European Commission

Draft Renewal Assessment Report prepared according to Regulation (EC) N° 1107/2009

Heptamaloxyloglucan

List of End Points

Rapporteur Member State: France
Co-Rapporteur Member State: Spain

Version History

When	What
2020-09	Initial RAR

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

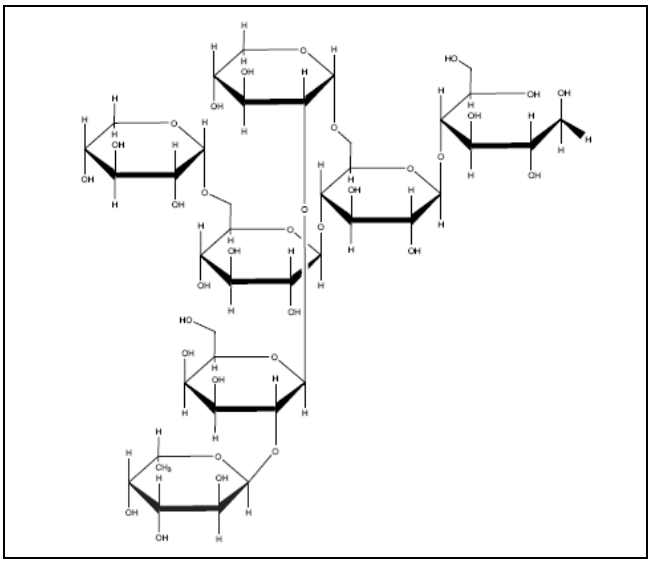
Active substance (ISO Common Name)	Heptamaloxyloglucan
Function (*e.g.* fungicide)	Frost-protecting agent

Rapporteur Member State	France
Co-rapporteur Member State	Spain

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

Chemical name (IUPAC)	*{[α-D-Xyl p-*(1→6)]*-β-D-Glc p-*(1→4)}{[*α-L- Fuc p-*(1→2)*-β-D-Gal p-*(1→2)*-α-D-Xyl p-*(1→6)]*-β-D-Glc p-*(1→4)}*-D-Glc-ol* with: Xyl p: xylopyranosyl Glc p: glucopyranosyl Fuc p: fucopyranosyl Gal p: galactopyranosyl Glc-ol: glucitol
Chemical name (CA)	/
CIPAC No	Not available
CAS No	870721-81-6
EC No (EINECS or ELINCS)	Not available
FAO Specification (including year of publication)	Not available
Minimum purity of the active substance as manufactured	780 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Patulin, max. 50 µg/kg
Location of the (proposed) reference specification (for significant impurities)	DAR Volume 4 (2007)
Molecular formula	$C_{40}H_{70}O_{33}$
Molar mass	1078.96 g/mol

Structural formula



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

Melting point (state purity)	172.7 ± 0.5 °C (>99%)
Boiling point (state purity)	>525 °C (>99%)
Temperature of decomposition (state purity)	281.4 – 305.5 °C (>99%)
Appearance (state purity)	White beige highly expanded solid
Vapour pressure (state temperature, state purity)	$<10^{-5}$ Pa at 20 °C
Henry's law constant (state temperature)	ca. $0.24*10^{-13}$ $Pa.m^3/mol$ (not validated)
Solubility in water (state temperature, state purity and pH)	558 g/L at 20 °C (pH 7) (87%)
Solubility in organic solvents (state temperature, state purity)	In n-heptane: 0.001 g/L at 20 °C (87%) In p-xylene: <0.001 g/L at 20 °C (87%) In 1,2-dichloroethane: 0.015 g/L at 20 °C (87%) In methanol: 10 g/L at 20 °C (87%) In acetone: 0.003 g/L at 20 °C (87%) In ethyl acetate: 0.001 g/L at 20 °C (87%) In n-octanol: 0.019 g/L at 20 °C (87%)
Surface tension (state concentration and temperature, state purity)	70.6 mN/m at 20 °C (1 g/L solution) (87%)
Partition coefficient (state temperature, pH and purity)	log P_{OW} <0 at 20 °C (pH 7)
Dissociation constant (state purity)	The active substance does not dissociate
UV/VIS absorption (max.) incl. ε (state purity, pH)	(>99%) | | pH5 | pH7 | pH9 | | Wavelength (nm) | 285 | 288 | 292 | | Absorbance (µA) | 0.044 | 0.038 | 0.025 | | ε ($L.mol^{-1}.cm^{-1}$) | 4.4 | 3.8 | 2.5 | No absorbance with ε > 10L/mol/cm at wavelength >290 nm
Flammability (state purity)	Not flammable (>78%)
Explosive properties (state purity)	Not explosive (>78%)
Oxidising properties (state purity)	No oxidising properties (>78%)

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	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	mg a.i./hl min max (l)	Water l/ha min max	mg a.i./ha min max (l)		
Vine	FR	PEL101GV	F	Frost damage	XX	780 g/kg	Foliar spraying using an air pressured system	BBCH 07-16 (budding to 6 leaves) Early spring	4	4 days	109.25 mg mg ai/hL	100-400	0.54 – 437 mg ai/ha	F	1-4 applications 12 to 48 h before freezing temperatures

(a) For crops, the EU and Codex classification (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) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i) g/kg or g/L. 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 synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) 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

RMS comment: This GAP table format is different from the one provided by the applicant. RMS has updated the table format following EFSA request. EFSA has requested to "update the GAP table using the template on the EC website (for chemical active substances)". The applicant is kindly asked to check if this update is in accordance with its initial GAP table.

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))

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

Crop and/or situation (a)	**Member State or Country**	**Product name**	**F 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	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															

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

Further information, Efficacy

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

Considering that the substance is approved and authorizations of plant protection products containing the substance have already been evaluated according to the Uniform Principles, no other efficacy documentation is deemed to be necessary at this stage. More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

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

See above

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

See above

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

	Met1	*Met2*	*Met3*	*Met4*	*Met5*	*Met6*
Activity against target organism	*yes/no*	*yes/no*	*yes/no*	*yes/no*	*yes/no*	*yes/no*

Methods of Analysis

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

Technical a.s. (analytical technique)	HPAEC-PAD
Impurities in technical a.s. (analytical technique)	HPLC-UV HPAEC-PAD
Plant protection product (analytical technique)	HPAEC-PAD

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		None
Food of animal origin		None
Soil		None
Sediment		None
Water	surface	None
	drinking/ground	None
Air		None
Body fluids and tissues		None

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Soil (analytical technique and LOQ)	Not required
Water (analytical technique and LOQ)	Not required
Air (analytical technique and LOQ)	Not required
Body fluids and tissues (analytical technique and LOQ)	Not required

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

Substance	Heptamaloxyloglucan
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
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	None

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

[2] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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 ADME studies were performed except an *in vitro* acidic hydrolysis intended for mimicking gastric hydrolysis of heptamaloxyloglucan. An ADME argumentation has mainly been built on published references. Heptamaloxyloglucan is not absorbed. Via oral route, it is expected heptamoloxyloglucan to be hydrolyzed into an array of monosaccharides and hexamers. Monosaccharides are absorbed in the small intestine by passive diffusion (except glucitol) or metabolized in the large intestine by fermentation into fatty acids. Hexamers are not absorbable. They pass into the large intestine where they can undergo enzymatic hydrolysis or the remaining fraction of unmetabolized or unhydrolyzed heptamaloxyloglucan be excreted in the faeces.
Toxicokinetics	No data
Distribution	No data, only monosaccharides are expected to be absorbed and distributed (see above)
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	Excretion is expected to happen by faeces (see above). No study has been performed to quantify excretion.
Metabolism in animals	Only enzymatic or acidic hydrolysis is expected to happen (see above). No study was available for metabolism quantification.
In vitro metabolism	No data
Toxicologically relevant compounds (animals and plants)	Parent compound and related metabolites are not expected to be of toxicological concern
Toxicologically relevant compounds (environment)	Parent compound and related metabolites are not expected to be of toxicological concern

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	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	Non Sensitising (LLNA)	

Phototoxicity	Not required	

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

Target organ / critical effect	Not observed	
Relevant oral NOAEL	28-day, rat: > 1000 mg/kg b.w. per day based on the absence of systemic effects at the highest tested dose	
Relevant dermal NOAEL	No data	
Relevant inhalation NOAEL	No data	

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

In vitro studies	Two negative mutagenicity tests, *in vitro* clastogenicity lacking	
In vivo studies	No data	
Photomutagenicity	Not required	
Potential for genotoxicity	Data gap for clastogenicity	

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, literature suggested not accepted	
Relevant long-term NOAEL	No data	
Carcinogenicity (target organ, tumour type)	No data, literature suggested not accepted	
Relevant NOAEL for carcinogenicity	No data	

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

Reproduction toxicity

Reproduction target / critical effect	No data	
Relevant parental NOAEL	No data	
Relevant reproductive NOAEL	No data	
Relevant offspring NOAEL	No data	

Developmental toxicity

Developmental target / critical effect	No data	
Relevant maternal NOAEL	No data	
Relevant developmental NOAEL	No data	

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

Acute neurotoxicity	Study not required	

Repeated neurotoxicity	Study not required	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	Study not required	

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

Supplementary studies on the active substance	Not required
Endocrine disrupting properties	No EATS study has been provided. No endocrine disrupting properties expected based on 28-day study outcome and on physicochemical properties, absence of accumulation expected.
Studies performed on metabolites or impurities	Not required

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

No data available

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)	N/A	N/A	N/A
Acute Reference Dose (ARfD)	N/A	N/A	N/A
Acceptable Operator Exposure Level (AOEL)	N/A	N/A	N/A
Acute Acceptable Operator Exposure Level (AAOEL)	N/A	N/A	N/A

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

Representative formulation (Name: *PEL101GV, Type: water soluble powder, Concentration of active substance: 100%*)	N/A

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

Operators	Due to the absence of reference values, no risk assessment could be conducted by comparison to exposure modelling.
Workers	Due to the absence of reference values, no risk assessment could be conducted by comparison to exposure modelling.
Bystanders and residents	Due to the absence of reference values, no risk assessment could be conducted by comparison to exposure modelling.

[3] 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 :	Heptamaloxyloglucan
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
Peer review proposal [5] for harmonised classification according to Regulation (EC) No 1272/2008:	No classification

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

[5] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Residues in or on treated products food and feed

Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling** (DAT)	**Comment/Source**
	No data required Heptamaloxyloglucan is a signal molecule (elicitor) naturally occurring at low levels in plant tissues which is not expecting to exhibit toxic effect.				
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI** (DAT)	**Comment/Source**
	No data required Heptamaloxyloglucan is a signal molecule (elicitor) naturally occurring at low levels in plant tissues which is not expecting to exhibit toxic effect. Furthermore representative use is a permanent crop.				
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Not triggered/not required		
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Not triggered/not required		
	Sterilisation (20 min, 120°C, pH 6)		Not triggered/not required		
	Other processing conditions				

Can a general residue definition be proposed for primary crops?	Not relevant	
Rotational crop and primary crop metabolism similar?	Not relevant	
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not relevant	

Plant residue definition for monitoring (RD-Mo)	Not relevant Heptamaloxyloglucan is a signal molecule (elicitor) naturally occurring at low levels in plant tissues which is not expecting to exhibit toxic effect.
Plant residue definition for risk assessment (RD-RA)	Not relevant Heptamaloxyloglucan is a signal molecule (elicitor) naturally occurring at low levels in plant tissues which is not expecting to exhibit toxic effect.
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Not required

Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T** (°C)	**Stability period**		**Compounds covered**	**Comment/Source**
				Value	**Unit**		
	No data required						

Magnitude of residues in plants

Summary of residues data from the supervised residue trials – Primary crops

Commodity	**Region/ Indoor** (a)	**Residue levels observed in the supervised residue trials** (mg/kg)	**Comments/Source**	**Calculated MRL** (mg/kg)	**HR** (b) (mg/kg)	**STMR** (c) (mg/kg)	**CF** (d)
Grapes	Residues trials to determine the residue level of heptamaloxyloglucan in grapes are not required as heptamaloxyloglucan is a signal molecule (elicitor) naturally occurring at low levels in plant tissues which is not expecting to exhibit toxic effect.						

* Indicates that the MRL is proposed at the limit of quantification.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

Residues in rotational crops

Overall summary

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered and not required	
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered and not required	

Summary of residues data from the rotational crops residue trials (if relevant, e.g. MRL, STMR, HR derived from rotational crops)

Commodity	**Region/ Indoor** (a)	**PBI (days)** (b)	**Residue levels observed in the supervised residue trials** (mg/kg)	**Comments/Source**	**Calculated MRL** (mg/kg)	**HR** (c) (mg/kg)	**STMR**(d) (mg/kg)	**CF** (e)
	Not data required							

* Indicates that the MRL is proposed at the limit of quantification.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Country code: if non-EU trials.

(b): Plant-back interval: The interval (days, months, years) between the final application of a pesticide product to a primary crop and the planting of a rotational crop.

(c): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(d): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

Processing factors

Processed commodity	**Number of valid studies**[(a)]	**Processing Factor** (PF)		**CF_P**[(b)]	**Comment/ Source**
		Individual values	Median PF		
	No data required				

PF: Processing factor (=Residue level in processed commodity expressed according to RD-Mo/ Residue level in raw commodity expressed according to RD-Mo);
CF_p: Conversion factor for risk assessment in processed commodity (=Residue level in processed commodity expressed according to RD-RA / Residue level in processed commodity expressed according to RD-Mo)
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur)

Residues in livestock

Not relevant

Consumer risk assessment

Not relevant since no ARfD and no ADI have been considered necessary.

Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Not required				
Representative uses				
	Grapevine	None Hepyamaloxyloglucan is included n the Annex IV of regulation 396/2005/EC	Not relevant. Heptamaloxyloglucan is a natural component of dicotyledone plant walls. This substance is already present in different food commodities of plant origine, among them apple juice, and dietary supplement, and then the consumer is already exposed to this active substance. Furthermore, if heptamaloxyloglucan is consumed it will be broken down to simple sugars naturally presents in fruits and vegetables and will be utilised as an energy source and will exhibit no toxic effects. Additionally, due to its low toxicity no ADI nor ARFD is proposed for this active substance. It is proposed to maintain heptamaloxyloglucan in the Annex IV of regulation 396/2005/EC (active substances for which no MRL are required).	

* Indicates that the MRL is set at the limit of analytical quantification (LOQ)

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005

(F): Fat soluble

Environmental fate and behaviour

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

Mineralisation after 100 days	No study submitted, not required. Heptamaloxyloglucan is a polysaccharide which leads to smaller-sized oligosaccharides and monosaccharides after degradation.
Non-extractable residues after 100 days	No study submitted, not required.
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	Heptamaloxyloglucan is a polysaccharide which leads to smaller-sized oligosaccharides and monosaccharides after degradation. No other relevant metabolites, degradation or reaction products are expected to appear.

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

Mineralisation after 100 days	No study submitted, not required.
Non-extractable residues after 100 days	No study submitted, not required.
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Heptamaloxyloglucan is a polysaccharide which leads to smaller-sized oligosaccharides and monosaccharides after degradation. No other relevant metabolites, degradation or reaction products are expected to appear.

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)	Heptamaloxyloglucan is photochemically stable as it has no peak absorption with molecular absorption coefficient higher than 10 L/mol/cm at wavelength > 290nm. UV radiation has a small but positive effect on degradation of hemicellulose compared to other decomposition processes.
Mineralisation at study end	No study submitted, not required.
Non-extractable residues at study end	No study submitted, not required.

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (χ^2)	Method of calculation
no study, not required	-	-	30 (default) [a)]	-	-	-

[a)] Default value according to Guidance on Biocidal Products Regulation: Volume IV Environment - Assessment and Evaluation (Parts B+C); Reference: ECHA-17-G-23-EN; Cat. Number: ED-01-17-897-EN-N ISBN: 978-92-9020-151-9 DoI: 10.2823/033935 Publ.date: October 2017

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)

Parent	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm.	Method of calculation
no study, not required	-	-	-	-	-	-	-	-

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

Soil accumulation and plateau concentration	no study, not required

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)

Parent	Dark anaerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C	St. (χ^2)	Method of calculation
no study, not required	-	-	-	-	-	-

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

Parent	Soil photolysis				
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	St. (χ^2)	Method of calculation
no study, not required	-	-	-	-	-

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	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Default values for modelling purpose [a)]	-	-	-	-	-	0 / 10000	1

a) no study, not relevant due to the nature of the active substance

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	no study, not required

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

Lysimeter/ field leaching studies	no study, not required

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

Hydrolytic degradation of the active substance and metabolites > 10 %	pH 5: stable at 20°C
	pH 7: stable at 20°C
	pH 9: stable at 20°C

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 %	stable due to its low molar absorption coefficient
Quantum yield of direct phototransformation in water at Σ > 290 nm	not relevant

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

Readily biodegradable (yes/no)	Yes

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)

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	t. °C	DT_{50} /DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised		At study temp	Normalised		
no study, not required	-	-	-	-	-	-	-	-	-	-

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										
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
no study, not required	-	-	-	-	-	15 [a)]	-	30 [a)]	-	-

[a)] Default value according to Guidance on Biocidal Products Regulation: Volume IV Environment - Assessment and Evaluation (Parts B+C); Reference: ECHA-17-G-23-EN; Cat. Number: ED-01-17-897-EN-N ISBN: 978-92-9020-151-9 DoI: 10.2823/033935 Publ.date: October 2017

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 27 minutes derived by the Atkinson model (AOPWIN version 1.92). OH (12 h) concentration assumed = 1.5 x 10^6 OH/cm^{-3}
Volatilisation	from plant surfaces (BBA guideline): no data
	from soil surfaces (BBA guideline): no data
Metabolites	none

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: Heptamaloxyloglucan Surface water: Heptamaloxyloglucan Sediment: Heptamaloxyloglucan Ground water: Heptamaloxyloglucan Air: Heptamaloxyloglucan

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)	no monitoring data available, not required
Surface water (indicate location and type of study)	no monitoring data available, not required
Ground water (indicate location and type of study)	no monitoring data available, not required
Air (indicate location and type of study)	no monitoring data available, not required

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

Parent Method of calculation	DT_{50} (d): no degradation (worst-case) Kinetics: - Field or Lab: -
Application data	Crop: Vines Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 40 % Number of applications: 4 Interval (d): multiple applications are simultaneous (worst-case) Application rate(s): 0.56 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	0.0004		0.0018	

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)	No calculations performed, not required.

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	Version control no. of FOCUS calculator: v3.2 Molecular weight (g/mol): 1079 K_{OC} (mL/g): 0 (worst-case for PECsw) 10 000 (worst-case for PECsed) DT_{50} soil (d): not needed for STEP 1 DT_{50} water/sediment system (d): 1000 (worst-case value) DT_{50} water (d): not needed for STEP 1

	DT_{50} sediment (d): not needed for STEP 1 Crop interception (%): not needed for STEP 1
Parameters used in FOCUSsw step 3 (if performed)	not calculated
Application rate	Crop and growth stage: Vines BBCH 07-16 Number of applications: 1 (combined applications) Interval (d): - Application rate(s): 2.24 g a.s./ha (= 4 x 0.56 g a.s./ha) Application window: not needed for STEP 1

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vines, early applications	0 h	0.77		5.35	

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

Method of calculation	not relevant

Ecotoxicology

The representative formulation is composed of technical heptamaloxylglucan only.

Thus endpoints presented below for the active substance heptamaloxylglucan is also applicable to the representative formulation.

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 (mg/kg bw per day)	Toxicity (mg/kg feed)
Birds				
No data available				
Mammals				
Rat	heptamaloxyloglucan	Acute	LD_{50} > 5000	-
	heptamaloxyloglucan	Long-term (28-day oral toxicity)	NOAEL = 1000	-
Endocrine disrupting properties (Annex Part A, points 8.1.5) Heptamaloxyloglucan is not expected to have endocrine disruption properties.				
Additional higher tier studies (Annex Part A, points 10.1.1.2): No data. Not necessary.				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): No data. Not necessary.				

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

Vine at 0.560 g a.s./ha [x 4 applications with 4 days interval]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous birds	Acute	0.11	-	10
All	Small omnivorous birds	Long-term	0.06		5
Tier 1 (Birds)					
Not necessary					
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	0.16	> 31 170.8	10
All	Small herbivorous mammal	Long-term	0.11	8821	5
Tier 1 (Mammals)					
Not necessary					
Risk from bioaccumulation and food chain behaviour					
Not relevant. Log kow≤3					
Risk from consumption of contaminated water					

Scenarios	Indicator or focal species	Time scale	PEC_{dw}xDWR	TER	Trigger
Leaf scenario	Not relevant for use in vineyard				
Puddle scenario, Screening step Application rate (0.56 g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed					
			AReff (g a.s./ha)		
Puddle scenario	Birds	acute	-	-	10
Puddle scenario	Mammals	acute	1.568	0.00031	10
Puddle scenario	Birds	Long-term	-	-	5
Puddle scenario	Mammals	Long-term	1.568	0.0016	5

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

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Laboratory tests				
Fish				
Oncorhynchus mykiss	heptamaloxyloglucan	Acute 96 hr (static)	Mortality, LC_{50}	> 150 mg a.s./ $L_{(nom)}$
	heptamaloxyloglucan	Chronic	Growth, or development, or behaviour, or reproduction NOEC	No quantitative data available. Not required.
Aquatic invertebrates				
Daphnia magna	heptamaloxyloglucan	48 h (static)	Mortality, EC_{50}	> 150 mg a.s./ $L_{(nom)}$
	heptamaloxyloglucan	21 d	Reproduction or development, NOEC	No quantitative data available. Not required.
Sediment-dwelling organisms				
	heptamaloxyloglucan	28 d	NOEC	No quantitative data available. Not required.

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Algae				
Scenedesmus subcapitata	heptamaloxyloglucan	72 h (static)	Growth rate: E_rC_{50} Growth rate: E_rC_{10} Biomass: E_bC_{50} Biomass: E_bC_{10} Yield: E_bC_{50} Yield: E_bC_{10}	>150 mg a.s./$L_{(nom)}$
Higher plant				
	a.s.		Fronds number, EC_{50} (NOEC) <u>Frond area/fresh weight/dry weight</u>, E_rC_{50} (NOEC)	No quantitative data available. Not required.
Further testing on aquatic organisms Not required				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) *Heptamoloxyloglucan is not expected to have endocrine disrupting properties.*				

[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	Metabolite 1	Metabolite 2	Metabolite 3
$logP_{O/W}$	< 0	Not applicable.		
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	-			
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	-			
Annex VI Trigger for the bioconcentration factor	-			
Clearance time (days) (CT_{50})	-			
(CT_{90})	-			
Level and nature of residues (%) in organisms after the 14 day depuration phase	-			
Higher tier study				

* based on total ^{14}C or on specific compounds

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 – ETR (trigger PEC/RAC <1) for heptamaloxyloglucan – Vineyard at 0.56 g a.s./ha x 4 applications

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
		Onchorhynchus mykiss	-	*Daphnia magna*	-	*Scenedesmus subcapitata*	-	-	-
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}	NOEC	NOEC
	Endpoint	>150 000 µg/L	-	>150 000 µg/L	-	>150 000 µg/L			
	Assessment factor	100	-	100	-	10	-	-	
	RAC	>1500 µg/L		>1500 µg/L		>1500 µg/L	-	-	-
FOCUS Step 1	0.77	<0.000513	-	<0.000513	-	<0.000513	-	-	-
			-		-		-	-	-
Trigger		1		1		1			

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

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

Species	Test substance	Time scale/type of endpoint	End point	toxicity
Apis mellifera	Technical heptamaloxyloglucan	Acute	Oral toxicity (LD_{50})	> 100 µg/bee
		Acute	Contact toxicity (LD_{50})	> 100 µg/bee
		Chronic	10 d-LDD50	No data available. Not necessary.
	Galactose	Chronic	16 d-LDD50	> 1620 µg/bee/d
		Bee brood development	NOEClarvae	No data available. Not necessary.

Potential for accumulative toxicity: no
Semi-field test (Cage and tunnel test): No data. Not required.
Field tests: No data. Not required.

Risk assessment for – vineyard - 0.56 g a.s./ha x 4 applications]

SANCO/10329/2002 guidance document

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	Technical heptamaloxyloglucan	HQcontact	<0.0056	50
		HQoral	<0.0056	

EFSA 2013 guidance document

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	Technical heptamaloxyloglucan	HQcontact	<0.0056	42
		ETRacute adult oral	< 0.00006	0.2
		ETRchronic adult oral	-	-
	galactose	ETRchronic* adult oral	3.7×10^{-6}	0.03
	a.s.	ETRlarvae	--	
	a.s.	ETRhpg	-	-

* exposure calculation based on worst-case assumption that all heptamaloxylogucan will be completely transformed in galactose

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	No data. Not necessary.		
Aphidius rhopalosiphi			
Additional species			
	No data available. Not necessary.		

First tier risk assessment

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
	Typhlodromus pyri	-	-	-	2
	Aphidius rhopalosiphi	-	-		2

[1]indicate distance assumed to calculate the drift rate

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)	End point	% effect	ER_{50}
No data. Not necessary.							

Risk assessment

Species	ER_{50} (g/ha)	In-field rate	Off-field rate
-	-	-	-

Semi-field tests
No data. Not necessary.
Field studies
No data. Not necessary.
Additional specific test
No data. Not necessary.

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					
No data. Not necessary. From literature, it was shown that earthworms ingested microflora together with soil in order to degrade oligosaccharides (heptamaloxyloglucan) into monomeric sugars.					
Other soil macroorganisms					
No data. Not necessary.					

[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 necessary.

Nitrogen transformation	No data. Not necessary.

Toxicity/exposure ratios for soil organisms

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
	a.s. /preparation	Chronic	-	-	5
Other soil macroorganisms					
	a.s. /preparation	-	-	-	-

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

Laboratory dose response tests

Species	Test substance	ER_{50} (g a.s./ha) vegetative vigour	ER_{50} (g a.s./ha) emergence	Exposure[1] (g a.s./ha)	TER	Trigger
red cover, wheat, mustard	Heptamaloxyloglucan	> 20	-	0.041	>487	5
Extended laboratory studies: No data. Not required. Semi-field and field test: No data. Not required.						

[1] based on Ganzelmeier drift data for 1 application (2.77%) as worst case (the 90th percentile of the one for 4 application is 1.85%)

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. Not necessary.
Pseudomonas sp	

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. / effect of the PPP. No data.

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

Compartment	
soil	heptamaloxyloglucan
water	heptamaloxyloglucan
sediment	heptamaloxyloglucan
groundwater	heptamaloxyloglucan

[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	heptamaloxyloglucan
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]:	
Peer review proposal[7] for harmonised classification according to Regulation (EC) No 1272/2008:	Not classified for environmental hazard

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

[7] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Used compounds code(s)

Code/Trivial name*	IUPAC name/SMILES notation	Structural formula

* The compound code / trivial name in bold is the name used in the list of endpoints.