------------------------------|----------------------------------|-------------------------------|----------------------------------|
| Rye, straw*             | 0.05                          | Median residue (tentative)       | 0.17                          | Highest residue (tentative)      |
| Rye, grain*             | 0.08                          | Median residue                   | 0.08                          | Median residue                   |

(a) Levels of trinexapac (free and conjugated) in straw are derived from combined datasets with major part of the samples not supported by storage stability. Contribution of metabolite CGA300405 residues not considered.
**Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)**

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

| MRL calculations | Ruminant | Pig/Swine | Poultry | Fish |
|------------------|----------|-----------|---------|------|
| **Highest expected intake**<br>(mg/kg bw/d)<br>(mg/kg DM for fish) | | | | |
| Beef cattle | 0.006 | | | |
| Dairy cattle | 0.010 | | | |
| **Intake >0.004 mg/kg bw**<br>**Feeding study submitted**<br>Yes (cattle)<br>No<br>Refer to cattle study | Yes | No | No | Yes |
| **Representative feeding level**<br>(mg/kg bw/d, mg/kg DM for fish) and N rates | | | | |
| Beef: 10.6N | Level: 0.068 | | | |
| Dairy: 6.6 N | Level: 0.068 | | | |
| Ewe: 5.8N | Level: 0.068 | | | |
| Lamb: 3.9 N | Level: 0.068 | | | |
| **Muscle**<br>Estimated HR<sup>a</sup> at 1N | <0.01 | <0.01 | <0.01 | 0.01* |
| **Fat**<br>Estimated HR<sup>a</sup> at 1N | <0.01 | <0.01 | <0.01 | <0.01 |
| **Meat**<sup>b</sup><br>Estimated HR<sup>a</sup> at 1N | <0.01 | <0.01 | <0.01 | <0.01 |
| **Liver**<br>Estimated HR<sup>a</sup> at 1N | <0.01 | <0.01 | <0.01 | <0.01 |
| **Kidney**<br>Estimated HR<sup>a</sup> at 1N | <0.01 | <0.01 | <0.01 | <0.01 |
| **Milk**<sup>a</sup><br>Estimated HR<sup>a</sup> at 1N | <0.01 | <0.01 | <0.01 | <0.01 |
| **Eggs**<br>Estimated HR<sup>a</sup> at 1N | <0.01 | <0.01 | <0.01 | <0.01 |
| **Method of calculation**<sup>c</sup> | Tf | Tf | Tf | |

<sup>a</sup> Estimated HR calculated at 1N level (estimated mean level for milk).

<sup>b</sup> HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry.

<sup>c</sup> 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 extrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.
## STMR calculations

| Median expected intake (mg/kg bw/d) (mg/kg DM for fish) | Ruminant | Pig/Swine | Poultry | Fish |
|--------------------------------------------------------|----------|-----------|---------|------|
| Beef cattle                                            | 0.0057   | 0.0101    | 0.008   | Beef: 12 N |
| Dairy cattle                                           | 0.0092   | 0.0154    | 0.011   | Dairy: 7.5N |
| Ram/Ewe                                               |          |           |         | Ewe: 6.8N |
| Lamb                                                   |          |           |         | Lamb: 4.5N |
| Breeding                                               |          |           |         | Level 0.68 |
| Finishing                                              |          |           |         | 8.5/6.2N |
| Breeding/Finishing                                     |          |           |         | Level 0.85 |
| Layer                                                  |          |           |         | Broiler: 63.1N |
| Finishing                                              |          |           |         | Layer: 63.1N |
| Turkey                                                 |          |           |         | Level 0.85 |
|                                                      |          |           |         | Carp/Trout |

| Representative feeding level (mg/kg bw/d. mg/kg DM for fish) and N rates |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| Level 0.068                 | Beef: 12 N                 | Level 0.068                 | Ewe: 6.8N                   | Level 0.85                  |
| Dairy: 7.5N                 |                            | Lamb: 4.5N                 |                            | Broiler: 63.1N              |
|                            |                            |                            | 8.5/6.2N                   | Layer: 63.1N                |
|                            |                            |                            | Level 0.85                  | Turkey: 63.1N               |

| Method of calculation (c)  | Tf                          | Tf                          | Tf                          | Tf                          |
|---------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| (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 intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals. |
Conversion Factors (CF) for monitoring to risk assessment

Plant products

| Mean Conversion Factors (CF) calculated at the different PHIs in the supervised residues trials\(^{(a)}\) | OECD Guidance, series on Pesticides No 66 | Comments |
|---|---|---|
| **Representative uses** | | |
| Barley grain | NEU: 2.00  
SEU: 2.00 | Based on the data on wheat and barley, the proposed median conversion factors for small grain cereals is: 1.8 |
| Wheat grain | NEU: 0.86  
SEU: 1.60 | |
| Barley straw | NEU: open  
SEU: open | |
| Wheat straw | NEU: open  
SEU: open | |
| **MRL application** | | |
| Rye grain | - | See as above |

No studies provided for rye, extrapolated from wheat.

\(^{(a)}\): CF calculated at the supported PHI are underlined.

\(^{(b)}\): 0/-0+ for samples collected just before/after the last application
Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)
OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

| Crop (RAC)/Edible part or Crop (RAC)/Processed product | Number of studies (a) | Processing Factor (PF) | Conversion Factor (CF_P) for RA (c) |
|--------------------------------------------------------|-----------------------|------------------------|------------------------------------|
|                                                        |                       | Individual values      | Median PF Mo/RA (b)               |

Representative uses
Residue definition in processed products: open

MRL application

(a): Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration).
(b): Mo - The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(c): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

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).

The risk assessment is indicative only, considering the missing information to finalise the residue definitions in primary crops, processed products and products of animal origin, the data gap identified in the residue section and pending submission of toxicological information for major metabolites in feed items and in processed products.

ADl
0.32 mg/kg bw per day

TMDI according to EFSA PRIMo
Highest TMDI: 1.6% ADI (DK, child)

NTMDI, according to (to be specified)
Highest NTMDI: not calculated

IEDI (% ADI), according to EFSA PRIMo
Highest IEDI: 0.2% ADI (DK, child)

NEDI (% ADI), according to (to be specified)
(not calculated)

Factors included in the calculations

ARfD
Not allocated

IESTI (% ARfD), according to EFSA PRIMo

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

Factors included in IESTI and NESTI

Additional contribution to the consumer intakes through drinking water resulting from groundwater metabolite(s) expected to be present above 0.75 µg/L
Not relevant for metabolites of trinexapac-ethyl

Consumer risk assessment limited to the representative uses

TMDI according to EFSA PRIMo
1.3% ADI (WHO Cluster diet B)

NTMDI, according to (to be specified)
not calculated

IEDI (% ADI), according to EFSA PRIMo
0.2% ADI (WHO Cluster diet B)

NEDI (% ADI), according to (to be specified)
(not calculated)

Factors included in the calculations

IESTI (% ARfD), according to EFSA PRIMo

NESTI (% ARfD), according to (to be specified)
Factors included in IESTI and NESTI

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**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** | | |
| 0500010 | Barley | - | Not supported |
| 0500090 | Wheat | 0.5 | Based on combined NEU/SEU data |
| **MRL application** | | |
| 0500070 | Rye | 0.5 | Based on wheat combined NEU/SEU data | Extrapolation from wheat. **Current MRL is 0.5 mg/kg**. |
| **Confirmatory data following the review of existing MRLs** | | |
| 0300010 | Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas) | 9 or 10 | Risk Managers to decide whether to decrease the MRL to 9 mg/kg as only the SEU use is fully supported or to maintain the existing MRL of 10 mg/kg. |

(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.
## Section 4 Environmental fate and behaviour

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

| Environmental Fate and Behaviour | Mineralisation after 100 days | Non-extractable residues after 100 days |
|----------------------------------|-------------------------------|----------------------------------------|
|                                  | 58.0% after 90 d [1,2,6-\(^{14}\)C]-label (n = 1) | 6.8 % after 90 d [1,2,6-\(^{14}\)C]-label (n = 1) |
|                                  | 84.6% after 28 d, [3,5,\(-14\)C]cyclohexane[\(^{14}\)C]carboxylic acid ethyl ester]-label (n = 3) | 10% after 28 d [3,5-\(^{14}\)C]cyclohexane[\(^{14}\)C]carboxylic acid ethyl ester]-label (n = 3) |
|                                  | 65.6% after 32 d [cyclohexanedione-1,2,6-\(^{14}\)C]-label (n = 5) | 32.9% after 60 d [cyclohexanedione-1,2,6-\(^{14}\)C]-label (n = 5) |
|                                  | 66.8% after 28 d [cyclopropylhydroxy[\(^{14}\)C]methylene]-label (n = 3) | 31.1% after 28 d [cyclopropylhydroxy[\(^{14}\)C]methylene]-label (n = 3) |
| Metabolites requiring further consideration | CGA179500: 93.1% at 3 d (n = 12) | CGA179500: max 86.7% AR at 121 d (n=4) |
|                                  | [1,2,6-\(^{14}\)C] & [3,5-\(^{14}\)C]cyclohexane[\(^{14}\)C]carboxylic acid ethyl ester] & [cyclohexanedione-1,2,6-\(^{14}\)C] & [cyclopropylhydroxy[\(^{14}\)C]methylene] labels |

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

| Environmental Fate and Behaviour | Mineralisation after 100 days | Non-extractable residues after 100 days |
|----------------------------------|-------------------------------|----------------------------------------|
|                                  | 8.5% AR after 121 d [cyclohexanedione-1,2,6-\(^{14}\)C] label (n=4) | 13.3% AR after 121 d [cyclohexanedione-1,2,6-\(^{14}\)C] label (n=4) |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | CGA179500: max 86.7% AR at 121 d (n=4) | |
|                                  | [cyclohexanedione-1,2,6-\(^{14}\)C] label |

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

| Environmental Fate and Behaviour | Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) |
|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
|                                  | Dry soil conditions [cyclohexyl-1,2,6-\(^{14}\)C ]-label (n = 1): |
|                                  | CGA179500: max 22.8% at 2 d |
|                                  | CGA300405 max 12.5% at 2 d |
|                                  | CGA275537 max 10.8% at 2 d |
|                                  | Moist soil conditions [cyclohexyl-1,2,6-\(^{14}\)C ]-label (n = 1): |
|                                  | CGA179500: max 61.5% at 2 d |
|                                  | CGA275537 max 6.5% at 1 d |
| Mineralisation at study end      | 48.7% after 17 d, [cyclohexyl-1,2,6-\(^{14}\)C]-label (n= 2*) |
| Non-extractable residues at study end | 44.8 % after 17 d, [cyclohexyl-1,2,6-\(^{14}\)C]-label (n= 2*) |
**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)**

| Soil type                  | Dark aerobic conditions                                      |
|----------------------------|-------------------------------------------------------------|
| **Trinexapac-ethyl**       | **pH** | **T °C / % MWHC** | **DT\textsubscript{50}/ DT\textsubscript{90} (d)** | **St. (χ\textsuperscript{2})** | **Method of calculation** | **DT\textsubscript{50} (d) 20 °C pF2/10kP** | **St. (χ\textsuperscript{2})** | **Method of calculation** |
| Loam (Vouvry I)           | 7.1    | 20 / pF 2.0 to 2.5 | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} |
| sandy loam (Vouvry II)    | 7.2    | 20 / pF 2.0 to 2.5 | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} |
| loamy sand (Borstel)      | 6.4    | 20 / pF 2.0 to 2.5 | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} |
| loam (Gartenacker)        | 7.26   | 20.6 / pF 2       | 0.04 / 0.15             | 1.0 | DFOP | 0.046 | 4.8 | SFO |
| sandy Clay loam (18 Acres)| 6.47   | 20.6 / pF 2       | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} |
| Clay loam (Capay)         | 6.6    | 20.6 / pF 2       | 0.72 / 2.4              | 2   | SFO  | 0.72  | 2   | SFO |
| silt loam (Sarpy)         | 6.7    | 20.6 / pF 2       | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} |
| sandy loam (East Anglia)  | 6.9    | 20.6 / pF 2       | 0.013 / 0.22            | 1.4 | DFOP | 0.045\textsuperscript{e)} | 19.7 | FOMC |
| silt loam (Filsis)        | 7.3    | 20.6 / pF 2       | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} |
| sandy loam (Speyer 2.3)   | 6.4    | 20.6 / pF 2       | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} |
| loamy sand (Borstel)      | 6.7    | 20.6 / pF 2       | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} | .\textsuperscript{c)} |
| sandy Loam (Maryland I)   | 7.2\textsuperscript{a)} | 25 / 75% FC of 1/3 bar | 0.14 / 0.71             | 10.3 | FOMC | 0.19\textsuperscript{b)} | 12.7 | SFO |

**Geometric mean (if not pH dependent)**: 0.13

**pH dependence**: No

*\textsuperscript{a)} Measured in calcium chloride solution

*\textsuperscript{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

*\textsuperscript{c)} Due high percent of bound residues DT\textsubscript{50} values based on extractable trinexapac-ethyl were considered unreliable

*\textsuperscript{d)} No medium was specified

*\textsuperscript{e)} Back-calculate DT\textsubscript{50} from DT\textsubscript{90} for FOMC (DT\textsubscript{50} = DT\textsubscript{90} / 3.32)
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)

| CGA179500 | Dark aerobic conditions, parent applied |
|-----------|----------------------------------------|
| Soil type | pH<sup>a</sup> | T °C / % MWHC | DT<sub>50</sub>/ DT<sub>90</sub> (d) | St. (<chi squared>) | Method of calculation | DT<sub>50</sub> (d) 20 °C pF2/10kPa | f. f. k<sub>i</sub> / k<sub>k</sub> | St. (<chi squared>) | Method of calculation |
| Loam (VouvryI) | 7.1 | 20 / pF 2.0 to 2.5 | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> |
| Sandy loam (Vouvry II) | 7.2 | 20 / pF 2.0 to 2.5 | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> |
| Loamy sand (Borstel) | 6.4 | 20 / pF 2.0 to 2.5 | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> |
| Loam (Gartenacker) | 7.26 | 20.6 / pF 2 | 1.7 / 5.7 | 7.85 | DFOP-SFO | 2.7 | 0.77 | 11.4 | SFO-SFO |
| Sandy Clay Loam (18 Acres) | 6.47 | 20.6 / pF 2 | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> |
| Clay loam (Capay) | 6.6 | 20.6 / pF 2 | 7.7 / 25.6 | 21.7 | SFO-SFO | 7.7 | 0.57 | 21.7 | SFO-SFO |
| Silt loam (Sarpy) | 6.7 | 20.6 / pF 2 | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> |
| Sandy loam (East Anglia) | 6.9 | 20.6 / pF 2 | 1.0 / 3.33 | 5.2 | DFOP-SFO | 1.0 | 0.82 | 5.7 | FOMC-SFO |
| Silt loam (Filsis) | 7.3 | 20 / pF 2.0 to 2.5 | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> |
| Sandy loam (Speyer 2.3) | 6.4 | 20 / pF 2.0 to 2.5 | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> |
| Loamy sand (Borstel) | 6.7 | 20 / pF 2.0 to 2.5 | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> | -<sup>c</sup> |
| Sandy Loam (Maryland I) | 7.2 | 25 / 75% FC of 1/3 bar | 32 / 106 | 10.8 | FOMC-SFO | 39.5<sup>e</sup> | 1 | 11.8 | SFO-SFO |

Geometric mean (if not pH dependent) | 5.4 |
Worst case assumption | 1 |

pH dependence | No |

<sup>a</sup> Measured in calcium chloride solution
<sup>b</sup> No medium was specified
<sup>c</sup> Due high percent of bound residues DT<sub>50</sub> values based on extractable trinexapac-ethyl were considered unreliable
<sup>d</sup> Acceptable fit was not obtained
<sup>e</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
| Soil type                          | pH<sup>a</sup> | T °C / % MWHC | DT<sub>50</sub>/DT<sub>90</sub> (d) | f. f. k<sub>f</sub> / k<sub>dp</sub> | Method of calculation | DT<sub>50</sub> (d) 20 °C pF2/10kPa<sup>b</sup> | St. (χ²) | Method of calculation |
|-----------------------------------|----------------|---------------|----------------------------------|------------------------------------|-----------------------|-----------------------------------------------|----------|-----------------------|
| 18 Acres (Clay loam)              | 6.1            | 20°C / pF 2   | 0.08 / 1.71                       | -                                  | FOMC                  | 0.52<sup>c</sup>                             | 7.9      | FOMC                  |
| East Anglia (Sandy loam)          | 7.0            | 20°C / pF 2   | 0.03 / 0.37                       | -                                  | DFOP                  | 0.11<sup>c</sup>                             | 6.0      | FOMC                  |
| Gartenacker (Loam)                | 7.0            | 20°C / pF 2   | 0.06 / 0.45                       | -                                  | HS                    | 0.21<sup>d</sup>                             | 10.7     | HS                    |

Geometric mean                         |                |               |                                   |                                    |                       | 0.23                                           |          |                       |

Arithmetic mean                        |                |               |                                   |                                    |                       |                                                |          |                       |

pH dependence                          |                |               |                                   |                                    |                       | No                                             |          |                       |

<sup>a</sup> Measured in calcium chloride solution
<sup>b</sup> Normalised using a Q<sub>10</sub> of 2.58 and Walker equation coefficient of 0.7
<sup>c</sup> As degradation is described by FOMC kinetics, DT<sub>50</sub> = DT<sub>90</sub>/3.32
<sup>d</sup> As degradation is described by HS kinetics, DT<sub>50</sub> = ln<sub>2</sub>/k<sub>2</sub> where k<sub>2</sub> is the rate constant of the slow phase
<sup>e</sup> Back-calculate DT50 from DT90 for FOMC (DT50 = DT90 / 3.32)

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| Soil type                          | pH<sup>a</sup> | T °C / % MWHC | DT<sub>50</sub>/DT<sub>90</sub> (d) | f. f. k<sub>f</sub> / k<sub>dp</sub> | Method of calculation | DT<sub>50</sub> (d) 20 °C pF2/10kPa<sup>b</sup> | St. (χ²) | Method of calculation |
|-----------------------------------|----------------|---------------|----------------------------------|------------------------------------|-----------------------|-----------------------------------------------|----------|-----------------------|
| 18 Acres (Sandy clay loam)        | 6.6            | 20°C / pF 2   | 0.27 / 0.91                      | -                                  | SFO                   | 0.27                                          | 4.29     | SFO                   |
| East Anglia (Sandy loam)          | 7.1            | 20°C / pF 2   | 0.21 / 0.7                       | -                                  | SFO                   | 0.21                                          | 6.92     | SFO                   |
| Gartenacker (Loam)                | 7.2            | 20°C / pF 2   | 0.17 / 0.56                      | -                                  | SFO                   | 0.17                                          | 4.2      | SFO                   |

Geometric mean                         |                |               |                                   |                                    |                       | 0.21                                           |          |                       |

Arithmetic mean                        |                |               |                                   |                                    |                       |                                                |          |                       |

pH dependence                          |                |               |                                   |                                    |                       | No                                             |          |                       |

<sup>a</sup> Measured in calcium chloride solution
<sup>b</sup> 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 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

| Parent | Aerobic conditions |
|--------|-------------------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). |
| X^6 | pH^a | Depth (cm) | DT_{50} (d) actual | DT_{90} (d) actual | St. (χ^2) | DT_{50} (d) Norm^b) | Method of calculation |
| | | | | | | | |
| Geometric mean (if not pH dependent) | | | | | | | |
| 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

^6 X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.
Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

| Endpoint                                                                 | Value |
|--------------------------------------------------------------------------|-------|
| Rate of degradation in soil active substance, normalised geometric mean  | --    |
| Rate of degradation in soil transformation products, normalised geometric mean | --    |
| Kinetic formation fraction (f.f. $k_f / k_dp$) of transformation products, arithmetic mean | -- |

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

Soil accumulation (Regulation (EU) No. 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) No. 284/2013, Annex Part A, point 9.1.1.2.2)

| Endpoint                                                      | Value              |
|---------------------------------------------------------------|--------------------|
| Soil accumulation and plateau concentration                   | No triggered not relevant |

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) No. 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) No. 284/2013, Annex Part A, point 9.1.1.1)

| Trinexapac-ethyl | Dark anaerobic conditions |
|------------------|--------------------------|
| Soil type        | pH<sup>a</sup> | t. °C / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) | DT<sub>50</sub> (d) 20 °C<sup>b</sup> | St. ($\chi^2$) | Method of calculation |
| Loam (Gartenacker) | 7.3 | 20.9 / pF2 | 0.3 / 1.0 | - <sup>c</sup> | 15.6 | SFO |
| Sandy Clay Loam (18 Acres) | 6.0 | 20.9 / pF2 | 0.7 / 2.4 | - <sup>c</sup> | 14.3 | SFO |
| Clay loam (Capay) | 6.6 | 20.9 / pF2 | 2.0 / 6.7 | - <sup>c</sup> | 9.2 | SFO |
| Silt loam (Sarpy) | 6.7 | 20.9 / pF2 | 0.6 / 2.1 | - <sup>c</sup> | 10.6 | SFO |

Geometric mean (if not pH dependent) -

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<sup>a</sup> Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b</sup> Normalised using a Q10 of 2.58

<sup>c</sup> Due study deficiencies degradation rate should not be used for the risk assessment but for indicative value only
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)

| Met 1 | Dark anaerobic conditions | Metabolite dosed or the precursor from which the f.f. was derived was xxx. |
|-------|---------------------------|---------------------------------------------------------------------|
| Soil type | pH<sup>a</sup> | t. °C / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) | f. f. | DT<sub>50</sub> (d) | 20°C<sup>b</sup> | St. | (χ²) | Method of calculation |
| - | - | - | - | - | - | - | - | - | - |

Geometric mean (if not pH dependent)

Arithmetic mean

<sup>a</sup> Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b</sup> Normalised using a Q10 of 2.58

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

| Trinexapac-ethyl | Soil photolysis |
|------------------|-----------------|
| Soil type | pH<sup>a</sup> | t. °C / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) calculated from 30 to 50°N | St. | (χ²) | Method of calculation |
| Dry soil conditions | - | - | - | - | - | - |
| Loam (Gartenacker) | 7.2 | 20±2°C | 5.7 / 19.0 b) | 17.2 | SFO |
| Moist soil conditions | - | - | - | - | - | - |
| Loam (Gartenacker) | 7.2 | 20±2°C | 0.7 / 2.2 b) | 3.9 | SFO |

<sup>a</sup> Measured in calcium chloride solution

<sup>b</sup> Provided as indicative values
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)

| Soil Type       | OC % | Soil pH | K_d (mL/g) | K_\text{doc} (mL/g) | K_F (mL/g) | K_Foc (mL/g) | 1/n |
|-----------------|------|---------|------------|---------------------|------------|-------------|-----|
| Clay            | 2.8  | 5.9     | -          | -                   | 17.77      | 629         | 0.92|
| Sand            | 0.5  | 6.5     | -          | -                   | 1.50       | 289         | 1.01|
| Loam            | 0.5  | 6.7     | -          | -                   | 0.67       | 143         | 0.92|
| Sandy loam      | 1.1  | 7.5     | -          | -                   | 0.66       | 60          | 0.92|
| Worst case value|      |         |            |                     |            |             | 60  |
| Associated with worst case K_Foc value | | | | | | | 0.92 |
| pH dependence  |      |         |            |                     |            |             | Yes |

a) Medium is not stated

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)

| Soil Type                  | OC % | Soil pH | K_d (mL/g) | K_\text{doc} (mL/g) | K_F (mL/g) | K_Foc (mL/g) | 1/n |
|----------------------------|------|---------|------------|---------------------|------------|-------------|-----|
| CGA179500                  |      |         |            |                     |            |             |     |
| Clay                       | 2.8  | 5.9     | -          | -                   | 16.4       | 581         | 0.92|
| Sand                       | 0.5  | 6.5     | -          | -                   | 3.22       | 609         | 0.85|
| Loam                       | 0.5  | 6.7     | -          | -                   | 1.54       | 328         | 0.90|
| Sandy loam                 | 1.1  | 7.5     | -          | -                   | 1.61       | 145         | 0.90|
| Worst case value           |      |         |            |                     |            |             | 145 |
| Associated with worst case K_Foc value | | | | | | | 0.90 |
| pH dependence              |      |         |            |                     |            |             | Yes |

a) Medium is not stated

| Soil Type                  | OC % | Soil pH | K_d (mL/g) | K_\text{doc} (mL/g) | K_F (mL/g) | K_Foc (mL/g) | 1/n |
|----------------------------|------|---------|------------|---------------------|------------|-------------|-----|
| CGA300405                  |      |         |            |                     |            |             |     |
| Gartenacker (loam)         | 3.6  | 7.0     | - b)       | - b)                | - b)       | - b)        | - b) |
| 18 Acres (sandy clay loam) | 3.4  | 6.1     | - b)       | - b)                | - b)       | - b)        | - b) |
| East Anglia (sandy loam)   | 3.6  | 7.0     | - b)       | - b)                | - b)       | - b)        | - b) |
| Sarpy (loamy sand)         | 1.2  | 5.6     | - b)       | - b)                | - b)       | - b)        | - b) |
| Seven Spring (silt loam)   | 3.6  | 6.6     | - b)       | - b)                | - b)       | - b)        | - b) |
| Geometric mean (if not pH dependent) |   |         |            |                     |            |             |     |
| Arithmetic mean (if not pH dependent) | | | | | | |     |
| pH dependence              |      |         |            |                     |            |             |     |

a) Measured in calcium chloride solution
Reliable mobility data could not be generated due to the high instability of photolytic metabolite CGA300405 in soil-water systems. Therefore, the Kfoc was determined using QSPR method (using KOCWIN™) = 1 mL/g.

| Soil Type                | OC % | Soil pH | Kd (mL/g) | Koc (mL/g) | Kf (mL/g) | Kfoc (mL/g) | 1/n |
|--------------------------|------|---------|-----------|------------|-----------|-------------|-----|
| Gartenacker (loam)       | 2.0  | 7.2     | 0.08      | 3.75       | 0.087     | 4.35        | 0.71|
| 18 Acres (sandy clay loam) | 2.5  | 5.9     | 1.36      | 54.2       | 1.32      | 52.8        | 0.68|
| East Anglia (sandy loam) | 1.9  | 7.1     | 0.26      | 13.5       | 0.27      | 14.0        | 0.83|
| Sarpy (loamy sand)       | 2.3  | 6.5     | 0.43      | 18.7       | 0.47      | 20.4        | 0.83|
| Seven Spring (silt loam) | 0.54 | 5.2     | 5.84      | 1081       | 6.7       | 1241        | 0.76|
| Worst case value         |      |         |           |            |           | 4.35        |     |
| Associated with worst case KFoc value | | | | | | 0.71|
| pH dependence            |      |         |           |            |           |             | Yes |

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

| Column leaching | No data available |
|-----------------|-------------------|
|                  | Not required, no further data were generated |

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

| Column leaching | No data available |
|-----------------|-------------------|
|                  | Not required, no further data were generated |

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

| Location: Vouvry, Switzerland |
| Study type: field leaching study |
| Soil properties: loamy sand, pH = 7.6, OM = 1.8, MWHC = not stated |
| Dates of application: 14 May 1993 |
| Crop: wheat /Interception not estimated: BBCH 32 |
| Number of applications: one application per year |
| Duration: 329 days |
| Application rate: 125 g a.i./ha/year |
| Cumulative annual rainfall (mm): 1027 mm, 132% of the long-term average |
Average annual leachate volume (mm): information not available
% radioactivity in leachate (maximum/year): < 0.5 % AR
Individual annual maximum concentrations (1st yr): < 0.05 µg/L CGA179500.

Location: Vouvry, Switzerland
Study type: field leaching study, prolongation of the previous study
Soil properties: loamy sand, pH = 7.6, OM = 1.8, MWHC = not stated
Dates of application: 3 May 1994
Crop: wheat /Interception not estimated: BBCH 33
Number of applications: one application per year
Duration: 497 days
Application rate: 250 g/ha/year
Cumulative annual rainfall (mm): 1754 mm, 144% of the long-term average
Average annual leachate volume (mm): information not available
% radioactivity in leachate (maximum/year): < 1 % AR
Individual annual maximum concentrations (1st yr): 0.05 µg/L CGA179500.

Due to some technical deficiencies and low use rate used, results are not used for the risk assessment.

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

Hydrolytic degradation of the trinexapac-ethyl and metabolites > 10 %

| pH   | DT₅₀ (d) | Temperature (°C) | Order | χ² |
|------|----------|------------------|-------|----|
| pH 4 | DT₅₀ 188.3 | 24.7 | 1st | 1.9 |
|      | SYN549299 | 23 % AR | 24.7 | 64 d |
| pH 5 | DT₅₀ 221 | 25 | 1st | 2.05 |
|      | DT₅₀ 514 | 25 | 1st | 0.75 |
|      | CGA179500 | 18 % AR | 25 | 179 d |
|      | Mono-ethyl ester of tricarboxylic acid | 12.5 % AR | 25 | 179 d |
| pH 7 | DT₅₀ 432 | 25 | 1st | 3.2 |
|      | DT₅₀ 782 | 25 | 1st | 1.11 |
|      | CGA179500 | 16 % AR | 25 | 179 d |

hydrolytically stable
Hydrolytic degradation of the CGA179500 and metabolites > 10 %

| pH 9: | DT$_{50}$ 7.2 d at 25 °C ($1^{st}$ order, $\chi^2$=3.05) |
|---|---|
| DT$_{50}$ 11.3 d at 24.7 °C ($1^{st}$ order, $\chi^2$=2.7) |
| CGA179500: 88.2 % AR at 25 °C (30 d) |
| CGA179500: 85.6 % AR at 24.7 °C (30 d) |

| pH 4: | DT$_{50}$ 81.6 d at 20 °C ($1^{st}$ order, $\chi^2$= 1.53) |
|---|---|
| DT$_{50}$ 76.5 d at 24.9 °C ($1^{st}$ order, $\chi^2$= 3.3) |
| DT$_{50}$ 72.7 d at 20 °C ($1^{st}$ order, $\chi^2$= 9.49) |
| CGA313458: 31% AR at 20 °C (91 d) |
| Unknown (proposed as cyclopropanecarboxylic acid or CGA224439): 25% AR at 20 °C (91 d) |
| CGA313458: 36.8% AR at 24.9 °C (91 d) |
| CGA113745: 18.6% AR at 24.9 °C (91 d) |
| CGA313458: 12% AR at 20 °C (91 d) |

| pH 5: | DT$_{50}$ 80 d at 20 °C ($1^{st}$ order, $\chi^2$= 1.72) |
|---|---|
| DT$_{50}$ 71.3 d at 20 °C ($1^{st}$ order, $\chi^2$= 8.48) |
| CGA313458: 22% AR at 20 °C (91 d) |
| unknown (proposed as cyclopropanecarboxylic acid CGA224439): 35% AR at 20 °C (91 d) |

| pH 7: stable |
| pH 9: stable |
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 %

|                      | Direct photolysis | Indirect photolysis |
|----------------------|-------------------|---------------------|
|                      | DT50: 2.8 days    | DT50: 2.6 days      |
|                      | Natural light, 50°N; DT50 5.4 days | Natural light, 35°N; DT50 15.3 days (SFO) |
| CGA300405:           | 41 % AR (15 d)    | CGA300405: 83 % AR (7 d) |
|                      | Continuously formed during the study, DT50 was not determined | Continuously formed during the study, DT50 was not determined |
| M2                   | 17.9 % AR (5 d)   |                      |
|                      | Estimated DT50 at 50°N 34.4 days | Estimated DT50 at 50°N 27.5 days |
| CGA300405:           | 16.9 % AR (5 d)   |                      |
|                      | Estimated DT50 at 50°N 34.4 days | Estimated DT50 at 50°N 27.5 days |
|                      | Not calculated    |                      |

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

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

| Readily biodegradable  | No |

Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

| Trinexapac-ethyl | pH water phase | pH sed | t (°C) | DT50 /DT90 whole sys. (suspended sediment test) | St. (χ²) | DT50 /DT90 Water (pelagic test) | St. (χ²) | Method of calculation |
|------------------|----------------|--------|--------|---------------------------------------------|--------|---------------------------------|--------|-----------------------|
| System identifier (indicate fresh, estuarine or marine) | At study temp | Normalised to x °C<sup>b</sup> | At study temp | Normalised to x °C<sup>c</sup> |                  |                  |                  |
| Fresh water (low dose) | 7.85 | - | 20.9 | - | - | 25.9 | - | 4.9 | SFO |
| Fresh water (high dose) | 7.85 | - | 20.9 | - | - | 21.2 | - | 5.8 | SFO |
| Sterile water (high dose) | 7.85 | - | 20.9 | - | - | 69.9 | - | 2.1 | SFO |
|--------------------------|------|---|------|---|---|------|---|----|-----|

\[ 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).

| Metabolite | Max in total system x % after n days | 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) At study temp | Normalised to x \[°C\] \[c\] | St. (\(\chi^2\)) | DT\(_{50}\) /DT\(_{90}\) Water (pelagic test) At study temp | Norma lised to x \[°C\] \[c\] | St. (\(\chi^2\)) | Method of calculation |
|------------|-----------------------------------|-----------------------------------------------|---------------|---------------|----------------|-------------------------------------------|----------------|-------------------|----------------|----------------|-----------------|----------------|

\[ 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).
### Mineralisation and non extractable residues (for parent dosed experiments)

| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed | Mineralisation x % after n d. (end of the study) | Non-extractable residues. max x % after n d (suspended sediment test) | Non-extractable residues. max x % after n d (end of the study) (suspended sediment test) |
|-------------------------------------------------------|----------------|--------|--------------------------------------------------|---------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Fresh water (low dose)                                 | 7.85           | -      | 4.0 % after 62 d.                                | -                                                                   | -                                                                                 |
| Fresh water (high dose)                                | 7.85           | -      | 4.1 % after 62 d.                                | -                                                                   | -                                                                                 |
| Sterile water (high dose)                              | 7.85           | -      | < 0.1 % after 62 d.                              | -                                                                   | -                                                                                 |

### 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)

| Trinexapac-ethyl | Distribution (max. in sed: 6 % of AR after 1 d. in river and 4.4% of AR in pond after 3 d.) |
|------------------|-----------------------------------------------------------------------------------------------|
| Water / sediment system | pH water phase | pH sed | t. °C | DT$_{50}$/DT$_{90}$ whole sys. | St. ($\chi^2$) | DT$_{50}$/DT$_{90}$ water | St. ($\chi^2$) | DT$_{50}$/DT$_{90}$ sed | St. ($\chi^2$) | Method of calculation |
| River (sand)      | 7.7/8.5         | 7.6    | 20    | 3.7 / 12.3      | 3.8           | 3.3 / 11 | 4.6 | - | - | SFO                  |
| Pond (loam)       | 7.3/8.3         | 7.3    | 20    | 5.1 / 17        | 6.4           | 4.9 / 16.2 | 5.0 | - | - | SFO                  |

**Geometric mean at 20°C**

- 4.4 / 14.5
- 4.0 / 13.3
- 

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### Metabolite CGA179500

| Metabolite CGA179500 | Distribution (Max in water 64% of AR after 14 d., max in sediment 6.9 % AR after 14 d.). Max in total system 70.9 % of AR after 14 days. | Kinetic formation fraction ($k_f/k_d$): not available |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| Water / sediment system | pH water phase | pH sed | t. °C | DT$_{50}$/DT$_{90}$ whole sys. | St. ($\chi^2$) | DT$_{50}$/DT$_{90}$ water | St. ($\chi^2$) | DT$_{50}$/DT$_{90}$ sed | St. ($\chi^2$) | Method of calculation |
| River (sand)          | 7.7/8.5         | 7.6    | 20    | 14 / 46.6       | 17.1          | - | - | - | SFO-SFO |
| Pond (loam)           | 7.3/8.3         | 7.3    | 20    | 18 / 60.9       | 16.5          | - | - | - | SFO-SFO |

**Geometric mean at 20°C**

- 16 / 53.3

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### Mineralisation and non extractable residues (from parent dosed experiments)

| Water / sediment system | pH water phase | pH sed | Mineralisation x % after n d. (end of the study) | Non-extractable residues in sed. max x % after n d | Non-extractable residues in sed. max x % after n d (end of the study) |
|-------------------------|----------------|--------|--------------------------------------------------|--------------------------------------------------|---------------------------------------------------------------------|
| River (sand)            | 7.7/8.5        | 7.6    | 69 % after 111 d.                                | 26 % after 55 d.                                  | 16 % after 111 d.                                                   |
| Pond (loam) | 7.3/8.3 | 7.3 | 59% after 111 d. | 39% after 55 d. | 27% after 111 d. |
|------------|---------|-----|-----------------|----------------|-----------------|

**Fate and behaviour in air (Regulation (EU) No 283/2013, Annex Part A, point 7.3.1)**

| Pathology in air | Description |
|------------------|-------------|
| Direct photolysis in air | Not studied - no data requested |
| Photochemical oxidative degradation in air | **Trinexapac-ethyl**<br>DT$_{50}$ of 4.08 hours estimated according to Atkinson method, $k_{OH} = 94.3 \times 10^{-12}$ cm$^3$molecule$^{-1}$sec$^{-1}$. DT$_{50}$ of 1.29 – 10.8 hours derived by the Atmospheric Oxidation program (ver. 1.85). OH (12h) concentration assumed 99.2 $\times 10^{-12}$ – 11.9 $\times 10^{-12}$ cm$^3$molecule$^{-1}$sec$^{-1}$.<br><br>**CGA179500**<br>DT$_{50}$ of 3.2 – 3.9 hours estimated according to Atkinson method, $k_{OH} = 99.0 \times 10^{-12}$ – 119.8 $\times 10^{-12}$ cm$^3$molecule$^{-1}$sec$^{-1}$. |
| Volatilisation | from plant surfaces (BBA guideline): <15% after 24 hours from soil surfaces (BBA guideline): negligible after 10 days |
| Metabolites | None |

**Residues requiring further assessment (Regulation (EU) No 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: trinexapac-ethyl, CGA179500, CGA300405 and CGA275537
- Surface water and Sediment: trinexapac-ethyl, CGA179500, CGA300405, CGA275537, M2 and WaterM3Photolysis
- Ground water: trinexapac-ethyl, CGA179500, CGA300405 and CGA275537
- Air: trinexapac-ethyl

**Definition of the residue for monitoring (Regulation (EU) No 283/2013, Annex Part A, point 7.4.2)**

See section 5, Ecotoxicology

**Monitoring data, if available (Regulation (EU) No 283/2013, Annex Part A, point 7.5)**

| Pathology | Description |
|-----------|-------------|
| Soil (indicate location and type of study) | Not required |
| Surface water (indicate location and type of study) | Not required |
| Ground water (indicate location and type of study) | Not required |
| Air (indicate location and type of study) | Not required |
PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent

Method of calculation

DT\textsubscript{50} (d): 0.72 days
Kinetics: SFO
Field or Lab: representative worst case from laboratory studies

Application data

Crop: cereals
Depth of soil layer: 5cm
Soil bulk density: 1.5g/cm\textsuperscript{3}
% plant interception: 20
Number of applications: 1
Interval (d): n.a.

Application rate(s): 200 g a.s./ha

| PEC\textsubscript{(s)} (mg/kg) | \multicolumn{1}{l}{Single application Actual} | \multicolumn{1}{l}{Single application Time weighted average} | \multicolumn{1}{l}{Multiple application Actual} | \multicolumn{1}{l}{Multiple application Time weighted average} |
|-------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Initial                       | 0.213                           |                                 |                                 |                                 |
| Short term 24h                 | 0.082                           | 0.147                           | -                               | -                               |
|                               | 0.031                           | 0.102                           | -                               | -                               |
|                               | 0.0045                          | 0.058                           | -                               | -                               |
| Long term 7d                   | 0.0003                          | 0.034                           | -                               | -                               |
|                               | <0.001                          | 0.009                           | -                               | -                               |
|                               | <0.001                          | 0.005                           | -                               | -                               |
|                               | <0.001                          | 0.002                           | -                               | -                               |
| Plateau concentration          | No accumulation                 |                                 |                                 |                                 |

CGA179500

Method of calculation

Molecular weight relative to the parent: 0.889
DT\textsubscript{50} (d): 53 days
Kinetics: SFO
Field or Lab: representative worst case from laboratory studies (normalised for temperature but not moisture content value)

Application data

Application rate assumed: 132 g/ha (assumed CGA179500 is formed at a maximum of 93.1 % of the applied dose)

| PEC\textsubscript{(s)} (mg/kg) | \multicolumn{1}{l}{Single application Actual} | \multicolumn{1}{l}{Single application Time weighted average} | \multicolumn{1}{l}{Multiple application Actual} | \multicolumn{1}{l}{Multiple application Time weighted average} |
|-------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Initial                       | 0.177                           |                                 |                                 |                                 |
| Short term 24h                 | 0.174                           | 0.175                           |                                 |                                 |
|        | 2d       | 4d       | Long term |         |         | 100d     |
|--------|----------|----------|-----------|---------|---------|----------|
|        | 0.172    | 0.167    | 0.161     | 0.122   | 0.092   | 0.048    |
|        | 0.174    | 0.172    | 0.168     | 0.147   | 0.129   | 0.098    |
| Plateau concentration | No accumulation | | | | | |

**CGA300405**

Method of calculation

- Molecular weight relative to the parent: 0.809
- $DT_{50}$ (d): 0.52 days
- Kinetics: FOMC (back-calculated $DT_{50}$ from $DT_{90}$ for FOMC ($DT_{50} = DT_{90} / 3.32$)
- Field or Lab: representative of the worst case from laboratory studies (not-normalised value)

Application data

- Application rate assumed: 16.2 g/ha (assumed CGA300405 is formed at a maximum of 12.5% of the applied dose)

| PEC\(_{(s)}\) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|----------------------|----------------------------|----------------------------------------|----------------------------|----------------------------------------|
| Initial              | 0.022                      |                                        |                            |                                        |
| Short term 24h       | 0.006                      | 0.014                                  |                            |                                        |
| 2d                   | 0.002                      | 0.009                                  |                            |                                        |
| 4d                   | <0.001                     | 0.005                                  |                            |                                        |
| Long term 7d         | <0.001                     | 0.003                                  |                            |                                        |
| 28d                  | <0.001                     | <0.001                                 |                            |                                        |
| 50d                  | <0.001                     | <0.001                                 |                            |                                        |
| 100d                 | <0.001                     | <0.001                                 |                            |                                        |
| Plateau concentration| No accumulation            |                                        |                            |                                        |

**CGA275537**

Method of calculation

- Molecular weight relative to the parent: 0.698
- $DT_{50}$ (d): 0.27
- Kinetics: SFO
- Field or Lab: representative of the worst case from laboratory studies (not-normalised value)

Application data

- Application rate assumed: 12.1 g/ha (assumed CGA275527 is formed at a maximum of 10.8% of the applied dose)
| PEC<sub>(s)</sub> (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|--------------------------|--------------------------|------------------------------------------|-----------------------------|------------------------------------------|
| Initial                  | 0.016                    | -                                        | -                           | -                                        |
| Short term 24h           | <0.001                   | 0.009                                    | -                           | -                                        |
| 2d                       | <0.001                   | 0.005                                    | -                           | -                                        |
| 4d                       | <0.001                   | 0.002                                    | -                           | -                                        |
| Long term 7d             | <0.001                   | 0.001                                    | -                           | -                                        |
| 28d                      | <0.001                   | <0.001                                   | -                           | -                                        |
| 50d                      | <0.001                   | <0.001                                   | -                           | -                                        |
| 100d                     | <0.001                   | <0.001                                   | -                           | -                                        |
| Plateau concentration   | No accumulation          |                                          |                             |                                          |
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)

For FOCUS gw modelling, values used –
Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.
Model(s) used: PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4
Crop: Winter and spring cereals

Trinexapac-ethyl (parent)
Crop uptake factor: 0%
Water solubility (mg/L): 21 100 at pH 8.2 and 25°C
Vapour pressure: 0 Pa at 20°C
Geometric mean DT\textsubscript{50\_lab} 0.15 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7). Correct value is 0.13 days.
Worst case K\textsubscript{OC}: 60 mL/g, with worst case Koc associated \(\frac{1}{n} = 0.92\).

CGA179500
Crop uptake factor: 0%
Water solubility (mg/L): 200 000 at pH 6.8 and 25°C
Vapour pressure: 0 Pa at 20°C
Geometric mean DT\textsubscript{50\_lab} 5.4 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).
Formation fraction: 1 from trinexapac-ethyl (conservative value).
Worst case K\textsubscript{OC}: 145 mL/g, with worst case Koc associated \(\frac{1}{n} = 0.90\).

CGA300405
Crop uptake factor: 0%
Water solubility (mg/L): 21 100 surrogate value from precursor trinexapac-ethyl
Vapour pressure: 0 Pa at 20°C
Geometric mean DT\textsubscript{50\_lab} 0.23 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).
Formation fraction: not available, not used
Worst case value obtained with KOCWIN\textsuperscript{TM} K\textsubscript{OC}: 1 mL/g, worst case \(\frac{1}{n} = 1\).
Maximum observed: 12.5 % (simulated based on adjusted application rate, corresponding to the max amount of metabolite formed in soil photolysis study).

CGA275537
Crop uptake factor: 0%
Water solubility (mg/L): 200 000 surrogate value from precursor CGA179500
Vapour pressure: 0 Pa at 20°C
Geometric mean DT50 lab 0.21 d normalisation to 10kPa or pH2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7 n = 3).
Formation fraction: not available, not used
KOC: 1 mL/g (surrogate CGA300405 value), worst case 1/n= 1. Correct value is KFOC of 4.35 mL/g with worst case Koc associated 1/n = 0.71).
Maximum observed: 10.8 % (simulated based on adjusted application rate, corresponding to the max amount of metabolite formed in soil photolysis study).

Application rate

| Crop       | Scenario   | Application date |
|------------|------------|------------------|
| Winter cereals | Châteaudun | 13- Feb          |
|            | Hamburg    | 15-Feb           |
|            | Jokioinen  | 15-Oct a         |
|            | Kremsmünster | 15-Feb         |
|            | Okehampton | 05-Feb           |
|            | Piacenza   | 20-Feb           |
|            | Porto      | 15-Feb           |
|            | Sevilla    | 28-Dec           |
|            | Thiva      | 27-Jan           |
| Spring cereals | Châteaudun | 02-Apr          |
|            | Hamburg    | 21-Apr           |
|            | Jokioinen  | 31-May           |
|            | Kremsmünster | 21-Apr        |
|            | Okehampton | 17-Apr           |
|            | Porto      | 07-Apr           |

a Agricultural practices actually indicate that winter cereals are planted end of August in Finland. BBCH 25 has therefore been predicted to occur at week 41 or 42 of the year. Consequently the modelling has been carried out using 15/10/02 as date of application.
### PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

| Scenario       | Parent (µg/L) | Metabolite (µg/L) |
|----------------|--------------|-------------------|
|                |              | CGA179500 | CGA300405 | CGA275537 |
| PELMO/Winter cereals |             |           |           |           |
| Chateaudun     | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Hamburg        | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Jokioinen      | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Kremsmunster   | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Okehampton     | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Piacenza       | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Porto          | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Sevilla        | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Thiva          | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| PEARL/Winter cereals |         |           |           |           |
| Chateaudun     | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Hamburg        | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Jokioinen      | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Kremsmunster   | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Okehampton     | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Piacenza       | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Porto          | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Sevilla        | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Thiva          | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| PELMO/Spring cereals |     |           |           |           |
| Chateaudun     | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Hamburg        | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Jokioinen      | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Kremsmunster   | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Okehampton     | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
| Porto          | < 0.001     | < 0.001   | < 0.001   | < 0.001   |
### PEARL - Spring cereals

| Scenario       | Parent (µg/L) | Metabolite (µg/L) | CGA179500 | CGA300405 | CGA275537 |
|----------------|---------------|-------------------|-----------|-----------|-----------|
| Chateaudun     | < 0.001       |                   | < 0.001   | < 0.001   | < 0.001   |
| Hamburg        | < 0.001       |                   | < 0.001   | < 0.001   | < 0.001   |
| Jokioinen      | < 0.001       |                   | < 0.001   | < 0.001   | < 0.001   |
| Kremsmunster   | < 0.001       |                   | < 0.001   | < 0.001   | < 0.001   |
| Okehampton     | < 0.001       |                   | < 0.001   | < 0.001   | < 0.001   |
| Porto          | < 0.001       |                   | < 0.001   | < 0.001   | < 0.001   |

### MACRO

| Scenario/Crop                  | Parent (µg/L) | Metabolite (µg/L) | CGA179500 | CGA300405 | CGA275537 |
|-------------------------------|---------------|-------------------|-----------|-----------|-----------|
| Chateaudun/Winter cereals     | < 0.001       |                   | < 0.001   | < 0.001   | < 0.001   |
| Chateaudun/Spring cereals     | < 0.001       |                   | < 0.001   | < 0.001   | < 0.001   |

### PEC<sub>gw</sub> From lysimeter / field studies

|          | 1<sup>st</sup> year | 2<sup>nd</sup> year | 3<sup>rd</sup> year |
|----------|----------------------|---------------------|---------------------|
| Parent   | Annual average (µg/L)| not required, no data generated | - | - |
| Metabolite X | Annual average (µg/L)| not required, no data generated | - | - |

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

**Trinexapac-ethyl**

Version control no. of FOCUS calculator: version 3.2
Molecular weight (g/mol): 252.3
K<sub>OC</sub> (mL/g): 60, the correct worst case Koc associated is \( \frac{1}{\gamma_{oc}} = 0.92 \)
DT<sub>50</sub> soil (d): 0.15 (correct value is 0.13 days)
DT<sub>50</sub> water/sediment system (d): 4.4
DT<sub>50</sub> water (d): 4.4
DT<sub>50</sub> sediment (d): 1000
Crop interception (%): 20 (average crop cover)

Parameters used in FOCUSsw step 1 and 2

Application rate
Crop and growth stage: winter and spring cereals, BBCH 25
Number of applications: 1
Application rate(s): 200 g a.s./ha
Application windows: Oct-Feb, Mar-May, Jun-Sep

Parameters used in FOCUSsw step 3 (if performed)
Not performed
### FOCUS STEP 1

| Scenario | Day after overall maximum | PEC_{SW} (µg/L) | PEC_{SED} (µg/kg) | Actual | TWA | Actual | TWA |
|----------|----------------------------|------------------|-------------------|--------|-----|--------|-----|
| Winter cereals 1 × 200 g a.s./ha | 0 h                         | 63.57            | 37.04             |        |     |        |     |
|                                     | 24 h                        | 54.19            | 58.88             | 32.51  | 34.77|
|                                     | 2 d                         | 46.29            | 54.51             | 27.77  | 32.43|
|                                     | 4 d                         | 33.78            | 47.11             | 20.27  | 28.13|
|                                     | 7 d                         | 21.06            | 38.45             | 12.63  | 22.99|
|                                     | 14 d                        | 6.99             | 25.61             | 4.19   | 15.32|
|                                     | 21 d                        | 2.32             | 18.48             | 1.39   | 11.06|
|                                     | 28 d                        | 0.77             | 14.21             | 0.46   | 8.51 |
|                                     | 42 d                        | 0.08             | 9.58              | 0.05   | 5.73 |

### FOCUS STEP 2

| Scenario | Day after overall maximum | PEC_{SW} (µg/L) | PEC_{SED} (µg/kg) | Actual | TWA | Actual | TWA |
|----------|----------------------------|------------------|-------------------|--------|-----|--------|-----|
| Northern EU Winter cereals 1 × 200 g a.s./ha | 0 h                         | 1.84             | 0.68              |        |     |        |     |
|                                     | 24 h                        | 1.49             | 1.67              | 0.60   | 0.64|
|                                     | 2 d                         | 1.28             | 1.53              | 0.52   | 0.60|
|                                     | 4 d                         | 0.95             | 1.32              | 0.56   | 0.55|
|                                     | 7 d                         | 0.60             | 1.08              | 0.36   | 0.51|
|                                     | 14 d                        | 0.22             | 0.73              | 0.13   | 0.37|
|                                     | 21 d                        | 0.08             | 0.53              | 0.05   | 0.27|
|                                     | 28 d                        | 0.03             | 0.41              | 0.02   | 0.21|
|                                     | 42 d                        | 0.004            | 0.28              | 0.002  | 0.14|

| Southern EU Winter cereals 1 × 200 g a.s./ha | 0 h                         | 1.84             | 0.68              |        |     |        |     |
|                                     | 24 h                        | 1.49             | 1.67              | 0.60   | 0.64|
|                                     | 2 d                         | 1.28             | 1.53              | 0.52   | 0.60|
|                                     | 4 d                         | 0.95             | 1.32              | 0.56   | 0.55|
|                                     | 7 d                         | 0.60             | 1.08              | 0.36   | 0.51|
|                                     | 14 d                        | 0.22             | 0.73              | 0.13   | 0.37|
|                                     | 21 d                        | 0.08             | 0.53              | 0.05   | 0.27|
|                                     | 28 d                        | 0.03             | 0.41              | 0.02   | 0.21|
|                                     | 42 d                        | 0.004            | 0.28              | 0.002  | 0.14|
### CGA179500

**Parameters used in FOCUSsw step 1 and 2**

- Molecular weight: 224.3
- Soil or water metabolite: both
- Koc (mL/g): 145, the correct worst case Koc associated is $1/K_{oc} = 0.90$
- DT$_{50}$ soil (d): 5.4
- DT$_{50}$ water/sediment system (d): 16
- DT$_{50}$ water (d): 16 / 1000
- DT$_{50}$ sediment (d): 1000 / 16
- Two cases are considered due to the $K_{FOC}$
- Crop interception (%): 20 (average crop cover)
- Maximum occurrence observed (% molar basis with respect to the parent)
- Total Water and Sediment: 70.9
- Soil: 93.1

**Application rate**

- Crop and growth stage: winter and spring cereals, BBCH 25
- Number of applications: 1
- Application rate(s): 200 g a.s./ha
- Application window: Oct-Feb, Mar-May, Jun-Sep

**Main routes of entry**

- Spray drift

#### FOCUS STEP 1

| Scenario         | Day after overall maximum | PEC$_{sw}$ (µg/L) | PEC$_{sed}$ (µg/kg) |
|------------------|----------------------------|-------------------|---------------------|
|                  |                            | Actual            | TWA                 | Actual             | TWA                 |
| 0h               |                            | 82.57             |                     | 118.05             |                     |
| 24h              |                            | 78.89             | 80.73               | 114.40             | 116.22              |
| 2d               |                            | 75.55             | 78.97               | 109.55             | 114.09              |
| 4d               |                            | 69.28             | 75.67               | 100.45             | 109.51              |
| 7d               |                            | 60.84             | 71.08               | 88.21              | 102.94              |
| 14d              |                            | 44.92             | 61.78               | 65.14              | 89.52               |
| 21d              |                            | 33.17             | 54.10               | 48.10              | 78.41               |
| 28d              |                            | 24.49             | 47.73               | 35.52              | 69.18               |
| 42d              |                            | 13.36             | 37.94               | 19.37              | 55.00               |
FOCUS STEP 2 Scenario | Day after overall maximum | \( \text{PEC}_{\text{sw}} (\mu g/L) \) | \( \text{PEC}_{\text{SED}} (\mu g/kg) \) | Actual | TWA | Actual | TWA |
--- | --- | --- | --- | --- | --- | --- | --- |
Northern EU Winter cereals 1 × 200 g a.s./ha | 0 h | 12.07 | 16.98 | | | | |
Oct-Feb | 24 h | 12.00 | 16.68 | 16.83 | | | |
\( \text{DT}_{50} \) water (d): 1000 and \( \text{DT}_{50} \) sediment (d): 16 (worst endpoints presented) | 2 d | 11.91 | 12.00 | 16.56 | 16.72 | | |
| 4 d | 11.74 | 16.31 | 16.58 | | | |
| 7 d | 11.48 | 11.78 | 15.95 | 16.39 | | |
| 14 d | 10.89 | 11.48 | 15.14 | 15.96 | | |
| 21 d | 10.34 | 11.19 | 14.36 | 15.56 | | |
| 28 d | 9.81 | 10.91 | 13.63 | 15.17 | | |
| 42 d | 8.83 | 10.38 | 12.28 | 14.43 | | |
Southern EU Winter cereals 1 × 200 g a.s./ha | 0 h | 9.86 | 13.77 | | | | |
Southern EU Oct-Feb; Mar-May | 24 h | 9.79 | 9.83 | 13.70 | 13.69 | | |
| 2 d | 9.72 | 9.79 | 13.51 | 13.62 | | |
| 4 d | 9.58 | 9.72 | 13.31 | 13.51 | | |
| 7 d | 9.36 | 9.61 | 13.01 | 13.36 | | |
| 14 d | 8.89 | 9.37 | 12.35 | 13.02 | | |
| 21 d | 8.43 | 9.13 | 11.72 | 12.69 | | |
| 28 d | 8.00 | 8.90 | 11.12 | 12.37 | | |
| 42 d | 7.21 | 8.47 | 10.02 | 11.77 | | |

**Metabolite CGA300405**

Parameters used in FOCUSsw step 1 and 2

- **Molecular weight**: 204.2
- **Soil or water metabolite**: both
- **Koc (mL/g)**: 1, with \( \frac{1}{n} = 1.0 \)
- **\( \text{DT}_{50} \) soil (d)**: 0.23
- **\( \text{DT}_{50} \) water/sediment system (d)**: 1000 (default)
- **\( \text{DT}_{50} \) water (d)**: 1000 (default)
- **\( \text{DT}_{50} \) sediment (d)**: 1000 (default)
- **Crop interception (%)**: 20 % (average crop cover)
- **Maximum occurrence observed (% molar basis with respect to the parent)**: Total Water and Sediment: 41 % (Max in aqueous photolysis)
- **Soil**: 12.5% (Max in soil photolysis)

**Application rate**

- **Crop and growth stage**: winter and spring cereals, BBCH 25
- **Number of applications**: 1
- **Application rate(s)**: 200 g a.s./ha
- **Application window**: Oct-Feb, Mar-May, Jun-Sep

**Main routes of entry**

- **Spray drift**
FOCUS STEP 1 Scenario

| Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|---------------------------|-------------------------|--------------------------|
|                           | Actual | TWA | Actual | TWA |
| 0 h                       | 29.4   |     | 0.29   |     |
| 24 h                      | 29.4   | 29.4| 0.29   | 0.29|
| 2 d                       | 29.4   | 29.4| 0.29   | 0.29|
| 4 d                       | 29.4   | 29.4| 0.29   | 0.29|
| 7 d                       | 29.3   | 29.4| 0.29   | 0.29|
| 14 d                      | 29.2   | 29.3| 0.29   | 0.29|
| 21 d                      | 29.0   | 29.2| 0.29   | 0.29|
| 28 d                      | 28.8   | 29.2| 0.29   | 0.29|
| 42 d                      | 28.6   | 29.0| 0.29   | 0.29|

FOCUS STEP 2 Scenario

| Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|---------------------------|-------------------------|--------------------------|
|                           | Actual | TWA | Actual | TWA |
| Northern EU               | 0 h    | 0.61| 0.01   |     |
|                           | 24 h   | 0.61| 0.61   | 0.01|
|                           | 2 d    | 0.61| 0.61   | 0.01|
|                           | 4 d    | 0.61| 0.61   | 0.01|
|                           | 7 d    | 0.61| 0.61   | 0.01|
|                           | 14 d   | 0.60| 0.61   | 0.01|
|                           | 21 d   | 0.60| 0.61   | 0.01|
|                           | 28 d   | 0.60| 0.60   | 0.01|
|                           | 42 d   | 0.59| 0.60   | 0.01|

| Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|---------------------------|-------------------------|--------------------------|
|                           | Actual | TWA | Actual | TWA |
| Southern EU               | 0 h    | 0.61| 0.01   |     |
|                           | 24 h   | 0.61| 0.61   | 0.01|
|                           | 2 d    | 0.61| 0.61   | 0.01|
|                           | 4 d    | 0.61| 0.61   | 0.01|
|                           | 7 d    | 0.61| 0.61   | 0.01|
|                           | 14 d   | 0.60| 0.61   | 0.01|
|                           | 21 d   | 0.60| 0.61   | 0.01|
|                           | 28 d   | 0.60| 0.60   | 0.01|
|                           | 42 d   | 0.59| 0.60   | 0.01|
CGA275537

Parameters used in FOCUSsw step 1 and 2

| Scenario               | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|------------------------|-------------------------|---------------------------|
| **FOCUS STEP 1**       |                         |                           |
| Day after overall      | Actual                  | TWA                       | Actual                  | TWA                       |
| Maximum                |                         |                           |                         |                           |
| Winter cereals         | 1 × 200 g a.s./ha       |                           |                           |
| 0 h                    | 5.00                    | 0.22                      |                           |                           |
| 24 h                   | 5.00                    | 5.00                      | 0.22                     | 0.22                      |
| 2 d                    | 5.00                    | 5.00                      | 0.22                     | 0.22                      |
| 4 d                    | 4.99                    | 4.99                      | 0.22                     | 0.22                      |
| 7 d                    | 4.98                    | 4.99                      | 0.22                     | 0.22                      |
| 14 d                   | 4.95                    | 4.98                      | 0.22                     | 0.22                      |
| 21 d                   | 4.93                    | 4.96                      | 0.21                     | 0.22                      |
| 28 d                   | 4.90                    | 4.95                      | 0.21                     | 0.22                      |
| 42 d                   | 4.86                    | 4.93                      | 0.21                     | 0.21                      |

Parameters used in FOCUSsw step 3 (if performed)

Application rate

Crop interception (%): no interception

Main routes of entry

Run-off and drainage
| FOCUS STEP 2 Scenario | Day after overall maximum | PEC<sub>sw</sub> (µg/L) | PEC<sub>sed</sub> (µg/kg) |
|-----------------------|---------------------------|-------------------------|-------------------------|
|                       |                           | Actual | TWA | Actual | TWA |
| Winter cereals        |                           |        |     |        |     |
| 1 × 200 g a.s./ha     | 0 h                       | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Northern EU           | 24 h                      | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Oct-Feb; Mar-May; Jun-Sep | 2 d                      | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
|                       | 4 d                       | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
|                       | 7 d                       | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
|                       | 14 d                      | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
|                       | 21 d                      | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
|                       | 28 d                      | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
|                       | 42 d                      | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Winter cereals        | 0 h                       | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Southern EU           | 24 h                      | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Oct-Feb; Mar-May; Jun-Sep | 2 d                      | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
|                       | 4 d                       | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
|                       | 7 d                       | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
|                       | 14 d                      | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
|                       | 21 d                      | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
|                       | 28 d                      | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
|                       | 42 d                      | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
Metabolites:

| M2           | WaterM3Photolysis |
|--------------|-------------------|

Parameters used in PEC\textsubscript{SW} and PEC\textsubscript{SED}:

PEC for metabolite was derived from the PEC of the active substance according to the following equation:

\[
\text{PEC}_{\text{Metabolite}} = \frac{\text{PEC}_{\text{Parent}} \times \text{Max metabolite [\%]} \times \frac{100}{\text{MM}_{\text{Metabolite}}}}{\text{MM}_{\text{Parent}}}
\]

- **M2**
  - Molecular weight: 290.3
  - Molar correction factor: 1.15
  - Soil or water metabolite: water
  - Max occurrence in water: 18 % (aqueous photolysis)

- **WaterM3Photolysis**
  - Molecular weight: 252.3
  - Molar correction factor: 1
  - Soil or water metabolite: water
  - Max occurrence in water: 17 % (aqueous photolysis)

Application rate:

- Crop and growth stage: winter and spring cereals, BBCH 25
- Number of applications: 1
- Application rate(s): 200 g a.s./ha
- Application window: October-February

Calculations based on max parent PEC:

### FOCUS STEP 1

| Scenario | Day after overall maximum | PEC\textsubscript{SW} (µg/L) | PEC\textsubscript{SED} (µg/kg) |
|----------|---------------------------|-------------------------------|-------------------------------|
| Winter cereals 1 × 200 g a.s./ha | Actual | TWA | Actual | TWA |
| M2       | 0 h                       | 13.2                          | 7.7                           |
| WaterM3Photolysis | 0 h                       | 10.8                          | 6.3                           |

### FOCUS STEP 2

| Scenario | Day after overall maximum | PEC\textsubscript{SW} (µg/L) | PEC\textsubscript{SED} (µg/kg) |
|----------|---------------------------|-------------------------------|-------------------------------|
| Winter cereals 1 × 200 g a.s./ha | Actual | TWA | Actual | TWA |

#### Northern EU
- **M2** 0 h 0.38 0.14
- **WaterM3Photolysis** 0 h 0.31 0.12

#### Southern EU
- **M2** 0 h 0.38 0.14
- **WaterM3Photolysis** 0 h 0.31 0.12

Main routes of entry:

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

Method of calculation

No other routes of exposure are expected following the proposed use of A8587F

PEC

Maximum concentration

No other routes of exposure are expected following the proposed use of A8587F
### Section 5 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 as/kg bw per day) |
|------------------|----------------------|------------|-----------|-------------------------------|
| **Birds**        |                      |            |           |                               |
| Mallard duck     | Trinexapac-ethyl     | Acute      | LD$_{50}$ | >2000                         |
| Bobwhite quail   | Trinexapac-ethyl     | Acute      | LD$_{50}$ | >2250                         |
| Mallard duck     | Trinexapac-ethyl     | Long-term  | NOEL      | 100                           |
| Bobwhite quail   | Trinexapac-ethyl     | Long-term  | NOEL      | 17.6                          |
| **Mammals**      |                      |            |           |                               |
| Rat              | Trinexapac-ethyl     | Acute      | LD$_{50}$ | 4210                          |
| Rat              | Trinexapac-ethyl     | Acute      | LD$_{50}$ | > 2000 and < 5000             |
| Mouse            | Trinexapac-ethyl     | Acute      | LD$_{50}$ | > 2000                        |
| Rat              | A 7725 M (250 EC) ***| Acute      | LD$_{50}$ | >5000 (mg prep./kg bw)        |
| Rat              | A8587B*              | Acute      | LD$_{50}$ | >3000 (mg prep./kg bw) > 750  |
| Rat              | Metabolite CGA275537 | Acute      | LD$_{50}$ | 330 < LD$_{50}$ < 2000 (M & F)|
| Rat              | Metabolite CGA329773 | Acute      | LD$_{50}$ | > 2000 (M & F)                |
| Rat              | Metabolite CGA313458 | Acute      | LD$_{50}$ | > 2000 (M & F)                |
| Rat              | Metabolite CGA329773 | Short- term| NOAEL    | ≥ 1021 (M & F)**              |
| Rabbit           | Trinexapac-ethyl     | Long-term  | NOAEL     | 60 (maternal)                 |
|                  |                      | toxicity and reproduction |          |                               |
Endocrine disrupting properties (Annex Part A, points 8.1.5)
The available ecotoxicological data are not sufficient to conclude on the endocrine disruption potential of trinexapac-ethyl. Pending on the outcome of the data gap in Section 2, further ecotoxicological tests might be necessary to address the potential endocrine disrupting properties of trinexapac-ethyl.

Additional higher tier studies (Annex Part A, points 10.1.1.2):
No further data were generated. Not required.

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):
- An acute study on the frog (Xenopus laevis) was conducted with the technical active substance, to fulfil data requirements in China. The 48 hour LC50 was >106 mg/L was greater than the existing aquatic acute vertebrate data with fish.

Notes: **bold – endpoint used for the current risk assessment**
* A8587F equivalent formulation A8587B
M – male, F – female
**28 d oral rat: NOAEL ≥ 12000 ppm (1021 mg/kg bw per day)
*** Supportive data, test performed with a formulation different from the representative one, the comparability of this formulation with the representative formulation could not be fully demonstrated.

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

| Winter Barley at 200 g a.s./ha x 1 |
|----------------------------------|

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | All | Small omnivorous bird | Acute | 31.8 | >63 | 10 |
| | All | Small omnivorous bird | Long-term | 6.87 | 2.6 | 5 |
| Tier 1 (Birds) | Acute not required |
| Cereals Early (shoots) autumn-winter BBCH 10-29 | Large herbivorous bird “goose” | Long-term | 1.72 | 10 | 5 |
| Cereals BBCH 10-29 | Small omnivorous bird “lark” | Long-term | 1.16 | 15 | 5 |
| Cereals BBCH 30-39 | Small omnivorous bird “lark” | Long-term | 0.6 | 29 | 5 |
| Cereals BBCH ≥ 40 | Small omnivorous bird “lark” | Long-term | 0.35 | 50 | 5 |
| Higher tier (birds): | | | | | | |
| Not required |
| Screening Step (Mammals) | All | | Acute | 23.7 | >32 | 10 |
| | All | | Long-term | 5.12 | 12 | 5 |
| Tier 1 (Mammals) | Not required |
| Not required |
| Higher tier (Mammals): | | | | | | |
| Not required |

**Metabolites: data gap**

**Risk from bioaccumulation and food chain behaviour**
The octanol - water partition coefficient of trinexapac-ethyl is pH-dependent and at environmentally relevant pH-values of about 7, trinexapac-ethyl has a log Pow of well below 3 (pH 6.9 log Pow = -0.29). It was therefore not necessary to consider the risk from secondary poisoning.

A risk assessment for exposure via secondary poisoning is not triggered for the pertinent soil and surface water metabolites of trinexapac-ethyl.

**Risk from consumption of contaminated water**
The “Leaf scenario” does not apply to the use of A8587F.
Puddle scenario, Screening step
Trinexapac-ethyl has a koc of 60 L/kg and the application rate (g a.s./ha)/relevant endpoint ratios for both birds and mammals are below the trigger <50, indicating that further assessment of the acute and long-term risk to birds and mammals from drinking water from puddles is not required for trinexapac-ethyl.

Toxicity data for all aquatic tested species (Regulation (EU) № 283/2013, Annex Part A, points 8.2 and Regulation (EU) № 284/2013 Annex Part A, point 10.2)

| Group                      | Test substance | Time-scale (Test type) | End point          | Toxicity¹ |
|----------------------------|----------------|------------------------|--------------------|-----------|
| Laboratory tests           |                |                        |                    |           |
| **Fish**                   |                |                        |                    |           |
| *Ictalurus punctatus*      | Trinexapac-ethyl | Acute 96 h (flow-through) | Mortality, LC₅₀   | 35 mg a.s./L<sub>(mm)</sub> |
| *Oncorhynchus mykiss*      | Trinexapac-ethyl | Acute 96 h (semi static) | Mortality, LC₅₀   | 68 mg a.s./L<sub>(nom)</sub> |
| *Lepomis macrochirus*      | Trinexapac-ethyl | Acute 96 h (semi static) | Mortality, LC₅₀   | >130 mg a.s./L<sub>(nom)</sub> |
| *Cyprinus carpio*          | Trinexapac-ethyl | Acute 96 h (flow-through) | Mortality, LC₅₀   | 57 mg a.s./L<sub>(nom)</sub> |
| *Cyprinodon variegatus*    | Trinexapac-ethyl | Acute 96 h (flow-through) | Mortality, LC₅₀   | 180 mg a.s./L<sub>(mm)</sub> |
| *Oncorhynchus mykiss*      | A 7725 M (250 EC)*** | Acute 96 h (static) | Mortality, LC₅₀   | 6 mg prep./L<sub>(nom)</sub> |
| *Oncorhynchus mykiss*      | A8587F (250 ME) | Acute 96 h (static) | Mortality, LC₅₀   | 94 mg prep./L<sub>(nom)</sub> (25.4 mg a.s./L) |
| *Pimephales promelas*     | Trinexapac-ethyl | 35 d (flow-through) ELS | NOEC                | 0.41 mg a.s./L<sub>(mm)</sub> |
|                           |                |                        | EC<sub>10</sub> wet weight | 0.57 mg a.s./L |
|                           |                |                        | EC<sub>10</sub> length    | 1.37 mg a.s./L |
|                           |                |                        | EC<sub>20</sub> wet weight | 1.03 mg a.s./L |
|                           |                |                        | EC<sub>20</sub> length    | 3.08 mg a.s./L |
| *Oncorhynchus mykiss*      | Trinexapac     | 96 h (static, limit test) | Mortality, LC₅₀     | >100 mg a.s./L<sub>(nom)</sub> |
| *Cyprinus carpio*          | Trinexapac     | 96 h (static, limit test) | Mortality, LC₅₀     | >100 mg a.s./L<sub>(nom)</sub> |
| Aquatic invertebrates      |                |                        |                    |           |
| *Daphnia magna*            | Trinexapac-ethyl | 48 h (semi-static) | Immobility, EC₅₀   | >142.5 mg a.s./L<sub>(nom)</sub> |
| *Mysidopsis bahia*         | Trinexapac-ethyl | 96 h (flow-through) | Mortality, EC₅₀    | 6.5 mg a.s./L<sub>(mm)</sub>* |
| *Crassostrea virginica*    | Trinexapac-ethyl | 96 h (flow-through) | Shell deposition, EC₅₀ | 89 mg a.s./L<sub>(mm)</sub> |
**Daphnia magna**

| Treatment | 48 h (static) | Immobility, EC<sub>50</sub> | 0.73 mg prep./L<sub>(nom)</sub> |
|-----------|---------------|-------------------------------|----------------------------------|

**Daphnia magna**

| Treatment | 48 h (static) | Immobility, EC<sub>50</sub> | >100 mg prep./L<sub>(nom)</sub> (>27.1 mg a.s./L) |
|-----------|---------------|-------------------------------|----------------------------------|

**Daphnia magna**

| Treatment | 21 d (flow-through) | Reproduction, mortality, growth F0, NOEC | 11 mg a.s./L<sub>(nom)</sub> |
|-----------|----------------------|-----------------------------------------------|-------------------------------|

**Daphnia magna**

| Treatment | 21 d (semi-static) | Reproduction, mortality, growth F0, NOEC | 0.25 mg prep./L<sub>(nom)</sub> |
|-----------|---------------------|----------------------------------------------|-------------------------------|

**Daphnia magna**

| Treatment | 48 h (static) | Immobility, EC<sub>50</sub> | >111 mg a.s./L<sub>(nom)</sub> |
|-----------|---------------|-------------------------------|----------------------------------|

**Daphnia magna**

| Treatment | 48 h (static) | Immobility, EC<sub>50</sub> | >100 mg a.s./L<sub>(nom)</sub> |
|-----------|---------------|-------------------------------|----------------------------------|

**Sediment-dwelling organisms**

No toxicity test with the sediment dwelling midge *Chironomus spp.* was deemed necessary for trinexapac-ethyl, trinexapac (CGA179500) or CGA300405, due to the short residence time of trinexapac-ethyl in the aquatic system and its moderate toxicity to *D. magna*. Also CGA179500 has low Kfoc (140 mL/g). The amount of the degradation product never reaches more than 6.9% AR in the sediment. Finally, the metabolites were shown to be of lower toxicity to aquatic organisms.

**Algae**

**Pseudokirchneriella subcapitata**

| Treatment | Growth rate: | NOEC |
|-----------|---------------|------------------|
| 96 h (static) | E<sub>r</sub>C<sub>50</sub> | 24.5 mg a.s./L<sub>(nom)</sub> |
|           | E<sub>r</sub>C<sub>10</sub> | 13.91 mg a.s./L |
|           | E<sub>r</sub>C<sub>20</sub> | 16.89 mg a.s./L |
|           | Biomass: | 14.3 mg a.s./L<sub>(nom)</sub> |
|           | E<sub>b</sub>C<sub>50</sub> | 14.3 mg a.s./L<sub>(nom)</sub> |
|           | Yield: | 10.49 mg a.s./L |
|           | E<sub>y</sub>C<sub>50</sub> | 11.75 mg a.s./L |
|           | E<sub>y</sub>C<sub>10</sub> | 7.7 mg a.s./L |
|           | E<sub>y</sub>C<sub>20</sub> | 8 mg a.s./L |

**Pseudokirchneriella subcapitata**

| Treatment | Growth rate: | NOEC |
|-----------|---------------|------------------|
| 72 h (static) | E<sub>r</sub>C<sub>50</sub> | 61 mg a.s./L<sub>(nom)</sub> |
|           | E<sub>r</sub>C<sub>10</sub> | 18 mg a.s./L |
|           | E<sub>r</sub>C<sub>20</sub> | 28 mg a.s./L |
|           | Yield: | 20 mg a.s./L<sub>(nom)</sub> |
|           | E<sub>y</sub>C<sub>50</sub> | 4.7 mg a.s./L |
|           | E<sub>y</sub>C<sub>10</sub> | 7.7 mg a.s./L |
|           | E<sub>y</sub>C<sub>20</sub> | 10 mg a.s./L |

**Pseudokirchneriella subcapitata**

| Treatment | Growth rate: | NOEC |
|-----------|---------------|------------------|
| 72 h (static) | E<sub>r</sub>C<sub>50</sub> | 60 mg a.s./L<sub>(nom)</sub> |
|           | E<sub>r</sub>C<sub>10</sub> | 17 mg a.s./L<sub>(nom)</sub> |
|           | E<sub>r</sub>C<sub>20</sub> | 27.8 mg a.s./L |
|           | Biomass: | 27 mg a.s./L<sub>(nom)</sub> |
|           | E<sub>b</sub>C<sub>50</sub> | 27 mg a.s./L<sub>(nom)</sub> |
| Organism                        | Active Sub.           | Test Duration | EC50/EC10/EC20 (mL/L) | EC50/EC10/EC20 (mM) |
|--------------------------------|-----------------------|---------------|-----------------------|---------------------|
| *Pseudokirchneriella subcapitata* | Trinexapac-ethyl      | 72 h (static) | Yield: E<sub>yC</sub>50 9.4 mg a.s./L
                     |                       |               | E<sub>yC</sub>10 13.2 mg a.s./L
                     |                       |               | E<sub>yC</sub>20 9.1 mg a.s./L |
|                                |                       |               | NOEC                  | 10 mg a.s./L        |
|                                |                       |               | NOEC                  | 16.8 mg a.s./L      |
|                                |                       |               | NOEC                  | 14.1 mg a.s./L      |
|                                |                       |               | NOEC                  | 22.8 mg a.s./L      |
|                                |                       |               | NOEC                  | 26.6 mg a.s./L      |
|                                |                       |               | NOEC                  | 20.6 mg a.s./L      |
|                                |                       |               | NOEC                  | 41.6 mg a.s./L      |
| *Anabaena flos-aquae* Trinexapac-ethyl 72 h (static) | Yield: E<sub>yC</sub>50 22.8 mg a.s./L
                     |                       |               | E<sub>yC</sub>10 16.8 mg a.s./L
                     |                       |               | E<sub>yC</sub>20 14.1 mg a.s./L |
|                                |                       |               | NOEC                  | 10 mg a.s./L        |
|                                |                       |               | NOEC                  | 16.8 mg a.s./L      |
|                                |                       |               | NOEC                  | 22.8 mg a.s./L      |
| *Anabaena flos-aquae* A7725 M (250 EC)*** | Biomass: E<sub>bC</sub>50 5.6 mg prep./L (nom)
                     |                       | 96 h (static) | Growth: E<sub>rC</sub>50
                     |                       |               | E<sub>rC</sub>10
                     |                       |               | E<sub>rC</sub>20
                     |                       |               | Yield: E<sub>yC</sub>50
                     |                       |               | E<sub>yC</sub>10
                     |                       |               | E<sub>yC</sub>20
                     |                       |               | NOEC
|                                |                       |               | NOEC                  | 295 mg a.s./L (nom)
|                                |                       |               | NOEC                  | 184 mg a.s./L       |
|                                |                       |               | NOEC                  | 215 mg a.s./L       |
|                                |                       |               | NOEC                  | 214 mg a.s./L (nom) |
|                                |                       |               | NOEC                  | 151 mg a.s./L       |
|                                |                       |               | NOEC                  | 165 mg a.s./L       |
|                                |                       |               | NOEC                  | 100 mg a.s./L       |
| *Anabaena flos-aquae* A8587F (250 ME) | Biomass: E<sub>bC</sub>50 5.6 mg prep./L (nom)
                     |                       | 96 h (static) | Growth: E<sub>rC</sub>50
                     |                       |               | E<sub>rC</sub>10
                     |                       |               | E<sub>rC</sub>20
                     |                       |               | Yield: E<sub>yC</sub>50
                     |                       |               | E<sub>yC</sub>10
                     |                       |               | E<sub>yC</sub>20
                     |                       |               | NOEC
|                                |                       |               | NOEC                  | >100 mg a.s./L (nom) |
|                                |                       |               | NOEC                  | >27.1 mg a.s./L     |
|                                |                       |               | NOEC                  | 50 mg a.s./L (nom)  |
|                                |                       |               | NOEC                  | 13.5 mg a.s./L      |
| *Pseudokirchneriella subcapitata* | Trinexapac 72 h (static) | Yield: E<sub>yC</sub>50 49.2 mg met./L (nom)
                     |                       |               | Growth: E<sub>rC</sub>50
                     |                       |               | E<sub>rC</sub>10
                     |                       |               | NOEC
|                                |                       |               | NOEC                  | >100 mg a.s./L (nom) |
|                                |                       |               | NOEC                  | >27.1 mg a.s./L     |
|                                |                       |               | NOEC                  | 50 mg a.s./L (nom)  |
|                                |                       |               | NOEC                  | 13.5 mg a.s./L      |
|                                |                       |               | NOEC                  | 32 mg met./L        |
| *Pseudokirchneriella* Trinexapac 72 h (static) | Biomass: E<sub>bC</sub>50 5.6 mg prep./L (nom)

| Organism                      | Substance | EC50 (nom) | EC10 (nom) | EC20 (nom) | NOEC (nom) | Growth rate: | Yield: |
|-------------------------------|-----------|------------|------------|------------|------------|--------------|--------|
| *Anabaena flos-aquae*         | Trinexapac| 79 mg met./L| 63 mg met./L| 68 mg met./L| >100 mg met./L| EC50 | EY50 |
| *Microcystis aeruginosa*      | Trinexapac| 62 mg met./L| 72 mg met./L| 56.3 mg met./L| >100 mg met./L| EC50 | EY50 |
| *Pseudokirchneriella subcapitata* | CGA300405 | 57 mg met./L| 33 mg met./L| >100 mg met./L| >100 mg met./L| EC50 | EY50 |
| Higher plant                  | Lemna gibba| Trinexapac-ethyl | 8.8 mg a.s./L | 8.8 mg a.s./L | 8.8 mg a.s./L | EC50 | EY50 |
| Species          | Active Substance | Duration          | Endpoint                                  | EC_{50}     | EC_{10}     | EC_{20}     | ER_C_{50} | ER_C_{10} | ER_C_{20} | YIELD:  |
|------------------|------------------|-------------------|-------------------------------------------|------------|------------|------------|------------|------------|------------|---------|
| *Lemna gibba*    | Trinexapac-ethyl | 7 d (static)      | Frond number                              | 27.4 mg a.s./L (mm) | 2.3 mg a.s./L | 5.7 mg a.s./L | 0.62 mg a.s./L (mm) | 1.4 mg a.s./L | 2.3 mg a.s./L |
|                  |                  |                   | Growth rate:                              |            |            |            |            |            |            |         |
|                  |                  |                   |                                           | 65 mg a.s./L (mm) | 2.7 mg a.s./L | 8 mg a.s./L | 11.1 mg a.s./L (mm) | 0.93 mg a.s./L | 2.2 mg a.s./L |
|                  |                  |                   | Dry weight                                |            |            |            |            |            |            |         |
|                  |                  |                   | Growth rate:                              |            |            |            |            |            |            |         |
|                  |                  |                   |                                           |            |            |            |            |            |            |         |
|                  |                  |                   | NOEC                                      |            |            |            |            |            |            |         |
| *Myriophyllum spicatum* | Trinexapac-ethyl | 14 d (semi-static) | Shoot length:                             | 1.2 mg a.s./L (mm) | 0.022 mg a.s./L | 0.31 mg a.s./L | 0.60 mg a.s./L |
|                  |                  |                   |                                           |            |            |            |            |            |            |         |
|                |                |                   |                   |                   |
|----------------|----------------|-------------------|-------------------|-------------------|
| **Lemna gibba**| A 7725 M (250 EC)*** | 7 d (static) | Biomass: E\textsubscript{50} | 35 mg prep./L\textsubscript{(nom)} (8.75 mg a.s./L) |
|                |                |                   |                   |                   |
| **Lemna gibba**| A8587F (250 ME) | 7 d (static) | Biomass: E\textsubscript{50} | 119.2 mg prep./L\textsubscript{(nom)} (38.1 mg a.s./L) |
|                |                | Growth rate: E\textsubscript{50} | 140.7 mg prep./L\textsubscript{(mm)} (3.03 mg a.s./L) |                   |
|                |                |                   |                   |                   |
| **Lemna gibba**| Trinexapac     | 7 d (static) | Biomass: E\textsubscript{50} | 1.5 mg met./L\textsubscript{(nom)} |
|                |                | Growth rate: E\textsubscript{50} | **2.5 mg met./L\textsubscript{(nom)}** |                   |
|                |                |                   | 0.2 mg met./L | 0.6 mg met./L |
|                |                |                   |                   |                   |
| **Lemna gibba**| Trinexapac     | 7 d (static) | Frond number | 49 mg met./L\textsubscript{(nom)} |
|                |                | Growth rate: E\textsubscript{50} | 0.40 mg met./L | 2.1 mg met./L |
|                |                |                   |                   |                   |
|                |                |                   |                   | 3.4 mg met./L\textsubscript{(nom)} |
|                              | Trinexapac | CGA300405 | 7 d (static) | 7 d (static) | NOEC | NOEC |
|------------------------------|-----------|-----------|--------------|--------------|------|------|
| **Lemna gibba**              |           |           |              |              |      |      |
| Frond number                 |           |           |              |              |      |      |
| Growth rate:                 |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| Yield:                       |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| Dry weight                   |           |           |              |              |      |      |
| Growth rate:                 |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| Er<sub>10</sub>              |           |           |              |              |      |      |
| Yield:                       |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| NOEC                         |           |           |              |              |      |      |
| **Lemna gibba**              |           |           |              |              |      |      |
| Frond number                 |           |           |              |              |      |      |
| Growth rate:                 |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| Yield:                       |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| Dry weight                   |           |           |              |              |      |      |
| Growth rate:                 |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| Er<sub>10</sub>              |           |           |              |              |      |      |
| Yield:                       |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| NOEC                         |           |           |              |              |      |      |
| **Lemna gibba**              |           |           |              |              |      |      |
| Frond number                 |           |           |              |              |      |      |
| Growth rate:                 |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| Yield:                       |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| Dry weight                   |           |           |              |              |      |      |
| Growth rate:                 |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| Er<sub>10</sub>              |           |           |              |              |      |      |
| Yield:                       |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| NOEC                         |           |           |              |              |      |      |
| **Lemna gibba**              |           |           |              |              |      |      |
| Frond number                 |           |           |              |              |      |      |
| Growth rate:                 |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| Yield:                       |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| Dry weight                   |           |           |              |              |      |      |
| Growth rate:                 |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| Er<sub>10</sub>              |           |           |              |              |      |      |
| Yield:                       |           |           |              |              |      |      |
| E<sub>50</sub>               |           |           |              |              |      |      |
| NOEC                         |           |           |              |              |      |      |

Further testing on aquatic organisms

No additional higher tier data on aquatic organisms are required as the risk assessment presented above indicates an acceptable risk from the supported uses of A8587F.

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

The available ecotoxicological data are not sufficient to conclude on the endocrine disruption potential of trinexapac-ethyl. Pending on the outcome of the data gap in Section 2, further ecotoxicological tests might be...
necessary to address the potential endocrine disrupting properties of trinexapac-ethyl.

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

* A drop in oxygen was observed in all treatment excepts control at the end of the study (72-96 h), oxygen level range 44-58%.

#lowest concentration tested

*** Supportive data, test performed with a formulation different from the representative one, the comparability of this formulation with the representative formulation could not be fully demonstrated.

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

*Trinexapac-ethyl has a low bioaccumulation potential and so no study is necessary.*

|                       | Trinexapac-ethyl | Trinexapac |
|-----------------------|------------------|------------|
| logP<sub>O/W</sub>    | -0.29            | 1.8        |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) | 6 L/kg wwt for whole fish tissue | - |
| Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content) | 100% after 14 days | - |
| Annex VI Trigger for the bioconcentration factor | - | - |
| Clearance time (days) (CT<sub>50</sub>) | 1.4 d | - |
| (CT<sub>90</sub>) | Not available | - |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | Below detection limit | - |
| Higher tier study | No further data were generated | |

* based on total <sup>14</sup>C or on specific compounds
Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) No 284/2013, Annex Part A, point 10.2)

**FOCUSsw step 1-2 - TERs for trinexapac-ethyl – Winter Barley at 200 g a.s./ha x 1**

| Scenario       | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|----------------|-----------------------|------------|--------------|-----------------------|----------------------------------|-------|--------------|------------------------|----------------------|
|                |                       | Ictalurus | Pimephales   | Myzostoma              | Daphnia                         |       |              |                        |                      |
|                |                       | punctatus | promelas     | bahia                 | magna                            |       |              |                        |                      |
|                |                       | LC<sub>50</sub> | NOEC       | EC<sub>50</sub> | NOEC                           |       |              |                        |                      |
|                |                       | 35 000 µg/L | 410 µg/L | 6500 µg/L | 2400 µg/L | 24500 µg/L | 1200 µg/L | 18.9 | n/a  | n/a  |
| FOCUS Step 1   | 63.6                  | 550        | 6.4          | 102                    | 38                               | 387   | 18.9         | n/a                    | n/a                  |
| FOCUS Step 2   |                        |            |              |                        |                                  |       |              |                        |                      |
| North Europe   | 1.84                  | 19022      | 223          | 3533                   | 1304                             | 13315 | 652          | n/a                    | n/a                  |
| South Europe   | 1.84                  | 19022      | 223          | 3533                   | 1304                             | 13315 | 652          | n/a                    | n/a                  |
| Trigger        | 100                   | 10         | 100          | 10                     | 10                               | 10    | 10           | 10                     | 10                   |

**FOCUSsw step 1-2 - TERs for trinexapac-acid**

| Scenario       | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|----------------|-----------------------|------------|--------------|-----------------------|----------------------------------|-------|--------------|------------------------|----------------------|
|                |                       | Oncorhynchus mykiss | Pimephales promelas | Daphnia magna | Daphnia magna | Anabaena flos-aquae | Lemna gibba | n/a |                          |
|                |                       | LC<sub>50</sub> | NOEC*          | EC<sub>50</sub> | NOEC*          | EC50 | EC<sub>50</sub> | NOEC                   | NOEC                |
|                |                       | >100 000 µg/L | 410 µg/L | >111 000 µg/L | 2400 µg/L | 20100 µg/L | 2500 µg/L | n/a  | n/a  |
| FOCUS Step 1   | 82.6                  | >1210       | 4.96         | >1344                  | 29.1                             | 243   | 30.3         | n/a                    | n/a                  |
| FOCUS Step 2   |                        |            |              |                        |                                  |       |              |                        |                      |
| North Europe   | 12.1                  | >8264       | 33.8         | 9173                   | n/a                             | 952   | 206.6        | n/a                    | n/a                  |
| South Europe   | 9.86                  | >10142      | 41.6         | 11257                  | n/a                             | 2038  | 253.5        | n/a                    | n/a                  |
| Trigger*       | 100                   | 10          | 100          | 10                     | 10                               | 10    | 10           | 10                     | 10                   |

* The toxicity of trinexapac was assumed comparable to the toxicity of trinexapac-ethyl due to the close structural similarity.
### FOCUSsw step 1-2 - TERs for CGA300405

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|----------|------------------------|------------|--------------|-----------------------|---------------------------------|-------|--------------|------------------------|----------------------|
|          |                        | n/a        | n/a          | Daphnia magna         | n/a                             | Pseudokirchneriella subcapitata | Lemma gibba | n/a |                      |                      |
|          |                        |            |              | LC₅₀                  | NOEC                            | EC₃₀            | NOEC         | EC₃₀                   | NOEC                 |
|          |                        |            |              | >100 000 µg/L         | 33 000 µg/L                     | >100 000 µg/L  |              |                        |                      |
| FOCUS Step 1 |          | 29.4             | n/a          |                       | n/a                             |                  | 1122          |                        | n/a                  |
| FOCUS Step 2 |          | North Europe | 0.61         |                       | n/a                             |                  |              |                        | n/a                  |
|          |                        |            |              | 163934                | n/a                             | 54098          | 163934        | n/a                    | n/a                  |
|          |                        |            |              |                       |                                |                  |              |                        |                      |
|          |                        |            |              | Mysidopsis bahia     |                                |                  |              |                        |                      |
|          |                        |            |              | LC₅₀                  | NOEC                            | EC₃₀            | NOEC         | EC₃₀                   | NOEC                 |
|          |                        |            |              | 650 µg/L*             |                                |                  |              |                        |                      |
| FOCUS Step 1 |          | 13.2             | n/a          |                       | n/a                             |                  | 9.1           |                        | n/a                  |
| FOCUS Step 2 |          | North Europe | 0.38         |                       | n/a                             |                  |              |                        | n/a                  |
|          |                        |            |              | 1710                  | n/a                             | 315.8          | n/a           | n/a                    | n/a                  |
|          |                        |            |              |                       |                                |                  |              |                        |                      |
|          |                        |            |              | Myriophyllum spicatum |                                |                  |              |                        |                      |
|          |                        |            |              | LC₅₀                  | NOEC                            | EC₃₀            | NOEC         | EC₃₀                   | NOEC                 |
|          |                        |            |              | 120 µg/L*             |                                |                  |              |                        |                      |
| FOCUS Step 1 |          | 10.0             | n/a          |                       | n/a                             |                  |              |                        | n/a                  |
| FOCUS Step 2 |          | North Europe | 0.38         |                       | n/a                             |                  |              |                        | n/a                  |
|          |                        |            |              | 1710                  | n/a                             | 315.8          | n/a           | n/a                    | n/a                  |
|          |                        |            |              |                       |                                |                  |              |                        |                      |
|          |                        |            |              |                        |                                |                  |              |                        |                      |
* acute and chronic data for M2 are estimated based on to be up to 10 times more toxic than parental compound.
FOCUSsw step 1-2 - TERs for WaterM3Photolysis

| Scenario   | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|------------|------------------------|------------|--------------|-----------------------|-------------------------------|-------|--------------|------------------------|----------------------|
|            |                        |            |              | Mysisidopsis bahia    | Myriophyllum spicatum         |       | n/a          | n/a                    | n/a                  |
|            |                        |            |              | LC₅₀ NOEC             | EC₅₀ NOEC                    | EC₅₀  | n/a          | 120µg/L*               | n/a                  |
| FOCUS Step 1 | 10.8                  | n/a        | n/a          | 60                    | n/a                           | n/a   | 11.1         | n/a                    | n/a                  |
| FOCUS Step 2 |                       |            |              |                       |                               |       |              |                        |                      |
| North Europe | 0.31                  | n/a        | n/a          | 2097                  | n/a                           | n/a   | 387.1        | n/a                    | n/a                  |
| South Europe | 0.31                  | n/a        | n/a          | 2097                  | n/a                           | n/a   | 387.1        | n/a                    | n/a                  |
| Trigger     |                        |            |              | 100                   | 10                            | 10    | 10           | 10                     |                      |

* acute and chronic data for WaterM3Photolysis are estimated based on to be up to 10 times more toxic than parental compound

FOCUSsw step 1-2 - TERs for CGA275537Photolysis

| Scenario   | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|------------|------------------------|------------|--------------|-----------------------|-------------------------------|-------|--------------|------------------------|----------------------|
|            |                        |            |              | Mysisidopsis bahia    | Myriophyllum spicatum         |       | n/a          | n/a                    | n/a                  |
|            |                        |            |              | LC₅₀ NOEC             | EC₅₀ NOEC                    | EC₅₀  | n/a          | 120µg/L*               | n/a                  |
| FOCUS Step 1 | 4.85                  | n/a        | n/a          | 130                   | n/a                           | n/a   | 24           | n/a                    | n/a                  |
| FOCUS Step 2 |                       |            |              |                       |                               |       |              |                        |                      |
| North Europe | 0.14 <0.001           | n/a        | n/a          | 650.000               | n/a                           | n/a   | 120000       | n/a                    | n/a                  |
| South Europe | 0.14<0.001           | n/a        | n/a          | 650.000               | n/a                           | n/a   | 120000       | n/a                    | n/a                  |
| Trigger     |                        |            |              | 100                   | 10                            | 10    | 10           | 10                     |                      |

* acute and chronic data for CGA275537 are estimated based on to be up to 10 times more toxic than parental compound
Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

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

| Species          | Test substance | Time scale/type of endpoint | End point                  | toxicity                  |
|------------------|----------------|----------------------------|----------------------------|---------------------------|
| *Apis mellifera* | Trinexapac-ethyl | Acute                     | Oral toxicity (LD$_{50}$)  | >200 µg as/bee            |
| *Apis mellifera* | Trinexapac-ethyl | Acute                     | Oral toxicity (LD$_{50}$)  | >83 µg a.s./bee           |
| *Apis mellifera* | Trinexapac-ethyl | Acute                     | Oral toxicity (LD50)       | >216 µg a.s./bee          |
| *Apis mellifera* | A 7725 M (250 EC)*** | Acute                  | Oral toxicity (LD$_{50}$)  | >108 µg as/bee            |
| *Apis mellifera* | A8587F (250 ME) | Acute                     | Oral toxicity (LD$_{50}$)  | >104 µg as/bee            |
| *Apis mellifera* | Trinexapac-ethyl | Acute                     | Contact toxicity (LD$_{50}$)| >200 µg as/bee            |
| *Apis mellifera* | Trinexapac-ethyl | Acute                     | Contact toxicity (LD50)    | >100 µg a.s./bee          |
| *Apis mellifera* | Trinexapac-ethyl | Acute                     | Contact toxicity (LD50)    | >200 µg a.s./bee          |
| *Apis mellifera* | A 7725 M (250 EC)*** | Acute                  | Contact toxicity (LD$_{50}$)| 69.6 µg as/bee           |
| *Apis mellifera* | A8587F (250 ME) | Acute                     | Contact toxicity (LD$_{50}$)| 168 µg as/bee            |
| *Apis mellifera* | A8587F (250 ME) | Adult chronic            | 10 d-NOED 10 d-LC50       | 26.9 µg a.s./bee/day 46.6 µg a.s./bee/day |
| *Apis mellifera* | Trinexapac-ethyl | Bee brood development    | 8 d NOED                   | 12.6 µg ai/larva/developmental period |
| *Apis mellifera* | A8587F (250 ME) | Bee brood development    | 8 d NOED                   | 314.2 µg A8587F/beelarva/day (83.4 µg ai/beelarva/day) |

*** Supportive data, test performed with a formulation different from the representative one, the comparability of this formulation with the representative formulation could not be fully demonstrated.

Potential for accumulative toxicity: No data

Semi-field test (Cage and tunnel test) - As the risk to bees is low following use of A8587F according to the proposed use pattern, further tests are not necessary.
Field tests - As the risk to bees is low following use of A8587F according to the proposed use pattern, further tests are not necessary.

### Risk assessment for Winter Barley at 200 g a.s./ha x 1

| Species           | Test substance          | Risk quotient | HQ/ETR   | Trigger |
|-------------------|-------------------------|---------------|----------|---------|
| Apis mellifera    | Trinexapac-ethyl        | EFSA screening | HQcontact | <2      | 42      |
| Apis mellifera    | A8587F (250 ME)         | EFSA screening | HQcontact | <1.19   | 42      |
| Apis mellifera    | Trinexapac-ethyl        | EFSA screening | ETRoral   | 0.018   | 0.2     |
| Apis mellifera    | A8587F (250 ME)         | EFSA screening | ETRoral   | 0.0145  | 0.2     |
| Apis mellifera    | A8587F (250 ME)         | EFSA screening | ETRchronic adult oral | **0.032** | 0.0300 |
| Apis mellifera    | Trinexapac-ethyl        | EFSA ETR larvae |            | 0.070   | 0.2000  |

#### Screening assessment (guttation)

| Species           | Test substance          | Risk quotient | ETR     | Trigger |
|-------------------|-------------------------|---------------|---------|---------|
| Apis mellifera    | Trinexapac-ethyl        | EFSA ETRacute | 2.9     | 0.20000 |
| Apis mellifera    | Trinexapac-ethyl        | EFSA ETRchronic | 2.8     | 0.03000 |
| Apis mellifera    | Trinexapac-ethyl        | EFSA ETR larvae chronic | 134     | 0.2000  |

#### Tier 1 risk assessment (chronic)

| scenario          | BBCH     | ETR     | Honeybee trigger |
|-------------------|----------|---------|------------------|
| treated crop      |          |         |                  |
|                   | 10 - 29  | 0.0028  | 0.03             |
|                   | 30 - 39  | 0.0028  | 0.03             |
|                   | 40 - 69  | 0.0028  | 0.03             |
| weeds             |          |         |                  |
|                   | 10 - 29  | 0.0090  | 0.03             |
|                   | 30 - 39  | 0.0045  | 0.03             |
|                   | 40 - 69  | 0.0027  | 0.03             |
| field margin      |          |         |                  |
|                   | 10 - 29  | 0.0001  | 0.03             |
|                   | 30 - 39  | 0.0001  | 0.03             |
|                   | 40 - 69  | 0.0001  | 0.03             |
| adjacent crop     |          |         |                  |
|                   | 10 - 29  | 0.0001  | 0.03             |
|                   | 30 - 39  | 0.0001  | 0.03             |
|                   | 40 - 69  | 0.0001  | 0.03             |
| next crop         |          |         |                  |
|                   | 10 - 29  | 0.0017  | 0.03             |
|                   | 30 - 39  | 0.0017  | 0.03             |
|                   | 40 - 69  | 0.0017  | 0.03             |
Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

| Species                      | Test Substance | End point                     | Toxicity                      |
|------------------------------|----------------|-------------------------------|-------------------------------|
| *Typhlodromus pyri*          | A 7725 M (250 EC)*** | Mortality, LR<sub>50</sub> Reproduction, ER<sub>50</sub> | 197 g as/ha \>600 g as/ha |
| *Typhlodromus pyri*          | A8587B (250 ME)   | Mortality, LR<sub>50</sub>    | \>15 \<200 g as/ha            |
| *Aphidius rhopalosiphi*      | A 7725 M (250 EC)*** | Mortality, LR<sub>50</sub> Parasitisation | 114 g as/ha \Not affected at 50 g as/ha |
| *Aphidius rhopalosiphi*      | A8587B (250 ME)   | Mortality, LR<sub>50</sub>    | \>15 \<200 g as/ha            |

Additional species

| Species                      | Test Substance | End point                     | Toxicity                      |
|------------------------------|----------------|-------------------------------|-------------------------------|
| *Orius insidiosus*           | A 7725 M (250 EC)*** | Mortality Reproduction | % effect at 150 g/ha = -2 \% effect at 150 g/ha = +5 |
| *Coccinella septempunctata*  | A 7725 M (250 EC)*** | Mortality                     | % effect at 16 g/ha = 76 \% effect at 200 g/ha = 48 \% effect at 400 g/ha = 64 |
| *Aleochara bilineata*        | A 7725 M (250 EC)*** | Reproduction                  | % effect at 16 g/ha = 5.7 \% effect at 200 g/ha = 5.8 \% effect at 400 g/ha = 13 |
| *Poecilus cupreus*           | A 7725 M (250 EC)*** | Mortality (Food consumption)  | % effect at 16 g/ha = 3.3 (1.4) \% effect at 200 g/ha = 0 (1.4) \% effect at 400 g/ha = 0 (1.4) |

*** Supportive data, test performed with a formulation different from the representative one, the comparability of this formulation with the representative formulation could not be fully demonstrated.

First tier risk assessment for – Winter Barley at 200 g a.s./ha x 1

| Test substance | Species               | Effect (LR<sub>50</sub> g/ha) | HQ in-field | HQ off-field\(^1\) | Trigger |
|----------------|-----------------------|-------------------------------|-------------|---------------------|---------|
| A8587B         | *Typhlodromus pyri*   | \>15                          | \<13        | n/a                 | 2       |
| A8587B         | *Aphidius rhopalosiphi* | \>15                          | \<13        | n/a                 | 2       |

\(^1\) indicate distance assumed to calculate the drift rate
### Extended laboratory tests, aged residue tests

| Species                        | Life stage | Test substance, substrate | Time scale | Dose (g/ha) | End point                                      | % effect | ER<sub>50</sub> |
|--------------------------------|------------|---------------------------|------------|-------------|------------------------------------------------|----------|-----------------|
| *Typhlodromus pyri*            | protonymphs| A 7725 M (250 EC)         | 100-1600   |             | Mortality, Reproduction LR<sub>50</sub>       | >1600 g  | >1600 g         |
|                                |            | (leaf discs)               |            | 23-750      | Mortality, LR<sub>50</sub>                     | >750 g   | >750 g          |
|                                | protonymphs| A8587B (250 ME) (leaf discs) |          |             | Reproduction, ER<sub>50</sub>                |          |                 |
| *Aphidius rhopalosiphi*        | adults     | A 7725 M (250 EC) (barley seedlings) | 50-4050 |             | Mortality, Reproduction LR<sub>50</sub>       | >4050 g  | >4050 g         |
|                                | adults     | A8587B (250 ME) (3D design barley seedlings) | 23-750 |             | Parasitisation                                | >750 g   |                 |
|                                |            |                           |            |             | Not affected at 750 g as/ha                   |          |                 |
| *Orius laevigatus insidiosus*  | larvae     | A8587F (250 ME) (leaf discs) | 375, 750   |             | Mortality, LR<sub>50</sub>                    | >750 g   |                 |
| *Chrysoperla carnea*           | larvae     | A8587F (250 ME) (leaf discs) | 375, 750   |             | Mortality, LR<sub>50</sub>                    | >750 g   |                 |
| *Chrysoperla carnea*           | larvae     | A 7725 M (250 EC) (leaf discs) | 28-400 |             | Mortality, Reproduction LR<sub>50</sub>       | >400 g   | >400 g          |
| *Coccinella septempunctata*    | larvae     | A 7725 M (250 EC) (leaf discs) | 28-400 |             | Mortality, Reproduction LR<sub>50</sub>       | >400 g   | >400 g          |

<sup>1</sup> Indicate whether initial or aged residues<br>
<sup>2</sup> For preparations indicate whether dose is expressed in units of a.s. or preparation<br>
<sup>3</sup> Indicate if positive percentages relate to adverse effects or not

### Risk assessment for – Winter Barley at 200 g a.s./ha x 1 based on extended lab test or aged residue tests

| Species                  | ER<sub>50</sub> (g/ha) | In-field rate (g/ha) | Off-field rate<sup>1</sup> |
|--------------------------|------------------------|----------------------|----------------------------|
| *T. pyri*                | >750                   | 200                  | 0.554 g/ha – 2.77% drift at 1m 2D |
A. rhopalosiphi | >750 | 200 | 5.54 g/ha – 2.77% drift at 1m 3D
---|---|---|---
Orius insidiosus | >750 | 200 | 0.554 g/ha – 2.77% drift at 1m 2D
Chrysoperla carnea | >750 | 200 | 0.554 g/ha – 2.77% drift at 1m 2D

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

| Semi-field tests | No further data were generated |
|------------------|-------------------------------|
| Field studies    | No further data were generated |
| Additional specific test | No further data were generated |

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) No 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) No 284/2013 Annex Part A, points 10.4, 10.5)

| Test organism | Test substance | Application method of test a.s./OM¹ | Time scale | End point | Toxicity |
|---------------|----------------|-------------------------------------|------------|-----------|----------|
| Earthworms    |                |                                     |            |           |          |
| *Eisenia fetida* | A8587F (250 ME) | Soil incorporation 10% peat | Chronic | Growth, reproduction, behaviour | NOEC<sub>repro</sub>: 309 mg form/kg soil d.w (81.9 mg a.s./kg) EC<sub>10</sub>: 327 mg form/kg soil d.w EC<sub>20</sub>: 446 mg form/kg soil d.w EC<sub>50</sub>: 805 mg form/kg soil d.w |
| *Eisenia fetida* | Trinexapac | Soil incorporation 10% peat | Chronic | Mortality, reproduction, biomass | NOEC: 8.1 mg met/kg soil d.w |
| *Eisenia fetida* | CGA300405 | Soil incorporation 10% peat | Chronic | Mortality, reproduction, biomass | NOEC: 1000 mg met/kg soil d.w |
| Other soil macro-organisms |                |                                     |            |           |          |
| *Folsomia candida* | A8587F (250 ME) | Soil incorporation 5% peat | Chronic | Mortality, reproduction | NOEC<sub>repro</sub>: 95 mg form/kg soil d.w (25.2 mg a.s./kg) NOEC<sub>mortality</sub>: 309 mg form/kg dry soil EC<sub>10</sub>: 117 mg |
### Peer review of the pesticide risk assessment of the active substance trinexapac

| Test Organism | Test Substance | Test Method | Toxicity Endpoint | Toxicity Values |
|---------------|----------------|-------------|-------------------|-----------------|
| **Folsomia candida** | CGA300405 | Soil incorporation 5% peat | Chronic Mortality, reproduction | NOEC: 1000 mg met/kg soil d.w EC<sub>10</sub>: >1000 mg met/kg soil d.w EC<sub>20</sub>: >1000 mg met/kg soil d.w EC<sub>50</sub>: >1000 mg met/kg soil d.w |
| **Hypoaspis aculeifer** | A8587F (250 ME) | Soil incorporation 5% peat | Chronic Mortality, reproduction | NOEC<sub>mortality</sub>: 1000 mg form/kg dry soil NOEC<sub>repro</sub>: 95 mg form/kg dry soil (25.2 mg a.s./kg dw soil) |
| **Hypoaspis aculeifer** | CGA300405 | Soil incorporation 5% peat | Chronic Mortality, reproduction | NOEC: 1000 mg met/kg soil d.w |

1To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).

### Higher tier testing (e.g. modelling or field studies) No further data were generated

| Nitrogen transformation | Trinexap-acetyl* | <25 % effect after 28 days at 8.6 mg a.s./kg d.w.soil |
|-------------------------|-----------------|--------------------------------------------------------|
| Nitrogen transformation | A7725M (250 EC)*** | <25 % effect after 57 days at 5.3 mg a.s./kg d.w.soil |
| Nitrogen transformation | A8587F (250 ME) | <25 % effect after 28 day at 10.7 mg form/kg dry soil (2.6 mg a.s./kg d.w.soil) |
| Nitrogen transformation | CGA300405 | <25 % effect after 28 day at 200 mg met/kg dry soil |
| Nitrogen transformation | CGA275537* | <25 % effect after 28 day at 0.26 mg form/kg dry soil |

* It is assumed that metabolites are up to 10 times more toxic than parental compound trinexap-acetyl.

* A rapid transformation from the parent to trinexapac is expected (formation rates up to 98% after 1 day), therefore, the risk for these metabolites is considered covered by the available data on trinexap-acetyl.
*** Supportive data, test performed with a formulation different from the representative one, the comparability of this formulation with the representative formulation could not be fully demonstrated.

**Toxicity/exposure ratios for soil organisms**

Winter Barley at 200 g a.s./ha x 1

| Test organism | Test substance     | Time scale | Soil PEC<sup>1</sup> | TER  | Trigger |
|---------------|--------------------|------------|-----------------------|------|---------|
| **Earthworms** |                    |            |                       |      |         |
| *Eisenia fetida* | A8587F (250 ME)    | Chronic    | 0.807<sub>max, initial</sub> | 383  | 5       |
| *Eisenia fetida* | Trinexapac-ethyl  | Chronic    | 0.213                 | 385  |         |
| *Eisenia fetida* | Trinexapac         | Chronic    | 0.177                 | 46   |         |
| *Eisenia fetida* | CGA300405          | Chronic    | 0.022                 | 322  | 45454   |
| *Eisenia fetida* | CGA275537<sup>a</sup> | Chronic   | 0.016                 | 512  |         |
| **Other soil macro-organisms** | | | | | |
| *Folsomia candida* | A8587F (250 ME)    | Chronic    | 0.807<sub>max, initial</sub> | 118  | 5       |
| *Folsomia candida* | Trinexapac-ethyl  | Chronic    | 0.213                 | 118  |         |
| *Folsomia candida* | Trinexapac<sup>a</sup> | Chronic   | 0.177                 | 14   |         |
| *Folsomia candida* | CGA300405          | Chronic    | 0.022                 | 45454|         |
| *Folsomia candida* | CGA275537<sup>a</sup> | Chronic   | 0.016                 | 158  |         |
| *Hypoaspis aculeifer* | A8587F (250 ME)    | Chronic    | 0.807<sub>max, initial</sub> | 118  |         |
| *Hypoaspis aculeifer* | Trinexapac-ethyl  | Chronic    | 0.213                 | 118  |         |
| *Hypoaspis aculeifer* | Trinexapac<sup>a</sup> | Chronic   | 0.177                 | 14   |         |
| *Hypoaspis aculeifer* | CGA300405          | Chronic    | 0.022                 | 45454|         |
| *Hypoaspis aculeifer* | CGA275537<sup>a</sup> | Chronic   | 0.016                 | 158  |         |

<sup>1</sup>maximum initial PEC soil was used

<sup>a</sup> It is assumed that metabolites are up to 10 times more toxic than parental compound trinexapac-ethyl.

**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<sub>50</sub> tests should be provided

**Laboratory dose response tests**

| Species | Test substance | ER<sub>50</sub> (g/ha)<sup>2</sup> vegetative | ER<sub>50</sub> (g/ha)<sup>2</sup> emergence | Exposure<sup>1</sup> (g/ha)<sup>2</sup> | TER | Trigger |
|---------|----------------|---------------------------------------------|-------------------------------------------|---------------------------------|-----|---------|

<sup>1</sup>maximum initial PEC soil was used
| Species | Active Substance | Concentration | Description |
|---------|-----------------|---------------|-------------|
| 10 species (soya, lettuce, carrot, tomato, cucumber, cabbage, oat, ryegrass, onion, and maize) | Trinexapac-ethyl | >760 g as/ha >840 g as/ha | Single application of 200 g a.s./ha to field crops, relevant drift rate is 2.77%, gives a maximum off-field foliar PER of 5.54 g a.s./ha. | 137 | 5 |
| 6 species (carrot, lettuce, oilseed rape, pea, oat, and onion) | A7725 M (250 EC)*** | >400 g as/ha >400 g a.s./ha | | 69 |
| 6 species (carrot, lettuce, oilseed rape, pea, oat, and onion) | A8587F (250 ME)³ | >400 g as/ha >400 g a.s./ha | | 69 |
| 6 species (carrot, lettuce, oilseed rape, pea, oat, and onion) | A8587B (250 ME)³ | >380 g as/ha >380 g a.s./ha | | 72 |

Extended laboratory studies: No further data were generated
Semi-field and field test: No further data were generated

1^ explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)
2^ for preparations indicate whether dose is expressed in units of a.s. or preparation
3^ non-GLP studies to be considered as supportive.
*** Supportive data, test performed with a formulation different from the representative one, the comparability of this formulation with the representative formulation could not be fully demonstrated.

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

| Test type/organism | Endpoint |
|--------------------|----------|
| Activated sludge   | EC\textsubscript{50} >100 mg as/L |
| Pseudomonas sp     | n/a      |

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.
  - n/a
- Available monitoring data concerning effect of the PPP.
  - n/a

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

Ecotoxicologically relevant compounds\(^1\)

| Compartment | Active Substance |
|--------------|------------------|
| soil         | Trinexapac-ethyl |
| Environment | Relevant Metabolite |
|-------------|--------------------|
| water       | Trinexapac-ethyl   |
| sediment    | Trinexapac-ethyl   |
| groundwater | n/a                |

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

| Substance                  | Trinexapac-ethyl |
|----------------------------|------------------|
| 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] | * |
| Peer review proposal for harmonised classification according to Regulation (EC) No 1272/2008: | The lowest relevant LC/EC50 value used in support of the active substance is the ErC50 from testing with the aquatic plant Myriophyllum spicatum. The ErC50 is 1.2 mg a.s./L. This is above the trigger for acute classification of 1.0 mg/L. The lowest NOEC value, also from the above study, is 0.025 mg a.s./L (growth rate inhibition). According to the environmental fate data the active substance is classified as not readily biodegradable. As this lowest NOEC is less than 0.1 mg a.s./L and the substance is not readily biodegradable the classification Chronic category 1 (H410) ‘very toxic to aquatic life with long lasting effects’ is triggered. The related chronic M-factor is 1. Pictogram: GHS09 Signal word: ‘Warning’ Hazard statement: H410 - ‘Very toxic to aquatic life with long lasting effects’ (M-factor 1) |