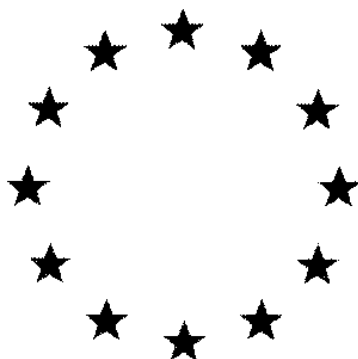


European Commission



**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**

Volume 3 – B.8 (PPP) – Alar

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

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B.8 ENVIRONMENTAL FATE AND BEHAVIOUR AND ENVIRONMENTAL EXPOSURE ASSESSMENT

The product Alar is a water soluble granule (SG) formulation, containing daminozide at a concentration of 850 g a.s./kg, for use as a plant growth regulator. The representative uses applied for are a maximum of 5 applications to ornamental crops grown either indoors or in the field. The representative GAPs for the purposes of the AIR process are summarised in Table B.8-1.

Table B.8-1: Intended application pattern

Crop	Pests or group of pests controlled	Application				Application rate per treatment		PHI days
		method kind	growth stage & season	number min max	interval between applications (min)	water l/ha min max	kg a.s./ha min max	
Ornamentals – Indoor	Plant Growth Regulator	Foliar spraying (gantry)	Actively growing plants	Max. 5	7 days	500 - 1500	7.65	-
Ornamentals - Field	Plant Growth Regulator	Foliar spraying	Actively growing plants	Max.5	7 days	500 - 1500	4.25	-

The impact of formulants is limited to short-term effects such as the formation of stable spray dispersions or to facilitate uptake by target organisms, while their influence on long-term processes, such as degradation and distribution is negligible. Therefore, for the purposes of this risk assessment it is assumed that formulants do not influence the fate and behaviour of the active substance in the environment and are not considered further.

B.8.1 Fate and Behaviour in Soil**B.8.1.1 Rate of degradation in soil****B.8.1.1.1 Laboratory studies**

See separate Annex B.8 for the active substance data.

B.8.1.1.2 Field studies

Reference:	Smilo, A., Blaszczyński, E., Stanton, D.T., Harned, W.H. (1986)
Report No.:	Daminozide Field Dissipation Study
Document No:	A.8.1.7
Guideline:	-
GLP:	None stated
	No – Study performed prior to GLP being required
Previous evaluation:	In DAR (1999)

Test formulation: ALAR-85SP

Lot no. 2202900

Description

A field dissipation study with daminozide (applied as ALAR 85 soluble powder) was performed in Connecticut, USA. Groundwater table at 10 meters, slope 0-1%. The formulation was sprayed onto bare soil at a rate of 4.76 kg a.i./ha in June, 1986. Sampling at 0, 3h, 6h, and 1, 2, 3, and 7 days post treatment. Soil samples (1 kg on wet weight basis, in triplicate) were taken at each sampling interval from two depths: 0-15 cm (0-6 inches) and 15-30 cm (6-12 inches). Extraction of samples with hydrochloric acid. Analysis with GLC and nitrogen detection (analytical recoveries daminozide 63 and 46% for the 0-15 and 15-30 cm layers, UDMH 101-130%).

Table B.8.1.1.2-1: Soil characterisation

Soil type	Sandy loam
Sand %	54
Silt %	34
Clay %	10
pH	6.1
Organic matter %	3.3
Slope %	0-1
Water Table	30 ± 10 feet
Crop	No crop used, bare soil
Plot size	12 x 70 feet

Results

No rainfall during 48 hours after treatment, after 72h 10 mm, after 7 days 48 mm total. Soil (5 cm) and air averaged temperature 0-6h post treatment 20.5 and 16 °C. Samples were analysed immediately after sampling.

Maximum daminozide concentrations in 0-15 cm layer after 6 hours (4.4 mg/kg), and diminished to <0.5 mg/kg (limit of detection) within one week. In 15-30 cm layer max. level was 1.2 mg/kg at 3 hours, <0.5 mg/kg after 7 days.

The total UDMH method quantifies the presence of daminozide, free UDMH, metabolites containing UDMH and presumably any bound residues containing UDMH. The limit of detection is 0.01 ppm for a 50 g sample. Maximum total UDMH concentrations in 0-15 cm layer after 6 hours (4.5 mg/kg), and diminished to 0.17 mg/kg (limit of detection was 0.01 mg/kg) within one week. In 15-30 cm layer max. level was 0.87 mg/kg at 3 hours, <0.01 mg/kg after 7 days.

Table B.8.1.1.2-1: Summary of residues, daminozide and total UDMH, in soil samples

Time (hr)	ppm (0 - 15 cm)	
	Daminozide	Total UDMH
0	2.7	2.63
3	1.5	1.83
6	4.4	4.48
24	1.9	0.54
48	0.6	0.36
72	0.8	0.96
168	<0.5	0.17

	ppm (15 - 30 cm)	
	Daminozide	Total UDMH
0	0.9	0.68
3	1.2	0.87
6	0.7	0.58
24	0.5	0.044
48	0.5	0.046
72	0.5	0.060
168	<0.5	<0.010

Conclusion

Daminozide and UDMH-containing residue levels paralleled one another closely and reached the maximum detected level within 6 hours. Levels for both diminished to less than 0.5 ppm after 1 week. No detectable residues were found in the pretreatment soil samples at either sampling level 0-6 inch or 6-12 inch).

RMS comments and conclusion

This no guideline field soil dissipation study was conducted on one site only in USA. No comparison to EU conditions has been performed. No information on the history of the soil. Recoveries of analytical method for daminozide was too low (<70%). Detected level of daminozide was higher in some sampling points than total UDMH (daminozide + UDMH-containing metabolites and bound residues).

Study is not accepted by the RMS, results of this study will not be used for the risk assessment. However, laboratory DT₅₀ values at 20°C and pF2 for active substance daminozide and metabolite methanol do not exceed 60 days or the DT₉₀ 200 days. Therefore, field soil dissipation studies are not required in accordance with Comm. Reg. (EU) No. 283/2013.

B.8.1.2 Mobility in the soil

Specific studies on the preparation have not been performed. Refer to Section B8 of the active substance document.

B.8.2 Predicted environmental concentrations in soil (PECs)

PECs for Alar in soil have been calculated according to FOCUS 1997.

Alar is used in ornamental crops as a plant growth regulator at a maximum application rate of 7.65 kg a.s./ha indoors or 4.25 kg a.s./ha in the field. A maximum of five applications may be made either indoors or in the field, with a minimum application interval of 7 days. Daminozide is a plant growth regulator used on a wide range of ornamental crops. It is typically applied to mature plants with large amounts of foliage and with high crop interception. Where it is applied to younger plants, those plants still have a significant amount of foliage and are grown in much smaller individual pots. In both cases (younger and mature plants) pots are typically tightly packed,

with little or no space between them, and hence crop interception is likely to be significant in both cases. No crop interception values for ornamental crops are given in available guidance. A crop interception value of 50% was therefore selected as a realistic worst case for applications made to younger plants early in the growing season in accordance with the GAP. Applications made to more mature plants are anticipated to have a higher crop interception.

The EFSA guidance document on clustering and ranking emissions from protected crops (EFSA 2014¹), states that for soil in permanent protection structures a risk assessment is only necessary for persistent substances ($DT_{90} > 1$ year), because soil within the permanent structure is changed such that risk assessment is not relevant i.e. soil within the permanent structure is considered to be an artificial, rather than a natural, environment. Daminozide and its metabolites have DT_{90} values significantly < 1 year, and therefore soil risk assessment is not required for the indoor use.

For applications made in the field PEC_{soil} values for daminozide were calculated assuming that residues were evenly distributed through the upper 5 cm soil layer, which has a bulk density of 1.5 g/cm³.

For the modelling of the decline of the daminozide residues in soil the maximum laboratory DT_{50} in aerobic soil of 0.37 days, calculated with SFO kinetics, was used. The calculated PEC_{soil} values are detailed in Table 9.1.3-02. Because of the very rapid degradation of daminozide individual application PEC_{soil} values are the same as when multiple applications are considered.

PEC values for M1 (identified as methanol) were calculated based on the assumptions given for parent daminozide PEC_{soil} calculations. Additionally, because of daminozide's very rapid degradation, it was assumed that peak methanol concentrations were observed immediately after application. Therefore, metabolite PECs were calculated by adjusting the maximum application rate of daminozide for the differences in molecular weight of parent and the metabolites, and the maximum percentage formed in the aerobic soil degradation study of Möndel, 2015, (27.2% AR), to give an equivalent application rate for methanol. Degradation between applications was taken into account using the maximum laboratory DT_{50} values in soil for methanol. The substance specific input parameters used for the metabolite in the PEC_{soil} calculations are given in Table B.8.2-1. The calculated PECs for the metabolite are given in Table B.8.2-2. The maximum PEC_{soil} value for methanol arose following multiple applications.

¹ EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615, 43 pp., doi:10.2903/j.efsa.2014.3615.

Table B.8.2-1: Substance specific parameters used for the calculation of PEC_{soil} values for daminozide and methanol

	Daminozide	Methanol
Molar mass [g/mol]	160.2	32.0
Maximum in soil (%)	-	27.2
Correction factor	-	0.0543
Rate applied (g/ha)	Field – 5 x 4250	Field – 5 x 230.8
Interval (days)	7	7
Crop interception (%)	50	50
DT ₅₀ in soil (days)	0.37 (SFO)	6.2 (SFO)

Table B.8.2-2: PEC_{soil} values for daminozide in soil after application of Alar to ornamental crops grown in the field

Days after application	Single application		Multiple application	
	PEC _{soil} (mg/kg)	Time weighted Average PEC _{soil} (mg/kg)	PEC _{soil} (mg/kg)	Time weighted Average PEC _{soil} (mg/kg)
0	2.833	2.833	2.833	2.833
1	0.435	1.280	0.435	1.280
2	0.067	0.738	0.067	0.738
4	0.002	0.378	0.002	0.378
7	0.000	0.216	0.000	0.216
14	0.000	0.108	0.000	0.108
21	0.000	0.072	0.000	0.072
28	0.000	0.054	0.000	0.054
50	0.000	0.030	0.000	0.030
100	0.000	0.015	0.000	0.015

Table B.8.2-3: PEC_{soil} values for metabolite methanol in soil after application of Alar to ornamental crops grown in the field

Days after application	Single application		Multiple application	
	PEC _{soil} (mg/kg)	Time weighted Average PEC _{soil} (mg/kg)	PEC _{soil} (mg/kg)	Time weighted Average PEC _{soil} (mg/kg)
0	0.154	-	0.278	0.278
1	0.138	0.146	0.248	0.263
2	0.123	0.138	0.222	0.249
4	0.098	0.124	0.178	0.224
7	0.070	0.107	0.127	0.193
14	0.032	0.078	0.058	0.140
21	0.015	0.059	0.027	0.107
28	0.007	0.047	0.012	0.085
50	0.001	0.027	0.001	0.050
100	0.000	0.014	0.000	0.025

RMS comments and conclusion:

It is not specified in the GAP that indoor uses are limited to permanent structures only, therefore all structures including non-permanent should be considered in the risk assessment. Due to higher application rate for indoor uses, the PEC_{soil} have been calculated by the RMS. The input data and method of calculation are the same as for field uses (see above), only the rate of application changed to 5 x 7.65 kg a.s./ha, interception 50 %. Results are summarised in the table below.

Table B.8.2-4: Substance specific parameters used for the calculation of PEC_{soil} values for daminozide and methanol

	Daminozide	Methanol
Molar mass [g/mol]	160.2	32.0
Maximum in soil (%)	-	27.2
Correction factor	-	0.0543
Rate applied (g/ha)	Indoor – 5 x 7650	Indoor – 5 x 415.4
Interval (days)	7	7
Crop interception (%)	50	50
DT ₅₀ in soil (days)	0.37 (SFO)	6.2 (SFO)

Table B.8.2-5: PEC_{soil} values for daminozide in soil after application of Alar to ornamental crops grown indoor

Days after application	Single application		Multiple application	
	PEC _{soil} (mg/kg)	Time weighted Average PEC _{soil} (mg/kg)	PEC _{soil} (mg/kg)	Time weighted Average PEC _{soil} (mg/kg)
0	5.100	-	5.100	-
1	0.783	2.304	0.783	2.304
2	0.120	1.304	0.120	1.304
4	0.003	0.680	0.003	0.680
7	0.000	0.389	0.000	0.389
14	0.000	0.194	0.000	0.194
21	0.000	0.130	0.000	0.130
28	0.000	0.097	0.000	0.097
50	0.000	0.054	0.000	0.054
100	0.000	0.027	0.000	0.027

Table B.8.2-6: PEC_{soil} values for metabolite methanol in soil after application of Alar to ornamental crops grown indoor

Days after application	Single application		Multiple application	
	PEC _{soil} (mg/kg)	Time weighted Average PEC _{soil} (mg/kg)	PEC _{soil} (mg/kg)	Time weighted Average PEC _{soil} (mg/kg)
0	0.277	-	0.500	-
1	0.248	0.262	0.447	0.473
2	0.221	0.248	0.400	0.448
4	0.177	0.223	0.320	0.403
7	0.127	0.192	0.229	0.347
14	0.058	0.140	0.105	0.253
21	0.026	0.107	0.048	0.193
28	0.012	0.085	0.022	0.153
50	0.001	0.049	0.002	0.089
100	0.000	0.025	0.000	0.045

B.8.3 Predicted environmental concentrations in groundwater (PEC_{gw})

Reference:	Hilton, M., Callow, B. (2016a) Predicted Environmental Concentrations of daminozide and its metabolite methanol in groundwater using the FOCUS PEARL 4.4.4 model and FOCUS groundwater scenarios.
Report No.:	1007582.UK0 – 1916
Document No:	-
Guideline:	FOCUS (2000, 2009, 2012)
GLP:	No (not applicable - calculation)
Previous evaluation:	Submitted for the purpose of renewal

Executive Summary

Groundwater modelling of daminozide and its metabolite, methanol, has been undertaken using the FOCUS groundwater scenarios and the FOCUS PEARL 4.4.4 model. The modelling was based on the proposed GAPs to ornamental crops in the EU. The FOCUS models do not have an ornamental crop included, and therefore maize was used as a surrogate crop for ornamentals. This covered an application of 5 x 7.65 kg a.s./ha (7 day interval) for applications made indoors, and 5 x 4.25 kg a.s./ha (7 days interval) for applications made in the field. The GAPs were modelled for applications made in spring. A crop interception value of 50% was considered. Indoor scenarios are not yet available and therefore for applications to indoor crops, the outdoor FOCUS scenarios were considered as a worst case.

A soil DT₅₀ value of 0.12 days (20°C and pF2), K_{oc} of 26.6 mL/g, and 1/n of 1.27 were input for daminozide. Values of 3.9 days, 1.0 mL/g and 1.0 were considered for the DT₅₀, K_{oc}, and 1/n values respectively for methanol. A plant uptake factor of 0.5 was input for both parent daminozide and methanol as daminozide is a systemic plant growth regulator.

PEC_{gw} values for daminozide were <<0.1 µg/L in all scenarios, for both application timings, made both in the field and in glasshouses. For methanol, applications made both indoors and in the field resulted in all scenarios displaying PEC_{gw} values <0.1 µg/L.

I. MATERIAL AND METHODS

Predicted Environmental Concentrations in groundwater were calculated for daminozide and its soil metabolite methanol, using the FOCUS groundwater scenarios (FOCUS, 2000, 2009, 2012)^{2,3} and the FOCUS PEARL 4.4.4 model.

Methanol has a high vapour pressure (1.69 x 10⁴ Pa at 25°C), which would be expected to result in losses of the metabolite from soil via volatilisation. Of the FOCUS groundwater models FOCUS PEARL is considered to best approximate the likely volatile loss of highly volatile metabolites such as methanol, and therefore in this report modelling was performed with FOCUS PEARL 4.4.4 only. It should be noted that FOCUS PELMO does not

² FOCUS (2000). FOCUS groundwater scenarios in the EU review of active substances - The report of the work of the Groundwater Scenarios Workgroup of FOCUS (Forum for the Co-ordination of pesticide fate models and their USE), Version 1 of November 2000. EC Document Reference Sanco/321/2000 rev.2.

³ FOCUS (2009). Assessing potential for Movement of Active substances and their metabolites to Groundwater in the EU” Sanco/13144/2010 v 2.0, June 2009

consider volatilisation of metabolites, and would therefore be expected to significantly underestimate losses of methanol by volatilisation, and hence, significantly over-estimate groundwater PECs.

The agronomic parameters used as input for the simulations were as presented below.

Crop: Ornamental Crops (Field application)

FOCUS Crop: maize

Application Rate: 5 x 4.25 kg a.s./ha (7 days interval)

Crop Interception: 50%

Application Timing: First application 1st April

Crop: Ornamental Crops (Indoor application)

FOCUS Crop: maize

Application Rate: 5 x 7.65 kg a.s./ha (7 days interval)

Crop Interception: 50%

Application Timing: First application 1st April

The FOCUS models do not have an ornamental crop included. Therefore, maize was used as a surrogate crop for ornamentals as it is included in most of the groundwater scenarios in the FOCUS models.

The EFSA guidance document for clustering and ranking emissions from protected crops (EFSA, 2014) recommends that for soil bound crops groundwater modelling should be performed even for permanent protection structures. However, no standard indoor/glasshouse groundwater scenarios are currently available for regulatory submission in the EU, and therefore, as a worst case, groundwater modelling has been performed considering the outdoor scenarios.

Applications to ornamental crops are made to actively growing plants. Therefore, it is assumed that in the field applications may occur between the 1st April and the end of August. Considering the multiple application regime, the timing of the first application was set to 1st April. Groundwater exposure for subsequent application timings will be lower since rainfall and leaching through the soil profile is lower in the summer months, and crop interception would typically be higher for more mature plants. Though indoor crops may be grown year round, it is not envisaged that they would be exposed to conditions outside of those experienced in the field. Therefore, these application timings considered for the modelling of field applications are considered to represent a worst case for glasshouse crops.

No crop interception values for ornamental crops are given in available guidance. Daminozide is a plant growth regulator used on a wide range of ornamental crops. In order for it to be effective, the active substance must be targeted to the plant foliage. Therefore it is usually applied to mature plants with large amounts of foliage and with high crop interception. Where it is applied to younger plants, those plants still have a significant amount of foliage and are grown in much smaller individual pots. In both cases (younger and mature plants) pots are typically tightly packed, with little or no space between them, and hence crop interception is significant in both cases.

Therefore, a crop interception value of 50% was selected, as a worst case assumption, for spring applications, assuming that those applications are made to younger plants early in the growing season. Later applications would be likely to be made to more mature plants, and therefore crop interception values would be anticipated to be higher.

A metabolism scheme in which daminozide degraded to the metabolite methanol and a sink compartment, and methanol degraded to the same sink compartment was considered in the simulations.

A summary of substance specific input parameters is shown in Table B.8.3-1. It was not possible to perform reliable batch adsorption studies for methanol because of the practical difficulties created by its high volatility. Therefore, 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.

Water solubility and vapour pressure values for methanol were also derived from the EPIWEB 4.1 suite of programmes.

Geometric mean soil DT_{50} values for both daminozide and methanol, and the arithmetic mean formation fraction for methanol, were derived from the aerobic soil degradation study of Möndel, 2014.

A crop uptake factor of 0.5 was used for parent daminozide and its metabolite methanol. Daminozide has a systemic mode of action, while both compounds are highly soluble with low molecular weights, and as such can be expected to be taken up by any crops present.

Table B.8.3-1: Summary of substance specific input parameters for daminozide and its metabolite methanol for the leaching simulation with FOCUS PEARL v 4.4.4

Properties	Daminozide		Methanol	
Molecular Mass (g mol ⁻¹)	160.2	-	32.0	-
Vapour Pressure (Pa at 25°C)	1.5 x 10 ⁻⁶	Tremain (2001)	1.69 x 10 ⁴	EPIWEB 4.1
Aqueous Solubility (g/L at 20°C)	128	Friedlander (2011)	1,000 (at 25°C)	EPIWEB 4.1
K_{foc} (mL/g)	26.6	Arithmetic mean	1.0	EPIWEB 4.1
K_{fom} (mL/g)	15.4	Arithmetic mean	0.6	EPIWEB 4.1
Freundlich Exponent	1.27	Arithmetic mean	1.0	Default
DT_{50} (20 °C/ pF2; days)	0.12	Geomean	3.9	Geomean
Formation Fraction	-	-	0.27	Arithmetic mean
Plant Uptake Coefficient	0.5	Default	0.5	Default
Arrhenius Coefficient (kJ/mol)	65.4	Default	65.4	Default

II. RESULTS AND DISCUSSION

Reported PEC_{gw} values were the 80th percentile annual average concentrations from 20 years. PEC_{gw} values from modelling with FOCUS PEARL 4.4.4 for daminozide and methanol are shown in Table B.8.3-2 - Table B.8.3-3.

Table B.8.3-2: PEC_{gw} (µg/L) values for daminozide and its metabolite, methanol, after application to ornamental crops grown indoors

LOCATION	Daminozide (µg/l)	Methanol (µg/l)
CHATEAUDUN	<0.0001	0.0033
HAMBURG	<0.0001	0.0144
KREMSMUNSTER	<0.0001	0.0388
OKEHAMPTON	<0.0001	0.0806
PIACENZA	<0.0001	0.0413
PORTO	<0.0001	0.0231
SEVILLA	<0.0001	<0.0001
THIVA	<0.0001	<0.0001

Table B.8.3-3: PEC_{gw} (µg/L) values for daminozide and its metabolite, methanol, after application to ornamental crops grown in the field

LOCATION	Daminozide (µg/l)	Methanol (µg/l)
CHATEAUDUN	<0.0001	0.0018
HAMBURG	<0.0001	0.0080
KREMSMUNSTER	<0.0001	0.0217
OKEHAMPTON	<0.0001	0.0448
PIACENZA	<0.0001	0.0230
PORTO	<0.0001	0.0128
SEVILLA	<0.0001	<0.0001
THIVA	<0.0001	<0.0001

III. CONCLUSION

PEC_{gw} values for daminozide were $<<0.1$ µg/L in all scenarios, for both application timings, made both in the field and in glasshouses. For methanol, applications made both indoors and in the field resulted in PEC_{gw} values <0.1 µg/L in all scenarios.

The modelling represents a significant worst case scenario for applications made in glasshouses since the FOCUS scenarios modelled are representative of the outdoor field situation, and leaching would be anticipated to be lower for applications made in glasshouses.

RMS comments and conclusion:

Results from soil adsorption/desorption study for daminozide are not accurate, therefore the worst case Koc value of 18.4 mL/g and corresponding 1/n of 1.368 is preferred to use for the modelling by the RMS (max. 1/n of 1.3 can be entered into the model).

The use of plant uptake factor of 0.5 for metabolite methanol is not scientifically justified. No systemic mode of action has been shown for methanol. Moreover, methanol is practically not absorbed by soil, in a real field situation its leaching to deeper soil levels most likely would be faster than uptake by plant roots.

Table B.8.3-4: Summary of substance specific input parameters for daminozide and its metabolite methanol for the leaching simulation with FOCUS PEARL v 4.4.4

Properties	Daminozide		Methanol	
Molecular Mass (g mol ⁻¹)	160.2	-	32.0	-
Vapour Pressure (Pa at 25°C)	1.5 x 10 ⁻⁶	Tremain (2001)	1.69 x 10 ⁴	EPIWEB 4.1
Aqueous Solubility (mg/L at 20°C)	128,000	Friedlander (2011)	1,000,000 (at 25°C)	EPIWEB 4.1
K _{foc} (mL/g)	18.4	Arithmetic mean	1.0	EPIWEB 4.1
K _{fom} (mL/g)	10.7	Arithmetic mean	0.6	EPIWEB 4.1
Freundlich Exponent	1.368*	Arithmetic mean	1.0	Default
DT ₅₀ (20 °C/ pF2; days)	0.12	Geomean	3.9	Geomean
Formation Fraction	-	-	0.27	Arithmetic mean
Plant Uptake Coefficient	0.5	Default	0	Default
Arrhenius Coefficient (kJ/mol)	65.4	Default	65.4	Default

* max. value of 1.3 is possible in the model PEARL

Table B.8.3-5: PEC_{gw} (µg/L) values for daminozide and its metabolite, methanol, after application to ornamental crops grown indoors

LOCATION	Daminozide (µg/l)	Methanol (µg/l)
CHATEAUDUN	<0.0001	0.004
HAMBURG	<0.0001	0.028
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

Table B.8.3-6: PEC_{gw} (µg/L) values for daminozide and its metabolite, methanol, after application to ornamental crops grown in the field

LOCATION	Daminozide (µg/l)	Methanol (µg/l)
CHATEAUDUN	<0.0001	0.002
HAMBURG	<0.0001	0.016
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} values for daminozide were <<0.1 µg/L in all scenarios, for applications made both in the field and in glasshouses. For methanol, applications made both indoors and in the field resulted in all scenarios displaying PEC_{gw} values <0.1 µg/L. A relevance assessment for methanol is therefore not required. However, the results are from one model only. Due to the fact that FOCUS PELMO does not consider the volatility of metabolites, modelling with FOCUS PELMO is not relevant and is not required.

B.8.4 Fate and behavior in water and sediment

B.8.4.1 Aerobic mineralisation in surface water

See separate Annex B.8 for the active substance data.

B.8.4.2 Water/sediment study

See separate Annex B.8 for the active substance data.

B.8.4.3 Irradiated water/sediment study

See separate Annex B.8 for the active substance data.

B.8.5 Predicted environmental concentrations in surface water and sediment (PEC_{sw}, PEC_{sed})

Reference:	Hilton, M., Callow, B. (2016b) Predicted Environmental Concentrations of daminozide and its metabolite methanol in surface water in the EU using the FOCUS surface water scenarios.
Report No.:	Report No: 1007582.UK0 – 1770
Document No:	-
Guideline:	FOCUS (2001, 2005, 2012)
GLP:	No (not applicable - calculation)
Previous evaluation:	Submitted for the purpose of renewal. Notifier's calculations were modified by the RMS where deemed necessary

Executive Summary

Surface water modelling of daminozide and its metabolite, methanol, was undertaken based on the GAPs on ornamental crops in the EU. This covered an application of 5 x 7.65 kg a.s./ha (7 day interval) for applications made indoors, and 5 x 4.25 kg a.s./ha (7 day interval) for applications made in the field. The FOCUS models do not have an ornamental crop included, therefore for FOCUS SW Steps 1 and 2 for daminozide and methanol applications were made considering hand-held application to crops of both < 50 cm (maize) and > 50 cm height. Step 3 PEC values were based on simulations using the FOCUS surface water scenarios. Step 3 simulations for daminozide were performed utilising the suite of FOCUS models. In the absence of hand-held applications to ornamental crops being included in the FOCUS crops at Step 3, simulations were performed considering the FOCUS crops 'maize' and 'vines, late applications' since these two crops are in the same crop groupings as hand-held applications to crops <50cm and >50cm respectively in the FOCUS SW guidance. For indoor applications, calculations were performed outside the FOCUS models, based upon a worst case a loss of active substance of 0.1% of applied, which was assumed in accordance with existing Dutch guidance. In this case Step 4 assessments were not required; as an acceptable risk was demonstrated in ecotoxicological risk assessments at Step 3.

At Steps 1 and 2 applications were assumed to be made in March – May for spring applications, and June – September for late summer applications. At Step 3 application dates were selected by the PAT. Application windows for spring applications were set to commence on the 1st April, while those for late summer applications were set to end on 31st August. Both single and multiple applications were considered in the modelling.

Geometric mean soil DT₅₀ values of 0.12 days and 3.9 days for daminozide and methanol respectively were input. At Step 1 and 2 whole system geometric mean DT₅₀ values of 0.906 and 59.4 days for daminozide and methanol respectively for the whole system, water phase and sediment phase DT₅₀ values were input. Maximum formations of methanol, in soil of 27.2% AR, and in water of 75.7% AR, were input. At Step 3 default sediment DT₅₀ values of 1000 days were input for daminozide. A Plant Uptake Factor of 0.5 was utilised for daminozide at Step 3. Plant uptake factors are not required at Steps 1 and 2, and therefore were not required for methanol.

For field applications a maximum Step 1 PEC_{sw} value of 1480 µg/L, a Step 2 PEC_{sw} value of 113.7 µg/L, and a Step 3 PEC_{sw} value of 75.4 µg/L were calculated for daminozide after applications to ornamental crops > 50 cm in height. Step 1 and 2 PEC_{sw} values for methanol were 470.3 µg/L and 68.53 µg/L, respectively.

For ornamental crops < 50 cm tall a maximum Step 1 PEC_{sw} value of 1410 µg/L, Step 2 PEC_{sw} value of 39.09 µg/L, and Step 3 PEC_{sw} value of 50.7 µg/L were calculated for daminozide. Step 1 and 2 PEC_{sw} values for methanol were 413.9 µg/L and 26.25 µg/L, respectively.

For indoor applications a maximum daminozide PEC_{sw} value of 2.6 µg/L and a maximum methanol PEC_{sw} value of 1.6 µg/L were calculated.

I. MATERIAL AND METHODS

Glasshouse/Indoor Applications

For the proposed application to crops grown indoors the EFSA guidance document for clustering and ranking emissions from protected crops (EFSA, 2014) recommends that PEC_{sw} values be calculated following emission from the facility using simulation models with appropriately defined scenarios. However, relevant models and defined scenarios are not currently available. Therefore, as a worst case, a loss of 0.1% of applied active substance was assumed in accordance existing Dutch guidance⁴. Calculations were performed outside the FOCUS SW models, in accordance with the indoor GAP of 5 x 7.65 kg a.s./ha, with a 7 day application interval. Losses were assumed to be input in to a surface water body 100m long, 1 m wide, and 0.3m deep. For the calculation of sediment PECs a sediment density of 1.3 g/cm³ and height of 5cm were also considered.

The substance specific input parameters considered in the calculations are presented in Table B.8.5-1 in the following ‘Steps 1 and 2’ subsection. Whole system DT_{50} values were considered for both daminozide and methanol in the calculations for the individual water and sediment compartments.

For the calculation of methanol PECs it was assumed that daminozide was instantly degraded, and therefore daminozide application rates were corrected for the relative molecular masses of parent and metabolite, as well as for the maximum formation of methanol. The aquatic mineralisation study of Button (2015) demonstrated a maximum mean formation of an unidentified polar metabolite of 75.7% AR. The metabolite is assumed to be methanol, and therefore the maximum formation of 75.7% AR value was considered for the calculation of PEC_{sw} values following glasshouse applications. However, 100% AR was used by the RMS as default worst case value due to several deviations of the aqueous mineralisation study. For the calculation of PEC_{sw} values for methanol an application rate of 5 x 1.157 kg a.s./ha was considered by the Notifier, and was modified to 1528 g a.s./ha by the RMS..

The maximum observed concentration of daminozide in sediment of 6.7% AR was considered in the calculation of daminozide PEC_{sed} values. Because methanol concentrations in sediment were increasing at the final characterised sample in the water/sediment study of De Vette and van Es (2002), it was assumed that all of the radioactivity in sediment at study termination (12.4% AR; radioactivity in the final sample was not characterised) was attributable to methanol. Concentrations of radioactivity in sediment were decreasing at the study termination and therefore this assumption is a worst case for methanol. Calculations of sediment PEC values for methanol were therefore made based upon an application rate 5 x 1.528 kg a.s./ha which considered correction for molecular masses only. The formation and partitioning of methanol to sediment (with a maximum occurrence of 12.4% AR) was considered separately within the calculations.

⁴ CTGB (2011). Evaluation Manual for the Authorisation of Plant protection products and Biocides. NL part. Plant protection products. Chapter 6 fate and behaviour in the environment: behaviour in surface water and sediment. Version 1.0; January 2013.

FOCUS Steps 1 and 2

PEC_{sw} and PEC_{sed} values were calculated for parent daminozide and the metabolite methanol according to the FOCUS surface water guidance document, using the STEPS 1-2 in FOCUS calculator vers. 2.1. Calculations were performed in accordance with the GAP for field applications of 5 x 4.25 kg a.s./ha, with a 7 day application interval. Calculations were performed for applications made to ornamental crops < 50 cm in height and for ornamental crops > 50 cm in height. Maize was used as a surrogate for ornamental crops < 50cm height, and Application hand (crop > 50cm) was selected for taller crops.

Daminozide is a plant growth regulator, used on a wide range of ornamental crops, and applications will therefore occur on actively growing plants. Therefore in the field applications were assumed to occur between the 1st April and the end of August. Two sets of calculations were performed; 1 for spring applications and 1 for late summer applications. Application timings in the FOCUS Step 1 & 2 calculator were therefore selected accordingly.

In order for daminozide to be effective the active substance must be targeted to the plant foliage. Therefore it is usually applied to mature plants with large amounts of foliage and with high crop interception. Where it is applied to younger plants, those plants still have a significant amount of foliage and are grown in much smaller individual pots. In both cases (younger and mature plants) pots are typically tightly packed, with little or no space between them, and hence crop interception is significant in both cases.

No crop interception values for ornamental crops are given in available guidance. However, based on the uses of daminozide, at Step 2 ‘average crop cover’ was selected as a worst case assumption for spring applications, assuming that those applications are made to younger plants early in the growing season. Later applications are anticipated to be made to more mature plants, and therefore a crop interception of ‘Full canopy’ was selected as a reasonable crop interception value for all late summer applications.

The agronomic input parameters were therefore as follows:

Crop: Ornamental Crops (Field application - Spring)

FOCUS Crop: Maize/ Application hand (crop > 50cm)

Application Rate: 5 x 4.25 kg a.s./ha

Interval: 7 days

Crop Interception: Average crop cover

Region/season of application: SEU/NEU – March - May

Crop: Ornamental Crops (Field application – Late summer)

FOCUS Crop: Maize/ Application hand (crop > 50cm)

Application Rate: 5 x 4.25 kg a.s./ha

Interval: 7 days

Crop Interception: Full canopy

Region/season of application: SEU/NEU – June – Sept

A summary of substance specific input parameters for daminozide and methanol is presented in Table B.8.5-1. It was not possible to perform reliable batch adsorption studies for methanol because of the practical difficulties

created by its high volatility (the vapour pressure and Henry's Law Constant of methanol were calculated to be 1.69×10^4 Pa and $0.46 \text{ Pa}\cdot\text{m}^3\cdot\text{mol}^{-1}$, both at 25°C , using the EPIWEB 4.1 experimental database). Instead QSAR calculations were performed using the EPIWEB 4.1 software tool, and specifically the KOCWIN v 2.0 tool. K_{oc} values of 1.0 mL/g using the MCI method, 1.224 L/kg using the LogK_{ow} method and 2.75 L/kg from the experimental database were obtained for methanol. Therefore, the worst case K_{oc} value of 1.0 mL/g , and a default $1/n$ value of 1.0 were input.

The rates of degradation for both daminozide and methanol in aqueous systems were derived in the study of Hilton and Callow (2014) for the two whole water/sediment systems investigated in the study of De Vette and van Es (2002). The geometric mean values of 0.906 days and 59.4 days (1000 days was used by the RMS for methanol) for daminozide and methanol respectively were input for the whole system at Step 1 and the individual water and sediment compartments at Step 2.

The aquatic mineralisation study of Button (2015) demonstrated a maximum mean formation of an unidentified polar metabolite of 75.7% AR. Later identified as methanol and therefore the formation is higher than the maximum in the whole system of water/sediment study (24.1% AR), and therefore this value was considered as the maximum whole system formation at Steps 1 and 2 as a worst case.

Table B.8.5-1: Summary of input parameters for daminozide and its metabolite methanol for the PEC_{sw} calculations with FOCUS Step 1 & 2 and for PEC_{sw} calculations following indoor applications

Parameter	Compound	Value	Remarks
Molecular weight [g mol^{-1}]	Daminozide Methanol	160.2 32.0	-
Water solubility [g L^{-1}] at 20°C	Daminozide Methanol	128 $1,000 (25^\circ\text{C})$	Friedlander (2011) Value from EPIWEB 4.1
DT_{50} soil [d]	Daminozide Methanol	0.12 3.9	Geometric mean ($n=4$) Geometric mean ($n=4$)
K_{loc} [mL g^{-1}]	Daminozide Methanol	26.6 1.0	Arithmetic mean Worst case value from KOCWIN 2.0
Maximum formation in soil [% AR]	Daminozide Methanol	- 27.2	- Maximum
DT_{50} water [days]	Daminozide Methanol	0.906 59.4	Geomean whole system Geomean whole system
DT_{50} sediment [days]	Daminozide Methanol	0.906 59.4	Geomean whole system Geomean whole system
DT_{50} system (water/sediment) [days]	Daminozide Methanol	0.906 59.4	Geomean whole system Geomean whole system
Maximum proportion formed in water-sediment [%]	Daminozide Methanol	-* 75.7**	- Max. aq. mineralisation

* The maximum occurrence of daminozide in sediment was 6.7% AR. This value is used in the calculation of PEC_{sed} values following indoor applications.

**A sediment concentration of 12.4% AR was assumed for methanol for the calculation of PEC_{sed} values following indoor applications, based upon the maximum total radioactivity in the sediment phase of the water/sediment study of De Vette and van Es (2002), and the assumption that it is all attributable to methanol. An unidentified polar metabolite was observed in the aerobic mineralisation study of Button (2015) at a maximum concentration of 75.7% AR. This metabolite was assumed to be methanol, and the maximum formation of 75.7% AR was considered for PEC_{sw} calculations following indoor applications.

FOCUS Step 3

FOCUS surface water modelling at Step 3 was used to examine the potential of daminozide to reach surface water and sediment following the application of daminozide to ornamental crops of <50 cm height and >50 cm height, in accordance with the field GAP of 5 x 4.25 kg a.s./ha. For FOCUS Step 3, FOCUS (2001, 2005, 2012) developed crop, climate and soil data for ten representative locations within the EU. These aim to provide a realistic worst case for surface water exposure within the EU. The scenarios were developed to include spray drift exposure and drainage or run-off exposure to surface water as well as the fate of the compound within the water. Run-off input is simulated with PRZM v3.1.1 and drainage input simulated with MACRO v5.5.3. To manage these input data, an electronic interfacing program (SWASH v3.1) was developed which ensures that all relevant inputs are formulated for TOXSWA v3.3.1, the surface water fate model. In this case Step 4 assessments were not required; as an acceptable risk was demonstrated in ecotoxicological risk assessments at Step 3.

The modelling was performed in accordance with the proposed field GAP. Agronomic parameters used as input for these simulations were as follows:

Crop: Ornamental Crops (Field application – spring and late summer)
FOCUS Crop: Maize/ Vines – late applications
Application Rate: 5 x 4.25 kg a.s./ha (7 days interval)
Application timing: Spring - 1st April to 29th May (multiple application; actual dates set by PAT)
Spring - 1st April to 1st May (single application; actual dates set by PAT)
Late summer – Multiple: 4th July to 31st August (actual dates set by PAT)
Late summer – Individual: 1st August to 31st August (actual dates set by PAT)
Crop Interception: Calculated internally by MACRO or PRZM (CAM 1, DEPI 4, defined in SWASH)
Appropriate Scenarios: D3, D4, D5, D6, R1, R2, R3 and R4

The FOCUS models do not have an ornamental crop included; therefore maize was used as a surrogate crop for ornamentals < 50 cm in height, as it is included in most of the surface water scenarios in the FOCUS models. Hand-held applications may also be made to crops of > 50 cm height; the FOCUS crop ‘vines, late applications’ was selected as this crop is in the same crop grouping as hand-held applications to crops >50 cm in FOCUS SW guidance.

Because applications to ornamental crops will occur on actively growing plants, applications were assumed to occur between the 1st April and the end of August. Application windows were assumed to commence on 1st April for spring applications and to end on 31st August for late summer applications. The duration of the application window was then calculated based upon the number of applications, the application interval and the recommendations in FOCUS SW guidance. The actual application dates were selected by the PAT application in the FOCUS SW models.

As described above, daminozide is a plant growth regulator used on a wide range of ornamental crops, and is typically used in situations in which crop interception is significant. At Step 3, crop interception is calculated internally by the FOCUS models based upon the application dates. In this case, because representative crops are selected for modelling purposes a Chemical Application Method (CAM) of 1 was selected, which is representative of application directly to soil. Consequently no crop interception was assumed by the FOCUS model at Step 3, which is a significant underestimation for the proposed uses and therefore the modelling is conservative in this regard. However, final modelled peak PEC_{sw} values are largely unaffected since peak values predominantly arise due to spray drift inputs.

The substance specific input parameters for daminozide used for the simulations are summarised in Table B.8.5-2.

The rates of degradation for daminozide in aqueous systems were derived in the study of Hilton and Callow (2014) for the two whole water/sediment systems investigated in the study of De Vette and van Es (2002). At Step 3 the geometric mean value of 0.906 days was input for the water phase degradation of daminozide. A default worst case value of 1000 days was input for sediment.

In addition to the tabulated values, a default Arrhenius value for temperature correction of 65.4 kJ/mol, equivalent to a Q10 value of 2.58, and a default Walker exponent of 0.7 were set for modelling with PRZM, according to FOCUS (2000, 2005, 2012) guidance. However, for modelling with FOCUS MACRO 5.5.3 the ‘exponent for the effect of water content’ parameter in the input screen of the SWASH shell was amended to 0.49 in place of the default 0.7 in line with the Important warning (05/12/2012) on the FOCUS MACRO website.

Table B.8.5-2: Summary of input parameters for daminozide for the PEC_{sw} simulations with FOCUS Surface Water at Step 3

Parameter	Compound	Value	Remarks
PHYSICO-CHEMICAL PARAMETERS			
Molecular weight [g mol ⁻¹]	Daminozide	160.2	-
Water solubility [g L ⁻¹] at 20°C	Daminozide	128	Friedlander (2011)
Vapour pressure [Pa] at 25°C	Daminozide	1.5 x 10 ⁻⁶	Tremain (2001)
DEGRADATION IN SOIL			
DT ₅₀ soil at 20°C and pF2 [d]	Daminozide	0.12	Möndel (2014). Lab geometric mean (n=4)
SORPTION TO SOIL			
K _{f,oc} [mL g ⁻¹]	Daminozide	26.6	Spare (1987). Arithmetic mean (n=4).
Freundlich exponent 1/n [-]	Daminozide	1.27	Spare (1987)
DEGRADATION IN AQUATIC SYSTEMS			
DT ₅₀ water at 20 °C [d]	Daminozide	0.906	De Vette and van Es (2002) Geometric mean (n=2)
DT ₅₀ sediment [d]	Daminozide	1000	FOCUS recommendation
CROP/ MANAGEMENT RELATED PARAMETERS			
Crop uptake factor [-]	Daminozide	0.5	-

II. RESULTS AND DISCUSSION

Glasshouse/Indoor Applications

The maximum PEC_{sw} and PEC_{sed} values calculated for daminozide and methanol with the Dutch glasshouse model, following indoor applications of daminozide to ornamental crops are presented in Table B.8.5-3.

Table B.8.5-3: PEC values for daminozide and its metabolite methanol following indoor applications of daminozide

Crop	Daminozide		Methanol	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Ornamental Crops (Indoor application)	2.562 (2.550)	0.792 (0.789)	1.649 (0.386)	1.246 (0.291)

Values in brackets refer to single application

FOCUS Steps 1 and 2

The maximum Step 1 and Step 2 PEC_{sw} and PEC_{sed} values following applications to ornamental crops <50 cm, and ornamental crops >50 cm are presented in Table B.8.5-4. The maximum peak PEC_{sw} values for daminozide at Step 2 arose from the single application scenario, indicating that Step 2 peak PEC_{sw} values arose following inputs via drift. For methanol peak PEC_{sw} values arose following multiple applications, indicating that the dominant route of input to surface waters is via run-off or drainflow. For methanol, Step 2 PEC values were higher following spring applications than for late summer applications.

Table B.8.5-4: FOCUS Surface Water Step 1 & 2 PEC values for daminozide and its metabolite methanol

Crop	FOCUS STEP	Daminozide		Methanol	
		PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Ornamental Crops - <50cm (Field application – Spring)	1	1410	363.9	413.9	4.09
	2 (SEU; March – May)	25.54 (39.09)	2.04 (3.13)	26.25 (13.19)	0.26 (0.13)
	2 (NEU; March – May)	25.54 (39.09)	2.04 (3.13)	20.96 (9.41)	0.21 (0.09)
Ornamental Crops - <50cm (Field application – Late summer)	1	1410	363.9	413.9	4.09
	2 (SEU; June – Sept)	25.54 (39.09)	2.04 (3.13)	19.64 (8.47)	0.19 (0.08)
	2 (NEU; June – Sept)	25.54 (39.09)	2.04 (3.13)	18.31 (7.52)	0.18 (0.07)
Ornamental Crops - >50 cm	1	1480	363.9	470.3	4.65
	2	94.46 (113.7)	7.55 (9.09)	68.53 (23.95)	0.68 (0.24)

Crop	FOCUS STEP	Daminozide		Methanol	
		PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
(Field application – Spring)	(SEU; March – May)				
	2 (NEU; March – May)	94.46 (113.7)	7.55 (9.09)	63.24 (20.17)	0.62 (0.20)
	1	1480	363.9	470.3	4.65
Ornamental Crops - >50 cm (Field application – Late summer)	2 (SEU; June – Sept)	94.46 (113.7)	7.55 (9.09)	62.71 (19.80)	0.62 (0.20)
	2 (NEU; June – Sept)	94.46 (113.7)	7.55 (9.09)	61.12 (18.66)	0.60 (0.18)

Values in brackets refer to single application

FOCUS Step 3

The highest maximum initial PEC values for daminozide at FOCUS Step 3, from multiple or respective single applications, are shown in Tables B.8.5-5 for applications made in spring and late summer, to ornamental crops of < 50 cm and > 50 cm height.

In the majority of cases drift was the main route of exposure for daminozide and therefore the maximum PEC_{sw} values arose from individual applications. The only exceptions were for the R1 pond and stream scenarios following applications to ornamental crops < 50cm in height, for which the peak PEC_{sw} values were driven by run-off inputs following multiple applications.

Table B.8.5-5: Maximum FOCUS Step 3 PEC values for daminozide after field application to ornamental crops

Step3					
Scenario	Surface water			Sediment	
	PEC _{sw} (µg/L)	Main exposure route	Application regime	PEC _{sed} (µg/kg)	Application regime
Daminozide - Spring Applications – Ornamental crops <50cm					
D3 Ditch	22.26	Drift	Single	1.423	Single
D4 Pond	0.900	Drift	Single	0.142	Multiple
D4 Stream	17.85	Drift	Single	0.304	Single
D5 Pond	0.900	Drift	Single	0.095	Multiple
D5 Stream	18.77	Drift	Single	0.280	Single
D6 Ditch	22.28	Drift	Single	1.402	Single
R1 Pond	1.803	Run-off	Multiple	0.248	Multiple
R1 Stream	50.73	Run-off	Multiple	3.323	Multiple
R2 Stream	20.49	Drift	Single	0.481	Single
R3 Stream	21.80	Drift	Single	1.020	Single
R4 Stream	15.41	Drift	Single	0.529	Single
Daminozide - Spring Applications – Ornamental crops >50cm					
D6 Ditch	72.501	Drift	Single	8.0960	Multiple
R1 Pond	2.5960	Drift	Single	0.4700	Multiple
R1 Stream	52.991	Drift	Single	1.8410	Single
R2 Stream	70.399	Drift	Single	1.7510	Multiple
R3 Stream	74.966	Drift	Single	3.3980	Single
R4 stream	53.391	Drift	Single	2.0190	Single
Daminozide – Late Summer Applications – Ornamental crops <50cm					
D3 Ditch	22.262	Drift	Single	1.201	Single
D4 Pond	0.900	Drift	Single	0.0741	Multiple
D4 Stream	17.922	Drift	Single	0.540	Multiple

Step3					
Scenario	Surface water			Sediment	
	PEC _{sw} (µg/L)	Main exposure route	Application regime	PEC _{sed} (µg/kg)	Application regime
D5 Pond	0.901	Drift	Single	0.0748	Multiple
D5 Stream	21.817	Drift	Single	0.986	Single
D6 Ditch	22.273	Drift	Single	1.031	Single
R1 Pond	0.900	Drift	Single	0.0763	Multiple
R1 Stream	15.469	Drift	Single	0.555	Single
R2 Stream	20.735	Drift	Single	0.526	Single
R3 Stream	21.803	Drift	Single	0.906	Single
R4 Stream	15.467	Drift	Single	0.537	Single
Daminozide – Late Summer Applications – Ornamental crops >50cm					
D6 Ditch	72.968	Drift	Single	5.779	Multiple
R1 Pond	2.596	Drift	Single	0.294	Multiple
R1 Stream	53.494	Drift	Single	2.044	Single
R2 Stream	71.703	Drift	Single	1.934	Single
R3 Stream	75.399	Drift	Single	3.520	Multiple
R4 stream	53.486	Drift	Single	1.978	Single

III. CONCLUSION

For field applications a maximum Step 1 PEC_{sw} value of 1480 µg/L, a Step 2 PEC_{sw} value of 113.7 µg/L and a Step 3 PEC_{sw} value of 75.4 µg/L were calculated for daminozide after applications to ornamental crops > 50 cm in height. Step 1 and 2 PEC_{sw} values for methanol were 470.3 µg/L and 68.53 µg/L, respectively.

For ornamental crops < 50 cm tall a maximum Step 1 PEC_{sw} value of 1410 µg/L, Step 2 PEC_{sw} value of 39.09 µg/L and Step 3 PEC_{sw} value of 50.7 µg/L were calculated for daminozide. Step 1 and 2 PEC_{sw} values for methanol were 413.9 µg/L and 26.25 µg/L, respectively.

For indoor applications a maximum daminozide PEC_{sw} value of 2.6 µg/L and a maximum methanol PEC_{sw} value of 1.6 µg/L were calculated.

RMS comments and conclusion:

For indoor application the deposition using Dutch approach (0.1% of applied active substance) was calculated. According to EFSA guidance the same approach as for open field should be used for all structures except walk-in tunnels, closed buildings and greenhouses, as the situation is similar to the open field. For walk-in tunnels it is proposed that the FOCUS surface water drainage scenarios are used. For greenhouses drainage, example scenarios are presented in the guidance. However, the guidance was not in force at the time of submission of the dossier and therefore, the approach taken is considered acceptable.

PEC_{sw} calculation for methanol presented by the Notifier were based on maximum observed value of methanol of 75.7% AR from aerobic mineralization study, however this study has several deficiencies and the amount of methanol could be even higher. Therefore, default value of 100% in water/sediment for methanol was considered by the RMS. For the calculation of PEC_{sw} values for methanol following glasshouse applications an application rate of 5 x 1.157 kg a.s./ha was considered by the Notifier, and was modified to 1528 g a.s./ha by the RMS..

FOCUS Steps 1-2 and STEP 3 values for open field have been recalculated by the RMS using Koc of 18.4 for daminozide. Lowest Koc of 18.4 is worst case for surface water assessment but not for sediment (daminozide was mainly presented in surface water). However, new adsorption/desorption study should be performed.

Default values of 1000 days for water, sediment and whole system was used for metabolite methanol instead of whole system DT50 proposed by the Notifier as this value was not accepted by the RMS.

The input parameters used by the RMS are presented in the tables below. The modelling was performed in accordance with the proposed field GAP and remains the same as used by the Notifier above.

Table B.8.5-6: Summary of input parameters for daminozide and its metabolite methanol for the PEC_{sw} calculations with FOCUS Step 1 & 2 and indoor (RMS)

Parameter	Compound	Value	Remarks
Molecular weight [g mol ⁻¹]	Daminozide	160.2	-
	Methanol	32.0	
Water solubility [mg L ⁻¹] at 20°C	Daminozide	128,000	Friedlander (2011)
	Methanol	1,000,000 (25 °C)	Value from EPIWEB 4.1
DT ₅₀ soil [d]	Daminozide	0.12	Geometric mean (n=4)
	Methanol	3.9	Geometric mean (n=4)
K _{loc} [mL g ⁻¹]	Daminozide	18.4	Arithmetic mean
	Methanol	1.0	KOCWIN 2.0
Maximum formation in soil [% AR]	Daminozide	-	-
	Methanol	27.2	Maximum
DT ₅₀ water [days]	Daminozide	0.906	Geomean whole system
	Methanol	1000	Default value
DT ₅₀ sediment [days]	Daminozide	0.906 (Step 1&2)	Geomean whole system
	Methanol	1000	Default value
DT ₅₀ system (water/sediment) [days]	Daminozide	0.906	Geomean whole system
	Methanol	1000	Default value
Maximum proportion formed in water-sediment [%]	Daminozide	-	-
	Methanol	100	Worst case default
Maximum proportion formed in sediment used for indoor applications [%]	Daminozide	6.7	De Vette and van Es (2002)
	Methanol	12.4*	

* A sediment concentration of 12.4% AR was assumed for methanol for the calculation of PEC_{sed} values following indoor applications, based upon the maximum total radioactivity in the sediment phase of the water/sediment study of De Vette and van Es (2002), and the assumption that it is all attributable to methanol.

Table B.8.5-7: Summary of input parameters for daminozide for the PEC_{sw} simulations with FOCUS Surface Water at Step 3 (RMS)

Parameter	Compound	Value	Remarks
Physico-Chemical parameters			
Molecular weight [g mol ⁻¹]	Daminozide	160.2	-
Water solubility [mg L ⁻¹] at 20°C	Daminozide	128,000	Friedlander (2011)

Parameter	Compound	Value	Remarks
Vapour pressure [Pa] at 25°C	Daminozide	1.5×10^{-6}	Tremain (2001)
Degradation in soil			
DT ₅₀ soil at 20°C and pF2 [d]	Daminozide	0.12	Möndel (2015). Lab geometric mean (n=4)
Sorption to soil			
K _{f,oc} [mL g ⁻¹]	Daminozide	18.4	Spare (1987). Arithmetic mean (n=4).
Freundlich exponent 1/n [-]	Daminozide	1.368	Spare (1987)
Degradation in aquatic systems			
DT ₅₀ water at 20 °C [d]	Daminozide	0.906	De Vette and van Es (2002) Geometric mean (n=2)
DT ₅₀ sediment [d]	Daminozide	1000	FOCUS recommendation
Crop/ Management related parameters			
Crop uptake factor [-]	Daminozide	0.5	-

Glasshouse/Indoor Applications

The maximum PEC_{sw} and PEC_{sed} values calculated for daminozide and methanol with the Dutch glasshouse model, following indoor applications of daminozide to ornamental crops are presented in Table B.8.5-8.

Table B.8.5-8: PEC values for daminozide and its metabolite methanol following indoor applications of daminozide

Crop	Daminozide		Methanol	
	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Ornamental Crops (Indoor application)	2.562 (2.550)	0.792 (0.789)	2.522 (0.509)	1.443 (0.291)

Values in brackets refer to single application

FOCUS Steps 1 and 2

The maximum Step 1 and Step 2 PEC_{sw} and PEC_{sed} values following applications to ornamental crops <50 cm, and ornamental crops >50 cm are presented in Table B.8.5-9.

Table B.8.5-9: FOCUS Surface Water Step 1 & 2 PEC values for daminozide and its metabolite methanol

Crop	FOCUS STEP	Daminozide		Methanol	
		PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Ornamental Crops - <50cm (Field application – Spring)	1	1420	254.4	423.4	4.23 (Day 1)
	2 (SEU; March – May)	25.53 (39.09)	1.42 (2.18)	35.63 (15.33)	0.36 (0.15)
	2 (NEU; March – May)	25.54 (39.09)	1.43 (2.18)	30.34 (11.55)	0.30 (0.12)

Crop	FOCUS STEP	Daminozide		Methanol	
		PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)
Ornamental Crops - <50cm (Field application – Late summer)	1	1420	254.4	423.4	4.23 (Day 1)
	2 (SEU; June – Sept)	25.54 (39.09)	1.43 (2.18)	29.02 (10.61)	0.29 (0.11)
	2 (NEU; June – Sept)	25.54 (39.09)	1.43 (2.18)	27.69 (9.67)	0.28 (0.10)
Ornamental Crops - >50 cm (Field application – Spring)	1	1500	254.4	497.9	4.97 (Day 1)
	2 (SEU; March – May)	94.46 (113.7)	5.28 (6.36)	103.2 (30.19)	1.03 (0.30)
	2 (NEU; March – May)	94.46 (113.7)	5.28 (6.36)	97.94 (26.41)	0.98 (0.26)
Ornamental Crops - >50 cm (Field application – Late summer)	1	1500	254.4	497.9	4.97 (Day 1)
	2 (SEU; June – Sept)	94.46 (113.7)	5.28 (6.36)	97.41 (26.03)	0.97 (0.26)
	2 (NEU; June – Sept)	94.46 (113.7)	5.28 (6.36)	95.82 (24.90)	0.96 (0.25)

Values in brackets refer to single application

FOCUS Step 3

The highest maximum initial PEC values for daminozide at FOCUS Step 3, from multiple or respective single applications, are shown in Tables B.8.5-10 – B.8.5-17 for applications made in spring and late summer, to ornamental crops of < 50 cm and > 50 cm height.

Table B.8.5 -10: FOCUS Step 3 PEC values for daminozide after field application to ornamental crops in spring (ornamental crops <50 cm, multiple application)

FOCUS STEP 3 Scenario	Water	Day after overall maximum	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg)	
	body		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
		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
		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

Table B.8.5-11: FOCUS Step 3 PEC values for daminozide after field application to ornamental crops in spring (ornamental crops <50 cm, single application)

FOCUS STEP 3 Scenario	Water	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
	body		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
		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
		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

Table B.8.5-12: FOCUS Step 3 PEC values for daminozide after field application to ornamental crops in late summer (ornamental crops <50 cm, multiple application)

FOCUS STEP 3 Scenario	Water	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
	body		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
		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
		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

Table B.8.5-13: FOCUS Step 3 PEC values for daminozide after field application to ornamental crops in late summer (ornamental crops <50 cm, single application)

FOCUS STEP 3 Scenario	Water	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
	body		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
		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
		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

Table B.8.5-14: FOCUS Step 3 PEC values for daminozide after field application to ornamental crops in spring (ornamental crops >50 cm, multiple application)

FOCUS STEP 3 Scenario	Water	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
	body		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
		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
R3	stream	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
		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

R4	stream	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
		28 d	43.05	0.903	1.157	0.327
		42 d	<0.001	0.734	0.160	0.298

Table B.8.5-15: FOCUS Step 3 PEC values for daminozide after field application to ornamental crops in spring (ornamental crops >50 cm, single application)

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
		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
R3	stream	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
		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
R4	stream	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
		28 d	<0.001	0.373	0.049	0.154
		42 d	<0.001	0.249	0.030	0.116

Table B.8.5-16: FOCUS Step 3 PEC values for daminozide after field application to ornamental crops in late summer (ornamental crops >50 cm, multiple application)

FOCUS STEP 3 Scenario	Water	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
	body		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
		14 d	<0.001	0.893	0.167	0.374

R3	stream	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

Table B.8.5-17: FOCUS Step 3 PEC values for daminozide after field application to ornamental crops in late summer (ornamental crops >50 cm, single application)

FOCUS STEP 3 Scenario	Water	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
	body		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
		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
R3	stream	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
		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
R4	stream	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

B.8.6 Fate and behaviour in air

The type of formulation used is not expected to affect the volatility of the active substance and therefore it is possible to extrapolate from data obtained with the active substance.

B.8.6.1 Route and rate of degradation in air and transport via air

Values for the vapour pressure and Henry's Law Constant for daminozide of 1.5×10^{-6} Pa at 25°C and 1×10^{-9} Pa m³/mole are reported, indicating the low volatility of daminozide. The Atkinson half-life of daminozide was calculated using AOPWIN v.1.92, assuming a 12-hour day and a hydroxyl radical concentration of 1.5×10^6 cm⁻³. A half-life in the upper atmosphere of 10.570 hours or 0.881 days (based on a 12 hour day) was calculated.

The compound methanol is formed in significant quantities in an aerobic soil degradation study. Polar metabolites, considered most likely to be methanol, are observed in aquatic mineralisation and water/sediment studies at concentrations > 10% AR. For the purposes of exposure assessments, these unidentified polar compounds are considered as methanol. ~~However, further work is ongoing to confirm the identity of the polar metabolite, and will be submitted as soon as identification is available.~~

Methanol is known to be volatile, and a vapour pressure of 1.69×10^4 Pa at 25°C, and a Henry's Law constant of 0.46 Pa.m³/mole at 25°C were obtained using the EPIWEB 4.1 experimental database. The Atkinson half-life of methanol was calculated in the same manner as for daminozide, as 17.36 days (based on a 12 hour day).

B.8.6.2 Predicted environmental concentrations from airborne transport

Short range transport:

The trigger values for relevance of atmospheric deposition (short range transport) following volatilisation are defined by the FOCUS Air group to be > 10^{-5} Pa (20°C) for volatilisation from plant surfaces and > 10^{-4} Pa (20 °C) for volatilisation from soil surfaces. Thus, while daminozide is not considered to be volatile, methanol is considered to be volatile and its short-range transport potential has to be considered.

According to FOCUS (2008) deposition after volatilisation is not significant compared to spray drift within the short-range (i.e. < 2 m) following FOCUS surface water Step 3 calculations. Consequently, deposition from volatilisation (dry deposition) needs only be considered in addition to drift for distances greater than 1 m if drift mitigation is required. Drift mitigation measures are not required to demonstrate an acceptable risk to aquatic systems following the proposed applications of daminozide, and FOCUS modelling is not required beyond Step 2 calculations for methanol. Therefore, the volatilisation and deposition of methanol on surface water bodies does not require further consideration.

RMS comments and conclusion:

According to FOCUS Air guidance (2008) metabolite methanol is very volatile compound (based on vapour pressure $V_p > 10^{-2}$ Pa) and in this case volatilisation and subsequent deposition can result in a substantially higher emission and off-site exposure rates and it is not covered by FOCUS Step 2 calculation. Therefore, the assessment of short-range transport is considered necessary.

Long range transport:

Considering the vapour pressure and Henry's Law constant values reported above, daminozide is not anticipated to be volatilised to air. The calculated Atkinson half-life demonstrates that any daminozide that is volatilised would be rapidly degraded. Daminozide is not anticipated to be subject to long range transport.

The high vapour pressure and Henry's Law constant values of methanol indicate that it would be volatilised from soil surfaces. However, the calculated Atkinson half-life of 17.4 days for methanol indicates that it may be subject to long-range atmospheric transport.

The data requirements stipulated in Comm. Reg. (EU) No. 283/2013 which sets out the active substance data requirements in accordance with Comm. Reg (EC) No. 1107/2009, require that for substances that are applied in high amounts atmospheric effects are required to be considered should it not be possible to rule out long-range transport on the basis of a substances volatility and Atkinson half-life. However, methanol is not applied in high

amounts and therefore further investigation is not required. The proposed use of daminozide is for a maximum application of 5 x 7.65 kg a.s./ha indoors or 5 x 4.25 kg a.s./ha in the field and methanol is observed at a maximum of 27% AR in aerobic soil degradation studies. The amount of methanol formed from the use of daminozide is insignificant when compared to the tonnage of methanol registered under REACH (Regulation (EC) No. 1907/2006) of 10,000,000 – 100,000,000 tonnes of methanol used per annum in the EU. Numerous uses have been assessed under the REACH regulation including several outdoor uses with environmental release directly to air. No exposure controls are in place for those uses and the exposure of methanol to air from the proposed use of daminozide is anticipated to be significantly lower than uses approved under the REACH regulation. Therefore, further consideration of the local and global effects of methanol is not required and no additional data are submitted.

RMS comments and conclusion:

Local and global effects are discussed in separate document B-8 for active substance data (under point B.8.3.3). The trigger for long-range transport (DT in air of 2 days) is exceeded for metabolite methanol and therefore, the long-range transport has to be addressed. Total amount of daminozide used in the EU is not a criterion for exclusion of long-range transport.

B.8.7 Predicted environmental concentrations from other routes of exposure

Not applicable.

B.8.8 References relied on

New studies

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 9.2.4.1/01	Hilton, M., Callow, B.	2016	Predicted Environmental Concentrations of daminozide and its metabolite in groundwater using FOCUS PEARL 4.4.4 model and FOCUS groundwater scenarios Exponent International Limited. Report No. 1007582.UK0 – 1916 Non-GLP Unpublished Previous evaluation: Submitted for the purpose of renewal.	N	N	Not applicable	EU Daminozide Task Force
CP 9.2.5/01	Hilton, M., Callow, B.	2016	Predicted Environmental Concentrations of daminozide and its metabolite in surface water in the EU using the FOCUS surface water scenarios Exponent International Limited. Report No. 1007582.UK0 – 1770 Non-GLP Unpublished Previous evaluation: Submitted for the purpose of renewal.	N	N	Not applicable	EU Daminozide Task Force

Studies relied upon for the first inclusion of daminozide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) No 1107/2009

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 7.1.2.2 .1/01	Smilo, A., Błaszczynski, E., Stanton, D.T., Harned, W.H.	1986	Daminozide field dissipation study Uniroyal Chemical. Report No. A.8.1.7 Non-GLP Unpublished Previous evaluation: In DAR 1999	N	N	Not applicable	Arysta LifeScience Great Britain Limited