Annex to: Conclusion on the peer review of the pesticide risk assessment of the active substance fat distillation residues. doi:10.2903/j.efsa.2023.7811

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)	Fat distillation residues (FDR) no ISO common name
Function (*e.g.* fungicide)	Repellent

Rapporteur Member State	Czech Republic
Co-rapporteur Member State	France

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

Chemical name (IUPAC)	not available
Chemical name (CA)	not available
CIPAC No	915
CAS No	not available
EC No (EINECS or ELINCS)	not available
FAO Specification (including year of publication)	not available
Minimum purity of the active substance as manufactured	≥ 400 g/kg of cleaved fatty acids (free/ester bonded) palmitic acid min 19% of cleaved fatty acids stearic acid min 18% of cleaved fatty acids oleic acid min 37% of cleaved fatty acids acid value min 70 mg KOH/g
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	nickel max 0.1 g/kg open for other impurities
Location of the (proposed) reference specification (for significant impurities)	RAR Volume 4 (2022)
Molecular formula	not available
Molar mass	not available
Structural formula	not available

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

Melting point (state purity)	above 60°C (no purity stated)
Boiling point (state purity)	not relevant
Temperature of decomposition (state purity)	not relevant
Appearance (state purity)	black paste at 20°C, viscous liquid above 60°C with very intensive odour after decomposed fat (no purity stated)
Vapour pressure (state temperature, state purity)	not relevant
Henry's law constant (state temperature)	not relevant
Solubility in water (state temperature, state purity and pH)	insoluble (no purity stated)
Solubility in organic solvents (state temperature, state purity)	Acetone 20 g/l at 20°C Heptane < 0.001 g/l at 20°C Xylene 500 g/l at 20°C Dichloromethane 100 g/l at 20°C 1-butanol 20 g/l at 20°C Ethyl acetate 20 g/l at 20°C (no purity stated)
Surface tension (state concentration and temperature, state purity)	not relevant
Partition coefficient (state temperature, pH and purity)	not relevant
Dissociation constant (state purity)	not relevant
UV/VIS absorption (max.) incl. ε (state purity, pH)	not relevant
Flammability (state purity)	not flammable not auto-flammable (no purity stated)
Explosive properties (state purity)	not relevant
Oxidising properties (state purity)	not relevant
Density (temperature and purity)	930 kg/m^3 at 15°C (no purity stated)

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*Fat Distillation Residues*)
(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 of product/1000 seedlings min max	kg a.i./hL min max	Water L/1000 seedlings min max	kg a.i./ 1000 seedlings min max		
Seedlings of coniferous and deciduous trees	CZ, SK, DE	Morsuvin	F	Ruminant animals : Deer family (*Cervus Elaphus*) Roe family (*Capreolus Capreolus*) Fallow Deer (*Dama Dama*)	Paste (PA)	255 g/kg quartz sand and 40 g/kg FDR	Coating of individual plants with special brush or with rubber or plastic glove	Seedlings old up to 2 years August - November	1	-	4 – 5	80	0.2 – 0.25	0.160 – 0.200	n.a.	
Seedlings of coniferous and deciduous trees	CZ, SK, DE	Morsuvin	F	Ruminant animals : Deer family (*Cervus Elaphus*) Roe family (*Capreolus Capreolus*) Fallow Deer (*Dama Dama*)	Paste (PA)	255 g/kg quartz sand and 40 g/kg FDR	Coating of individual plants with special brush or with rubber or plastic glove	Seedlings old 2 - 5 years August - November	1	-	5 – 6	80	0.25 – 0.30	0.200 – 0.240	n.a.	

(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 applicable

Further information, Efficacy

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

	Products with fat distillation residues have been registered in several member states in the EU based on detailed national assessments of the efficacy package in compliance with Annex III data requirements of Directive 91/414/EEC and according to the Uniform Principles.

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

	Products with fat distillation residues have been registered in several member states in the EU based on detailed national assessments of the efficacy package in compliance with Annex III data requirements of Directive 91/414/EEC and according to the Uniform Principles.

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

	Products with fat distillation residues have been registered in several member states in the EU based on detailed national assessments of the efficacy package in compliance with Annex III data requirements of Directive 91/414/EEC and according to the Uniform Principles.

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

Activity against target organism	Not needed

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, GC/MS, chromatographic techniques, TLC, titration methods
Impurities in technical a.s. (analytical technique)	GC/FID, GC/MS, chromatographic techniques, TLC, titration methods, AAS, ELISA Data gap : demonstration of applicability of the CSN ISO 8070 method for determination of nickel in fat distillation residues
Plant protection product (analytical technique)	GC-FID Data gap: accuracy of the method for determination of the active substance in the formulation and; Method for determination of the relevant impurity in the formulation

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

Residue definitions for monitoring purposes

Food of plant origin		not relevant (no residue definition)
Food of animal origin		not relevant (no residue definition)
Soil		not available (no residue definition)
Sediment		not available (no residue definition)
Water	surface	not available (no residue definition)
	drinking/ground	not available (no residue definition)
Air		not available (no residue definition)
Body fluids and tissues		not available (no residue definition)

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	none
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	none
Soil (analytical technique and LOQ)	none
Water (analytical technique and LOQ)	none
Air (analytical technique and LOQ)	none

Body fluids and tissues (analytical technique and LOQ)	none

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

Substance	Fat distillation residues (FDR)
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. Fat distillation residues will not be classified from physical / chemical point of view.
According to the peer review, criteria for harmonised classification according to Regulation (EC) No 1272/2008 may be met for:	None

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

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	No data available; not needed (mixture of fatty acids and un-hydrolysed fats)
Toxicokinetics	No data available; not needed (mixture of fatty acids and un-hydrolysed fats)
Distribution	No data available; not needed (mixture of fatty acids and un-hydrolysed fats)
Potential for bioaccumulation	No data available; not needed (mixture of fatty acids and un-hydrolysed fats)
Rate and extent of excretion	No data available; not needed (mixture of fatty acids and un-hydrolysed fats)
Metabolism in animals	No data available; not needed (mixture of fatty acids and un-hydrolysed fats)
In vitro metabolism	No data available; not needed (mixture of fatty acids and un-hydrolysed fats; PPP used as a repellent, not applied on edible crops)
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	> 2000 mg/kg bw	
Rat LC_{50} inhalation	No data available; not needed	
Skin irritation	Non-irritant (classification not required)	
Eye irritation	Non-irritant (classification not required)	
Skin sensitisation	Non-sensitizer (GPMT)	
Phototoxicity	Not required (mixture of fatty acids and un-hydrolysed fats; PPP used as a repellent, not applied on edible crops); Information on absorption of electromagnetic radiation and the value of ultraviolet/visible molar extinction/absorption coefficient of FDR is not available.	

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

Target organ / critical effect	No data available	

Relevant oral NOAEL	No data available; not needed	
Relevant dermal NOAEL	no data available; not needed	
Relevant inhalation NOAEL	Not required	

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

In vitro studies	Negative bacterial reverse mutation test (Supplementary study)	
In vivo studies	No studies available and not required	
Photomutagenicity	Not required	
Potential for genotoxicity	FDR 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 available	
Relevant long-term NOAEL	Not stated; not needed	
Carcinogenicity (target organ, tumour type)	No data available; not needed	
Relevant NOAEL for carcinogenicity	No data available; not needed	

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

Reproduction toxicity

Reproduction target / critical effect	No data available; not needed	
Relevant parental NOAEL	Not stated; not needed	
Relevant reproductive NOAEL	Not stated; not needed	
Relevant offspring NOAEL	Not stated; not needed	

Developmental toxicity

Developmental target / critical effect	No data available ; not needed	
Relevant maternal NOAEL	Not stated; not needed	
Relevant developmental NOAEL	Not stated; not needed	

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

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

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

Supplementary studies on the active substance	No data available

Endocrine disrupting properties	No data available; not required; Due to the phys-chem properties and the (eco) toxicological profile of the active substance the assessment does not appear to be scientifically necessary. Fat distillation residues are unlikely 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	No data available

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

Data gap

Summary[2] (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)	Not required		
Acute Reference Dose (ARfD)	Not required		
Acceptable Operator Exposure Level (AOEL)	Not required		
Acute Acceptable Operator Exposure Level (AAOEL)	Not required		

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

Representative formulation (*Morsuvin* ,Paste (PA))	No study available; not required

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

Operators	Use: seedlings of conifer and deciduous trees, coating of individual plants with brush or glove, application rate max 0.24 kg a.s./1000 seedlings Application of FDR as paste was not considered to be a source of significant exposure
Workers	Application of FDR as paste was not considered to be a source of significant exposure
Bystanders and residents	Application of FDR as paste was not considered to be a source of significant exposure

[2] If available include also reference values for metabolites

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

Substance :	Fat distillation residues
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][3] :	No current harmonised classification
According to the peer review, criteria for harmonised classification according to Regulation (EC) No 1272/2008 may be met for:	None

[3] 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.

Residues in or on treated products food and feed

Not relevant. Consumer exposure via dietary intake to fat distillation residues is not expected following the representative uses.

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 relevant
Non-extractable residues after 100 days	Not relevant
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	No metabolites

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

Mineralisation after 100 days	Not relevant
Non-extractable residues after 100 days	Not relevant
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No metabolites

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 metabolites
Mineralisation at study end	Not relevant
Non-extractable residues at study end	Not relevant

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)

Not relevant

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 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 relevant

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

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)	Not relevant	
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	Not relevant	Not relevant
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	Not relevant	Not relevant

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

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

Soil accumulation and plateau concentration	Not relevant

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 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 relevant

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

Not 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)

Not available

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 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)

Column leaching	Not 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)

Column leaching	Not 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)

Lysimeter/ field leaching studies	Not 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 %	Not relevant

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 %	Not relevant
Quantum yield of direct phototransformation in water at $\Sigma > 290$ nm	Not relevant

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

Readily biodegradable (yes/no)	Not available, substance considered not readily biodegradable

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 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)

Not relevant

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

Direct photolysis in air	Not relevant
Photochemical oxidative degradation in air	Not relevant
Volatilisation	Not relevant
Metabolites	No metabolites

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

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Considering the nature of the substance mixture and the limited exposure from the representative uses, a definition of residue in the environment for risk assessment triggering assessment of effects data is considered unnecessary for fat distillation residues.

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

No residue definitions are proposed for all environmental compartments. Fat distillation residues is expected to follow the normal pathways of dissipation and degradation common to naturally occurring cleaved fatty acid residues of biological origin.

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

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

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

Parent Method of calculation	Not calculated, not relevant

Application data	Not calculated, not relevant

Not calculated, not relevant

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Not calculated, not relevant
Application rate	Not calculated, not relevant

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

Not calculated, not relevant

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

Parent Parameters used in FOCUSsw step 1 and 2	Not calculated, not relevant
Parameters used in FOCUSsw step 3 (if performed)	Not calculated, not relevant
Application rate	Not calculated, not relevant

Not calculated, not relevant

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

Method of calculation	Not relevant

PEC

Maximum concentration	Not relevant

Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Indicate species	a.s.	Acute	LD_{50}	No data available
	Preparation	Acute	LD_{50}	No data available
	a.s.	Long-term	NOAEL	No data available
Mammals				
Rat	a.s.	Acute	LD_{50}	LD_{50}>2000
	Preparation	Acute	LD_{50}	No data available
	a.s.	Long-term [*for first tier risk assessment*]	NOAEL [*amend as appropriate*]	No data available
Endocrine disrupting properties (Annex Part A, points 8.1.5) Due to the phys-chem properties and the (eco) toxicological profile of the active substance the assessment does not appear to be scientifically necessary. Fat distillation residues are unlikely to meet the criteria for endocrine disruption for non-target organisms 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 (Annex Part A, points 10.1.1.2): No data, not required.				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): No data, not required.				

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

Brush or glove application to tree seedlings at 0.160 – 0.240 kg a.s./100 seedlings

No quantitative risk assessment performed since it was not needed for the representative uses.

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)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Laboratory tests				
Fish				
	a.s.	Acute 96 hr (static, or semi-static or flow-through)	Mortality, LC_{50}	No data available
	a.s.	Chronic (static, or semi-static or flow-through)	Growth, or development, or behaviour, or reproduction NOEC	No data available
Aquatic invertebrates				
Daphnia magna	a.s.	48 h (static)	Immobility, EC_{50}	No data available
	a.s.	21 d (static, or semi-static or flow-through)	Reproduction or development, NOEC	No data available
Sediment-dwelling organisms				
Indicate species	a.s.	28 d (static, or semi-static or flow-through)	NOEC	No data available
Algae				
	a.s.	72 h (static, or semi-static or flow-through)	Growth rate: E_rC_{50} (NOEC) [Biomass: E_bC_{50} (NOEC) Yield: E_yC_{50} (NOEC)]	No data available
Higher plant				
Indicate species	a.s.	(static, or semi-static or flow-through)	Fronds number, EC_{50} (NOEC) Frond area/fresh weight/dry weight, E_rC_{50} (NOEC)	No data available

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Further testing on aquatic organisms No data, not required.				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) Due to the phys-chem properties and the (eco) toxicological profile of the active substance the assessment does not appear to be scientifically necessary. Fat distillation residues are unlikely to meet the criteria for endocrine disruption for non-target organisms according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.				

[1] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; prep.: preparation; a.s.: active substance

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$				
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	No data available			
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)				
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase				
Higher tier study				

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

FOCUS$_{sw}$ step 1-3 - TERs for fat distillation residues: Brush or glove application to tree seedlings at 0.160 – 0.240 kg a.s./100 seedlings

No quantitative risk assessment performed since it was not needed for the representative uses.

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

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

Species	Test substance	Time scale/type of endpoint	End point	toxicity
	a.s.	Acute	Contact toxicity (LD_{50}) Oral toxicity (LD_{50})	No data available
	a.s.,	Chronic	10 d-LC50	No data available
	a.s.,	Bee brood development	NOEClarvae	No data available

Potential for accumulative toxicity: *yes/no* No data, since they were not needed for the representative uses.
Semi-field test (Cage and tunnel test) No data.
Field tests No data.

Risk assessment for fat distillation residues - Brush or glove application to tree seedlings at 0.160 – 0.240 kg a.s./100 seedlings

No quantitative risk assessment performed since it was not needed for the representative uses.

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
Typhlodromus pyri	a.s., preparation	Mortality, LR_{50} Reproduction, ER_{50}	No data available
Aphidius rhopalosiphi	a.s., preparation	Mortality, LR_{50} Reproduction, ER_{50}	No data available

First tier risk assessment for fat distillation residues - Brush or glove application to tree seedlings at 0.160 – 0.240 kg a.s./100 seedlings

No quantitative risk assessment performed since it was not needed for the representative uses.

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Earthworms					
Eisenia fetida	a.s.	-	Chronic	Growth, reproduction, behaviour	No data available
Other soil macroorganisms					
Folsomia candida	a.s.			Mortality, reproduction, behaviour	No data available
Hypoaspis aculeifer	a.s.			Mortality, growth, reproduction, behaviour	No data available

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

Higher tier testing (e.g. modelling or field studies)
No data, not needed for the representative uses.

Nitrogen transformation	a.s.		No data available

Toxicity/exposure ratios for soil organisms for fat distillation - Brush or glove application to tree seedlings at 0.160 – 0.240 kg a.s./100 seedlings

No quantitative risk assessment performed since it was not needed for the representative uses.

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Not required for herbicides or plant growth regulators as ER_{50} tests should be provided

No data available

Laboratory dose response tests

Species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
No data available						
Extended laboratory studies: Semi-field and field test: No data available						

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

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

Test type/organism	end point
Activated sludge	No data available
Pseudomonas sp	No data available

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

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

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds[1]

Compartment	
soil	-
water	-
sediment	-
groundwater	-

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

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

Substance	Fat distillation residues

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
According to the peer review, criteria for harmonised classification according to Regulation (EC) No 1272/2008 may be met for:	None

[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.