Appendix to:
EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance carvone. EFSA Journal 2018;16(7):5390, 26 pp. doi:10.2903/j.efsa.2018.5390
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Appendix A – List of end points for the active substance and the representative formulation

| Active substance (ISO CommonName) | d-carvone (non-ISO) ISO 1750 published name for mixture of d- and l-carvone: carvone. |
|----------------------------------|-----------------------------------------------------------------------------------|
| Function (e.g. fungicide)        | Plant growth regulator                                                            |
| Rapporteur Member State          | The Netherlands                                                                   |
| Co-rapporteur Member State       | Sweden                                                                            |

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

| Chemical name (IUPAC)            | (S)-5-isopropenyl-2-methylcyclohex-2-en-1-one Or (S)-p-mentha-6,8-dien-2-one |
|----------------------------------|-------------------------------------------------------------------------------|
| Chemical name (CA)               | (S)-2-methyl-5-(1-methylene)2-cyclohexene-1-one                               |
| CIPAC No                         | Carvone: 602 d-carvone: not allocated                                          |
| CAS No                           | 2244-16-8 (d-carvone = S-carvone = (+)-carvone)                                |
| EC No (EINECS or ELINCS)         | 218-827-2 (d-carvone = S-carvone = (+)-carvone)                                |
| FAO Specification (including year of publication) | Not allocated |
| Minimum purity of the active substance as manufactured | 923 g/kg d-carvone |
| Identity of relevant impurities (of toxicological, ecotoxicalogical and/or environmental concern) in the active substance as manufactured | None |
| Molecular formula                | C_{10}H_{14}O                                                                |
| Molarmass                        | 150.21 g/mol                                                                   |
Structural formula
Physical and chemical properties (Regulation (EU) No 283/2013, Annex Part A, point 2)

| Property                                                      | Value                                                                 |
|---------------------------------------------------------------|----------------------------------------------------------------------|
| Melting point (state purity)                                  | Freezing point: -43 °C (85% d-carvone, 14% l-carvone, 99% sum of isomers) |
| Boiling point (state purity)                                  | 233 °C (85% d-carvone, 14% l-carvone, 99% sum of isomers)            |
| Temperature of decomposition (state purity)                   | Not relevant                                                         |
| Appearance (state purity)                                     | Colourless to yellow liquid with penetrating odour (85% d-carvone, 14% l-carvone, 99% sum of isomers) |
| Vapour pressure (state temperature, state purity)             | 1.9 Pa at °C (85% d-carvone, 14% l-carvone, 99% sum of isomers)       |
| Henry’s law constant (state temperature)                      | 3.6 - 10.6 Pa m⁻³ mol⁻¹ (20°C)                                       |
| Solubility in water (state temperature, state purity and pH)  | 27 – 79 mg/L at 20°C (pH independent)                                |
| Solubility in organic solvents (state temperature, state purity) |                                                        |
| xylene                                                        | > 250 g/L                                                            |
| heptane                                                       | > 250 g/L                                                            |
| ethyl acetate                                                 | > 250 g/L                                                            |
| methanol                                                      | > 250 g/L                                                            |
| acetone                                                       | > 250 g/L                                                            |
| dichloromethane                                               | > 250 g/L                                                            |
| Surface tension (state concentration and temperature, state purity) | 57.2 mN/m at °C (90% saturated solution) (85% d-carvone, 14% l-carvone, 99% sum of isomers) |
| Partition coefficient (state temperature, pH and purity)      | log \( P_{OW} = 2.4 \) at 20°C (pH independent) (85% d-carvone, 14% l-carvone, 99% sum of isomers) |
| Dissociation constant (state purity)                          | No dissociation within an environmentally relevant pH range          |
| UV/VIS absorption (max.) incl. \( \varepsilon \) (state purity, pH) | The substance absorbs significantly above 290nm.                      |
| Solution                                                      | Max. wavelength / mol. abs. co                                        |
| Neutral                                                      | 236 nm 9.5 x 10³                                                    |
|                                                             | 318 nm 45.3                                                          |
| Acidic                                                       | 236 nm 9.27 x 10³                                                   |
|                                                             | 315 nm 48.6                                                          |
| Alkaline                                                      | 237 nm 9.49 x 10³                                                   |
|                                                             | 308 nm 69.4                                                          |
| Flammability (state purity)                                   | Auto-flammability: 295°C (85% d-carvone, 14% l-carvone, 99% sum of isomers) |
|                                                             | Flash point: 98°C (85% d-carvone, 14% l-carvone, 99% sum of isomers)  |
|                                                             | The substance is not classified with regard to flammability in the sense of Regulation (EC) 1272/2008. |
| Explosive properties (state purity)                           | Not explosive (expert statement)                                    |
| Oxidising properties (state purity)                           | Not oxidising (expert statement)                                     |
Summary of representative uses evaluated, for which all risk assessments needed to be completed (d-carvone) (Regulation (EU) No 284/2013, Annex Part A, points 3, 4)

Carvone was defined as a 100:1 mixture of d-carvone and l-carvone respectively, with a minimum purity of 93%. For the renewal, the substance definition is changed to d-carvone at a minimum purity of 92.3%. l-carvone is now considered an impurity (for details on the substance composition, please refer to volume 4 – confidential information). The redefinition has no significant effect on the properties of the substance. Read-across of existing data is considered acceptable.

According to the new specifications: concentration of the product is 0.923 kg a.s/kg product, at a density of 0.96 kg/L product the concentration of active substance is 0.88608 kg a.s/L product.

| Crop and situation | Member State or Country | Product name | Pests or Group of pest controlled | Formulation | Application | Application rate per treatment | PHI (days) | Remarks: |
|--------------------|-------------------------|--------------|----------------------------------|-------------|-------------|-------------------------------|----------|----------|
| Seed potatoes      | NL, DE                  | Talent       | I Sprout regulation              | AL (any other liquid) | Use internal ventilation; Apply the product with a suitable fogging equipment into the air stream behind the fan during storage season; at start of sprouting (BBCH 01) in November (first day of treatment) followed by daily treatment during storage season; after day 1 [see row 1] at start of sprouting (BBCH 01); Nov-April | 154 (for 22 weeks storage) 182 (for 26 weeks storage) | mL/ton | water L/ha | g as/tonne seed potatoes |
|                    |                         |              |                                  |             |             |                               |          |          |
|                    |                         |              |                                  |             |             |                               |          |          | (a) (b)  |
|                    |                         |              |                                  |             |             |                               |          |          |          |

- Seed potatoes: Treatment during storage before planting in spring; 2000-5000 kg tubers per hectare; Rhythm of rotation: Seed potatoes every 3 years. Application in daily scheme from 25 mL/ton/d (only first day); [row 1] followed by 2.5 decreasing to 0.5 mL/ton/d [row 2] Minimum respectively maximum total seasonal applied dosage during storage period: 227 resp. 264 gram as/tonne seed potatoes. Waiting period between last application and planting: 28 d.

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

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

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

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

e) GCPF Codes - GIFAP Technical Monograph No 2, 1989.

(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.

(j) Growth stage at 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 application possible under practical conditions of use.

(l) PHI - minimum pre-harvest interval.

(m) Remarks may include: Extent of use/economic importance/restrictions.

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**Daily application, first day always start with 25 mL/tonne. Thereafter follow the scheme below for the daily dose. Amount is expressed in mL Talent/day/tonne potatoes for each weeknumber.**

| week number | November | December | January | February | March | April |
|-------------|----------|----------|---------|----------|-------|-------|
| 45          | 46       | 47       | 48      | 49       | 50    | 51    | 52 | 53 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
| Talent/ton  | ---      | ---      | ---     | 2.5      | 2.5    | 2.5   | 2.5 | 2  | 2  | 2  | 2  | 2  | 2   | 2  | 1.5 | 1.5 | 1.5 | 1.5 | 1  | 1  | 1  | 1 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| ml          |         |          |         |          |       |       |     |    |    |    |    |    |     |     |     |     |     |     |    |    |    |    |    |    |    |    |    |    |    |    |
| Talent/ton  | ---      | ---      | ---     | 2.5      | 2.5    | 2.5   | 2.5 | 2  | 2  | 2  | 2  | 2  | 2   | 2  | 1.5 | 1.5 | 1.5 | 1.5 | 1  | 1  | 1  | 1 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| ml          |         |          |         |          |       |       |     |    |    |    |    |    |    |     |     |     |     |     |     |    |    |    |    |    |    |    |    |    |    |    |
## Table

| Talent/ton ml | 2.5 | 2.5 | 2.5 | 2.5 | 2 | 2 | 2 | 2 | 2 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1 | 1 | 1 | 1 | 0.5 | 0.5 | 0.5 | 0.5 |
|---------------|-----|-----|-----|-----|---|---|---|---|---|----|----|----|----|----|----|---|---|---|---|----|----|----|----|
| Talent/ton ml | 2.5 | 2.5 | 2.5 | 2.5 | 2 | 2 | 2 | 2 | 1.5| 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1 | 1 | 1 | 1 | 0.5 | 0.5 | 0.5 | 0.5 |
Further information, Efficacy

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

The representative product has been authorised at Member State level for more than 10 years and has therefore been assessed in line with Uniform Principles.

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

The representative product has been authorised at Member State level for more than 10 years and has therefore been assessed in line with Uniform Principles. No unacceptable side effects are known.

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

The representative product has been authorised at Member State level for more than 10 years and has therefore been assessed in line with Uniform Principles. No unacceptable side effects are known.

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

Activity against target organism

|                  | Not relevant |
|------------------|--------------|
|                  | Not relevant |
Methods of Analysis

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

| Technical a.s. (analytical technique) | GC-FID with internal standard (sum of isomers) |
|--------------------------------------|------------------------------------------------|
|                                      | GC-MS with internal standard (d-carvone)        |
| Impurities in technical a.s. (analytical technique) | GC-MS                                      |
|                                      | Karl-Fischer titration                         |
| Plant protection product (analytical technique) | GC-FID with internal standard (sum of isomers) |
|                                      | GC-MS with internal standard (d-carvone)        |

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

Residue definitions for monitoring purposes

|            |                                                                 |
|------------|------------------------------------------------------------------|
| Food of plant origin | Not required                                                      |
| Food of animal origin | Not required                                                      |
| Soil       | Carvone (sum of isomers)                                         |
| Sediment   | Not required                                                      |
| Water      | Carvone (sum of isomers)                                         |
| Surface    | Carvone (sum of isomers)                                         |
| Drinking/ground | Carvone (sum of isomers)                                        |
| Air        | Carvone (sum of isomers)                                         |
| Body fluids and tissues | Carvone, carvonic acid, dihydrocarvonic acid and utopterpenolone |

Monitoring/Enforcement methods

|            |                                                                 |
|------------|------------------------------------------------------------------|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | Not required                                                      |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Not required                                                      |
| Soil (analytical technique and LOQ) | GC-MS with internal standardisation                |
|                                      | Confirmatory method: 3 mass fragments                  |
|                                      | LOQ 0.05 mg/kg                                           |
| Water (analytical technique and LOQ) | GC-MS with internal standardisation | Confirmatory method: 3 mass fragments | LOQ 0.1 µg/L | Drinking water ILV: available |
| Air (analytical technique and LOQ)   | GC-MS                                               |
|                                      | LOQ 7.5 µg/m³                                        |
| Body fluids and tissues (analytical technique and LOQ) | Data gap                                          |
Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance

| Carvone (d-carvone) |
|---------------------|
| Not established.    |

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]¹:

Peer review proposal² for harmonised classification according to Regulation (EC) No 1272/2008:

| Carvone is not classified regarding chemical or physical hazards. |

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) N° 283/2013, Annex Part A, point 5.1)

|                          |                                                                 |
|--------------------------|------------------------------------------------------------------|
| Rate and extent of oral absorption/systemic bioavailability | 83-90% (Lipinsky rule of five and OECD Toolbox)                   |
| Toxicokinetics           | No data available                                                 |
| Distribution             | No quantitative data available.                                   |
| Potential for bioaccumulation | No quantitative data available.                               |
| Rate and extent of excretion | Rapid elimination mostly via urine, with a half-life of 2.4 hours. |
| Metabolism in animals    | Available data suggest that metabolism of carvone is likely to be different between rats and humans, with carvonic acid, dihydrocarvonic acid and uroterpenolone being the main human metabolites and carveol being the main metabolite in rats. |
| In vitro metabolism      | Human and rat microsomes: results indicate different metabolism by humans and rats. |
| Toxicologically relevant compounds (animals and plants) | None |
| Toxicologically relevant compounds (environment) | None |

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

|                                |                                                                 |
|--------------------------------|------------------------------------------------------------------|
| Rat LD$_{50}$ oral            | >2000 mg/kg bw                                                   |
| Rat LD$_{50}$ dermal          | >4000 mg/kg bw                                                   |
| Rat LC$_{50}$ inhalation      | >5.66 mg/L air/4h (state way, e.g. nose only)                    |
| Skin irritation               | Non-irritant                                                     |
| Eye irritation                | Non-irritant                                                     |
| Skin sensitisation            | Sensitising (Maximisation)                                       |
| Phototoxicity                 | not phototoxic                                                   |

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

|                                |                                                                 |
|--------------------------------|------------------------------------------------------------------|
| Target organ / critical effect  | Rat: decreased body weight gain and food consumption, increased kidney and liver weight, increased partial thromboplastin time (PTT), decreased albumin |
|                                | Mouse: Increased liver weight, decreased thymus weight           |
| Relevant oral NOAEL            | 90-day, rat: 5 mg/kg bw per day                                 |
|                                | 90-day mouse: n.a. (range finding study)                         |
### Relevant dermal NOAEL
No data

### Relevant inhalation NOAEL
No data - not required

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

**In vitro studies**
- Ames study – negative;
- Mammalian cell gene mutation – equivocal;
- Chromosome aberration human lymphocytes – positive without S9 / negative with S9;
- Chromosome aberration CHO cells – equivocal;
- Micronucleus – negative;
- Sister chromatid exchange - positive

**In vivo studies**
- Micronucleus – negative
- UDS – negative
- Comet - negative

Photomutagenicity
- not required

Potential for genotoxicity
- Carvone is unlikely to be genotoxic

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

**Long-term effects (target organ/critical effect)**
- Mouse: histopathological changes in kidney, uterus, lymph node, spleen, nasal cavity, forestomach.

**Relevant long-term NOAEL**
- 18-month, mouse: LOAEL of 375 mg/kg bw per day

**Carcinogenicity (target organ, tumour type)**
- Mouse: no tumours
- Carvone is unlikely to pose a hazard to humans

**Relevant NOAEL for carcinogenicity**
- 18-month, mouse: 375 mg/kg bw per day

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

**Reproduction toxicity**

**Reproduction target / critical effect**
- Parental toxicity: increased liver weight
- Reproductive toxicity: no adverse effect observed in rat 2-generation study
- Offspring’s toxicity: no adverse effects

**Relevant parental NOAEL**
- 30 mg/kg bw per day

**Relevant reproductive NOAEL**
- 30 mg/kg bw per day

**Relevant offspring NOAEL**
- 30 mg/kg bw per day
### Developmental toxicity

**Developmental target / critical effect**
- Rat: Maternal toxicity: no adverse effects.
- Maternal toxicity: no adverse effects.
- Developmental toxicity: no adverse effects.

**Relevant maternal NOAEL**
- Rat: 200 mg/kg bw per day

**Relevant developmental NOAEL**
- Rat: 200 mg/kg bw per day

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

**Acute neurotoxicity**
- Study not required

**Repeated neurotoxicity**
- Study not required

**Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)**

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

**Supplementary studies on the active substance**

**Endocrine disrupting properties**
- No specific studies performed. Based on the data package available, carvone is unlikely to have endocrine mediated activity.

**Studies performed on metabolites or impurities**

- **Dihydrocarvone**:
  - Oral LD50 > 5 g/kg bw
  - Dermal LD50 > 5 g/kg bw
  - S.c. LD50 2900 mg/kg bw
  - Not a skin irritant (rabbit, human) and not a skin sensitiser (human)

- **Dihydrocarveol**:
  - Oral LD50 > 5 g/kg bw
  - Dermal LD50 > 5 g/kg bw
  - Not a skin irritant (human), and not a skin sensitiser (human)

### Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)
- No accidents or health complaints have been reported.
- Medical surveillance data on manufacturing plant personnel or monitoring studies are not available.
### Summary

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

| Parameter | Value (mg/kg bw (per day)) | Study | Uncertainty factor |
|-----------|-----------------------------|-------|-------------------|
| Acceptable Daily Intake (ADI) | 0.6 | Rat and mouse, 90-day, BMDL modelling | 100 |
| Acute Reference Dose (ARfD) | Not required | | |
| Acceptable Operator Exposure Level (AOEL) | 0.6 | rat and mouse, 90-day, BMDL modelling | 100 |
| Acute Acceptable Operator Exposure Level (AAOEL) | Not required | | |

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

| Representative formulation (indicate name, type e.g. EC and concentration of active substance) | Concentrate: 25% | Default value based on the EFSA Guidance on dermal absorption (2012) |

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

| Operators | Use: potatoes, storage treatment application rate 25mL product/tonne potatoes | Exposure estimates (model): % of AOEL |
|-----------|-------------------------------|-------------------------------------|
|           | EFSA AOEM Without PPE: 65     |                                     |
| Workers   | Exposure during inspections or failure solving: | |
|           | Without PPE: 15                |                                     |
|           | Exposure during removal of potatoes before planting: | |
|           | Without PPE: 17                |                                     |
| Bystanders and residents | Bystander: n.a. | |
|           | Resident:                      |                                     |
|           | Child                          | 85                                  |
|           | Adult                          | 18                                  |

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

| Substance | d-Carvone |
|-----------|-----------|
|           | Skin Sens.1 H317 “May cause an allergic skin reaction”. ATP Inserted/Updated: ATP07 |

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3 If available include also reference values for metabolites
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.
Peer review proposal\textsuperscript{5} for harmonised classification according to Regulation (EC) No 1272/2008:

\begin{center}
\begin{tabular}{|c|}
\hline
\textbf{Skin Sens.1 H317} “May cause an allergic skin reaction” \\
\hline
\end{tabular}
\end{center}

\textsuperscript{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) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

| Primary crops (Plant groups covered) | Crop groups | Crop(s) | Application(s) | DAT (days) |
|--------------------------------------|-------------|---------|----------------|------------|
| OECD Guideline 501                    | Fruit crops |         |                |            |
|                                       | Root crops  |         |                |            |
|                                       | Leafy crops |         |                |            |
|                                       | Cereals/grass crops | |             |            |
|                                       | Pulses/Oilseeds | |              |            |
|                                       | Miscellaneous | |                |            |

From the unlabelled studies d-carvone is shown to be the predominant compound of the total residues in treated potatoes and a negligible translocation of the residues from the peel to the pulp is also observed. It can therefore reasonably be assumed that any potential other metabolite will have a similar behaviour.

Radiolabelled metabolism data conducted in accordance with the current recommendations are not required to support the use of d-carvone on seed potatoes.

| Rotational crops (metabolic pattern) | Crop groups | Crop(s) | PBI (days) | Comments |
|--------------------------------------|-------------|---------|------------|----------|
| OECD Guideline 502                    | Root/tuber crops | |          |          |
|                                      | Leafy crops |         |            |          |
|                                      | Cereal (small grain) | |          |          |
|                                      | Other |         |            |          |

Confined rotational crops metabolism studies are not required provided that d-carvone is not persistent in soil (DT₅₀ range: 0.2-5 days).

| Processed commodities (standard hydrolysis study) | Conditions |
|---------------------------------------------------|------------|
|                                                  | 20 min, 90°C, pH 4 |
|                                                  | 60 min, 100°C, pH 5 |
|                                                  | 20 min, 120°C, pH 6 |

Residue pattern in processed commodities similar to residue pattern in raw commodities?

(upto 250 characters)

Not required since residues of d-carvone are expected to be negligible in potatoes grown from the treated seed potatoes.

| Plant residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31 | Plant residue definition for risk assessment (RD-RA) |
|----------------------------------------------------------------------------------------|-----------------------------------------------------|
| Not required                                                                           | Not required                                        |
Conversion factor (monitoring to risk assessment) | Not applicable
---|---

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

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

(Up to 250 characters)

Since residues of d-carvone are expected to be negligible in potatoes grown from the treated seed potatoes, a livestock exposure assessment to d-carvone residues is not triggered.

| Time needed to reach a plateau concentration in milk and eggs (days) | Not applicable |
|---|---|
| Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31 | Not required |
| Animal residue definition for risk assessment (RD-RA) | Not required |
| Conversion factor (monitoring to risk assessment) | Not applicable |
| Metabolism in rat and ruminant similar (Yes/No) (FAO, 2009) | Not applicable |
| Fat soluble residues (Yes/No) | Not applicable |

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

| Confined rotational crop study (Quantitative aspect) OECD Guideline 502 | No studies available, not required |
|---|---|
| Field rotational crop study OECD Guideline 504 | Not required.
### Stability of residues (Regulation (EU) No 283/2013, Annex Part A, point 6.1)

OECD Guideline 506

| Plant products (Category) | Commodity | T (°C) | Stability (Month/Year) |
|---------------------------|-----------|--------|------------------------|
| High water content        | carvone   |        |                        |
| High oil content          |           |        |                        |
| High protein content      |           |        |                        |
| High starch content       |           |        |                        |
| High acid content         |           |        |                        |

(up to 250 characters)

Not required as residue trials compliant with the representative use on seed potatoes are not needed.

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

(up to 250 characters)

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) (c) | STMR (mg/kg) (d) |
|-----------------------|---------------|-----------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|---------------|-----------------|
| Seed potatoes         | I             | Residue trials compliant with the representative use on seed potatoes are not required.         |                                             | -                    | -             | -               |

(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, 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 (HRMo).

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

| Feed commodity | Median dietary burden (mg/kg) | Comment | Maximum dietary burden (mg/kg) | Comment |
|----------------|-------------------------------|---------|-------------------------------|---------|
| Not applicable |                               |         |                               |         |

Since residues of d-carvone are expected to be negligible in potatoes grown from the treated seed potatoes, a livestock exposure assessment to d-carvone residues is not triggered.

Conversion Factors (CF) for monitoring to risk assessment

Not applicable

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) | Conversion Factor (CFP) for RA(b) |
|--------------------------------------------------------|----------------------|------------------------|----------------------------------|
| Not applicable                                         |                      |                        |                                  |

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

Consumer risk assessment (Regulation (EU) No 283/2013, Annex Part A, point 6.9)
Including all uses (representative uses and uses related to an MRL application).

The inclusion of d-carvone in Annex IV to the Regulation (EC) No 396/2005 remains appropriate for the representative use on seed potatoes. The representative use of d-carvone on seed potatoes does not therefore require the setting of a MRL on potatoes and there is no need to perform a consumer dietary risk assessment.

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

| Code(a) | Commodity/Group | MRL/Import tolerance(b) (mg/kg) and Comments |
|---------|-----------------|-----------------------------------------------|
| Plant commodities |
| potato | Not required | Not applicable, since the inclusion of d-carvone in Annex IV to the Regulation (EC) No 396/2005 remains appropriate for the representative use on seed potatoes. |

(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)

| Mineralisation after 100 days | No data were submitted, not required |
|------------------------------|------------------------------------|
| Non-extractable residues after 100 days | No data were submitted, not required |
| Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) | No data were submitted, not required |

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

| Mineralisation after 100 days | No data were submitted, not required |
|------------------------------|------------------------------------|
| Non-extractable residues after 100 days | No data were submitted, not required |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | No data were submitted, not required |

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

| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | No data were submitted, not required |
| Mineralisation at study end | No data were submitted, not required |
| Non-extractable residues at study end | No data were submitted, not required |

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)

| Parent          | Dark aerobic conditions          | Parent          | Dark aerobic conditions          |
|-----------------|---------------------------------|-----------------|---------------------------------|
| Soil type       | pH<sup>a</sup> | t. °C / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) | DT<sub>50</sub> (d) 20 °C pF2/10kPa<sup>b</sup> | St. (χ²) | Method of calculation |
| Loamy sand      | 4.9     | 20 / 44.2     | 5.04 / 16.7        | 5.04         | 8.39   | SFO                  |
| Loam            | 7.4     | 20 / 50.8     | 0.173 / 0.576      | 0.161        | 5.94   | SFO                  |
| Clay            | 7.2     | 20 / 50.4     | 0.453 / 1.51       | 0.254        | 14     | SFO                  |
| Silt loam       | 6.6     | 20 / 51.9     | 1.85 / 6.14        | 1.73         | 12.9   | SFO                  |
Geometric mean (if not pH dependent) | 0.773
---|---
P pH dependence, Yes or No | No

a) Measured in 0.01 mol/L CaCl₂
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

**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)**

No data were submitted.

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

No data were submitted.

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

Soil accumulation and plateau concentration | No data were submitted.

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

No data were submitted.

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

No data were submitted.

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

No data were submitted.

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

No data were submitted. An estimation of the equilibrium sorption constant was made based on the octanol-water partition coefficient using EUSES version 2.1.2 for the chemical class of substances “predominantly hydrophobics”, according to Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC concerning placement of biocides products on the market, Part II, European Commission Joint Research Centre, EUR 20418 EN/2 (2003).

K_{doc} = 111 (mL/g)
1/n = 1 (default value for QSAR estimates)

**Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)**
No data were submitted.

**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 data were submitted. |

**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 | No data were submitted. |

**Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)**

| Lysimeter/field leaching studies | No data were submitted. |
Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)

| pH    | Stability at 50°C |
|-------|-------------------|
| 4     |                   |
| 7     |                   |
| 9     |                   |

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

| Photolytic degradation of active substance and metabolites above 10% | No data were submitted. |
|---------------------------------------------------------------------|-------------------------|
| Quantum yield of direct phototransformation in water at Σ > 290 nm |                         |

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

| Readily biodegradable (yes/no) | No (62 to 68% ThOD in 28 days but failing the 10 d window) |
|--------------------------------|----------------------------------------------------------|

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

No data were submitted. **Data gap.**

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)

No data were submitted. Half-life in water estimated using EUSES version 2.1.2 according to Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC concerning placement of biocides products on the market, Part II, European Commission Joint Research Centre, EUR 20418 EN/2 (2003).

DT₅₀ 26.4 days at 20°C (following the temperature correction procedure of the Guidance for industrial chemicals and biocidal products (equation 25 TGD Part II, (European Commission, 2003)); When the normalisation procedure is based on a Q10 value of 2.58 would result in a DT₅₀ value of 23.4 days at 20°C.)

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 | DT₅₀ of 0.909 hours derived by the Atkinson model (version 1.92). OH (12 h) concentration assumed = 1.5 × 10⁶ OH-radicals/cm³ |
| Volatilisation | Not studied - no data requested |
| Metabolites | Not studied - no data requested |
Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

| Environment          | Residue  |
|----------------------|----------|
| Soil                 | carvone (expressed as sum of isomers) |
| Surface water        | carvone (expressed as sum of isomers) |
| Sediment             | carvone (expressed as sum of isomers) |
| Ground water         | carvone (expressed as sum of isomers) |
| Air                  | carvone (expressed as sum of isomers) |

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

See section 5, Ecotoxicology

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

| Environment          | Data Available |
|----------------------|----------------|
| Soil (indicate location and type of study) | No data available |
| Surface water (indicate location and type of study) | No data available |
| Ground water (indicate location and type of study) | No data available |
| Air (indicate location and type of study) | No data available |

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

| Parameter                      | Value (days) |
|--------------------------------|--------------|
| DT₅₀ (d): 5.04 days at 20 °C |              |
| Kinetics: SFO                 |              |
| Field or Lab: laboratory      |              |

Application data

Exposure through planting of treated seed potatoes (homogeneous distribution):

- Crop: seed potato
- Depth of soil layer: 10cm
- Soil bulk density: 1.5g/cm³
- % plant interception: 0%
- Number of applications: 1
- Interval (d): -
- Application rate(s): 16 g a.s./ha *

* based on a maximum residue of 3.2 mg d-carvone/kg seed potato and a maximum planting density 5000 kg seed potato/ha

* value to be confirmed due to the data gap on comprehensible and complete information on the efficacy trial B176 ((AN-645) by Hartmans (1996)
### PEC<sub>(s)</sub> (mg/kg)

|                | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|----------------|---------------------------|------------------------------------------|----------------------------|--------------------------------------------|
| Initial        | 0.011                     |                                          |                            |                                            |
| Short term     |                           |                                          |                            |                                            |
| 24h            | 0.009                     | 0.010                                    |                            |                                            |
| 2d             | 0.008                     | 0.009                                    |                            |                                            |
| 4d             | 0.006                     | 0.008                                    |                            |                                            |
| Long term      |                           |                                          |                            |                                            |
| 7d             | 0.004                     | 0.007                                    |                            |                                            |
| 28d            | 0.000                     | 0.003                                    |                            |                                            |
| 50d            | 0.000                     | 0.002                                    |                            |                                            |
| 100d           | 0.000                     | 0.001                                    |                            |                                            |
| Plateau concentration | not required          |                                          |                            |                                            |

### Application data

**Exposure through planting of treated seed potatoes (spherical distribution):**

- **Crop:** -
- **Depth of soil layer:** spherical layer of 5 cm around a tuber with a radius of 2.25 cm
- **Soil bulk density:** 1.5 g/cm³
- **% plant interception:** 0%
- **Number of applications:** 1
- **Interval (d):** -
- **Application rate(s):** 16 g a.s./ha *

Based on a maximum residue of 3.2 mg d-carvone/kg seed potato and a maximum planting density 5000 kg seed potato/ha

**This calculation method is included in the draft Guidance document on the authorisation of plant protection products for seed treatment (SANCO/10553/2012 rev. 0, 8 March 2012)**

* value to be confirmed due to the data gap on comprehensible and complete information on the efficacy trial B176 ((AN-645) by Hartmans (1996)

**Initial PEC sphere:** 0.115 mg/kg (not valid for the EU risk assessment)
Application data

| Exposure through volatilisation & deposition from storage: |
|----------------------------------------------------------|
| Crop: -                                                   |
| Depth of soil layer: 5 cm                                 |
| Soil bulk density: 1.5 g/cm³                              |
| % plant interception: 0%                                  |
| Number of applications: 1                                 |
| Interval (d): -                                           |
| Application rate(s): 186 g a.s./ha                        |
| based on FOCUS Air deposition percentage of 0.05% for indoor uses following an initial dose of 22.3 g a.s./ton potatoes in a storage room with an inner width of about 10 m, an inner length of about 15 m and an inner height of 6 m containing 250 ton seeds potatoes: 

\[(22.3 \times 250) / (10 \times 15) \times 0.0005 = 0.0186 \text{ g/m}^2\]

| Initial PECsoil: 0.248 mg/kg                             |
| PECsoil,TWA 21-d: 0.081 mg/kg                            |

PEC ground water (Regulation (EU) No 284/2013, Annex Part A, point 9.2.4.1)

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

For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS_PEARL 4.4.4, FOCUS_PELMO 5.5.3

Crop: potato

Crop uptake factor: 0

Water solubility (mg/L): 27 or 79 at pH 7 and 20°C

Vapour pressure: 1.9 Pa at 20°C

DT₅₀ in soil 0.773 d at 20°C

Kₒc: 111 mL/g (QSAR estimate)

\(1/n=1\) (default for QSAR estimates).

Application rate

Soil exposure from planting treated seed potatoes:

Gross application rate: 16 g/ha.

based on a maximum residue of 3.2 mg d-carvone/kg seed potato and a maximum planting density 5000 kg seed potato/ha

Crop growth stage: sowing of treated seed potatoes

Canopy interception %: -

Application rate net of interception: 16 g/ha.*

No. of applications: 1

Time of application (absolute or relative application dates): at planting according to FOCUS crop calendar

Soil exposure through volatilisation and deposition

Indirect exposure to soil may occur through volatilisation and deposition during venting of potato storage rooms.

Soil deposition of 186 g/ha based on a deposition percentage of 0.05% (FOCUS Air, 2008) for indoor uses.
following an initial dose of 22.3 g a.s./ton potatoes in a storage room with an inner width of about 10 m, an inner length of about 15 m and an inner height of 6 m containing 250 ton seeds potatoes: 

\[(22.3 \times 250)/(10 \times 15)) = 0.0186 \text{ g/m}^2\]

\* value to be confirmed due to the data gap on comprehensible and complete information on the efficacy trial B176 ((AN-645) by Hartmans (1996)

\* Only relevant after implementation of the published EFSA guidance.

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

| Scenario | Parent (µg/L) |
|----------|--------------|
|          | annual application | triennial application |
| Chateaudun | <0.001 | <0.001 |
| Hamburg   | <0.001 | <0.001 |
| Jokioinen | <0.001 | <0.001 |
| Kremsmunster | <0.001 | <0.001 |
| Okehampton | <0.001 | <0.001 |
| Piacenza  | <0.001 | <0.001 |
| Porto     | <0.001 | <0.001 |
| Sevilla   | <0.001 | <0.001 |
| Thiva     | <0.001 | <0.001 |

| Scenario | Parent (µg/L) |
|----------|--------------|
|          | annual application | triennial application |
| Chateaudun | <0.001 | <0.001 |
| Hamburg   | <0.001 | <0.001 |
| Jokioinen | <0.001 | <0.001 |
| Kremsmunster | <0.001 | <0.001 |
| Okehampton | <0.001 | <0.001 |
| Piacenza  | <0.001 | <0.001 |
| Porto     | <0.001 | <0.001 |
| Sevilla   | <0.001 | <0.001 |
| Thiva     | <0.001 | <0.001 |

**Indirect exposure through volatilisation and deposition**

| Scenario | Parent (µg/L) |
|----------|--------------|
|          |              |
| Chateaudun | <0.001 |
| Hamburg   | <0.001 |
| Jokioinen | <0.001 |
| Kremsmunster | <0.001 |
| Okehampton | <0.001 |
| Piacenza  | <0.001 |
| Porto     | <0.001 |
| Sevilla   | <0.001 |
| Thiva     | <0.001 |

| Scenario | Parent (µg/L) |
|----------|--------------|
|          |              |
| Chateaudun | <0.001 |
| Hamburg   | <0.001 |
| Jokioinen | <0.001 |
| Kremsmunster | <0.001 |
| Okehampton | <0.001 |
| Piacenza  | <0.001 |
| Porto     | <0.001 |
| Sevilla   | <0.001 |
| Thiva     | <0.001 |
PEC surface water and PEC sediment (Regulation (EU) No 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

| Parent Parameters used in FOCUSsw step 1 and 2 | Version control no. of FOCUS calculator: 3.2 |
|------------------------------------------------|---------------------------------------------|
| Molecular weight (g/mol): 150.21               | MOC/KOM (mL/g): 111 / 64.4 |
| DT$_{50}$ soil (d): 0.773 d at 20°C          | DT$_{50}$ water/sediment system (d): 26.4 |
| DT$_{50}$ water (d): 26.4                    | DT$_{50}$ sediment (d): 1000               |
| Crop interception (%): -                      |                                             |

| Application rate | Surface water exposure from planting treated seed potatoes: |
|------------------|-------------------------------------------------------------|
| Crop and growth stage: potato BBCH 0 | |
| Number of applications: 1 | |
| Interval (d): - | |
| Application rate(s): 16 g a.s./ha | based on a maximum residue of 3.2 mg d-carvone/kg |
| seed potato and a maximum planting density 5000 kg seed potato/ha | |
| Application window: All possible application periods (Oct-Feb; Mar-May; June-Sept) | |

| Surface water exposure through volatilisation and deposition: |
|---------------------------------------------------------------|
| Indirect exposure to surface water may occur through volatilisation and deposition during venting of potato storage rooms. Surface water deposition of 186 g/ha based on a deposition percentage of 0.05% (FOCUS Air, 2008) for indoor uses following an initial dose of 22.3 g a.s./ton potatoes in a storage room with an inner width of about 10 m, an inner length of about 15 m and an inner height of 6 m containing 250 ton seeds potatoes: $((22.3 \times 250)/(10 \times 15)) \times 0.0005 = 0.0186$ g/m$^2$. |
| This results in an Initial PECsw of 62 $\mu$g/L for a standard water body (100 m long, 1 m wide, 30 cm deep). |
Direct exposure from planting treated seed potatoes

| FOCUS STEP 1 Scenario | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|----------------------|---------------------------|-------------------------|-------------------------|
|                      |                           | Actual (TWA)            | Actual (TWA)            |
| 0 h                  |                           | 4.6458                  | 5.1568                  |
| 24 h                 |                           | 4.5254                  | 5.0232                  |
| 2 d                  |                           | 4.4081                  | 4.893                   |
| 4 d                  |                           | 4.1826                  | 4.6427                  |
| 7 d                  |                           | 3.8658                  | 4.291                   |
| 14 d                 |                           | 3.2168                  | 3.5706                  |
| 21 d                 |                           | 2.6767                  | 2.9711                  |
| 28 d                 |                           | 2.2273                  | 2.4723                  |
| 42 d                 |                           | 1.5422                  | 1.7119                  |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|----------------------|---------------------------|-------------------------|-------------------------|
|                      |                           | Actual (TWA)            | Actual (TWA)            |
| Northern EU (March-May) potatoes | 0 h                  | 0.0257                  | 0.0286                  |
|                      |                           | 0.0251                  | 0.0285                  |
|                      |                           | 0.0245                  | 0.0279                  |
|                      |                           | 0.0234                  | 0.0266                  |
|                      |                           | 0.0218                  | 0.0249                  |
|                      |                           | 0.0186                  | 0.0212                  |
|                      |                           | 0.0158                  | 0.018                   |
|                      |                           | 0.0135                  | 0.0154                  |
|                      |                           | 0.0098                  | 0.0111                  |

| Southern EU (March-May) potatoes | 0 h                  | 0.0515                  | 0.0571                  |
|                                  |                      | 0.0501                  | 0.0571                  |
|                                  |                      | 0.049                   | 0.0558                  |
|                                  |                      | 0.0468                  | 0.0533                  |
|                                  |                      | 0.0437                  | 0.0497                  |
|                                  |                      | 0.0372                  | 0.0424                  |
|                                  |                      | 0.0317                  | 0.0361                  |
|                                  |                      | 0.027                   | 0.0307                  |
|                                  |                      | 0.0196                  | 0.0223                  |

| FOCUS STEP 2 | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|--------------|---------------------------|-------------------------|-------------------------|
### Table 1: Pesticide Residues in Water and Soil

| Scenario | overall maximum | PECSW (µg/L) | PECSED (µg/kg) |
|----------|-----------------|-------------|---------------|
|          | Actual          | TWA         | Actual        | TWA         |
|          | Northern EU (June-Sept) potatoes | 0 h | 0.0257 | 0.0286 | 24 h | 0.0251 | 0.0254 | 0.0285 | 0.0285 |
|          |                 | 2 d | 0.0245 | 0.0251 | 0.0279 | 0.0284 |
|          |                 | 4 d | 0.0234 | 0.0245 | 0.0266 | 0.0278 |
|          |                 | 7 d | 0.0218 | 0.0237 | 0.0249 | 0.0269 |
|          |                 | 14 d | 0.0186 | 0.0219 | 0.0212 | 0.025 |
|          |                 | 21 d | 0.0158 | 0.0204 | 0.018 | 0.0232 |
|          |                 | 28 d | 0.0135 | 0.0189 | 0.0154 | 0.0215 |
|          |                 | 42 d | 0.0098 | 0.0165 | 0.0111 | 0.0187 |
|          | Southern EU (June-Sept) potatoes | 0 h | 0.0386 | 0.0428 | 24 h | 0.0376 | 0.0381 | 0.0428 | 0.0428 |
|          |                 | 2 d | 0.0367 | 0.0376 | 0.0418 | 0.0426 |
|          |                 | 4 d | 0.0351 | 0.0368 | 0.04 | 0.0417 |
|          |                 | 7 d | 0.0328 | 0.0355 | 0.0373 | 0.0404 |
|          |                 | 14 d | 0.0279 | 0.0329 | 0.0318 | 0.0374 |
|          |                 | 21 d | 0.0238 | 0.0305 | 0.0271 | 0.0347 |
|          |                 | 28 d | 0.0202 | 0.0284 | 0.0231 | 0.0323 |
|          |                 | 42 d | 0.0147 | 0.0247 | 0.0167 | 0.0281 |

### Table 2: Pesticide Residues in Water and Soil (FOCUS STEP 2)

| Scenario | Day after overall maximum | PECSW (µg/L) | PECSED (µg/kg) |
|----------|---------------------------|-------------|---------------|
|          | Actual | TWA         | Actual | TWA         |
|          | Northern EU (Oct-Feb) potatoes | 0 h | 0.0643 | 0.0714 | 24 h | 0.0626 | 0.0635 | 0.0713 | 0.0714 |
|          |        | 2 d | 0.0612 | 0.0627 | 0.0697 | 0.0709 |
|          |        | 4 d | 0.0585 | 0.0613 | 0.0666 | 0.0695 |
|          |        | 7 d | 0.0546 | 0.0592 | 0.0622 | 0.0673 |
|          |        | 14 d | 0.0465 | 0.0548 | 0.053 | 0.0624 |
|          |        | 21 d | 0.0396 | 0.0509 | 0.0451 | 0.0579 |
|          |        | 28 d | 0.0337 | 0.0473 | 0.0384 | 0.0538 |
|          |        | 42 d | 0.0245 | 0.0412 | 0.0279 | 0.0468 |
|          | Southern EU (Oct-Feb) potatoes | 0 h | 0.0515 | 0.0571 | 24 h | 0.0501 | 0.0508 | 0.0571 | 0.0571 |
|          |        | 2 d | 0.049 | 0.0502 | 0.0558 | 0.0568 |
|          |        | 4 d | 0.0468 | 0.049 | 0.0533 | 0.0556 |
|          |        | 7 d | 0.0437 | 0.0474 | 0.0497 | 0.0539 |
|          |        | 14 d | 0.0372 | 0.0439 | 0.0424 | 0.0499 |
FOCUS STEP 2
Scenario

| Day after overall maximum | PEC_{sw} (µg/L) | PEC_{sed} (µg/kg) |
|----------------------------|----------------|-----------------|
|                            | Actual | TWA    | Actual | TWA    |
| 21 d                       | 0.0317 | 0.0407 | 0.0361 | 0.0463 |
| 28 d                       | 0.027  | 0.0378 | 0.0307 | 0.0431 |
| 42 d                       | 0.0196 | 0.0329 | 0.0223 | 0.0375 |
Estimation of concentrations from other routes of exposure (Regulation (EU) No 284/2013, Annex Part A, point 9.4)

| Method of calculation | Indirect exposure to soil and surface water may occur through volatilisation and deposition during venting of potato storage rooms. This route of exposure was assessed. |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PEC                   |                                                                                                                                                                                                  |
| Maximum concentration | See summaries of predicted exposure presented above under PEC_{soil}, PEC_{gw} and PEC_{sw} and PEC_{sed}.                                                                                                                                                   |
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              |                      |            |           |                             |
| No study is available for birds.                                  |                      |            |           |                             |
| Mammals            |                      |            |           |                             |
| Rat                | a.s. / preparation¹ | Acute      | LD₅₀      | > 2000 mg a.s./kg bw         |
|                    | a.s. / preparation¹ | Long-term  | NOAEL     | 30 mg a.s./kg bw/d          |

Endocrine disrupting properties (Annex Part A, points 8.1.5)
There is no indication that carvone has potential for endocrine disrupting properties.

Additional higher tier studies (Annex Part A, points 10.1.1.2): Not available

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): Not available

¹ The composition of the preparation TALENT is considered to be comparable to that of the active substance carvone.

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) No 284/2013, Part A, Annex point 10.1)

Treatment of seed potato tubers at 266 g a.s./tonne seed potatoes (maximum total applied dosage resulting from maximum 182 application with 1 day interval at variable dose rates) – exposure via treated potatoes and seedlings and via deposition after ventilation of storage rooms

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|----------------------------|------------|------------------------|-----|---------|
| Tier 1 (Birds) – theoretical exposure via eating potato seedlings | seedling | small omnivorous bird | acute | 1.6 | > 1250 | 10 |
|              | long term                  |            | 1.6                    | 19  |         |
| Screening step (Birds) – exposure via deposition | any | small omnivorous bird | acute | 29.8 | > 67  | 10 |
|              | long term                  |            | 6.45                   | 4.65| 5       |
| Tier 1 (Birds) – exposure via deposition | any | Frugivorous bird | long term | 3.15 | 9.51 | 5 |
| Higher tier (birds): not required | | | | | | |
| Tier 1 (mammals) – exposure via eating treated potato tubers | tuber | Wild boar | acute | 0.544 | 3676 | 10 |
|              | long term                  |            | 0.544                  | 55.14| 5       |
| Tier 1 (mammals) – theoretical exposure via eating potato seedlings | seedling | small omnivorous mammal | acute | 0.384 | > 5208 | 10 |
|              | long term                  |            | 0.384                  | 78  | 5       |
| Screening step/Tier 1 (mammals) – exposure via deposition | any | Small herbivorous mammal | acute | 25.4 | > 79  | 10 |
|              | long term                  |            | 7.13                   | 4.2  | 5       |
| Higher tier (mammals): no quantitative refinements available | | | | | | |
### Growth stage
| Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|------------|------------------------|-----|---------|
| Indicator or focal species | | | |

### Risk from bioaccumulation and food chain behaviour:
not relevant (Log kow≤3)

### Risk from consumption of contaminated water

#### Leaf scenario:
not relevant

#### Puddle scenario, Screening step
Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed

Note: in the risk assessment for birds, the toxicity data for mammals was considered (i.e. these data were extrapolated from mammals to birds)

### 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  | *Brachydanio rerio* | a.s./preparation⁶ | Acute 96 hr (semi-static) | Mortality, LC₅₀ | 56 mg a.s./L (nom) |
| Algae | *Selenastrum capricornutum* | a.s./preparation⁶ | 71 hour (static) | Growth rate: E₅₀, C₅₀ | 34.3 mg a.s./L (nom)² |
| Algae | *Selenastrum capricornutum* | a.s./preparation⁶ | 192 hour (semi-static) | Fronds number, NOEC⁷ | 4.6 mg a.s./L (nom) or (mm) |
| Higher plant | *Lemma minor* | a.s./preparation⁶ | 48 h (static) | Mortality, EC₅₀ | 46 mg a.s./L (nom) |

Further testing on aquatic organisms:
not available

Potential endocrine disrupting properties (Annex Part A, point 8.2.3):
In the section in human toxicology it is concluded by the RMS that carvone is unlikely to have endocrine mediated activity. According to the draft criteria there is no indication that carvone is an endocrine disruptor.

1 (nom) nominal concentration; (mm) mean measured concentration; a.s.: active substance
2 Mean measured based on nominal concentrations at t=0 and extrapolated concentration 69% of nominal at t=71 h (extrapolated from the next higher and lower test concentrations, where measured concentrations were 69% of nominal)
3 After re-evaluation of the study it was concluded that a definitive EC₅₀ cannot be derived, as the EC₅₀ values based on biomass during the period of 0-4 days are expected to be lower than the EC₅₀ values based on frond number during the same period, but these could not be calculated. Therefore, instead of an EC₅₀ value, the NOEC from the study is used in a conservative approach
4 The composition of the preparation TALENT is considered to be comparable to that of the active substance carvone
Bioconcentration in fish (Annex Part A, point 8.2.2.3)

|                     | Active substance | Metabolite1 | Metabolite2 | Metabolite3 |
|---------------------|------------------|-------------|-------------|-------------|
| \( \log P_{\text{OW}} \) | 2.4              |             |             |             |
| Steady-state bioconcentration factor (BCF) (total wet weight/normailised to 5% lipid content) | Not available, not required |
| Uptake/depuration kinetics BCF (total wet weight/normailised to 5% lipid content) |             |             |             |             |
| Annex VI Trigger for the bioconcentration factor |             |             |             |             |
| Clearance time (days) \((CT_{50})\) |             |             |             |             |
| Level and nature of residues (%) in organisms after the 14 day depuration phase |             |             |             |             |

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) No 284/2013, Annex Part A, point 10.2)

Aquatic TERs for active substance carvone – after planting of treated seed potatoes (max 22.3 g a.s./tonne seed potatoes) and after ventilation of storage rooms

| Scenario                      | PEC max (mg L) | fish acute | Aquatic invertebrates | Algae | Higher plant |
|-------------------------------|----------------|------------|-----------------------|-------|--------------|
|                               |                | \( Brachydania rerio \) | \( Daphnia magna \) | \( Selenastrum capricornutum \) | \( Lemna minor \) |
|                               |                | \( \text{LC}_{50} \) | \( \text{EC}_{50} \) | \( E_{10}C_{50} \) | \( E_{50}C_{50} \) | \( \text{NOEC} \) |
| Planting of treated seed potatoes | NE – Oct-Feb (worst case scenario) | 56 mg/L | 46 mg/L | 22.4 mg/L | 34.3 mg/L | 4.6 µg/L |
|                               | 0.000064       | 875000     | 718750                | 350000 | 53937        | 71875 |

Volutilisation and deposition during venting of a store

| Scenario                      | PEC max (mg L) | fish acute | Aquatic invertebrates | Algae | Higher plant |
|-------------------------------|----------------|------------|-----------------------|-------|--------------|
|                               |                | \( Brachydania rerio \) | \( Daphnia magna \) | \( Selenastrum capricornutum \) | \( Lemna minor \) |
|                               |                | \( \text{LC}_{50} \) | \( \text{EC}_{50} \) | \( E_{10}C_{50} \) | \( E_{50}C_{50} \) | \( \text{NOEC} \) |
| Storage season*               | 0.062          | 903        | 742                   | 361   | 553          | 74    |
| Trigger                       | 100            | 100        | 10                    | 10    | 10           | 10    |

* Initial PEC_sw considering an initial dose of 22.3 g a.s./tonne potatoes on the first day of storage; subsequent applications will be lower (from day 2 onwards the daily dose is lowered to 2.23 g carvone/ton potatoes/day, and further lowering in the subsequent periods of 4 weeks)
Effects on bees (Regulation (EU) No 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) No 284/2013 Annex Part A, point 10.3.1)

| Laboratory endpoints: No laboratory data are available |
|--------------------------------------------------------|
| Potential for accumulative toxicity: not determined    |
| Semi-field test (Cage and tunnel test): not available   |
| Field tests: not available                              |
| A public literature study in which carvone was found in propolis indicated natural exposure of bees to carvone. Another study has shown that caraway is a attractive to honey bees. |
| Risk assessment: No quantitative risk assessment was performed. |

Effects on other arthropod species (Regulation (EU) No 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) No 284/2013 Annex Part A, point 10.3.2)

No data available.

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

| Test organism          | Test substance | Application method of test a.s./OM | Time scale | End point                      | Toxicity [mg a.s./kg d.w.soil] |
|------------------------|----------------|------------------------------------|------------|-------------------------------|-------------------------------|
| Earthworms             |                |                                    |            |                               |                               |
| Eisenia fetida         | a.s.           | Mixed / 10%OM                      | Acute (14d) | Mortality, EC50               | 190                           |
| Other soil macroorganisms |              |                                    |            |                               |                               |
| Folsomia candida      | a.s.           | Mixed / 5%OM                       | Chronic (28d) | Mortality, NOEC Reproduction, NOEC | 50                           |
| Hypoaspis aculeifer   | a.s.           | Mixed / 5%OM                       | Chronic (14d) | Mortality, NOEC Reproduction, NOEC | ≥ 200                         |

Higher tier testing (e.g. modelling or field studies): not available

Nitrogen transformation | Talent¹ | Max. 7.44% effect at day 4 at 3.258 mg a.s./kg d.w.soil

¹ Tests were performed with product Talent containing 97% (w/w) carvone, therefore the endpoint in mg product/kg soil dw is considered to be practically equal to mg a.s./kg soil dw (i.e. without correcting for carvone content).

Toxicity/exposure ratios for soil organisms

Planting of treated seed potatoes (max 22.3 g a.s./tonne seed potatoes) and ventilation of storage rooms.
Peer review of the pesticide risk assessment of the active substance carvone

| Test organism                  | Test substance | Time scale | Soil PEC | TER     | Trigger |
|--------------------------------|----------------|------------|----------|---------|---------|
| Earthworms                     |                |            |          |         |         |
| *Eisenia fetida*               | a.s.           | Acute      | 0.011<sup>a</sup> 0.248<sup>b</sup> | 8636 383 | 5       |

Other soil macroorganisms

| Test organism                  | Test substance | Time scale | Soil PEC | TER     | Trigger |
|--------------------------------|----------------|------------|----------|---------|---------|
| *Folsomia candida*             | a.s.           | chronic    | 0.011<sup>a</sup> 0.248<sup>b</sup> | 2273 101 | 5       |
| *Hypoaspis aculeifer*          | a.s.           | chronic    | 0.011<sup>a</sup> 0.248<sup>b</sup> | 18182 806 | 5       |

<sup>a</sup> Planting of treated seed potatoes: homogeneous distribution of a.s.

<sup>b</sup> Volatilisation and deposition after ventilation of storage room

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

Screening toxicity data indicate <50% effects on plants at an exposure rate of ≤ 16.4 g a.s./ha.

Laboratory dose response tests

| Species                  | Test substance | ER<sub>50</sub> (g/ha)<sup>2</sup> vegetative vigour | ER<sub>50</sub> (g/ha)<sup>2</sup> emergence | Exposure<sup>1</sup> (g/ha)<sup>2</sup> | TER     | Trigger |
|--------------------------|----------------|-----------------------------------------------------|--------------------------------------------|----------------------------------|---------|---------|
| Not available            |                |                                                     |                                            |                                  |         |         |

Extended laboratory studies: Not available

Semi-field and field test: Not 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 | Not available |
|--------------------|-----------|------------------|---------------|

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.: Not available |
|-----------------------------------------------------------------------------|
| Available monitoring data concerning effect of the PPP: Not available |

Definition of the residue for monitoring (Regulation (EU) No 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds<sup>1</sup>

| Compartments | Carvone |
|--------------|---------|
| soil         | carvone |
| water        | carvone |
| sediment     | carvone |
| groundwater  | carvone |

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

| Substance       | Classification                                                                 |
|-----------------|-------------------------------------------------------------------------------|
| Carvone (d-carvone) | None                                                                          |

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

In lack of sufficient data, no proposal for classification was proposed.

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

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