REGISTRATION REPORT
Part B

Section 5 Environmental Fate

Detailed summary of the risk assessment

Product code:	**BAS 758 00 H (Pontos)**
Active Substance:	**100 g Picolinafen and 240 g Flufenacet /L**

Central Zone
Zonal Rapporteur Member State: United Kingdom

NATIONAL ADDENDUM – Netherlands

Applicant:	**BASF**
Date:	**November 2018**
Evaluator:	**Ctgb, NL**

Table of Contents

IIIA 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT

This is the National Addendum for BAS 758 00 H in the Netherlands and should be reviewed in conjunction with the core assessment for picolinafen and flufenacet active substances.

Introduction

This section of the submission summarises the environmental fate and behaviour information and modelling for the active substances picolinafen and flufenacet resulting from the intended use of the product 'BAS 758 00 H'. Full details of the proposed use pattern that will be assessed is shown in Appendix 2 of this document and summarised in Table 9-1.

Table 9-1: Proposed use pattern of BAS 758 00 H

Crop and/ or situation	**Application**			**Application rate**	
	Method / Kind	Timing / Growth stage of crop & season	Max. number of applications	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season
BAS 758 00 H					
Cereals (winter sown)	Low volume broadcast foliar application	BBCH 00 – 29 (autumn / spring)	a) 1 (-) b) 1 (-)	a) 1 (-) b) 1 (-)	0.100 Picolinafen 0.240 Flufenacet 0.100 Picolinafen 0.240 Flufenacet

Additonally, PECsw calculations are included using a lower dose rate. Please find the GAP in Table 9-2.

Table 9-2: Proposed use pattern of BAS 758 00 H

Crop and/ or situation	**Application**			**Application rate**	
	Method / Kind	Timing / Growth stage of crop & season	Max. number of applications	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season
BAS 758 00 H					
Cereals (winter sown)	Low volume broadcast foliar application	BBCH 00 – 29 (autumn / spring)	a) 1 (-) b) 1 (-)	a) 1 (-) b) 1 (-)	0.050 Picolinafen 0.120 Flufenacet 0.050 Picolinafen 0.120 Flufenacet

IIIA 9.1 Rate of Degradation in Soil

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.1.1 Aerobic degradation of the preparation in soil

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.1.2 Anaerobic degradation of the preparation in soil

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.2 Field Studies

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.2.1 Soil dissipation testing on a range of representative soils

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.2.2 Soil residue testing

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.2.3 Soil accumulation testing

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.2.4 Aquatic (sediment) field dissipation

This is not an EC data requirement.

IIIA 9.2.5 Forestry field dissipation

This is not an EC data requirement.

IIIA 9.3 Mobility of the Plant Protection Product in Soil

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.3.1 Column leaching

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.3.2 Lysimeter studies

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.3.3 Field leaching studies

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.3.4 Volatility – laboratory study

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.3.5 Volatility – field study

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.4 Predicted Environmental Concentrations in Soil (PECs) for the Active Substance

Please refer to the core dossier of BAS 758 00 H. A summary of the initial calculated PECs concentrations are presented in Table 9.4.-1.

Table 9.4-1: Summary of the PEC_{soil} calculations

Method of calculation	Assuming soil depth of 5 cm and bulk density of 1.5 g/mL
Application rate	1 L/ha (product) Equivalent to 100 g/ha picolinafen and 240 g/ha flufenacet

	BAS 758 00 H		**Picolinafen**		**CL 153815**	
PECsoil (mg/kg)	Actual [1]	TWA	Actual	TWA	Actual	TWA
Initial (**5.0 cm**)	1.525	--	0.133	--	0.055	--

	BAS 7581 00 H		**Flufenacet**		**FOE sulfonic acid**		**FOE oxalate**	
PECsoil (mg/kg)	Actual [1]	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial (**5.0 cm**)	1.525	--	0.320	--	0.064	--	0.031	--

[1]: Based on a bulk density of 1 g/mL

IIIA 9.4.1 Initial PECs values

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.4.2 Short-term PECs values (1-4 days after last application)

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.4.3 Long-term PECs values (from 7-100 days after last application)

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.5 Predicted Environmental Concentrations in Soil (PECs) for Relevant Metabolites

Please refer to the core dossier of BAS 758 00 H. A summary of the initial calculated PECs concentrations are presented in Table 9.4.-1.

IIIA 9.5.1 Initial PECs values

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.5.2 Short-term PECs values (1-4 days after last application)

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.5.3 Long-term PECs values (from 7-100 days after last application)

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.6 Predicted Environmental Concentrations in Ground Water (PECgw)

The assessment of the potential for contamination of groundwater by plant protection products in The Netherlands follows a tiered approach (van der Linden *et al* (2004)). This can be summarised as follows:

Tier 1: Calculation using the FOCUS groundwater Kremsmünster scenario

Tier 2: Calculations using GEOPEARL, use of field lysimeter studies or additional laboratory studies. Monitoring of upper groundwater

Tier 3: Examination of the transformation rate in the saturated zone, monitoring of deeper groundwater.

If an unacceptable risk is indicated at Tier 1 (i.e. PECgw >0.01 µg/L [an additional threshold is applied for groundwater protection areas]) then it is necessary to proceed to Tier 2 and perform GEOPEARL modelling. If the GEOPEARL modelling then indicates a concern then further work may be necessary in Tier 2 and possibly Tier 3. For certain compounds it is also necessary to proceed straight to Tier 2 and perform GEOPEARL modelling on the basis of their properties.

Input values for both active substances and their metabolites taken from the Core dossier are summarized in Table 9.6-1. The endpoints mentioned in the Core dossier were not checked by zRMS. Therefore, the input values have been copied from the Core dossier into the NL Addendum, and brought in line with the EU review report and Addendum to the DAR (2003).

Table 9.6-1: Summary of input parameters for picolinafen, flufenacet and their metabolites for the leaching simulation with FOCUS PEARL v 4.4.4 model

Parameter	Compound	Value	Remarks
PHYSICO-CHEMICAL PARAMETERS			
Molecular weight [g mol^{-1}]	Picolinafen	376.3	EU review report
	CL 153815	283.3	EU review report
	Flufenacet	363.34	EU review report
	FOE sulfonic acid	275.3	Calculated
	FOE oxalate	225.2	Calculated
Water solubility [mg L^{-1}] at 20°C	Picolinafen	0.047	EU review report
	CL 153815	1000	Default
	Flufenacet	56	EU review report
	FOE sulfonic acid	1000	Default
	FOE oxalate	1000	Default
Molar enthalpy of dissolution [kJ mol^{-1}]		27	FOCUS recommendation
Vapour pressure [Pa] at 20°C	Picolinafen	1.7×10^{-7}	EU review report
	CL 153815	1.7×10^{-7}	Parent value was used
	Flufenacet	9×10^{-5}	EU review report
	FOE sulfonic acid	0	Default
	FOE oxalate	0	Default
Molar enthalpy of vaporization [kJ mol^{-1}]	95		FOCUS recommendation
Diffusion coefficient in water [$m^2 d^{-1}$]	4.3×10^{-5} (20 °C) (Pearl)		FOCUS recommendation
[$m^2 s^{-1}$]	5.0×10^{-10} (20 °C) (Macro)		
Diffusion coefficient in gas [$m^2 d^{-1}$]	0.43 (20 °C)		FOCUS recommendation
DEGRADATION IN SOIL			
Formation fraction [-]	CL 153815	1	Worst case
	FOE sulfonic acid	0.20**	Calculated
	FOE oxalate	0.40**	Calculated
DT_{50} soil [d]	Picolinafen	42.9	Laboratory geometric mean (normalized to pF2)
	CL 153815	53.9	Laboratory geometric mean (normalized to pF2)
	Flufenacet	16.5	Geometric mean (normalized to pF2) (Addendum to the DAR)
	FOE sulfonic acid	140	Geometric mean normalized to pF2 (Addendum to the DAR)
	FOE oxalate	6.6	Geometric mean (normalized to pF2)

Parameter	Compound	Value	Remarks
			(Addendum to the DAR)
SORPTION TO SOIL			
$K_{f,oc}$ [mL g^{-1}]	Picolinafen	15000	Worst case value
	CL 153815	440	Arithmetic mean (n=4) (EU review)
	Flufenacet	349	Arithmetic mean (n=7) (Addendum to the DAR)
	FOE sulfonic acid	12.5	Arithmetic mean (n=4) (Addendum to the DAR)
	FOE oxalate	14.0	Arithmetic mean (n=4) (Addendum to the DAR)
$K_{f,om}$ [mL g^{-1}]	Picolinafen	8701	Worst case value
	CL 153815	255	Arithmetic mean (n=4) (EU review)
	Flufenacet	202.4	Arithmetic mean (n=7) (Addendum to the DAR)
	FOE sulfonic acid	7.25	Arithmetic mean (n=4) (Addendum to the DAR
	FOE oxalate	8.12	Arithmetic mean (n=4) (Addendum to the DAR)
Freundlich exponent 1/n [-]	Picolinafen	0.99	Arithmetic mean (n=4) (EU review)
	CL 153815	0.955	Arithmetic mean (n=4) (EU review)
	Flufenacet	0.90	Arithmetic mean (n=7) (Addendum to the DAR)
	FOE sulfonic acid	0.99	Arithmetic mean (n=4) (Addendum to the DAR)
	FOE oxalate	1.04	Arithmetic mean (n=4) (Addendum to the DAR)
Method of sorption subroutine description	pH independent		
CROP/ MANAGEMENT RELATED PARAMETERS			
Crop uptake factor [-]	0 (and 0.5 for FOE sulfonic acid)		Worst case (based on logkow)

* The soil with very low organic carbon was not considered
** Calculated (Mamouni and Montesano 2014a)
† Value not specified in LoE but derived in kinetic evaluation included in DAR and amendment to DAR

PECgw values for active substance picolinafen and its metabolite CL 152815 mentioned in the Core dossier were confirmed by zRMS UK. PECgw values are reported in Tables 9.6-2 and 9.6-3.
Regarding active substance flufenacet and its metabolites FOE sulfonic acid and FOE oxalate, zRMS refers to the addendum to the DAR (January 2003) where a product using the same GAP as proposed for Pontos has been evaluated. As the model version used in the addendum calculations is not the appropriate model version any more, new PECgw modelling has been performed for active substance flufenacet and its metabolites using PEARL 4.4.4. by Ctgb. The modelling is based on the use of a pre-emergency spray application to cereals once every year with no crop interception which is considered worst case compared to spring application. Application date was set at November 1st. The 90th percentile concentration of active substance flufenacet and its metabolites FOE sulfonic acid and FOE oxalate are reported in Tables 9.6-2 and 9.6-3.

Table 9.6-2: Annual average PECgw values for picolinafen and flufenacet on winter cereals at 1 x 1L BAS 758 00 H /ha using FOCUS PEARL 4.4.4, PELMO 5.5.3 and GeoPEARL models, autumn application

Model	**PEARL 4.4.4**	
LOCATION	**Picolinafen**	**Flufenacet**
Kremsmuenster (µg/L)	<0.001	<0.001

Table 9.6-3: Annual average PECgw values for metabolites on winter cereals at 1 x 1L BAS 758 00 H /ha, autumn application

Model	**PEARL 4.4.4**		
Parent*	**Flufenacet**		**Picolinafen**
Metabolites*	**FOE sulfonic acid**	**FOE oxalate**	**CL 153815**
Kremsmuenster	5.117	0.059	<0.001

* A plant uptake factor of 0.5 for metabolite FOE sulfonic acid was used in the simulation

In the second tier, leaching in potential area of use is evaluated using the spatial distribution model GeoPEARL 3.3.3. The leaching potential of substances to the shallow groundwater in the potential area of use within The Netherlands is calculated using the GeoPEARL model. The same input data as used in the first tier with PEARL was used employed. Additional input is the crop Cereals and the number of plots (minimum 250).

Environmental Concentrations in groundwater (PECgw) at Kremsmünster are <0.01 µg/L for picolinafen, flufenacet and the metabolite CL 153815, when using the PEARL model, demonstrating that use is safe with regard to the risk to groundwater.
Predicted (PEC_{gw}) have been calculated for the active substance flufenacet and its soil major metabolites FOE oxalate and FOE sulfonic acid, using the GEOPEARL 3.3.3 groundwater model. The modelling was based on the use of a pre-emergence spray application to cereals once every year with no crop interception. The modelling is based on the use of a pre-emergency spray application to cereals once every year with no crop interception which is considered worst case compared to spring application. Application date was set at November 1st.

In accordance with the GAP, the agronomic parameters used as input for GEOPEARL 3.3.3 simulations were therefore as follows:

Crop:	cereals
Application Rate:	1 x 240 g flufenacet/ha
Application timing:	Autumn application: 1th November
Crop Interception:	0 % interception (autumn application)

The crop interception values were taken from the Generic Guidance for Tier 1 FOCUS Ground Water Assessments (2012).

The input parameters for flufenacet and its soil major metabolites FOE oxalate and FOE sulfonic acid are summarized in Table 9.6-1 of the NL Addendum.

Results and Discussion

Simulation results from GEOPEARL 3.3.3 are presented in Table 9.6-3.

Table 9.6–4: 90th percentile PEC_{gw} values in the upper layers of groundwater for flufenacet and its metabolites after application to cereals calculated using GEOPEARL 3.3.3 (µg/L)

Crop	**Cereals**		
Model	**GeoPEARL 3.3.3**		
Compound	**Flufenacet**	**FOE sulfonic acid**	**FOE oxalate**
Application	**Autumn application: November 1st - 0% interception**		
Kremsmuenster	<0.001	4.309	0.085

Conclusion

Following application of flufenacet to winter cereals, 90th percentile PEC_{gw} in the upper levels of groundwater in The Netherlands calculated using the GEOPEARL 3.3.3 groundwater model for flufenacet are predicted to be below 0.01 µg/L.

The 90th percentile concentration for FOE sulfonic acid is 4.309 µg/l. The 90th percentile concentration for FOE oxalate is 0.085 µg/l.

An assessment of the toxicological relevance of both metabolites is presented below.

Assessment of toxicological relevance of groundwater metabolite FOE-sulfonic acid

An assessment of the toxicological relevance of groundwater metabolites according to Sanco/221/2000 – rev. 10 Guidance Document on the assessment of the relevance of metabolites in groundwater (http://ec.europa.eu/food/plant/plant_protection_products/approval_active_substances/docs/wrkdoc21_en.pdf), for the ground water metabolite FOE sulfonic acid has been performed.

Hazard assessment:

Step 3, stage 2: Screening for genotoxicity:

The genotoxic potential of FOE 5043-sulfonic acid (M02) was investigated in bacteria and mammalian cells *in vitro* and in two *in vivo* tests in rats and mice.

The studies were evaluated by Ctgb and the results from the *in vitro* and *in vivo* genotoxicity studies are summarised in the table below.

Table 9.6-5: *In vitro* and *in vivo* genotoxicity studies with FOE-sulfonic acid

Study	Dose	Result	Reference
Bacterial reverse mutation assay (S. typhimurium TA1535, TA100, TA1537, TA98, TA102)	16-5000 µg/plate (+/- S9 mix)	Negative (+/- S9 mix)	M-019064-01-1*
Mammalian cell gene mutation test (Chinese hamster V79 cells)	202-3230 µg/ml (+S9) 101-808 µg/ml (-S9)	Negative (+/- S9 mix)	M-361158-01-1
Mammallian cell gene mutation test (Chinese hamster V79 cells)	250-3000 µg/ml (+S9) 200-1000 µg/ml (-S9)	Negative (+ S9 mix) Positive (-S9 mix)	M-366380-01-1
In vivo micronucleus test (Mouse bone marrow)	500-2000 mgkg bw (2x intraperitoneal)	Negative	M-368627-01-1

In vivo unscheduled DNA synthesis (UDS) assay (rat primary hepatocytes)	1000-2000 mg/kg bw (oral)	Negative	M-397810-01-1

** Study was already evaluated for the Annex I inclusion of flufenacet.*

FOE 5043-sulfonic acid (M02) was negative in the genotoxicity tests in bacteria and mammalian cells *in vitro* (bacterial reverse mutation, mammalian cell gene mutation). The *in vitro* chromosome aberration test was negative in the presence of metabolic activation, but showed a positive response in the absence of metabolic activation at cytotoxic concentrations. Due to the positive response in the *in vitro* chromosome aberration test, two *in vivo* genotoxicity tests were conducted. The *in vivo* micronucleus test and the unscheduled DNA synthesis (UDS) assay both showed clearly negative results. Overall, it can be concluded that FOE 5043-sulfonic acid (M02) is considered to be non-genotoxic.

Step 3, stage 3: Screening for toxicity:
The parent compound flufenacet is not classified as acutely or chronically toxic or very toxic and it is neither classified for reproductive toxicity nor as a carcinogen. Therefore, based on the toxicological classification of the parent compound a detailed assessment of the acute or the chronic toxicity of the metabolite is not required. Based on the negative results in the genotoxicity studies the metabolite FOE 5043-sulfonic acid (M02) is therefore considered to be not toxicologically relevant.

As the metabolite is present above 0.75 µg/ml a consumer exposure assessment has to be carried out and therefore a reference value is needed. An acute oral toxicity study already evaluated during the EU review process of flufenacet showed that FOE-sulfonic acid (M02) was not acutely toxic (LD50 > 2000 mg/kg bw). In contrast, the parent flufenacet is classified for acute oral toxicity, category 4 (H302 harmful if swallowed). No repeated dose toxicity studies were performed with M02. The metabolite was detected in significant, but relative low amount of 0.5% of the dose in urine of male and female rats exposed to flufenacet. However, two structurally very similar metabolites (M06 and M07) differing only in an additional thiomethyl group were formed in rat (4-6% of the applied dose). An additional similar metabolite (M15), which is dealkylated at the amide-N, was found in urine at 3-16%. Combined these metabolites account in total for 8 to 21% of the applied dose. Thus, it can be assumed that FOE 5043-sulfonic acid (M02) was adequately co-tested in the toxicity studies with the parent compound flufenacet. This is in line with the conclusion that was drawn for FOE 5043-sulfonic acid (M02) during the EU-review of flufenacet (see evaluation table of flufenacet, 7468/VI/98-rev). It can be concluded that the ADI of the parent compound (0.005 mg/kg bw/day) can be used for the assessment of consumer exposure to FOE 5043-sulfonic acid (M02).

Step 4: Exposure assessment – threshold of concern approach
According to the SANCO guidance document, metabolites which have not been identified as being relevant in step 3, should be further tested in an exposure assessment. Assuming the use of 2 liters water, an acceptable exposure level indicates an acceptable estimated upper limit for the concentration of the metabolite of 0.75µg/L. However, the metabolite FOE-sulfonic acid exceeds the threshold of concern of 0.75µg/L.

Step 5: refined risk assessment for non-relevant metabolites

Following the SANCO guidance document, a refined risk assessment considering all the contributions to the diet has been performed since FOE-sulfonic acid concentrations in groundwater were predicted to be higher than the threshold of concern of 0.75 µg/L.

The highest groundwater concentration of the metabolite given by the model was 4.309 µg/L. Since the ADI of the parent is used the concentration equivalent to the parent should be used. The molecular weight of parent is 363.34 and the MW of metabolite FOE 5043-sulfonic acid is 297.28. (4.309 µg/L / 297.28) * 363.34 = 5.27 µg/L.

Table 9.6-6: Assessment of FOE-sulfonic acid contribution to the diet via drinking water

	Weight (kg)	Water consumption (L/day)	Uptake (µg/kg bw/day)	% of ADI (ADI = 5 µg/kg bw/day)
Adult	65.8	2	0.160	3.2
Children	18.4	1	0.286	5.7
Infants	10.2	0.75	0.387	7.7

The contribution of metabolite FOE 5043-sulfonic acid through the diet has been compared with the ADI of the parent compound flufenacet. The ADI given in the List of Endpoints for the parent is 0.005 mg/kg bw/day.
As shown in Table 2, it is evident that the highest estimated exposure via the drinking water is 7.7% of the ADI, which is below the allocation factor of 20% set in the WHO Guidance for drinking-water quality by and is therefore considered acceptable.

Assessment of toxicological relevance of groundwater metabolite FOE 5043-oxalate

An assessment of the toxicological relevance of groundwater metabolites according to Sanco/221/2000 – rev. 10 Guidance Document on the assessment of the relevance of metabolites in groundwater (http://ec.europa.eu/food/plant/plant_protection_products/approval_active_substances/docs/wrkdoc21_en.pdf), for the ground water metabolite FOE sulfonic acid has been performed.

Hazard assessment:

Step 3, stage 2: Screening for genotoxicity:

The genotoxic potential of FOE 5043-oxalate was investigated in bacteria and mammalian cells *in vitro* and in two *in vivo* tests in rats and mice.

The studies were evaluated by Ctgb and the results from the *in vitro* and *in vivo* genotoxicity studies are summarised in the table below.

Table 9.6-7: *In vitro* and *in vivo* genotoxicity studies with FOE-sulfonic acid

Study	**Dose**	**Result**
Bacterial reverse mutation assay (S. typhimurium TA1535, TA1537, TA98, TA100, TA102)	16-5000 µg/plate (+/- S9 mix)	Negative (+/- S9 mix)
Mammalian cell gene	150-2400 µg/ml	Negative (+/- S9 mix)

mutation test (Chinese hamster V79 cells)	(+/- S9 mix)	
Mammallian chromosome aberration test (Chinese hamster overary (CHO) cells	600-2400 µg/ml (+/- S9 mix)	Negative (+/- S9 mix)

FOE 5043-oxalate is not mutagenic in an Ames test, not mutagenic in a mammalian cell gene mutation test, and not clastogenic in a chromosome aberration test. Overall, it can be concluded that FOE 5043-oxalate is considered to be non-genotoxic.

Step 3, stage 3: Screening for toxicity:
The parent compound flufenacet is not classified as acutely or chronically toxic or very toxic and it is neither classified for reproductive toxicity nor as a carcinogen. Therefore, based on the toxicological classification of the parent compound a detailed assessment of the acute or the chronic toxicity of the metabolites is not required. Based on the negative results in the genotoxicity studies the metabolite FOE 5043-oxalate is therefore considered to be not toxicologically relevant.

Step 4: Exposure assessment – threshold of concern approach
As the metabolite is present below 0.75 µg/ml a consumer exposure assessment does not have to be carried out.

IIIA 9.6.1 Active substance

Please refer to IIIA 9.6.

IIIA 9.6.2 Relevant metabolites

Please refer to IIIA 9.6.

IIIA 9.6.3 Additional field testing

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.6.4 Information on impact on water treatment procedures

Please refer to the core dossier of BAS 758 00 H.

IIIA 9.7 Predicted Environmental Concentrations in Surface Water (PECsw) for the Active Substance

This is the National Addendum for BAS 758 00 H in The Netherlands and should be reviewed in conjunction with the core assessment for BAS 758 00 H.

In the SANCO/1418/2001-final review report for picolinafen the metabolite CL 153815 was identified as being potentially relevant with regard to the risk assessment for surface water and sediment.

In the SANCO/7469/VI/98-Final review report for flufenacet two metabolites FOE methylsulfide and thiadone which are only formed in aquatic systems are considered.

Surface water modelling of picolinafen and flufenacet has been undertaken using the TOXSWA GUI model (Version 1.0) and the National Guidelines of The Netherlands. This modelling is summarised at IIIA 9.7.1.

Summary

The PEC of picolinafen and flufenacet in surface water (PEC_{sw} and PEC_{sed}) has been assessed with the TOXSWA-NL model and Dutch specific drift figures and the DT_{50} water/sediment values established in the EU review. For metabolites, maximum PECsw values were calculated from the respective maximum parent value correcting for molecular ratio and the maximum amount formed.

Surface water modelling of picolinafen, flufenacet and their metabolites has been undertaken using the TOXSWA GUI model (Version 1.0) and the National Guidelines of The Netherlands. The modelling was based on the use of a pre-emergence spray application to winter cereals with one application of 1L BAS 758 00 H /ha. The compounds properties used in the assessments are based on the EU end points and are given in the Table 9.7-1 and 9.7.2.

Table 9.7-1: Active substances picolinafen, flufenacet and CL 153815 input parameters for model runs

Properties	Picolinafen	Flufenacet	CL153815	Remark
Molecular Mass (g mol^{-1})	376.3	363.34	283.3	Phys.-chem. properties
Vapour Pressure (Pa) at 20°C	1.7×10^{-7}	9×10^{-5}	1.7×10^{-7} Parent value	Phys.-chem. Properties
Aqueous Solubility (mg/L) at 20°C	0.047	56	1000 (default)	Phys.-chem. Properties
Soil Adsorption Coefficient (K_{om}) ml/g	13037	202.4	255	Agreed endpoint
Freundlich Exponent	0.99	0.90	0.955	Agreed endpoint
DT_{50} water [days]	1000	44.7	57.5	Worst-case/Agreed endpoint/ DAR
DT_{50} sediment [days]	6.2	1000	1000	Agreed endpoint/ Default/Default/
Formation fraction in water sediment (%)	-	-	92.4	Review report
Exchange coefficient in liquid phase (m/d)	1.64	1.67	1.90	calculated
Exchange coefficient in gas phase (m/d)	157.47	160.26	181.81	calculated

Table 9.7-2: Flufenacet metabolites input parameters for calculation

Properties	FOE methylsulfide	Thiadone	Remark
Molecular Weight (g/mol)	241.3	170.1	Phys.-chem.
Maximum formed in aquatic system	11.4	84.3	Review Report and DAR

The model parameters used are presented in Table 9.7-3

Table 9.7-3 TOXSWA (v 1.0) input parameters

Parameter	Value	Remarks
Entry routes into surface water	Spray drift	-
Temperature correction function Reference temperature [°C]	20	FOCUS recommendation
Temperature correction function Reference temperature [°C] TOXSWA: activation energy [J mol^{-1}]	20 55000	FOCUS recommendation Default TOSXWA-NL

The calculated PEC_{sw} are given in Table 9.7-4 and Peak PEC_{sed} fare given in Table 9.7-5.

Table 9.7-4: PEC_{SW} for picolinafen, flufenacet and their metabolites in the edge-of-field ditch following spring/autumn application

Use	Substance	Rate [kg/ha]	Freq.	Interval	Drift [%]	PIEC [µg/L] *		PEC-TWA21d [µg/L] *		PEC-TWA28d [µg/L] *	
						Spring	Autumn	spring	autumn	spring	autumn
1	Picolinafen	0.100	1	--	1%	0.434	0.434	0.215	0.057	0.19	0.043
1	Picolinafen	0.100	1	--	0.5%	0.217	0.217	0.107	0.028	0.095	0.021
1	Picolinafen**	0.100	1	--	0.2%	0.087	0.087	0.043	0.011	0.038	0.009
1#	Picolinafen	0.050	1	--	1%	0.217	0.217	-	-	-	-
1#	Picolinafen	0.050	1	--	0.5%	0.109	0.109	-	-	-	-
1#	Picolinafen**	0.050	1	--	0.2%	0.043	0.043	-	-	-	-
1	CL 153815	-	1	--	1%	0.331	0.331	0.275	0.046	0.263	0.035
1	CL 153815	-	1	--	0.5%	0.165	0.165	0.137	0.023	0.131	0.017
1	Flufenacet	0.240	1	--	1%	1.141	1.141	0.939	0.16	0.891	0.12
1	Flufenacet**	0.240	1	--	0.5%	0.571	0.571	-	-	-	-
1	Flufenacet**	0.240	1	--	0.2%	0.228	0.228	-	-	-	-
1#	Flufenacet	0.120	1	--	1%	0.571	0.571	-	-	-	-
1#	Flufenacet**	0.120	1	--	0.5%	0.285	0.285	-	-	-	-
1#	Flufenacet**	0.120	1	--	0.2%	0.114	0.114	-	-	-	-
1	FOE methylsulfide***	-	1	--	1%	0.086	0.086	-	-	-	-
1	Thiadone***	-	1	--	1%	0.451	0.451	-	-	-	-

* calculated according to TOXSWA

** calculated based on a drift value of 0.2% resp 0.5%

lower limit dose range; PECsw calculated

*** PECsw values based on PIEC a.s. flufenacet, corrected for relative molecular weight and maximum occurence

Table 9.7-5: PEC_{sed} for picolinafen, flufenacet and their metabolites in the edge-of-field ditch following spring/autumn application

Compound	Rate a.s. [kg/ha]	Freq.	drift [%]	PIECsediment [g a.s./m^3 sediment] *		PIECsediment [mg a.s./kg sediment DW]**		Days after application
				spring	autumn	spring	autumn	
Picolinafen	0.10	1	1	5.954×10^{-3}	3.901×10^{-3}	0.074	0.049	11.5/3.0
Picolinafen	0.10	1	0.5	2.98×10^{-3}	1.95×10^{-3}	0.037	0.024	10.5-12.5/3.0
Picolinafen**	0.10	1	0.2	1.191×10^{-3}	0.782×10^{-3}	0.015	0.010	10-13.5/3.0
Flufenacet	0.24	1	1	3.07×10^{-3}	2.12×10^{-3}	0.038	0.027	16.0/2.5
CL 153815	0.0696	1	1	1.10×10^{-3}	6.94×10^{-2}	0.014	0.868	17.0 -20.5/2.5
CL 153815	0.0696	1	0.5	5.6×10^{-4}	3.52×10^{-2}	0.007	0.440	18.0 - 20.0/2.5

* TOXSWA output

** calculated based on a drift value of 0.2%

IIIA 9.7.1 Initial PECsw value for static water bodies

Spray drift to edge of field ditch

PEC_{sw} and PEC_{sed} were calculated for Flufenacet, Picolinafen and their metabolites according to the National Guidelines of The Netherlands (CTGB 2011) using the TOXSWA GUI model (Version 1.0).

The TOXSWA GUI model (Version 1.0) was used to model the surface water exposure from Flufenacet, Picolinafen and their metabolites when used on winter cereals. The input parameters for Flufenacet, Picolinafen and metabolites are shown in Table 9.7-1 and 9.7-2.

1.0% drift from field crops was assumed in line with Dutch guidance (CTGB 2006). In accordance with the GAP, the agronomic parameters used as input for these simulations were therefore as follows:

The table below shows the GAP for the product BAS 758 00 H.

Crop and/ or situation **(crop destination / purpose of crop)**	**Application**			**Application rate**
	Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season
BAS 758 00 H				
Cereals (winter sown)	Low volume broadcast foliar application	BBCH 00 – 29 (autumn / spring)	a) 1 (-) b) 1 (-)	0.100 Picolinafen 0.240 Flufenacet 0.100 Picolinafen 0.240 Flufenacet

Based on this information, the agronomic parameters used as input for the simulations were as follows:

Crop:	Winter cereals
Application Rate:	1 x 240 g flufenacet/ha
	1 x 100 g picolinafen/ha
Scenarios:	Netherlands standard autumn and Netherlands standard spring
Drift:	1% (downward spraying technique)
Drift mass loading:	1 x 0.00024 g flufenacet /m^2
	1 x 0.00010 g picolinafen /m^2

The initial PEC_{sw} values for the respective metabolites were calculated by correcting the initial PEC_{sw} value of the parent for molecular weight and maximum percentage observed in the aquatic system (water/sediment).

Initial PEC_{sw} values for both picolinafen and flufenacet corresponding to the lower limit of the dose rate applied for (0,5 L product /ha) are additionally calculated.

Further refinement of the PECsw-initial for picolinafen was undertaken by assessing the effect of spray drift reduction. Spray drift reducing techniques are considered as a tool for mitigating the risk to aquatic organisms from the use of pesticides. These typically include the use of specialised drift reducing nozzles or tunnel/reflector sprayers, sometimes combined with equipment adjustment (e.g. reduction of spray pressure, adjustment of air assistance, etc.). The objective is to increase droplet size (coarse sprays result in less drift than fine sprays). The use of a 0.5% and 0.2% drift values, corresponding to resp. a 75% and 90% drift reduction nozzle, was considered for field crops.
Each simulation was run for 30 days.
Additionally the effect of spray drift reduction (75% and 90% drift reduction nozzle) is calculated for the lower limit of the dose range applied for too.

The TOXSWA GUI model (Version 1.0) was used to model the surface water exposure from flufenacet, picolinafen and their respective metabolites.

The PEC_{sw} and PEC_{sed} value for the active substances and picolinafen metabolite CL 153815 after spring and autumn application are summarised in Tables 9.7.1-1 and 9.7.1-2, respectively. Initial PEC_{sw} values for the flufenacet metabolites are summarised in Table 9.7.1-3.

Tables 9.7.1-4 and 9.7.1-5 show PEC_{sw} and PEC_{sed} values for picolinafen and CL 153815 after spring and autumn application with 75% and 90% nozzle reduction mitigation.

Tables 9.7.1-6 show the calculated PEC_{sw} values for flufenacet after spring and autumn application with 75% and 90% nozzle reduction mitigation.

Table 9.7.1-1a: PEC_{SW} for picolinafen(1 x 100 g a.s./ha), flufenacet(1 x 240 g a.s./ha) and CL 153815(1 x 69.6 g a.s./ha) in the edge-of-field ditch following spring/autumn application on winter cereals

Compound	Picolinafen (1 x 100 g a.s./ha)		Flufenacet (1 x 240 g a.s./ ha)		CL 153815 (1 x 69.6 g a.s./ha)	
Time	Spring (µg/l)	Autumn (µg/l)	Spring (µg/l)	Autumn (µg/l)	Spring (µg/l)	Autumn (µg/l)
Initial	0.434	0.434	1.141	1.141	0.331	0.331
TWA 4d	0.341	0.274	1.066	0.824	0.308	0.239
TWA 21d	0.215	0.057	0.939	0.160	0.275	0.046
TWA 28d	0.190	0.043	0.891	0.120	0.263	0.035

Additioanlly the PECsw(initial) for the lower limit of the dose range applied for are calculated.

Table 9.7.1-1b: PEC_{SW} for picolinafen (1 x 50 g a.s./ha), flufenacet (1 x 120 g a.s./ ha) in the edge-of-field ditch following spring/autumn application on winter cereals

Compound	Picolinafen (1 x 50 g a.s./ha)		Flufenacet (1 x 120 g a.s./ ha)	
Time	Spring (µg/l)	Autumn (µg/l)	Spring (µg/l)	Autumn (µg/l)
Initial#	0.217	0.217	0.571	0.571

 # calculated, based upon PEC sw (initial) of the upper limit of the dose range

Table 9.7.1-2: PEC_{SED} for picolinafen and flufenacet in the edge-of-field ditch following spring/autumn application on winter cereals

Compound	Rate a.s. [kg/ha]	Freq.	drift [%]	PIECsediment [g a.s./m^3 sediment] *		PIECsediment [mg a.s./kg sediment DW]**		Days after application
				spring	autumn	spring	autumn	
picolinafen	0.10	1	1	5.954×10^{-3}	3.901×10^{-3}	0.074	0.049	11.5/3.0
flufenacet	0.24	1	1	3.07×10^{-3}	2.12×10^{-3}	0.038	0.027	16.0/2.5
CL 153815	0.0696	1	1	1.10×10^{-3}	6.94×10^{-2}	0.014	0.868	17.0 -20.5/2.5

* TOXSWA output
** calculated as (PECsed in g/m^3 / 80 kg/m^3)*1000 (conversion of g/kg to mg/kg)

Table 9.7.1-3: PEC_{SW} for FOE methylsulfide and Thiadone (flufenacet metabolites) in the edge-of-field ditch following spring/autumn application on winter cereals

Compound	FOE methylsulfide		Thiadone	
Time	Spring (µg/l)	Autumn (µg/l)	Spring (µg/l)	Autumn (µg/l)
Winter cereals	0.086	0.086	0.451	0.451

Table 9.7.1-4a: PEC_{SW} for picolinafen (1 x 100 g a.s./ha) and CL 153815 (1 x 69.6 g a.s./ha) in the edge-of-field ditch following spring/autumn application on winter cereals – Mitigation: 75% and 90% nozzle reduction

Compound		Picolinafen (1 x 100 g a.s./ha)				CL 153815 (1 x 69.6 g a.s./ha)	
Reduction nozzle		75%		90%		75%	
Time		Spring	Autumn	Spring	Autumn	Spring	Autumn
Initial	(µg/l)	0.217	0.217	0.087	0.087	0.165	0.165
TWA 4d	(µg/l)	0.170	0.137	0.068	0.055	0.154	0.119
TWA 21d	(µg/l)	0.107	0.028	0.043	0.011	0.137	0.023
TWA 28d	(µg/l)	0.095	0.021	0.038	0.009	0.131	0.017

Table 9.7.1-4b: PEC_{SW} for picolinafen (1 x 50 g a.s./ha) in the edge-of-field ditch following spring/autumn application on winter cereals – Mitigation: 75% and 90% nozzle reduction

Compound	Picolinafen (1 x 50 g a.s./ha)			
Reduction nozzle	75%		90%**	
Time	Spring	Autumn	Spring	Autumn
Initial# (µg/l)	0.109	0.109	0.043	0.043

calculated, based upon PEC sw (initial) of the upper limit of the dose range
** calculated based on a drift value of 0.2% resp 0.5%

Table 9.7.1-5: PEC_{SED} for picolinafen and CL 153815 in the edge-of-field ditch following spring/autumn application on winter cereals – Mitigation: 75% and 90% nozzle reduction

Compound	Rate a.s. [kg/ha]	Freq.	drift [%]	PIECsediment [g a.s./m^3 sediment] *		PIECsediment [mg a.s./kg sediment DW]**		Days after application
				spring	autumn	spring	autumn	
Picolinafen	0.1	1	0.5	2.98×10^{-3}	1.95×10^{-3}	0.037	0.024	10.5-12.5/3.0
	0.1	1	0.2	1.191×10^{-3}	0.782×10^{-3}	0.015	0.010	10-13.5/3.0
CL 153815	0.0696	1	0.5	5.6×10^{-4}	3.52×10^{-2}	5.6×10^{-4}	0.440	18.0 - 20.0/2.5

Additionally also for flufenacet the use of a 0.5% and 0.2% drift values, corresponding to resp. a 75% and 90% drift reduction nozzle, was considered for field crops, for both the upper and lower limit of the dose range applied for.

Table 9.7.1-6a: PEC_{SW} for flufenacet (1 x 240 g a.s./ha) in the edge-of-field ditch following spring/autumn application on winter cereals – Mitigation: 75% and 90% nozzle reduction

Compound	**flufenacet (1 x 240 g a.s./ha)**			
Reduction nozzle	**75%****		**90%****	
Time	**Spring**	**Autumn**	**Spring**	**Autumn**
Initial (µg/l)	0.571	0.571	0.228	0.228

** calculated based on a drift value of 0.2% resp 0.5%

Table 9.7.1-6b: PEC_{SW} for flufenacet (1 x 120 g a.s./ha) in the edge-of-field ditch following spring/autumn application on winter cereals – Mitigation: 75% and 90% nozzle reduction

Compound	**flufenacet (1 x 120 g a.s./ha)**			
Reduction nozzle	**75%****		**90%****	
Time	**Spring**	**Autumn**	**Spring**	**Autumn**
Initial # (µg/l)	0.285	0.285	0.114	0.114

calculated, based upon PEC sw (initial) of the upper limit of the dose range
** calculated based on a drift value of 0.2% resp 0.5%

IIIA 9.7.2 Initial PECsw value for slow moving water bodies

Please refer to the assessment made in IIIA 9.7.1.
For flowing water bodies, dissipation through dilution rapidly reduces the concentration; therefore the PEC_{sw} from static water bodies is used to assess risk.

IIIA 9.7.3 Short-term PECsw values for static water bodies (1-4 days after last application)

Please refer to Annex Point IIIA 9.7.1

IIIA 9.7.4 Short-term PECsw values for slow moving water bodies (1-4 days after last application)

Please refer to Annex Point IIIA 9.7.1

IIIA 9.7.5 Long-term PECsw values for static water bodies (7-42 days after last application)

Please refer to Annex Point IIIA 9.7.1

IIIA 9.7.6 Long-term PECsw values for slow moving water bodies (7-42 days after last application)

Please refer to Annex Point IIIA 9.7.1

IIIA 9.8 Predicted Environmental Concentrations in Surface Water (PECsw) for Metabolites

In the SANCO/1418/2001-final review report for picolinafen the metabolite CL 153815 was identified as being potentially relevant with regard to the risk assessment for surface water. CL 153815 represented up to 92.4% in the water sediment study.

In the SANCO/7469/VI/98-Final for flufenacet, two metabolites FOE methylsulfide and thiadone which are only formed in aquatic systems at maximum levels of 11.4% and 84.3%, respectively, are considered.

Calculation of PECsw and PECsed were conducted according to recommendations in the Netherlands (see section IIIA 9.7.1). The results are presented in Sections 9.7 and 9.7.1.

IIIA 9.8.1 Initial PECsw value for static water bodies

Please refer to Annex Point IIIA 9.8.

IIIA 9.8.2 Initial PECsw value for slow moving water bodies

Please refer to Annex Point IIIA 9.8.

IIIA 9.8.3 Short-term PECsw values for static water bodies 1-4 days after last application)

Please refer to Annex Point IIIA 9.8.

IIIA 9.8.4 Short-term PECsw values for slow moving water bodies 1-4 days after last application)

Please refer to Annex Point IIIA 9.8.

IIIA 9.8.5 Long-term PECsw values for static water bodies 7-42 days after last application)

Please refer to Annex Point IIIA 9.8.

IIIA 9.8.6 Long-term PECsw values for slow moving water bodies 7-42 days after last application)

Please refer to Annex Point IIIA 9.8.

IIIA 9.8.7 Additional field testing

Not required

Monitoring data groundwater
There are no data available regarding the presence of the substances picolinafen and flufenacet in groundwater.

Monitoring data surface water
There are data available in the Pesticide Atlas regarding the presence of the substance picolinafen and flufenacet in surface water.

In 2016, data bank version (24-11-2016, 3.2) of the Pesticide, includes a statistical correlation analysis between concentrations, threshold exceedance and land use, which may indicate probable relationships. In this version also the correlation analysis of land use with the environmental quality standards (EQS) of the Water Framework Directive (WFD) is included.

Data from the Pesticide Atlas are used to evaluate potential exceedances of the authorisation threshold and environmental quality standards (MKN in Dutch, data source http://www.rivm.nl/rvs/Normen). These environmental quality standards consist either of the harmonised WFD thresholds derived according to the Fraunhofer methodology (AA-EQS and MAC-EQS) or of an MPC value (which is usually derived on the basis of outdated guidance). When EQS values according to the Water Framework Directive are available, the MPC value is not used further in the analysis of monitoring data for the purpose of the registration.

Data were derived from www.bestrijdingsmiddelenatlas.nl (Version 3.2 with databank version of 24-11-2016). Additionally, the number and size of exceedings (if any) of the authorisation threshold, ad hoc/indicative MPC and MAC-EQS & AA-EQS (the last two threshold are not available for all substances in the Pesticide Atlas).

Picolinafen

The active substance picolinafen was observed in the surface water (most recent data from 2016). In Table 9.8.7.2-1 and figure below the number of observations in surface water are presented.
The authorisation threshold (Toelatingscriterium Kaart) (consisting of first tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, is not reported.

The currently available MPC (maximum permissible concentration, 28/11/2005) value of 0.09 µg/L is used for information purposes as no EQS values are available.

Table 9.8.7.2-1 Monitoring data in Dutch surface water (from www.pesticidesatlas.nl, version 3.2)

Jaar	Aantal locaties	Aantal metingen				
Year	**Total no of locations**	**Total no of measurements**	***n* > authorisation threshold**	***n* > EQS**		
				MAC-EQS (MAK-MKN)	**AA-EQS** (JG-MKN)	**MPC (adhoc/ indicative)**
2015	74	437	n.a.	n.a.	n.a.	0

n.a.: not available

As there is no exceeding of thresholds, the monitoring data have no consequences for the proposed uses of the product.

Flufenacet

The active substance flufenacet was observed in the surface water (most recent data from 2016). In Table 9.8.7.2-2 and figure below the number of observations in surface water are presented.
The authorisation threshold (Toelatingscriterium Kaart) equals 4 µg a.s./L (consisting of first tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case the EAC (NOEC lemna/alg met veiligheidsfactor 3, 1/4/2016).

The currently available MAC-EQS and AA-EQS values are 0.61 and 0.137 µg/L, respectively.

Table 9.8.7.2-2 Monitoring data in Dutch surface water (from www.pesticidesatlas.nl, version 3.2)

Jaar	Aantal locaties	Aantal metingen				
Year	**Total no of locations**	**Total no of measurements**	***n* > authorisation threshold**	***n* > EQS**		
				MAC-EQS (MAK-MKN)	**AA-EQS** (JG-MKN)	**MPC (adhoc/ indicative)****
				11/11/2013		
2015	115	687	0	1 (1-5 * threshold)	1 (1-5 * threshold)	n.r.

n.r.: not relevant

The exceedance of the WFD water quality standards, AA-EQS and MAC-EQS, is from 2016 onwards addressed by the ERP (Emission Reduction Plan), which is carried out under responsibility of the Ministry of Infrastructure and Environment (I&M). Ctgb has no active role in this process, unless the outcome of the ERP leads to label changes on request of the applicant. Therefore Ctgb cannot draw consequences regarding the authorisation of Pontos due to exceedance of these water quality standards.

As there is no exceeding of the authorisation threshold, the monitoring data have no consequences for the proposed uses of the product.

Drinking water criterion

Article 8g of the Plant Protection Products and Biocides Decree (BGB) describes the Assessment of the drinking water criterion.

It follows from the decision of the Court of Appeal on Trade and Industry of 19 August 2005 (Awb 04/37 (General Administrative Law Act)) that when considering an application, the Ctgb should, on the basis of the scientific and technical knowledge and taking into account the data submitted with the application, also judge the application according to the drinking water criterion 'surface water intended for drinking water production'.
The assessment methodology followed is developed by the WG implementation drinking water criterion and outlined in Alterra report 1635 .

Substances are categorized as new substances on the Dutch market (less than 3 years authorisation) or existing substances on the Dutch market (authorised for more than 3 years).
- For new substances, a preregistration calculation is performed.
- For existing substances, the assessment is based on monitoring data of VEWIN (drinking water board).

o If for an existing substance based on monitoring data no problems are expected by VEWIN, Ctgb follows this VEWIN assessment.
o If for an existing substance based on monitoring data a potential problem is identified by VEWIN, Ctgb assesses whether the 90th percentile of the monitoring data meet the drinking water criterion at each individual drinking water abstraction point.

<u>Flufenacet</u>
Active substance flufenacet has been on the Dutch market for > 3 years (authorised since 03-02-2012; prior to this date, it already has been authorised from 2002-2004). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water as laid down in the RGB/BGB are met.

<u>Picolinafen</u>

As is a new active substance, there are no data available regarding its presence in surface water at drinking water abstraction points.
The decision tree as outlined in Alterra report 1635 (2010) should be followed. The tool DROPLET (described in Alterra report 2020, 2010) to calculate concentrations on drinking water abstraction points is available at Ctgb and is used since it represents the current scientific insight.

The following data are used for the assessment:

Input in SWASH:

Substance input parameters:

Molecular mass:	376.3 g/mol
Saturated vapour pressure:	1.7E-7 Pa (20 °C)
Solubility in water:	0.047 mg/L (20 °C)
Arithmetic mean Kom:	13037 L/kg
Arithmetic mean 1/n	0.99
Factor plant uptake:	0.0 (default)
Geometric mean DT_{50} Water (DT_{50} system):	1000 d (default)
Geometric mean field/lab DT_{50} Soil:	42.9 d
DT50 Sediment:	6.2 d
DT50 Crop (default 10 d)	10 d (default)

Scenario (Focus wizard):
Selected crop: Winter cereals
Selected scenario: D3
Input in FOCUS-TOXSWA: NL Drift value 1%

Input in DROPLET:
Selected crop: Cereals
$f_{market:}$ 0.4 (default)
$f_{additional\ dilution}$: 1 for all abstraction points, except for Andijk: 0.17 (default)

Other parameters: standard settings SWASH 2.1 and DROPLET 1.0

See Table 9.8.7.2-3 for results for each drinking water abstraction point.

Table 9.8.7.2-3 Predicted concentrations of active substance at drinking water abstraction points in The Netherlands as calculated by DROPLET 1.0

Drinking water abstraction point	FOCUS D3 crop	$f_{useintensity}$ (-)	Relative Cropped Area (-)	$PEC_{drinking\ water\ abstraction\ point}$ (µg/L)
De Punt	Cereals	0.014099	0.070947	<0.004
Andijk	Cereals	0.007295	0.036473	<0.001
Nieuwegein	Cereals	0.007859	0.039296	<0.002
Heel	Cereals	0.017786	0.088929	<0.005
A'dam Rijnkanaal	Cereals	0.006344	0.031720	<0.002
Brakel	Cereals	0.006794	0.033972	<0.002
Petrusplaat	Cereals	0.006674	0.033369	<0.002

Drinking water abstraction point	FOCUS D3 crop	$f_{useintensity}$ (-)	Relative Cropped Area (-)	$PEC_{drinking\ water\ abstraction\ point}$ (µg/L)
Twentekanaal	Cereals	0.002189	0.010945	<0.001
Scheelhoek	Cereals	0.008811	0.044057	<0.003
Bommelerwaard (subarea of Brakel)	Cereals	0.003185	0.015926	<0.001

Results show that for all drinking water abstraction points the predicted concentrations are below 0.1 µg/L.

Therefore, the application of Pontos is not expected to exceed the drinking water criterion. The standards for surface water destined for the production of drinking water as laid down in the BGB are met.

IIIA 9.9 Fate and Behaviour in Air

Please refer to the core dossier of BAS 758 00H.

IIIA 9.9.1 Spray droplet size spectrum – laboratory studies

This is not an EC data requirement.

IIIA 9.9.2 Drift – field evaluation

This is not an EC data requirement.

IIIA 9.10 Other/Special Studies

There are no additional European requirements for formulated products.

IIIA 9.10.1 Laboratory studies

This is not an EC data requirement.

IIIA 9.10.2 Field studies

This is not an EC data requirement.

Appendix 1: List of data submitted in support of the evaluation

Annex point	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Yes/No**	**Owner**	**Data protection granted Y/N**	**Study used Y/N**
KIIIA 9.6/1	2014 b	Assessment of potential for contamination of groundwater by Flufenacet, Picolinafen and their metabolites in the Netherlands following a tiered approach Exponent International Ltd., Harrogate Yorkshire HG2 8RE, United Kingdom 2014/1132880 no Unpublished	Yes	BASF	N	Y

Annex point	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Yes/No**	**Owner**	**Data protection granted Y/N**	**Study used Y/N**
KIIIA 9.7.1/1	2014 a	Predicted environmental concentrations of Flufenacet, Picolinafen and their metabolites in surface water using the Toxswa Gui model and the National Guidelines of the Netherlands Exponent International Ltd., Harrogate Yorkshire HG2 8RE, United Kingdom 2014/1132881 no Unpublished	Yes	BASF	N	Y

Appendix 2: Critical Uses – justification and GAP tables

The critical uses for the risk envelope are indicated in the relevant parts of the risk assessment in this section. For the NL-GAP it is referred to 2.3 in Part A.