Appendix to:
EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance fosetyl. EFSA Journal 2018;16(6):5307, 31 pp. doi:10.2903/j.efsajournal.2018.5307
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Appendix A — List of end points for the active substance and the representative formulation

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

Active substance (ISO Common Name) | Fosetyl
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Following data relate to the variant fosetyl-aluminium
Function (e.g. fungicide) | Fungicide, bactericide.
Rapporteur Member State | France
Co-rapporteur Member State | Estonia

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

| Chemical name (IUPAC) | Fosetyl: ethyl hydrogen phosphonate
| | Fosetyl-aluminium: aluminium tris(ethyl phosphonate)
| Chemical name (CA) | ethyl hydrogen phosphonate
| | aluminium tris[ethyl phosphonate]
| CIPAC No | 384 (fosetyl), 384.013 (fosetyl-Al)
| CAS No | 15845-66-6 (fosetyl), 39148-24-8 (fosetyl-Al)
| EC No (EINECS or ELINCS) | 254-320-2 (fosetyl-Al)
| FAO Specification (including year of publication) | 384.013/TC, January 2013
| Minimum purity of the active substance as manufactured | 960 g/kg (Bayer CropScience AG, SAPEC Agro S.A.)
| | 970 g/kg (Cheminova Agro S.A.-Probelte-Proplan)
| | 965 g/kg (Industrias Afrasa S.A.)
| | 965 and 974 g/kg (Oxon-Italia SpA and Suni Agro Europe Limited)
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | Open (Bayer CropScience AG)
| Molecular formula | fosetyl: C₇H₇O₄P
| | fosetyl-aluminium: C₆H₁₅AlO₅P₃
| Molar mass | fosetyl: 110.0 g/mol
Peer review of the pesticide risk assessment of the active substance fosetyl

Structural formula

fosetyl-aluminium
354.1 g/mol

$$\begin{array}{c}
\text{H}_3\text{C} - \text{H} - \text{P} - \text{O} - \text{O} - \text{O}\hfill \\
\text{H}
\end{array}$$

$$\text{Al}^{3+}$$

$$\left[ \begin{array}{c}
\text{H}_3\text{C} - \text{H} - \text{P} - \text{O} - \text{O} - \text{O}\hfill \\
\text{H}
\end{array} \right]_3$$
**Physical and chemical properties (Regulation (EU) No 283/2013, Annex Part A, point 2)**

The data refer to variant fosetyl-aluminium, unless otherwise stated.

| Property                                      | Value                                                                 |
|-----------------------------------------------|----------------------------------------------------------------------|
| Melting point (state purity)                 | 215 °C (99.1%)                                                       |
| Boiling point (state purity)                 | /                                                                   |
| Temperature of decomposition (state purity)  | 277-279 °C (99.1%)                                                   |
| Appearance (state purity)                    | White powder (99.1%)                                                 |
| Vapour pressure (state temperature, state purity) | < 10⁻² Pa (25°C)                                               |
| Henry’s law constant (state temperature)     | < 3.2 x 10⁻¹⁰ Pa m² mol⁻¹ (20°C)                                     |
| Solubility in water (state temperature, state purity and pH) | Solubility at 20°C  
111.3 g/L (pure water at pH 6.0)  
111.4 g/L (buffer at pH 5.1)  
109.8 g/L (buffer at pH 8.6)  
Purity (99.1%) |
| Solubility in organic solvents (state temperature, state purity) | Solubility at 20°C  
6 mg/L (acetone)  
1 mg/L (acetonitrile)  
4 mg/L (dichloromethane)  
< 1 mg/L (ethyl acetate)  
< 1 mg/L (n-heptane)  
1 mg/L (xylene)  
807 mg/L (methanol)  
10 mg/L (n-octanol)  
Purity (97.6 %) |
| Surface tension (state concentration and temperature, state purity) | 75.1 mN/m at 20 °C (1 g/L solution)  
Purity 99.1% |
| Partition coefficient (state temperature, pH and purity) | log Pow = -2.1 at 21-23 °C  
As water solubility is not pH-dependent, log Pow is considered as not pH-dependent  
Purity (99.1%) |
| Dissociation constant (state purity)          | pKa = 4.7 at 20-25 °C (99.1%)                                        |
| UV/VIS absorption (max.) incl. \( \varepsilon \) (state purity, pH) | No relevant absorption peaks between 190 and 800 nm  
(solvent: water; c = 0.1%) |
| Flammability (state purity)                   | Not flammable                                                        |
| Explosive properties (state purity)           | Not explosive                                                        |
| Oxidising properties (state purity)           | Not oxidizing                                                        |
**Summary of representative uses evaluated, for which all risk assessments needed to be completed (name of active substance or the respective variant)**

(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) | Formulation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|---------------------------|-------------------------|--------------|--------------|--------------------------------------|-------------|------------|-------------------------------|----------------|---------|
| Grapes                    | Northern, central, southern EU | FEA + FLC WG 71.11 | F | Plasmodora viticola | WG | FEA : 666.7 FLC : 44.4 | Spray BBCH 15 - 81 | 3 | 10 | FEA: 2.0 FLC: 0.133 | 100-1000 | FEA: 2.0 FLC: 0.133 | 21 |  |
| Grapes                    | Northern, central, southern EU | SIP 409 58 | F | Plasmodora viticola | WG | Fos.: 300 Cym.: 28.5 Cu.: 160 | Spray BBCH 11 - 79 | 4 | 10 | Fos.: 0.3375 Cym.: 0.0321 Cu.: 0.18 | 400-1000 | Fos.: 1.35 Cym.: 0.1282 Cu.: 0.720 | 40 |  |
| Citrus                    | Southern EU | Fosetyl-Al 80% WP | F | Phytophthora spp. | WP | 800 | Tractor mounted sprayer | 1st appl.: flowering | 3 | 3 months | 0.36** | 1000-1500 | 3.6 | 15 | Application rate (min-max): 0.25-0.3 kg product/hL (0.20 – 0.24 kg as/hL)**
| Grapes                    | Southern EU | Fosetyl-Al 80% WP | F | Downy mildew (Plasmodora viticola) | WP | 800 | Tractor mounted sprayer | Flowering/post-flowering | 4 | 10 days | 0.88** | 300-1100 | 2.64 | 28 | Application rate (min-max): 0.25-0.3 kg product/hL (0.20 – 0.24 kg as/hL)**
| Pome fruits               | EU | FEA WG 80 (e.g. Aliette) | F | Phytophthora spp. Erwinia amylovora | WG | 800 | Foliar spray | BBCH 55-85 | 3 | 7-10 days* | 0.24 – 1.2 | 300 - 1500 | 3.6 | 28 | |

* Following a GAP modification by the applicant, an interval of 10 days between applications is now supported.

** Maximum concentration, corresponding to the use of low water volumes.

*** Minimum concentration (= label dose range for southern MS) to be applied in situations of use of high water volumes.

**** Following the request of additional data by EFSA, the applicant indicated that the use is now intended in the Southern zone only.

(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

(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. fluoxycyprin). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavicalcar-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.
(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.

(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 (b) | Pests or Group of pests controlled (c) | Preparation Type (d-f) Conc. a.s. (i) | Application Method kind (h) | Range of growth stages & season (j) | Number min-max (k) | Interval between application (min) | Application rate per treatment kg a.s./L (l) | PHI (days) (m) | Remarks |
|---------------------------|-------------------------|--------------|------------|--------------------------------------|-------------------------------------|----------------------------------|-------------------------------|----------------|--------------------------|---------------------------------|-----------|---------|

MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)

Not applicable in the case of this renewal dossier.

(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 pesticides
(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. fluroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. bentiavalicarb-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)

| No new data has been provided (not required for renewal of approval of active substances). |
|---|
| Fosetyl-Al contained in FEA + FLC WG 71.11, SIP40958, Fosetyl-Al 80% WP and Fosetyl-Al WG 80 has been tested in field development trials which demonstrated efficacious activity. Products containing fosetyl-Al has been registered in many EU countries based on detailed national assessments of the efficacy package in compliance with Annex III data requirements of Directive 91/414/EEC and according to the Uniform Principles, with which Member States authorities were satisfied. |
| More detailed consideration will be fully assessed in the context of subsequent applications for products authorisation. |

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

| Same as above. |

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

| Same as above. |

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

| Activity against target organism |
| fosetyl-Al | phosphonic acid | ethanol |
|---|---|---|
| yes | yes | no |
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)

| Analytical method | Technique |
|-------------------|-----------|
| Technical a.s.    | ion chromatography coupled with conductivity detector |
| Impurities in technical a.s. | ion chromatography coupled with conductivity detector |
| Plant protection product | ion chromatography coupled with UV detector |

The specificity of the analytical method for the determination of the counterion in the PPP is required.

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

Residue definitions for monitoring purposes

| Matrix                  | Residue Definition                                           |
|-------------------------|-------------------------------------------------------------|
| Food of plant origin    | Sum of fosetyl and phosphonic acid and their salts, expressed as phosphonic acid |
| Food of animal origin   | Phosphonic acid                                             |
| Soil                    | Fosetyl and phosphonic acid                                 |
| Sediment                | Fosetyl and phosphonic acid                                 |
| Water surface           | Fosetyl and phosphonic acid                                 |
| Drinking/ground         | Fosetyl and phosphonic acid                                 |
| Air                     | Fosetyl                                                     |
| Body fluids and tissues | Fosetyl and phosphonic acid                                 |

Monitoring/Enforcement methods

| Analytical method                      | Technique and LOQ for methods for monitoring purposes |
|----------------------------------------|--------------------------------------------------------|
| Food/feed of plant origin              | Bayer: QuPPe LC-MS/MS (matrices: high water, dry, acid, high oil), ILV missing and extraction efficiencies provided except for high oil and dry. Fosetyl LOQ: 0.01 mg/kg fosetyl-aluminium for all matrices, Phosphonic acid LOQ: 0.1 mg/kg for high water, dry, acid and 0.5 mg/kg for high oil. |
|                                        | Task Force Iberica: LC-MS/MS (matrices: high water, dry, acid, high oil), ILV provided and validated, extraction efficiencies missing, Fosetyl (expressed as fosetyl-aluminium) and phosphonic acid LOQ: 0.01 mg/kg for all matrices except acid LOQ is 1 mg/kg, |
|                                        | Task Force Oxon: LC-MS/MS (matrices: high water, dry, acid, high oil), Phosphonic acid: not validated, ILV provided and validated, extraction efficiencies missing, Fosetyl LOQ: 0.05 mg/kg fosetyl-aluminium for all matrices |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | **Bayer**: LC-MS/MS (matrices: milk, bovine meat, bovine kidney, bovine liver, egg, poultry muscle), ILV available, extraction efficiency missing
   Fosetyl (expressed as fosetyl-aluminium) and phosphonic acid LOQ: 0.05 mg/kg except for milk 0.01 mg/kg
   **Task Force Iberica**: LC-MS/MS (milk, egg, fat, muscle meat, kidney), ILV provided and validated, extraction efficiency missing
   Fosetyl (expressed as fosetyl-aluminium) and phosphonic acid LOQ: 0.05 mg/kg milk and egg, 0.1 mg/kg muscle meat, kidney and fat.
   **Task Force Oxon**: LC-MS/MS (milk, egg, fat, muscle meat, kidney), ILV provided and validated, extraction efficiency missing
   Fosetyl LOQ: 0.05 mg/kg fosetyl-aluminiun for all matrices
   Phosphonic acid: 2 mg/kg for all matrices |
| Soil (analytical technique and LOQ) | **Bayer**: LC-MS/MS, LOQ = 0.05 mg/kg for fosetyl (expressed as fosetyl-aluminium) and phosphonic acid
   **Task Force Iberica**: LC-MS/MS, LOQ = 0.025 mg/kg for fosetyl (expressed as fosetyl-aluminium) and phosphonic acid
   **Task Force Oxon**: LC-MS/MS, LOQ = 0.05 mg/kg for fosetyl (expressed as fosetyl-aluminium) and 0.2 mg/kg for phosphonic acid. Data gap for an analytical method for the determination of phosphonic acid in soil with a LOQ of 0.05 mg/kg. |
| Water (analytical technique and LOQ) | **Bayer**: LC-MS/MS, Fosetyl LOQ = 0.1 µg/L (expressed as fosetyl-aluminium), LOQ phosphonic acid = 0.1 µg/L for surface and drinking water
   ILV available.
   **Task force Iberica**: LC-MS/MS, LOQ Fosetyl (expressed as fosetyl-aluminium) = 0.05 µg/L for surface and drinking water, LOQ phosphonic acid = 0.1 µg/L ILV for phosphonic acid: open.
   **Task force Oxon**: LC-MS/MS, LOQ Fosetyl (expressed as fosetyl-aluminium) = 0.1 µg/L for surface and drinking water
   Data gap: determination of phosphonic acid in drinking water with an LOQ of 0.1 µg/L and its ILV |
Air (analytical technique and LOQ)

- **Bayer**: GC-FID, LOQ = 0.1 mg/m³ (expressed as fosetyl-aluminium)
- **Task Force Iberica**: LC-MS/MS, LOQ = 0.1 mg/m³ (expressed as fosetyl-aluminium)
- **Task Force Oxon**: LC-MS/MS, LOQ = 3 µg/m³ (expressed as fosetyl-aluminium)

Body fluids and tissues (analytical technique and LOQ)

- Bayer, Task Force Iberica and Task Force Oxon: LC-MS/MS (matrix: plasma), LOQ = 0.05 mg/L (expressed as fosetyl-aluminium) and phosphonic acid respectively

**Classification and labelling with regard to physical and chemical data (Regulation (EU) No 283/2013, Annex Part A, point 10)**

| Substance | Classification and Labelling | Peer Review Proposal |
|-----------|-----------------------------|----------------------|
| Fosetyl   | none                        | none                 |

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

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

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

| Rate and extent of oral absorption/systemic bioavailability | Rapid and extensive (80–100%) within 24 h over the dose rate range of 100 to 3000 mg/kg bw based on single/repeated low/high dose studies. |
|------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Toxicokinetics                                             | $^{14}$C-fosetyl-Al single dose 3 000 mg/kg bw ($\delta + \varphi$)  |
|                                                           | $C_{max}$: 315.4/460.4 µg/mL ($\delta/\varphi$)  |
|                                                           | $T_{max}$: 24 h ($\delta/\varphi$)  |
|                                                           | $AUC_{0-168}$ h: 33 786/40053 µg x h/mL ($\delta/\varphi$)  |
|                                                           | $T_{1/2}$: 124/81 h ($\delta/\varphi$)  |
| Distribution                                               | Widely distributed (kidneys, liver, lungs, spleen, fat, skin adrenal glands and gonads) |
| Potential for bioaccumulation                               | No evidence for accumulation |
| Rate and extent of excretion                                | Rapid and extensive (56% dose in air expired and 30% dose in urine) within 24 h in single dose studies. |
|                                                           | In repeated dose studies, faeces are the main route of excretion |
| Metabolism in animals                                       | Rapid, metabolised in CO$_2$ (excreted via exhaled air) and phosphonates (eliminated in urine with unchanged parent and ethanol). |
| In vitro metabolism                                         | No metabolism in human and rat liver microsomes was observed |
| Toxicologically relevant compounds                          | Fosetyl-Al |
| (animals and plants)                                        | Fosetyl-Al |

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

| Rat LD$_{50}$ oral                                         | > 2000 mg/kg bw |
|------------------------------------------------------------|----------------|
| Rat LD$_{50}$ dermal                                       | > 2000 mg/kg bw |
| Rat LC$_{50}$ inhalation                                   | > 5.11 mg/L air /4h (nose only) |
| Skin irritation                                            | Non-irritant |
| Eye irritation                                              | Irritant |
|                                                            | H319 |
| Skin sensitisation                                         | Non-sensitizer (M&K tests) |
| Phototoxicity                                              | Not required |

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

| Target organ / critical effect                             | Rat, mouse: low toxicity, no specific target organ detected |
|------------------------------------------------------------|------------------------------------------------------------|
|                                                            | Dog: decreased absolute weight gonads and |
### Relevant oral NOAEL

90-day, rat: 1196 mg/kg bw/day  
90-day, dog: 274 mg/kg bw/day  
See also mechanistic data

### Relevant dermal NOAEL

NOAEL for systemic effects = 1000 mg/kg bw per day (rat 21-day)  
LOAEL for local effects = 1050 mg/kg bw per day (rat 28-day)

### Relevant inhalation NOAEL

No data - not required

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

**In vitro studies**

- Ames test: negative  
- Mammalian cell gene mutation tests: negative  
- Chromosomal aberration tests: negative

**In vivo studies**

- Micronucleus tests: negative

**Photomutagenicity**

- Not required

**Potential for genotoxicity**

- Unlikely to be genotoxic

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

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

- Mouse: no adverse effect  
- Rat: calculi, hyperplasia and inflammation of the urinary bladder.  
- Dog: decrease of body weight, vacuolar tubular lesions in kidney ♀ and testicular degenerations

**Relevant long-term NOAEL**

- 2-year, mouse: 3956 mg/kg bw per day  
- 2-year, rat: 348 mg/kg bw per day  
- 2-year, dog: 288 mg/kg bw per day

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

- Mouse: no tumours  
- Rat: transitional cell papilloma and carcinoma of the urinary tract.  
- Adverse effects are considered not relevant for human based on MoA proposed: changes in urine physical/chemical with calculi formation and chronic irritation leading to tumours at very high doses.

**Relevant NOAEL for carcinogenicity**

- 2-year, mouse: 3956 mg/kg bw per day  
- 2-year, rat: 348 mg/kg bw per day

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

**Reproductive toxicity**

**Reproduction target / critical effect**

- 3-generation study:  
- Parental toxicity: decreased body weight during pre-mating period in F2B.
Reproductive and fertility toxicity: decrease of corpora lutea in F0 and F1B generations.
Foetal toxicity: decreased spleen weight in F3B generation.

| Relevant parental NOAEL | 482 mg/kg bw per day |
|-------------------------|----------------------|
| Relevant reproductive NOAEL | 954 mg/kg bw per day |
| Relevant offspring NOAEL | LOAEL = 482 mg/kg bw per day |

### Developmental toxicity

**Developmental target / critical effect**

- **Rat:**
  - Maternal toxicity: mortality and decreased bw (gain) (at 4000 mg/kg bw/day)
  - Developmental toxicity: decreased litter and foetal weights, marginally increased incidence of fetal anomalies (at 4000 mg/kg bw/day)

- **Rabbit:**
  - Maternal toxicity: No adverse effects
  - Developmental toxicity: Increased incidence of dilated ureter at the high dose (at 300 mg/kg bw per day)

| Relevant maternal NOAEL | Rat: 1000 mg/kg bw per day
Rabbit: 300 mg/kg bw per day (highest dose) |
|-------------------------|-----------------------------|
| Relevant developmental NOAEL | Rat: 1000 mg/kg bw per day
Rabbit: 100 mg/kg bw per day |

### Neurotoxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.7)

- **Acute neurotoxicity**: Study not required
- **Repeated neurotoxicity**: No neurotoxicological effect in a 90-day rat study including FOB.
  NOAEL: 1 196 mg/kg bw per day
- **Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)**: No effect in a delayed neurotoxicity study in the domestic hen.
  NOAEL: 2000 mg/kg bw
  Data gap for the existing DNT study for Aluminium (pending the analysis of it, further data might be requested for fosetyl-Al).
Other toxicological studies (Regulation (EU) No 283/2013, Annex Part A, point 5.8)

| Supplementary studies on the active substance | Two mechanistic studies:  
28-day oral rat study: functional alterations and histopathological changes in kidney  
NOAEL = 1000 mg/kg bw per day  
90-day oral rat study: increased calcium levels in urine and related changes in the urinary bladder (calculi, hyperplasia), kidney (functional alterations and histopathological changes) and ureters (dilatation)  
NOAEL: 500 mg/kg bw per day  
Immunotoxicity: no evidence of immunotoxic effects are observed in the available data package. |
|---|---|
| Endocrine disrupting properties | Data gap:  
Involvement of parathyroid hormones in the hypothesised mode of action of fosetyl-Al should be further clarified.  
According to the conceptual framework, submission of level 2/3 studies is needed to conclude on the ED potential of fosetyl-Al. |
Studies performed on metabolites or impurities

| Metabolite          | Oral LD₅₀ Rat  | Oral LD₅₀ Mouse | Mouse LD₅₀ | In vivo Micronucleus |
|---------------------|----------------|----------------|------------|----------------------|
| Phosphonic acid     | 2950 mg/kg bw  | 1650 mg/kg bw  | 2450 mg/kg bw | Negative            |
| Sodium phosphonate  | 5300 mg/kg bw  | 2450 mg/kg bw  | 2450 mg/kg bw | Negative            |
| Potassium phosphonate| 3624 mg/kg bw  | > 2000 mg/kg bw| > 6.14 mg/L | Negative            |

In vivo micronucleus in mice negative

Reference values of phosphonic acid:
Since phosphonic acid is a major metabolite in rat (73% in the urine), its toxicity (including developmental and reproductive toxicity) is considered covered by the studies performed with fosetyl-Al.
The reference values of the parent are applied to phosphonic acid.

Aluminium (metabolite for worker and resident)
Reference values, oral absorption and dermal absorption from EFSA conclusion on Aluminium ammonium sulphate (EFSA Journal 2012;10(3):2491)

ADI = 0.14 mg/kg bw per day
ARID = 0.14 mg/kg bw
AOEL = 0.002 mg/kg bw per day
Oral absorption = 1%
Dermal absorption = 1%

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

No detrimental effects on health in manufacturing personnel
Summary (Regulation (EU) No 1107/2009, Annex II, point 3.1 and 3.6)

**Fosetyl-Al**

|                  | Value (mg/kg bw (per day)) | Study          | Uncertainty factor |
|------------------|-----------------------------|----------------|-------------------|
| **Acceptable Daily Intake (ADI)** | 1\(^{(1)}\) | Rabbit, developmental Developmental NOAEL | 100 |
| **Acute Reference Dose (ARfD)** | Not needed | | |
| **Acceptable Operator Exposure Level (AOEL)** | 1\(^{(2)}\) | Rabbit, developmental Developmental NOAEL | 100 |
| **Acute Acceptable Operator Exposure Level (AAOEL)** | Not needed | | |

\(^{(1)}\) Previous ADI = 3 mg/kg bw per day based on the chronic studies (European Commission, 2012b)

\(^{(2)}\) Previous AOEL = 5 mg/kg bw per day based on mechanistic study (European Commission, 2012b)

**Dermal absorption** (Regulation (EU) No 284/2013, Annex Part A, point 7.3)

| Representative formulation | Concentrate (666.7 g/kg): 0.1% | Intermediate (20 g/L): 1% | Spray dilution (2 g/L): 4% | In vitro human study performed on formulation |
|----------------------------|----------------------------------|--------------------------|---------------------|---------------------------------------------|
| FEA + FLC WG71.11; 666.7 g/kg fosetyl-Al |                                   |                          |                     |                                             |

| Representative formulation | Concentrate: 0.2% | Spray dilution: 6% | In vitro human study performed on formulation |
|----------------------------|-------------------|--------------------|---------------------------------------------|
| SIP40958; WG; 300 g/kg fosetyl-Al |                   |                    |                                             |

| Representative formulation | Concentrate (800 g/kg): 0.4% | Spray dilution (2 g/L): 4% | In vitro human study performed on formulation |
|----------------------------|--------------------------------|---------------------|---------------------------------------------|
| FOSETYL-AL 80% WP; 800 g/kg fosetyl-Al |                        |                     |                                             |

| Representative formulation | Concentrate (500 g/kg): 1% | Spray dilution (1 g/L): 3% | In vitro human study performed on formulation |
|----------------------------|-----------------------------|-----------------------------|---------------------------------------------|
| FEA WG80; 800 g/kg fosetyl-Al |                              |                              |                                             |

\(^{3}\) If available include also reference values for metabolites
Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

* Exposure estimations with EFSA model are reported for information purposes only since EFSA guidance was not in force when the dossier was submitted.

| Operators | Use: grapes, tractor mounted equipment, application rate 2 kg a.s./ha | Exposure estimates (model): % of AOEL |
|-----------|-------------------------------------------------|-----------------------------------|
| UK POEM   | Without PPE:                                     | 105%                             |
|           | With PPE (gloves M/L/A):                         | 69%                              |
| German model | Without PPE:                                   | 11%                              |
|           | EFSA model*;                                     |                                   |
|           | Without PPE AOEL:                               | 4.9%                             |
| Use: grapes, Hand-held sprayer, application rate 2 kg a.s./ha | Exposure estimates (model): % of AOEL |
| German model | Without PPE:                                   | 5.6%                             |
| EFSA model* | Without PPE AOEL:                             | 2%                               |
| SIP40958 | Use: grapes, tractor mounted equipment, application rate 1.35 kg a.s./ha | Exposure estimates (model): % of AOEL |
|           | Without PPE:                                     | 27%                              |
| German model | Without PPE:                                   | 11%                              |
|           | EFSA model*;                                     |                                   |
|           | Without PPE AOEL:                               | 4.8%                             |
|           | Use: grapes, manual-knapsack, application rate 1.35 kg a.s./ha | Exposure estimates (model): % of AOEL |
|           | EFSA model*;                                     |                                   |
|           | Without PPE AOEL:                               | 0.7%                             |
|           | Use: grapes, handheld equipment (high level target), application rate 1.35 kg a.s./ha | Exposure estimates (model): % of AOEL |
|           | German model | Without PPE:                                   | 5.3%                             |
| **Efsa model:** |  |
|----------------|---|
| **Without PPE AOEL:** | 1.9% |

**FOSETYL-AL **WG 80 (FEA WG 80)
Fosetyl-Aluminium

**Use:** pome fruit, **tractor mounted equipment,** application rate 3.6 kg a.s./ha

| Exposure estimates (model): | % of AOEL |
|-----------------------------|-----------|
| **UK POEM**                  |           |
| Without PPE:                | 87%       |
| German model                |           |
| Without PPE:                | 16%       |
| **EFSA model:**             |           |
| Without PPE AOEL:           | 6.7%      |

**Use:** pome fruit, **hand-held sprayer application** rate 3.6 kg a.s./ha

| Exposure estimates (model): | % of AOEL |
|-----------------------------|-----------|
| **German model**            |           |
| Without PPE:                | 9%        |
| **EFSA model:**             |           |
| Without PPE AOEL:           | 2.9%      |
| **FOSETYL-AL 80% WP** |  |
|------------------------|------------------|
| **Fosetyl-Aluminium**  |  |
| **Use**: citrus, **tractor mounted equipment**, application rate 3.6 kg a.s./ha  |  |
| **Exposure estimates (model)**:  | % of AOEL  |
| **UK POEM**  |  |
| Without PPE:  | 55%  |
| German model  |  |
| Without PPE:  | 24%  |
| **EFSA model**:  |  |
| Without PPE:  | 21%  |
| **Use**: citrus, **hand-held sprayer application** rate 3.6 kg a.s./ha  |  |
| **German model**  |  |
| Without PPE:  | 15%  |
| **EFSA model**:  |  |
| Without PPE:  | 13%  |
| **Use**: grapes, **tractor mounted equipment**, application rate 2.64 kg a.s./ha  |  |
| **Exposure estimates (model)**:  | % of AOEL  |
| **UK POEM**  |  |
| Without PPE:  | 63%  |
| German model  |  |
| Without PPE:  | 17%  |
| **EFSA model**:  |  |
| Without PPE:  | 18%  |
| **Use**: grapes, **hand-held sprayer**, application rate 2.64 kg a.s./ha  |  |
| **German model**  |  |
| Without PPE:  | 11%  |
| **EFSA model**:  |  |
| Without PPE:  | 11%  |
|             | FEA + FLC WG 71.11 | SIP40958 |
|-------------|---------------------|----------|
| Use:        | grapes              | grapes   |
| **Fosetyl-Aluminium** |                     |          |
| Exposure estimates (model): | % of AOEL       |          |
| EUROPOEM II  |                      |          |
| Without PPE: | 78%                 | 93%      |
| EFSA model*: | 78%                 | 94%      |
| Without PPE: |                      |          |
| Aluminium   |                     |          |
| Exposure estimates (model): | % of AOEL       |          |
| EUROPOEM II  |                      |          |
| Without PPE: | 727%                | 586%     |
| EFSA model*: | 734%                |          |
| Without PPE: |                      |          |
### Fosetyl-Aluminium

#### Use: pome fruit

| Exposure estimates (model)                  | % of AOEL |
|-------------------------------------------|-----------|
| EUROPOEM II Without PPE:                  | 51%       |
| EFSA model*: Without PPE:                 | 50%       |

#### Use: citrus

| Exposure estimates (model)                  | % of AOEL |
|-------------------------------------------|-----------|
| EUROPOEM II With PPE (gloves):            | 315%      |
| EFSA model*: With PPE (gloves):           | 238%      |

#### Use: grapes

| Exposure estimates (model)                  | % of AOEL |
|-------------------------------------------|-----------|
| EUROPOEM II Without PPE:                  | 29%       |
| EFSA model*: Without PPE:                 | 30%       |

#### Aluminium

| Exposure estimates (model)                  | % of AOEL |
|-------------------------------------------|-----------|
| EUROPOEM II Without PPE:                  | 124%      |
| EFSA model*: Without PPE:                 | 125%      |

#### Use: citrus

| Exposure estimates (model)                  | % of AOEL |
|-------------------------------------------|-----------|
| EUROPOEM II With PPE (gloves):            | 134%      |
| EFSA model*: With PPE (gloves):           | 139%      |

#### Use: grapes

| Exposure estimates (model)                  | % of AOEL |
|-------------------------------------------|-----------|
| EUROPOEM II Without PPE:                  | 1187%     |

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**FOSE TYL AL WG 80 (FEA WG 80)**

#### Use: pome fruit

| Exposure estimates (model)                  | % of AOEL |
|-------------------------------------------|-----------|
| EUROPOEM II Without PPE:                  | 51%       |
| EFSA model*: Without PPE:                 | 50%       |

#### Use: citrus

| Exposure estimates (model)                  | % of AOEL |
|-------------------------------------------|-----------|
| EUROPOEM II With PPE (gloves):            | 315%      |
| EFSA model*: With PPE (gloves):           | 238%      |

#### Use: grapes

| Exposure estimates (model)                  | % of AOEL |
|-------------------------------------------|-----------|
| EUROPOEM II Without PPE:                  | 124%      |
| EFSA model*: Without PPE:                 | 125%      |

#### Aluminium

| Exposure estimates (model)                  | % of AOEL |
|-------------------------------------------|-----------|
| EUROPOEM II Without PPE:                  | 124%      |
| EFSA model*: Without PPE:                 | 125%      |

#### Use: citrus

| Exposure estimates (model)                  | % of AOEL |
|-------------------------------------------|-----------|
| EUROPOEM II With PPE (gloves):            | 134%      |
| EFSA model*: With PPE (gloves):           | 139%      |

#### Use: grapes

| Exposure estimates (model)                  | % of AOEL |
|-------------------------------------------|-----------|
| EUROPOEM II Without PPE:                  | 1177%     |
| EFSA model*: Without PPE:                 | 1187%     |
|                | FEA + FLC WG 71.11 |
|----------------|-------------------|
| **Use:**       | grapes            |
| **Fosetyl-Aluminium** |                   |
| Exposure estimates (model): | \% of AOEL |
| **EUROPOEM**   |                   |
| Bystander (adults): | 0.7%              |
| Martin et al. (2008) |                   |
| Bystander (adults): | 2.6%              |
| Bystander (children): | 2.0%             |
| Resident (adults): | 0.2%              |
| Resident (children): | 0.8%             |
| **EFSA model**  |                   |
| Resident (adults) all pathways: | 5.6%       |
| Resident (children) all pathways: | 11%         |

|                |                |
|----------------|----------------|
| **Aluminium**  |                |
| Exposure estimates (model): | \% of AOEL |
| Martin et al. (2008) |                   |
| Resident (adults): | 3.2%              |
| Resident (children): | 4.6%             |
| **EFSA model**  |                   |
| Resident (adults) all pathways: | 65%          |
| Resident (children) all pathways: | 157%        |

Bystanders and residents
### Fosetyl-Aluminium

| Exposure estimates (model) | % of AOEL |
|----------------------------|-----------|
| **EUROPOEM**               |           |
| Bystander (adults)         | 0.5%      |
| Martin et al. (2008)       |           |
| Bystander (adults)         | 3.1%      |
| Bystander (children)       | 2.4%      |
| Resident (adults)          | 0.2%      |
| Resident (children)        | 0.8%      |
| **EFSA model**             |           |
| Resident (adults)          | 2.8%      |
| Resident (children)        | 5.4%      |

### Aluminium

| Exposure estimates (model) | % of AOEL |
|----------------------------|-----------|
| Martin et al. (2008)       |           |
| Resident (adults)          | 1.4%      |
| Resident (children)        | 2.1%      |
| **EFSA model**             |           |
| Resident (adults) all pathways: | 29% |
| Resident (children) all pathways: | 87% |
| FOSE TYL-AL 80% WP |  |
|---|---|
| **FOSE TYL-AL 80% WP (FEA WG 80)** |  |
| **Use**: pome fruit |  |
| **Fosetyl-Aluminium** |  |
| Exposure estimates (model): | % of AOEL |  |
| **EUROPOEM** |  |
| Bystander (adults): | 1.6% |  |
| Martin et al. (2008) |  |
| Bystander (adults): | 3.8% |  |
| Bystander (children): | 3.0% |  |
| Resident (adults): | 1% |  |
| Resident (children): | 5.6% |  |
| **EFSA model***: |  |
| Resident (adults) all pathways: | 4.3% |  |
| Resident (children) all pathways: | 9.7% |  |
| **Aluminium** |  |
| Exposure estimates (model): | % of AOEL |  |
| Martin et al. (2008) |  |
| Resident (adults): | 12% |  |
| Resident (children): | 18% |  |
| **EFSA model*** |  |
| Resident (adults) all pathways: | 66% |  |
| Resident (children) all pathways: | 158% |  |
| **FOSE TYL-AL 80% WP** |  |
| **Fosetyl-Aluminium** |  |
| Exposure estimates (model): | % of AOEL |  |
| **EUROPOEM** |  |
| Bystander (adults): | 5.1% |  |
| Martin et al. (2008) |  |
| Bystander (adults): | 4.2% |  |
| Bystander (children): | 3.3% |  |
| Resident (adults): | 0.3% |  |
| Resident (children): | 1.4% |  |
| **EFSA model*** |  |
| Resident (adults): | 2.1% |  |
| Resident (children): | 4.1% |  |
| **Use**: citrus |  |
| **Use**: grapes |  |
| **Exposure estimates (model):** | % of AOEL |  |
| **EUROPOEM** |  |
| Bystander (adults): | 0.7% |  |
| Martin et al. (2008) |  |
| Bystander (adults): | 4.1% |  |
| Bystander (children): | 3.3% |  |
| Resident (adults): | 0.3% |  |
| Substance | Use | Exposure Estimates (Model) | % of AOEL | Martin et al. (2008) | EFSA Model* |
|-----------|-----|----------------------------|-----------|----------------------|-------------|
| Residues (children): | | | 1.4% | | |
| Residues (adults): | | | 4.2% | | |
| Residues (children): | | | 8% | | |

**Aluminium**

| Use | Exposure Estimates (Model) | % of AOEL |
|-----|----------------------------|-----------|
| Residents (adults): | 2.8% | |
| Residents (children): | 4.1% | |

**Use:** citrus

**Exposure estimates (model):**

- Martin et al. (2008)
  - Residents (adults): 2.8%
  - Residents (children): 4.1%

**EFSA model**

- Residents (adults): 31%
- Residents (children): 90%

**Use:** grapes

**Exposure estimates (model):**

- Martin et al. (2008)
  - Residents (adults): 2.8%
  - Residents (children): 4.1%

**EFSA model**

- Residents (adults): 52%
- Residents (children): 130%

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

**Substance:** Fosetyl - Al

- 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]:
  - Eye Dam. 1 H318 “Causes serious eye damage”
  - Eye Irrit. 2 H319 “Causes serious eye irritation”

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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.
Residues in or on treated products food and feed

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

| Primary crops (Plant groups covered) | Crop groups | Crop(s) | Application(s) | DAT (days) |
|---------------------------------------|-------------|---------|----------------|------------|
| OECD Guideline 501                    | Fruit crops| Oranges | 3-4 x 1 g a.s./15 trees (paintbrush application) | 75         |
|                                       |             | Apples  | 2 x unknown dose/ha | 0; 0+; 7; 14 |
|                                       |             | Pineapples | 1 dipping treatment of crowns (2.4 g/L solution) | 0; 7; 14; 28; 56; 120 |
|                                       |             |         | And 1 spraying treatment (2.4 g/L solution) | 115; 122   |
|                                       |             | Tomatoes | 2 x 4.4 kg a.s./ha | -14, 0+, 14 & 42 |
|                                       |             | Grapes  | 1 x 3024 µg a.s. per plant | 7, 14, 21 |

The initial step of fosetyl-Al metabolism proceeds through dissociation and the hydrolytic cleavage of the ethyl ester bond with phosphonic acid and ethanol as the major plant metabolites. Ethanol, when not lost by volatilisation, is further incorporated into natural products.

| Rotational crops (metabolic pattern) | Crop groups | Crop(s) | PBI (days) | Comments |
|--------------------------------------|-------------|---------|------------|----------|
| OECD Guideline 502                   | Root/tuber crops | Radish | 32; 182 | Residues of phosphonic acid are observed in plants grown only one month after application to the soil. Radish root: 0.8 mg/kg Lettuce: 0.76 mg/kg In all other crop parts phosphonic acid residues <LOQ (0.5 mg/kg). |
|                                      | Leafy crops | Lettuce | 32        |          |
|                                      | Cereals (small grain) | Barley | 32 |          |
|                                      | Others      |         |           |          |

Rotational crop and primary crop metabolism similar? Yes. Fosetyl-Al degrades in soil very rapidly to its metabolite, phosphonic acid. However, the study was not conducted with a radiolabelled material.

| Processed commodities (standard hydrolysis study) | Conditions | Fosetyl-Al | Phosphonic acid |
|---------------------------------------------------|------------|------------|-----------------|
| OECD Guideline 507                                | 30 min, 90°C, pH 4 | 99.8% | 101.8% | The test substances were not radiolabelled |
|                                                    | 60 min, 100°C, pH 5 | 101.3% | 102.6% | |
|                                                    | 20 min, 120°C, pH 6 | 99.5% | 101.9% | |

Residue pattern in processed commodities similar to residue pattern in raw commodities? Fosetyl-Al and phosphonic acid are therefore considered to be hydrolytically stable under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation.

| Plant residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31 | Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid – All categories of crops |
|------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| Plant residue definition for risk assessment (RD-RA)                                      | Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid – All categories of crops |
Conversion factor (monitoring to risk assessment) Not applicable

**Metabolism in livestock** (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

| OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish) | Animal | Dose (mg/kg bw/d) | Duration (days) | N rate/comment |
|-------------------------------------------------------|--------|-------------------|-----------------|----------------|
| Animals covered | Laying hen | Not required | | |
| | Goat/Cow | 0.42-0.43 mg/kg bw/d | 7 | 1.1N |
| | | 0.51 mg/kg bw/d | 7 | 1.34N |
| | | 1.46-1.50 mg/kg bw/d | 7 | 3.92N |
| Pig | Not required | | | |
| Fish | Not required | | | |

Time needed to reach a plateau concentration in milk and eggs (days) Day 2 to day 3 of dosing.

Animal residue definition for monitoring (RD-Mo) Phosphonic acid

**OECD Guidance, series on pesticides No 31**

Animal residue definition for risk assessment (RD-RA) Phosphonic acid

Conversion factor (monitoring to risk assessment) Not applicable

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

Fat soluble residues (Yes/No) (FAO, 2009) No (Log Po/w: -2.1)

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

Confined rotational crop study (Quantitative aspect) Not relevant as rotational crops field trials were provided.

OECD Guideline 502
Field rotational crop study

OECD Guideline 504

Field trials on rotational crops (carrots, lettuce and winter wheat or winter barley) were performed following three spraying applications with fosetyl at a dose rate of 0.775 kg a.s./ha. The residues of phosphonic acid were < LOQ (LOQ = 0.10 mg/kg in lettuce (head), carrots (root and leaf) and cereal (grain) and LOQ = 0.50 mg/kg in straw) except in the Spanish trial where apparent residue of phosphonic acid were found in the grain sample at 0.21 mg/kg.

Since these trials were under dosed compared to the critical GAPs that were assessed in the framework of the Article 12 MRL review, no conclusion can be drawn on the actual residue levels of fosetyl and phosphonic acid in rotational crops.
Stability of residues (Regulation (EU) No 283/2013, Annex Part A, point 6.1)
OECD Guideline 506

| Plant products (Category) | Commodity   | T (°C) | Stability (Months) |
|--------------------------|-------------|--------|--------------------|
|                          |             |        | Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid |
| High water content       | Cucumbers   | -20    | 25                 |
|                          | Cabbages    | -18    | 24                 |
|                          | Lettuces    | -18    | 24                 |
|                          | Tomatoes    | -18    | 24                 |
| High oil content         | Avocados    | -18    | 29                 |
| High protein content     | Beans       | -18    | 24                 |
| High starch content      | Potatoes    | -20    | 25                 |
| High acid content        | Grapes      | -20    | 25                 |
|                          | Oranges     | -18    | 24                 |

Data gap for IBERICA: Valid storage stability data on citrus fruit and covering the maximum storage time period of the residues from the trials on oranges and mandarins are requested.

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

Storage stability data on phosphonic acid in animal matrices were not submitted and are not required.
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) | STMR (mg/kg) |
|---------------------|---------------|-------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|------------|--------------|
| Citrus              | SEU           | Mandarins: 3.5, 3.6, 4.0, 4.2, 4.8, 7.7, 12.7, 15.10                                            | Data gap: a complete residue dataset on oranges compliant with the critical SEU GAP and supported by acceptable storage stability data (data gap; IBERICA). | 30 (mandarins)        | 15.1       | 4.5          |
|                     | (a)           |                                                                                                 |                                             |                       |            |              |
|                     |               |                                                                                                 |                                             |                       |            |              |
|                     | NEU           | 7.6; 8.2; 11; 12; 14; 15; 16; 17;                                                               | According to the Student test, 5% and Mann-Whitney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. | 50                    | 22         | 15           |
| Pome fruits (Bayer) |               |                                                                                                 |                                             |                       |            |              |
|                     | SEU           | 12, 13, 15, 15, 15.6, 17, 17.2, 22;                                                             |                                             |                       |            |              |
|                     | (Bayer)       |                                                                                                 |                                             |                       |            |              |
| Grapes              | NEU           | 10.11, 11.16, 14.23, 14.78, 16.25, 16.40, 19.32, 22.42, 23.42, 25.01, 27.23, 27.37, 39.78       | According to the Student test, 5% and Mann-Whitney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. | 60                    | 39.8       | 16.25        |
|                     | SEU           | 4.73, 7.97, 11.61, 11.91, 12.18, 12.32, 13.04, 13.54, 23.63, 31.25, 31.71, 37.15              |                                             |                       |            |              |
| Grapes (Iberica)    | SEU           | -                                                                                                | Data gap: the submitted residue trials are not compliant with the time interval between application and a complete residue dataset on grapes compliant with the critical SEU GAP is required (data gap: IBERICA). | -                     | -          | -            |
|                     |               |                                                                                                 |                                             |                       |            |              |
| Grapes (Iberica)    |               |                                                                                                 |                                             |                       |            |              |
|                     | (Iberica)     |                                                                                                 |                                             |                       |            |              |
|                     | NEU           | 8.5, 20.2, 26.6, 29.3                                                                            | Data gap: 4 additional residue trials compliant respectively with the NEU and SEU GAP on grapes are required to complete the residue dataset (data gap: OXON) | -                     | -          | -            |
|                     | SEU           | 3.1, 3.7, 9.3, 12.6                                                                              |                                             |                       |            |              |

Summary of the data on formulation equivalence OECD Guideline 509

No information provided and not requested

Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)
### Crop Residue Data and Recommendations

| Product(s)       | Region / Indoor (a) | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b) | Recommendations / comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) (c) | STMR (mg/kg) (d) |
|------------------|---------------------|---------------------------------------------------------------------------------------------------|------------------------------------------------|----------------------|----------------|-----------------|
| Citrus Nectar    | SEU / Spain         | At 0 DALA: 9.4, 31.7, 65.2 At 1 DALA: <2.8, 4.1, 10.2                                            | For sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid | -                    | -              | 31.7            |
| Citrus Flowers   | SEU / Spain         | At 0 DALA: 63.2, 72.5, 106 At 1 DALA: 21.7, 70.7, 72.1                                              |                                                 | -                    | -              | -               |

Data gap: Determination of residues of fosetyl-Al and phosphonic acid in pollen and bee products for human consumption resulting from residues taken up by honeybees from pome fruit and grapes at blossom (IBERICA, BCS, OXON).

(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\textsubscript{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\textsubscript{Mo}).

# if both Northern and Southern data set are not merged the calculated MRLs based on each zone data are: 8 mg/kg (NEU data) and 15 mg/kg (SEU data)
Inputs for animal burden calculations

| Feed commodity             | Median dietary burden (mg/kg) | Comment | Maximum dietary burden (mg/kg) | Comment |
|----------------------------|-------------------------------|---------|-------------------------------|---------|
|                            |                               |         |                               |         |
| **Risk assessment residue definition:** sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid |
| Apple, wet pomace          | 21 (15 x 1.2)                 | STMRp (STMR x PF) | 21 (15 x 1.2)                 | STMRp (STMR x PF) |
| Citrus, dried pulp         | 45 (4.5 x 10^1)              | STMRp (STMR x PF) | 45 (4.5 x 10^1)              | STMRp (STMR x PF) |

^ as no data on dried pulp are available, the default factor of 10 is used
Residues from livestock feeding studies (Regulation (EU) No 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)
Residue definition for monitoring and risk assessment: Phosphonic acid

| MRL calculations | Ruminant | Pig/Swine | Poultry | Fish |
|------------------|----------|-----------|---------|------|
| Highest expected intake (mg/kg bw/d) | Beef cattle 0.216 | Ram/Ewe 0.150 | Breeding 0.171 | Broiler |
| (mg/kg DM for fish) | Dairy cattle 0.380 | Lamb 0.191 | Finishing | Layer |
| Intake >0.004 mg/kg bw | Yes | Yes | Yes | No |
| Feeding study submitted | Yes (evaluated in the initial DAR) | / | / | No |

| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | Level 0.352 mg/kg bw | Beef: 1.6 N Dairy: 0.9 N | Level 0.352 mg/kg bw | Lamb: 1.8 N |
|------------------|----------------------|----------------------|----------------------|-------------|
| Muscle | HR<sub>(a)</sub> at 1N | MRL proposals | HR<sub>(a)</sub> at 1N | MRL proposals |
| Fat | 0.500 | 0.5 | 0.000 | <0.5 |
| Meat<sup>(b)</sup> | 0.500 | 0.5 | 0.000 | <0.5 |
| Liver | 0.500 | 0.5 | 0.000 | <0.5 |
| Kidney | 0.495 | 0.5 | 0.000 | <0.5 |
| Milk<sup>(c)</sup> | 0.000 | <0.1 | 0.000 | <0.1 |
| Eggs | | | | |

| Method of calculation<sup>(c)</sup> | |
|------------------|----------------------|----------------------|----------------------|----------|

<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.
Conversion Factors (CF) for monitoring to risk assessment

Not relevant

Processing factors (Regulation (EU) No 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) Individual values | Conversion Factor (CF) for RA(b) |
|--------------------------------------------------------|----------------------|-----------------------------------------|---------------------------------|
|                                                        |                      |                                         |                                 |
| Orange/mandarin, peeled                                 | 33                   | 0.21; 0.24; 0.33; 0.4; 0.48; 0.48; 0.48; 0.48; 0.5; 0.5; 0.54; 0.6*; 0.6*; 0.62; 0.8; 0.8; 0.8; 0.8*; 0.8*; 0.9*; 0.9; 1.0; 1.0; 1.0; 1.0*; 1.1; 1.1; 1.1*; 1.1*; 1.1*; 1.2; 1.3; 2.0; 3.8; | 0.8 |
| Orange, wet pomace                                      | 4                    | 0.9; 0.1; 0.1;                          | 0.1 |
| Orange, juice                                          | 7                    | 0.9; 0.9*; 1.1; 1.3; 1.6*;              | 1.1 |
| Orange, marmelade                                      | 4                    | 0.5*; 0.7*;                             | 0.6 |
| Apple, wet pomace                                      | 4                    | <0.5*; <0.8*; 1.6*; 1.6*                | <1.2 |
| Apple, juice                                           | 4                    | <0.6*; <1.2*; <2.5*; <2.9*;            | <1.9 |
| Apple, puree                                           | 4                    | 0.4*; 0.7*; 1.1*; 1.6*                 | 0.9 |
| Grape, white wine                                      | 8                    | 0.4; 0.4; 0.5; 0.5; 0.6; 1.1; 1.5; 1.4*; 1.6* | 0.6 |
| Grape, red wine                                        | 13                   | 0.1; 0.5; 0.6; 0.7; 0.8; 0.8; 1.1; 1.3; 1.8; 1.4; 1.2; 1.5*; 2.5;   | 1.1 |
| Grape, juice                                           | 7                    | 0.5; 0.7; 0.9; 1.0; 1.0; 1.1; 1.2;     | 1.0 |

*a new data submitted by Iberica
b new data submitted by Bayer

Consumer risk assessment (Regulation (EU) No 283/2013, Annex Part A, point 6.9)
Limited to the representative uses.

Residue definition for risk assessment: sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid

ADI

1 mg/kg bw per day

TMDI according to EFSA PRIMo

Highest TMDI: 73% ADI (DE, child)

NTMDI, according to (to be specified)

Highest NTMDI: Not provided, not required

IEDI (% ADI), according to EFSA PRIMo

Highest IEDI: Not provided, not required

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

Highest NEDI: Not provided, not required

Factors included in the calculations

None

ARfD

ARfD not allocated; not required

IESTI (% ARfD), according to EFSA PRIMo

Factors included in IESTI and NESTI
Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Residue definition for monitoring: sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid

| Code<sup>(a)</sup> | Commodity/Group | MRL/Import tolerance<sup>(b)</sup> (mg/kg) and Comments |
|-------------------|-----------------|--------------------------------------------------------|
| Plant commodities |                 |                                                        |
| 0110050           | Mandarin s      | 30                                                     |
| 0130000           | Pome fruits     | 50                                                     |
| 0151000           | Wine grapes     | 60                                                     |
| 1000000           | Products of animal origin | MRLs are not required. |

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005
(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure
Environmental fate and behaviour

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

| Parameter | Value |
|-----------|-------|
| Mineralisation after 100 days | 19.6 % after 15 h, [ethyl-1-^{14}C]-fosetyl-Al (n=4) |
| Non-extractable residues after 100 days | 47 % after 16 h, [ethyl-1-^{14}C]-fosetyl-Al (n=4) |
| Metabolites requiring further consideration | Phosphonic acid: 100 % assumed (not measured) Ethanol: 78 % at 1.5 h (n=4) |

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

| Parameter | Value |
|-----------|-------|
| Mineralisation after 100 days | 48 % after 10 days, [ethyl-1-^{14}C]-fosetyl-Al (n=2) 47% after 10 days, [ethyl-1-^{14}C]-fosetyl-ammonium (n=1) |
| Non-extractable residues after 100 days | 6% after 1.33 days, [ethyl-1-^{14}C]-fosetyl-Al (n=2) 7% after 1.33 days, [ethyl-1-^{14}C]-fosetyl-ammonium (n=1) |
| Metabolites that may require further consideration | [ethyl-1-^{14}C]-fosetyl-ammonium (n=1) Ethanol; 22% after 5 days |

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

| Parameter | Value |
|-----------|-------|
| Metabolites that may require further consideration | - |
| Mineralisation at study end | No data |
| Non-extractable residues at study end | No data |

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)

| Fosetyl-Al | Dark aerobic conditions |
|-----------|------------------------|
| Data package | Soil type | pH | t. °C / Moisture | DT_{so}/DT_{so} (d) | DT_{so} (20 °C pF2/10kPa) | St. (χ²) | Method of calculation |
| Previous Approval | sandy loam (Soil 1) | 5.3 | 20°C/75%WHC (1/3 bar) | 0.01/0.04 | 0.01 | 2.3 | SFO |
| | loamy sand (Soil 2) | 6.6 | 20°C/75%WHC (1/3 bar) | 0.05/0.16 | 0.04 | 0.6 | SFO |

n corresponds to the number of soils.
### 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 9.1.1.1.1)

#### Trigger endpoints:

| Phosphonic acid | Dark aerobic conditions. Study performed with phosphonic acid. |
|-----------------|---------------------------------------------------------------|
| **Data package** | **Soil type** | **pH a)** | **T °C / Moisture** | **DT 50/DT 90** | **DT 50 (d)** | **St. (χ2)** | **Method of calculation** |
| PREVIOUS APPROVAL | clay loam | - | - | - | - | - | - |
| | Sandy loam | 5.0 | 20°C / 75%WHC (1/3 bar) | 130/432 | - | 6.88 | SFO |
| BAYER CROP SCIENCE | silt loam | 6.0 | 20°C / 50%MWHC | 115/441 b) | - | 2.60 | DFOP |
| | clay loam | 7.2 | 20°C / 50%MWHC | 31/143 c) | - | 3.37 | DFOP |
| | sandy loam | 5.0 | 20°C / 50%MWHC | >1000/>1000 d) | - | 3.49 | DFOP |
| | sandy loam | 6.1 | 20°C / 50%MWHC | 28/91 | - | 11.3 | SFO |
| IBERICA | Loamy sand | 5.2 | 20°C / 45%MWHC | 240/10000 e) | - | 3.17 | FOMC |

a) Measured in calcium chloride solution  
b) Kinetic parameters: k1=0.0953; k2=0.0049; g=0.1201  
c) Kinetic parameters: k1=0.1572; k2=6.984x10^{-5}; g=0.04124  
d) Kinetic parameters: k1=0.04619; k2=7.1x10^{-13}; g=0.300  
e) Kinetic parameters: alpha=0.2236; beta=11.31

#### Modelling endpoints:

| Phosphonic acid | Dark aerobic conditions. Study performed with phosphonic acid. |
|-----------------|---------------------------------------------------------------|
| **Data package** | **Soil type** | **pH a)** | **T °C / Moisture** | **DT 50/DT 90** | **DT 50 (d)** | **St. (χ2)** | **Method of calculation** |
| PREVIOUS APPROVAL | clay loam | - | - | - | - | - | - |
| | Sandy loam | 5.0 | 20°C / 75%WHC (1/3 bar) | 130/432 | 88 | 6.88 | SFO |
### Geometric mean

| Soil Type | pH | t. °C / Moisture | DT₅₀/DT₉₀ (d) | FF | St. (Q²) | Method of calculation |
|-----------|----|-----------------|----------------|----|---------|----------------------|
| clay loam (Soil 1) | 7.2 | 20°C/50%MWHC | 38.9/129 | 38.9 | 7.17 | SFO |
| sandy loam | 5.0 | 20°C/50%MWHC | 1000 c) | 1000 c) | - | DFOP |
| sandy loam | 6.1 | 20°C/50%MWHC | 27.5/91.4 | 27.5 | 11.3 | SFO |
| Loamy sand | 5.2 | 20°C/45%MWHC | 532 (slow phase) | 3.43 | HS |

### 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)

| Ethanol | Data package | Soil type | pH a) | t. °C / Moisture | DT₅₀/DT₉₀ (d) | DT₅₀(20 °C) pF2/10kPa b) | FF | St. (Q²) | Method of calculation |
|---------|--------------|-----------|-------|-----------------|----------------|-----------------------|----|---------|----------------------|
| Sandy loam (Soil 1) | 5.3 | 20°C/75%WHC (1/3 bar) | 0.16/0.54 | 0.13 | 1 | 9.6 | SFO-SFO Fosetyl-Al applied |
| Sandy loam (Soil 1) | 5.3 | 20°C/75%WHC (1/3 bar) | 0.17/0.57 | 0.14 | 1 | 8.3 | SFO Ethanol applied |
| Loamy sand (Soil 2) | 6.6 | 20°C/75%WHC (1/3 bar) | 0.12/0.41 | 0.11 | 1 | 4.8 | SFO-SFO Fosetyl-Al applied |
| Silt loam (Soil 3) | 6.6 | 20°C/75%WHC (1/3 bar) | 0.18/0.58 | 0.14 | 1 | 4.3 | SFO-SFO Fosetyl-Al applied |
| Clay loam (Soil 4) | 7.6 | 20°C/75%WHC (1/3 bar) | 0.08/0.28 | 0.07 | 1 | 20.0 | SFO-SFO Fosetyl-Al applied |
| Clay loam (S261) | 6.9 | 20°C/40%MWHC | - | - | - | - |
| Sand (S262) | 5.4 | 20°C/40%MWHC | - | - | - | - |
| Sandy loam (S263) | 6.6 | 20°C/40%MWHC | - | - | - | - |

- a) Measured in calcium chloride solution
- b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
- c) Default value on the basis of kinetic evaluation of second slower phase
- Fraction of formation from fosetyl-Al = 1.0

### pH dependence:

- No
Rate of degradation field soil dissipation studies (Regulation (EU) No 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.1.2.1)

No data submitted.
Data gap for phosphonic acid: field studies should be conducted (DT50, lab > 60 days).

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*
Not relevant since no field data submitted.

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)
No soil accumulation study submitted. For PEC_{soil,accumulation}, please refer to PEC_{soil} section.

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)
No reliable data.

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) No 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.1.1)
No reliable data.
The route of degradation of Fosetyl-Al in soil under anaerobic conditions is not expected to be distinct from the one observed under aerobic conditions.

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) No 283/2013, Annex Part A, point 7.1.1.3)
No data submitted.

Soil adsorption active substance (Regulation (EU) No 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.2.1)

Fosetyl-Al: Low adsorption to soil. No reliable data could be determined as indicated by a batch adsorption equilibrium study due to very short half-life in soil.
The $K_{foc}$ value of 0.1 L/kg in association with a Freundlich exponent of 1 is proposed by the applicants in the exposure calculations.

Soil adsorption transformation products (Regulation (EU) No 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.2.1)

| Phosphonic acid | Soil Type | OC % | Soil pH$^0$ | $K_{dl}$ (mL/g) | $K_{doc}$ (mL/g) | $K_{f}$ (mL/g) | $K_{foc}$ (mL/g) | 1/n |
|-----------------|-----------|------|-------------|----------------|----------------|--------------|----------------|-----|
| Data package    |           |      |             |                |                |              |                |     |
| EFSA (2013)*    |           |      |             |                |                |              |                |     |
| Batch study     |           |      |             |                |                |              |                |     |
| sandy loam      | 1.7       | 7.2  | -           | 4.2            | 246            | 0.88         |                 |     |
| silt loam       | 1.18      | 6.97 | -           | 12.8           | 1086           | 0.74         |                 |     |
| sand            | 1.08      | 5.8  | -           | 32.8           | 3038           | 0.66         |                 |     |
| silt loam       | 2.6       | 6.7  | -           | 5.0            | 193            | 0.78         |                 |     |
| loam            | 1.46      | 7.1  | -           | 4.9            | 332            | 0.92         |                 |     |
| Soil Type                | pH     | CEC (mEq/kg) | Kd (mL/g) | Elution (mm) | Time period (d) |
|-------------------------|--------|--------------|-----------|--------------|-----------------|
| **IBERICA Batch study** |        |              |           |              |                 |
| loamy sand              | 2.3    | 5.7          | -         | 17.7         | 770             |
| sandy silt loam         | 2.19   | 7.2          | -         | 9.0          | 409             |
| clay loam               | 1.4    | 6.6          | -         | 35.8         | 2557            |
| silt loam               | 4      | 5.6          | -         | 82.4         | 2060            |
| light silty sand        | 2.9    | 5.1          | -         | 50.5         | 1741            |
| Geometric mean          | 15.9   | 827          |           |              |                 |
| Arithmetic mean         | 16     | 5307         |           |              |                 |
| **EFSA (2012)**         |        |              |           |              |                 |
| Loam                    | 1.36   | 6.80         | 3.10      | 228          | -               |
| Clay loam               | 4.13   | 7.55         | 10.37     | 251          | -               |
| Silty clay loam         | 2.67   | 5.00         | 15.67     | 587          | -               |
| Sandy loam              | 2.3    | 5.6          | 5.30      | 230          | -               |
| Silt loam               | 1.95   | 5.52         | 18.96     | 972          | -               |
| Geometric mean          | -      | -            |           |              |                 |
| Arithmetic mean         | -      | -            |           |              |                 |
| **BAYER CROP SCIENCE**  |        |              |           |              |                 |
| Sand                    | 2.4    | 6.2          | 43.9      | 1829         | -               |
| Sandy loam              | 3.0    | 4.6          | 46.3      | 1543         | -               |
| Clay loam               | 4.3    | 7.2          | 28        | 650          | -               |
| Sandy loam              | 1.6    | 5.0          | 87        | 5429         | -               |
| Sandy loam              | 1.2    | 6.1          | 30        | 1650         | -               |
| Geometric mean          | -      | -            |           |              |                 |
| Arithmetic mean         | -      | -            |           |              |                 |

- Measured in calcium chloride solution
- *EFSA conclusion on disodium phosphonate (2013)
- **EFSA conclusion on potassium phosphonates (2012)

**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 | No reliable data |

**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 (Phosphonic acid) | Elution (mm): 508 mm | Time period (d): 15 d |
|----------------------------------|----------------------|----------------------|
| Leachate: 0% total radioactivity in leachate 54.0-63.2% phosphonic acid retained in top 2.5 cm. Not detected in other segments |
| Kd (mL/g) = see above |
| Elution (mm): 508 mm | Time period (d): 5 d |
Leachate: 0% phosphonic acid in leachate (only compound sought) 
Between 35.2-74.1% phosphonic acid retained in top 5 cm. < 3% phosphonic acid below 10 cm. 
Kd (mL/g) = see above

Lysimeter / field leaching studies (Regulation (EU) No 283/2013, Annex Part A, points 7.1.4.2/7.1.4.3 and Regulation (EU) No 284/2013, Annex Part A, points 9.1.2.2/9.1.2.3)
No data submitted.

Hydrolytic degradation (Regulation (EU) No 283/2013, Annex Part A, point 7.2.1.1)
Hydrolytic degradation of the active substance and metabolites > 10% 
Stable at pH 5 to 9 at 20 to 70 °C

Aqueous photochemical degradation (Regulation (EU) No 283/2013, Annex Part A, points 7.2.1.2/7.2.1.3)
Photolytic degradation of active substance and metabolites above 10% 
DT$_{50}$: 35 days (direct photolysis, sterile pure water) 
DT$_{50}$: 77 days (indirect photolysis, sterile natural water) 
Metabolites:
Ethyl phosphate: 24.3% AR (7 d) 
Ethanol: 14.3% AR (7 d) 
Acetic acid: 44.6% AR (7 d)

Quantum yield of direct phototransformation in water at $\Sigma > 290$ nm

‘Ready biodegradability’ (Regulation (EU) No 283/2013, Annex Part A, point 7.2.2.1)
Readily biodegradable (yes/no) 
No

Aerobic mineralisation in surface water (Regulation (EU) No 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) No 284/2013, Annex Part A, point 9.2.1)

| Data package | System | pH water phase | pH sed | t. °C$^\circ$ | DT$_{50}$/DT$_{90}$ whole sys. (suspended sediment test) | St. ($\chi^2$) | DT$_{50}$/DT$_{90}$ Water (pelagic test) | St. ($\chi^2$) | Method of calculation |
|--------------|--------|----------------|--------|-------------|-------------------------------------------------|--------------|----------------------------------------|--------------|------------------------|
| BAYER        | Fresh water (low dose) | 8.0 | - | 20 | - | - | 6.9/23.0 | 14.7/48.9 | 26.4 | SFO |
| Data package | System          | pH water phase | pH sed | Mineralisation                      | Non-extractable residues | Non-extractable residues | Method of calculation |
|--------------|----------------|----------------|--------|-------------------------------------|--------------------------|--------------------------|-----------------------|
| **BAYER**    | Fresh water    | 8.0            | -      | 44.2 % after 63 d. (end of the study). | -                        | -                        |                       |
|              | Fresh water    | 8.0            | -      | 58.1 % after 63 d. (end of the study). | -                        | -                        |                       |
| **IBERICA**  | Fresh water    | 7.9            | -      | 56.6 % after 21 d. (then decrease until the end of study at 61 days). | -                        | -                        |                       |
|              | Fresh water    | 7.9            | -      | 96.5 % after 30 d. (then decrease until the end of study at 61 days). | -                        | -                        |                       |
| **OXON**     | Fresh water    | 7.8            | -      | 48.2 % after 62 d. (end of the study). | -                        | -                        |                       |
|              | Fresh water    | 7.8            | -      | 55.2 % after 62 d. (end of the study). | -                        | -                        |                       |

**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)**

| Fosetyl-Al | Distribution (Max. sed 0.6 % after 1d) |
|------------|---------------------------------------|
| Water / sediment system | pH | pH | t. °C | DT<sub>50</sub> / DT<sub>90</sub> whole sys. | St. (χ<sup>2</sup>) | DT<sub>50</sub> / DT<sub>90</sub> water | St. (χ<sup>2</sup>) | DT<sub>50</sub> / DT<sub>90</sub> sed | St. (χ<sup>2</sup>) | Method of calculation |
| Water / sediment system |     |     |      |                          |                    |                          |                    |                          |                    |                        |
| Maningtree  | 6.94 | 6.1 | 20   | 3.68/12.22               | 3.4               | 3.64/12.10               | 3.6               | -                          | -                   | SFO                    |
| Ongar       | 7.90 | 7.7 | 20   | 2.44/8.12                | 5.5               | 2.44/8.12                | 5.5               | -                          | -                   | SFO                    |
| Geometric mean at 20°C<sup>b</sup> | 3.00/9.96 | - | - | - | - | - | - | SFO | - |

<sup>a</sup> Measured in calcium chloride solution
<sup>b</sup> Normalised using a Q10 of 2.58
### Phosphonic acid

| Method of calculation | Water / sediment system | pH water phase | pH sed | t. °C | DT<sub>50</sub> / DT<sub>90</sub> whole sys. | St. (χ²) | DT<sub>50</sub> / DT<sub>90</sub> water | St. (χ²) | DT<sub>50</sub> / DT<sub>90</sub> sed | St. (χ²) |
|-----------------------|-------------------------|----------------|--------|--------|-----------------------------|----------|-----------------------------|----------|-----------------------------|----------|
| Maningtree            |                         | 6.94           | 6.1    | 20     | No data                     | -        | No data                     | -        | No data                     | -        |
| Ongar                 |                         | 7.90           | 7.7    | 20     | No data                     | -        | No data                     | -        | No data                     | -        |

Geometric mean at 20°C<sup>60</sup> - - - -

<sup>60</sup> Measured in calcium chloride solution
<sup>d</sup> Normalised using a Q10 of 2.58

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

| Water / sediment system | pH water phase | pH sed | Mineralisation | Non-extractable residues in sed. | Non-extractable residues in sed. |
|-------------------------|----------------|--------|----------------|----------------------------------|----------------------------------|
| Maningtree              | 6.94           | 6.1    | 75.9 % after 100 d. (end of the study). | max 28.8 % after 14 d            | max 19.4 % after 100 d (end of the study) |
| Ongar                   | 7.90           | 7.7    | 70.9 % after 100 d. (end of the study). | max 24 % after 30 d             | max 20.8 % after 100 d (end of the study) |

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

- **Direct photolysis in air**: Not studied - no data requested
- **Photochemical oxidative degradation in air**: DT<sub>50</sub> of 2.22 hours derived by the Atkinson model (AOPWIN version 1.92a). OH (12) concentration assumed = 1.5x10⁶ cm⁻³
- **Volatilisation**: Not studied - no data requested
- **Metabolites**: -

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

- **Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure**
  - **Soil**: fosetyl-Al, phosphonic acid and ethanol
  - **Surface water**: fosetyl-Al and phosphonic acid
  - **Sediment**: fosetyl-Al and phosphonic acid
  - **Ground water**: fosetyl-Al, phosphonic acid and ethanol
  - **Air**: fosetyl-Al

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

See section 5, Ecotoxicology
Monitoring data, if available (Regulation (EU) No 283/2013, Annex Part A, point 7.5)
No data provided by the Applicants

PEC soil (Regulation (EU) No 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

| Fosetyl-Al | DT$_{50}$ (d): 0.1 days |
|------------|-------------------------|
| Method of calculation | Kinetics: SFO |
| | Field or Lab: Representative worst case from laboratory studies |

Application data

| | Depth of soil layer: 5 cm |
| | Soil bulk density: 1.5 g/cm$^3$ |
| Crop: | |
| A.) Grapes | |
| % plant interception: 60 (BBCH 15-81) | |
| Number of applications: 3 | |
| Interval (d): 10 | |
| Application rate(s): 2000 g a.s./ha | |
| B.) Grapes | |
| % plant interception: 60 (flowering) | |
| Number of applications: 4 | |
| Interval (d): 10 | |
| Application rate(s): 2640 g a.s./ha | |
| C.) Grapes | |
| % plant interception: 50 (BBCH 11-79) | |
| Number of applications: 4 | |
| Interval (d): 10 | |
| Application rate(s): 1350 g a.s./ha | |
| D.) Pome fruits | |
| % plant interception: 60 (BBCH 55-85) | |
| Number of applications: 3 | |
| Interval (d): 7 | |
| Application rate(s): 3600 g a.s./ha | |
| E.) Citrus | |
| % plant interception: 80 (flowering) | |
| Number of applications: 3 | |
| Interval (d): 90 | |
| Application rate(s): 3600 g a.s./ha | |

A.) Grapes (3 x 2000 g a.s./ha) Formulated product Fosetyl-Al + Fluopicolide WG 71.11 (Bayer CropScience)
### B.) Grapes (4 x 2640 g a.s./ha) Formulated product FOSETYL AL 80% WP (Iberica)

| PEC<sub>(s)</sub> (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|--------------------------|----------------------------|----------------------------------------|----------------------------|----------------------------------------|
| Initial                  | n.c.                       |                                        | 1.067                      |                                        |
| Short term 24h            | n.c.                       | n.c.                                   | -                          | -                                      |
|                          | n.c.                       | n.c.                                   | -                          | -                                      |
|                          | n.c.                       | n.c.                                   | -                          | -                                      |
| Long term 7d             | n.c.                       | n.c.                                   | -                          | -                                      |
|                          | n.c.                       | n.c.                                   | -                          | -                                      |
|                          | n.c.                       | n.c.                                   | -                          | -                                      |
|                          | n.c.                       | n.c.                                   | -                          | -                                      |
| 100d                     | n.c.                       | n.c.                                   | -                          | -                                      |
| Plateau concentration    | Not needed                 |                                        |                            |                                        |

- not required for the risk assessment of the soil organisms. n.c. not calculated

### C.) Grapes (4 x 1350 g a.s./ha) Formulated product SIP40958 (Oxon SAE Fosetyl Task Force)

| PEC<sub>(s)</sub> (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|--------------------------|----------------------------|----------------------------------------|----------------------------|----------------------------------------|
| Initial                  | n.c.                       |                                        | 0.900                      |                                        |
| Short term 24h            | n.c.                       | n.c.                                   | -                          | -                                      |
|                          | n.c.                       | n.c.                                   | -                          | -                                      |
|                          | n.c.                       | n.c.                                   | -                          | -                                      |
| Long term 7d             | n.c.                       | n.c.                                   | -                          | -                                      |
|                          | n.c.                       | n.c.                                   | -                          | -                                      |
|                          | n.c.                       | n.c.                                   | -                          | -                                      |
|                          | n.c.                       | n.c.                                   | -                          | -                                      |
| 100d                     | n.c.                       | n.c.                                   | -                          | -                                      |
| Plateau concentration    | Not needed                 |                                        |                            |                                        |

- not required for the risk assessment of the soil organisms. n.c. not calculated
### PE C\(_{(s)}\) (mg/kg)

|          | Single application | Single application | Multiple application | Multiple application |
|----------|-------------------|--------------------|----------------------|----------------------|
|          | Actual            | Time weighted average | Actual               | Time weighted average |

|          | Initial | Short term | Long term | Plateau concentration |
|----------|---------|------------|-----------|-----------------------|
|          |         | 24h        | 7d        |                       |
|          | n.c.    | n.c.       | n.c.      | Not needed            |
|          |         | 2d         | 28d       |                       |
|          | n.c.    | n.c.       | n.c.      |                       |
|          |         | 4d         | 50d       |                       |
|          | n.c.    | n.c.       | n.c.      |                       |
|          |         |            | 100d      |                       |
|          | n.c.    |            | n.c.      |                       |

- not required for the risk assessment of the soil organisms.

n.c. not calculated

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### D) Pome fruits (3 x 3600 g a.s./ha) - Formulated product Fosetyl-ALUMINIUM WG 80 (Bayer CropScience)

|          | Single application | Single application | Multiple application | Multiple application |
|----------|-------------------|--------------------|----------------------|----------------------|
|          | Actual            | Time weighted average | Actual               | Time weighted average |

|          | Initial | Short term | Long term | Plateau concentration |
|----------|---------|------------|-----------|-----------------------|
|          |         | 24h        | 7d        |                       |
|          | n.c.    | n.c.       | n.c.      | Not needed            |
|          |         | 2d         | 28d       |                       |
|          | n.c.    | n.c.       | n.c.      |                       |
|          |         | 4d         | 50d       |                       |
|          | n.c.    | n.c.       | n.c.      |                       |
|          |         |            | 100d      |                       |
|          | n.c.    |            | n.c.      |                       |

- not required for the risk assessment of the soil organisms.

n.c. not calculated

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### E) Citrus (3 x 3600 g a.s./ha) - Formulated product FOSETYL AL 80 % WP (Iberica)

|          | Single application | Single application | Multiple application | Multiple application |
|----------|-------------------|--------------------|----------------------|----------------------|
|          | Actual            | Time weighted average | Actual               | Time weighted average |

|          | Initial | Short term | Long term | Plateau concentration |
|----------|---------|------------|-----------|-----------------------|
|          |         | 24h        | 7d        |                       |
|          | n.c.    | n.c.       | n.c.      | Not needed            |
|          |         | 2d         | 28d       |                       |
|          | n.c.    | n.c.       | n.c.      |                       |
|          |         | 4d         | 50d       |                       |
|          | n.c.    | n.c.       | n.c.      |                       |
|          |         |            | 100d      |                       |
|          | n.c.    |            | n.c.      |                       |

- not required for the risk assessment of the soil organisms.

n.c. not calculated
| PEC<sub>(s)</sub> (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|--------------------------|---------------------------|------------------------------------------|-----------------------------|------------------------------------------|
| 100d                     | n.c.                      | n.c.                                     | -                           | -                                        |

Plateau concentration: Not needed

- not required for the risk assessment of the soil organisms.

n.c. not calculated

**Phosphonic acid**

**Method of calculation**

- Molecular weight relative to the parent: 0.695 (considering 3 molecules of phosphonic acid are formed from a single molecule of fosetyl-Al)
- DT<sub>50</sub> (d): 1000 days
- Kinetics: SFO. Worst case from laboratory studies
- Application rate assumed: x g/ha (assumed Met I is formed at a maximum of 100% of the applied dose)

**Application data**

- Depth of soil layer: 5 cm
- Soil bulk density: 1.5 g/cm<sup>3</sup>

Crop:

- **A.) Grapes**
  - % plant interception: 60 (BBCH 15-81)
  - Number of applications: 3
  - Interval (d): 10
  - Application rate(s) assumed: 1390 g a.s./ha

- **B.) Grapes**
  - % plant interception: 60 (flowering)
  - Number of applications: 4
  - Interval (d): 10
  - Application rate(s) assumed: 1835 g a.s./ha

- **C.) Grapes**
  - % plant interception: 50 (BBCH 11-79)
  - Number of applications: 4
  - Interval (d): 10
  - Application rate(s) assumed: 938 g a.s./ha

- **D.) Pome fruits**
  - % plant interception: 60 (BBCH 55-85)
  - Number of applications: 3
  - Interval (d): 7
  - Application rate(s) assumed: 2502 g a.s./ha

- **E.) Citrus**
  - % plant interception: 80 (flowering)
  - Number of applications: 3
  - Interval (d): 90
  - Application rate(s) assumed: 2502 g a.s./ha
A.) Grapes (3 x 2000 g a.s./ha)  Formulated product Fosetyl-Al + Fluopicolide WG 71.11 (Bayer CropScience)

|          | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|----------|---------------------------|------------------------------------------|-----------------------------|---------------------------------------------|
| Initial  | n.c.                      |                                          | 2.207                       |                                             |
| Short term 24h | n.c.                      | n.c.                              | -                           | -                                           |
|           | n.c.                      | n.c.                              | -                           | -                                           |
|          | n.c.                      | n.c.                              | -                           | -                                           |
| Long term 7d | n.c.                      | n.c.                              | -                           | -                                           |
|           | n.c.                      | n.c.                              | -                           | -                                           |
|           | n.c.                      | n.c.                              | -                           | -                                           |
|          | n.c.                      | n.c.                              | -                           | -                                           |
| Plateau concentration | 9.875 mg/kg             |                                          |                             |                                             |

- not required for the risk assessment of the soil organisms.

n.c. not calculated

B.) Grapes (4 x 2640 g a.s./ha)  Formulated product Fosetyl-Al 80% WP

|          | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|----------|---------------------------|------------------------------------------|-----------------------------|---------------------------------------------|
| Initial  | n.c.                      |                                          | 3.874                       |                                             |
| Short term 24h | n.c.                      | n.c.                              | -                           | -                                           |
|           | n.c.                      | n.c.                              | -                           | -                                           |
|           | n.c.                      | n.c.                              | -                           | -                                           |
| Long term 7d | n.c.                      | n.c.                              | -                           | -                                           |
|           | n.c.                      | n.c.                              | -                           | -                                           |
|           | n.c.                      | n.c.                              | -                           | -                                           |
|           | n.c.                      | n.c.                              | -                           | -                                           |
| Plateau concentration | 17.331 mg/kg             |                                          |                             |                                             |

- not required for the risk assessment of the soil organisms.

n.c. not calculated

C.) Grapes (4 x 1350 g a.s./ha)  Formulated product SIP40958 (Oxon SAE Fosetyl Task Force)
### PEC\(_{\text{s}}\) (mg/kg)

|                | Single application | Single application | Multiple application | Multiple application |
|----------------|--------------------|--------------------|----------------------|----------------------|
|                | Actual             | Time weighted average | Actual             | Time weighted average |
| Initial        | n.c.               | 2.476              |                      |                      |
| Short term     | n.c.               | n.c.               | -                    | -                    |
| 24h            | n.c.               | n.c.               | -                    | -                    |
| 2d             | n.c.               | n.c.               | -                    | -                    |
| 4d             | n.c.               | n.c.               | -                    | -                    |
| Long term      | n.c.               | n.c.               | -                    | -                    |
| 7d             | n.c.               | n.c.               | -                    | -                    |
| 28d            | n.c.               | n.c.               | -                    | -                    |
| 50d            | n.c.               | n.c.               | -                    | -                    |
| 100d           | n.c.               | n.c.               | -                    | -                    |
| Plateau        | 11.076 mg/kg       |                    |                      |                      |
| concentration  |                    |                    |                      |                      |

- not required for the risk assessment of the soil organisms.

n.c. not calculated

**D.) Pome fruits (3 x 3600 g a.s./ha) Formulated product Fosetyl-ALUMINIUM WG (Bayer CropScience)**

|                | Single application | Single application | Multiple application | Multiple application |
|----------------|--------------------|--------------------|----------------------|----------------------|
|                | Actual             | Time weighted average | Actual             | Time weighted average |
| Initial        | n.c.               | 3.982              |                      |                      |
| Short term     | n.c.               | n.c.               | -                    | -                    |
| 24h            | n.c.               | n.c.               | -                    | -                    |
| 2d             | n.c.               | n.c.               | -                    | -                    |
| 4d             | n.c.               | n.c.               | -                    | -                    |
| Long term      | n.c.               | n.c.               | -                    | -                    |
| 7d             | n.c.               | n.c.               | -                    | -                    |
| 28d            | n.c.               | n.c.               | -                    | -                    |
| 50d            | n.c.               | n.c.               | -                    | -                    |
| 100d           | n.c.               | n.c.               | -                    | -                    |
| Plateau        | 17.810 mg/kg       |                    |                      |                      |
| concentration  |                    |                    |                      |                      |

- not required for the risk assessment of the soil organisms.

n.c. not calculated

**E.) Citrus (3 x 3600 g a.s./ha) Formulated product FOSETYL AL 80% WP (Iberica)**
### PEC\textsubscript{(s)}

|                  | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|------------------|---------------------------|------------------------------------------|----------------------------|--------------------------------------------|
| **Initial**      | n.c.                      |                                          | 1.881                      |                                            |
| **Short term**   |                           |                                          |                            |                                            |
| 24h              | n.c.                      | n.c.                                     |                            |                                            |
| 2d               | n.c.                      | n.c.                                     |                            |                                            |
| 4d               | n.c.                      | n.c.                                     |                            |                                            |
| **Long term**    |                           |                                          |                            |                                            |
| 7d               | n.c.                      | n.c.                                     |                            |                                            |
| 28d              | n.c.                      | n.c.                                     |                            |                                            |
| 50d              | n.c.                      | n.c.                                     |                            |                                            |
| 100d             | n.c.                      | n.c.                                     |                            |                                            |
| **Plateau**      |                           |                                          |                            |                                            |
| **concentration**| n.c.                      |                                          |                            |                                            |

- not required for the risk assessment of the soil organisms.

n.c. not calculated

### PEC ground water (Regulation (EU) \textnumero 284/2013, Annex Part A, point 9.2.4.1)

See below.

### PEC\textsubscript{(gw)} - FOCUS modelling results (80\textsuperscript{th} percentile annual average concentration at 1m)

#### A.) Formulated product Fosetyl-Al + Fluopicolide WG 71.11 (Bayer CropScience):
Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)

For FOCUS gw modelling, values used –
Modelling using FOCUS models, with appropriate FOCUSgw scenarios, according to FOCUS guidance.
Models used: FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3

**Fosetyl-Al**
Crop uptake factor: 0
Water solubility (mg/L): 110000 at pH 7 and 20°C
Vapour pressure: $1.10^{-7}$ Pa at 20°C
Geometric mean parent DT$_{50\text{lab}}$ 0.1 d (default conservative assumption).
$K_{OC}$: 0.1 mL/g, $\gamma_a$= 1 (default conservative assumptions).

**Phosphonic acid**
Molar mass: 246 (considering 3 molecules of phosphonic acid are formed from 1 molecule of fosetyl-Al)
Crop uptake factor: 0
Water solubility (mg/L): 110000 at pH 7 and 20°C
Vapour pressure: $1.10^{-7}$ Pa at 20°C
Geometric mean parent DT$_{50\text{lab}}$ 133.7 d (normalisation to pH2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).
Formation fraction from parent: 1
$K_f$: geometric mean 15.9 mL/g (manually implemented and kept constant in all soil horizons) arithmetic mean $\overline{\gamma_a}= 0.69$

**Application rate**

**Grapes (3 x 2000 g a.s./ha)**
Crop growth stage: BBCH 15-81
Canopy interception: 60%
Delay between applications: 10 days

| Scenario       | 1$^{st}$ App. Date |
|----------------|--------------------|
| Chateaudun     | 02 May             |
| Hamburg        | 24 May             |
| Kremsmunster   | 24 May             |
| Piacenza       | 02 May             |
| Porto          | 20 Apr             |
| Sevilla        | 20 Apr             |
| Thiva          | 12 Apr             |

| Mines          | PEARL 4.4.4 | PELMO 5.5.3 |
|----------------|-------------|-------------|
| (3 x 2000 g a.s./ha) |             |             |
| Chateaudun     | <0.001      | <0.001      |
| Hamburg        | <0.001      | <0.001      |
| Kremsmunster   | <0.001      | <0.001      |
| Piacenza       | <0.001      | <0.001      |
| Porto          | <0.001      | <0.001      |
| Sevilla        | <0.001      | <0.001      |
| Thiva          | <0.001      | <0.001      |
B.) Formulated product Fosetyl-Al WG 80 (Bayer CropScience):

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter): For FOCUS gw modelling, values used – Modelling using FOCUS models, with appropriate FOCUSgw scenarios, according to FOCUS guidance. Models used: FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3

**Fosetyl-Al**
- Crop uptake factor: 0
- Water solubility (mg/L): 110000 at pH 7 and 20°C
- Vapour pressure: 1.10^{-7} Pa at 20°C
- Geometric mean parent DT_{50,lab} 0.1 d (default conservative assumption).
- K_{OC}: 0.1 mL/g, \( \frac{1}{n} = 1 \) (default conservative assumptions).

**Phosphonic acid**
- Molar mass: 246 (considering 3 molecules of phosphonic acid are formed from 1 molecule of fosetyl-Al)
- Crop uptake factor: 0
- Water solubility (mg/L): 110000 at pH 7 and 20°C
- Vapour pressure: 1.10^{-7} Pa at 20°C
- Geometric mean parent DT_{50,lab} 133.7 d (normalisation to pF2, 20°C with Q10 of 2.58 and Walker equation coefficient 0.7).
- Formation fraction from parent: 1
- K_f: geometric mean 15.9 mL/g (manually implemented and kept constant in all soil horizons) arithmetic mean \( \frac{1}{n} = 0.69 \)

Application rate

**Pome fruits (3 x 3600 g a.s./ha)**
- Crop growth stage: BBCH 55-85
- Canopy interception: 60%
- Delay between applications: 7 days
- Time of application (absolute application dates):

| Scenario      | 1st App. Date |
|---------------|---------------|
| Chateaudun    | 21 May        |
| Hamburg       | 08 May        |
| Jokioinen     | 23 May        |
| Kremsmuenster | 08 May        |
| Okehampton    | 02 Jun        |
| Piacenza      | 21 May        |
| Porto         | 13 Jun        |
| Sevilla       | 19 May        |
| Thiva         | 13 Jun        |
C.) Formulated product SIP40958 (Oxon SAE Fosetyl Task Force):

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

For FOCUS gw modelling, values used –
Modelling using FOCUS models, with appropriate FOCUS gw scenarios, according to FOCUS guidance.
Models used: FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3

**Fosetyl-Al**
- Crop uptake factor: 0
- Water solubility (mg/L): 110000 at pH 7 and 20°C
- Vapour pressure: $1.10^{-7}$ Pa at 20°C
- Geometric mean parent DT$_{50,lab}$ 0.1 d (default conservative assumption).
- $K_{OC}$: 0.1 mL/g, $I_a$= 1 (default conservative assumptions).

**Phosphonic acid**
- Molar mass: 246 (considering 3 molecules of phosphonic acid are formed from 1 molecule of fosetyl-Al)
- Crop uptake factor: 0
- Water solubility (mg/L): 110000 at pH 7 and 20°C
- Vapour pressure: $10^{-7}$ Pa at 20°C
- Geometric mean parent DT$_{50,lab}$ 133.7 d (normalisation to pH2, 20°C with Q10 of 2.58 and Walker equation coefficient 0.7).
- Formation fraction from parent: 1
- $K_f$: geometric mean 15.9 mL/g (manually implemented and kept constant in all soil horizons) arithmetic mean $I_a$= 0.69

Application rate

**Grapes (4 x 1350 g a.s./ha)**
- Crop growth stage: BBCH 11-79
- Canopy interception: 50% (1st and 2nd app) - 60% (3rd and 4th app)
- Delay between applications: 10 days
- Time of application (relative application dates: at emergence)

| Scenario | 1st App. Date |
|----------|---------------|
| Chateaudun | 1 Apr        |
D.) Formulated product FOSETYL AL 80% WP (Iberica):

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

For FOCUS gw modelling, values used – Modelling using FOCUS models, with appropriate FOCUSgw scenarios, according to FOCUS guidance. Models used: FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3

**Fosetyl-Al**
- Crop uptake factor: 0
- Water solubility (mg/L): 110000 at pH 7 and 20°C
- Vapour pressure: $1.10^{-7}$ Pa at 20°C
- Geometric mean parent DT$_{50}$ (default conservative assumption): $K_{OC}$: 0.1 mL/g, $t_{1/2}$= 1-(default conservative assumptions).

**Phosphonic acid**
- Molar mass: 246 (considering 3 molecules of phosphonic acid are formed from 1 molecule of fosetyl-Al)
- Crop uptake factor: 0
- Water solubility (mg/L): $1.1.10^6$ at pH 7 and 20°C
- Vapour pressure: 0 at 20°C
- Geometric mean parent DT$_{50}$ 133.7 d (normalisation to pF2, 20°C with Q10 of 2.58 and Walker equation coefficient 0.7).
- Formation fraction from parent: 1
- $K_r$: geometric mean 15.9 mL/g (manually implemented and corrected by the different sorption factors in each horizon) arithmetic mean $t_{1/2}$= 0.69

Application rate

**Grapes (4 x 2640 g a.s./ha)**
- Crop growth stage: at flowering
Canopy interception: 60%
Delay between applications: 10 days

| Scenario     | 1st App. Date |
|--------------|---------------|
| Chateaudun   | 31 Jul        |
| Hamburg      | 15 Jul        |
| Kremsmuenster| 15 Jul        |
| Piacenza     | 31 Jul        |
| Porto        | 31 Jul        |
| Sevilla      | 15 Jul        |
| Thiva        | 30 Jun        |

**Citrus (3 x 3600 g a.s./ha)**
Crop growth stage: at flowering
Canopy interception: 80%
Delay between applications: 90 days

| Scenario     | 1st App. Date (Julian day) |
|--------------|-----------------------------|
| Piacenza     | 15 Apr                      |
| Porto        | 15 Apr                      |
| Sevilla      | 15 Apr                      |
| Thiva        | 15 Apr                      |

**Vines**

| Scenario     | PEARL 4.4.4 | PELMO 5.5.3 |
|--------------|-------------|-------------|
| Chateaudun   | <0.001      | <0.001      |
| Hamburg      | <0.001      | <0.001      |
| Kremsmuenster| <0.001      | <0.001      |
| Piacenza     | <0.001      | <0.001      |
| Porto        | <0.001      | <0.001      |
| Sevilla      | <0.001      | <0.001      |
| Thiva        | <0.001      | <0.001      |

**Citrus**

| Scenario     | PEARL 4.4.4 | PELMO 5.5.3 |
|--------------|-------------|-------------|
| Piacenza     | <0.001      | <0.001      |
| Porto        | <0.001      | <0.001      |
| Sevilla      | <0.001      | <0.001      |
| Thiva        | <0.001      | <0.001      |

PEC surface water and PEC sediment (Regulation (EU) No 284/2013, Annex Part A, points 9.2.5/9.3.1)

**FOSETYL-AL**

A.) Formulated product Fosetyl-Al + Fluopicolide WG 71.11 (Bayer CropScience):
Parameters used in FOCUSsw step 1 and 2

| Parameter                  | Value                      |
|----------------------------|----------------------------|
| Version control no. of FOCUS calculator: | v3.2.                     |
| Molecular weight           | 354.14 g/mol               |
| K<sub>OC</sub>             | 0.1 mL/g                   |
| DT<sub>50</sub> soil      | 0.1 d (conservative assumption in lab. In accordance with FOCUS SFO) |
| DT<sub>50</sub> water/sediment system | 3 d (geomean from sediment water studies) |
| DT<sub>50</sub> water (d) | 3 d                        |
| DT<sub>50</sub> sediment (d) | 1000 d                     |

Parameters used in FOCUSsw step 3 (if performed)

| Parameter                  | Value                      |
|----------------------------|----------------------------|
| Version control no. of FOCUS software: | FOCUS SWASH 5.3 (FOCUS PRZM SW 4.3.1; FOCUS MACRO 5.5.4; FOCUS TOXSWA 4.4.3) |
| SWAN tool, version          | 4.0.1                      |
| Water solubility (mg/L)     | 110000 (20 °C)             |
| Vapour pressure (Pa at 25 °C) | 1x10<sup>-7</sup>         |
| Kom/Koc (mL/g)              | 0.10/0.06                  |
| 1/n                         | 1.0 (Freundlich exponent general or for soil, susp. solids or sediment respectively) |
| Q10                         | 2.58, Walker equation coefficient 0.7 |
| Crop uptake factor          | 0                          |

Application rate:

Crop and growth stage: Grapes (3 x 2000 g a.s./ha), BBCH 15-81

Application scheme:

Number of applications: 1-3
Delay between applications: 10 days
Application rate(s): 2000 g a.s./ha
Crop interception (%) and application window:

| Scenario          | Early app. | Late app. |
|-------------------|------------|-----------|
| vines, late      | vines, late|
| Minimal canopy    | Full canopy|
| Mar-may           | Jun-sept   |

Application window: late spray drift selected

| Scenarios       | Early application | Late application |
|-----------------|-------------------|------------------|
| D6 Ditch        | 24-Feb/27-Apr     | 27-Apr/13-Sep    |
| Pond/Stream     | 05-May/27-Jun     | 27-Jun/24-Sep    |
| R1              | 20-Apr/24-Jul     | 24-Jul/12-Sep    |
| R2 Stream       | 02-May/25-Jul     | 25-Jul/04-Oct    |
| R4 Stream       | 13-Apr/13-Jul     | 13-Jul/01-Sep    |

Major route of contamination: Spray drift

**GRAPES (3 x 2000 g/ha)**
### FOCUS STEP 1

| Vines (3 x 2000 g a.s./ha) | PEC_{SW, MAX} (µg/L) | PEC_{SED, MAX} (µg/kg) |
|---------------------------|----------------------|------------------------|
|                           | Actual | TWA | Actual | TWA |
| early                     | 720.10 |     | 0.6666 |     |
| late                      | 720.10 |     | 0.6666 |     |

### FOCUS STEP 2

#### Vines (3 x 2000 g a.s./ha)

|                                      | PEC_{SW} (µg/L) | PEC_{SED} (µg/kg) |
|--------------------------------------|-----------------|-------------------|
|                                      | Actual | TWA | Actual | TWA |
| **Early app.**                       |        |     |        |     |
| March-May, minimal crop cover        |        |     |        |     |
| Northern EU                          |        |     |        |     |
| single                               | 53.520  |     | 0.0357 |     |
| multiple                             | 51.002  |     | 0.0340 |     |
| Southern EU                          |        |     |        |     |
| single                               | 53.520  |     | 0.0357 |     |
| multiple                             | 51.002  |     | 0.0340 |     |
| **Late app.**                        |        |     |        |     |
| June-sept, full canopy               |        |     |        |     |
| Northern EU                          |        |     |        |     |
| single                               | 53.520  |     | 0.0357 |     |
| multiple                             | 51.002  |     | 0.0340 |     |
| Southern EU                          |        |     |        |     |
| single                               | 53.520  |     | 0.0357 |     |
| multiple                             | 51.002  |     | 0.0340 |     |
| FOCUS STEP 3 | Water | Day after overall maximum | PEC_{SW} (µg/L) Actual | PEC_{SW} (µg/L) TWA | PEC_{SED} (µg/kg) Actual | PEC_{SED} (µg/kg) TWA |
|--------------|-------|---------------------------|------------------------|---------------------|---------------------------|------------------------|
| Scenario     |       |                           |                        |                     |                           |                        |
| Multiple applications; early application |       |                           |                        |                     |                           |                        |
| D6 Ditch     | 0 h   | 29.250                    | -                      | 2.4640              | -                         |                        |
| R1 Pond      | 0 h   | 1.1950                    | -                      | 0.2446              | -                         |                        |
| R1 Stream    | 0 h   | 21.410                    | -                      | 0.6621              | -                         |                        |
| R2 Stream    | 0 h   | 28.660                    | -                      | 0.6336              | -                         |                        |
| R3 Stream    | 0 h   | 30.250                    | -                      | 1.2850              | -                         |                        |
| R4 Stream    | 0 h   | 21.050                    | -                      | 0.5425              | -                         |                        |
| Single application; early application |       |                           |                        |                     |                           |                        |
| D6 Ditch     | 0 h   | 33.700                    | -                      | 1.3700              | -                         |                        |
| R1 Pond      | 0 h   | 1.2220                    | -                      | 0.1678              | -                         |                        |
| R1 Stream    | 0 h   | 24.610                    | -                      | 0.5638              | -                         |                        |
| R2 Stream    | 0 h   | 33.140                    | -                      | 0.5952              | -                         |                        |
| R3 Stream    | 0 h   | 35.120                    | -                      | 1.1370              | -                         |                        |
| R4 Stream    | 0 h   | 24.700                    | -                      | 0.5754              | -                         |                        |
| Multiple applications; late application |       |                           |                        |                     |                           |                        |
| D6 Ditch     | 0 h   | 30.530                    | -                      | 5.0100              | -                         |                        |
| R1 Pond      | 0 h   | 1.1810                    | -                      | 0.1962              | -                         |                        |
| R1 Stream    | 0 h   | 21.400                    | -                      | 0.6196              | -                         |                        |
| R2 Stream    | 0 h   | 28.770                    | -                      | 0.6667              | -                         |                        |
| R3 Stream    | 0 h   | 30.250                    | -                      | 1.2750              | -                         |                        |
| R4 Stream    | 0 h   | 21.460                    | -                      | 0.7240              | -                         |                        |
| Single application; late application |       |                           |                        |                     |                           |                        |
| D6 Ditch     | 0 h   | 34.330                    | -                      | 3.8550              | -                         |                        |
| R1 Pond      | 0 h   | 1.2220                    | -                      | 0.1362              | -                         |                        |
| R1 Stream    | 0 h   | 25.100                    | -                      | 0.7270              | -                         |                        |
| R2 Stream    | 0 h   | 33.750                    | -                      | 0.7161              | -                         |                        |
| R3 Stream    | 0 h   | 35.490                    | -                      | 1.3260              | -                         |                        |
| R4 Stream    | 0 h   | 25.180                    | -                      | 0.7528              | -                         |                        |

| FOCUS STEP 4 | Water | Day after overall maximum | PEC_{SW} (µg/L) including 5 m non-spray buffer zone (corresponding to ≤ 95 % drift reduction) | PEC_{SW} (µg/L) including 10 m non-spray buffer zone and 10 m vegetative buffer strip (corresponding to ≤ 95 % drift reduction) |
|--------------|-------|---------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
### Parameters used in FOCUSsw step 1 and 2

| Parameter                      | Value                                      |
|-------------------------------|--------------------------------------------|
| Version control no. of FOCUS calculator | v3.2                                       |
| Molecular weight              | 354.14 g/mol                                |
| K<sub>OC</sub>                | 0.1 mL/g                                    |
| DT<sub>50</sub> soil          | 0.1 d (conservative assumption in lab. In accordance with FOCUS SFO) |
| DT<sub>50</sub> water/sediment system | 3 d (geomean from sediment water studies) |
| DT<sub>50</sub> water (d)    | 3 d                                        |
| DT<sub>50</sub> sediment (d) | 1000 d                                     |

### Parameters used in FOCUSsw step 3 (if performed)

| Parameter                      | Value                                      |
|-------------------------------|--------------------------------------------|
| Version control n° of FOCUS software |                                             |
| FOCUS SWASH 5.3 (FOCUS PRZM SW 4.3.1; FOCUS MACRO 5.5.4; FOCUS TOXSWA 4.4.3) |                                             |
| SWAN tool, version 4.0.1       |                                             |
| Water solubility (mg/L)        | 110000 (20 °C)                              |
| Vapour pressure                | 1x10<sup>-7</sup> Pa at 25 °C              |
| Kom/Koc (mL/g)                 | 0.10/0.06                                  |
| 1/n: 1.0 (Freundlich exponent general or for soil, susp. solids or sediment respectively) | 0.7 |
| Q<sub>10</sub> = 2.58, Walker equation coefficient 0.7 | |
| Crop uptake factor             | 0                                          |

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### Formulated product Fosetyl-Al WG 80 (Bayer CropScience):

**B.**

#### Early application *

| Location | Application Time | 0% Reduction by Drift Nozzle | 50% Reduction by Drift Nozzle | 0% Reduction by Drift Nozzle | 50% Reduction by Drift Nozzle |
|----------|-----------------|-----------------------------|-------------------------------|-------------------------------|-------------------------------|
| Ditch    | 0 h             | 20.390                      | 10.210                        | 7.4100                        | 3.7240                        |
| Pond     | 0 h             | 1.4190                      | 0.7093                        | 0.7811                        | 0.3906                        |
| Stream   | 0 h             | 17.930                      | 8.9640                        | 6.4940                        | 3.2470                        |
| Stream   | 0 h             | 24.140                      | 12.070                        | 8.7440                        | 4.3720                        |
| Stream   | 0 h             | 25.590                      | 12.790                        | 9.2680                        | 4.6340                        |
| Stream   | 0 h             | 17.990                      | 8.9960                        | 6.5170                        | 3.2580                        |

#### Late application *

| Location | Application Time | 0% Reduction by Drift Nozzle | 50% Reduction by Drift Nozzle | 0% Reduction by Drift Nozzle | 50% Reduction by Drift Nozzle |
|----------|-----------------|-----------------------------|-------------------------------|-------------------------------|-------------------------------|
| Ditch    | 0 h             | 20.760                      | 10.380                        | 7.5180                        | 3.7590                        |
| Pond     | 0 h             | 1.4190                      | 0.7095                        | 0.7813                        | 0.3906                        |
| Stream   | 0 h             | 18.290                      | 9.1450                        | 6.6250                        | 3.3120                        |
| Stream   | 0 h             | 24.590                      | 12.290                        | 8.9060                        | 4.4530                        |
| Stream   | 0 h             | 25.860                      | 12.930                        | 9.3660                        | 4.6830                        |
| Stream   | 0 h             | 18.340                      | 9.1710                        | 6.6440                        | 3.3220                        |

* Maximum PECsw derived from single application
Application rate:
Crop and growth stage: **Pome fruits (3 x 3600 g a.s./ha)**, BBCH 55-85

Application scheme:
Number of applications: 1-3
Delay between applications: 7 days
Application rate(s): 3600 g a.s./ha

Crop interception (%) and application window:

| Scenario | Pome/stone fruit, late |
|----------|------------------------|
| Crop intercept. | Full canopy |
| Timing | Mar-May |

Application window: late spray drift selected

| Scenarios | PAT start/end date |
|-----------|--------------------|
| D3 Ditch | 08-May/26-Sep |
| D4 Pond/Stream | 23-Jun/11-Oct |
| D5 Pond/Stream | 21-May/18-Sep |
| R1 Pond/Stream | 08-May/26-Sep |
| R2 Stream | 08-Jul/20-Sep |
| R3 Stream | 21-May/22-Sep |
| R4 Stream | 19-May/22-Sep |

Major route of contamination: Spray drift

### POME FRUITS (3 x 3600 g/ha)

| FOCUS STEP 1 | PEC_{SW,MAX} (µg/L) | PEC_{SED,MAX} (µg/kg) |
|--------------|----------------------|------------------------|
| **Pome fruits (3 x 3600 g a.s./ha)** | Actual | TWA | Actual | TWA |
| Late app. Mar-May, full canopy | 4165.6 | 3.5995 |

| FOCUS STEP 2 | PEC_{SW} (µg/L) | PEC_{SED} (µg/kg) |
|--------------|----------------|------------------|
| Pome/Fruit (3 x 3600 g a.s./ha) | Actual | TWA | Actual | TWA |
| **Late app. Mar-May, full canopy** | | | | |
| Northern EU | single | 188.70 | 0.1257 |
| Multiple | 163.56 | 0.1090 |
| Southern EU | single | 188.70 | 0.1257 |
| Multiple | 163.56 | 0.1090 |
### FOCUS STEP 3

#### Scenario

| Water body | Day after overall maximum | PEC$_{sw}$ (µg/L) | PEC$_{SED}$ (µg/kg) |
|------------|--------------------------|-------------------|--------------------|
|            | Actual | TWA   | Actual | TWA   |

#### Multiple applications

|            | Actual | TWA   | Actual | TWA   |
|------------|--------|-------|--------|-------|
| D3 Ditch   | 93.930 | -     | 7.6890 | -     |
| D4 Pond    | 4.9500 | -     | 0.9342 | -     |
| D4 Stream  | 94.640 | -     | 3.1780 | -     |
| D5 Pond    | 4.9440 | -     | 0.8517 | -     |
| D5 Stream  | 102.30 | -     | 4.3700 | -     |
| R1 Pond    | 4.4280 | -     | 0.7465 | -     |
| R1 Stream  | 72.520 | -     | 2.3050 | -     |
| R2 Stream  | 97.200 | -     | 2.3120 | -     |
| R3 Stream  | 102.20 | -     | 4.4120 | -     |
| R4 Stream  | 72.510 | -     | 2.3740 | -     |

#### Single application

|            | Actual | TWA   | Actual | TWA   |
|------------|--------|-------|--------|-------|
| D3 Ditch   | 132.10 | -     | 8.2860 | -     |
| D4 Pond    | 5.9290 | -     | 0.6522 | -     |
| D4 Stream  | 132.60 | -     | 4.4530 | -     |
| D5 Pond    | 5.9300 | -     | 0.7446 | -     |
| D5 Stream  | 143.20 | -     | 5.5600 | -     |
| R1 Pond    | 5.9250 | -     | 0.8144 | -     |
| R1 Stream  | 99.710 | -     | 2.3460 | -     |
| R2 Stream  | 136.20 | -     | 2.8900 | -     |
| R3 Stream  | 143.20 | -     | 5.4840 | -     |
| R4 Stream  | 99.320 | -     | 2.2750 | -     |

### FOCUS STEP 4

#### Scenario

| Water body | Day after overall maximum | PEC$_{sw}$ (µg/L) including 5 m non-spray buffer zone (corresponding to ≤ 95 % drift reduction) * |
|------------|---------------------------|----------------------------------------------------------------------------------|
|            | Actual | 0% reduction by drift nozzle | 50% reduction by drift nozzle | 75% reduction by drift nozzle | 90% reduction by drift nozzle |
|            |       | Actual | Actual | Actual | Actual |

| D3 Ditch   | 89.13 | 44.57  | 22.28  | 8.913  |
| D4 Pond    | 6.781 | 3.39   | 1.695  | 0.6781 |
| D4 Stream  | 103.5 | 51.75  | 25.87  | 10.35  |
| D5 Pond    | 6.782 | 3.391  | 1.696  | 0.6782 |
| D5 Stream  | 111.8 | 55.89  | 27.94  | 11.18  |
### FOCUS STEP 4 Scenario

**Water**

| Scenario | Day after overall maximum | PECsw (µg/L) including 5 m non-spray buffer zone (corresponding to ≤ 95 % drift reduction) * |
|----------|---------------------------|-------------------------------------------------------------------------------------|
|          |                           | 0% reduction by drift nozzle | 50% reduction by drift nozzle | 75% reduction by drift nozzle | 90% reduction by drift nozzle |
|          |                           | Actual | Actual | Actual | Actual |
| R1       | Pond 0 h                  | 6.776  | 3.388  | 1.694  | 0.6776 |
| R1       | Stream 0 h                | 77.83  | 38.91  | 19.46  | 7.783  |
| R2       | Stream 0 h                | 106.3  | 53.15  | 26.58  | 10.63  |
| R3       | Stream 0 h                | 111.8  | 55.89  | 27.95  | 11.18  |
| R4       | Stream 0 h                | 77.52  | 38.76  | 19.38  | 7.752  |

* *Maximum PECsw derived from single application

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**FOCUS STEP 4 Scenario**

| Water   | Day after overall maximum | PECsw (µg/L) including 10 m non-spray buffer zone and 10 m vegetative buffer strip (corresponding to ≤ 95 % drift reduction) * |
|---------|---------------------------|-------------------------------------------------------------------------------------|
|         |                           | 0% reduction by drift nozzle | 50% reduction by drift nozzle | 75% reduction by drift nozzle | 90% reduction by drift nozzle |
|         |                           | Actual | Actual | Actual | Actual |
| D3      | Ditch 0 h                 | 39.83  | 19.92  | 9.958  |         |
| D4      | Pond 0 h                  | 3.761  | 1.88   | 0.9402 |         |
| D4      | Stream 0 h                | 46.25  | 23.12  | 11.56  |         |
| D5      | Pond 0 h                  | 3.762  | 1.881  | 0.9404 |         |
| D5      | Stream 0 h                | 49.95  | 24.97  | 12.49  |         |
| R1      | Pond 0 h                  | 3.758  | 1.879  | 0.9395 |         |
| R1      | Stream 0 h                | 34.78  | 17.39  | 8.694  |         |
| R2      | Stream 0 h                | 47.5   | 23.75  | 11.88  |         |
| R3      | Stream 0 h                | 49.95  | 24.98  | 12.49  |         |
| R4      | Stream 0 h                | 34.64  | 17.32  | 8.66   |         |

* *Maximum PECsw derived from single application

- PECsw values > 95 % drift reduction

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**FOCUS STEP 4 Scenario**

| Water   | Day after overall maximum | PECsw (µg/L) including 15 m non-spray buffer zone and 10 m vegetative buffer strip (corresponding to ≤ 95 % drift reduction) * |
|---------|---------------------------|-------------------------------------------------------------------------------------|
|         |                           | 0% reduction by drift nozzle | 50% reduction by drift nozzle |
|         |                           | Actual | Actual | Actual | Actual |
### FOCUS STEP 4 Scenario

| Water | Day after overall maximum | PECsw (µg/L) including 20 m non-spray buffer zone and 20 m vegetative buffer strip (corresponding to ≤ 95% drift reduction) * |
|-------|---------------------------|------------------------------------------------------------------------------------------------------------------|
| body  | Actual                    | 0% reduction by drift nozzle | 50% reduction by drift nozzle |
|       | Actual                    | Actual                  | Actual                  |
| D3    | Ditch 0 h                 | 12.29                   | -                      |
| D4    | Pond 0 h                  | 1.711                   | 0.8555                 |
| D4    | Stream 0 h                | 14.27                   | 7.136                  |
| D5    | Pond 0 h                  | 1.711                   | 0.8556                 |
| D5    | Stream 0 h                | 15.41                   | 7.707                  |
| R1    | Pond 0 h                  | 1.71                    | 0.8549                 |
| R1    | Stream 0 h                | 10.73                   | 5.366                  |
| R2    | Stream 0 h                | 14.66                   | 7.329                  |
| R3    | Stream 0 h                | 15.41                   | 7.707                  |
| R4    | Stream 0 h                | 10.69                   | 5.345                  |

* Maximum PECsw derived from single application
- PECsw values > 95% drift reduction

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### C. Formulated product SIP40958 (Oxon SAE Fosetyl Task Force):

[Table and text as per the document]
Parameters used in FOCUSsw step 1 and 2

- Version control no. of FOCUS calculator: v3.2
- Molecular weight: 354.14 g/mol
- KOC: 0.1 mL/g
- DT₅₀ soil: 0.13 d (conservative assumption in lab. In accordance with FOCUS SFO)
- DT₅₀ water/sediment system: 3 d (geomean from sediment water studies)
- DT₅₀ water (d): 3 d
- DT₅₀ sediment (d): 1000 d

Parameters used in FOCUSsw step 3 (if performed)

- Version control no. of FOCUS software: FOCUS SWASH 5.3 (FOCUS PRZM SW 4.3.1; FOCUS MACRO 5.5.4; FOCUS TOXSWA 4.4.3)
- SWAN tool, version 4.0.1
- Water solubility (mg/L): 110000 (20 °C)
- Vapour pressure: 1x10⁻⁷ Pa at 25 °C
- DT₅₀ soil: 0.1 d (conservative assumption in lab. In accordance with FOCUS SFO)
- Kon/Koc (mL/g): 0.10/0.06
- 1/n: 1.0 (Freundlich exponent general or for soil, susp. solids or sediment respectively)
- Q₁₀=2.58, Walker equation coefficient 0.7
- Crop uptake factor: 0

Application rate:

- Crop and growth stage: Grapes (4 x 1350 g a.s./ha; BBCH 11-79)
- Number of applications: 1-4
- Delay between applications: 10 days
- Application rate(s): 1350 g a.s./ha
- Crop interception (%) and application window:

| Scenario | Early app. | Late app. |
|----------|------------|-----------|
| Timing   | Minimal canopy | Minimal canopy |
| Mar-May; Jun-Sept; Oct-Feb | Mar-May; Jun-Sept; Oct-Feb |

Application window: early/late spray drift selected

| Scenarios       | PAT start/end date |
|-----------------|---------------------|
| R1 Pond/Stream  | Early application: 96-263 Late application: 203-233 |
| R2 Stream       | 68-233              | 173-233              |
| R3 Stream       | 77-265              | 205-265              |
| R4 Stream       | 63-223              | 163-223              |
| D6 Ditch        | 18-274              | 214-274              |

Major route of contamination: Spray drift

**GRAPES (4 x 1350 g/ha)**
### FOCUS STEP 1

|                | PEC\textsubscript{SW,MAX} (µg/L) | PEC\textsubscript{SED,MAX} (µg/kg) |
|----------------|----------------------------------|----------------------------------|
| **Vines** (4 x 1350 g a.s./ha) |                                  |                                  |
| early          | 462.09                           | 0.450                            |
| late           | 486.07                           | 0.450                            |

### FOCUS STEP 2

|                | PEC\textsubscript{SW} (µg/L) | PEC\textsubscript{SED} (µg/kg) |
|----------------|------------------------------|-------------------------------|
| **Vines** (4 x 1350 g a.s./ha) |                  |                              |
| **Early app.** |                              |                              |
| March-May, June Sept, Oct-Feb Minimal crop cover | | |
| Northern EU    | single 12.146                 | 0.008                          |
|                | multiple 12.483               | 0.008                          |
| Southern EU    | single 12.146                 | 0.008                          |
|                | multiple 12.483               | 0.008                          |
| **Late app.**  |                              |                              |
| March-May, June Sept, Oct-Feb Minimal crop cover | | |
| Northern EU    | single 36.126                 | 0.024                          |
|                | multiple 33.123               | 0.022                          |
| Southern EU    | single 36.126                 | 0.024                          |
|                | multiple 33.123               | 0.022                          |
| FOCUS STEP 3 Scenario | Water body | Day after overall maximum | $\text{PEC_{SW}}$ ($\mu$g/L) | $\text{PEC_{SED}}$ ($\mu$g/kg) |
|-----------------------|------------|---------------------------|-----------------------------|-------------------------------|
|                       |            |                           | Actual | TWA | Actual | TWA |
| **Multiple applications; early application** | | | | | |
| D6                    | Ditch      | 0 h                       | 6.916  | -   | 0.8891 | -   |
|                       | Pond       | 0 h                       | 0.2620 | -   | 0.05146 | -   |
|                       | Stream     | 0 h                       | 4.979  | -   | 0.1598 | -   |
|                       | Stream     | 0 h                       | 6.649  | -   | 0.1480 | -   |
|                       | Stream     | 0 h                       | 6.977  | -   | 0.2883 | -   |
|                       | Stream     | 0 h                       | 4.930  | -   | 0.1392 | -   |
| **Single application; early application** | | | | | |
| D6                    | Ditch      | 0 h                       | 7.696  | -   | 0.9893 | -   |
|                       | Pond       | 0 h                       | 0.2605 | -   | 0.03946 | -   |
|                       | Stream     | 0 h                       | 5.562  | -   | 0.1503 | -   |
|                       | Stream     | 0 h                       | 7.373  | -   | 0.1294 | -   |
|                       | Stream     | 0 h                       | 7.833  | -   | 0.2566 | -   |
|                       | Stream     | 0 h                       | 5.560  | -   | 0.1443 | -   |
| **Multiple applications; late application** | | | | | |
| D6                    | Ditch      | 0 h                       | 19.24  | -   | 2.667  | -   |
|                       | Pond       | 0 h                       | 0.7514 | -   | 0.1594 | -   |
|                       | Stream     | 0 h                       | 13.98  | -   | 0.4718 | -   |
|                       | Stream     | 0 h                       | 18.74  | -   | 0.4426 | -   |
|                       | Stream     | 0 h                       | 19.71  | -   | 0.8224 | -   |
|                       | Stream     | 0 h                       | 13.98  | -   | 0.4773 | -   |
| **Single application; late application** | | | | | |
| D6                    | Ditch      | 0 h                       | 23.17  | -   | 1.729  | -   |
|                       | Pond       | 0 h                       | 0.8247 | -   | 0.08944 | -   |
|                       | Stream     | 0 h                       | 16.53  | -   | 0.3658 | -   |
|                       | Stream     | 0 h                       | 22.78  | -   | 0.4828 | -   |
|                       | Stream     | 0 h                       | 23.96  | -   | 0.8951 | -   |
|                       | Stream     | 0 h                       | 16.99  | -   | 0.5133 | -   |

| FOCUS STEP 4 Scenario | Water body | Day after overall maximum | $\text{PEC_{SW}}$ ($\mu$g/L) including 5 m non-spray buffer zone (corresponding to ≤ 95% drift reduction) * |
|-----------------------|------------|----------------------------|-----------------------------------------------------------------|
|                       |            |                           | 0% reduction by drift nozzle                                      |
|                       |            |                           | Actual                                                           |
### D. Formulated product FOSETYL AL 80% WP (Iberica):

Parameters used in FOCUSsw step 1 and 2

| Parameter                             | Value               |
|---------------------------------------|---------------------|
| Version control no. of FOCUS calculator | v3.2                |
| Molecular weight                      | 354.14 g/mol        |
| KOC                                   | 0.1 mL/g            |
| DT50 soil                             | 0.1 d               |
| DT50 water/sediment system            | 3 d                 |
| DT50 water (d)                        | 3 d                 |
| DT50 sediment (d)                     | 1000 d              |

Parameters used in FOCUSsw step 3 (if performed)

| Parameter                             | Value               |
|---------------------------------------|---------------------|
| Version control n°’s of FOCUS software | FOCUS SWASH 5.3 (FOCUS PRZM SW 4.3.1; FOCUS MACRO 5.5.4; FOCUS TOXSWA 4.4.3) |
| Water solubility (mg/L)                | 110000 (20 °C)      |
| Vapour pressure                       | 1x10⁻⁷ Pa at 25 °C  |
| Kom/Koc (mL/g)                        | 0.10/0.06           |
| 1/n                                   | 1.0 (Freundlich exponent general or for soil, susp. solids or sediment respectively) |
| Q10                                   | 2.58, Walker equation coefficient 0.7 |
| Crop uptake factor                    | 0                   |

Application rate:

| Application rate:                      | Crop and growth stage: Citrus (3 x 3600 g a.s./ha) |
|                                       | 1st appl.: flowering; 2nd appl. July; 3rd application: Oct-Nov |
| Number of applications                 | 1-3 |
| Delay between applications             | 90 days |
| Application rate(s)                    | 3600 g a.s./ha |

Application scheme:

| Scenario | Citrus |
|----------|--------|
| Crop intercept. | Full canopy |
Timing | Mar-May, Jun-Sept, Oct-Feb

Application window:

| Scenarios     | PAT start/end date |
|---------------|--------------------|
| D6 Ditch      | 11 Apr–7 Nov       |
| R4 Stream     | 4 Mar–30 Sep       |

Major route of contamination: Spray drift

Crop and growth stage: Grapes (4 x 2640 g a.s./ha) , Flowering / Post-flowering
Number of applications: 1-4
Delay between applications: 10 days
Application rate(s): 2640 g a.s./ha
Crop interception (%) and application window:

| Scenario | vines, late |
|----------|-------------|
| Crop intercept | Full canopy |

Application window: late spray drift selected

| Scenarios     | PAT start/end date |
|---------------|--------------------|
| R1 Pond/Stream| 24 Jul–23 Sep      |
| R2 Stream     | 23 Jun–22 Aug      |
| R3 Stream     | 10 Jul–8 Sep       |
| R4 Stream     | 18 Jun–17 Aug      |
| D6 Ditch      | 11 Jun–10 Aug      |

Major route of contamination: Spray drift

GRAPES (4 x 2640 g/ha)

| FOCUS STEP 1 | PEC_{SW,MAX} (µg/L) | PEC_{SED,MAX} (µg/kg) |
|--------------|---------------------|-----------------------|
| Vines (4 x 2640 g a.s./ha) | Actual TWA | Actual TWA |
| 950.5 | 0.880 |

| FOCUS STEP 2 | Vines (4 x 2640 g a.s./ha) | PEC_{SW} (µg/L) | PEC_{SED} (µg/kg) |
|--------------|-----------------------------|-----------------|-------------------|
| Late app.    | June-sept, full canopy      | Actual TWA     | Actual TWA       |
| Northern EU  | single | 70.65 | 0.047 |
|              | multiple | 64.77 | 0.043 |
| Southern EU  | single | 70.65 | 0.047 |
|              | multiple | 64.77 | 0.043 |
### FOCUS STEP 3

| Water body | Day after overall maximum | PECesw (µg/L) Actual | TWA | PECsed (µg/kg) Actual | TWA |
|------------|--------------------------|----------------------|-----|------------------------|-----|
| **Multiple applications** | | | | | |
| D6 Ditch 0 h | 37.850 | - | 5.369 | - | |
| R1 Pond 0 h | 1.500 | - | 0.325 | - | |
| R1 Stream 0 h | 27.34 | - | 0.916 | - | |
| R2 Stream 0 h | 36.65 | - | 0.866 | - | |
| R3 Stream 0 h | 38.54 | - | 1.736 | - | |
| R4 Stream 0 h | 27.34 | - | 0.948 | - | |
| **Single application** | | | | | |
| D6 Ditch 0 h | 45.32 | - | 4.539 | - | |
| R1 Pond 0 h | 1.613 | - | 0.200 | - | |
| R1 Stream 0 h | 32.33 | - | 1.014 | - | |
| R2 Stream 0 h | 44.55 | - | 0.945 | - | |
| R3 Stream 0 h | 46.85 | - | 1.775 | - | |
| R4 Stream 0 h | 33.23 | - | 0.994 | - | |

### FOCUS STEP 4

| Water body | Day after overall maximum | PECesw (µg/L) including 10 m non-spray buffer zone (corresponding to ≤ 95 % drift reduction) * | 0% reduction by drift nozzle | Actual |
|------------|--------------------------|-------------------------------------------------------------------------------------------------|-----------------------------|-------|
| **FOCUS STEP 4 Scenario** | | | | |
| D6 Ditch 0 h | 3.481 | | | |
| R1 Pond 0 h | 0.519 | | | |
| R1 Stream 0 h | 2.992 | | | |
| R2 Stream 0 h | 4.123 | | | |
| R3 Stream 0 h | 4.336 | | | |
| R4 Stream 0 h | 3.076 | | | |

* Maximum PECsw derived from single application

### CITRUS (3 x 3600 g/ha)

| FOCUS STEP 1 | PECsw.max (µg/L) Actual | TWA | PECsed.max (µg/kg) Actual | TWA |
|---------------|-------------------------|-----|---------------------------|-----|
| citrus (3 x 3600 g a.s./ha) | 1390 | | 1.200 | |

| FOCUS STEP 2 | PECsw (µg/L) Actual | TWA | PECsed (µg/kg) Actual | TWA |
|---------------|---------------------|-----|-----------------------|-----|
| Citrus (3 x 3600 g a.s./ha) | | | | |
**FOCUS STEP 2**

| Citrus (3 x 3600 g a.s./ha) | PEC<sub>sw</sub> (µg/L) | PEC<sub>sed</sub> (µg/kg) |
|-----------------------------|--------------------------|--------------------------|
|                             | Actual | TWA | Actual | TWA |
| March-May, June Sept, Oct-Feb | Southern EU | single | 188.7 | 0.126 |
|                             |        | multiple | 132.1 | 0.088 |
| March-May, June Sept, Oct-Feb | Northern EU | single | n.c. | n.c. |
|                             |        | multiple | n.c. | n.c. |

n.c. not calculated

**FOCUS STEP 3**

| Scenario | Water body | Day after overall maximum | PEC<sub>sw</sub> (µg/L) | PEC<sub>sed</sub> (µg/kg) |
|----------|------------|---------------------------|--------------------------|--------------------------|
|          |            | Actual | TWA | Actual | TWA |
| Multiple applications | Ditch | 0 h | 94.40 | - | 10.650 | - |
|          | Stream | 0 h | 72.51 | - | 2.220 | - |
| Single application | Ditch | 0 h | 133.0 | - | 17.590 | - |
|          | Stream | 0 h | 101.6 | - | 3.055 | - |

**FOCUS STEP 4**

| Scenario | Water body | Day after overall maximum | PEC<sub>sw</sub> (µg/L) including 20 m non-spray buffer zone (corresponding to ≤ 95% drift reduction) * |
|----------|------------|---------------------------|-------------------------------------------------------------------------------------------------------------------|
|          |            | Actual | 0% reduction by drift nozzle | Actual |
|          |            | Ditch | 0 h | 12.37 |
|          |            | Stream | 0 h | 10.93 |

* Maximum PEC<sub>sw</sub> derived from single application

**PHOSPHONIC ACID**

A.) Formulated product Fosetyl-Al + Fluopicolide WG 71.11 (Bayer CropScience):

Parameters used in FOCUS<sub>sw</sub> step 1 and 2

Molecular weight: 246 g/mol (considering 3 molecules of phosphonic acid are formed from 1 molecule of fosetyl-Al)

Soil and water metabolite

K<sub>oc</sub>/K<sub>om</sub>: 318 mL/g (Using the K<sub>f</sub> parameter instead of K<sub>oc</sub> requires the following changes in the FOCUS surface water calculations: a pseudo-K<sub>oc</sub> of 318 mL/g has been derived from the effective K<sub>d</sub> of 15.9 mL/g, assuming an OC content of 5%)
DT_{50} soil: 133.7 d (Lab. In accordance with FOCUS SFO)
DT_{50} water/sediment system(d): 1000 d (conservative assumption)
DT_{50} water (d): 1000 d (conservative assumption)
DT_{50} sediment (d): 1000 d (conservative assumption)
Maximum occurrence observed (% molar basis with respect to the parent)
- Total Water/Sediment: 100% (conservative assumption)
- Soil: 100% (conservative assumption)

Parameters used in FOCUSsw step 3 (if performed)
Not used in risk assessment

Application scheme
Grapes (3 x 2000 g a.s./ha), 10d-interval, BBCH 15-81

| Scenario  | Early app. | Late app. |
|-----------|------------|-----------|
| Crop intercept. | Minimal canopy | Full canopy |
| Timing | Mar-May | Jun-Sept |

**GRAPES (3 x 2000 g/ha)**

| FOCUS STEP 1 | PEC_{SW,MAX} (µg/L) | PEC_{SED,MAX} (µg/kg) |
|--------------|---------------------|-----------------------|
| Actual | TWA | Actual | TWA |
| Vines (3 x 2000 g a.s./ha) | | | |
| early | 2062.8 | | 6449.5 |
| late | 2062.8 | | 6449.5 |

| FOCUS STEP 2 | PEC_{SW} (µg/L) | PEC_{SED} (µg/kg) |
|--------------|----------------|------------------|
| Actual | TWA | Actual | TWA |
| Vines (3 x 2000 g a.s./ha) | | | |
| Early app. March-May, minimal crop cover | | | |
| Northern EU | single | 67.129 | 204.20 |
| Southern EU | single | 105.35 | 558.10 |
| multiple | 182.97 | 325.67 |
| multiple | 291.94 | 904.40 |
| Late app. June-sept, full canopy | | | |
| Northern EU | single | 54.387 | 163.71 |
| Southern EU | single | 146.64 | 442.67 |
| multiple | 67.129 | 204.20 |
| multiple | 182.97 | 558.10 |

**B.) Formulated product Fosetyl-Al WG 80 (Bayer CropScience):**

Parameters used in FOCUSsw step 1 and 2
Molecular weight: 246 g/mol (considering 3 molecules of phosphonic acid are formed from 1 molecule of fosetyl-Al)
Soil and water metabolite
Koc/Kom: 318 mL/g (Using the K_{f} parameter instead of K_{oc} requires the following changes in the FOCUS surface water calculations: a pseudo-K_{oc} of 318 mL/g has been derived from the effective K_{d} of 15.9 mL/g, assuming an OC content of 5%)
DT_{50} soil: 133.7 d (Lab. In accordance with FOCUS SFO)
Parameters used in FOCUSgw step 3 (if performed)

Application scheme

| POME FRUITS (3 x 3600 g/ha) |
|----------------------------|

| FOCUS STEP 1 | PEC$_{SW,MAX}$ (µg/L) | PEC$_{SED,MAX}$ (µg/kg) |
|--------------|------------------------|--------------------------|
| Pome fruits (3 x 3600 g a.s./ha) | Actual | TWA | Actual | TWA |
|--------------|--------|-----|-------|-----|
| Pome fruits (3 x 3600 g a.s./ha) | 3905.5 | 12039 |

| FOCUS STEP 2 | PEC$_{SW}$ (µg/L) | PEC$_{SED}$ (µg/kg) |
|--------------|-------------------|---------------------|
| Pome/Fruit (3 x 3600 g a.s./ha) | Actual | TWA | Actual | TWA |
| Late app. Mar-May, full canopy | Northern EU | single | 142.05 | 419.25 |
| | multiple | 329.21 | 978.96 |
| | Southern EU | single | 182.18 | 546.79 |
| | multiple | 445.37 | 1348.1 |

C.) Formulated product SIP40958 (Oxon / SAE Fosetyl Task Force):

Metabolite Phosphonic acid

Parameters used in FOCUSgw step 1 and 2

Molecular weight: 246 g/mol (considering 3 molecules of phosphonic acid are formed from 1 molecule of fosetyl-Al)

Soil and water metabolite
Koc/Kom: 0 mL/g
DT$_{50}$ soil: 133.7 d (Lab. In accordance with FOCUS SFO)
DT$_{50}$ water/sediment system(d): 1000 d (conservative assumption)
DT$_{50}$ water (d): 1000 d (conservative assumption)
DT$_{50}$ sediment (d): 1000 d (conservative assumption)
Maximum occurrence observed (% molar basis with respect to the parent)
- Total Water/Sediment: 100% (conservative assumption)
- Soil: 100% (conservative assumption)

Parameters used in FOCUSgw step 3 (if performed)

Not used in risk assessment
### Application scheme

|                | Early app. | Late app. |
|----------------|------------|-----------|
| **Scenario**   | vines, early | vines, late |
| **Crop intercept** | Minimal canopy | Minimal canopy |
| **Timing**     | Mar-May; Jun-Sept; Oct-Feb | Mar-May; Jun-Sept; Oct-Feb |

**GRAPES (4 x 1350 g/ha)** (using a Kof of 0 L/kg)

### FOCUS STEP 1

| Vines (4 x 1350 g a.s./ha) | PEC<sub>SW,M</sub> (µg/L) Actual | TWA | PEC<sub>SED,MAX</sub> (µg/kg) Actual | TWA |
|-----------------------------|---------------------------------|-----|---------------------------------|-----|
| early                       | 2540                            | 0   | 0                               | 0   |
| late                        | 2600                            | 0   | 0                               | 0   |

### FOCUS STEP 2

#### Vines (4 x 1350 g a.s./ha)

**Early app.**
- **March-May,** Minimal crop cover
- **June-Sept,** Minimal crop cover
- **Oct-Feb,** Minimal crop cover

|                | PEC<sub>SW</sub> (µg/L) Actual | TWA | PEC<sub>SED</sub> (µg/kg) Actual | TWA |
|----------------|--------------------------------|-----|---------------------------------|-----|
| **Northern EU** |                                 |     |                                 |     |
| single          | Northern EU                     |     |                                 |     |
| multiple        |                                 |     |                                 |     |
| single          | Southern EU                     |     |                                 |     |
| multiple        |                                 |     |                                 |     |

| **Late app.**   | PEC<sub>SW</sub> (µg/L) Actual | TWA | PEC<sub>SED</sub> (µg/kg) Actual | TWA |
|-----------------|--------------------------------|-----|---------------------------------|-----|
| **March-May,**  |                                 |     |                                 |     |
| **June-Sept,**  |                                 |     |                                 |     |
| **Mineral crop cover** |                   |     |                                 |     |
| **Oct-Feb,**    |                                 |     |                                 |     |

**D. Formulated product FOSETYL AL 80 % WP (Iberica):**

- **Parameters used in FOCUSsw step 1 and 2**
- **Molecular weight:** 246 g/mol (considering 3 molecules of phosphonic acid are formed from 1 molecule of fosetyl-Al)
- **Soil and water metabolite**
- **Koc/Kom:** 318 mL/g (Using the K<sub>f</sub> parameter instead of K<sub>f</sub> requires the following changes in the FOCUS surface water calculations: a pseudo-K<sub>f</sub> of 318 mL/g has been derived from the effective K<sub>d</sub> of 15.9 mL/g, assuming an OC content of 5%)
DT₅₀ soil: 133.7 d (Lab. In accordance with FOCUS SFO)
DT₅₀ water/sedimentsystem(d): 1000 d (conservative assumption)
DT₅₀ water (d): 1000 d (conservative assumption)
DT₅₀ sediment (d): 1000 d (conservative assumption)
Maximum occurrence observed (% molar basis with respect to the parent)
- Total Water/Sediment: 100% (conservative assumption)
- Soil: 100% (conservative assumption)

Parameters used in FOCUSsw step 3 (if performed)
Application scheme

Not used in risk assessment

**Grapes (4 x 2640 g a.s./ha) at flowering**

| Scenario   | vines, late |
|------------|-------------|
| Crop intercept. | Full canopy |
| Timing     | Jun-Sept    |

**Citrus (3 x 3600 g a.s./ha) at flowering**

| Scenario | Citrus |
|----------|--------|
| Crop intercept. | Full canopy |
| Timing     | Mar-May, Jun-Sept, Oct-Feb |

### GRAPES (4 x 2640 g/ha)

| FOCUS STEP 1 | PEC₅₀₅₀,MAX (µg/L) | PEC₅₀₅₀,MAX (µg/kg) |
|--------------|-------------------|---------------------|
| Vines (4 x 2640 g a.s./ha) | Actual | TWA | Actual | TWA |
|              | 3630 | 10900 |

| FOCUS STEP 2 | PEC₅₀₅₀ (µg/L) | PEC₅₀₅₀ (µg/kg) |
|--------------|----------------|----------------|
| Vines (4 x 2640 g a.s./ha) | Actual | TWA | Actual | TWA |
| Late app. | Northern EU | single | 71.8 | 216.1 |
|           |           | multiple | 249.5 | 753.3 |
|           | Southern EU | single | 88.6 | 269.5 |
|           |           | multiple | 311.8 | 268.5 |

### CITRUS (3 x 3600 g/ha)

| FOCUS STEP 1 | PEC₅₀₅₀,MAX (µg/L) | PEC₅₀₅₀,MAX (µg/kg) |
|--------------|-------------------|---------------------|
| citrus (3 x 3600 g a.s./ha) | Actual | TWA | Actual | TWA |
|              | 3910 | 11200 |
### FOCUS STEP 2

**Citrus (3 x 3600 g a.s./ha)**

| Period   | Season       | Application | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|----------|--------------|-------------|--------------------------|--------------------------|
| March-May| Full canopy  | single      | 147.8                    | 437.5                    |
|          |              | multiple    | 294.1                    | 871                      |
| June Sept| Full canopy  | single      | 136.3                    | 401                      |
|          |              | multiple    | 270.9                    | 797.3                    |
| Oct-Feb  | Full canopy  | single      | 147.8                    | 437.5                    |
|          |              | multiple    | 294.1                    | 871                      |

Estimation of concentrations from other routes of exposure (Regulation (EU) No 284/2013, Annex Part A, point 9.4)

No data, not required
### Ecotoxicology

**Effects on birds and other terrestrial vertebrates (Regulation (EU) Nº 283/2013, Annex Part A, point 8.1 and Regulation (EU) Nº 284/2013, Annex Part A, point 10.1)**

| Species | Test substance | Time scale | End point | Toxicity (mg/kg bw per day) |
|---------|----------------|------------|-----------|-----------------------------|
| **Birds** | | | | |
| *Colinus virginianus* | a.s. (unprotected) | Acute | LD$_{50}$ | > 8000 |
| *Colinus virginianus* | a.s. (unprotected) | Acute | LD$_{50}$ | > 2000 |
| *Coturnix coturnix japonica* | a.s. (unprotected) | Acute | LD$_{50}$ | 4997 |
| *Colinus virginianus* | Phosphonic acid (unprotected) | Acute | LD$_{50}$ | > 675 |
| *Colinus virginianus* | Fosetyl-Al WG 80 (Bayer CropScience) | Acute | LD$_{50}$ | > 6400 mg product/kg bw (> 5082 mg a.s./kg bw) |
| *Colinus virginianus* | FEA + FLC WG 71.11 (Bayer CropScience) | Acute | LD$_{50}$ | > 2000 mg product/kg bw |
| *Colinus virginianus* | SIP 40958 (OXN-SA) | Acute | LD$_{50}$ | > 2000 mg product/kg bw |
| *Colinus virginianus* | a.s. | Long-term | LD$_{50}$/10 | 499.7 |
| *Coturnix coturnix japonica* | a.s. (unprotected) | Long-term | NOEC (NOEL) | 1500 mg a.s./kg diet 216 mg a.s./kg b.w./d* |
| *Colinus virginianus* | a.s. (Bayer CropScience) | Long-term | NOEC (NOEL) | 3000 mg a.s./kg diet 331 mg a.s./kg b.w./d* |
| *Colinus virginianus* | a.s. (Iberica Taskforce) | Long-term | NOEC (NOEL) | 6500 mg a.s./kg b.w./d |
| **Mammals** | | | | |
| *Rat* | a.s. (unprotected) | Acute | LD$_{50}$ | > 7080 |
| *Rat* | Fosetyl-Al WG 80 (Bayer CropScience) | Acute | LD$_{50}$ | > 2000 mg product/kg bw |
Rat  FEA + FLC WG 71.11 (Bayer CropScience)  Acute  LD₅₀  > 2000 mg product/kg bw
Rat  Fosetyl-Al80% WP (Iberica Taskforce)  Acute  LD₅₀  > 2000 mg product/kg bw
Rat  SIP 40958 (OXN-SAE)  Acute  LD₅₀  > 2500 mg product/kg bw
Rat  Phosphonic acid  (unprotected)  Acute  LD₅₀  3624
Rat  a.s.  (unprotected)  Long-term  NOAEL  482
Rat  Phosphonic acid  (unprotected)  Long-term  NOAEL  390**

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 fosetyl-Al. 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 fosetyl-Al.

Additional higher tier studies (Annex Part A, points 10.1.1.2):
A residue decline study on arthropods is available. The DT₅₀ values estimated in this are based on 2 trials only. The number of trials was not considered sufficient by the experts at the Pesticide Peer Review TC 167; in order to use this refinement additional data may be needed as the number of trials was not sufficient.

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):
No relevant data are available from open literature.

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)
Fosetyl-Al 80 WG: Orchards (Pome fruits) at 3600 g a.s./ha [3 applications]

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|----------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | | | | | |
| All | Small insectivorous birds | Acute | 252.7 | 19.8 | 10 |
| All | Small insectivorous birds | Long-term | 62.5 | 8.0 | 5 |
| Tier 1 (Birds) | | | | | |
| Not required | | | | | |
| Screening Step (Mammals) | | | | | |
| All | Small herbivorous mammal | Acute | 736.6 | > 9.6 | 10 |
| All | Small herbivorous mammal | Long-term | 248.3 | 1.94 | 5 |
| Tier 1 (Mammals) | | | | | |
| Not required | | | | | |
| Application crop directed BBCH ≥ 40 | Large herbivorous mammal “lagomorph” 100% Non-grass herbs | Acute | 56.7 | > 124.9 | 10 |
| Application crop directed BBCH ≥ 40 | Small herbivorous mammal “vole Grass + cereals 100% grass” | Acute | 220.9 | > 32.1 | 10 |
| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|-----------------------|-----|---------|
| Application crop directed BBCH ≥ 40 | Small omnivorous mammal “mouse” 25% weeds 50% weed seeds 25% ground arthropods | Acute | 28.1 | > 252.1 | 10 |
| Fruit stage BBCH 71-79 currants | Frugivorous mammal “dormouse” larger fruits 100% fruit | Acute | 258.7 | > 27.4 | 10 |
| Application crop directed BBCH ≥ 40 | Large herbivorous mammal “lagomorph” 100% Non-grass herbs | Long-term | 14.8 | 32.6 | 5 |
| Application crop directed BBCH ≥ 40 | Small herbivorous mammal “vole Grass + cereals 100% grass” | Long-term | 74.5 | 6.5 | 5 |
| Application crop directed BBCH ≥ 40 | Small omnivorous mammal “mouse” 25% weeds 50% weed seeds 25% ground arthropods | Long-term | 7.9 | 61.0 | 5 |
| Fruit stage BBCH 71-79 currants | Frugivorous mammal “dormouse” larger fruits 100% fruit | Long-term | 74.5 | 6.2 | 5 |

Higher tier (Mammals): [in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)]

Risk from bioaccumulation and food chain behaviour [not relevant since Log kow ≤ 3]

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------|------------|-----------------------|-----|---------|
| Earthworm-eating birds   | Long-term | -                     | -   | 5       |
| Earthworm-eating mammals | Long-term | -                     | -   | 5       |
| Fish-eating birds        | Long-term | -                     | -   | 5       |
| Fish-eating mammals      | Long-term | -                     | -   | 5       |

Higher tier: [in higher tier refinement provide brief details of any refinements used]

Risk from consumption of contaminated water

Scenarios

Leaf scenario

Not relevant for the representative use

Puddle scenario, Screening step

1) Application rate (3600 g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed for birds and mammals

| Puddle scenario | Indicator | Type | Time scale | DDD | TER | Trigger |
|-----------------|-----------|------|------------|-----|-----|---------|
| Puddle scenario | Birds     | acute| -          | -   | -   | 10      |
| Puddle scenario | Mammals   | acute| -          | -   | -   | 10      |
| Puddle scenario | Birds     | Long-term | -   | -   | 5     |
| Puddle scenario | Mammals   | Long-term | -   | -   | -     |
### FEA + FLC WG 71.11: Grapes at 2000 g a.s./ha [3 applications]

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|----------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | | | | | |
| All | Small omnivorous birds | Acute | 285.9 | 17.5 | 10 |
| All | Small omnivorous birds | Long-term | 74.2 | 6.7 | 5 |
| Tier 1 (Birds) | | | | | |
| All | Small herbivorous mammal | Acute | 400.2 | > 17.3 | 10 |
| All | Small herbivorous mammal | Long-term | 138 | 3.5 | 5 |
| Tier 1 (Mammals) | | | | | |
| Application | Small herbivorous mammal | Long-term | 82.8 | 5.8 | 5 |
| crop directed | "vole Grass + cereals 100% grass" | | | | |
| BBCH 10 - 19 | | | | | |
| Application | Small omnivorous mammal | Long-term | 9.0 | 53.7 | 5 |
| crop directed | "mouse" 25% weeds 50% weed seeds 25% ground arthropods | | | | |
| BBCH 10 - 19 | | | | | |
| Application | Large herbivorous mammal | Long-term | 12.8 | 37.7 | 5 |
| BBCH 10 - 19 | "lagomorph" 100% Non-grass herbs | | | | |
| Application | Large herbivorous mammal | Long-term | 10.1 | 47.5 | 5 |
| BBCH 20 - 39 | "lagomorph" 100% Non-grass herbs | | | | |
| Application | Large herbivorous mammal | Long-term | 6.1 | 79.2 | 5 |
| BBCH ≥ 40 | "lagomorph" 100% Non-grass herbs | | | | |
| Application | Small insectivorous mammal | Long-term | 8.0 | 60.1 | 5 |
| BBCH 10 - 19 | "shrew" 100% ground arthropods | | | | |
| Application | Small insectivorous mammal | Long-term | 3.5 | 137.6 | 5 |
| BBCH ≥ 20 | "shrew" 100% ground arthropods | | | | |
| Application | Small herbivorous mammal | Long-term | 68.9 | 7.0 | 5 |
| crop directed | "vole Grass + cereals 100% grass" | | | | |
| BBCH 20 - 39 | | | | | |
| Application | Small omnivorous mammal | Long-term | 7.4 | 64.8 | 5 |
| crop directed | "mouse" 25% weeds 50% weed seeds 25% ground arthropods | | | | |
| BBCH 20 - 39 | | | | | |
| Application | Small herbivorous mammal | Long-term | 41.4 | 11.6 | 5 |
| crop directed | "vole Grass + cereals 100% grass" | | | | |
| BBCH ≥ 40 | | | | | |
| Application | Small omnivorous mammal | Long-term | 4.4 | 109.8 | 5 |
| crop directed | "mouse" 25% weeds 50% weed seeds 25% ground arthropods | | | | |
| BBCH ≥ 40 | | | | | |

**Risk from bioaccumulation and food chain behaviour** [not relevant since Log Kow ≤ 3]

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds    | Long-term  | -                      | -   | 5       |
| Earthworm-eating mammals  | Long-term  | -                      | -   | 5       |
| Fish-eating birds         | Long-term  | -                      | -   | 5       |
| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|-----------------------|-----|---------|
| Fish-eating mammals | Long-term | - | - | 5 |
| Higher tier: [in higher tier refinement provide brief details of any refinements used] |

### Risk from consumption of contaminated water

#### Scenarios

| Scenario | Details |
|----------|---------|
| Leaf scenario | Not relevant for the representative use |

#### Puddle scenario, Screening step

1) Application rate (g a.s./ha)/relevant endpoint < 50 (koc < 500 L/kg), TER calculation not needed

| Scenario | Species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|----------|---------|------------|-----------------------|-----|---------|
| Puddle scenario | Birds | acute | - | - | 10 |
| Puddle scenario | Mammals | acute | - | - | 10 |
| Puddle scenario | Birds | Long-term | - | - | 5 |
| Puddle scenario | Mammals | Long-term | - | - | 5 |

### Fosetyl-Al WP 80: Citrus at 3600 g a.s./ha [3 applications]

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|-----------------------|-----|---------|
| Screening Step (Birds) | All | Small insectivorous birds | Acute | 168.5 | 29.7 | 10 |
| | All | Small insectivorous birds | Long-term | 34.7 | 14.4 | 5 |
| Tier 1 (Birds) | Not required. |
| Screening Step (Mammals) | All | Small herbivorous mammal | Acute | 491.0 | > 14.4 | 10 |
| | All | Small herbivorous mammal | Long-term | 138.0 | 3.5 | 5 |
| Tier 1 (Mammals) | Application crop directed BBCH ≥ 40 | Large herbivorous mammal “lagomorph” 100% Non-grass herbs | Long-term | 8.2 | 58.7 | 5 |
| | Application crop directed BBCH ≥ 40 | Small herbivorous mammal “vole Grass + cereals 100% grass” | Long-term | 41.4 | 11.6 | 5 |
| | Application crop directed BBCH ≥ 40 | Small omnivorous mammal “mouse” 25% weeds 50% weed seeds 25% ground arthropods | Long-term | 4.4 | 109.8 | 5 |
| | Fruit stage BBCH 71-79 currants | Frugivorous mammal “dormouse” larger fruits 100% fruit | Long-term | 43.3 | 11.1 | 5 |

### Risk from bioaccumulation and food chain behaviour [not relevant since Log kow<3]

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------|------------|-----------------------|-----|---------|
| Earthworm-eating birds    | Long-term | - | - | 5 |
| Earthworm-eating mammals  | Long-term | - | - | 5 |
| Fish-eating birds         | Long-term | - | - | 5 |
| Fish-eating mammals       | Long-term | - | - | 5 |

### Risk from consumption of contaminated water

#### Scenarios

| Scenario | Details |
|----------|---------|
| Leaf scenario | |
### Fosetyl-Al WP 80: Grapes at 2640 g a.s./ha [4 applications]

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | | | | | |
| All | Small omnivorous birds | Acute | 377.4 | 13.2 | 10 |
| All | Small omnivorous birds | Long-term | 103.4 | 4.8 | 5 |
| Tier 1 (Birds) | | | | | |
| BBCH ≥ 40 | Small granivorous bird “finch” | Long-term | 9.0 | 55.3 | 5 |
| BBCH ≥ 40 | Small omnivorous bird “lark” | Long-term | 8.8 | 57.9 | 5 |
| BBCH ≥ 20 | Small insectivorous species “redstart” | Long-term | 26.3 | 19.0 | 5 |
| Ripening | Frugivorous bird “thrush/starling” | Long-term | 38.3 | 13.1 | 5 |
| Screening Step (Mammals) | | | | | |
| All | Small herbivorous mammal | Acute | 540.1 | > 13.1 | 10 |
| All | Small herbivorous mammal | Long-term | 192.2 | 2.5 | 5 |
| Tier 1 (Mammals) | | | | | |
| Application BBCH ≥ 20 | Small insectivorous mammal “shrew” | Long-term | 5.1 | 95.4 | 5 |
| Application crop directed BBCH ≥ 40 | Small herbivorous mammal “vole Grass + cereals 100% grass” | Long-term | 57.7 | 8.4 | 5 |
| Application crop directed BBCH ≥ 40 | Small omnivorous mammal “mouse” 25% weeds 50% weed seeds 25% ground arthropods | Long-term | 6.1 | 78.8 | 5 |
| Application BBCH ≥ 40 | Large herbivorous mammal “lagomorph” | Long-term | 8.8 | 54.9 | 5 |

### Risk from bioaccumulation and food chain behaviour

[not relevant since \( \log K_{ow} \leq 3\)]

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds    | Long-term  | -                      | -   | 5       |
| Earthworm-eating mammals  | Long-term  | -                      | -   | 5       |
| Fish-eating birds         | Long-term  | -                      | -   | 5       |
| Fish-eating mammals       | Long-term  | -                      | -   | 5       |

Higher tier: [in higher tier refinement provide brief details of any refinements used]

### Risk from consumption of contaminated water
## Scenarios

Leaf scenario

Not relevant for the representative use

### Puddle scenario, Screening step

1) Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed

| Puddle scenario | Indicator or focal species | Acute | Long-term | TER | Trigger |
|-----------------|----------------------------|-------|-----------|-----|---------|
| Puddle scenario | Birds | acute | - | - | 10 |
| Puddle scenario | Mammals | acute | - | - | 10 |
| Puddle scenario | Birds | Long-term | - | - | 5 |
| Puddle scenario | Mammals | Long-term | - | - | 5 |

### SIP40958: Grapes at 1350 g a.s./ha [4 applications]

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | | | | | |
| All | Small omnivorous birds | Acute | 193.0 | 25.9 | 10 |
| All | Small omnivorous birds | Long-term | 52.9 | 9.4 | 5 |
| Tier 1 (Birds) | | | | | |
| Not required | | | | | |
| Screening Step (Mammals) | | | | | |
| All | Small herbivorous mammal | Acute | 276.2 | > 25.6 | 10 |
| All | Small herbivorous mammal | Long-term | 98.3 | 4.9 | 5 |
| Tier 1 (Mammals) | | | | | |
| Application | Small herbivorous mammal | Long-term | 59.0 | 8.2 | 5 |
| crop directed BBCH 10 - 19 | “vole Grass + cereals 100% grass” | | | | |
| Application | Small omnivorous mammal | Long-term | 6.4 | 75.4 | 5 |
| crop directed BBCH 10 - 19 | “mouse” | 25% weeds 50% weed seeds 25% ground arthropods | | | |
| Application | Large herbivorous mammal | Long-term | 9.1 | 52.9 | 5 |
| BBCH 10 - 19 | “lagomorph” | 100% Non-grass herbs | | | |
| Application | Large herbivorous mammal | Long-term | 7.3 | 65.7 | 5 |
| BBCH 20 - 39 | “lagomorph” | 100% Non-grass herbs | | | |
| Application | Large herbivorous mammal | Long-term | 4.4 | 109.5 | 5 |
| BBCH ≥ 40 | “lagomorph” | 100% Non-grass herbs | | | |
| Application | Small insectivorous mammal | Long-term | 5.7 | 84.4 | 5 |
| BBCH 10 - 19 | “shrew” | 100% ground arthropods | | | |
| Application | Small insectivorous mammal | Long-term | 2.5 | 190.3 | 5 |
| BBCH ≥ 20 | “shrew” | 100% ground arthropods | | | |
| Application | Small herbivorous mammal | Long-term | 49.1 | 9.8 | 5 |
| crop directed BBCH 20 - 39 | “vole Grass + cereals 100% grass” | | | | |
| Application | Small omnivorous mammal | Long-term | 5.3 | 90.9 | 5 |
| crop directed BBCH 20 - 39 | “mouse” | 25% weeds 50% weed seeds 25% ground arthropods | | | |
| Application | Small herbivorous mammal | Long-term | 29.5 | 16.3 | 5 |
| crop directed BBCH ≥ 40 | “vole Grass + cereals 100% grass” | | | | |
| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
| Application crop directed BBCH ≥ 40 | Small omnivorous mammal “mouse” 25% weeds 50% weed seeds 25% ground arthropods | Long-term | 3.1 | 154.2 | 5 |

**Risk from bioaccumulation and food chain behaviour**  
*not relevant since Log kow≤3*

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds    | Long-term  | -                      | -   | 5       |
| Earthworm-eating mammals  | Long-term  | -                      | -   | 5       |
| Fish-eating birds         | Long-term  | -                      | -   | 5       |
| Fish-eating mammals       | Long-term  | -                      | -   | 5       |

Higher tier: [in higher tier refinement provide brief details of any refinements used]

**Risk from consumption of contaminated water**

**Scenarios**
- Leaf scenario
- Not relevant for the representative use

**Puddle scenario, Screening step**

1) Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed

| Puddle scenario | Test substance | Time-scale (Test type) | End point | Toxicity |
|-----------------|----------------|------------------------|-----------|----------|
| Puddle scenario | Birds          | acute                  | LC₅₀ > 122 mg a.s./L (mm) |
| Puddle scenario | Mammals        | acute                  | LC₅₀ > 100 mg a.s./L (nom) |
| Puddle scenario | Birds          | Long-term              | LC₅₀ > 5 (nom)  |
| Puddle scenario | Mammals        | Long-term              | LC₅₀ > 5 (nom)  |

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

*This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.*

| Group               | Test substance | Time-scale (Test type) | End point | Toxicity |
|---------------------|----------------|------------------------|-----------|----------|
| Fish                | Oncorhynchus mykiss a.s. (unprotected) | Acute 96 hr (semi-static) | Mortality, LC₅₀ | > 122 mg a.s./L (mm) |
|                     | Cyprinus carpio a.s. (Bayer CropScience) | Acute 96 hr (static) | Mortality, LC₅₀ | > 100 mg a.s./L (nom) |
|                     | Oncorhynchus mykiss Fosetyl-aluminium WG 80 (Bayer CropScience) | Acute 96 hr (semi-static) | Mortality, LC₅₀ | > 120 mg prep./L (> 95 mg a.s./L atnom) |
| Group                        | Test substance                  | Time-scale (Test type) | End point          | Toxicity¹                  |
|-----------------------------|---------------------------------|------------------------|--------------------|----------------------------|
| Oncorhynchus mykiss         | FEA + FLC WG 71.11 (Bayer CropScience) | Acute 96 hr (static)  | Mortality, LC₅₀    | 8.54 mg product/L (nom)    |
| Oncorhynchus mykiss         | a.s. (unprotected)              | Chronic (semi-static)  | Growth, NOEC       | 100 mg a.s./L (nom)        |
| Pimephales promelas         | a.s. (Bayer Cropscience)        | Chronic (flow-through) | Hatching, NOEC     | 0.213 mg a.s./L (nom)      |
|                             |                                 |                        | Hatching, EC₁₀     | 0.31 mg a.s./L (nom)       |
|                             |                                 |                        | Hatching, EC₂₀     | 0.44 mg a.s./L (nom)       |
| Oncorhynchus mykiss         | Phosphonic acid (unprotected)   | Acute 96 hr (static)   | Mortality, LC₅₀    | > 28.6 mg met./L (nom)     |
| Lepomis macrochirus         | Phosphonic acid (unprotected)   | Acute 96 hr (flow-through) | Mortality, LC₅₀    | > 35.7 mg met./L (nom)     |
| Oncorhynchus mykiss         | Phosphonic acid (Bayer CropScience) | Acute 96 hr (static)   | Mortality, LC₅₀    | > 400 mg met./L (nom)      |
| Oncorhynchus mykiss         | Phosphonic acid (Iberica Taskforce) | Acute 96 hr (semi-static) | Mortality, LC₅₀    | > 100 mg met./L (nom)      |
| Aquatic invertebrates       | Daphnia magna                   | a.s. (unprotected)    | 48 h (static)      | > 100 mg a.s./L (nom)      |
|                             | Fosetyl-aluminium WG 80 (Bayer CropScience) | 48 h (static)      | Mortality, EC₅₀    | 37 mg product/L (nom) (29.6 mg a.s./L) |
|                             | FEA + FLC WG 71.11 (Bayer CropScience) | 48 h (static)      | Mortality, EC₅₀    | > 100 mg product/L (nom)   |
|                             | Phosphonic acid (unprotected)   | 48 h (static)         | Mortality, EC₅₀    | > 29.7 mg met./L (nom)     |
|                             | Phosphonic acid (Bayer CropScience) | 48 h (static)       | Mortality, EC₅₀    | > 400 mg met./L (nom)      |
|                             | Phosphonic acid (Iberica Taskforce) | 48 h (static)      | Mortality, EC₅₀    | > 100 mg met./L (nom)     |
| Group                              | Test substance     | Time-scale (Test type) | End point                  | Toxicity |
|-----------------------------------|--------------------|------------------------|----------------------------|----------|
| **Daphnia magnæ**                 | a.s. (unprotected) | 21 d (semi-static)     | Reproduction, NOEC         | 17.0 mg a.s./L (nom) |
| **Daphnia magnæ**                 | a.s. (Iberica Taskforce) | 23 d (semi-static)  | Reproduction, NOEC         | 10.1 mg a.s./L (nom) |
| Sediment-dwelling organisms       |                    |                        |                            |          |
| Chironomus riparius               | Phosphonic acid (unprotected) | 28 d (static) | NOEC                       | 100.2 mg met./L (nom) |
| Chironomus riparius               | Phosphonic acid (Iberica Taskforce) | 28 d (static) | NOEC                       | 100 mg met./L (nom) |
| **Algae**                         |                    |                        |                            |          |
| Pseudokirchneriella subcapitata   | a.s. (Bayer CropScience) | 72 h (static) | Growth rate: E<sub>50</sub> | 9.54 mg a.s./L (nom) |
|                                  |                    |                        | Growth rate: E<sub>20</sub> | 4.85 mg met./L (nom) |
|                                  |                    |                        | Biomass: E<sub>50</sub>    | 4.99 mg a.s./L (nom) |
|                                  |                    |                        | Biomass: E<sub>20</sub>    | 2.11 mg met./L (nom) |
|                                  |                    |                        | (NOEC)                     | (2.28 mg a.s./L (nom)) |
| Desmodesmus subspicatus           | a.s. (Bayer CropScience) | 72 h (static) | Growth rate: E<sub>50</sub> | 43.3 mg a.s./L (nom) |
|                                  |                    |                        | Growth rate: E<sub>20</sub> | 24.91 mg met./L (nom) |
|                                  |                    |                        | Biomass: E<sub>50</sub>    | 24.9 mg a.s./L (nom) |
|                                  |                    |                        | Biomass: E<sub>20</sub>    | 12.12 mg met./L (nom) |
|                                  |                    |                        | (NOEC)                     | (9.77 mg a.s./L (nom)) |
| Navicula pelliculosa              | a.s. (Bayer CropScience) | 72 h (static) | Growth rate: E<sub>50</sub> | 18.11 mg a.s./L (nom) |
|                                  |                    |                        | (NOEC)                     | (Not available at 72 h) |
| Group                          | Test substance             | Time-scale (Test type) | End point          | Toxicity     |
|-------------------------------|-----------------------------|------------------------|--------------------|--------------|
| *Pseudokirchneriella subcapitata* | FEA + FLC WG 71.11 (Bayer CropScience) | 72 h (static)          | Growth rate: E<sub>C50</sub> | 12.5 mg prep./L |
|                               |                             |                        | Biomass: E<sub>bC50</sub> | 3.9 mg prep./L  |
|                               |                             |                        | (NOEC)              | 4.7 mg prep./L  |
|                               | Fosetyl-A180% WP (Iberica Taskforce) | 72 h (static)          | Growth rate: E<sub>C50</sub> | 14.8 mg prep./L |
|                               |                             |                        | Growth rate: E<sub>C20</sub> | 5.77 mg prep./L |
|                               |                             |                        | Growth rate: E<sub>C10</sub> | 3.32 mg prep./L |
|                               |                             |                        | Yield: E<sub>yC50</sub>  | 6.8 mg prep./L  |
|                               |                             |                        | Yield: E<sub>yC20</sub>  | 4.74 mg prep./L |
|                               |                             |                        | Yield: E<sub>yC10</sub>  | 3.84 mg prep./L |
|                               |                             |                        | (NOEC)              | (3.05 mg prod./L) |
|                               | Phosphonic acid (unprotected) | 72 h (static)          | Growth rate: E<sub>C50</sub> | 29.4 mg met./L<sub>(nom)</sub> |
|                               |                             |                        | Growth rate: E<sub>C20</sub> | 25.96 mg met./L<sub>(nom)</sub> |
|                               |                             |                        | (NOEC)              | (2.3 mg met./L<sub>(nom)</sub>) |
|                               |                             |                        | Biomass: E<sub>bC50</sub> | 8.6 mg met./L<sub>(nom)</sub> |
|                               |                             |                        | Biomass: E<sub>bC20</sub> | 13.03 mg met./L<sub>(nom)</sub> |
|                               |                             |                        | (NOEC)              | (2.3 mg met./L<sub>(nom)</sub>) |
| Group         | Test substance | Time-scale (Test type) | End point | Toxicity¹ |
|--------------|----------------|------------------------|-----------|-----------|
| Higher plant | *Lemna gibba*  | a.s. (unprotected)     | 14 d (static) | Fronds number², 14d-
|              |                |                        |           | EC₅₀       |
|              |                |                        |           | 79.67 mg  |
|              |                |                        |           | a.s./L(mm) |
|              |                |                        |           | 166.6 mg  |
|              |                |                        |           | a.s./L(mm) |
|              |                |                        |           | 90.0 mg   |
|              |                |                        |           | a.s./L(mm) |
|              |                |                        |           | (20.4 mg  |
|              |                |                        |           | a.s./L(mm)) |

Further testing on aquatic organisms

*Not available and not required*

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 fosetyl-Al. 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 fosetyl-Al.

¹ (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance
² in this study only the variable frond number was measured
Bioconcentration in fish (Annex Part A, point 8.2.2.3)

|                          | Active substance | Phosphonic acid |
|--------------------------|------------------|-----------------|
| logP<sub>O/W</sub>       | -2.1             | -4.96           |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) | - | - |
| Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content) | - | - |
| Annex VI Trigger for the bioconcentration factor | - | - |
| Clearance time (days) (CT<sub>50</sub>) | - | - |
| (CT<sub>90</sub>) | - | - |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | - | - |

RAC values for the risk assessment

**Estimation of the acute RAC**

| Test substance | Test species | Endpoint (mg/L) | RAC value (µg/L) |
|----------------|--------------|-----------------|-----------------|
| Fosetyl-Al | Fish, acute<br/)*Cyprinus carpio* | LC<sub>50</sub> > 100 mg a.s./L | > 1 000 |
| | Invertebrate, acute<br/)*Daphnia magna* | EC<sub>50</sub> > 100 mg a.s./L | > 1 000 |
| Phosphonic acid | Fish, acute<br/)*Lepomis macrochirus* | LC<sub>50</sub> > 35.7 mg a.s./L | > 357 |
| | Invertebrate, acute<br/)*Daphnia magna* | EC<sub>50</sub> > 400 mg a.s./L | > 4 000 |

**Estimation of the chronic RAC**

| Test substance | Test species | Endpoint (mg/L) | RAC value (µg/L) |
|----------------|--------------|-----------------|-----------------|
| Fish, chronic<br/)*Pimephales promelas* | NOEC = 0.213 mg a.s./L | 21.3 |
| Invertebrate, chronic<br/)*Daphnia magna* | NOEC = 10.1mg a.s./L | 1010 |
| Algae<br/)*Pseudokirchneriella subcapitata* | ErC<sub>50</sub> = 9.54 mg a.s./L | 954 |
| Sediment dweller<br/)*Chironomus riparius* | NOEC = 100.2 mg /L | 10 200 |
| Algae<br/)*Pseudokirchneriella subcapitata* | ErC<sub>50</sub> = 29.4 mg a.s./L | 2 940 |
Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) No 284/2013, Annex Part A, point 10.2)

Comparison RAC/PECsw for fosetyl-Al – Fosetyl-Al WG 80 - Orchards (Pome fruits) at 3600 g a.s./ha [3 applications]

Acute RAC value for aquatic organisms for fosetyl-Al compared to relevant PECsw values (Step 1 and Step 2) from the proposed uses of Fosetyl-Al WG 80

| Crop                      | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PECsw [µg/L] | Acute RAC (> 1000 µg/L) PEC< RAC |
|----------------------------|--------------|-------------------------------------|------|--------------|---------------------------------|
| Orchards (Pome fruits)     | 55-85        | 3600                                | 1    | 4166         | No                              |
|                            |              |                                     | 2    | 188.7        | Yes                             |

Acute RAC value for aquatic organisms for phosphonic acid compared to relevant PECsw values (Step 1 and Step 2) from the proposed uses of Fosetyl-Al WG 80

| Crop                      | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PECsw [µg/L] | Acute RAC (> 357 µg/L) PEC< RAC |
|----------------------------|--------------|-------------------------------------|------|--------------|---------------------------------|
| Orchards (Pome fruits)     | 55-85        | 3600                                | 1    | 3905         | No                              |
|                            |              |                                     | 2    | 445.4        | No                              |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to relevant PECsw values (Step 1 and Step 2) from the proposed uses of Fosetyl-Al WG 80

| Crop                      | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PECsw [µg/L] | Chronic RAC (= 21.3 µg/L) PEC< RAC |
|----------------------------|--------------|-------------------------------------|------|--------------|---------------------------------|
| Orchards (Pome fruits)     | 55-85        | 3600                                | 1    | 4166         | No                              |
|                            |              |                                     | 2    | 188.7        | No                              |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to PECsw values (Step 3) from the proposed uses of Fosetyl-Al WG 80 (late application)
### Chronic RAC value for aquatic organisms for fosetyl-Al compared to PEC<sub>sw</sub> values (Step 4) from the proposed uses of Fosetyl-Al WG 80 (late application)

| Crop                  | Growth Stage | Maximum Application Rate | Scenario | Buffer | PEC<sub>sw</sub> | Chronic RAC (= 21.3 µg/L) PEC<sub>sw</sub>&lt;RAC |
|-----------------------|--------------|--------------------------|----------|--------|-----------------|-----------------------------------------------|
| Orchards (Pomefruits) | 55-85        | 3600                     |          |        |                 |                                               |
| BBCH [g a.s./ha]     |              |                          |          |        |                 |                                               |
| Orchards (Pomefruits) |              |                          |          |        |                 |                                               |
| BBCH [g a.s./ha]     |              |                          |          |        |                 |                                               |
| BBCH [g a.s./ha]     |              |                          |          |        |                 |                                               |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to PEC<sub>sw</sub> values (Step 4) from the proposed uses of Fosetyl-Al WG 80 (late application)

| Crop                  | Growth Stage | Maximum Application Rate | Scenario | Buffer | PEC<sub>sw</sub> | Chronic RAC (= 21.3 µg/L) PEC<sub>sw</sub>&lt;RAC |
|-----------------------|--------------|--------------------------|----------|--------|-----------------|-----------------------------------------------|
| Orchards (Pomefruits) | 55-85        | 3600                     | D3 Ditch |        |                 |                                               |
| BBCH [g a.s./ha]     |              |                          |          |        |                 |                                               |
|                | Description                                                                 | Value | Status |
|----------------|-----------------------------------------------------------------------------|-------|--------|
| D4 Pond        | 5 m non-spray and 90% reduction drift                                       | 0.7   | Yes    |
|                | 10 m non-spray, 10 m vegetative buffer strip and 75% reduction drift         | 0.9   | Yes    |
|                | 15 m non-spray, 10 m vegetative buffer strip and 50% reduction drift         | 1.2   | Yes    |
|                | 20 m non-spray and 20 m vegetative buffer strip                             | 1.7   | Yes    |
| D4 Stream      | 5 m non-spray and 90% reduction drift                                       | 10.4  | Yes    |
|                | 10 m non-spray, 10 m vegetative buffer strip and 75% reduction drift         | 11.6  | Yes    |
|                | 15 m non-spray, 10 m vegetative buffer strip and 50% reduction drift         | 11.7  | Yes    |
|                | 20 m non-spray and 20 m vegetative buffer strip                             | 14.3  | Yes    |
| D5 Pond        | 5 m non-spray and 90% reduction drift                                       | 0.7   | Yes    |
|                | 10 m non-spray, 10 m vegetative buffer strip and 75% reduction drift         | 0.9   | Yes    |
|                | 15 m non-spray, 10 m vegetative buffer strip and 50% reduction drift         | 1.2   | Yes    |
|                | 20 m non-spray and 20 m vegetative buffer strip                             | 1.7   | Yes    |
| D5 Stream      | 5 m non-spray and 90% reduction drift                                       | 11.2  | Yes    |
|                | 10 m non-spray, 10 m vegetative buffer strip and 75% reduction drift         | 12.5  | Yes    |
|                | 15 m non-spray, 10 m vegetative buffer strip and 50% reduction drift         | 12.6  | Yes    |
| Region | Description | Distance | Reduction |
|--------|-------------|----------|-----------|
| R1 pond | 20 m non-spray and 20 m vegetative buffer strip | 15.4 | Yes |
|         | 5 m non-spray and 90% reduction drift | 0.7 | Yes |
|         | 10 m non-spray, 10 m vegetative buffer strip and 75% reduction drift | 0.9 | Yes |
|         | 15 m non-spray, 10 m vegetative buffer strip and 50% reduction drift | 1.2 | Yes |
|         | 20 m non-spray and 20 m vegetative buffer strip | 1.7 | Yes |
| R1 Stream | 5 m non-spray and 90% reduction drift | 7.8 | Yes |
|         | 10 m non-spray, 10 m vegetative buffer strip and 75% reduction drift | 8.7 | Yes |
|         | 15 m non-spray, 10 m vegetative buffer strip and 50% reduction drift | 8.8 | Yes |
|         | 20 m non-spray and 20 m vegetative buffer strip | 10.7 | Yes |
| R2 Stream | 5 m non-spray and 90% reduction drift | 10.6 | Yes |
|         | 10 m non-spray, 10 m vegetative buffer strip and 75% reduction drift | 11.9 | Yes |
|         | 15 m non-spray, 10 m vegetative buffer strip and 50% reduction drift | 12.0 | Yes |
|         | 20 m non-spray and 20 m vegetative buffer strip | 14.7 | Yes |
| R3 Stream | 5 m non-spray and 90% reduction drift | 11.2 | Yes |
|         | 10 m non-spray, 10 m vegetative buffer strip and 75% reduction drift | 12.5 | Yes |
|         | 15 m non-spray, 10 m | 12.6 | Yes |
| Crop                   | Growth Stage BBCH | Maximum Application Rate [g a.s./ha] | Step | $\text{PEC}_{\text{sw}}$ [µg/L] | Chronic RAC (2940 µg/L) $\text{PEC}_{\text{sw}}$ < RAC |
|------------------------|-------------------|--------------------------------------|------|-----------------------------|--------------------------------------------------|
| Orchards (Pome fruits) | 55-85             | 3600                                 | 1    | 3905                        | No                                               |
|                        |                   |                                      | 2    | 445.4                       | Yes                                              |

**Chronic RAC value for aquatic organisms for phosphonic acid compared to relevant $\text{PEC}_{\text{sw}}$ values (Step 1 and Step 2) from the proposed uses of Fosetyl-Al WG 80**

| Crop | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | $\text{PEC}_{\text{sw}}$ [µg/L] | R4 Stream | vegetative buffer strip and 50% reduction drift | 20 m non-spray and 20 m vegetative buffer strip | 15.4 | Yes |
|------|--------------|--------------------------------------|------|-----------------------------|-----------|-----------------------------------------------|------------------------------------------------|------|-----|
|      |              |                                      |      |                             |           | 5 m non-spray and 90% reduction drift         | 7.8                               | Yes  |     |
|      |              |                                      |      |                             |           | 10 m non-spray, 10 m vegetative buffer strip and 75% reduction drift | 8.7                               | Yes  |     |
|      |              |                                      |      |                             |           | 15 m non-spray, 10 m vegetative buffer strip and 50% reduction drift | 8.7                               | Yes  |     |
|      |              |                                      |      |                             |           | 20 m non-spray and 20 m vegetative buffer strip | 10.7                              | Yes  |     |
Comparison RAC/PECsw for fosetyl-Al– FEA + FLC WG 71.11 - Grapevines at 2000 g a.s./ha [3 applications]

Acute RAC value for aquatic organisms for fosetyl-Al compared to relevant PECsw values (Step 1 and Step2) from the proposed uses of FEA + FLC WG 71.11.

| Crop  | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PECsw [µg/L] | Acute RAC (> 1000 µg/L) PEC< RAC |
|-------|--------------|-------------------------------------|------|-------------|----------------------------------|
| Grapes | 15-81        | 2000                                | 1    | 720.1       | Yes                              |
|        |              |                                     | 2    | 53.5        | Yes                              |

Acute RAC value for aquatic organisms for phosphonic acid compared to relevant PECsw values (Step 1 and Step2) from the proposed uses of FEA + FLC WG 71.11.

| Crop  | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PECsw [µg/L] | Acute RAC (>357 µg/L) PEC< RAC |
|-------|--------------|-------------------------------------|------|-------------|----------------------------------|
| Grapes | 15-81        | 2000                                | 1    | 2062.8      | No                               |
|        |              |                                     | 2    | 291.9       | Yes                              |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to relevant PECsw values (Step1 and Step 2) from the proposed uses of FEA + FLC WG 71.11.

| Crop  | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PECsw [µg/L] | Chronic RAC (= 21.3 µg/L) PEC< RAC |
|-------|--------------|-------------------------------------|------|-------------|----------------------------------|
| Grapes | 15-81        | 2000                                | 1    | 720.1       | No                               |
|        |              |                                     | 2    | 53.5        | No                               |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to PECsw values (Step 3) from the proposed uses of FEA + FLC WG 71.11 (early application).
| Crop     | Growth Stage | Maximum Application Rate | Scenario   | Buffer                        | PEC<sw | Chronic RAC (= 21.3 µg/L) PEC<RAC |
|----------|--------------|--------------------------|------------|-------------------------------|--------|----------------------------------|
|          | BBCH [g a.s./ha] |                          |            |                               |        |                                  |
|          | D6 Ditch     | Step 3                  | 33.7       | No                            |        |                                  |
| Grapes   | 15-81        | 2000                    |            |                               |        |                                  |
|          | R1 Pond      | Step 3                  | 1.2        | Yes                           |        |                                  |
|          | R1 Stream    | Step 3                  | 24.6       | No                            |        |                                  |
|          | R2 Stream    | Step 3                  | 33.1       | No                            |        |                                  |
|          | R3 Stream    | Step 3                  | 35.1       | No                            |        |                                  |
|          | R4 Stream    | Step 3                  | 24.7       | No                            |        |                                  |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to PEC<sw values (Step 4) from the proposed uses of FEA + FLC WG 71.11 (early application).

| Crop     | Growth Stage | Maximum Application Rate | Scenario   | Buffer                        | PEC<sw | Chronic RAC (= 21.3 µg/L) PEC<RAC |
|----------|--------------|--------------------------|------------|-------------------------------|--------|----------------------------------|
|          | BBCH [g a.s./ha] |                          |            |                               |        |                                  |
|          | D6 Ditch     |                          |            | 5 m non-spray and 50% reduction drift | 10.2   | Yes                              |
|          | R1 Pond      |                          |            | 10 m non-spray and 10 m vegetative buffer strip | 7.4    | Yes                              |
|          | R1 Stream    |                          |            | 5 m non-spray and 50% reduction drift | 0.7    | Yes                              |
|          | R2 Stream    |                          |            | 10 m non-spray and 10 m vegetative buffer strip | 0.8    | Yes                              |
| Grapes   | 15-81        | 2000                    |            |                               |        |                                  |
|          | R1 Stream    |                          |            | 5 m non-spray and 50% reduction drift | 9.0    | Yes                              |
|          | R2 Stream    |                          |            | 10 m non-spray and 10 m vegetative buffer strip | 6.5    | Yes                              |
|          |              |                          |            |                               |        |                                  |
### Chronic RAC value for aquatic organisms for fosetyl-Al compared to PEC$_{sw}$ values (Step 3) from the proposed uses of FEA + FLC WG 71.11 (late application).

| Crop  | Growth Stage | Maximum Application Rate | Scenario   | Buffer                             | PEC$_{sw}$ | Chronic RAC (= 21.3 µg/L) PEC< RAC |
|-------|--------------|---------------------------|------------|------------------------------------|------------|-----------------------------------|
|       |              |                           |            | R3 Stream 5 m non-spray and 50% reduction drift | 12.8       | Yes                               |
|       |              |                           |            | 10 m non-spray and 10 m vegetative buffer strip | 9.3        | Yes                               |
|       |              |                           |            | R4 Stream 5 m non-spray and 50% reduction drift | 9.0        | Yes                               |
|       |              |                           |            | 10 m non-spray and 10 m vegetative buffer strip | 6.5        | Yes                               |

### Chronic RAC value for aquatic organisms for fosetyl-Al compared to PEC$_{sw}$ values (Step 4) from the proposed uses of FEA + FLC WG 71.11 (late application).

| Crop  | Growth Stage | Maximum Application Rate | Scenario | Buffer                             | PEC$_{sw}$ | Chronic RAC (= 21.3 µg/L) PEC< RAC |
|-------|--------------|---------------------------|----------|------------------------------------|------------|-----------------------------------|
|       |              |                           |          | D6 Ditch Step 3                   | 34.3       | No                                |
| Grapes| 15-81        | 2000                      |          | R1 Pond Step 3                    | 1.2        | Yes                               |
|       |              |                           |          | R1 Stream Step 3                  | 25.1       | No                                |
|       |              |                           |          | R2 Stream Step 3                  | 33.8       | No                                |
|       |              |                           |          | R3 Stream Step 3                  | 35.5       | No                                |
|       |              |                           |          | R4 Stream Step 3                  | 25.2       | No                                |

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| Crop       | Growth Stage BBCH | Maximum Application Rate [g a.s./ha] | Step | \( PEC_{sw} \) [\( \mu g/L \)] | Chronic RAC (2940 \( \mu g/L \)) PEC< RAC |
|------------|-------------------|-------------------------------------|------|-----------------|------------------------------------------|
| Grapes     | 15-81             | 2000                                | 1    | 2062.8          | Yes                                      |
|            |                   |                                     | 2    | 291.9           | Yes                                      |

**Chronic RAC value for aquatic organisms for phosphonic acid compared to relevant \( PEC_{sw} \) values (Step 1 and Step 2) from the proposed uses of FEA + FLC WG 71.11.**
Comparison RAC/PECsw for fosetyl-Al– Fosetyl-Al 80% WP - Citrus at 3600 g a.s./ha [3 applications]

Acute RAC value for aquatic organisms for fosetyl-Al compared to relevant PECsw values (Step 1 and Step 2) from the proposed uses of Fosetyl-Al 80% WP on citrus.

| Crop | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PECsw [µg/L] | Acute RAC (> 1000 µg/L) PEC<RAC |
|------|--------------|--------------------------------------|------|--------------|---------------------------------|
| Citrus | Flowering (> 60) | 3600 | 1 | 1390 | No |
| | | | 2 | 188.7 | Yes |

Acute RAC value for aquatic organisms for phosphonic acid compared to relevant PECsw values (Step 1 and Step 2) from the proposed uses of Fosetyl-Al 80% WP on citrus.

| Crop | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PECsw [µg/L] | Acute RAC (> 357 µg/L) PEC<RAC |
|------|--------------|--------------------------------------|------|--------------|---------------------------------|
| Citrus | Flowering (> 60) | 3600 | 1 | 3910 | No |
| | | | 2 | 294.1 | Yes |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to relevant PECsw values (Step 1 and Step 2) from the proposed uses of Fosetyl-Al 80% WP on citrus.

| Crop | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PECsw [µg/L] | Chronic RAC (= 21.3 µg/L) PEC<RAC |
|------|--------------|--------------------------------------|------|--------------|---------------------------------|
| Citrus | Flowering (> 60) | 3600 | 1 | 1390 | No |
| | | | 2 | 188.7 | No |
Chronic RAC value for aquatic organisms for fosetyl-Al compared to relevant PEC_{sw} values (Step 3) from the proposed uses of Fosetyl-Al 80% WP on citrus (late application).

| Crop      | Growth Stage | Maximum Application Rate | Scenario  | Buffer | PEC_{sw} | Chronic RAC (= 21.3 µg/L) PEC<RAC |
|-----------|--------------|---------------------------|-----------|--------|----------|-----------------------------------|
| Citrus    | Flowering > 60 | 3600                      | D6 Ditch  | Step 3 | 133.0    | No                                |
|           |              |                           | R4 Stream | Step 3 | 101.6    | Yes                               |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to relevant PEC_{sw} values (Step 3) from the proposed uses of Fosetyl-Al 80% WP on citrus (late application).

| Crop      | Growth Stage | Maximum Application Rate | Scenario          | Buffer   | PEC_{sw} | Chronic RAC (= 21.3 µg/L) PEC<RAC |
|-----------|--------------|---------------------------|--------------------|----------|----------|-----------------------------------|
| Citrus    | Flowering > 60 | 3600                      | D6 Ditch 20 m non-spray | 12.4     | Yes                                |
|           |              |                           | R4 Stream 20 m non-spray | 11.0     | Yes                                |

Chronic RAC value for aquatic organisms for phosphonic acid compared to relevant PEC_{sw} values (Step 1 and Step 2) from the proposed uses of Fosetyl-Al 80% WP on citrus.

| Crop   | Growth Stage | Maximum Application Rate | Step | PEC_{sw} | Chronic RAC (= 2940 µg/L) PEC<RAC |
|--------|--------------|---------------------------|------|----------|-----------------------------------|
| Citrus | Flowering > 60 | 3600                    | 1    | 3910     | No                                |
|        |               |                          | 2    | 294.1    | Yes                               |

Comparison RAC/PEC_{sw} for fosetyl-Al– Fosetyl-Al 80% WP - Grapevines at 2640 g a.s./ha [4 applications]
Acute RAC value for aquatic organisms for fosetyl-Al compared to relevant PEC\textsubscript{sw} values (Step 1 and Step 2) from the proposed uses of Fosetyl-Al 80% WP on grapevine.

| Crop | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PEC\textsubscript{sw} [µg/L] | Acute RAC (> 1000 µg/L) PEC<RAC |
|------|--------------|--------------------------------------|------|-----------------------------|---------------------------------|
| Grapes | Flowering > 60 | 2640 | 1 | 950.5 | No |
|       |               |     | 2 | 70.7 | Yes |

Acute RAC value for aquatic organisms for phosphonic acid compared to relevant PEC\textsubscript{sw} values (Step 1 and Step 2) from the proposed uses of Fosetyl-Al 80% WP on grapevine.

| Crop | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PEC\textsubscript{sw} [µg/L] | Acute RAC (>357 µg/L) PEC<RAC |
|------|--------------|--------------------------------------|------|-----------------------------|--------------------------------|
| Grapes | Flowering > 60 | 2640 | 1 | 3630 | No |
|       |               |     | 2 | 311.8 | Yes |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to relevant PEC\textsubscript{sw} values (Step 1 and Step 2) from the proposed uses of Fosetyl-Al 80% WP on grapevine.

| Crop | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PEC\textsubscript{sw} [µg/L] | Chronic RAC (= 21.3 µg/L) PEC<RAC |
|------|--------------|--------------------------------------|------|-----------------------------|---------------------------------|
| Grapes | Flowering > 60 | 2640 | 1 | 950.5 | No |
Chronic RAC value for aquatic organisms for fosetyl-Al compared to relevant PEC_{sw} values (Step 3) from the proposed uses of Fosetyl-Al 80 % WP on grapevine (late application).

| Crop     | Growth Stage | Maximum Application Rate | Scenario | Buffer | PEC_{sw} | Chronic RAC (= 21.3 µg/L) PEC<RAC |
|----------|--------------|--------------------------|----------|--------|----------|----------------------------------|
|          | BBCH [g a.s./ha] |                          |          |        |          |                                  |
| Grapes   | Flowering > 60 | 2640                     | D6 Ditch | Step 3 | 45.3     | No                               |
|          |               |                          | R1 Pond  | Step 3 | 1.6      | Yes                              |
|          |               |                          | R1 Stream| Step 3 | 32.3     | No                               |
|          |               |                          | R2 Stream| Step 3 | 45.6     | No                               |
|          |               |                          | R3 Stream| Step 3 | 46.9     | Yes                              |
|          |               |                          | R4 Stream| Step 3 | 33.2     | Yes                              |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to relevant PEC_{sw} values (Step 4) from the proposed uses of Fosetyl-Al 80 % WP on grapevine (late application).

| Crop     | Growth Stage | Maximum Application Rate | Scenario | Buffer | PEC_{sw} | Chronic RAC (= 21.3 µg/L) PEC<RAC |
|----------|--------------|--------------------------|----------|--------|----------|----------------------------------|
|          | BBCH [g a.s./ha] |                          |          |        |          |                                  |
| Grapes   | Flowering > 60 | 2640                     | D6 Ditch | 10 m non-spray | 3.5 | Yes |
|          |               |                          | R1 Pond  | 10 m non-spray | 0.5 | Yes |
|          |               |                          | R1 Stream| 10 m non-spray | 3.0 | Yes |
|          |               |                          | R2 Stream| 10 m non-spray | 4.1 | Yes |
|          |               |                          | R3 Stream| 10 m non-spray | 4.3 | Yes |
|          |               |                          | R4 Stream| 10 m non-spray | 3.1 | Yes |

Chronic RAC value for aquatic organisms for phosphonic acid compared to relevant PEC_{sw} values (Step 1 and Step 2) from the proposed uses of Fosetyl-Al 80 % WP on grapevine
| Crop | Growth Stage BBCH | Maximum Application Rate [g a.s./ha] | Step | $\text{PEC}_{\text{sw}}$ [µg/L] | Chronic RAC (= 2940 µg/L) PEC<RAC |
|------|------------------|--------------------------------------|------|-----------------|---------------------------------|
| Grapes | Flowering > 60 | 2640 | 1 | 3630 | No |
|       |                  |      | 2 | 311.8 | Yes |
Comparison RAC/PECsw for fosetyl-Al– SIP40958 - Grapevine at 1350 g a.s./ha [4 applications]

Acute RAC value for aquatic organisms for fosetyl-Al compared to relevant PECsw values (Step 1 and Step2) from the proposed uses of SIP40958.

| Crop     | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PECsw [µg/L] | Acute RAC (> 1000 µg/L) PEC<RAC |
|----------|--------------|--------------------------------------|------|--------------|----------------------------------|
| Grapes   | 11-79        | 1350                                 | 1    | 462.1        | Yes                              |
|          |              |                                      | 2    | 36.1         | Yes                              |

Acute RAC value for aquatic organisms for phosphonic acid compared to relevant PECsw values (Step 1 and Step2) from the proposed uses of SIP40958.

| Crop     | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PECsw [µg/L] | Acute RAC (> 357 µg/L) PEC<RAC |
|----------|--------------|--------------------------------------|------|--------------|----------------------------------|
| Grapes   | 11-79        | 1350                                 | 1    | 2600         | No                               |
|          |              |                                      | 2    | 422.5        | No                               |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to relevant PECsw values (Step 1 and Step 2) from the proposed uses of SIP40958.

| Crop     | Growth Stage | Maximum Application Rate [g a.s./ha] | Step | PECsw [µg/L] | Chronic RAC (= 21.3 µg/L) PEC<RAC |
|----------|--------------|--------------------------------------|------|--------------|-----------------------------------|
| Grapes   | 11-79        | 1350                                 | 1    | 462.1        | No                               |
|          |              |                                      | 2    | 36.1         | No                               |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to relevant PECsw values (Step3) from the proposed uses of SIP40958 (early application).
### Crop Growth Stage Maximum Application Rate

| Crop | Growth Stage | Maximum Application Rate |
|------|--------------|--------------------------|
| Grapes | 11-79 | 1350 |

### Scenario Buffer PEC<sub>sw</sub> Chronic RAC (= 21.3 µg/L) PEC<sub>sw</sub><RAC

| Scenario | Buffer | PE C<sub>sw</sub> | Chronic RAC (= 21.3 µg/L) PEC<sub>sw</sub><RAC |
|----------|--------|-----------------|------------------------------------------|
| D6 Ditch | Step 3 | 7.7             | Yes                                      |
| R1 Pond  | Step 3 | 0.3             | Yes                                      |
| R1 Stream| Step 3 | 5.6             | Yes                                      |
| R2 Stream| Step 3 | 7.4             | Yes                                      |
| R3 Stream| Step 3 | 7.8             | Yes                                      |
| R4 Stream| Step 3 | 5.6             | Yes                                      |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to relevant PE C<sub>sw</sub> values (Step3) from the proposed uses of SIP40958 (late application).

### Crop Growth Stage Maximum Application Rate

| Crop | Growth Stage | Maximum Application Rate |
|------|--------------|--------------------------|
| Grapes | 11-79 | 1350 |

### Scenario Buffer PEC<sub>sw</sub> Chronic RAC (= 21.3 µg/L) PEC<sub>sw</sub><RAC

| Scenario | Buffer | PE C<sub>sw</sub> | Chronic RAC (= 21.3 µg/L) PEC<sub>sw</sub><RAC |
|----------|--------|-----------------|------------------------------------------|
| D6 Ditch | Step 3 | 23.17 | No                                       |
| R1 Pond  | Step 3 | 0.8247 | Yes                                      |
| R1 Stream| Step 3 | 16.53 | Yes                                      |
| R2 Stream| Step 3 | 22.78 | No                                       |
| R3 Stream| Step 3 | 23.96 | No                                       |
| R4 Stream| Step 3 | 16.99 | Yes                                      |

Chronic RAC value for aquatic organisms for fosetyl-Al compared to relevant PE C<sub>sw</sub> values (Step4) from the proposed uses of SIP40958 (late application).

### Crop Growth Stage Maximum Application Rate

| Crop | Growth Stage | Maximum Application Rate |
|------|--------------|--------------------------|
| Grapes | 11-79 | 1350 |

### Scenario Buffer PEC<sub>sw</sub> Chronic RAC (= 21.3 µg/L) PEC<sub>sw</sub><RAC

| Scenario | Buffer | PE C<sub>sw</sub> | Chronic RAC (= 21.3 µg/L) PEC<sub>sw</sub><RAC |
|----------|--------|-----------------|------------------------------------------|
| D6 Ditch | 5 m non-spray | 14.0 | Yes                                       |
| R2 Stream| 5 m non-spray | 16.6 | Yes                                       |
| R3 Stream| 5 m non-spray | 17.5 | Yes                                       |
Chronic RAC value for aquatic organisms for phosphonic acid compared to relevant PEC\textsubscript{sw} values (Step 1 and Step 2) from the proposed uses of SIP40958.

| Crop  | Growth Stage BBCH | Maximum Application Rate [g a.s./ha] | Step | PEC\textsubscript{sw} [µg/L] | Chronic RAC (= 2940 µg/L) PEC<\textsubscript{RAC} |
|-------|-------------------|--------------------------------------|------|---------------------------|-----------------------------------------------|
| Grapes | 11-79             | 1350                                 | 1    | 2600                      | Yes                                           |
|        |                   |                                      | 2    | 422.5                     | Yes                                           |
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* | a.s. (unprotected)                 | Acute                       | Oral toxicity   | > 140 µg/bee                       |
| *Apis mellifera* | a.s. (unprotected)                 | Acute (96 h)                | Oral toxicity   | 461.8 µg/bee                       |
| *Apis mellifera* | a.s. (Bayer CropScience)           | Acute                       | Oral toxicity   | > 108.5 µg/bee                     |
| *Apis mellifera* | a.s. (unprotected)                 | Acute                       | Contact toxicity| > 100 µg/bee                       |
| *Apis mellifera* | a.s. (unprotected)                 | Acute                       | Contact toxicity| > 1000 µg/bee                      |
| *Apis mellifera* | a.s. (Bayer CropScience)           | Acute                       | Contact toxicity| > 100 µg/bee                       |
| *Apis mellifera* | Phosphonic acid (unprotected)      | Acute                       | Oral toxicity   | > 212 µg met./bee                  |
| *Apis mellifera* | Phosphonic acid (Bayer CropScience) | Acute                       | Oral toxicity   | > 848 µg met./bee                  |
| *Apis mellifera* | Phosphonic acid (Iberica Taskforce) | Acute                       | Oral toxicity   | > 98.24 µg met./bee                |
| *Apis mellifera* | Phosphonic acid (unprotected)      | Acute                       | Contact toxicity| > 29.7 µg met./bee                 |
| *Apis mellifera* | Phosphonic acid (Bayer CropScience) | Acute                       | Contact toxicity| > 1050 µg met./bee                 |
| *Apis mellifera* | Phosphonic acid (Iberica Taskforce) | Acute                       | Contact toxicity| > 100 µg met./bee                  |
| *Apis mellifera* | Fosetyl-A1WG80 (Bayer CropScience) | Acute                       | Oral toxicity   | >440 µg prod/bee (>390 µg a.s./bee) |
| *Apis mellifera* | Fosetyl-A1WG80 (Bayer)             | Acute                       | Oral toxicity   | >136.3 µg prod/bee (>110.4 µg a.s./bee) |
| Crop | Pesticide | Test Type | Effect | Toxicity |
|------|-----------|-----------|--------|----------|
| **Apis mellifera** | Fosetyl-A1WG80 (Bayer CropScience) | Acute Contact toxicity (LD₉₀) | >390 µg prod/bee (>310 µg a.s./bee) |
| **Apis mellifera** | Fosetyl-A1WG80 (Bayer CropScience) | Acute Contact toxicity (LD₉₀) | >123.5 µg prod/bee (>100 µg a.s./bee) |
| **Apis mellifera** | FEA + FLC WG71.11 (Bayer CropScience) | Acute Oral toxicity (LD₉₀) | >169 µg prod/bee |
| **Apis mellifera** | FEA + FLC WG71.11 (Bayer CropScience) | Acute Oral toxicity (LD₉₀) | >219 µg prod/bee |
| **Apis mellifera** | FEA + FLC WG71.11 (Bayer CropScience) | Acute Contact toxicity (LD₉₀) | >70 µg prod/bee |
| **Apis mellifera** | FEA + FLC WG71.11 (Bayer CropScience) | Acute Contact toxicity (LD₉₀) | >200 µg prod/bee |
| **Apis mellifera** | Fosetyl-A180% WP (Iberica Taskforce) | Acute Oral toxicity (LD₉₀) | >222.99 µg prod/bee (>182.85 µg a.s./bee) |
| **Apis mellifera** | Fosetyl-A180% WP (Iberica Taskforce) | Acute Contact toxicity (LD₉₀) | >200 µg prod/bee (>164 µg a.s./bee) |
| **Apis mellifera** | SIP 40958 (OXN-SAE) | Acute Oral toxicity (LD₉₀) | >90.8 µg prod/bee |
| **Apis mellifera** | SIP 40958 (OXN-SAE) | Acute Contact toxicity (LD₉₀) | >400 µg prod/bee |
| **Bombus terrestris** | a.s., (Bayer CropScience) | Acute Contact toxicity (LD₉₀) | >250 µg a.s./bumble bee |
| **Bombus terrestris** | a.s., (Bayer CropScience) | Acute Oral toxicity (LD₉₀) | >206.49 µg a.s./bumble bee |
| **Bombus terrestris** | FEA + FLC WG71.11 | Acute Contact toxicity (LD₉₀) | >450 µg prod./bumble bee |
| Species            | Product Formulation | Study Type | Endpoint and Effect Level | Test Results |
|--------------------|---------------------|------------|---------------------------|--------------|
| Bombus terrestris  | FEA + FLC WG 71.11  | Acute      | Oral toxicity (LD₅₀)      | > 664.1 µg prod./bumble bee |
| Apis mellifera     | Fosetyl-A1 WG80 a.s. | Chronic    | 10 d-LC₅₀ 10 d-LDD₅₀      | > 750 mg a.s./kg > 37.3 µg/bee/day |
| Apis mellifera     | Fosetyl-A180% WP    | Chronic    | 10 d-LC₅₀ 10 d-LDD₅₀      | > 750 mg a.s./kg > 14.78 µg a.s./bee/day |
| Apis mellifera     | a.s. (OXN-SAE)      | Chronic    | 10 d-LC₅₀                  | 71.98 µg a.s./bee/day |
| Apis mellifera     | Fosetyl-A180% WP    | Bee brood development | NOEC larvae               | 99.9 µg/larva/developmental period* |
| Apis mellifera     | a.s. (OXN-SAE)      | Bee brood development | NOEC larvae               | 120.5 µg/larva/developmental period |
| -                  | -                   | Sub-lethal effects (behavioural and reproductive) | NOEC hypopharyngeal glands | Not available |

* study duration is 8 days

Potential for accumulative toxicity: Not studied

The following high tier studies were available. It is noted that these studies were considered by EFSA as sufficient to cover effects on mortality but were not considered sufficient to cover potential chronic effects.

**Semi-field test (Cage and tunnel test)**

**Oomen test (Bayer CropScience):**
A single dose brood feeding test was conducted at a rate of 2.4 g fosetyl-Al/L sucrose solution (corresponding to 2.97 g Fosetyl-A1 WG 80/L, derived from a theoretical spray application of 4.0 kg Thiram 80 WG/ha). The termination rate of eggs was significantly higher in the test item treatment group when compared to the control. The brood index and brood compensation index increased continuously indicating a development of the brood during the test.

**Semi-field brood development study according to OECD 75 (2007), tunnel test on Phacelia (Bayer CropScience):**
No adverse effects on mortality, flight intensity, brood development (brood termination rate, brood index, compensation index) as well as on brood and food abundance at 3600 g a.s./ha.
Some significant effects (higher mortality, effects on brood development-termination rates, brood and compensation indices) were observed at 570 g a.s./ha. These effects were considered not treatment related since the mortality in this treatment group was already higher during the pre-application period indicating that the colonies
used in this group seemed to be more sensitive to restricted conditions in the tunnels and since no significant effects on mortality were observed at 3600 g a.s./ha. A second semi-field study using the application rate of 588 g a.s./ha was available (see below).

**Semi-field brood development study according to OECD 75 (2007), tunnel test on Phacelia (Bayer CropScience):**

No adverse effects on mortality, flight intensity, behavior, brood development (brood termination rate, brood index, compensation index) as well as on brood and food abundance at 570 g a.s./ha.

**Semi-field honey bee study (OEPP/EPPO Guideline No. 170(4), tunnel test on Phacelia (Bayer CropScience):**

Application up to 80 kg product/ha at approx. 30% flowering of Phacelia, 28 h before the introduction of bees in the tents (7-day exposure) did not cause adverse effects to honeybees. It is, however, noted that in this study the product was applied on soil and that the post-exposure phase was short and not sufficient to conclude on potential effects on the colonies.

**Semi-field honey bee study (OEPP/EPPO Guideline No. 170(4), tunnel test in flowering apple orchard (Bayer CropScience):**

No adverse effects on mortality, foraging activity, behavior, amount of brood and food storage after one application of 1214 g a.s./ha/m canopy height (corresponding to 3600 g a.s./ha/3 m canopy height).

**Semi-field honey bee study (OEPP/EPPO Guideline No. 170(4), tunnel test in flowering apple orchard (Bayer CropScience):**

No adverse effects on mortality, behavior amount of brood and food storage after two applications of 1200 g a.s./ha/m canopy height (corresponding to 3600 g a.s./ha/3 m canopy height) in a 6-day spray interval. Foraging activity of the honeybees in the test item group was slightly but statistically significantly reduced compared to the control directly after the first application and directly before the second application but no difference was detected during any other assessment.

**Field tests**

*Not available*

**Risk assessment** for Fosetyl-Al WG80 – Orchards (Pome fruits) at 4500 g product/ha [3 applications]

| Species     | Test substance | Risk quotient | HQ   | Trigger |
|-------------|----------------|---------------|------|---------|
| *Apis mellifera* | Fosetyl-Al WG80 | HQcontact     | < 36.0 | 50      |
| *Apis mellifera* | Phosphonic acid | HQcontact     | < 2.4  | 50      |
| *Apis mellifera* | Fosetyl-Al WG80 | HQoral        | < 32.6 | 50      |
| *Apis mellifera* | Phosphonic acid | HQoral        | < 2.9  | 50      |

**Risk assessment** for FEA + FLC WG 71.11 – Vine at 3000 g product/ha [3 applications]

| Species     | Test substance | Risk quotient | HQ   | Trigger |
|-------------|----------------|---------------|------|---------|
| *Apis mellifera* | a.s.           | HQcontact     | < 20.0 | 50      |
| *Apis mellifera* | FEA + FLC WG 71.11 | HQcontact | < 15.0 | 50      |
| *Apis mellifera* | Phosphonic acid | HQcontact     | < 1.3  | 50      |
Risk assessment for Fosetyl-Al 80% WP – Citrus at 3600 g a.s./ha [3 applications] (worst-case exposure for Fosetyl-Al 80% WP)

| Species              | Test substance       | Risk quotient | HQ/ETR | Trigger |
|----------------------|----------------------|---------------|--------|---------|
| Apis mellifera       | a.s.,                | HQoral        | < 18.4 | 50      |
| Apis mellifera       | FEA + FLC WG 71.11   | HQoral        | < 13.7 | 50      |
| Apis mellifera       | Phosphonic acid      | HQoral        | < 1.6  | 50      |

Risk assessment for SIP40958 – Vine at 4500 g preparation/ha [4 applications]

| Species              | Test substance       | Risk quotient | HQ/ETR | Trigger |
|----------------------|----------------------|---------------|--------|---------|
| Apis mellifera       | a.s.,                | HQcontact     | < 36   | 50      |
| Apis mellifera       | Fosetyl-Al 80% WP    | HQcontact     | < 19.7 | 50      |
| Apis mellifera       | Phosphonic acid      | HQcontact     | < 11.8 | 50      |
| Apis mellifera       | a.s.,                | HQoral        | < 36   | 50      |
| Apis mellifera       | Fosetyl-Al 80% WP    | HQoral        | < 22   | 50      |
| Apis mellifera       | Phosphonic acid      | HQoral        | < 25.5 | 50      |

* risk can be considered acceptable for bees since the LD50 value of 29.7 µg/bee corresponds to the highest tested rate in the study and since phosphonic acid is not considered more toxic to bees than fosetyl-Al.

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  | Fosetyl-A1WG80 (Bayer CropScience) | Mortality, LR50   | < 11 880 g product/ha   |
| Typhlodromus pyri  | Fosetyl-A1WG80 (Bayer CropScience) | Mortality, LR50   | > 18 870 g product/ha   |
|                    |                              | Reproduction, ER50 | > 2 520 g product/ha    |
| Species                        | Test Substance                  | End point          | Toxicity                  |
|-------------------------------|---------------------------------|--------------------|--------------------------|
| *Aphidius rhopalosiphi*       | Fosetyl-A1WG80 (Bayer CropScience) | Mortality, LR<sub>50</sub> | > 18 560 g product/ha    |
|                               |                                 | Reproduction, ER<sub>50</sub> | > 18 560 g product/ha    |
| *Aphidius rhopalosiphi*       | Fosetyl-A1WG80 (Bayer CropScience) | Mortality, LR<sub>50</sub> | > 80 000 g product/ha    |
|                               |                                 | Reproduction, ER<sub>50</sub> | > 80 000 g product/ha    |
| *Typhlodromus pyri*           | FEA + FLC WG 71.11 (Bayer CropScience) | Mortality, LR<sub>50</sub> | 7130 g product/ha        |
|                               |                                 | Reproduction, ER<sub>50</sub> | > 6900 g product/ha      |
| *Aphidius rhopalosiphi*       | FEA + FLC WG 71.11 (Bayer CropScience) | Mortality, LR<sub>50</sub> | > 400 g product/ha       |
|                               |                                 | Reproduction, ER<sub>50</sub> | > 400 g product/ha       |
| *Aphidius rhopalosiphi*       | FEA + FLC WG 71.11 (Bayer CropScience) | Mortality, LR<sub>50</sub> | 8230 g product/ha        |
|                               |                                 | Reproduction, ER<sub>50</sub> | > 4600 g product/ha      |
| *Typhlodromus pyri*           | Fosetyl-A180% WP (Iberica Taskforce) | Mortality, LR<sub>50</sub> | > 8400 g a.s./ha         |
|                               |                                 | Reproduction, ER<sub>50</sub> | > 8400 g a.s./ha         |
| *Aphidius rhopalosiphi*       | Fosetyl-A180% WP (Iberica Taskforce) | Mortality, LR<sub>50</sub> | > 8400 g a.s./ha         |
|                               |                                 | Reproduction, ER<sub>50</sub> | > 8400 g a.s./ha         |
| *Aphidius rhopalosiphi*       | SIP 40958 (OXN-SAE) | Mortality, LR<sub>50</sub> | > 13500 g product/ha     |
|                               |                                 | Reproduction, ER<sub>50</sub> | > 13500 g product/ha     |

Additional species

| *Coccinella septempunctata*   | Fosetyl-A1WG80 (Bayer CropScience) | Mortality, LR<sub>50</sub> | > 11 880 g product/ha    |
|                               |                                 | Reproduction, ER<sub>50</sub> | < 18 560 g product/ha    |
| *Aleochara bilineata*         | Fosetyl-A1WG80 (Bayer CropScience) | Reproduction, ER<sub>50</sub> | > 18 560 g product/ha    |
| *Poecilus cupreus*            | Fosetyl-A1WG80 (Bayer CropScience) | Reproduction, ER<sub>50</sub> | > 18 890 g product/ha    |
First tier risk assessment for Fosetyl-Al WG80 – Orchards (Pome fruits) at 4500 g product/ha [3 applications]

| Test substance   | Species               | Effect (LR50 g/ha) | HQ in-field | HQ off-field | Trigger |
|------------------|-----------------------|--------------------|-------------|--------------|---------|
| Fosetyl-Al WG80  | Typhlodromus pyri     | > 18870            | < 0.55      | < 0.13       | 2       |
| Fosetyl-Al WG80  | Aphidius rhopalosiphi| > 80000            | < 0.13      | < 0.03       | 2       |

First tier risk assessment for FEA + FLC WG 71.11 – Vine at 3000 g product/ha [3 applications]

| Test substance      | Species               | Effect (LR50 g product/ha) | HQ in-field | HQ off-field | Trigger |
|---------------------|-----------------------|-----------------------------|-------------|--------------|---------|
| FEA + FLC WG 71.11  | Typhlodromus pyri     | 7130                         | 0.97        | 0.067        | 2       |
| FEA + FLC WG 71.11  | Aphidius rhopalosiphi| 8230                         | 0.84        | 0.058        | 2       |

First tier risk assessment for Fosetyl-Al 80% WP – Citrus at 3600 g a.s./ha [3 applications] (worst-case exposure for Fosetyl-Al 80% WP)

| Test substance        | Species               | Effect (LR50 g/ha) | HQ in-field | HQ off-field | Trigger |
|-----------------------|-----------------------|--------------------|-------------|--------------|---------|
| Fosetyl-Al 80% WP     | Typhlodromus pyri     | > 8400             | < 0.99      | < 0.24       | 2       |
| Fosetyl-Al 80% WP     | Aphidius rhopalosiphi| > 8400             | < 0.99      | < 0.24       | 2       |

First tier risk assessment for SIP40958 – Vine at 4500 g preparation/ha [4 applications]

| Test substance   | Species               | Effect (LR50 g/ha) | HQ in-field | HQ off-field | Trigger |
|------------------|-----------------------|--------------------|-------------|--------------|---------|
| SIP40958         | Aphidius rhopalosiphi| > 13500            | <0.9        | < 0.06       | 2       |
| -                 | Typhlodromus pyri     |                    |             |              | 2       |

Extended laboratory tests, aged residue tests

| Species          | Life stage | Test substance, substrate | Time scale | Dose (kg/ha) | End point | % effect | ER50 |
|------------------|------------|---------------------------|------------|--------------|-----------|----------|------|
| Typhlodromus pyri| protonymphs| Fosetyl-Al WG80 (Bayer CropScience) | 7-d        | 7.43 18.56   | Mortality | 69.3 98.9 | < 7.43 kg product/ha |
| Species                        | Life stage          | Test substance, substrate | Time scale | Dose (kg/ha) | End point          | % effect | ER<sub>50</sub> |
|-------------------------------|---------------------|---------------------------|------------|--------------|--------------------|----------|--------------|
| *Typhlodromus pyri*           | protonymphs         | Fosetyl-Al WG 80 (Bayer CropScience) | 7-d        | 2.5, 5.0, 11.25, 20.0, 40.0, 80.0 | Reproduction | 7.9, 57.6, 11.2, 43.8, 32.3, -20.2 | > 80.0 kg product/ha |
|                               |                     | SIP40958 (OZN-SAE)        | 7-d        | 1.5, 2.0, 3.0, 7.0, 13.5 | Reproduction | 34.65, 42.65, 43.04, 46.16, 52.01 | 10.23 kg product/ha |
| *Coccinella septempunctata*   | larvae              | Fosetyl-Al WG 80 (Bayer CropScience) | 20-22 d    | 12, 19, 33, 58, 82 | Mortality and reproduction | No effects on mortality or reproduction | > 82 kg product/ha |
|                               |                     | SIP40958 (OZN-SAE)        | 20-22-d    | 0.42, 0.84, 1.69, 3.38, 6.75, 13.5 | Reproduction | 34.8, 37.5, 31.6, 39.4, 31.3, 32.4 | > 13.5 kg product/ha |
| *Aleochara bilineata*         | adult               | Fosetyl-Al WG 80 (Bayer CropScience) | 68-d       | 36, 57, 67 | Reproduction | 7.4, 16.8, 21.9 | > 67 kg product/ha |

1 dose is expressed in units of preparation
2 positive percentages relate to adverse effects

**Risk assessment** for Fosetyl-Al WG 80– Orchards (Pome fruits) at 4500 g product/ha [3 applications] based on extended lab test or aged residue tests

| Species                        | ER<sub>50</sub> (g/ha) | In-field rate | Off-field rate<sup>1</sup> |
|-------------------------------|-------------------------|---------------|-----------------------------|
| *Typhlodromus pyri*           | 10234.4                 | 12150         | 815                         |

The Tier 2 risk assessment is not required since the HQv values of Tier 1 are below the trigger value of 2.

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

**Risk assessment** for SIP40958 – Vine at 4500 g preparation/ha [4 applications] based on extended lab test

| Species                        | ER<sub>50</sub> (g/ha) | In-field rate | Off-field rate<sup>1</sup> |
|-------------------------------|-------------------------|---------------|-----------------------------|
| *Typhlodromus pyri*           |                         | 12150         | 815                         |
| Species                  | ER$_{50}$ (g/ha) | In-field rate | Off-field rate$^1$ |
|-------------------------|------------------|---------------|-------------------|
| *Coccinella septempunctata* | $> 13500$        | 12150         | 815               |

$^1$ drift rate at 3 m and if for 3D studies.

|                      |                  |
|----------------------|------------------|
| Semi-field tests     | No studies are available |
| Field studies        |                  |

Field study of the effects of Fosetyl-Al WG 80 on predatory mite populations in apple orchard (southern France):
No unacceptable effects on predatory mite populations at 3 x 3.2 kg prod/ha (2 d spray interval) and 3 x 4.0 kg prod/ha (18-21 d spray interval).

Field study of the effects of Fosetyl-Al WG 80 on predatory mite populations in apple orchard (central zone):
No unacceptable effects on predatory mite populations at 3 x 4.5 kg prod/ha (3-4 d spray interval), 3 x 7.5 kg prod/ha (7 d spray interval) and 3 x 3.75 kg prod/ha (9 d spray interval).

| Additional specific test | No studies are available |
**Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation**

*Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5*

| Test organism | Test substance | Application method of test a.s./OM† | Time scale | End point | Toxicity |
|---------------|---------------|-------------------------------------|------------|-----------|----------|
| Earthworms    | **Eisenia fetida** | Fosetyl-AlWG 80 (Bayer CropScience) | Mixed with soil / 10% OM | Chronic | Reproduction | NOEC = 316 mg product/kg d.w. soil (254.4 mg a.s./kg d.w. soil corresponding to 176.8 mg H₃PO₃/kg d.w. soil) EC₉⁰ = 459 mg product/kg d.w. soil (369.5 mg a.s./kg d.w. soil corresponding to 256.8 mg H₃PO₃/kg d.w. soil) EC₅₀ = 360 mg product/kg d.w. soil (289.8 mg a.s./kg d.w. soil corresponding to 201.4 mg H₃PO₃/kg d.w. soil) |
| **Eisenia fetida** | FEA + FLC WG 71.11 (Bayer CropScience) | Sprayed on soil / 10% OM | Chronic | Reproduction | NOEC = 40500 g product/ha (153.7 mg product/kg d.w.soil) |
| **Eisenia fetida** | FEA + FLC WG 71.11 (Bayer CropScience) | Mixed with soil / 10% OM | Chronic | Reproduction | NOEC = 178 mg product/kg d.w. soil EC₉⁰ = 223 mg product/kg d.w. soil EC₅₀ = 133 mg product/kg d.w. soil |
| Test organism    | Test substance                                      | Application method of test a.s./OM | Time scale | End point    | Toxicity                                                                 |
|------------------|-----------------------------------------------------|-----------------------------------|------------|--------------|--------------------------------------------------------------------------|
| *Eisenia fetida* | Phosphonic acid (Iberica Taskforce)                 | Mixed with soil/ 10% OM           | Chronic    | Reproduction | No NOEC nor EC10 can be derived*                                          |
| *Eisenia fetida* | Fosetyl-A180 % WP (Iberica Taskforce)               | Mixed with soil/ 10% OM           | Acute      | Mortality    | LC50 > 1000 mg/kg soil d.w.                                              |
| *Eisenia fetida* | Fosetyl-A180 % WP (Iberica Taskforce)               | Mixed with soil/ 10% OM           | Chronic    | Reproduction | NOEC = 200 mg product/kg d.w. soil (164 mg a.s./kg d.w. soil corresponding to 114 mg H3PO3/kg d.w. soil) |
| *Eisenia andrei* | SIP 40958 (Oxn-SAE)                                 | Mixed with soil/ 10% OM           | Chronic    | Reproduction | NOEC = 40 mg product/kg d.w. soil                                       |
| Other soil macroorganisms |                                                   |                                    |            |              |                                                                           |
| *Folsomia candida* | Phosphonic acid (Bayer CropScience)               | Mixed with soil/ 5% OM           | Chronic    | Mortality, reproduction | NOEC = 1000 mg H3PO3/kg d.w. soil              |
| *Folsomia candida* | Phosphonic acid (Oxn-SAE)                           | Mixed with soil/ 5% OM           | Chronic    | Reproduction | NOEC = 3.15 mg H3PO3/kg d.w. soil**                                      |
| *Folsomia candida* | Fosetyl-A1WG 80 (Bayer CropScience)                 | Mixed with soil/ 5% OM           | Chronic    | Reproduction | NOEC = 562 mg product/kg d.w. soil (452.4 mg a.s./kg d.w. soil) (EC10 = 774 mg product/kg d.w. soil (623.1 mg a.s./kg d.w. soil) EC20 = 1191 mg product/kg d.w. soil (958.8 mg a.s./kg d.w. soil) |
| *Folsomia candida* | FEA + FLC WG 71.11 (Bayer CropScience)              | Mixed with soil/ 5% OM           | Chronic    | Mortality, reproduction | NOEC = 1000 mg product/kg d.w. soil                                      |
| Test organism     | Test substance                          | Application method of test a.s./OM¹  | Time scale | End point                        | Toxicity                        |
|-------------------|-----------------------------------------|--------------------------------------|------------|---------------------------------|---------------------------------|
| Folsomia candida | SIP 40958 (OXN-SAE)                     | Mixed with soil/5% OM                | Chronic    | Mortality, reproduction         | NOEC = 1000 mg product/kg d.w. soil |
| Hypoaspis aculeifer | Phosphonic acid (Bayer CropScience) | Mixed with soil/5% OM                | Chronic    | Mortality, reproduction         | NOEC = 1000 mg H3PO4/kg d.w. soil |
| Hypoaspis aculeifer | Phosphonic acid (OXN-SAE)  | Mixed with soil/5% OM                | Chronic    | Mortality, reproduction         | NOEC = 52.49 mg H3PO4/kg d.w. soil** |
| Hypoaspis aculeifer | Fosetyl-AlWG 80 (Bayer CropScience) | Mixed with soil/5% OM                | Chronic    | Mortality, reproduction         | NOEC = 1000 mg product/kg d.w. soil |
| Hypoaspis aculeifer | FEA + FLC WG 71.11 (Bayer CropScience) | Mixed with soil/5% OM                | Chronic    | Mortality, reproduction         | NOEC = 1000 mg product/kg d.w. soil |
| Hypoaspis aculeifer | SIP 40958 (OXN-SAE)                    | Mixed with soil/5% OM                | Chronic    | Mortality, reproduction         | NOEC = 1000 mg product/kg d.w. soil |

¹To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).  
²Copper included in the composition of the product SIP 40958 would significantly contribute to the toxicity of this compound and the toxicity endpoint from this study is not suitable in the purpose of the renewal process of fosetyl-Al. 
*Statistically significant difference relative to the control in the number of juveniles observed at all concentration tested (lowest concentration tested 693 mg a.s./kg dry weight). 
**Highest tested concentration

Higher tier testing (e.g. modelling or field studies)
A field study (data from Bayer CropScience) is available for earthworms but the results of this study are not considered robust enough to be included in the risk assessment.

| Nitrogen transformation | a.s. (unprotected) | < 25 % effect at day 28 at 26.6 mg a.s./kg d.w. soil (20 kg a.s./ha) |
|-------------------------|--------------------|---------------------------------------------------------------------|
| Nitrogen transformation | Fosetyl-AlWG 80 (Bayer CropScience) | < 25 % effect at day 42 at 1304 mg prod/kg soil (1067 mg a.s./kg soil; 978 kg prod/ha) |
| Nitrogen transformation | FEA + FLC WG 71.11 (Bayer CropScience) | < 25 % effect at day 28 at 40.8 mg prod/kg soil (30.6 kg prod/ha) |
| Nitrogen transformation | Fosetyl-A180% WP (Iberica Taskforce) | < 25 % effect at day 28 at 30.0 mg/kg soil (24.60mg a.s./kg soil) |
| Nitrogen transformation | SIP40958 (OXN-SAE) | < 25 % effect at day 28 at 45 kg prod/ha |
|-------------------------|---------------------|-------------------------------------|
| Nitrogen transformation | Phosphonic acid (unprotected) | < 25 % effect at day 42 at 65.31 mg met./kg d.w.soil |

**Toxicity/exposure ratios for soil organisms**

**Fosetyl-Al WG 80 at 3600 g a.s./ha [3 applications on orchards (Pome fruits)]**

| Test organism          | Test substance | Time scale | Soil PEC<sup>1</sup> | TER | Trigger |
|------------------------|----------------|------------|----------------------|-----|---------|
| **Earthworms**         |                |            |                      |     |         |
| *Eisenia fetida*       | a.s.           | Chronic    | 1.92                 | 132.5 | 5       |
| *Eisenia fetida*       | Phosphonic acid* | Chronic    | 17.81                | 9.93  | 5       |
| **Other soil macroorganisms** |           |            |                      |     |         |
| *Folsomia candida*     | a.s.           | Chronic    | 1.92                 | 235.6 | 5       |
| *Folsomia candida*     | Phosphonic acid | Chronic    | 17.81                | 56.1  | 5       |
| *Hypoaspis aculeifer*  | a.s.           | Chronic    | 1.92                 | 419.3 | 5       |
| *Hypoaspis aculeifer*  | Phosphonic acid | Chronic    | 17.81                | 56.1  | 5       |

<sup>1</sup>The PEC values are the maximum value for the substance and the preparation and the plateau PEC for the metabolite

*The endpoint derived from the study with the formulated product was used in the risk assessment; this is considered acceptable since the parent is rapidly converted into phosphonic acid in soil.

**FEA + FLC WG 71.11 at 3000 g preparation/ha [3 applications on grapes]**

| Test organism          | Test substance | Time scale | Soil PEC<sup>1</sup> | TER | Trigger |
|------------------------|----------------|------------|----------------------|-----|---------|
| **Earthworms**         |                |            |                      |     |         |
| *Eisenia fetida*       | a.s.           | Chronic    | 1.067                | 238.4 | 5       |
| *Eisenia fetida*       | FEA + FLC WG 71.11 | Chronic    | 4.8                  | 27.8  | 5       |
| *Eisenia fetida*       | Phosphonic acid | Chronic    | 9.875                | 17.9  | 5       |
| **Other soil macroorganisms** |           |            |                      |     |         |
| *Folsomia candida*     | a.s.           | Chronic    | 1.067                | 424.0 | 5       |
| *Folsomia candida*     | FEA + FLC WG 71.11 | Chronic    | 4.8                  | 208.3 | 5       |
| *Folsomia candida*     | Phosphonic acid | Chronic    | 9.875                | 101.3 | 5       |
| *Hypoaspis aculeifer*  | FEA + FLC WG 71.11 | Chronic    | 4.8                  | 208.3 | 5       |
| *Hypoaspis aculeifer*  | Phosphonic acid | Chronic    | 9.875                | 101.3 | 5       |

<sup>1</sup>The PEC values are the maximum value for the substance and the preparation and the plateau PEC for the metabolite
### Fosetyl-Al 80% WP at 3600 g a.s./ha [3 applications on citrus]

| Test organism       | Test substance   | Time scale | Soil PEC\(^1\) | TER  | Trigger |
|---------------------|------------------|------------|----------------|------|---------|
| Earthworms          |                  |            |                |      |         |
| *Eisenia fetida*    | a.s.             | Chronic    | 0.96           | 166.7| 5       |
| *Eisenia fetida*    | Phosphonic acid* | Chronic    | 1.881          | 60.7 | 5       |
| Other soil macroorganisms |        |            |                |      |         |
| *Folsomia candida*  | a.s.             | Chronic    | 0.96           | 471.25 | 5       |
| *Folsomia candida*  | Phosphonic acid  | Chronic    | 1.881          | 531.6 | 5       |
| *Hypoaspis aculeifer*| a.s.             | Chronic    | 0.96           | 838.5 | 5       |
| *Hypoaspis aculeifer*| Phosphonic acid  | Chronic    | 1.881          | 531.6 | 5       |

\(^1\)The PEC values are the maximum value for the substance and the plateau PEC for the metabolite.

*In the absence of data the endpoints available for Fosetyl-Al WG80 were used in the risk assessment.

### Fosetyl-Al 80% WP at 2640 g a.s./ha [4 applications on grapes]

| Test organism       | Test substance   | Time scale | Soil PEC\(^1\) | TER  | Trigger |
|---------------------|------------------|------------|----------------|------|---------|
| Earthworms          |                  |            |                |      |         |
| *Eisenia fetida*    | a.s.             | Chronic    | 1.408          | 113.6| 5       |
| *Eisenia fetida*    | Phosphonic acid  | Chronic    | 17.33          | 6.58 | 5       |
| Other soil macroorganisms |         |            |                |      |         |
| *Folsomia candida*  | a.s.             | Chronic    | 1.408          | 321.3| 5       |
| *Folsomia candida*  | Phosphonic acid  | Chronic    | 17.33          | 57.7 | 5       |
| *Hypoaspis aculeifer*| a.s.             | Chronic    | 1.408          | 571.73| 5       |
| *Hypoaspis aculeifer*| Phosphonic acid  | Chronic    | 17.33          | 57.7 | 5       |

\(^1\)The PEC values are the maximum value for the substance and the plateau PEC for the metabolite.

### SIP40958 at 4500 g preparation/ha [4 applications]

| Test organism       | Test substance   | Time scale | Soil PEC\(^1\) | TER  | Trigger |
|---------------------|------------------|------------|----------------|------|---------|
| Earthworms          |                  |            |                |      |         |
| *Eisenia foetida*   | a.s.             | Chronic    | 3.0            | 13.3 | 5       |
| *Eisenia foetida*   | metabolite 1*    | Chronic    | 11.08          | 10.3 | 5       |
| Other soil macroorganisms |         |            |                |      |         |
| *Folsomia candida*  | SIP40958         | Chronic    | 3.0            | 333  | 5       |
| *Folsomia candida*  | Phosphonic acid  | Chronic    | 11.08          | 0.28 | 5       |
| *Hypoaspis aculeifer*| SIP40958         | Chronic    | 3.0            | 333  | 5       |
| *Hypoaspis aculeifer*| Phosphonic acid  | Chronic    | 11.08          | 4.74 | 5       |

\(^1\)The PEC values are the maximum value for the substance and the plateau PEC for the metabolite.
The PEC values are the maximum value for the substance and the plateau PEC for the metabolite.

*lowest available endpoint for phosphonic acid derived from the studies performed with ‘Fosetyl-Al 80% WP’ and ‘Fosetyl WG 80’.

**Effects on terrestrial non target higher plants (Regulation (EU) No 283/2013, Annex Part A, point 8.6 and Regulation (EU) No 284/2013 Annex Part A, point 10.6)**

**Screening data**

Not required for herbicides or plant growth regulators as ER50 tests should be provided.

**Laboratory dose response tests**

| Species |
|---------|
| 6 species for vegetative vigour and seedling emergence |
| 10 species for seedling emergence |

| Test substance | ER50 (g/ha)2 vegetative vigour | ER50 (g/ha)2 emergence | Exposure1 (g/ha)2 | TER | Trigger |
|----------------|-------------------------------|------------------------|-------------------|-----|---------|
| Fosetyl-Al 80% WG 80 | > 80 kg a.s./ha (tomato) | > 7 kg a.s./ha (oilseed rape) | 0.57 | 12.3 | 5 |
| FEA + FLC WG 71.11 | Data gap | > 3.0 kg prod/ha (lettuce) | - | - |
| Fosetyl-Al 80% WP | > 3.6 kg a.s./ha | Data gap | - | - |
| SIP 40958 | > 4.0 kg prod/ha | Data gap | - | - |

**Extended laboratory studies:**

Semi-field and field test:

No data available.

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

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

**Effects on biological methods for sewage treatment (Regulation (EU) No 283/2013, Annex Part A, point 8.8)**

| Test type/organism | end point |
|--------------------|-----------|
| Activated sludge | NOEC = 100 mg a.s./L |

**Monitoring data (Regulation (EU) No 283/2013, Annex Part A, point 8.9 and Regulation (EU) No 284/2013, Annex Part A, point 10.8)**

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

No data available.

Available monitoring data concerning effect of the PPP.

No data available.
Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

Ecotoxicologically relevant compounds

| Compartment   | Fosetyl-Al and phosphonic acid |
|---------------|--------------------------------|
| soil          |                               |
| water         |                               |
| sediment      |                               |
| groundwater   |                               |

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

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

| Substance                          | Fosetyl-Al               |
|------------------------------------|--------------------------|
| Harmonised classification          | Not classified for environment |
| 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: | H412 (based on the NOEC value of 0.213 mg/L for fish for this rapidly degradable substance) |

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

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