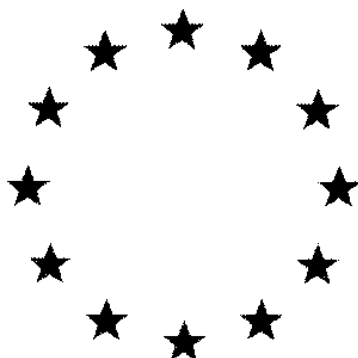


European Commission



**Draft (Renewal) Assessment Report prepared
according to the Commission Regulation (EC) No
1107/2009**

**Daminozide (ISO); 4-(2,2-
dimethylhydrazino)-4-oxobutanoic
acid; *N*-dimethylaminosuccinamic
acid**

List of Endpoints

Rapporteur Member State: Czech Republic
Co-Rapporteur Member State: Hungary

Version history page

Date	Version
May 2018	First draft
October 2018	Co-RMS, Notifier's comments
June 2019	Update following the ECHA accordance check

List of end points

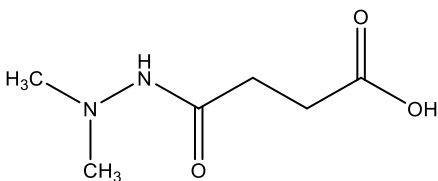
Rapporteur Member State	Month and year	Active substance (Name)
Czech Republic	October 2018	Daminozide

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information

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)	Daminozide (ISO)
Function (<i>e.g.</i> fungicide)	Plant Growth Regulator
Rapporteur Member State	Czech Republic
Co-rapporteur Member State	Hungary

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

Chemical name (IUPAC)	N-dimethylaminosuccinamic acid or 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid
Chemical name (CA)	Butanedioic acid mono(2,2-dimethylhydrazide)
CIPAC No	330
CAS No	1596-84-5
EC No (EINECS or ELINCS)	216-485-9
FAO Specification (including year of publication)	Not established
Minimum purity of the active substance as manufactured	990 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	N-nitrosodimethylamine (NDMA) max. 2.0 mg/kg 1,1-dimethylhydrazide (UDMH) max. 30 mg/kg
Molecular formula	C ₆ H ₁₂ N ₂ O ₃
Molar mass	160.2 g/mol
Structural formula	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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

Melting point (state purity)	153-154.5°C (99.9%)
Boiling point (state purity)	The test item decomposed at 142-145°C at normal atmospheric pressure with no boiling point observed (99.4%)
Temperature of decomposition (state purity)	142-145°C at normal atmospheric pressure (99.4%)
Appearance (state purity)	Slightly off-white crystalline solid (99.8%) Slightly off-white crystalline solid (99.9%)
Vapour pressure (state temperature, state purity)	1.5×10^{-6} Pa at 25°C (99.7%)
Henry's law constant (state temperature)	1×10^{-9} Pa m ³ mol ⁻¹ at 25°C
Solubility in water (state temperature, state purity and pH)	128 g/L at 20°C (pH 4) (100%)
Solubility in organic solvents (state temperature, state purity)	Acetone: 1.61 g/L at 20°C (100%) Methanol: 48.0 g/L at 20°C (100%) Toluene: < 0.01 g/L at 25°C (100.1%) Dichloromethane: 0.157 g/L at 25°C (100.1%) Acetone: 1.47 g/L at 20°C (99.9%) Methanol: 50 g/L at 20°C (99.9%) Ethyl acetate: 0.27 g/L at 20°C (99.9%)
Surface tension (state concentration and temperature, state purity)	69.8 mN/m at 25°C (0.1% solution of Daminozide in Milli-RO water) (99.9%)
Partition coefficient (state temperature, pH and purity)	Log P _{OW} = - 1.53 at 20°C (pH 3) (100%)
Dissociation constant (state purity)	pKa = 4.68 (99.3%)
UV/VIS absorption (max.) incl. ϵ (state purity, pH)	Neutral (pH = 6.99) (99.4%) λ_{\max} (191 nm): $\epsilon = 6520 \text{ L mol}^{-1} \text{ cm}^{-1}$ Acidic (pH = 1.95) (99.4%) λ_{\max} (198 nm): $\epsilon = 951 \text{ L mol}^{-1} \text{ cm}^{-1}$ Alkaline (pH = 10.10) (99.4%) λ_{\max} (192 nm): $\epsilon = 6966 \text{ L mol}^{-1} \text{ cm}^{-1}$ No absorption at wavelengths above 290 nm.
Flammability (state purity)	Not flammable (99.9%)
Explosive properties (state purity)	Not explosive (99.9%)
Oxidising properties (state purity)	Not an oxidizer (99.7%)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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	kg a.s./ha min-max (l)		
Ornamentals	EU	ALAR/Dazide Enhance	G	Plant growth regulator	SG	850 g/kg	gantry automated/hand held	Actively growing plants	5	7	0.51-1.53	500-1500	7.65		
Ornamentals	EU	ALAR/Dazide Enhance	F	Plant growth regulator	SG	850 g/kg	hand held	Actively growing plants	5	7	0.28-0.85	500-1500	4.25		

- (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

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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)															
Not applicable															

(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).**

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(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

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis**Further information, Efficacy****Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)**

Available efficacy data show that daminozide acts as a plant growth regulator to produce more robust plants. Representative use GAPs are supported by available data

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

There are no adverse effects on field crops

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

No undesirable or unintended side effects have been observed

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

Activity against target organism

-
-

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis**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)	HPLC-UV
Impurities in technical a.s. (analytical technique)	HPLC-UV; GC
Plant protection product (analytical technique)	HPLC-UV

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	Daminozide (sum of daminozide and 1,1-dimethyl-hydrazine (UDMH), expressed as daminozide)
Food of animal origin	Daminozide (sum of daminozide and 1,1-dimethyl-hydrazine (UDMH), expressed as daminozide)
Soil	Daminozide
Sediment	Daminozide
Water surface	Daminozide
drinking/ground	Daminozide
Air	Daminozide, 1,1-dimethyl-hydrazine (UDMH)
Body fluids and tissues	Not applicable

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Considering that the use of daminozide is restricted to non-consumable crops and that residues are not defined in commodities of plant and animal origin, methods for the determination of daminozide residues in or on food and feed of plant and animal origin are not required.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Considering that the use of daminozide is restricted to non-consumable crops and that residues are not defined in commodities of plant and animal origin, methods for the determination of daminozide residues in or on food and feed of plant and animal origin are not required.
Soil (analytical technique and LOQ)	HPLC-MS/MS; daminozide 0.05 mg/kg
Water (analytical technique and LOQ)	LC-MS/MS; 0.1 µg/L
Air (analytical technique and LOQ)	LC-MS/MS; daminozide 160 µg/m ³ (validation is not sufficient), UDMH 0.025 µg/m ³
Body fluids and tissues (analytical technique and LOQ)	According to guideline SANCO/825/00 rev. 8.1 method of analysis is not required if active substance is not classified as either toxic or highly toxic nor is classified according to CLP as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1). On the contrary under regulation 1107/2009 this method is always required. Method is ongoing and expected Q4 2018.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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

Substance

Daminozide

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:

None

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.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 2 Mammalian Toxicology

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

Absorption was rapid and estimated at 35% for risk assessment purposes, based on urinary and respiratory excretion. Absorption appears saturable.

Toxicokinetics

Toxicokinetic parameters of C_{max} , T_{max} , Plasma $t_{1/2}$ were not determined.

Distribution

Distribution is wide, with radioactivity found mainly in the liver.

Potential for bioaccumulation

No evidence for accumulation

Rate and extent of excretion

Elimination is rapid (nearly complete within 48 hours) with the faeces being the main route of excretion, followed by the urine and expired air. Bile is not an important route of excretion.

Metabolism in animals

Daminozide appears to be largely metabolised to unsymmetrical dimethylhydrazine (UDMH) in rats receiving an oral low dose (ca. 30% of administered dose). Approximately 40% of administered dose is found in urine and faeces of rats as the unchanged parent compound. In urine and faeces of miniature swine, daminozide is converted also to N-nitrosodimethylamine (NDMA) in addition to UDMH, and UDMH is found also in the liver.

In vitro metabolism

In vitro comparative study was not conclusive with regard to the role of UDMH and NDMA in human metabolism. It cannot be excluded that daminozide is *in vivo* extensively metabolised to the UDMH.

Toxicologically relevant compounds (animals and plants)

Daminozide, Unsymmetrical dimethylhydrazine (UDMH), Nitrosodimethylamine (NDMA)

Toxicologically relevant compounds (environment)

Daminozide, formaldehyde and unsymmetrical dimethylhydrazine (UDMH).

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 2 Mammalian Toxicology**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	> 2.1 mg/L air /4h (<i>nose only exposure</i>) (<i>highest dose attainable</i>)	
Skin irritation	Non-irritant	
Eye irritation	Mildly-irritant	
Skin sensitisation	Non-sensitiser (<i>LLNA</i>)	
Phototoxicity	Not required	

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

Target organ / critical effect	Rat: No adverse effects Dog: Renal cell adenoma, food-like emesis, soft stool	
Relevant oral NOAEL	1 –year dog: 80.5 mg/kg bw per day 90-day rat: 1000 mg/kg bw per day	
Relevant dermal NOAEL	28-day, rat: 2000 mg/kg bw per day	
Relevant inhalation NOAEL	No data - not required	

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

<i>In vitro</i> studies	No genotoxic potential	
<i>In vivo</i> studies	No genotoxic potential	
Photomutagenicity	No genotoxic potential	
Potential for genotoxicity	No genotoxic potential	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 2 Mammalian Toxicology

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

Long-term effects (target organ/critical effect)	Mouse (decreased blood platelet counts; carcinogenic effects) Rat (carcinogenic effects)	Carc. 1B
Relevant long-term NOAEL	2-year, mouse: 45 mg/kg bw per day 2-year, rat: 10 mg/kg bw per day	
Carcinogenicity (target organ, tumour type)	Pituitary adenomas, Pulmonary neoplasms (Carcinomas + adenomas)	
Relevant NOAEL for carcinogenicity	2-year, mouse: Cannot be derived 2-year, rat: Provisional NOAEL of 5 mg/kg/bw day	

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

Reproduction toxicity

Reproduction target / critical effect	Parental: loose faeces, excessive post-dose salivation, perianal fur staining, increased water consumption Developmental: No adverse effect observed Fertility: No adverse effect observed	
Relevant parental NOAEL	360 mg/kg bw per day	
Relevant reproductive NOAEL	1200 mg/kg bw per day	
Relevant offspring NOAEL	1200 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect	Maternal: mortality, clinical signs (soft/liquid faeces, hyperpnoea, hyperactivity, convulsions) Developmental: slight reduction in ossification	
Relevant maternal NOAEL	250 mg/kg bw per day	
Relevant developmental NOAEL	500 mg/kg bw per day	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 2 Mammalian Toxicology**Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)**

Acute neurotoxicity	The NOAEL was 1000 mg/kg bw per day. Decreased locomotor activity (basic and fine movement, total distance)	
Repeated neurotoxicity	The NOAEL was 1000 mg/kg bw per day (the top dose tested). No adverse signs of systemic toxicity or any evidence of neurotoxicity were evident.	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	No studies conducted.	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 2 Mammalian Toxicology

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

Supplementary studies on the active substance

Immunotoxicity Daminozide Technical was not immunotoxic in CD-1 Female Mice (Anti-Sheep Red Blood Cell (SRBC) Response, 28 day administration)

Endocrine disrupting properties

There were no effects in the repeat dose toxicity studies that could be interpreted as being mediated via the endocrine system

Studies performed on metabolites or impurities

Genotoxicity and repeat dose toxicity studies were provided for UDMH. The CLP Regulation lists UDMH with the following harmonised classification and labelling for toxicology (Index No: 007-012-00-5): Carc. 1B, Acute Tox. 3, Skin Corr. 1B, H350, H331, H301 and H314. The Carc. 1B classification applies at C \geq 0.001%.

Based on the available data, the genotoxic potential of UDMH cannot be unequivocally concluded.

90 day mice study - accentuation of liver lobulation, karyomegaly/hypertrophy of the liver.

90 days rat study – No treatment related effects

2 years rat study – chronic liver inflammation, decreases in water consumption, increased incidence of cloudy corneas, increased incidence of hepatocellular neoplasms

2 years mice study – low dose – increased incidence of lung tumours

2 years mice study – high dose – increased in mortality, inflammation and brown liver pigmentation, hepatocyte hypertrophy, increased incidences of liver hemangioma/hemangiosarcoma, alveolar/bronciolar adenoma/carcinoma

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 2 Mammalian Toxicology

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

No signs/symptoms related to possible exposure to daminozide technical have so far been recorded in manufacturing plant personnel.

Summary³ (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

Acceptable Daily Intake (ADI)

Acute Reference Dose (ARfD)

Acceptable Operator Exposure Level (AOEL)

Value (mg/kg bw (per day))	Study	Uncertainty factor
0.025	rat, 2-year	200
Not necessary	-	
0.009	rat, 2-year	200

* Including correction for limited oral absorption/bioavailability (35 %).

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

Representative formulation (Dazide Enchance (SG) 850 g/kg daminozide a.s.)

Concentrate: 0.2 %
 Spray dilution (0.425 g/L): 1.9 %
 Spray dilution (5.1 g/L): 1.2 %

For the purpose of assessing re-entry worker exposure a further two product dilutions were assessed after being mixed with an artificial sweat, **0.97%** for the highest re-entry product dilution (112 g/L) and **0.77%** for the lowest re-entry product dilution (11.2 g/L)
in vitro human skin

Representative formulation (Alar 850 SG, 850 g/kg daminozide a.s.)

Concentrate: 0.4 %
 Spray dilution (2.83 g/L): 2 %
in vitro human skin

B-Nine (UDMH as impurity in technical daminozide, 0.15%)

10.7 % at 0.116 µg/cm²
 20.1% at 1.13 µg/cm²
 24.5% at 12.5 µg/cm²
in vivo rat

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

Operators

Alar (daminozide)
Use: ornamentals, indoor, automated/hand-held equipment, application rate 7.65 kg a.s./ha

³ If available include also reference values for metabolites

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 2 Mammalian Toxicology

<u>Exposure estimates (model):</u>	<u>% of AOEL</u>
<u>UK POEM</u>	
Without PPE (automated application)	73
<u>German model</u>	
Without PPE (automated application)	20
<u>EFSA AOEM</u>	
PPE (gloves, RPE) (automated application)	17
<u>NL Glasshouse model</u>	
PPE (gloves, coverall and RPE) (hand-held application)	624
<u>Southern European Glasshouse model</u>	
PPE (gloves, coverall, RPE)(hand-held, low crops)	71
PPE (gloves, impervious clothing, RPE, headgear) (hand-held, high crops)	84
Alar (UDMH)	
<u>Use:</u> ornamentals, indoor, automated/hand-held equipment, application rate 7.65 kg a.s./ha	
<u>Exposure estimates (model):</u>	<u>% of AOEL</u>
<u>UK POEM</u>	
Without PPE (automated application)	2
<u>German model</u>	
Without PPE (automated application)	1
<u>EFSA AOEM</u>	
PPE (gloves, RPE) (automated application)	34
<u>NL Glasshouse model</u>	
PPE (gloves, coverall and RPE) (hand-held application)	57
<u>Southern European Glasshouse model</u>	
PPE (gloves, coverall, RPE)(hand-held, low crops)	2
PPE (gloves, impervious clothing, RPE, headgear) (hand-held, high crops)	8
Dazide Enhance (daminozide)	
<u>Use:</u> ornamentals, indoor, automated/hand-held equipment, application rate 7.65 kg a.s./ha	
<u>Exposure estimates (model):</u>	<u>% of AOEL</u>
<u>UK POEM</u>	
Without PPE (automated application)	59

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 2 Mammalian Toxicology

<u>German model</u>	
Without PPE (automated application)	15
<u>EFSA AOEM</u>	
PPE (gloves, RPE) (automated application)	16
<u>NL Glasshouse model</u>	
PPE (gloves, coverall and RPE) (hand-held application) 600	
<u>Southern European Glasshouse model</u>	
PPE (gloves, coverall, RPE)(hand-held, low crops)	70
PPE (gloves, impervious clothing, RPE, headgear) (hand-held, high crops)	81
Dazide Enhance (UDMH)	
<u>Use:</u> ornamentals, indoor, automated/hand-held equipment, application rate 7.65 kg a.s./ha	
<u>Exposure estimates (model):</u>	<u>% of AOEL</u>
<u>UK POEM</u>	
Without PPE (automated application)	2
<u>German model</u>	
Without PPE (automated application)	1
<u>EFSA AOEM</u>	
PPE (gloves, RPE) (automated application)	34
<u>NL Glasshouse model</u>	
PPE (gloves, coverall and RPE) (hand-held application)	57
<u>Southern European Glasshouse model</u>	
PPE (gloves, coverall, RPE)(hand-held, low crops)	2
PPE (gloves, impervious clothing, RPE, headgear) (hand-held, high crops)	8
Alar (daminozide)	
<u>Use:</u> ornamentals, outdoor, hand-held equipment, application rate 4.25 kg a.s./ha	
<u>Exposure estimates (model):</u>	<u>% of AOEL</u>
<u>UK POEM</u>	
PPE (gloves and coverall, RPE during M/L) (hand-held application)	692
<u>EFSA AOEM</u>	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 2 Mammalian Toxicology

PPE (gloves, RPE) (manual hand-held)	393
<u>EFSA AOEM</u>	
PPE (gloves, RPE) (manual knapsack)	99
Alar (UDMH)	
<u>Use:</u> ornamentals, outdoor, automated/hand-held equipment, application rate 4.25 kg a.s./ha	
<u>Exposure estimates (model):</u>	<u>% of AOEL</u>
<u>UK POEM</u>	
PPE (gloves and coverall, RPE during M/L)	
(hand-held application)	62
<u>EFSA AOEM</u>	
PPE (gloves, RPE) (manual hand-held)	17732
<u>EFSA AOEM</u>	
PPE (gloves, RPE) (manual knapsack)	17857
Dazide Enhance (daminozide)	
<u>Use:</u> ornamentals, outdoor, hand-held equipment, application rate 4.25 kg a.s./ha	
<u>Exposure estimates (model):</u>	<u>% of AOEL</u>
<u>UK POEM</u>	
PPE (gloves and coverall, RPE during M/L)	
(hand-held application)	665
<u>EFSA AOEM</u>	
PPE (gloves, RPE) (manual hand-held)	25
<u>EFSA AOEM</u>	
PPE (gloves, RPE) (manual knapsack)	12
Dazide Enhance (UDMH)	
<u>Use:</u> ornamentals, outdoor, automated/hand-held equipment, application rate 4.25 kg a.s./ha	
<u>Exposure estimates (model):</u>	<u>% of AOEL</u>
<u>UK POEM</u>	
PPE (gloves and coverall, RPE during M/L)	
(hand-held application)	62
<u>EFSA AOEM</u>	
PPE (gloves, RPE) (manual hand-held)	17732
<u>EFSA AOEM</u>	
PPE (gloves, RPE) (manual knapsack)	17857

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 2 Mammalian Toxicology

Workers

ALAR (daminozide)	
<u>German model</u>	
PPE (gloves, RPE)	141
<u>EFSA AOEM</u>	
PPE (gloves)	1273
ALAR (UDMH)	
<u>German model</u>	
PPE (gloves, RPE)	81
<u>EFSA AOEM</u>	
PPE (gloves)	96
DAZIDE ENHANCE (daminozide)	
<u>German model</u>	
PPE (gloves, RPE)	295
<u>EFSA AOEM</u>	
PPE (gloves)	1426
DAZIDE ENHANCE (UDMH)	
<u>German model</u>	
PPE (gloves, RPE)	79
<u>EFSA AOEM</u>	
PPE (gloves)	96

Bystanders and residents

ALAR (daminozide)	
72 % of AOEL (bystander, German model, adult)	
148 % of AOEL (bystander, German model, child)	
4 % of AOEL (residential, German model, adult)	
8 % of AOEL (residential, German model, child)	
377 % of AOEL (residential, EFSA AOEM, adult, all pathways)	
706 % of AOEL (residential, EFSA AOEM, child, , all pathways)	
ALAR (UDMH)	
2 % of AOEL (bystander, German model, adult)	
3 % of AOEL (bystander, German model, child)	
26 % of AOEL (residential, German model, adult)	
49 % of AOEL (residential, German model, child)	
266 % of AOEL (residential, EFSA AOEM, adult, all pathways)	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 2 Mammalian Toxicology

1209 % of AOEL (residential, EFSA AOEM, child, , all pathways)

DAZIDE ENHANCE (daminozide)

72 % of AOEL (bystander, German model, adult)

148 % of AOEL (bystander, German model, child)

4 % of AOEL (residential, German model, adult)

8 % of AOEL (residential, German model, child)

359 % of AOEL (residential, EFSA AOEM, adult, all pathways)

672 % of AOEL (residential, EFSA AOEM, child, , all pathways)

DAZIDE ENHANCE (UDMH)

2 % of AOEL (bystander, German model, adult)

3 % of AOEL (bystander, German model, child)

26 % of AOEL (residential, German model, adult)

49 % of AOEL (residential, German model, child)

266 % of AOEL (residential, EFSA AOEM, adult, all pathways)

1209 % of AOEL (residential, EFSA AOEM, child, , all pathways)

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

Substance :

Daminozide

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 :

Not classified for human health effects

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

Carc. 1B

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.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 3 Residues

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				
	Leafy crops				
	Cereals/grass crops				
	Pulses/Oilseeds				
	Miscellaneous				
Not relevant. Metabolism studies in plants are not required since the proposed use is in non-edible crops (ornamentals)					
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?	Not relevant. Metabolism studies in plants are not required since the proposed use is in non-edible crops (ornamentals)				
Processed commodities (standard hydrolysis study) OECD Guideline 507	Conditions				
	20 min, 90°C, pH 4				
	60 min, 100°C, pH 5				
	20 min, 120°C, pH 6				
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not relevant. No uses on edible crops.				
Plant residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31		Daminozide (sum of daminozide and 1,1-dimethylhydrazine (UDMH) expressed as daminozide)			
Plant residue definition for risk assessment (RD-RA)					
Conversion factor (monitoring to risk assessment)		Not relevant			

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)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 3 Residues

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		
	Not relevant. Metabolism studies in farm animals or fish are not required since the proposed use is in non-edible crops (ornamentals)			
Time needed to reach a plateau concentration in milk and eggs (days)		Not relevant		
Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31		Daminozide (sum of daminozide and 1,1-dimethylhydrazine (UDMH) expressed as daminozide)		
Animal residue definition for risk assessment (RD-RA)		Daminozide (sum of daminozide and 1,1-dimethylhydrazine (UDMH) expressed as daminozide)		
Conversion factor (monitoring to risk assessment)		None		
Metabolism in rat and ruminant similar (Yes/No)		Not relevant		
Fat soluble residues (Yes/No) (FAO, 2009)		No		

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	EFSA noted "that rotation of ornamental crops with edible crops is rather unusual due to their specificities". In addition, Daminozide has a very short DT ₉₀ (ca. 2-3 days) and the major metabolite, methanol, was seen at 21% after 16 hours (0.32 mg/kg) reducing to 0.02 mg/kg after 72 hours. A new aerobic soil metabolism study confirmed these findings; 2 days after treatment, >90% of Daminozide had degraded and 4 days after treatment >80% of the radioactivity was recovered as carbon dioxide. Based on this information, no detectable residues would be expected in following crops.
Field rotational crop study OECD Guideline 504	Not relevant – see comments on confined rotational crop study above

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 3 Residues**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						

Not relevant since residues trials are not required to support the use on non-edible crops (ornamentals)

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

Not relevant since feeding studies are not required to support the use on non-edible crops (ornamentals)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 3 Residues

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)
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Representative uses (row to be deleted if not relevant)

Ornamentals		Not relevant				
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Summary of the data on formulation equivalence OECD Guideline 509

Crop	Region	Residue data (mg/kg)	Recommendations/comments			

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

Product(s)	Region	Residue data (mg/kg)	Recommendations/comments			
			Not required at present since no guideline is available			

- (a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
- (b): Residue levels in trials conducted according to GAP reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Monitoring** and **Risk Assessment**.
- (c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{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}).

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 3 Residues**Inputs for animal burden calculations**

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Representative uses (row to be deleted if not relevant)				
		Not relevant since use is on non-edible crops (ornamentals)		

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 3 Residues

**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)
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) (mg/kg DM for fish)	Beef cattle	0	Ram/Ewe	0	Breeding	0	Broiler	0	Carp	0
	Dairy cattle	0	Lamb	0	Finishing	0	Layer	0	Trout	0
							Turkey		Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	No		No		No		No		No	
Feeding study submitted	No		No		No		No		No	
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

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 3 Residues

^(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	0	Ram/Ewe	0	Breeding	0	Broiler	0	Carp	0
	Dairy cattle	0	Lamb	0	Finishing	0	Layer	0	Trout	0
							Turkey			
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.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Czech Republic	October 2018	Daminozide

Section 3 Residues**Conversion Factors (CF) for monitoring to risk assessment**

Not relevant since use is on non-edible crops (ornamentals)

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

Not relevant since use is on non-edible crops (ornamentals)

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).

ADI	0.45 mg/kg bw per day
TMDI according to EFSA PRIMo	Highest TMDI: 0.3 % ADI (UK, toddler)
NTMDI, according to (to be specified)	Not calculated since TMDI <1% of ADI
IEDI (% ADI), according to EFSA PRIMo	Not calculated since TMDI <1% of ADI
NEDI (% ADI), according to (to be specified)	Not calculated since TMDI <1% of ADI
Factors included in the calculations	None
ARfD	Not required
IENTI (% ARfD), according to EFSA PRIMo	Not relevant
NESTI (% ARfD), according to (to be specified)	Not relevant
Factors included in IESTI and NESTI	None

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		
		No changes proposed to MRLs published Commission Regulation (EU) No. 2017/624 of 30 st March 2017

(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.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

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	57.9- 68.4 % after 62 d, [¹⁴ C-dimethylamino]-label (n ⁶ = 4)
Non-extractable residues after 100 days	23.1 – 33.5 % after 62 d, [¹⁴ C-dimethylamino]-label (n= 4)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	M1* – 18.6 – 27.2 % at 1-2 d (n=4) [¹⁴ C-dimethylamino]- label

* M1 subsequently identified as methanol

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

Mineralisation after 100 days	Study is not reliable.
Non-extractable residues after 100 days	-
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	-

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)	None – UV/ Vis spectra demonstrate negligible absorption of light of wavelengths > 290 nm. Soil photolysis not expected to occur.
Mineralisation at study end	Not applicable.
Non-extractable residues at study end	Not applicable.

⁶ n corresponds to the number of soils.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

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)

Modelling and trigger endpoints

Parent	Dark aerobic conditions					
Soil type	pH ^{a)}	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa ^{b)}	St. (χ ²)	Method of calculation
LUFA 2.4 - Loam	7.2	20/ 40	0.37/ 1.21	0.23	3.0	SFO
LUFA 2.2 – Loamy sand	5.5	20/ 40 ^{c)}	0.11/ 0.35	0.11	7.7	SFO
LUFA 5M – Sandy loam	7.3	20/ 40 ^{c)}	0.14/ 0.47	0.12	6.0	SFO
Fisilis – Silt loam	6.8	20/ 40 ^{c)}	0.15/ 0.50	0.06	8.0	SFO
Geometric mean (if not pH dependent)			-	0.12	-	-
pH dependence				No		

^{a)} Measured in 0.01M CaCl₂

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^{c)} Standard soil moisture values used from FOCUS (2012): Generic guidance for Tier 1 FOCUS groundwater assessments; V.2.1, Dec., 2012.

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)

Methanol (incl. evap. losses)	Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was daminozide						
Soil type	pH ^{a)}	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _f / k _{dp}	DT ₅₀ (d) 20 °C pF2/10kPa ^{b)}	St. (χ ²)	Method of calculation
LUFA 2.4 - Loam	7.2	20/ 40	6.2/ 20.5	0.25	3.8	24.6	SFO
LUFA 2.2 – Loamy sand	5.5	20/ 40 ^{c)}	6.1/ 20.1	0.29	6.1	18.9	SFO
LUFA 5M – Sandy loam	7.3	20/ 40 ^{c)}	5.9/ 19.4	0.26	5.1	18.3	SFO
Fisilis – Silt loam	6.8	20/ 40 ^{c)}	4.5/ 15.0	0.29	1.9	18.3	SFO
Geometric mean (if not pH dependent)			-	-	3.9	-	-
Arithmetic mean			-	0.27	-	-	-
pH dependence					No		

^{a)} Measured in 0.01M CaCl₂

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^{c)} Standard soil moisture values used from FOCUS (2012): Generic guidance for Tier 1 FOCUS groundwater assessments; V.2.1, Dec., 2012.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

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

No valid field dissipation study available, not required.

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

Not applicable.

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

Soil accumulation concentration is not required to be calculated - Maximum DT₉₀ << 1 year.

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 reliable endpoint available.

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

UV/ Vis absorption spectra demonstrate negligible absorption of light with wavelengths > 290 nm. Photolytic degradation expected to be negligible.

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)

Results are not accurate, new study is required.

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
Maryland – Clay+	2.8	5.9	-	-	0.642	23.0	1.107
Maryland – Sand	0.5	6.5	-	-	0.096	18.5	1.285
Mississippi - Loam	0.7	7.6	-	-	0.128	18.4	1.368
California- Sandy Loam	0.3	6.5	-	-	0.135	46.5	1.315
Geometric mean (if not pH dependent)*					-	-	-
Arithmetic mean (if not pH dependent)					0.250	26.6	1.269
pH dependence			No				

^{a)} Measured in [medium not stated]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

* Only relevant after implementation of the published EFSA guidance.

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)

Methanol – Batch adsorption/ desorption studies not possible due to methanol's high volatility – K_{oc} calculated using KOCWIN v2.0 = 1.0 L/kg (MCI method), 1.2 L/ kg (LogKow method).
Worst case value of 1.0 L/kg used in exposure assessments.

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 applicable.

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

Elution (mm): 132.6 mm (10 x 100 mL aliquots)
Time period (d): Aged for 2 days prior to leaching. Soil residue immediately prior to leaching comprised 28.8 % AR daminozide, 36.4 % AR polar fraction, < 5 % AR non-polar fraction.
Leachate: 56.3 % radioactivity in leachate (only active substance characterised (comprised 84.3 % leached radioactivity); remaining fractions < 5 % AR.
42 % radioactivity retained in soil (analysis displayed only polar products)
 K_{oc} (mL/g) = Not calculated.

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)

No studies submitted and none 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

pH 7: Stable

pH 9: Stable

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

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

Photolytic degradation of active substance and metabolites above 10 %

Daminozide

DT₅₀: stable (sterilised pure water)

36.8 days (sterilised natural water)

Metabolites

metabolite DT₅₀ values were not calculated.

The maximum metabolite concentration in sterilised natural water was 5.2 % AR (Unknown-2), all other metabolites < 5 % AR.

All maximum metabolite concentrations in sterilised pure water < 5 % AR.

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

Not calculated.

'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)

No endpoint is considered valid.

(Unknown polar metabolite (probably identified as methanol, this has to be confirmed) max. 75.7% AR).

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 (max in water 77.6 - 85.5 % AR after 0 d. Max. sed 2.7 – 6.7 % AR after 0 – 7 hours)									
Water / sediment system	pH water phase	pH sed ^{a)}	t. °C	DT ₅₀ /DT ₉₀ whole sys.	St. (X ²)	DT ₅₀ /DT ₉₀ water	St. (X ²)	DT ₅₀ /DT ₉₀ sed	St. (X ²)	Method of calculation
TNO Ditch	7.1	7.5	20	0.935/3.10	10.6	-	-	-	-	SFO
Kromme Rijn River	6.4	7.6	20	0.878/2.92	5.7	-	-	-	-	SFO
Geometric mean at 20°C ^{b)}				0.906/3.01						

^{a)} Measured in 0.01M CaCl₂

^{b)} Normalised using a Q10 of 2.58

Polar Metabolite ^{a)}	Distribution (max in water 15.1 – 17.0 % AR after 4 - 7 days. Max. in sed 7.1 – 9.5 % AR after 7 days). Max in total system 23.3 – 24.1 % AR after 7 days, Kinetic endpoints are not reliable
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List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

^{a)} The polar metabolite was reported in the study report to be formaldehyde. However, the identification of the polar metabolite is unreliable, and based on comparison to analysis of the polar metabolites in other studies is now considered most likely to be methanol.

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)
TNO Ditch	7.1	7.5	38.4 (7 days)	21.5 after 21 d	21.5 after 21 d
Kromme Rijn River	6.4	7.6	38.9 (7 days)	34.9 after 21 d	34.9 after 21 d

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 10.570 hours derived by the Atkinson model (AOPWIN version 1.92). OH (12 h) concentration assumed = $1.5 \times 10^6 \text{ cm}^{-3}$
Volatilisation	from plant surfaces (BBA guideline): Study not required. from soil surfaces (BBA guideline): Study not required.
Metabolites	Methanol: DT ₅₀ of 17.36 days derived by the Atkinson model (AOPWIN version 1.92). OH* (12 h) concentration assumed = $1.5 \times 10^6 \text{ cm}^{-3}$.

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: daminozide, methanol ² Surface water: daminozide, methanol ² Sediment: daminozide, methanol ² Ground water: daminozide, methanol ² Air: daminozide, methanol ²
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Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

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

Field use

Parent	DT ₅₀ (d): 0.37 days Kinetics: SFO Field or Lab: representative worst case from laboratory aerobic degradation studies.
Method of calculation	
Application data	Crop: Outdoor Ornamental crops Depth of soil layer: 5cm Soil bulk density: 1.5g/cm ³ % plant interception: 50 % ^{a)} Number of applications: 5 Interval (d): 7 Application rate(s): 4250 g a.s./ha

^{a)} a high crop interception in the field is anticipated; 50 % crop interception assumed as a worst case.

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	2.833	-	2.833	-
Short term 24h	0.435	1.280	0.435	1.280
2d	0.067	0.738	0.067	0.738
4d	0.002	0.378	0.002	0.378
Long term 7d	0.000	0.216	0.000	0.216
28d	0.000	0.054	0.000	0.054
50d	0.000	0.030	0.000	0.030
100d	0.000	0.015	0.000	0.015
Plateau concentration	Not required			

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

Indoor use

Parent

Method of calculation

DT₅₀ (d): 0.37 days

Kinetics: SFO

Field or Lab: representative worst case from laboratory aerobic degradation studies.

Application data

Crop: Indoor Ornamental crops

Depth of soil layer: 5cm

Soil bulk density: 1.5g/cm³

% plant interception: 50 % ^{a)}

Number of applications: 5

Interval (d): 7

Application rate(s): 7650 g a.s./ha

^{a)} a high crop interception in the field is anticipated; 50 % crop interception assumed as a worst case.

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	5.100	-	5.100	-
Short term 24h	0.783	2.304	0.783	2.304
2d	0.120	1.304	0.120	1.304
4d	0.003	0.680	0.003	0.680
Long term 7d	0.000	0.389	0.000	0.389
28d	0.000	0.097	0.000	0.097
50d	0.000	0.054	0.000	0.054
100d	0.000	0.027	0.000	0.027
Plateau concentration	Not required			

Field use

Methanol

Method of calculation

Molecular weight relative to the parent: 0.20 (32.0 g/mol/ 160.2 g/mol)

DT₅₀ (d): 6.2 days

Kinetics: SFO

Field or Lab: representative worst case from laboratory aerobic degradation studies.

Application data

Application rate assumed: 5 x 230.8 g/ha (assumed that methanol is formed at a maximum of 27.2 % of the applied dose)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.154	-	0.278	-
Short term 24h	0.138	0.146	0.248	0.263
2d	0.123	0.138	0.222	0.249
4d	0.098	0.124	0.178	0.224
Long term 7d	0.070	0.107	0.127	0.193
28d	0.007	0.078	0.012	0.085
50d	0.001	0.027	0.001	0.050
100d	0.000	0.014	0.000	0.025
Plateau concentration	Not required			

Indoor use

Methanol
Method of calculation

Molecular weight relative to the parent: 0.20 (32.0 g/mol/ 160.2 g/mol)
DT₅₀ (d): 6.2 days
Kinetics: SFO
Field or Lab: representative worst case from laboratory aerobic degradation studies.

Application data

Application rate assumed: 5 x 415.4 g/ha (assumed that methanol is formed at a maximum of 27.2 % of the applied dose)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.277	-	0.500	-
Short term 24h	0.248	0.262	0.447	0.473
2d	0.221	0.248	0.400	0.448
4d	0.177	0.223	0.320	0.403
Long term 7d	0.127	0.192	0.229	0.347
28d	0.012	0.085	0.022	0.153
50d	0.001	0.049	0.002	0.089
100d	0.000	0.025	0.000	0.045
Plateau concentration	Not required			

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

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

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

For FOCUS gw modelling, values used –
Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.
Model(s) used: FOCUS PEARL 4.4.4
Crop: Ornamentals (maize used as surrogate FOCUS crop)
Parent crop uptake factor: 0.5
Parent water solubility (mg/L): 128000 at pH 4 and 20°C
Parent vapour pressure: 1.5×10^{-6} Pa at 25°C
Geometric mean parent DT_{50lab} 0.12 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).
 K_{oc} : parent arithmetic mean 18.4 mL/g, arithmetic mean $1/n = 1.368$ (max. value of 1.3 can be used by the model).
Metabolites:
Methanol crop uptake factor: 0.0
Methanol water solubility (mg/L): 1,000,000 at pH 7 and 25°C
Methanol vapour pressure 1.69×10^4 Pa at 25°C
Geometric mean methanol DT_{50lab} : 3.9 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).
 K_{oc}^a : methanol 1.0 mL/g, $1/n = 1.0$.
Methanol formation fraction from parent: 0.27

Application rate

Ornamental Crops – Field application
Gross application rate: 4250 g/ha.
Crop growth stage: Actively growing plants
Canopy interception %: 50 %
Application rate net of interception: 2125 g/ha.
No. of applications: 5 (7-day application interval)
Time of application (absolute or relative application dates): 1, 8, 15, 22, 29 April
Ornamental Crops – Indoor application
Gross application rate: 7650 g/ha.
Crop growth stage: Actively growing plants
Canopy interception %: 50 %
Application rate net of interception: 3825 g/ha.
No. of applications: 5 (7-day application interval)
Time of application (absolute or relative application dates): 1, 8, 15, 22, 29 April

a) It was not possible to perform reliable batch adsorption studies for methanol because of the practical difficulties created by its high volatility. The input K_{oc} value for methanol was the worst case value derived from the KOCWIN v2.0 tool in EPIWEB of 1.0 mL/g. A default $1/n$ value of 1.0 was also input.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

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

FOCUS PEARL 4.4.4 / Ornamental Crops – Indoor application	Scenario	Parent (µg/L)	Methanol (µg/L)
	Chateaudun	<0.0001	0.004
	Hamburg	<0.0001	0.028
	Jokioinen	-	-
	Kremsmunster	<0.0001	0.048
	Okehampton	<0.0001	0.087
	Piacenza	<0.0001	0.046
	Porto	<0.0001	0.023
	Sevilla	<0.0001	<0.0001
	Thiva	<0.0001	<0.0001

FOCUS PEARL 4.4.4 / Ornamental Crops – Field application	Scenario	Parent (µg/L)	Methanol (µg/L)
	Chateaudun	<0.0001	0.002
	Hamburg	<0.0001	0.016
	Jokioinen	-	-
	Kremsmunster	<0.0001	0.027
	Okehampton	<0.0001	0.048
	Piacenza	<0.0001	0.026
	Porto	<0.0001	0.013
	Sevilla	<0.0001	<0.0001
	Thiva	<0.0001	<0.0001

PEC_(gw) From lysimeter / field studies

No studies submitted and none required.

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

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

Parent

Glasshouse/ indoor Applications

Calculation assuming 0.1 % loss of applied active substance to an adjacent surface water body 100 m x 1 m x 0.3 m, and sediment density 1.3 g/cm³ and sediment depth 5 cm.

Max observed daminozide in sediment (%): 6.7

Parameters used in FOCUSsw step 1 and 2

Version control no. of FOCUS calculator: 2.1
Molecular weight (g/mol): 160.2
K_{OC} (mL/g): 18.4
DT₅₀ soil (d): 0.12 days (Lab. geomean. In accordance with FOCUS SFO)
DT₅₀ water/sediment system (d): 0.906 days (geomean whole system from sediment water studies)
DT₅₀ water (d): 0.906 days (geomean whole system from sediment water studies)
DT₅₀ sediment (d): 0.906 days (geomean whole system from sediment water studies)
Crop interception (%): Spring applications – average; Autumn applications – full canopy

Parameters used in FOCUSsw step 3 (if performed)

Version control no.'s of FOCUS software: PRZM v.3.1.1, MACRO v.5.5.3, SWASH v3.1, TOXSWA v3.3.1
Water solubility (mg/L): 128000 at 20 °C
Vapour pressure: 1.5 x 10⁻⁶ Pa at 25°C
K_{OC} (mL/g): 18.4 (lowest value)
1/n: 1.368 (corresponding to K_{OC} value)
DT₅₀ sediment (d): 1000 days (Default worst case)
Q10=2.58, Walker equation coefficient 0.7 (0.49 for FOCUS MACRO 5.5.3)
Crop uptake factor:0.5

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

Application rate

Ornamental Crops – Glasshouse application
Number of applications: 5
Interval (d): 7
Application rate(s): 7650 g a.s./ha

Ornamental Crops – Field application – Spring
Crop and growth stage: Ornamental crops < 50cm (FOCUS crop – Maize); Ornamental crops > 50 cm (FOCUS crop – Vines – late applications at Step 3; Application hand (crop >50 cm at steps 1 & 2))
Number of applications: 5
Interval (d): 7
Application rate(s): 4250 g a.s./ha
Application window: Step 1&2: March - May;
Step 3: Multiple: 1 April – 29 May; Single: 1 April – 1 May

Ornamental Crops – Field application – Late summer
Crop and growth stage: Ornamental crops < 50cm (FOCUS crop – Maize); Ornamental crops > 50 cm (FOCUS crop – Vines – late applications at Step 3; Application hand (crop >50 cm at steps 1 & 2))
Number of applications: 5
Interval (d): 7
Application rate(s): 4250 g a.s./ha
Application window: Step 1&2: June – Sept.
Step 3: Multiple: 4 July – 31 August; Single: 1 August – 31 August

Glasshouse/ Indoor

Glasshouse/ Indoor	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	2.562 (2.550)		0.792 (0.789)	

Values in brackets refer to single application.

Field

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

Crop	FOCUS STEP	Daminozide	
		PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Ornamental Crops - <50cm (Field application – Spring)	1	1420	254.4
	2	25.53	1.42
	(SEU; March – May)	(39.09)	(2.18)
	2	25.54	1.43
	(NEU; March – May)	(39.09)	(2.18)
Ornamental Crops - <50cm (Field application – Late summer)	1	1420	254.4
	2	25.54	1.43
	(SEU; June – Sept)	(39.09)	(2.18)
	2	25.54	1.43
	(NEU; June – Sept)	(39.09)	(2.18)
Ornamental Crops - >50 cm (Field application – Spring)	1	1500	254.4
	2	94.46	5.28
	(SEU; March – May)	(113.7)	(6.36)
	2	94.46	5.28
	(NEU; March – May)	(113.7)	(6.36)
Ornamental Crops - >50 cm (Field application – Late summer)	1	1500	254.4
	2	94.46	5.28
	(SEU; June – Sept)	(113.7)	(6.36)
	2	94.46	5.28
	(NEU; June – Sept)	(113.7)	(6.36)

Values in brackets refer to single application

Ornamental crops <50 cm, multiple application in spring

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)
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Section 4 Environmental fate and behaviour

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3	ditch	0	14.37	-	1.043	-
		24	5.042	10.08	0.805	1.003
		2d	0.551	6.128	0.626	0.912
		4d	0.008	3.112	0.486	0.757
		7d	0.002	1.780	0.390	0.629
		14d	0.001	1.673	0.272	0.547
		21d	<0.001	1.162	0.206	0.524
		28d	<0.001	1.273	0.165	0.513
		42d	<0.001	1.134	0.117	0.461
D4	pond	0 h	0.719	-	0.131	-
		24 h	0.598	0.656	0.128	0.130
		2 d	0.498	0.601	0.122	0.129
		4 d	0.347	0.509	0.109	0.126
		7 d	0.167	0.402	0.091	0.119
		14 d	0.173	0.359	0.062	0.116
		21 d	0.174	0.322	0.046	0.113
		28 d	0.175	0.304	0.036	0.110
		42 d	0.001	0.256	0.025	0.100
D4	stream	0 h	11.90	-	0.225	-
		24 h	<0.001	0.797	0.052	0.087
		2 d	<0.001	0.398	0.041	0.066
		4 d	<0.001	0.199	0.032	0.051
		7 d	<0.001	0.114	0.025	0.041
		14 d	<0.001	0.101	0.017	0.037
		21 d	<0.001	0.097	0.013	0.034
		28 d	<0.001	0.098	0.010	0.031
		42 d	<0.001	0.079	0.007	0.028
D5	pond	0 h	0.581	-	0.088	-
		24 h	0.377	0.505	0.086	0.088
		2 d	0.246	0.447	0.081	0.087
		4 d	0.104	0.355	0.069	0.084
		7 d	0.024	0.262	0.056	0.077

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Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
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		14 d	0.001	0.182	0.038	0.073
		21 d	<0.001	0.186	0.029	0.068
		28 d	<0.001	0.148	0.023	0.065
		42 d	<0.001	0.142	0.016	0.061
D5	stream	0 h	12.93	-	0.239	-
		24 h	<0.001	0.969	0.054	0.092
		2 d	<0.001	0.484	0.043	0.070
		4 d	<0.001	0.242	0.033	0.054
		7 d	<0.001	0.138	0.026	0.043
		14 d	<0.001	0.122	0.018	0.040
		21 d	<0.001	0.108	0.013	0.034
		28 d	<0.001	0.085	0.010	0.032
		42 d	<0.001	0.077	0.007	0.027
D6	ditch	0 h	14.40	-	0.997	-
		24 h	5.883	9.833	0.825	0.973
		2 d	1.388	6.463	0.640	0.908
		4 d	0.032	3.426	0.475	0.765
		7 d	0.001	1.960	0.368	0.630
		14 d	0.004	1.832	0.423	0.552
		21 d	0.002	1.291	0.404	0.527
		28 d	<0.001	1.378	0.268	0.485
		42 d	<0.001	1.100	0.156	0.446
R1	pond	0 h	1.829	-	0.232	-
		24 h	1.411	1.630	0.228	0.231
		2 d	1.090	1.454	0.219	0.230
		4 d	0.652	1.170	0.197	0.226
		7 d	0.301	0.906	0.163	0.215
		14 d	0.051	0.582	0.130	0.184
		21 d	0.165	0.463	0.114	0.166
		28 d	0.160	0.399	0.113	0.157
		42 d	0.015	0.343	0.079	0.144
R1	stream	0 h	51.68	-	3.029	-
		24 h	0.013	17.36	1.159	1.996
		2 d	0.004	8.934	0.832	1.517

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

		4 d	0.001	4.808	0.589	1.117
		7 d	0.001	2.748	0.433	0.858
		14 d	<0.001	1.379	0.267	0.601
		21 d	<0.001	1.005	0.220	0.492
		28 d	<0.001	0.799	0.183	0.423
		42 d	<0.001	0.575	0.125	0.339
R2	stream	0 h	13.27	-	0.338	-
		24 h	<0.001	1.386	0.095	0.157
		2 d	<0.001	0.693	0.076	0.121
		4 d	<0.001	0.347	0.060	0.094
		7 d	<0.001	0.198	0.048	0.077
		14 d	<0.001	0.198	0.033	0.072
		21 d	<0.001	0.198	0.024	0.061
		28 d	<0.001	0.149	0.019	0.061
		42 d	<0.001	0.157	0.013	0.055
R3	stream	0 h	13.99	-	0.707	-
		24 h	0.046	4.977	0.340	0.536
		2 d	0.002	2.494	0.268	0.428
		4 d	0.001	1.257	0.210	0.336
		7 d	<0.001	0.718	0.168	0.274
		14 d	0.001	0.716	0.235	0.260
		21 d	<0.001	0.715	0.138	0.249
		28 d	<0.001	0.714	0.100	0.232
		42 d	<0.001	0.573	0.063	0.219
R4	stream	0 h	9.889	-	0.347	-
		24 h	0.001	1.836	0.121	0.201
		2 d	<0.001	0.918	0.095	0.156
		4 d	<0.001	0.475	0.073	0.120
		7 d	<0.001	0.271	0.057	0.100
		14 d	<0.001	0.267	0.083	0.090
		21 d	<0.001	0.265	0.088	0.080
		28 d	<0.001	0.239	0.048	0.077
		42 d	<0.001	0.189	0.026	0.072

Ornamental crops <50 cm, single application in spring

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)
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Section 4 Environmental fate and behaviour

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3	ditch	0	22.26	-	1.275	-
		24	7.520	15.33	0.851	1.191
		2d	0.562	9.149	0.583	1.027
		4d	0.008	4.631	0.401	0.787
		7d	0.002	2.648	0.292	0.606
		14d	0.001	1.325	0.179	0.423
		21d	<0.001	0.883	0.123	0.333
		28d	<0.001	0.663	0.090	0.277
		42d	<0.001	0.442	0.056	0.184
D4	pond	0 h	0.900	-	0.100	-
		24 h	0.748	0.820	0.099	0.100
		2 d	0.622	0.752	0.097	0.100
		4 d	0.432	0.636	0.090	0.099
		7 d	0.251	0.506	0.079	0.096
		14 d	0.059	0.324	0.051	0.087
		21 d	0.007	0.224	0.034	0.075
		28 d	0.001	0.169	0.025	0.066
		42 d	<0.001	0.112	0.015	0.051
D4	stream	0 h	17.85	-	0.278	-
		24 h	<0.001	0.896	0.036	0.075
		2 d	<0.001	0.448	0.025	0.053
		4 d	<0.001	0.224	0.018	0.037
		7 d	<0.001	0.128	0.013	0.027
		14 d	<0.001	0.064	0.008	0.019
		21 d	<0.001	0.043	0.005	0.015
		28 d	<0.001	0.032	0.004	0.012
		42 d	<0.001	0.021	0.002	0.009
D5	pond	0 h	0.900	-	0.083	-
		24 h	0.688	0.788	0.082	0.083
		2 d	0.527	0.696	0.078	0.083
		4 d	0.310	0.552	0.070	0.081
		7 d	0.141	0.408	0.057	0.077

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

		14 d	0.023	0.236	0.036	0.066
		21 d	0.004	0.161	0.025	0.056
		28 d	<0.001	0.121	0.018	0.048
		42 d	<0.001	0.081	0.011	0.037
D5	stream	0 h	18.77	-	0.254	-
		24 h	<0.001	0.794	0.032	0.065
		2 d	<0.001	0.397	0.022	0.046
		4 d	<0.001	0.198	0.015	0.032
		7 d	<0.001	0.113	0.011	0.024
		14 d	<0.001	0.057	0.007	0.016
		21 d	<0.001	0.038	0.005	0.013
		28 d	<0.001	0.028	0.003	0.011
		42 d	<0.001	0.019	0.002	0.008
D6	ditch	0 h	22.28	-	1.257	-
		24 h	8.568	15.26	0.914	1.197
		2 d	1.298	9.679	0.642	1.066
		4 d	0.032	5.010	0.437	0.837
		7 d	0.005	2.868	0.317	0.651
		14 d	0.001	1.435	0.195	0.456
		21 d	<0.001	0.957	0.133	0.360
		28 d	<0.001	0.718	0.097	0.300
		42 d	<0.001	0.479	0.060	0.226
R1	pond	0 h	0.900	-	0.084	-
		24 h	0.693	0.791	0.083	0.084
		2 d	0.535	0.701	0.079	0.084
		4 d	0.320	0.559	0.068	0.082
		7 d	0.119	0.409	0.054	0.077
		14 d	0.011	0.227	0.033	0.064
		21 d	0.001	0.153	0.022	0.054
		28 d	<0.001	0.115	0.016	0.046
		42 d	<0.001	0.077	0.010	0.035
R1	stream	0 h	15.41	-	0.481	-
		24 h	0.001	2.904	0.124	0.249
		2 d	<0.001	1.452	0.087	0.179

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

		4 d	<0.001	0.726	0.061	0.126
		7 d	<0.001	0.415	0.044	0.095
		14 d	<0.001	0.207	0.027	0.065
		21 d	<0.001	0.138	0.018	0.051
		28 d	<0.001	0.104	0.014	0.042
		42 d	<0.001	0.069	0.008	0.032
R2	stream	0 h	20.49	-	0.431	-
		24 h	<0.001	1.887	0.079	0.162
		2 d	<0.001	0.944	0.055	0.115
		4 d	<0.001	0.472	0.038	0.080
		7 d	<0.001	0.270	0.028	0.060
		14 d	<0.001	0.135	0.017	0.041
		21 d	<0.001	0.090	0.012	0.032
		28 d	<0.001	0.067	0.009	0.027
		42 d	<0.001	0.045	0.005	0.020
R3	stream	0 h	21.80	-	0.912	-
		24 h	0.072	7.755	0.340	0.643
		2 d	0.003	3.886	0.237	0.476
		4 d	0.022	1.944	0.166	0.341
		7 d	<0.001	1.112	0.121	0.257
		14 d	<0.001	0.556	0.074	0.176
		21 d	<0.001	0.371	0.051	0.138
		28 d	<0.001	0.278	0.037	0.115
		42 d	<0.001	0.185	0.023	0.086
R4	stream	0 h	15.41	-	0.474	-
		24 h	0.001	2.861	0.122	0.0245
		2 d	<0.001	1.431	0.085	0.176
		4 d	<0.001	0.715	0.060	0.124
		7 d	<0.001	0.409	0.043	0.093
		14 d	<0.001	0.204	0.027	0.064
		21 d	<0.001	0.136	0.018	0.050
		28 d	<0.001	0.102	0.013	0.041
		42 d	<0.001	0.068	0.008	0.031

Ornamental crops <50 cm, multiple application in late summer

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)
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Section 4 Environmental fate and behaviour

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3	ditch	0	14.37	-	1.038	-
		24	4.381	8.906	0.804	0.999
		2d	0.436	5.402	0.632	0.909
		4d	0.006	2.747	0.495	0.758
		7d	0.002	1.571	0.396	0.632
		14d	0.001	1.548	0.273	0.592
		21d	<0.001	1.510	0.204	0.536
		28d	<0.001	1.473	0.160	0.512
		42d	<0.001	1.217	0.111	0.464
D4	pond	0 h	0.573	-	0.069	-
		24 h	0.324	0.435	0.066	0.069
		2 d	0.183	0.342	0.061	0.068
		4 d	0.059	0.229	0.050	0.064
		7 d	0.011	0.146	0.039	0.057
		14 d	<0.001	0.141	0.026	0.054
		21 d	<0.001	0.141	0.019	0.050
		28 d	<0.001	0.140	0.015	0.046
		42 d	0.009	0.094	0.026	0.039
D4	stream	0 h	12.88	-	0.488	-
		24 h	0.004	2.807	0.188	0.307
		2 d	0.002	1.405	0.147	0.239
		4 d	0.002	0.704	0.115	0.185
		7 d	0.002	0.404	0.091	0.150
		14 d	0.007	0.378	0.062	0.136
		21 d	0.006	0.354	0.046	0.122
		28 d	0.006	0.335	0.036	0.110
		42 d	0.006	0.225	0.033	0.093
D5	pond	0 h	0.573	-	0.070	-
		24 h	0.326	0.435	0.067	0.070
		2 d	0.192	0.343	0.062	0.069
		4 d	0.066	0.231	0.052	0.065
		7 d	0.014	0.147	0.041	0.059

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

		14 d	<0.001	0.143	0.027	0.055
		21 d	<0.001	0.141	0.020	0.050
		28 d	<0.001	0.119	0.016	0.047
		42 d	<0.001	0.094	0.011	0.040
D5	stream	0 h	14.00	-	0.716	-
		24 h	0.045	4.829	0.358	0.550
		2 d	0.002	2.419	0.287	0.444
		4 d	0.001	1.210	0.228	0.353
		7 d	<0.001	0.692	0.182	0.291
		14 d	<0.001	0.692	0.125	0.276
		21 d	<0.001	0.692	0.093	0.257
		28 d	<0.001	0.691	0.073	0.231
		42 d	<0.001	0.461	0.051	0.201
D6	ditch	0 h	14.36	-	0.785	-
		24 h	2.635	7.528	0.557	0.735
		2 d	0.115	4.237	0.426	0.641
		4 d	0.002	2.129	0.332	0.519
		7 d	0.001	1.217	0.266	0.428
		14 d	0.004	1.160	0.185	0.390
		21 d	0.001	0.774	0.139	0.357
		28 d	0.001	0.871	0.111	0.356
		42 d	0.001	0.769	0.078	0.328
R1	pond	0 h	0.572	-	0.071	-
		24 h	0.320	0.434	0.068	0.071
		2 d	0.179	0.341	0.063	0.070
		4 d	0.056	0.227	0.052	0.066
		7 d	0.010	0.143	0.042	0.060
		14 d	0.020	0.140	0.028	0.057
		21 d	0.001	0.140	0.021	0.055
		28 d	<0.001	0.139	0.016	0.052
		42 d	<0.001	0.116	0.011	0.046
R1	stream	0 h	9.927	-	0.363	-
		24 h	0.001	2.006	0.130	0.216
		2 d	<0.001	1.003	0.102	0.167

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

		4 d	<0.001	0.502	0.080	0.129
		7 d	<0.001	0.287	0.063	0.104
		14 d	<0.001	0.246	0.043	0.092
		21 d	<0.001	0.232	0.031	0.086
		28 d	<0.001	0.227	0.025	0.080
		42 d	<0.001	0.185	0.017	0.071
R2	stream	0 h	13.31	-	0.348	-
		24 h	<0.001	1.414	0.105	0.168
		2 d	<0.001	0.707	0.085	0.132
		4 d	<0.001	0.353	0.067	0.104
		7 d	<0.001	0.202	0.054	0.085
		14 d	<0.001	0.202	0.037	0.082
		21 d	<0.001	0.202	0.027	0.079
		28 d	<0.001	0.201	0.021	0.074
		42 d	<0.001	0.168	0.015	0.064
R3	stream	0 h	13.99	-	0.639	-
		24 h	0.024	4.299	0.306	0.477
		2 d	0.001	2.152	0.241	0.381
		4 d	0.001	1.077	0.189	0.300
		7 d	<0.001	0.615	0.150	0.245
		14 d	<0.001	0.610	0.101	0.230
		21 d	<0.001	0.608	0.073	0.212
		28 d	0.024	0.607	0.244	0.190
		42 d	<0.001	0.406	0.076	0.161
R4	stream	0 h	9.925	-	0.357	-
		24 h	0.001	1.933	0.131	0.214
		2 d	<0.001	0.967	0.103	0.167
		4 d	<0.001	0.483	0.082	0.130
		7 d	<0.001	0.276	0.065	0.106
		14 d	<0.001	0.276	0.045	0.099
		21 d	<0.001	0.274	0.034	0.087
		28 d	<0.001	0.206	0.027	0.086
		42 d	<0.001	0.182	0.019	0.079

Ornamental crops <50 cm, single application in late summer

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)
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Section 4 Environmental fate and behaviour

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3	ditch	0	22.26	-	1.077	-
		24	5.164	13.03	0.690	1.000
		2d	0.282	7.468	0.470	0.849
		4d	0.005	3.761	0.324	0.641
		7d	0.002	2.150	0.236	0.492
		14d	0.001	1.076	0.144	0.342
		21d	<0.001	0.717	0.099	0.269
		28d	<0.001	0.538	0.072	0.224
		42d	<0.001	0.359	0.045	0.168
D4	pond	0 h	0.900	-	0.058	-
		24 h	0.522	0.692	0.055	0.058
		2 d	0.303	0.547	0.049	0.057
		4 d	0.103	0.366	0.039	0.053
		7 d	0.029	0.234	0.030	0.047
		14 d	0.002	0.122	0.018	0.036
		21 d	<0.001	0.082	0.012	0.029
		28 d	<0.001	0.062	0.009	0.025
		42 d	<0.001	0.041	0.005	0.019
D4	stream	0 h	17.92	-	0.281	-
		24 h	0.001	0.918	0.038	0.077
		2 d	<0.001	0.459	0.026	0.054
		4 d	<0.001	0.230	0.018	0.038
		7 d	<0.001	0.132	0.013	0.028
		14 d	<0.001	0.066	0.008	0.019
		21 d	<0.001	0.044	0.006	0.015
		28 d	<0.001	0.033	0.004	0.013
		42 d	<0.001	0.022	0.003	0.010
D5	pond	0 h	0.901	-	0.057	-
		24 h	0.504	0.681	0.053	0.056
		2 d	0.283	0.532	0.047	0.055
		4 d	0.089	0.350	0.036	0.051
		7 d	0.016	0.219	0.026	0.044

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

		14 d	<0.001	0.111	0.016	0.033
		21 d	<0.001	0.074	0.011	0.027
		28 d	<0.001	0.056	0.008	0.023
		42 d	<0.001	0.037	0.005	0.017
D5	stream	0 h	21.82	-	0.882	-
		24 h	0.069	7.523	0.329	0.623
		2 d	0.003	3.769	0.229	0.462
		4 d	0.001	1.885	0.160	0.331
		7 d	<0.001	1.077	0.116	0.249
		14 d	<0.001	0.539	0.071	0.171
		21 d	<0.001	0.359	0.049	0.134
		28 d	<0.001	0.269	0.036	0.111
		42 d	<0.001	0.180	0.022	0.083
D6	ditch	0 h	22.27	-	0.925	-
		24 h	3.380	11.04	0.574	0.847
		2 d	0.119	6.103	0.385	0.703
		4 d	0.003	3.063	0.264	0.525
		7 d	0.001	1.751	0.192	0.401
		14 d	<0.001	0.876	0.117	0.278
		21 d	<0.001	0.584	0.079	0.218
		28 d	<0.001	0.438	0.058	0.181
		42 d	<0.001	0.292	0.036	0.136
R1	pond	0 h	0.900	-	0.058	-
		24 h	0.515	0.688	0.054	0.057
		2 d	0.295	0.541	0.048	0.056
		4 d	0.097	0.360	0.038	0.052
		7 d	0.019	0.226	0.027	0.045
		14 d	0.001	0.116	0.016	0.035
		21 d	<0.001	0.077	0.011	0.028
		28 d	<0.001	0.058	0.008	0.023
		42 d	<0.001	0.039	0.005	0.018
R1	stream	0 h	15.47	-	0.499	-
		24 h	0.001	3.126	0.134	0.267
		2 d	<0.001	1.563	0.094	0.192

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

		4 d	<0.001	0.782	0.065	0.136
		7 d	<0.001	0.447	0.048	0.102
		14 d	<0.001	0.223	0.029	0.070
		21 d	<0.001	0.149	0.020	0.054
		28 d	<0.001	0.112	0.015	0.045
		42 d	<0.001	0.075	0.009	0.034
R2	stream	0 h	20.74	-	0.473	-
		24 h	<0.001	2.203	0.093	0.190
		2 d	<0.001	1.101	0.065	0.134
		4 d	<0.001	0.551	0.045	0.094
		7 d	<0.001	0.315	0.033	0.070
		14 d	<0.001	0.157	0.020	0.048
		21 d	<0.001	0.105	0.014	0.038
		28 d	<0.001	0.079	0.010	0.031
		42 d	<0.001	0.053	0.006	0.023
R3	stream	0 h	21.80	-	0.811	-
		24 h	0.038	6.698	0.295	0.557
		2 d	0.002	3.354	0.205	0.411
		4 d	0.001	1.677	0.142	0.294
		7 d	<0.001	0.959	0.103	0.221
		14 d	<0.001	0.479	0.063	0.151
		21 d	<0.001	0.320	0.043	0.118
		28 d	<0.001	0.240	0.031	0.098
		42 d	<0.001	0.160	0.019	0.074
R4	stream	0 h	15.47	-	0.483	-
		24 h	0.001	3.013	0.129	0.257
		2 d	<0.001	1.507	0.090	0.185
		4 d	<0.001	0.753	0.063	0.131
		7 d	<0.001	0.431	0.046	0.098
		14 d	<0.001	0.215	0.028	0.067
		21 d	<0.001	0.144	0.019	0.052
		28 d	<0.001	0.108	0.014	0.043
		42 d	<0.001	0.072	0.008	0.033

Ornamental crops >50 cm, multiple application

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)
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Section 4 Environmental fate and behaviour

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6	ditch	0	60.32	-	7.073	-
		24	29.82	47.47	6.617	7.007
		2d	14.91	38.54	5.917	6.829
		4d	3.565	26.72	4.777	6.317
		7d	0.332	17.06	3.766	5.571
		14d	0.016	14.40	2.593	5.266
		21d	0.009	12.88	1.937	4.905
		28d	0.006	12.69	1.517	4.604
		42d	0.004	10.12	1.033	4.231
R1	pond	0 h	2.432	-	0.427	-
		24 h	1.874	2.138	0.417	0.426
		2 d	1.448	1.894	0.397	0.423
		4 d	0.865	1.512	0.350	0.410
		7 d	0.400	1.124	0.289	0.384
		14 d	0.067	1.044	0.198	0.367
		21 d	0.971	0.890	0.147	0.343
		28 d	1.135	0.732	0.115	0.324
		42 d	0.101	0.770	0.079	0.297
R1	stream	0 h	43.48	-	1.441	-
		24 h	0.002	7.071	0.411	0.734
		2 d	0.001	3.536	0.309	0.550
		4 d	<0.001	1.768	0.231	0.409
		7 d	<0.001	1.010	0.176	0.332
		14 d	<0.001	1.010	0.113	0.320
		21 d	<0.001	0.832	0.254	0.316
		28 d	<0.001	0.758	0.302	0.284
		42 d	<0.001	0.753	0.190	0.260
R2	stream	0 h	58.62	-	1.563	-
		24 h	0.001	6.061	0.425	0.708
		2 d	<0.001	3.031	0.335	0.544
		4 d	<0.001	1.516	0.264	0.421
		7 d	<0.001	0.866	0.210	0.341

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

R3	stream	14 d	<0.001	0.866	0.144	0.318
		21 d	<0.001	0.866	0.107	0.270
		28 d	<0.001	0.650	0.084	0.267
		42 d	<0.001	0.666	0.058	0.241
		0 h	61.51	-	2.925	-
		24 h	0.043	17.89	1.272	2.040
		2 d	0.005	8.950	0.994	1.605
		4 d	0.004	4.494	0.778	1.249
		7 d	0.001	2.569	0.619	1.015
		14 d	0.001	2.563	0.891	0.964
R4	stream	21 d	<0.001	2.562	0.517	0.920
		28 d	0.001	2.561	0.376	0.860
		42 d	<0.001	2.065	0.235	0.814
		0 h	43.81	-	1.455	-
		24 h	0.003	8.567	0.375	0.758
		2 d	0.001	4.284	0.261	0.554
		4 d	<0.001	2.142	0.181	0.438
		7 d	43.05	1.224	1.075	0.361
		14 d	43.05	1.010	1.109	0.352
		21 d	43.05	0.938	1.136	0.340
	stream	28 d	43.05	0.903	1.157	0.327
		42 d	<0.001	0.734	0.160	0.298

Ornamental crops >50 cm, single application in spring

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)
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Section 4 Environmental fate and behaviour

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6	ditch	0	72.50	-	4.685	-
		24	36.25	52.91	3.864	4.563
		2d	11.65	37.66	2.896	4.254
		4d	0.836	20.97	1.955	3.534
		7d	0.059	12.09	1.402	2.807
		14d	0.012	6.059	0.862	1.989
		21d	0.006	4.042	0.593	1.578
		28d	0.003	3.033	0.434	1.316
		42d	0.001	2.022	0.266	0.994
R1	pond	0 h	2.596	-	0.247	-
		24 h	2.000	2.281	0.243	0.246
		2 d	1.544	2.021	0.232	0.245
		4 d	0.922	1.613	0.199	0.240
		7 d	0.344	1.179	0.157	0.226
		14 d	0.031	0.655	0.096	0.188
		21 d	0.003	0.441	0.065	0.157
		28 d	<0.001	0.331	0.047	0.134
		42 d	<0.001	0.221	0.029	0.103
R1	stream	0 h	52.99	-	1.638	-
		24 h	0.002	8.618	0.380	0.772
		2 d	0.001	4.310	0.264	0.549
		4 d	<0.001	2.155	0.183	0.385
		7 d	<0.001	1.232	0.133	0.287
		14 d	<0.001	0.616	0.081	0.196
		21 d	<0.001	0.411	0.056	0.153
		28 d	<0.001	0.308	0.041	0.127
		42 d	<0.001	0.205	0.025	0.095
R2	stream	0 h	70.40	-	1.464	-
		24 h	0.001	5.972	0.255	0.532
		2 d	<0.001	2.987	0.177	0.374
		4 d	<0.001	1.493	0.123	0.261
		7 d	<0.001	0.853	0.089	0.194

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

R3	stream	14 d	<0.001	0.427	0.055	0.132
		21 d	<0.001	0.284	0.037	0.103
		28 d	<0.001	0.213	0.027	0.085
		42 d	<0.001	0.142	0.017	0.064
		0 h	74.97	-	3.009	-
		24 h	0.052	21.80	1.000	1.926
		2 d	0.006	10.91	0.688	1.405
		4 d	0.002	5.455	0.475	0.996
		7 d	0.001	3.118	0.345	0.745
		14 d	<0.001	1.559	0.212	0.509
R4	stream	21 d	<0.001	1.039	0.145	0.398
		28 d	<0.001	0.780	0.106	0.330
		42 d	<0.001	0.520	0.065	0.248
		0 h	53.39	-	1.790	-
		24 h	0.004	10.44	0.459	0.931
		2 d	0.001	5.222	0.320	0.667
		4 d	<0.001	2.611	0.222	0.469
		7 d	<0.001	1.492	0.162	0.350
		14 d	<0.001	0.746	0.099	0.239
		21 d	<0.001	0.497	0.068	0.187
	stream	28 d	<0.001	0.373	0.049	0.154
		42 d	<0.001	0.249	0.030	0.116

Ornamental crops >50 cm, multiple application in late summer

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)
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Section 4 Environmental fate and behaviour

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6	ditch	0	60.03	-	5.076	-
		24	20.08	36.23	4.418	4.951
		2d	6.818	24.29	3.719	4.668
		4d	0.773	13.60	2.918	4.095
		7d	60.03	7.874	2.324	3.506
		14d	0.026	7.873	1.602	3.458
		21d	0.007	7.872	1.190	3.323
		28d	0.004	7.869	0.927	3.132
		42d	0.003	6.429	0.627	2.719
R1	pond	0 h	2.126	-	0.270	-
		24 h	1.187	1.613	0.258	0.268
		2 d	0.665	1.269	0.237	0.264
		4 d	0.209	0.845	0.198	0.249
		7 d	0.039	0.532	0.158	0.225
		14 d	0.076	0.521	0.107	0.217
		21 d	0.002	0.519	0.079	0.208
		28 d	<0.001	0.518	0.061	0.195
		42 d	<0.001	0.433	0.042	0.172
R1	stream	0 h	43.89	-	1.630	-
		24 h	0.003	8.868	0.536	0.935
		2 d	0.001	4.435	0.410	0.710
		4 d	<0.001	2.218	0.313	0.536
		7 d	<0.001	1.267	0.245	0.426
		14 d	<0.001	0.968	0.164	0.342
		21 d	<0.001	0.869	0.120	0.309
		28 d	<0.001	0.819	0.092	0.285
		42 d	<0.001	0.657	0.062	0.250
R2	stream	0 h	58.83	-	1.623	-
		24 h	0.001	6.250	0.479	0.772
		2 d	0.001	3.125	0.384	0.602
		4 d	<0.001	1.563	0.305	0.472
		7 d	<0.001	0.893	0.244	0.387

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

R3	stream	14 d	<0.001	0.893	0.167	0.374
		21 d	<0.001	0.892	0.124	0.358
		28 d	<0.001	0.891	0.097	0.337
		42 d	<0.001	0.742	0.066	0.292
		0 h	61.86	-	3.115	-
		24 h	0.109	19.01	1.530	2.341
		2 d	0.007	9.516	1.225	1.888
		4 d	0.002	4.760	0.975	1.502
		7 d	0.001	2.721	0.783	1.238
		14 d	0.001	2.720	0.539	1.195
R4	stream	21 d	<0.001	2.720	0.400	1.143
		28 d	<0.001	2.720	0.312	1.077
		42 d	<0.001	2.259	0.213	0.933
		0 h	43.88	-	1.736	-
		24 h	0.003	8.548	0.665	1.057
		2 d	0.001	4.275	0.535	0.835
		4 d	<0.001	2.138	0.426	0.659
		7 d	<0.001	1.222	0.342	0.541
		14 d	<0.001	1.222	0.174	0.522
		21 d	<0.001	1.222	0.135	0.499
		28 d	<0.001	1.216	0.092	0.470
		42 d	<0.001	1.010	0.078	0.407

Ornamental crops >50 cm, single application in late summer

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)
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Section 4 Environmental fate and behaviour

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6	ditch	0	72.97	-	3.521	-
		24	21.58	41.86	2.834	3.389
		2d	6.479	27.29	2.133	3.096
		4d	0.578	14.93	1.418	2.526
		7d	0.023	8.601	1.000	1.990
		14d	0.004	4.305	0.606	1.401
		21d	0.002	2.871	0.413	1.107
		28d	0.001	2.153	0.301	0.921
		42d	0.001	1.436	0.183	0.694
R1	pond	0 h	2.596	-	0.169	-
		24 h	1.484	1.984	0.158	0.167
		2 d	0.851	1.560	0.141	0.164
		4 d	0.281	1.038	0.110	0.152
		7 d	0.054	0.653	0.080	0.133
		14 d	0.002	0.334	0.048	0.101
		21 d	<0.001	0.223	0.032	0.081
		28 d	<0.001	0.167	0.024	0.068
		42 d	<0.001	0.111	0.015	0.052
R1	stream	0 h	53.49	-	1.813	-
		24 h	0.004	10.81	0.477	0.961
		2 d	0.001	5.405	0.332	0.690
		4 d	<0.001	2.703	0.230	0.485
		7 d	<0.001	1.545	0.167	0.362
		14 d	<0.001	0.772	0.102	0.247
		21 d	<0.001	0.515	0.070	0.193
		28 d	<0.001	0.386	0.051	0.160
		42 d	<0.001	0.257	0.032	0.120
R2	stream	0 h	71.70	-	1.725	-
		24 h	0.002	7.617	0.332	0.683
		2 d	0.001	3.809	0.229	0.482
		4 d	<0.001	1.905	0.159	0.336
		7 d	<0.001	1.088	0.115	0.250

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

R3	stream	14 d	<0.001	0.544	0.070	0.170
		21 d	<0.001	0.363	0.048	0.133
		28 d	<0.001	0.272	0.035	0.110
		42 d	<0.001	0.181	0.021	0.082
		0 h	75.40	-	2.962	-
		24 h	0.132	23.16	1.058	2.021
		2 d	0.007	11.60	0.729	1.485
		4 d	0.002	5.800	0.504	1.056
		7 d	0.001	3.315	0.366	0.791
		14 d	<0.001	1.658	0.223	0.540
R4	stream	21 d	<0.001	1.105	0.152	0.423
		28 d	<0.001	0.829	0.111	0.350
		42 d	<0.001	0.553	0.068	0.262
		0 h	53.49	-	1.755	-
		24 h	0.004	10.42	0.459	0.926
		2 d	0.001	5.210	0.319	0.664
		4 d	<0.001	2.605	0.221	0.467
		7 d	<0.001	1.489	0.161	0.349
		14 d	<0.001	0.744	0.098	0.238
		21 d	<0.001	0.496	0.067	0.186
		28 d	<0.001	0.372	0.049	0.154
		42 d	<0.001	0.248	0.030	0.115

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

Metabolite – Methanol Glasshouse/ indoor Applications	<p>Calculation assuming 0.1 % loss of applied active substance to an adjacent surface water body 100 m x 1 m x 0.3 m, and sediment density 1.3 g/cm³ and sediment depth 5 cm. Daminozide application rates were corrected for relative molecular masses of parent and methanol and the maximum formation of methanol in water and sediment.</p> <p>Max concentration methanol in water (%): 100 (worst case)</p> <p>Max concentration methanol in sediment (%): 12.4 (maximum total radioactivity in sediment)</p>
Parameters used in FOCUSsw step 1 and 2	<p>Molecular weight: 32.0</p> <p>Soil or water metabolite: Soil and Water</p> <p>Koc^b) (mL/g): 1.0</p> <p>DT₅₀ soil (d): 3.9 days (Lab geomean. In accordance with FOCUS SFO)</p> <p>DT₅₀ water/sediment system (d): 1000 d (default)</p> <p>DT₅₀ water (d): 1000 (default)</p> <p>DT₅₀ sediment (d): 1000 (default)</p> <p>Crop interception (%): Spring applications – average; Autumn applications – full canopy</p> <p>Maximum occurrence observed (% molar basis with respect to the parent)</p> <p>Total Water and Sediment^a): 100</p> <p>Soil: 27.2</p>
Parameters used in FOCUSsw step 3 (if performed)	Not required
Application rate	<p><u>Ornamental Crops – Glasshouse application</u></p> <p>Number of applications: 5</p> <p>Interval (d): 7</p> <p>Application rate(s): 7650 g a.s./ha</p> <p><u>Ornamental Crops – Field application – Spring</u></p> <p>Crop and growth stage: Ornamental crops < 50cm (FOCUS crop – Maize); Ornamental crops > 50 cm (Application hand (crop >50 cm) at steps 1 & 2)</p> <p>Number of applications: 5</p> <p>Interval (d): 7</p> <p>Application rate(s): 4250 g a.s./ha</p> <p>Application window: Step 1&2 – March - May</p> <p><u>Ornamental Crops – Field application – Autumn</u></p> <p>Crop and growth stage: Ornamental crops < 50cm (FOCUS crop – Maize); Ornamental crops > 50 cm (FOCUS crop – Application hand (crop >50 cm at steps 1 & 2))</p> <p>Number of applications: 5</p> <p>Interval (d): 7</p> <p>Application rate(s): 4250 g a.s./ha</p> <p>Application window: Step 1&2: June – Sept.</p>
Main routes of entry	Spray drift & run-off

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

a) default as a worst case.

b) It was not possible to perform reliable batch adsorption studies for methanol because of the practical difficulties created by its high volatility. The input K_{oc} value for methanol was the worst case value derived from the KOCWIN v2.0 tool in EPIWEB of 1.0 mL/g. A default 1/n value of 1.0 was also input.

Glasshouse/ Indoor

Glasshouse/ Indoor	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	2.522 (0.509)		1.443 (0.291)	

Values in brackets refer to single application.

Field use

Crop	FOCUS STEP	Methanol	
		PEC _{SW} (µg/L)	PEC _{sed} (µg/kg)
Ornamental Crops - <50cm (Field application – Spring)	1	423.4	4.23 (Day 1)
	2 (SEU; March – May)	35.63 (15.33)	0.36 (0.15)
	2 (NEU; March – May)	30.34 (11.55)	0.30 (0.12)
Ornamental Crops - <50cm (Field application – Late summer)	1	423.4	4.23 (Day 1)
	2 (SEU; June – Sept)	29.02 (10.61)	0.29 (0.11)
	2 (NEU; June – Sept)	27.69 (9.67)	0.28 (0.10)
Ornamental Crops - >50 cm (Field application – Spring)	1	497.9	4.97 (Day 1)
	2 (SEU; March – May)	103.2 (30.19)	1.03 (0.30)
	2 (NEU; March – May)	97.94 (26.41)	0.98 (0.26)
	1	497.9	4.97 (Day 1)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar/Dazide Enhance)

Section 4 Environmental fate and behaviour

Ornamental Crops - >50 cm (Field application – Late summer)	2 (SEU; June – Sept)	97.41 (26.03)	0.97 (0.26)
	2 (NEU; June – Sept)	95.82 (24.90)	0.96 (0.25)

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

Not applicable.

List of end points

Rapporteur Member State Month and year Active substance and Plant Protection Product (Name)

Czech Republic	October 2018	Daminozide
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Section 5 Ecotoxicology

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				
<i>Bobwhite quail</i>	Daminozide	Acute	LD50	>2250 mg/kg bw >4248 mg/kg bw¹
<i>Mallard duck</i>	Daminozide	Acute	LD50	>2250 mg/kg bw >4248 mg/kg bw¹
<i>Bobwhite quail</i>	Daminozide	Long-term	NOEC/ NOEL	1000 ppm 79.7 mg/kg bw/d

¹ Extrapolated from the reported endpoint of >2250 mg a.s./kg bw, based on a factor of 1.888.

Endpoints used in the regulatory risk assessment included in bold.

Mammals

Rat	Daminozide	Acute	LD50	>5000 mg/kg bw
Rat	Dazide Enhance	Acute	LD50	>5000 mg form./kg bw >4250 mg a.s./kg bw
Rat	B-Nine	Acute	LD50	>5000 mg form./kg bw >4250 mg a.s./kg bw
Rat	Daminozide	Short-term (90-day)	NOAEL	1000 mg/kg bw/d
Rat	Daminozide	Long-term (2-generation)	NOEL [NOEC]	Parental: 50 mg/kg bw/d [1000 ppm] Developmental: 500 mg/kg bw/d [10000 ppm] Fertility: 500 mg/kg bw/d [10000 ppm]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

Rat	Daminozide	Long-term (2-generation)	NOEL	Parental: 360 mg/kg bw/d Developmental: 1200 mg/kg bw/d Fertility: 1200 mg/kg bw/d
Rat	Daminozide	Long-term (developmental)	NOEL	Maternal: 150 mg/kg bw/d Developmental: 1500 mg/kg bw/d Teratogenicity: 1500 mg/kg bw/d
Rat ¹	Daminozide	Long-term (developmental)	NOAEL	Maternal: 1000 mg/kg bw/d Developmental: 1000 mg/kg bw/d Teratogenicity: 1000 mg/kg bw/d
Rabbit	Daminozide	Long-term (developmental)	NOAEL	Maternal: 300 mg/kg bw/d Developmental: 300 mg/kg bw/d Teratogenicity: 300 mg/kg bw/d
Rabbit	Daminozide	Long-term (developmental)	NAOEL	Maternal: 250 mg/kg bw/d Developmental: 500 mg/kg bw/d Teratogenicity: 1000 mg/kg bw/d

¹ Study considered as supplementary only.

Endpoints used in the regulatory risk assessment included in bold.

Endocrine disrupting properties (Annex Part A, points 8.1.5)

-

Additional higher tier studies (Annex Part A, points 10.1.1.2):

-

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
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Czech Republic	October 2018	Daminozide
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Section 5 Ecotoxicology

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List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
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Czech Republic	October 2018	Daminozide
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Section 5 Ecotoxicology

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

Ornamentals at 5 x 4.25 kg a.s./ha (field use)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small insectivorous bird	Acute	378	11.2	10
All	Small insectivorous bird	Long-term	98.4	0.81	5
Tier 1 (Birds)					
Application to plant	Small insectivorous bird "tit"	Long-term	98.4	0.81	5
Application to plant – exposure to underlying ground	Small insectivorous / worm feeding bird "thrush"	Long-term	14.1	5.46	5
Higher tier (birds): [<i>in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)</i>]					
Application to plant	Small insectivorous bird "blue tit"	Long-term	56.6 (PT: 0.58)	1.41	5
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	1101	>4.54	10
All	Small herbivorous mammal	Long-term	391	1.28	5
Tier 1 (Mammals)					
Application to plant – exposure to underlying ground	Small insectivorous mammal "shrew"	Acute	43.62	>115	10
BBCH 40-49	Small herbivorous mammal "vole"	Acute	1101	>4.54	10
Application crop directed BBCH 10-49	Small omnivorous mammal 'mouse'	Acute	139	>35.97	10
Application to plant – exposure to underlying ground	Small insectivorous mammal "shrew"	Long-term	10.27	48.69	5
BBCH 40-49	Small herbivorous mammal "vole"	Long-term	391	1.28	5
Application crop directed BBCH 10-49	Small omnivorous mammal 'mouse'	Long-term	44.85	11.15	5
Higher tier (Mammals): [<i>in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)</i>]					
BBCH 40-49	Small herbivorous mammal 'vole'	Acute	441 (DF: 0.4)	>11.34	10
BBCH 40-49	Small herbivorous mammal 'vole'	Long-term	119.9 (PD: 0.35 grass, 0.65 non-grass) (DF: 0.4)	4.17	5

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
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Czech Republic	October 2018	Daminozide
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Section 5 Ecotoxicology

Risk from bioaccumulation and food chain behaviour

Daminozide: Log Kow = -1.5, risk assessment not required.

Methanol: Log Kow = 0.77, risk assessment not required.

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

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

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
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Czech Republic	October 2018	Daminozide
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Section 5 Ecotoxicology

Risk from consumption of contaminated water					
Scenarios	Indicator or focal species	Time scale	PEC _{dw} xDWR	TER	Trigger
Leaf scenario	Birds	acute	Not relevant		10

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

Puddle scenario, Screening step

- 1) Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed
- 2) Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed

Birds - acute

Daminozide: Application rate (4250 g a.s./ha)/ (LD₅₀ 4248 mg a.s./kg bw) * MAF 1.00^a = 1.00 <50 (koc <500 L/kg),

TER calculation not needed.

Methanol: Application rate (4250 g a.s./ha)/ (LD₅₀ 424.8 mg a.s./kg bw^c) * MAF 1.40^b = 14.00 <50 (koc <500 L/kg),

TER calculation not needed.

Mammals - acute

Daminozide: Application rate (4250 g a.s./ha)/ (LD₅₀ >5000 mg a.s./kg bw) * MAF 1.00^a = <0.85 <50 (koc <500 L/kg),

TER calculation not needed.

Methanol: Application rate (4250 g a.s./ha)/ (LD₅₀ >500 mg a.s./kg bw^c) * MAF 1.40^b = <11.9 <50 (koc <500 L/kg),

TER calculation not needed.

Birds - long-term

Daminozide: Application rate (4250 g a.s./ha)/ (NOEL 79.7 mg a.s./kg bw/day) * MAF 1.00^a = **53.3** <50 (koc <500 L/kg),

TER calculation needed.

Methanol: Application rate (4250 g a.s./ha)/ (NOEL 7.97 mg a.s./kg bw/day^c) * MAF 1.40^b = **747** <50 (koc <500 L/kg),

TER calculation needed.

Mammals - long-term

Daminozide: Application rate (4250 g a.s./ha)/ (NOAEL 500 mg a.s./kg bw/day) * MAF 1.00^a = 8.50 <50 (koc <500 L/kg),

TER calculation not needed.

Methanol: Application rate (4250 g a.s./ha)/ (NOAEL 50 mg a.s./kg bw/day^c) * MAF 1.40^b = **119** <50 (koc <500 L/kg),

TER calculation not needed.

Daminozide: Tier 1 calculation

Puddle scenario	Birds	acute	-	-	10
Puddle scenario	Mammals	acute	-	-	10
Puddle scenario	Birds	Long-term	3.27	24.52	5
Puddle scenario	Mammals	Long-term	-	-	5

Methanol: Tier 1 calculation

Puddle scenario	Birds	acute	-	-	10
Puddle scenario	Mammals	acute	-	-	10
Puddle scenario	Birds	Long-term	9.09	0.88	5

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

Puddle scenario	Mammals	Long-term	4.74	10.55	5
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^a Based on the maximum soil DT50 of 0.37 days

^b Based on the soil DT50 of 3.9 days

^c There are no toxicity data available for the metabolites methanol, therefore the ametabolite has been assumed to be 10 times more toxic than the parent.

Bold figures fall below the Regulation (EU) 546/2011 trigger value

Ornamentals at 5 x 7.65 kg a.s./ha (protected use - other than permanent greenhouses)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small insectivorous bird	Acute	680	6.2	10
All	Small insectivorous bird	Long-term	177	0.45	5
Tier 1 (Birds)					
Application to plant	Small insectivorous bird "tit"	Acute	680	6.2	10
Application to plant – exposure to underlying ground	Small insectivorous / worm feeding bird "thrush"	Acute	177	0.45	10
Application to plant	Small insectivorous bird "tit"	Long-term	108	39.33	5
Application to plant – exposure to underlying ground	Small insectivorous / worm feeding bird "thrush"	Long-term	14.6	26.27	5
Higher tier (birds): [<i>in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)</i>]					
Application to plant	Small insectivorous bird "blue tit"	Acute	495.4 (PT: 0.58)	8.57	10
Application to plant	Small insectivorous bird "blue tit"	Long-term	101.9 (PT: 0.58)	0.78	5
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	1983	2.52	10
All	Small herbivorous mammal	Long-term	704	0.71	5
Tier 1 (Mammals)					
Application to plant – exposure to underlying ground	Small insectivorous mammal "shrew"	Acute	78.49	>63.70	10
BBCH 40-49	Small herbivorous mammal "vole"	Acute	1975	>2.53	10
Application crop directed BBCH 10-49	Small omnivorous mammal 'mouse'	Acute	250	>20.00	10
Application to plant – exposure to underlying ground	Small insectivorous mammal "shrew"	Long-term	17.52	28.54	5
BBCH 40-49	Small herbivorous mammal "vole"	Long-term	704	0.71	5
Application crop directed BBCH 10-49	Small omnivorous mammal 'mouse'	Long-term	75.90	6.59	5

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

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

BBCH 40-49	Small herbivorous mammal 'vole'	Acute	793 (DF: 0.4)	>6.31	10
BBCH 40-49	Small herbivorous mammal 'vole'	Long-term	215.8 (PD: 0.35 grass, 0.65 non-grass) (DF: 0.4)	2.52	5

Risk from bioaccumulation and food chain behaviour

Daminozide: Log Kow = -1.5, risk assessment not required.

Methanol: Log Kow = 0.77, risk assessment not required.

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

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

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
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Czech Republic	October 2018	Daminozide
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Section 5 Ecotoxicology

Risk from consumption of contaminated water					
Scenarios	Indicator or focal species	Time scale	PEC _{dw} xDWR	TER	Trigger
Leaf scenario	Birds	acute	Not relevant		10

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

Puddle scenario, Screening step

- 1) Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed
- 2) Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed

Birds - acute

Daminozide: Application rate (7650 g a.s./ha)/ (LD₅₀ 4248 mg a.s./kg bw) * MAF 1.00^a = 1.80 <50 (koc <500 L/kg),

TER calculation not needed.

Methanol: Application rate (7650 g a.s./ha)/ (LD₅₀ 424.8 mg a.s./kg bw^c) * MAF 1.40^b = 25.21 <50 (koc <500 L/kg),

TER calculation not needed.

Mammals - acute

Daminozide: Application rate (7650 g a.s./ha)/ (LD₅₀ >5000 mg a.s./kg bw) * MAF 1.00^a = <1.80 <50 (koc <500 L/kg),

TER calculation not needed.

Methanol: Application rate (7650 g a.s./ha)/ (LD₅₀ >500 mg a.s./kg bw^c) * MAF 1.40^b = <21.42 <50 (koc <500 L/kg),

TER calculation not needed.

Birds - long-term

Daminozide: Application rate (7650 g a.s./ha)/ (NOEL 79.7 mg a.s./kg bw/day) * MAF 1.00^a = **95.7** <50 (koc <500 L/kg),

TER calculation needed.

Methanol: Application rate (7650 g a.s./ha)/ (NOEL 7.97 mg a.s./kg bw/day^c) * MAF 1.40^b = **1344** <50 (koc <500 L/kg),

TER calculation needed.

Mammals - long-term

Daminozide: Application rate (7650 g a.s./ha)/ (NOAEL 500 mg a.s./kg bw/day) * MAF 1.00^a = 1.53 <50 (koc <500 L/kg),

TER calculation not needed.

Methanol: Application rate (7650 g a.s./ha)/ (NOAEL 50 mg a.s./kg bw/day^c) * MAF 1.40^b = **214** <50 (koc <500 L/kg),

TER calculation not needed.

Daminozide: Tier 1 calculation

Puddle scenario	Birds	acute	-	-	10
Puddle scenario	Mammals	acute	-	-	10
Puddle scenario	Birds	Long-term	5.87	13.58	5
Puddle scenario	Mammals	Long-term	-	-	5

Methanol: Tier 1 calculation

Puddle scenario	Birds	acute	-	-	10
Puddle scenario	Mammals	acute	-	-	10
Puddle scenario	Birds	Long-term	16.17	0.49	5
Puddle scenario	Mammals	Long-term	8.44	5.92	5

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

^a Based on the maximum soil DT50 of 0.37 days

^b Based on the soil DT50 of 3.9 days

^c There are no toxicity data available for the metabolites methanol, therefore the ametabolite has been assumed to be 10 times more toxic than the parent.

Bold figures fall below the Regulation (EU) 546/2011 trigger value

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

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.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹ (mg a.s./L)
Laboratory tests				
Fish				
Common carp (<i>Cyprinus carpio</i>)	Dazide Enhance SG	Acute, 96h (semi-static)	Mortality, LC ₅₀	420 form. 357 a.s. (nom)
Common carp (<i>Cyprinus carpio</i>)	Dazide Enhance	Acute, 96h (semi-static)	Mortality, LC ₅₀	75 form. 64 a.s. (nom)
Fathead minnow (<i>Pimephales promelas</i>)	Daminozide	Chronic, 33d ELS (flow-through)	Development and growth, NOEC	1.7 (mm)
Aquatic invertebrates				
<i>Daphnia magna</i>	Daminozide	Acute, 96h (flow-through)	Immobility, EC ₅₀	75.5 (mm)
<i>Daphnia magna</i>	Dazide Enhance	Acute, 48h (static)	Immobility, EC ₅₀	60 form. 51 a.s. (nom)
<i>Daphnia magna</i>	Dazide Enhance SG	Acute, 48h (static)	Immobility, EC ₅₀	>100 form. >85 a.s. (nom)
Sediment-dwelling organisms				
-				
Algae				
Freshwater green (<i>Pseudokirchneriella subcapitata</i>)	Daminozide	72 h (static)	Growth rate: E _r C ₅₀ Biomass: E _b C ₅₀ NOEC	>100 >100 100 (nom)
Freshwater cyanobacteria (<i>Anabaena flos-aquae</i>)	Daminozide	72 h (static)	Growth rate: E _r C ₅₀ Yield: E _y C ₅₀ NOEC	>100 >100 100 (nom)
Freshwater green (<i>Pseudokirchneriella subcapitata</i>)	Dazide Enhance	72 h (static)	Growth rate: E _r C ₅₀ Biomass: E _b C ₅₀ Yield: E _y C ₅₀ NOEC	>100 form. >85 a.s. >100 form. >85 a.s. >100 form. >85 a.s. 100 form. 85 a.s. (nom)
Higher plant				
-				

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹ (mg a.s./L)
Further testing on aquatic organisms				
-				

Potential endocrine disrupting properties (Annex Part A, point 8.2.3)

-

¹ (nom) nominal concentration; (ini nom) initial nominal concentration; (mm) mean measured concentration; (ini mm) initial mean measured concentration; prep.; (fin m) final measured concentration; preparation; a.s.: active substance
Endpoints used in the regulatory risk assessment included in bold.

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance	Metabolite methanol	Metabolite 2	Metabolite 3
logP _{OW}	-1.5	-0.77		
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 ¹⁴C

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar, Dazide Enhance)

Section 5 Ecotoxicology

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

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

FOCUS_{sw} step 1-2 - TERs for daminozide – ornamentals <50 cm (field use) at 4.25 kg a.s./ha x 5

Scenario	PEC _{sw} global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller
		<i>Cyprinus carpio</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	-	<i>Pseudokirchneriella subcapitata</i>	-	-
		LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	EC ₅₀	NOEC
		64000 µg/L	1700 µg/L	51000 µg/L	-	>85000 µg/L	-	-
FOCUS Step 1	1420 µg L	45.07	1.20	35.92	-	>59.86	-	-
FOCUS Step 2								
North Europe	39.09 µg L ^a	1637	43.49	1305	-	-	-	-
South Europe	39.09 µg L ^a	1637	43.49	1305	-	-	-	-
Trigger**		100	10	100	10	10	10	10

Bold figures fall below the Regulation (EU) 546/2011 trigger value

^aPEC_{sw} for a single application as a worse case

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar, Dazide Enhance)

Section 5 Ecotoxicology

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

FOCUS_{sw} step 1-2 - TERs for daminozide – ornamentals >50 cm (field use) at 4.25 kg a.s./ha x 5

Scenario	PEC _{sw} global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller
		<i>Cyprinus carpio</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	-	<i>Pseudokirchneriella subcapitata</i>	-	-
		LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	EC ₅₀	NOEC
		64000 µg/L	1700 µg/L	51000 µg/L	-	>85000 µg/L	-	-
FOCUS Step 1	1500 µg L	42.67	1.13	34.00	-	>56.67	-	-
FOCUS Step 2								
North Europe	113.7 µg L ^a	563	14.95	449	-	-	-	-
South Europe	113.7 µg L ^a	563	14.95	449	-	-	-	-
Trigger**		100	10	100	10	10	10	10

Bold figures fall below the Regulation (EU) 546/2011 trigger value

^aPEC_{sw} for a single application as a worse case

^{*}[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar, Dazide Enhance)

Section 5 Ecotoxicology

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

TERs for daminozide – ornamentals (protected use) at 7.65 kg a.s./ha x 5

Scenario	PEC _{sw} global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller
		<i>Cyprinus carpio</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	-	<i>Pseudokirchneriella subcapitata</i>	-	-
		LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	EC ₅₀	NOEC
		64000 µg/L	1700 µg/L	51000 µg/L	-	>85000 µg/L	-	-
Glasshouse/indoor	2.562 µg L	24980	664	19906	-	>33177	-	-
Trigger**		100	10	100	10	10	10	10

Bold figures fall below the Regulation (EU) 546/2011 trigger value

^aPEC_{sw} for a single application as a worse case

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar, Dazide Enhance)

Section 5 Ecotoxicology

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

FOCUS_{sw} step 1-2 - TERs for metabolite methanol – ornamentals <50 cm (field use) at 4.25 kg a.s./ha x 5

Scenario	PEC _{sw} global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller
		<i>Cyprinus carpio</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	-	<i>Pseudokirchneriella subcapitata</i>	-	-
		LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	EC ₅₀	NOEC
		6400 µg/L ¹	170 µg/L ¹	5100 µg/L ¹	-	>8500 µg/L ¹	-	-
FOCUS Step 1	423.4 µg L	15.12	0.40	12.05	-	>20.08	-	-
FOCUS Step 2								
North Europe	30.34 µg L	211	5.60	168	-	-	-	-
South Europe	35.63 µg L	180	4.77	143	-	-	-	-
Trigger**		100	10	100	10	10	10	10

Bold figures fall below the Regulation (EU) 546/2011 trigger value

¹ There are no valid toxicity data available for the metabolite methanol, therefore it was assumed to be 10 times more toxic than the parent.

^{*}[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar, Dazide Enhance)

Section 5 Ecotoxicology

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

FOCUS_{sw} step 1-2 - TERs for metabolite methanol – ornamentals >50 cm (field use) at 4.25 kg a.s./ha x 5

Scenario	PEC _{sw} global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller
		<i>Cyprinus carpio</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	-	<i>Pseudokirchneriella subcapitata</i>	-	-
		LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	EC ₅₀	NOEC
		6400 µg/L ¹	170 µg/L ¹	5100 µg/L ¹	-	>8500 µg/L ¹	-	-
FOCUS Step 1	497.9 µg L	15.12	0.40	12.05	-	>20.08	-	-
FOCUS Step 2								
North Europe	97.94 µg L	65.35	1.74	52.07	-	-	-	-
South Europe	103.2 µg L	62.02	1.65	49.42	-	-	-	-
Trigger**		100	10	100	10	10	10	10

Bold figures fall below the Regulation (EU) 546/2011 trigger value

¹ There are no valid toxicity data available for the metabolite methanol, therefore it was assumed to be 10 times more toxic than the parent.

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide (Alar, Dazide Enhance)

Section 5 Ecotoxicology

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

FOCUS_{SW} step 1-2 - TERs for metabolite methanol – ornamentals (protected use) at 7.65 kg a.s./ha x 5

Scenario	PEC _{SW} global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller
		<i>Cyprinus carpio</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	-	<i>Pseudokirchneriella subcapitata</i>	-	-
		LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	EC ₅₀	NOEC
		6400 µg/L ¹	170 µg/L ¹	5100 µg/L ¹	-	>8500 µg/L ¹	-	-
Glasshouse/indoor	2.522 µg L	2538	67.41	2022	-	>3370	-	-
Trigger**		100	10	100	10	10	10	10

Bold figures fall below the Regulation (EU) 546/2011 trigger value

¹ There are no valid toxicity data available for the metabolite methanol, therefore it was assumed to be 10 times more toxic than the parent.

*[Only scenarios where the trigger is not met at FOCUS_{SW} step 1-2 should be included in step 3.]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

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
<i>Apis mellifera</i>	Daminozide	Acute	Oral toxicity (LD ₅₀)	>200 µg a.s./bee
<i>Apis mellifera</i>	Daminozide	Acute	Contact toxicity (LD ₅₀)	>200 µg a.s./bee
<i>Apis mellifera</i>	Alar 85	Acute	Oral toxicity (LD ₅₀)	>100 µg form./bee >85 µg a.s./bee
<i>Apis mellifera</i>	Alar 85	Acute	Contact toxicity (LD ₅₀)	>100 µg form./bee >85 µg a.s./bee
<i>Apis mellifera</i>	Daminozide	Chronic	10 d chronic toxicity (LDD ₅₀)	>106.2 µg a.s./bee/day
<i>Apis mellifera</i>	Daminozide	Chronic, repeated exposure	Oral toxicity (LD ₅₀) (NOED)	>150 µg form./larva >124.5 µg a.s./larva 100 µg a.s./larva

Endpoints used in the regulatory risk assessment included in bold.

Potential for accumulative toxicity: *yes/no*

Semi-field test (Cage and tunnel test)

-

Field tests

-

Risk assessment for bees from contact and oral dietary exposure for ornamentals (field use) at 4.25 kg a.s./ha x 5, BBCH <50

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

Species	Test substance	Scenario	Risk quotient	HQ/ETR	Trigger
Screening level assessment					
<i>Apis mellifera</i>	a.s.	Not relevant	HQ _{contact}	<21.3	42
<i>Apis mellifera</i>	a.s.	Not relevant	ETR _{acute adult oral}	<0.16	0.2
<i>Apis mellifera</i>	Preparation	Not relevant	HQ _{contact}	<90	42
<i>Apis mellifera</i>	Preparation	Not relevant	ETR _{acute adult oral}	<0.68	0.2
<i>Apis mellifera</i>	a.s.	Not relevant	ETR _{chronic adult oral}	<0.304	0.03
<i>Apis mellifera</i>	a.s.	Not relevant	ETR _{chronic larva oral}	0.19	0.2
Tier 1 level assessment – BBCH <10 (leafy vegetables)					
<i>Apis mellifera</i>	a.s.	treated crop	ETR _{chronic adult oral}	0.016	0.03
<i>Apis mellifera</i>	a.s.	weeds	ETR _{chronic adult oral}	0.084	0.03
<i>Apis mellifera</i>	a.s.	field margin	ETR _{chronic adult oral}	0.001	0.03
<i>Apis mellifera</i>	a.s.	adjacent crop	ETR _{chronic adult oral}	0.001	0.03
<i>Apis mellifera</i>	a.s.	succeeding crop	ETR _{chronic adult oral}	0.016	0.03
Tier 1 level assessment – BBCH 10-49 (leafy vegetables)					
<i>Apis mellifera</i>	a.s.	treated crop	ETR _{chronic adult oral}	0.167	0.03
<i>Apis mellifera</i>	a.s.	weeds	ETR _{chronic adult oral}	0.084	0.03
<i>Apis mellifera</i>	a.s.	field margin	ETR _{chronic adult oral}	0.001	0.03
<i>Apis mellifera</i>	a.s.	adjacent crop	ETR _{chronic adult oral}	0.001	0.03
<i>Apis mellifera</i>	a.s.	succeeding crop	ETR _{chronic adult oral}	0.016	0.03

Figures in bold exceed the relevant trigger value

Risk assessment for honeybees from consumption of contaminated water

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

Czech Republic	October 2018	Daminozide
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Section 5 Ecotoxicology

Species	Test substance	Risk quotient	ETR	Trigger
Risk assessment from exposure to residues in guttation fluid (water solubility = 128 g/L)				
<i>Apis mellifera</i>	a.s.	ETR _{acute adult oral}	7.3	0.2
<i>Apis mellifera</i>	a.s.	ETR _{chronic adult oral}	7.42	0.03
<i>Apis mellifera</i>	a.s.	ETR _{chronic larva oral}	102.3	0.2
Risk assessment from exposure to residues in surface water (FOCUS step 2 PEC _{sw} of 0.1 mg/L)				
<i>Apis mellifera</i>	a.s.	ETR _{acute adult oral}	0.00	0.2
<i>Apis mellifera</i>	a.s.	ETR _{chronic adult oral}	0.000	0.03
<i>Apis mellifera</i>	a.s.	ETR _{chronic larva oral}	0.00	0.2
Risk assessment from exposure to residues in puddle water				
<i>Apis mellifera</i>	a.s.	ETR _{acute adult oral}	0.00	0.2
<i>Apis mellifera</i>	a.s.	ETR _{chronic adult oral}	0.000	0.03
<i>Apis mellifera</i>	a.s.	ETR _{chronic larva oral}	0.00	0.2

Figures in bold exceed the relevant trigger value

Risk assessment for bees from contact and oral dietary exposure for ornamentals (protected use - other than permanent greenhouses) at 7.65 kg a.s./ha x 5, BBCH <50

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

Species	Test substance	Scenario	Risk quotient	HQ/ETR	Trigger
Screening level assessment					
<i>Apis mellifera</i>	a.s.	Not relevant	HQ _{contact}	<38.3	42
<i>Apis mellifera</i>	a.s.	Not relevant	ETR _{acute adult oral}	<0.29	0.2
<i>Apis mellifera</i>	Preparation	Not relevant	HQ _{contact}	<50	42
<i>Apis mellifera</i>	Preparation	Not relevant	ETR _{acute adult oral}	<0.38	0.2
<i>Apis mellifera</i>	a.s.	Not relevant	ETR _{chronic adult oral}	<0.547	0.03
<i>Apis mellifera</i>	a.s.	Not relevant	ETR _{chronic larva oral}	0.34	0.2
Tier 1 level assessment – BBCH <10 (leafy vegetables)					
<i>Apis mellifera</i>	a.s.	treated crop	ETR _{acute adult oral}	0.03	0.2
<i>Apis mellifera</i>	a.s.	treated crop	ETR _{chronic adult oral}	0.028	0.03
<i>Apis mellifera</i>	a.s.	treated crop	ETR _{acute larva oral}	0.03	0.2
<i>Apis mellifera</i>	a.s.	weeds	ETR _{acute adult oral}	0.14	0.2
<i>Apis mellifera</i>	a.s.	weeds	ETR _{chronic adult oral}	0.150	0.03
<i>Apis mellifera</i>	a.s.	weeds	ETR _{acute larva oral}	0.14	0.2
<i>Apis mellifera</i>	a.s.	field margin	ETR _{acute adult oral}	0.00	0.2
<i>Apis mellifera</i>	a.s.	field margin	ETR _{chronic adult oral}	0.001	0.03
<i>Apis mellifera</i>	a.s.	field margin	ETR _{acute larva oral}	0.00	0.2
<i>Apis mellifera</i>	a.s.	adjacent crop	ETR _{acute adult oral}	0.00	0.2
<i>Apis mellifera</i>	a.s.	adjacent crop	ETR _{chronic adult oral}	0.001	0.03
<i>Apis mellifera</i>	a.s.	adjacent crop	ETR _{acute larva oral}	0.00	0.2
<i>Apis mellifera</i>	a.s.	succeeding crop	ETR _{acute adult oral}	0.03	0.2
<i>Apis mellifera</i>	a.s.	succeeding crop	ETR _{chronic adult oral}	0.028	0.03
<i>Apis mellifera</i>	a.s.	succeeding crop	ETR _{chronic larva oral}	0.03	0.2
Tier 1 level assessment – BBCH 10-49 (leafy vegetables)					
<i>Apis mellifera</i>	a.s.	treated crop	ETR _{acute adult oral}	0.29	0.2
<i>Apis mellifera</i>	a.s.	treated crop	ETR _{chronic adult oral}	0.301	0.03
<i>Apis mellifera</i>	a.s.	treated crop	ETR _{acute larva oral}	0.29	0.2
<i>Apis mellifera</i>	a.s.	weeds	ETR _{acute adult oral}	0.14	0.2
<i>Apis mellifera</i>	a.s.	weeds	ETR _{chronic adult oral}	0.150	0.03
<i>Apis mellifera</i>	a.s.	weeds	ETR _{acute larva oral}	0.14	0.2
<i>Apis mellifera</i>	a.s.	field margin	ETR _{acute adult oral}	0.00	0.2
<i>Apis mellifera</i>	a.s.	field margin	ETR _{chronic adult oral}	0.001	0.03
<i>Apis mellifera</i>	a.s.	field margin	ETR _{acute larva oral}	0.00	0.2

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
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<i>Apis mellifera</i>	a.s.	adjacent crop	ETR _{acute adult oral}	0.00	0.2
<i>Apis mellifera</i>	a.s.	adjacent crop	ETR _{chronic adult oral}	0.001	0.03
<i>Apis mellifera</i>	a.s.	adjacent crop	ETR _{acute larva oral}	0.00	0.2
<i>Apis mellifera</i>	a.s.	succeeding crop	ETR _{acute adult oral}	0.03	0.2
<i>Apis mellifera</i>	a.s.	succeeding crop	ETR _{chronic adult oral}	0.028	0.03
<i>Apis mellifera</i>	a.s.	succeeding crop	ETR _{chronic larva oral}	0.03	0.2

Figures in bold exceed the relevant trigger value

Risk assessment for honeybees from consumption of contaminated water

Species	Test substance	Risk quotient	ETR	Trigger
Risk assessment from exposure to residues in guttation fluid (water solubility = 128 g/L)				
<i>Apis mellifera</i>	a.s.	ETR _{acute adult oral}	7.3	0.2
<i>Apis mellifera</i>	a.s.	ETR _{chronic adult oral}	7.42	0.03
<i>Apis mellifera</i>	a.s.	ETR _{chronic larva oral}	102.3	0.2
Risk assessment from exposure to residues in surface water (FOCUS step 2 PEC _{sw} of 0.1 mg/L)				
<i>Apis mellifera</i>	a.s.	ETR _{acute adult oral}	0.00	0.2
<i>Apis mellifera</i>	a.s.	ETR _{chronic adult oral}	0.000	0.03
<i>Apis mellifera</i>	a.s.	ETR _{chronic larva oral}	0.00	0.2
Risk assessment from exposure to residues in puddle water				
<i>Apis mellifera</i>	a.s.	ETR _{acute adult oral}	0.00	0.2
<i>Apis mellifera</i>	a.s.	ETR _{chronic adult oral}	0.000	0.03
<i>Apis mellifera</i>	a.s.	ETR _{chronic larva oral}	0.00	0.2

Figures in bold exceed the relevant trigger value

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

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)

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

Czech Republic	October 2018	Daminozide
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Section 5 Ecotoxicology

Laboratory tests with standard sensitive species Species	Life stage	Test substance	Study type	Dose (kg /ha) ¹	Mortality/ Corr. mortality (%)	Sublethal effects ²
<i>Aphidius rhopalosiphii</i>	Adult	Alar 85 SP	Tier I Glass plate Limit test	Control 10 form. (8.5 a.s.)	2.5 12.5 / 10 LR ₅₀ >10 kg form./ha (>8.5 kg a.s./ha)	No. of pupae / % adverse effects: 21.1 22.6 / -7.1% ER ₅₀ >10 kg form./ha (>8.5 kg a.s./ha)
<i>Typhlodromus pyri</i>	Protonymph ¹	Daminozide	Tier I Glass plate Limit test	Control 7.225 a.s.	n.a.	n.a.
	Protonymph ¹	Dazide 85	Tier I Glass plate Limit test	Control 10 form. (8.5 a.s.)	n.a.	n.a.
	Protonymph	Alar 85 SP	Tier I Glass plate Limit test	Control 10 form. (8.5 a.s.)	3 14 / 11.3 LR ₅₀ >10 kg form./ha (>8.5 kg a.s./ha)	No. of eggs per female / % adverse effects: 7.2 3.9 / 45.8% ER ₅₀ >10 kg form./ha (>8.5 kg a.s./ha)
Additional species						
<i>Encarsia formosa</i>	Adult	Alar 85 SP	Tier I Glass plate Limit test	Control 10 form. (8.5 a.s.)	18 85 / 82 LR ₅₀ <10 kg form./ha (<8.5 kg a.s./ha)	No. of parasitized scales / % adverse effects: 18.2 17.8/ 2.2% ER ₅₀ >10 kg form./ha (>8.5 kg a.s./ha)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

Laboratory tests with standard sensitive species ^{Species}	Life stage	Test substance	Study type	Dose (kg /ha) ¹	Mortality/ Corr. mortality (%)	Sublethal effects ²
<i>Orius laevigatus</i>	Adult	Alar 85 SP	Tier I Glass plate Limit test	Control 10 form. (8.5 a.s.)	17 14 / 0 LR ₅₀ >10 kg form./ha (>8.5 kg a.s./ha)	No. of eggs per female / % adverse effects: 7.5 7.9 / -5.3% ER ₅₀ >10 kg form./ha (>8.5 kg a.s./ha)
<i>Poecilus cupreus</i>	Adult	Alar 85 SP	Tier I Glass plate Limit test	Control 10 form. (8.5 a.s.)	0 0 / 0 LR ₅₀ >10 kg form./ha (>8.5 kg a.s./ha)	No. of larvae consumed / % adverse effects: 4.83 4.90 / -1.4% ER ₅₀ >10 kg form./ha (>8.5 kg a.s./ha)
<i>Chrysoperla carnea</i>	Larva	Alar 85 SP	Tier I Glass plate Limit test	Control 10 form. (8.5 a.s.)	10 12 / 2 LR ₅₀ >10 kg form./ha (>8.5 kg a.s./ha)	No. of eggs per female / % adverse effects: 15.7 15.4 / 1.9 ER ₅₀ >10 kg form./ha (>8.5 kg a.s./ha)

¹ form. – formulation; a.s. - active substance

² positive percentages relate to adverse effects in comparison with control

n.a. – not applicable

First tier risk assessment for daminozide – ornamentals (field use) at 4.25 kg a.s./ha x 5 (worst case)

Test substance	Species	Effect (LR ₅₀ kg a.s./ha)	HQ in-field	HQ off-field ¹	Trigger
Alar 85 SP	<i>Aphidius rhopalosiphi</i>	> 8.50	<1.50	<0.099 (3 m)	2
Alar 85 SP	<i>Typhlodromus pyri</i>	> 8.50	<1.50	<0.099 (3 m)	2

¹ indicate distance assumed to calculate the drift rate

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

First tier risk assessment for daminozide – ornamentals (field use) at 4.25 kg a.s./ha x 5 (worst case)

Test substance	Species	Effect (LR ₅₀ kg a.s./ha)	HQ in-field	HQ off-field ¹	Trigger
Alar 85 SP	<i>Aphidius rhopalosiphii</i>	> 8.50	<1.50	<0.099 (3 m)	2
Alar 85 SP	<i>Typhlodromus pyri</i>	> 8.50	<1.50	<0.099 (3 m)	2

¹indicate distance assumed to calculate the drift rate

Figures in bold exceed the relevant trigger value

First tier risk assessment for daminozide – ornamentals (protected use - other than permanent greenhouses) at 7.65 kg a.s./ha x 5 (worst case)

Test substance	Species	Effect (LR ₅₀ kg a.s./ha)	HQ in-field	HQ off-field ¹	Trigger
Alar 85 SP	<i>Aphidius rhopalosiphii</i>	> 8.50	<2.70	<0.18 (3 m)	2
Alar 85 SP	<i>Typhlodromus pyri</i>	> 8.50	<2.70	<0.18 (3 m)	2

¹indicate distance assumed to calculate the drift rate

Figures in bold exceed the relevant trigger value

Extended laboratory tests, aged residue tests

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

Czech Republic	October 2018	Daminozide
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Section 5 Ecotoxicology

Species	Life stage	Test substance	Study type	Dose (L/ha) ¹	Mortality/ Corr. mortality (%)	Sublethal effects ²
<i>Typhlodromus pyri</i>	Protonymph	Alar 85 SP	Tier I Glass plate	Control 5 form. (4.25 a.s.) 10 form. (8.5 a.s.)	19 23 / 5 15 / 0 LR ₅₀ > 10 kg form./ha (>8.5 kg a.s./ha)	No. of eggs per female / % adverse effects: 5.3 6.0 / -13.2% 5.1 / 3.8% ER ₅₀ > 10 kg form./ha (>8.5 kg a.s./ha)
<i>Typhlodromus pyri</i>	Protonymph	Dazide 85	Tier I Glass plate	Control 1.176 form. (1.0 a.s.) 4.412 form. (3.75 a.s.) 8.824 form. (7.5 a.s.)	14 18 / 5 21 / 8 36 / 26 LR ₅₀ > 8.824 kg form./ha (>7.5 kg a.s./ha)	No. of eggs per female / % adverse effects: 8.1 8.1 / 0% 7.6 / 6.2% 6.5 / 19.8% ER ₅₀ > 8.824 kg form./ha (>7.5 kg a.s./ha)

¹ form. – formulation; a.s. - active substance

² positive percentages relate to adverse effects in comparison with control

Risk assessment for daminozide – ornamentals (protected use - other than permanent greenhouses) at 7.65 kg a.s./ha x 5 (worst case) based on extended lab test

Species	LR ₅₀ /ER ₅₀ (kg.a.s./ha)	In-field rate (kg.a.s./ha)	Off-field rate ¹	Risk acceptable?
<i>Typhlodromus pyri</i>	>8.5	22.95	-	No

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

Semi-field tests

-

Additional specific test

-

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)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

Test organism	Test substance	Application method of test a.s./ OM ¹	Time scale	End point	Toxicity
Earthworms					
<i>Eisenia fetida</i>	Daminozide	Mixed through soil / 10% OM	Chronic	Growth, reproduction, behaviour	NOEC = 684 mg/kg dws
Other soil macroorganisms					
-					

¹To 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)

-

Nitrogen transformation	-	-	-
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Toxicity/exposure ratios for soil organisms

Daminozide – ornamentals (field use) at 4.25 kg a.s./ha x 5

Test organism	Test substance	Time scale	Soil PEC ¹	TER	Trigger
Earthworms					
<i>Eisenia fetida</i>	Daminozide	Chronic	2.833	229	5
Other soil macroorganisms					
-					

¹indicate which PEC soil was used (e.g. plateau PEC)

Daminozide – ornamentals (protected use - other than permanent greenhouses) at 7.65 kg a.s./ha x 5

Test organism	Test substance	Time scale	Soil PEC ¹	TER	Trigger
Earthworms					
<i>Eisenia fetida</i>	Daminozide	Chronic	5.100	127	5
Other soil macroorganisms					
-					

¹indicate which PEC soil was used (e.g. plateau PEC)

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 ER₅₀ tests should be provided

Daminozide – worst case: ornamentals >50 cm in height, protected use - other than permanent greenhouses at 7.65 kg a.s./ha x 5

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
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Section 5 Ecotoxicology

Laboratory dose response tests

Species	Test substance	ER ₅₀ (kg a.s./ha) ² vegetative vigour	ER ₅₀ (kg s.s./ha) ² emergence	Exposure ¹ (kg a.s./ha)	TER	Trigger
Oat, barley, carrot, radish, cucumber, bean	Dazide Enhance	>7.5 kg a.s./ha	-	0.61	>12.30	5
Onion, wheat, sugar beet, oilseed rape, soybean, tomato	Dazide Enhance	>4.5 kg a.s./ha	-	0.61	>7.38	5
Onion, ryegrass, wheat, corn, sugar beet, oilseed rape, cabbage, soybean, lettuce, tomato	Alar 85 WSG	>13 kg a.s./ha	-	0.61	>21.31	5
Onion, ryegrass, wheat, corn, sugar beet, oilseed rape, cabbage, soybean, lettuce, tomato	Alar 85 WSG	-	>13 kg a.s./ha	0.61	>21.31	5

Extended laboratory studies : -
Semi-field and field test: -

¹ based on a worst-case drift value of 8.02% (3 m) and a maximal single application rate of 7.65 kg a.s./ha (ornamentals >50 cm in height, application rate 7.65 kg a.s./ha for protected use (other than permanent greenhouses))

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	-
<i>Pseudomonas sp</i>	Not required

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)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Czech Republic	October 2018	Daminozide

Section 5 Ecotoxicology

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 compounds¹

Compartment	
soil	Daminozide
water	Daminozide
sediment	Daminozide
groundwater	Daminozide

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

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
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Section 5 Ecotoxicology

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

Substance

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]⁷:

Peer review proposal⁸ for harmonised classification according to Regulation (EC) No 1272/2008:

Daminozide

-

No aquatic classification required.

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

⁸ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

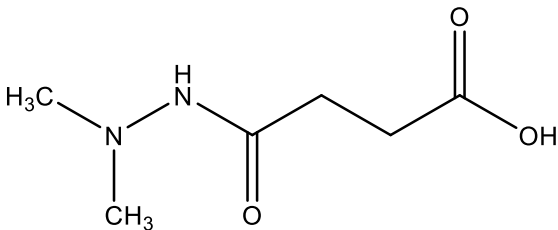
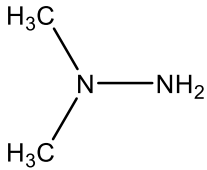
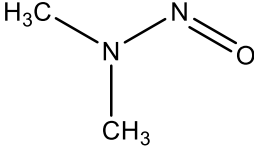
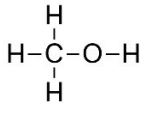
List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

Czech Republic	October 2018	Daminozide
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Section 5 Ecotoxicology

Used compounds code(s)

Code/Trivial name*	IUPAC name/SMILES notation	Structural formula
Daminozide	IUPAC: N-dimethylaminosuccinamic acid CAS: butanedioic acid mono(2,2-dimethylhydrazide)	
Unsymmetrical dimethyl hydrazine UDMH	1,1-dimethyl hydrazine	
N-nitrosodimethylamine NDMA	N-nitrosodimethylhydrazine / dimethylnitrosamine	
Methanol	Methanol	
Formaldehyde	Formaldehyde	$\text{H}_2\text{C}=\text{O}$

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