Appendix to:

EFSA (European Food Safety Authority), 2023. Conclusion on the peer review of the pesticide risk assessment of the active substance (3E)-dec-3-en-2-one. EFSA Journal 2023;21(1):7765, 27 pp. doi:10.2903/j.efsa.2023.7765

Appendix B - 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)

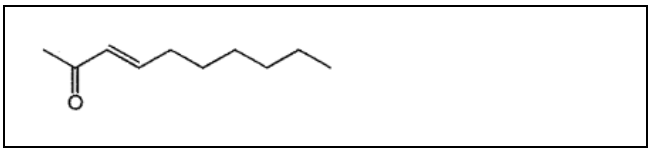
Active substance (ISO Common Name)	(3*E*)-dec-3-en-2-one (no ISO common name)
Function (*e.g.* fungicide)	Potato sprouting inhibitor

Rapporteur Member State	The Netherlands (NL)
Co-rapporteur Member State	Not applicable

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

Chemical name (IUPAC)	(3*E*)-dec-3-en-2-one
Chemical name (CA)	3-decen-2-one
CIPAC No	Not available
CAS No	18402-84-1
EC No (EINECS or ELINCS)	701-234-2
FAO Specification (including year of publication)	No FAO specification
Minimum purity of the active substance as manufactured	980 g/kg
Location of the (proposed) reference specification (for significant impurities)	DAR Volume 4 (04/2022); page 33
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula	$C_{10}H_{18}O$
Molar mass	154.2 g/mol

Structural formula



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

Melting point (state purity)	-40°C (98.6 % w/w)
Boiling point (state purity)	224°C (99.1 % w/w)
Temperature of decomposition (state purity)	No decomposition (up to 400°C) (98.6 % w/w)
Appearance (state purity)	Clear, pale straw coloured, liquid (98.6 % w/w)
Vapour pressure (state temperature, state purity)	430 Pa at 25°C (98.6 % w/w)
Henry's law constant (state temperature)	473.8 Pa m^3 mol^{-1} (25°C)
Solubility in water (state temperature, state purity and pH)	0.14 g/L at 24°C (pH 7) (99.1% w/w)
Solubility in organic solvents (state temperature, state purity)	n-Heptane > 250 g/L (25°C) (98.6 % w/w) p-Xylene > 250 g/L (25°C) (98.6 % w/w) 1,2-Dichloroethane > 250 g/L (25 °C) (98.6 % w/w) Methanol > 250 g/L (25°C) (98.6 % w/w) Acetone > 250 g/L (25°C) (98.6 % w/w) Ethyl Acetate > 250 g/L (25°C) (98.6 % w/w)
Surface tension (state concentration and temperature, state purity)	Neat active ingredient (98.6 % w/w) At 20°C: 29.4 mN/m At 40°C: 27.2 mN/m In saturated water solution At 20°C: 42.2 mN/m At 40°C: 44.1 mN/m
Partition coefficient (state temperature, pH and purity)	Log Pow = 3.45 ± 0.02 at 24°C (98.1 % w/w) pH 4: Log Pow = 3.45 at 22°C (98.6 % w/w) pH 7: Log Pow = 3.47 at 22°C (98.6 % w/w) pH 9: Log Pow = 3.43 at 22°C (98.6 % w/w)
Dissociation constant (state purity)	No dissociation constant between pH 4-10
UV/VIS absorption (max.) incl. ε (state purity, pH)	ε = 4237 L mol^{-1} cm^{-1} at 198 nm in a neutral solution of methanol and water. ε = 14153 L mol^{-1} cm^{-1} at 224 nm in neutral solution of methanol and water. Decomposes under acidic and alkaline conditions (in methanol) at λ > 290 nm: ε < 10 L mol^{-1} cm^{-1}
Flammability (state purity)	Flashpoint = 99°C (98.6 % w/w) Auto-flammability = 275°C (98.6 % w/w)
Explosive properties (state purity)	Not explosive (statement)
Oxidising properties (state purity)	Not oxidising (statement)

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

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	g a.s./ton min-max (l)		
Potatoes (SOLTU) (ware and starch)	AT, BE, CZ, DE, ES, FR, IE, IT, LU, NL, PL, PT, UK	**SmartBlock®**	*I*	growth regulator effect: sprout control	*HN*	**980 g/kg**	Hot fogging tuber treatment	During storage. BBCH 01-03. Jan-Dec	Max. 4	min. 4 weeks	N.A.	N.A	112 g a.s./ton potatoes Total per season: max: 448 g a.s./ton	14*	- Apply when the tubers have broken dormancy and show initial signs of sprouting - Re-apply as required. * Minimum interval between last application and unloading.

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

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (*name of active substance or the respective variant*)
Regulation (EC) N° 1107/2009 Article 8.1(g))

Not relevant

Further information, Efficacy

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

	The claimed use is supported. The proposed dose rate is realistic.

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

	The claimed use is supported. No unacceptable adverse effects are expected at the proposed rate.

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

	The claimed use is supported, no unacceptable unintended side effects are expected at the proposed dose rate.

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

Activity against target organism	No relevant metabolites

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)	Quantification GC-FID, confirmation GC-MS
Impurities in technical a.s. (analytical technique)	Quantification GC-FID, confirmation GC-MS
Plant protection product (analytical technique)	Identical to technical a.s.

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		(3*E*)-3-decen-2-one
Food of animal origin		Residue definition could not be concluded due to data gap (see section 3).
Soil		Not required (No definition proposed).
Sediment		Not applicable
Water	surface	Not required (No definition proposed).
	drinking/ground	Not required (No definition proposed).
Air		Not required (No definition proposed).
Body fluids and tissues		Not required (No definition proposed).

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Primary method + ILV: (3*E*)-dec-3-en-2-one-with GC-MS/MS (SIM-mode, confirmation methods provided), LOQ 0.01 mg/kg in potato (peel and pulp, high water matrix). Data gaps: 1. Validated analytical method(s) for monitoring residues of (3*E*)-dec-3-en-2-one in dry, high acid and high oil content commodities. 2. Data to address the extraction efficiency of the procedure used in the monitoring method for high water content commodities.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No method provided. Pending on the final residue definition for monitoring in food of animal origin, analytical methods might be required.
Soil (analytical technique and LOQ)	Method: (3*E*)-dec-3-en-2-one monitored with GC-MS/MS (two mass transitions), LOQ 0.01 mg/kg.

Water (analytical technique and LOQ)	Drinking water/Groundwater: Primary method + ILV: (3*E*)-dec-3-en-2-one monitored with GC-MS (SIM-mode, confirmation method provided), LOQ 0.1 µg/L. Surface water: Primary method + ILV: (3*E*)-dec-3-en-2-one monitored with GC-MS (SIM-mode, confirmation method provided), LOQ 0.1 µg/L.
Air (analytical technique and LOQ)	Method: (3*E*)-dec-3-en-2-one monitored with GC-MS (SIM-mode, confirmation transition provided), LOQ 0.1 mg/m^3.
Body fluids and tissues (analytical technique and LOQ)	Method: (3*E*)-dec-3-en-2-one monitored with GC-MS/MS (two mass transitions), LOQ 0.01 mg/L (fluids) or 0.01 mg/kg (tissues).

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

Substance	(3*E*)-dec-3-en-2-one
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][1]:	No current harmonised classification. RAC Opinion (2022): Asp. Tox. 1; H304
According to the peer review, criteria for harmonised classification according to Regulation (EC) No 1272/2008 may be met for:	See box above.

[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.

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	The systemic bioavailability (calculated based on AUC_t) of total [^{14}C], following single high dose oral administration, was approximately 91%.
Toxicokinetics	Oral administration (1000 mg/kg bw) C_{max} (ng/mL) = 0.920 T_{max} (h) = 4 Plasma $T_{1/2}$ (h) = 7.97 Intravenous administration (1 mg/kg bw) C_{max} (ng/mL) = 0.312 T_{max} (h) = 0.083 Plasma $T_{1/2}$ (h) = 0.0631
Distribution	Expected to be widely distributed
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	Expected to be mainly excreted via urine
Metabolism in animals	The likely metabolic pathways are via reduction of the carbon-carbon double bond and/or the carbonyl moiety, followed by conjugation with glucuronide and excretion via urine. Conjugation with glutathione and subsequent metabolism via the mercapturic acid pathway is also possible. All three of these pathways result in a loss of the α,β-unsaturated moiety. Ω-Oxidation at C_{10} is also a potential pathway
In vitro metabolism	No data. Not required.
Toxicologically relevant compounds (animals and plants)	(3*E*)-dec-3-en-2-one
Toxicologically relevant compounds (environment)	(3*E*)-dec-3-en-2-one

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

Rat LD_{50} oral	>5000 mg/kg bw	
Rat LD_{50} dermal	>5000 mg/kg bw	
Rat LC_{50} inhalation	0.52-2.04 mg/L (>1 mg/L)	Acute Tox 4
Skin irritation	Irritant	Skin Irritant 2
Eye irritation	Non-irritant	

Skin sensitisation	Sensitising (Buehler)	Skin Sens 1[2]
Phototoxicity	Not required.	

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

Target organ / critical effect	Lungs: macroscopic findings (i.e. incomplete deflation, abnormal colouration, firm, enlarged tracheobronchial and mediastinal lymph nodes), increase relative and absolute weight at 531 µg/L; Body weight change (reduced), food consumption (reduced) and microscopic findings (increased incidence and severity) at 278 µg/L	
Relevant oral NOAEL	No data – not required	
Relevant dermal NOAEL	No data – not required	
Relevant inhalation NOAEL	139 µg/L, corresponding to 27 mg/kg bw per day	

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

In vitro studies	Negative in Ames test Positive in gene mutation assay *in vitro* with mammalian cells (without metabolic activation)	
In vivo studies	Negative in micronucleus test *in vivo* (with proof of bone marrow exposure) Negative in UDS assay in liver *in vivo* Negative in Comet assay in liver and duodenum *in vivo*	
Photomutagenicity	Not required	
Potential for genotoxicity	(*E*)-3-decen-2-one 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)	No data – not required	
Relevant long-term NOAEL	No data – not required	
Carcinogenicity (target organ, tumour type)	No data – not required	
Relevant NOAEL for carcinogenicity	No data – not required	

[2] Skin sensitisation classification has been proposed in the DAR but it was eventually not confirmed by RAC Opinion (2022) (See also section Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

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

Reproduction toxicity

Reproduction target / critical effect	No data – not required	
Relevant parental NOAEL	No data – not required	
Relevant reproductive NOAEL	No data – not required	
Relevant offspring NOAEL	No data – not required	

Developmental toxicity

Developmental target / critical effect	Rat: Maternal: Reduced body weight gain Developmental toxicity: no effect	
Relevant maternal NOAEL	Rat: 300 mg/kg bw per day	
Relevant developmental NOAEL	Rat: 1000 mg/kg bw per day (highest dose tested)	

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

Acute neurotoxicity	No data - not required	
Repeated neurotoxicity	No data - not required	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	No data - not required	

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

Supplementary studies on the active substance	None.
Endocrine disrupting properties	ED assessment can be waived; ED criteria are not met. In view of the intrinsic properties of the active substance, the assessment does not appear scientifically necessary. (3*E*)-dec-3-en-2-one does not to meet the criteria for endocrine disruption for humans according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

Studies performed on metabolites or impurities	**2-decanol**: Based on read-across to 1-decanol, 2-decanol is expected to be of similar low oral toxicity as the parent. Reference values of the parent can be used. **2-decanone**: LD_{50} = 7937 mg/kg bw in mice, 7940 mg/kg bw in rat Based on read-across to methyl nonyl ketone and other aliphatic ketone compounds, 2-decanone is expected to be of similar low oral toxicity as the parent. Reference values of the parent can be used. **3-decen-2-ol** (free and conjugated): data gap for genotoxicity potential and general toxicity.

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

No adverse reactions reported during medical surveillance of manufacturing plant personnel.

Summary[3] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	0.5	rat, developmental	600*
Acute Reference Dose (ARfD)	-	Not required	-
Acceptable Operator Exposure Level (AOEL)	0.27	5-day inhalation study	100
Acceptable Operator Exposure Level (AOEC)	1.39 mg/m^3	5-day inhalation study	100
Acute Acceptable Operator Exposure Level (AAOEL)	0.27	5-day inhalation study	100
Acute Acceptable Operator Exposure Level (AAOEC)	1.39 mg/m^3	5-day inhalation study	100

*UF of 600 to account for subacute to chronic exposure extrapolation.

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 % (no study, default value) Spray dilution: Not applicable

[3] If available include also reference values for metabolites

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

Operators	Use: hot fogging concentrate (HN) an application rate of 112 grams a.s./tonne (treating a large warehouse containing 2000 tonnes of potatoes) Exposure estimates: (RISKOFDERM, 95th centile): %AAOEL Hand exposure without PPE: 72 Inhalation exposure: no data, use of RPE (RISKOFDERM, 75th centile): %AOEL Hand exposure without PPE: 14 Inhalation exposure: no data, use of RPE
Workers	Crop inspection (24 hours ventilation prior to entry): Exposure estimates: (field study) % of AOEL Without PPE 127 With PPE (gloves) 95.5 With PPE (gloves) + RPE 12.7 Removal of potatoes (mechanical activity, re-entry interval 14 days, 24 hours ventilation prior to entry, work duration of 2 hours): Exposure estimates: (field study) % of AOEL Without RPE 98.8 With RPE 9.9
Bystanders and residents	Exposure estimates based on air monitoring study (maximum values in % of AOEL):

Distance from storage facility	Adult	Child
10 m	52	249
50-80 m	1.5	7.2
100 m	2.8	13.4

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

Substance:	(3*E*)-dec-3-en-2-one
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][4] :	No current harmonised classification RAC Opinion (2022): Skin Irrit. 2: H315 Causes skin irritation Acute Tox. 4: H332 Harmful if inhaled

[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.

According to the peer review, criteria for harmonised classification according to Regulation (EC) No 1272/2008 may be met for:	See box above

Residues in or on treated products food and feed

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

Primary crops (Plant groups covered)
OECD Guideline 501

Crop groups	Crop(s)	Application(s)	DAT (days)
Fruit crops			
Root crops	Potato	1x 135.0 mg/kg potatoes (post-harvest, fogging)	1, 7, 14, 28
Leafy crops			
Cereals/grass crops			
Pulses/Oilseeds			
Miscellaneous			

No standard metabolism study with root crops or any other crop group has been submitted. In one scientific publication it has been shown that the metabolites 2-decanone and 2-decanol were detected after treatment with (3*E*)-dec-3-en-2-one. However, non-volatile compounds were not investigated, and no information is presented whether possible other metabolites have been found. In addition, a mass-balance study has been conducted. The reliability of this study can be questioned, since only 12% of applied radioactivity could be recovered. It was found that extensive metabolism occurred leading to the formation of CO_2. Besides (3*E*)-dec-3-en-2-one, 2-decanone and 2-decanol, other residues were present in potato peel in larger quantities, which could be of relevance. In conclusion, it is still unknown whether other relevant metabolites constitute the terminal and major residues after treatment with (3*E*)-dec-3-en-2-one. Therefore, a data requirement is set for further investigation of metabolites.

After the peer review, the applicant submitted a metabolism study with potatoes, treated post-harvest with radiolabelled (3*E*)-dec-3-en-2-one. This new metabolism study, although not fully guideline-compliant, provides further evidence on the nature of the residues after (3*E*)-dec-3-en-2-one application (i.e., (3*E*)-dec-3-en-2-one, 2-decanone, and 2-decanol, including conjugates). A **data gap** is set for the applicant to undertake all the analytical attempts to characterise and identify the unknown radioactive residues in potato rinse, peel and pulp in order to comply with the current data requirements.

Rotational crops (metabolic pattern)
OECD Guideline 502

Crop groups	Crop(s)	PBI (days)	Comments
Root/tuber crops			
Leafy crops			
Cereal (small grain)			
Other			

Rotational crop and primary crop metabolism similar?

Rotational crop studies are not required, since it concerns a post-harvest treatment.

Processed commodities (standard hydrolysis study)
OECD Guideline 507

Conditions	(3*E*)-dec-3-en-2-one	Uncharacterized peak	
20 min, 90°C, pH 4	99.9%	-	
60 min, 100°C, pH 5	94.5%	1.6%	
20 min, 120°C, pH 6	93.9%	4.1%	

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

Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	(3*E*)-dec-3-en-2-one
Plant residue definition for risk assessment (RD-RA)	Sum of (3*E*)-dec-3-en-2-one, 2-decanone and 2-decanol (free and conjugated) and 3-decen-2-ol (free and conjugated), expressed as (3*E*)-dec-3-en-2-one. Provisional (data gap for toxicological properties of 3-decen-2-ol (free and conjugated)). The proposed residue definitions are considered provisional and restricted to root crops following treatment in storage.
Conversion factor (monitoring to risk assessment)	Not possible to derive

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

OECD Guideline 503 and **SANCO/11187/2013 rev. 3** (fish)	**Animal**	**Dose** (mg/kg bw/d)	**Duration** (days)	**N rate/comment**
Animals covered	Laying hen			
	Goat/Cow			
	Pig			
	Fish	mg/kg DM		
	Data gap for metabolism data in animals and nature and magnitude of residues in fish have been identified			

Time needed to reach a plateau concentration in milk and eggs (days)	No studies submitted.
Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Pending data gap for metabolism data.
Animal residue definition for risk assessment (RD-RA)	Pending data gap for metabolism data.
Conversion factor (monitoring to risk assessment)	Pending data gap for metabolism data.
Metabolism in rat and ruminant similar (Yes/No)	Not applicable
Fat soluble residues (Yes/No) **(FAO, 2009)**	(3*E*)-dec-3-en-2-one: fat soluble 2-decanol and 2-decanone: fat soluble

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

Confined rotational crop study (Quantitative aspect) **OECD Guideline 502**	Rotational crop studies are not required, since it concerns a post-harvest treatment.
Field rotational crop study **OECD Guideline 504**	Rotational crop studies are not required, since it concerns a post-harvest treatment.

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

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

No storage stability data submitted. in the available trials, extra care was taken to avoid any loss of residue during sampling and transport. In addition, duplicate analyses of raw tuber tissue collected in the third supervised residue trial, frozen 1 day after treatment and then stored frozen at -80°C for 11 days and 32 days showed reasonable recoveries for all 3 analytes ((3*E*)-dec-3-en-2-one, 2-decanone and 2-decanol).

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

No studies submitted.

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

Crop	**Region/ Indoor** (a)	**Residue levels** (mg/kg) **observed in the supervised residue trials relevant to the supported GAPs** (b)	**Recommendations/comments** (OECD calculations)	**MRL** proposals (mg/kg)	**HR** (mg/kg) (c)	**STMR** (mg/kg) (d)
Representative uses						
Potatoes	Indoor	(3*E*)-dec-3-en-2-one: 0.067; 0.216; 1.5; 2.4; 3.3 mg/kg 2-decanone: 0.099; 0.259; 1.2; 1.7; 2.7 mg/kg 2-decanol: 1.4; 2.784; 2.3; 3.3; 4.9 mg/kg	According to the residue definition for risk assessment 'sum of (3E)-dec-3-en-2-one, 2-decanone and 2-decanol, expressed as (3*E*)-dec-3-en-2-one': 1.53; 3.18; 4.9; 8.2; 9.8 mg/kg. During the expert meeting (Pesticide Peer Review TC76 (04 – 05 May 2022)), a data gap was set for a complete dataset of eight GAP-compliant residue trials analysing for all the compounds in compliance with the residue definitions for monitoring and risk assessment once the residue definition for risk assessment is finalised and considering specifically the precautionary measures to avoid volatilization and storage stability issues.	Not required	9.8	4.9

(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 **Mo**nitoring and **R**isk **A**ssessment.
(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
(d): **STMR:** Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets ($STMR_{Mo}$).

Inputs for animal burden calculations according to the residue definition 'sum of (3*E*)-dec-3-en-2-one, 2-decanone and 2-decanol, expressed as (3*E*)-dec-3-en-2-one'

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Representative uses				
Potato culls	4.9	STMR	9.8	HR
Potato, process waste	98	STMR*20 (=default PF)	n.a.	
Potato, dried pulp	186	STMR*38 (=default PF)	n.a.	
Input is based on provisionally acceptable residue data but should be revised according to the agreed RDs for potatoes, the submission of the requested residue trials and the toxicity of the metabolite 3-decen-2-ol (free and conjugated) once these data are available (data gap).				

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4) according to the residue definition 'sum of (3*E*)-dec-3-en-2-one, 2-decanone and 2-decanol, expressed as (3*E*)-dec-3-en-2-one ' OECD Guideline 505 and OECD Guidance, series on pesticides No 73

MRL calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Highest expected intake (mg/kg bw/d)	Beef cattle	8.193	Ram/Ewe	11.379	Breeding	4.335	Broiler	3.333	Carp	0.165
	Dairy cattle	9.988	Lamb	7.358	Finishing	2.005	Layer	2.507	Trout	0
(mg/kg DM for fish)							Turkey	0.700	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	Yes		Yes		Yes		Yes		Yes	
Feeding study submitted	Not required		Not required		Not required		Not required		Not required	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals
Muscle										
Fat										
Meat[(b)]										
Liver										
Kidney										
Milk[(a)]										
Eggs										
Method of calculation[(c)]										

[(a)]: Estimated HR calculated at 1N level (**estimated mean level for milk**).
[(b)]: HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry
[(c)]: The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

STMR calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	8.0164	Ram/Ewe	11.1339	Breeding	4.052	Broiler	3.160	Carp	
	Dairy cattle	9.7058	Lamb	7.1499	Finishing	1.637	Layer	2.339	Trout	0
							Turkey	0.350		
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N
Muscle										
Fat										
Meat[(a)]										
Liver										
Kidney										
Milk										
Eggs										
Method of calculation[(c)]										

[(a)]: STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry
[(b)]: When the mean level is set at the LOQ, the STMR is set at the LOQ.
[(c)]: The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by interpolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

Conversion Factors (CF) for monitoring to risk assessment

Animal products
Not relevant

Plant products
Not relevant

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3) OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

No sufficient processing studies to proposed reliable processing factors (data gap)

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies[a]	Processing Factor (PF)		Conversion Factor (CF_P) for RA[b]
		Individual values	Median PF	
Representative uses (row to be deleted if not relevant)				
Potato, baking	1	0.45 ((3*E*)-dec-3-en-2-one) 0.81 (2-decanone) 0.34 (2-decanol)		
Potato, steaming	1	0.22 ((3*E*)-dec-3-en-2-one) 0.83 (2-decanone) 0.38 (2-decanol)		

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

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)
Including all uses (representative uses and uses related to an MRL application).

Provisional consumer risk assessment is presented. However, consumers risk assessment is considered as not finalised pending the data gaps identified during the peer review.

ADI	1 mg/kg bw per day (sum of (3*E*)-dec-3-en-2-one, 2-decanone and 2-decanol, expressed as (3*E*)-dec-3-en-2-one)		
TMDI according to EFSA PRIMo 3.1	Highest TMDI:	5 % ADI	(PT general)
NTMDI, according to (to be specified)	Highest NTMDI:	XX % ADI	(MS, diet)
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI:	XX % ADI	(MS, diet)
NEDI (% ADI), according to (to be specified)	Highest NEDI:	XX % ADI	(MS, diet)
Factors included in the calculations	Provisional STMR for potatoes		
ARfD	Not applicable		
IESTI (% ARfD), according to EFSA PRIMo 3.1	Not required		
NESTI (% ARfD), according to (to be specified)	Highest NESTI:	XX % ARfD	(commodity)
Factors included in IESTI and NESTI			

Additional contribution to the consumer intakes through drinking water resulting from groundwater metabolite(s) expected to be present above 0.75 µg/L

Not applicable

Metabolite(s)	
ADI (mg/kg bw per day)	
Intake of groundwater metabolites (% ADI)	Adult (60 kg bw, 2 L): XX % ADI
WHO Guideline (WHO, 2009)	Child (10 kg bw, 1 L): XX % ADI
	Infant (5 kg bw, 0.75 L): XX % ADI

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

Code[(a)]	Commodity/Group	MRL/Import tolerance[(b)] (mg/kg) and Comments	
Plant commodities			
Representative uses (row to be deleted if not relevant)			
	Potatoes	Pending data gaps identified	The criteria for inclusion into Annex IV of Reg. (EC) 396/2005 are not met

(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	*Not reported, not deemed necessary*
Non-extractable residues after 100 days	*Not reported, not deemed necessary*
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	*No range and maximum reported, not deemed necessary*

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

Mineralisation after 100 days	*Not reported, not deemed necessary*
Non-extractable residues after 100 days	*Not reported, not deemed necessary*
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	*Not reported, not deemed necessary*

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)	*Not reported, not deemed necessary, given the proposed use pattern*
Mineralisation at study end	*Not reported, not deemed necessary, given the proposed use pattern*
Non-extractable residues at study end	*Not reported, not deemed necessary, given the proposed use pattern*

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						
Soil type	*X*[5]	pH[a)]	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
n.a.				90	42.2		TGD – Part II, 2003 [a)]

-							
-							
-							
Geometric mean (if not pH dependent)					42.2		
pH dependence, *No*							

[a)] This value is determined based on the ready biodegradability test results and substance properties and Table 8 in the Technical Guidance Document on Risk Assessment – Part II (EU, 2003)

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)

Not applicable/relevant

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)

Not applicable/relevant

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

Not applicable/relevant

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	Not reported. Not needed.

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)

Not applicable/relevant

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)

Not applicable/relevant

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

Not applicable/relevant

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)

Parent							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
n.a. (QSAR – Episuite MCI method						165.2	1
n.a. (QSAR – Episuite Kow method)						1069	
n.a. (QSAR- USES (based on logKow)						785	
Geometric mean (if not pH dependent)*						*	
Arithmetic mean (if not pH dependent)							
pH dependence, *No*							

* For modelling most conservative value of range is used.

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)

Not applicable/relevant

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)

Not applicable/relevant

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)

Not applicable/relevant

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)

Not applicable/relevant

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

Hydrolytic degradation of the active substance and metabolites > 10 %	(3*E*)-dec-3-en-2-one will be stable to hydrolysis at 20°C and pH 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 %	(3*E*)-dec-3-en-2-one does not show any appreciable absorption above 270 nm and photodegradation will therefore not constitute a significant route of degradation/dissipation in the aquatic environment
Quantum yield of direct phototransformation in water at > 290 nm	-

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

Readily biodegradable (yes/no)	Yes, failing the 10 days 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)

Not applicable/relevant

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Parent	Distribution (*e.g. max in water x after n d. Max. sed x % after n d*)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
n.a.	50			50		50		50		TGD – Part II, 2003 [a)]
Geometric mean at 20°C						23.4				

[a)] This value is determined based on the ready biodegradability test results and substance properties and Table 8 in the Technical Guidance Document on Risk Assessment – Part II (EU, 2003)

Mineralisation and non extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
None					

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_{50} of 2 hours derived by the Atkinson model (version *US EPA AOP v.1.92*). OH (*12*) concentration assumed = *1.5 x 10 E6 radicals cm-3*
Volatilisation	from plant surfaces (BBA guideline): *not measured*
	from soil surfaces (BBA guideline): *not measured*
Metabolites	2-decanol, 2-decanone

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: (3*E*)-dec-3-en-2-one Surface water: (3*E*)-dec-3-en-2-one Sediment: (3*E*)-dec-3-en-2-one Ground water: (3*E*)-dec-3-en-2-one Air: (3*E*)-dec-3-en-2-one

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

See section 5, Ecotoxicology

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

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available
Ground water (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available

PEC calculations were conducted for two routes of exposure, both relevant for application in indoor potato storage rooms;

1. Exposure by volatilization and deposition following release from the storage room
A conservative estimation is made of the amount of substance that reaches the soil / surface water after venting of the storage room after treatment.
For this estimation a tiered approach is used.
As a first tier, it is assumed that 0.05% of the applied dosage reaches the soil (FOCUS air, 2008).
As a second tier, equations as presented by Thibodeaux (1996) are applied to the substance and (default) storage room parameters. This approach follows the approach taken for the Renewal of the active substance 1-MCP. Three ventilation and subsequent deposition events are simulated after each indoor application of (3E)-dec-3-en-2-one.
The total estimated deposition rate per application is as follows:

Deposition rate (g/ha)	***Tier 1[a]:*** *2200* ***Tier 2[b]:*** *6.35 DAT1* *3.36 DAT8* *1.53 DAT15*

a) Based on the assumption that 0.05% of the applied dosage reaches the soil (FOCUS air, 2008), in the first tier and the equations presented by Thibodeaux (1996) in the second tier.
b) Based on the equations for wet and dry deposition presented by Thibodeaux (1996); DAT = days after treatment

2. Exposure from the Sewage Treatment Plant, after processing of treated potatoes
The second route is the exposure following processing of treated potatoes. An estimation of the residue in potato (flesh and peel) is made based on residue studies and default parameters regarding potato processing. The estimation of exposure concentrations is done using the model EUSES.

Due to the difference of both routes in time and space, it is assumed that these processes do not occur simultaneously. ***The maximum of both routes is considered for risk assessment.***

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

Exposure route 1 – Tier 1

Parent Method of calculation	DT_{50} (d): *90 days* Kinetics: *SFO* Field or Lab: *QSAR*
Application data	Crop: *all* Depth of soil layer: *5 cm* Soil bulk density: *1.5g/cm³* % plant interception: *none* Number of applications: *4* Interval (d): *28* Application rate: Tier 1: *2200* g a.s./ha Tier 2: 6.*35* g a.s./ha *DAT1* *3.36* g a.s./ha *DAT8* *1.53* g a.s./ha *DAT15*

$PEC_{(s)}$ Tier 1 (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		-		8.739	
Short term	24h	-		8.672	8.706
	2d	-		8.606	8.672
	4d	-		8.474	8.606
Long term	7d	-		8.281	8.508
	28d	-		7.044	7.861
	50d	-		5.946	7.253
	100d	-		4.046	6.094
Plateau concentration		-			

Exposure route 1 – Tier 2

PEC$_{(s)}$ Tier 2 (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		-		0.0415	
Short term	24h	-		0.0412	0.0414
	2d	-		0.0409	0.0412
	4d	-		0.0403	0.0409
Long term	7d	-		0.0414	0.0406
	28d	-		0.0352	0.0393
	50d	-		0.0297	0.0371
	100d	-		0.0202	0.0339
Plateau concentration		-			

Exposure route 2 - application of sewage sludge originating from treatment of waste water from potato processing industry in a STP

Parent Method of calculation	DT_{50} (d): *90 days* Kinetics: *SFO* Field or Lab: *QSAR*
Application data	Crop: *agricultural land* Depth of soil layer: *20 cm* Soil bulk density: *1.5g/cm^3* % plant interception: *none* Number of applications: *1* Interval (d): - Application rate: *1085.5* g a.s./ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.3618			
Short term	24h	0.3591	0.3604		
	2d	0.3563	0.3591		
	4d	0.3509	0.3563		
Long term	7d	0.3428	0.3523		
	28d	0.2916	0.3255		
	50d	0.2462	0.3003		
	100d	0.1675	0.2523		

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Plateau concentration	-			

Application data

Crop: *grassland*
Depth of soil layer: *5 cm*
Soil bulk density: *1.5g/cm*^{3}
% plant interception: *none*
Number of applications: *1*
Interval (d): -
Application rate: *217.1* g a.s./ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.2895			
Short term	24h	0.2872	0.2884		
	2d	0.285	0.2873		
	4d	0.2807	0.2851		
Long term	7d	0.2743	0.2818		
	28d	0.2333	0.2604		
	50d	0.197	0.2402		
	100d	0.134	0.2019		
Plateau concentration		-			

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Exposure route 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 used: *PEARL 4.4.4 / PELMO 5.5.3* Crop: *Winter cereals, Grass, Potatoes* Crop uptake factor: *0* Water solubility (mg/L): *140 at pH 7 and 24°C* Vapour pressure: *430 Pa at 25°C* Geometric mean parent $DT_{50\ QSAR}$ *42.2 d (normalisation to 10kPa or pF2, 20℃ with Q10 of 2.58 and Walker equation coefficient 0.7)** K_{OC}: *165.2 L/kg***, $^1/_n$= *1* Metabolites: *N.a.*
Application rate	Gross application rate: *Tier 1:* *2200 g/ha* *Tier 2:* 6.*35 g/ha DAT1* *3.36 g/ha DAT8* *1.53 g/ha DAT15* Crop growth stage: *no interception* Canopy interception %: *no interception* Application rate net of interception: *Tier 1:* *2200 g/ha* *Tier 2:* 6.*35 g/ha DAT1* *3.36 g/ha DAT8* *1.53 g/ha DAT15* No. of applications: *4 (interval = 28 days)* Time of application: Tier 1: *October 1st* Tier 2: *September 1st* *(to keep all 4 applications in the same year (for modelling purposes; acceptable date for storage season for potatoes)*

** For Tier 1 modelling a DT50 value of 47.5 days was used, based on a Q10 value of 2.2, instead of the correct value of 42.2 days based on a Q10 of 2.58.*

*** lowest value of 3 QSAR estimates, for conservativeness.*

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

	Scenario	Parent (µg/L)	
		Tier 1	Tier 2
PELMO/Winter cereals	Chateaudun	< 0.001	0.001
	Hamburg	< 0.001	0.001
	Jokioinen	< 0.001	0.002
	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

PELMO/Grass	Scenario	Parent (µg/L)	
		Tier 1	Tier 2
	Chateaudun	< 0.001	<0.001
	Hamburg	< 0.001	0.001
	Jokioinen	< 0.001	0.002
	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

PELMO/Potatoes	Scenario	Parent (µg/L)	
		Tier 1	Tier 2
	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

PEARL /Winter cereals	Scenario	Parent (µg/L)	
		Tier 1	Tier 2
	Chateaudun	19.85	0.070
	Hamburg	15.89	0.062
	Jokioinen	31.10	**0.110**
	Kremsmunster	16.79	0.065

	Okehampton	20.16	0.083
	Piacenza	13.60	0.054
	Porto	14.00	0.039
	Sevilla	7.75	0.022
	Thiva	10.25	0.047

PEARL / Grass	Scenario	Parent (µg/L)	
		Tier 1	Tier 2
	Chateaudun	16.16	0.066
	Hamburg	13.80	0.063
	Jokioinen	14.29	**0.133**
	Kremsmunster	14.16	0.060
	Okehampton	17.74	0.076
	Piacenza	10.28	0.058
	Porto	11.11	0.040
	Sevilla	6.68	0.031
	Thiva	8.09	0.039

PEARL/ Potatoes	Scenario	Parent (µg/L)	
		Tier 1	Tier 2
	Chateaudun	22.53	0.052
	Hamburg	16.06	0.056
	Jokioinen	25.49	0.064
	Kremsmunster	18.26	0.055
	Okehampton	22.73	0.066
	Piacenza	13.26	0.043
	Porto	14.42	0.034
	Sevilla	2.55	0.031
	Thiva	16.26	0.037

Exposure route 2

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 used: *PEARL 4.4.4 / PELMO 5.5.3* Crop: *Winter cereals, Grass, Potatoes* Crop uptake factor: *0* Water solubility (mg/L): *140 at pH 7 and 24°C* Vapour pressure: *430 Pa at 25°C* Geometric mean parent $DT_{50\ QSAR}$ *42.2 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).** K_{OC}: *165.2 / 1069 L/kg *,* $^1/_n$*= 1* Metabolites: *N.a.*
Application rate	Gross application rate: Potatoes, winter cereals: 187 g a.s./ha (sludge conc. based on low Koc) 1085.5g a.s./ha (sludge conc. based on high Koc) Grass: 32.4 g a.s./ha (sludge conc. based on low Koc) 217.1 g a.s./ha (sludge conc. based on high Koc) Crop growth stage: *no interception* Canopy interception %: *no interception* Application rate net of interception: No. of applications: 1 Time of application: *November 1st* Application type: *FOCUS PEARL 4.4.4 : Soil incorporation over 20 cm (winter cereals, potatoes) and 5 cm (grass) (FOCUS PEARL 4.4.4)* *FOCUS PELMO 5.5.3 : Soil application at the soil surface (depth 0.2 m: winter cereals, potatoes; depth 0.05m: grass)*

** two simulations: one using sludge concentration based on a high Koc and a high Koc in FOCUS PEARL & FOCUS PELMO (i.e. Koc of 1069 mL/g), and one using sludge concentration based on a low Koc and a low Koc in FOCUS PEARL & FOCUS PELMO (i.e. Koc of 165.2 mL/g)*

	Scenario	Parent (µg/L)	
		Low Koc	High Koc
PELMO/Winter cereals	Chateaudun	0.398	0.001
	Hamburg	0.824	0.13
	Jokioinen	2.301	0.652
	Kremsmunster	1.054	0.014

	Okehampton	1.388	0.088
	Piacenza	0.755	0.158
	Porto	0.859	0.135
	Sevilla	0.207	<0.001
	Thiva	1.426	0.058

PELMO/Grass	Scenario	Parent (µg/L)	
		Low Koc	High Koc
	Chateaudun	0.016	<0.001
	Hamburg	0.092	0.002
	Jokioinen	0.134	0.012
	Kremsmunster	0.189	0.007
	Okehampton	0.078	0.001
	Piacenza	0.07	<0.001
	Porto	0.063	<0.001
	Sevilla	0.013	<0.001
	Thiva	0.018	<0.001

PELMO/Potatoes	Scenario	Parent (µg/L)	
		Low Koc	High Koc
	Chateaudun	0.299	<0.001
	Hamburg	1.371	0.185
	Jokioinen	0.966	0.049
	Kremsmunster	0.794	0.011
	Okehampton	1.258	0.051
	Piacenza	0.829	0.009
	Porto	0.871	0.005
	Sevilla	0.342	0.001
	Thiva	0.492	0.002

PEARL /Winter cereals	Scenario	Parent (µg/L)	
		Low Koc	High Koc
	Chateaudun	0.905	0.27
	Hamburg	0.658	0.30
	Jokioinen	0.824	2.34

	Kremsmunster	0.798	0.06
	Okehampton	1.029	0.46
	Piacenza	0.577	0.18
	Porto	0.465	0.13
	Sevilla	0.229	0.19
	Thiva	0.548	0.34

PEARL / Grass	Scenario	Parent (µg/L)	
		Low Koc	High Koc
	Chateaudun	0.068	0.001
	Hamburg	0.086	0.02
	Jokioinen	0.153	0.04
	Kremsmunster	0.071	0.002
	Okehampton	0.085	0.01
	Piacenza	0.074	0.01
	Porto	0.060	0.002
	Sevilla	0.047	0.01
	Thiva	0.057	0.005

PEARL/ Potatoes	Scenario	Parent (µg/L)	
		Low Koc	High Koc
	Chateaudun	0.755	0.08
	Hamburg	0.594	0.25
	Jokioinen	0.634	0.35
	Kremsmunster	0.589	0.05
	Okehampton	0.899	0.30
	Piacenza	0.524	0.17
	Porto	0.380	0.04
	Sevilla	0.533	0.25
	Thiva	0.655	0.12

PEC$_{(gw)}$ From lysimeter / field studies

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

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

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

Exposure route 1

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: *version 3.2* Molecular weight (g/mol): K_{OC}/K_{OM} (mL/g): 165.2 / 1069 L/kg DT_{50} soil (d): *42.2 days** DT_{50} water/sediment system (d): *23.4 d* * DT_{50} water (d): *23.4 d* * DT_{50} sediment (d): *23.4 d* * Crop interception (%): *none*
Parameters used in FOCUSsw step 3 (if performed)	*Not needed*
Application rate	Crop and growth stage: *Aerial spray (the application rate is corrected for the drift from the scenario ' aerial spray' in order to reach 100% deposition for all applications.* Number of applications: *12*** Interval (d): *7*** Application rate: *Tier 2: 3.75*** *g a.s./ha (corrected before modelling, see under 'crop and growth stage').* Region and season of application: *No runoff/drainage*

* *default value of 90 days (12 °C) for substances classified as "readily biodegradable, but failing the 10 days window" according to REACH/biocides Guidance (ECHA, 2017; 2016), normalised to 20 °C using Q10 of 2.58*

** *due to the limitations of Steps 1-2 in FOCUS, the three deposition events following each indoor application were simulated as three deposition events of 3.75 g a.s./ha and an interval of 7 days; in total 12 applications of 3.75 g/ha and an interval of 7 days were simulated.*

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Low Koc No runoff/drainage	0 h	5.4993		5.6384	
	24 h	5.1927	5.346	5.5379	5.5881
	2 d	5.0326	5.2293	5.38	5.5235
	4 d	4.7426	5.0579	5.0707	5.3739
	7 d	4.3393	4.8352	4.6395	5.1503
	14 d	3.5267	4.3772	3.7707	4.6704
	21 d	2.8663	3.9799	3.0646	4.2488
	28 d	2.3295	3.6321	2.4907	3.8786
	42 d	1.5387	3.0571	1.6452	3.2654
High Koc No runoff/drainage	0 h	3.7491		20.9235	
	24 h	3.164	3.4565	20.4418	20.6826
	2 d	2.9812	3.2645	19.8697	20.4192
	4 d	2.7897	3.0729	18.7322	19.8584
	7 d	2.5518	2.8998	17.1395	19.03
	14 d	2.0739	2.6023	13.9299	17.2552
	21 d	1.6855	2.3592	11.3213	15.6973
	28 d	1.3699	2.15	9.2012	14.3293
	42 d	0.9049	1.8072	6.0777	12.0637

Exposure route 2

The distribution of (3*E*)-3-dec-3-en-2-one in sewage treatment plant (STP), following discharge of waste water from potato processing facilities, was estimated using SimpleTreat 4.0 according to REACH and biocides Guidance (ECHA, 2016 and 2017). The main input parameters are presented below:

Emission scenario	**Unit**	**Value**
Quantity of potatoes processed per day per plant	[T/d]	1161
a.i. residues on processed potatoes	[mg/kg]	1.5
Share of potatoes treated with the a.i.	[%]	100
Share of residues released to the cleaning water	[%]	100
a.i. emitted per day (Elocalwater)	[kg/d]	1.7415
parameters		
Molecular weight	[g/mol]	154.25
organic carbon-water partitioning coefficient (Koc)	[mL/g]	165.2/1069
Vapour pressure	[Pa at 25°C]	430
Solubility	[mg/L at 24°C]	140
Biodegradation		Ready biodegradable, not fulfilling 10d window

Estimated distribution of (3*E*)-dec-3-en-2-onein a STP using SimpleTreat 4.0 and resulting predicted environmental concentrations in surface water and sediment according to REACH and biocides Guidance (ECHA, 2016 and 2017), presented in the table below:

Distribution	Unit	scenario	
		Koc 165.2 mL/g	**Koc 1069 mL/g**
F stp air	[%]	52.33	48.35
F stp water	[%]	9.1	8.47
F stp sludge	[%]	1.52	8.85
Fstp biodegraded	[%]	37.05	34.33
Concentrations			
$PEC_{effluent}$	[µg/L]	79.22	73.75
$PEC_{dry,sewage\ sludge}$	[mg/kg]	37.4	217.1
PEC_{sw} (large river)	[µg/L]	7.92	7.36
PEC_{SED}	[mg/kg dry weight]	0.875	0.813

Predicted environmental concentrations in surface water, resulting from direct discharge of waste water from potato processing industry onto surface water, are presented in the table below:

Scenario	**Emission of *(3E)*-3-decen-2-one** [g/ha]	**Receiving water body**	**Flow rate of water body** [m³/d]	**PECsw** [µg a.s./L]
Unpeeled Potatoes	174.15*	Small river	6000	290
Unpeeled Potatoes	174.15*	Large river	20000	87.1
Unpeeled Potatoes	40.05#	Small river	6000	6.7
Unpeeled Potatoes	40.05#	Large river	20000	2.0

* based on median residue value of 1.5 mg/kg 14 days after the last treatment, based on measured residues of Bortolomé (2016) and Van den Sandt (2020), and a total of 1161 tonnes potatoes processed per day

based on median residue value of 0.0345 mg/kg 28 days after the last treatment, based on measured residues of Bortolomé (2016), and a total of 1161 tonnes potatoes processed per day

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

Method of calculation	-

PEC

Maximum concentration	*Not assessed, not relevant*

Ecotoxicology

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Bobwhite quail	a.s.	Acute	-	
Bobwhite quail	a.s.	Long-term	-	
Mammals ‡				
Rat	a.s.	Acute	>5000	
Rat	a.s.	Long-term (teratogenicity study)	1000	
Endocrine disrupting properties (Annex Part A, points 8.1.5) In view of the intrinsic properties of the active substance and the (eco)toxicological profile of the substance the assessment does not appear scientifically necessary. (3*E*)-dec-3-en-2-one does not to meet the criteria for endocrine disruption for humans according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.				
Additional higher tier studies ‡				

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Not required.
The representative use of (3*E*)-dec-3-en-2-one envisages indoor (i.e., warehouse) applications in potato, for which the dietary exposure and risks to birds and mammals is likely low. Conversely, the exposure via consumption of contaminated water and secondary poisoning (i.e., via earthworms or fish) could not be excluded.
However, the risk to birds and mammals from these exposure routes could be considered low, considering the indication of low toxicity to mammals and the following lines of evidence:

- (3*E*)-dec-3-en-2-one is a naturally occurring (fruits, juices, spices, vegetables, coffee and tea) acyclic aliphatic ketone that is also used as a food flavouring ingredient.
- It is rapidly metabolised (known to be metabolised rapidly and extensively to innocuous substances).
- Previous evaluations by EFSA and JFCFA considered (3*E*)-dec-3-en-2-one acceptable for use as food flavouring (EFSA FAF Panel opinion, 2019 and EFSA FAF Panel, 2022; JECFA, 2002). Additionally, as collateral information, an evaluation by the US FDA was acknowledged to result in a GRAS (generally regarded as safe) classification.
- (3*E*)-dec-3-en-2-one is readily biodegradable and its DT_{50} in air is 2h.

The outcome of the illustrative risk assessment by the RMS is presented under Vol.3 B9

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Fish				
Oncorhynchus mykiss	a.s.	96 h (flow-through)	Mortality, EC_{50}	1.50 (mm)
Aquatic invertebrate				
Daphnia magna	a.s.	48 h (static)	Mortality, EC_{50}	1.68 (mm)
Sediment dwelling organisms				
Chironomus riparius	a.s.	28d (static, spiked sediment)	Cumulative emergence, NOEC	31.4 mg/kg sediment dw (mm)[2]
Algae				
Pseudokirchneriella subcapitata	a.s.	72 h (static)	E_rC_{50}	2.3 (mm)
			E_yC_{50}	0.55 (mm)
Aquatic plants				
Lemna gibba	a.s.	7 day (semi-static)	Biomass: E_yC_{50} Growth rate: E_rC_{50}	1.69 (mm) 2.84 (mm)
Microcosm or mesocosm tests				
-				
Endocrine disrupting properties (Annex Part A, points 8.2.3) In view of the intrinsic properties of the active substance and the (eco)toxicological profile of the substance the assessment does not appear scientifically necessary. (3*E*)-dec-3-en-2-one does not to meet the criteria for endocrine disruption for humans according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.				

[1] indicate whether based on nominal (nom) or mean measured concentrations (mm). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

[2]reliable with restriction, due to analytical issues (i.e., test item stability in sediment) and lack of analytical verification in pore water.

Maximum PEC_{sw} values and TER values for (3*E*)-dec-3-en-2-one application to potatoes

Scenario	**PEC max (µg L)[1]**	**fish acute**	**Daphnia acute**	**algae**	**plants**
		O. mykiss	***D. magna***	***P. subcapitata***	***Lemna gibba***
		LC_{50}	EC_{50}	E_rC_{50}	E_rC_{50}
		1500 µg/L	1680 µg/L	2300 µg/L	2840µg/L
Large surface water		TER	TER	TER	TER
	7.92	189	212	290	359

Emission scenario (1)	**PEC_{SED} (mg/kg)**	**$TER_{Chironomus}$**
STP route	0.875	36
Annex VI trigger		10

Bioconcentration				
	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	3.45	-	-	-
Bioconcentration factor (BCF)[1] ‡	*	-	-	-
Annex VI Trigger for the bioconcentration factor	100	-	-	-
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase	-			

[1] only required if log $P_{O/W}$ >3.

* No experimentally derived BCF value was available for the active substance. However, the risk to birds and mammals through secondary poisoning was considered low, based on the weight of evidence reported above.

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

No toxicity tests were performed on bees.
However, considering that i) the representative use of (3*E*)-dec-3-en-2-one is indoor and ii) the exposure through air deposition was considered low, low risk is indicated for honey bees.

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

No toxicity tests were performed on other arthropod species.
However, considering that i) the representative use of (3*E*)-dec-3-en-2-one is indoor and ii) the exposure through air deposition was considered low, low risk is indicate for non-target arthropods other than bees.

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

No toxicity tests were performed on earthworms, other soil macro-organisms and soil micro-organisms.
However, considering that i) the representative use of (3*E*)-dec-3-en-2-one is indoor and ii) the exposure through air deposition was considered low, low risk is indicated for soil macro- and micro-organisms.

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

No toxicity tests were performed on non target plants.
However, considering that i) the representative use of (3*E*)-dec-3-en-2-one is indoor and ii) the exposure through air deposition was considered low, low risk is indicated for non-target terrestrial plants.

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	93.7 mg a.s./L
Pseudomonas sp	

Ecotoxicologically relevant compounds

Active substance (in terms of compound under consideration, e.g. a variant such as an ester) must always be included in the soil, water and groundwater compartment. Ecotoxicological relevance of metabolites should be based on risk assessment.

Compartment	
soil	Parent
water	Parent
sediment	Parent
groundwater	Parent

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

Substance	(3*E*)-dec-3-en-2-one
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][6]:	No current harmonised classification. RAC Opinion (2022): Aquatic Chronic 2 (H 411)
According to the peer review, criteria for harmonised classification according to Regulation (EC) No 1272/2008 may be met for:	-

[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.