Draft Assessment Report

Evaluation of Active Substances

Plant Protection Products

Prepared according to **Regulation (EC) 1107/2009** as it applies in Great Britain (GB PPP)

Cinmethylin (BAS 684 H)

Volume 3 – B.8 (PPP) – BAS 684 03 H

Environmental Fate & Behaviour

Great Britain

November 2020

Version History

When	What
November 2020	Initial Draft Assessment Report (DAR)

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B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

Introduction

Studies for the derivation of endpoints for the assessment of and registration of cinmethylin have been evaluated within the CA document. This CP document relies upon the endpoints that were determined within the CA document. The exposure modelling for this product that utilises those endpoints is shown within this CP document.

One applicant (BASF) submitted the dossier for consideration with regards to the derivation of endpoints. All studies were conducted to a high quality and in accordance with the relevant guidance, and evaluated for the first time in the CA document.

BAS 684 03 H is the representative formulation supporting the application for the approval of the active substance cinmethylin in Great Britain. Exposure assessments were conducted for cinmethylin based on the intended use pattern. Table 8.1 provides the critical use pattern (also known as critical GAP) for BAS 684 03 H.

Table 8.1 Agricultural use pattern of cinmethylin

Crop	**Winter wheat and winter barley**		**Winter oilseed rape**
Field or glasshouse	Field		Field
Crop growth stage [BBCH]	00-29	00-29	00-18
Max. no. of applications [-]	1	1	1
Application rate [g a.s. ha^{-1}]	500	250	250
Application method [-]	Spray	Spray	Spray

Cinmethylin is a racemic mixture of two enantiomers. Throughout the evaluation of the fate and behaviour of cinmethylin in the environment, the Applicant studied and discussed the isomeric composition of cinmethylin. Further details of these considerations can be found in CA Section 8.1.1. The HSE evaluator notes that, in some routes of degradation, the rate of degradation varied for the two enantiomers, leading to shifts in the enantiomeric ratio over time. However, the HSE evaluator concluded that this did not warrant a change in the process of exposure assessments for cinmethylin; therefore, all following exposure assessments are conducted on the active substance as a whole. Table 8.2 summarises the compounds addressed in this document.

Table 8.2 Compounds relating to cinmethylin that are addressed in this document

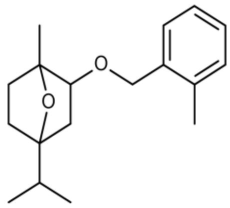
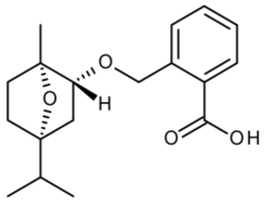
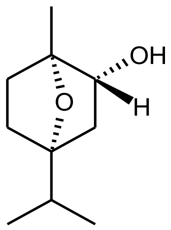
Compound	Structure	Compartments considered
Cinmethylin (BAS 684 H)		Soil Surface water Sediment Groundwater Air
M684H001		Surface water
M684H003		Surface water

Table 8.3 Models used within the cinmethylin exposure assessment

Compartment	Assessment / model	Model version
Soil	Tier 1: Excel PECsoil Calculator	v.1.0
Surface water – spray drift	Tier 1: HSE Excel Calculator “PECsw-sed (spray drift)”	v.1.0
Surface water – drain flow	Tier 1: HSE Excel Calculator “PECsw-sed (drain flow)”	v.1.0
	Tier 2: WEBFRAM FOCUS MACRO	- v.4.3b
Ground water	FOCUS PELMO FOCUS PEARL FOCUS MACRO	v.5.5.3 v.4.4.4 v.5.5.4

B.8.1. FATE AND BEHAVIOUR IN SOIL

In the aerobic soil studies, no metabolites were observed at amounts > 5%. See CA Section B.8.1 for further details.

B.8.1.1. **Route and rate of degradation in soil**

The Applicant did not perform any formulation-specific laboratory studies. For details on the active substance and its metabolites, please refer to CA Section B.8.1.1 of this dossier. Endpoints used in exposure and risk assessment are listed below in the respective study summaries and in Doc N2 of this dossier.

Two field dissipation studies were performed with the formulation BAS 684 02 H (EC formulation). These studies are presented in CA Section B.8.1.2.1. The HSE evaluator notes that the formulation BAS 684 02 H has the same formulation type and nominal concentration of cinmethylin (750 g/L) at the same enantiomeric ratio (50:50) as the formulation BAS 684 03 H, which is referred to throughout this document.

B.8.1.2. **Mobility in soil**

Mobility studies were not triggered for cinmethylin as the active substance K_{OC} was consistently greater than 25 mL/g.

B.8.2. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC_S)

Report	He, 2018
Title	Predicted environmental concentrations of BAS 684 H in soil following application to winter wheat and winter oilseed rape.
Document ID	2017/1217977
Guidelines	FOCUS Degradation Kinetics (2006) SANCO/10058/2005 version 1.1 (December 2014) FOCUS Groundwater (2014) Generic Guidance for Tier 1 v 2.2
GLP	No

Previous evaluation	None – new evaluation
HSE Evaluator comments	This study utilised endpoints which are not agreed with by the HSE evaluator. For this reason, the results obtained in this study regarding the active substance are not accepted and therefore to avoid any potential confusion the results have not been presented. Instead, the HSE evaluator's own modelling has been presented. The HSE evaluator accepted the Applicant's PEC calculations for the formulation and these are presented below.

INTRODUCTION

The predicted environmental concentrations in soil (PEC_{soil}) of cinmethylin was calculated using standard methodology relating to the representative uses of cinmethylin in winter cereals and winter oilseed rape, assuming 0% plant interception, 5 cm soil depth and a bulk density of 1.5 g/cm^3. The use of cinmethylin in winter cereals and winter oilseed rape in the United Kingdom was assessed according to the GAP, as summarised in Table 8.2.1. The HSE evaluator notes that there are two uses for cinmethylin in winter cereals, though throughout this assessment only the critical GAP (1 application of 500 g a.s./ha) has been considered.

Table 8.2.1 Application pattern used for PEC_{soil} calculations of cinmethylin.

Individual Crop	Application					Amount reaching the soil per application
	Rate per Season	Number of Applications	Interval	Plant Interception	BBCH Stage	
	[g a.s./ha]		[days]	[%]		[g a.s./ha]
Winter cereals	500	1	-	0	00-29	1 × 500
	250	1	-	0	00-29	1 × 250
Winter oilseed rape	250	1	-	0	00-18	1 × 250

METHODS

For deriving PEC_{soil}, the worst case, non-normalised best-fit DT_{50} value was used. The HSE evaluator notes that the Applicant chose the Denmark soil from the field studies (DT_{50} = 38.9 d; FOMC fit); however, the HSE evaluator notes that the Applicant did not consider endpoints derived from the US field dissipation study when determining the worst case DT_{50} (see Section CA 8.1.2 for further information). The Applicant submitted an ecoregion similarity study that concluded that five (out of six) US field soils were sufficiently relevant to European conditions; the HSE evaluator agreed with this conclusion and as such included the five US soils in all subsequent considerations. Further discussion can be found in CA Section 8.1.2.2.1.

When considering the five US soils as well as the six European soils, the HSE evaluator concluded that the Texas soil displayed the worst case DT_{50} (53.9 d; SFO), while the longest non-normalised DT_{90} was observed in the Denmark soil (207.6 d; FOMC). Therefore, the HSE evaluator repeated the derivation of PEC_{soil} calculations by considering both soils separately using these new endpoints.

For the PEC_{soil} calculations using the Texas soil, the HSE evaluator used the PEC_{soil} Excel calculator to derive the calculation based on the new endpoint of 53.9 d (SFO fit).

For the PEC_{soil} values using the Denmark soil, the HSE evaluator agreed with the Applicant's choice of the longest non-normalised DT_{90} of 207.6 d. The Applicant used the ESCAPE model (v.2.0) to calculate PEC_{soil}; the HSE evaluator validated this modelling also using ESCAPE (v.2.0). The HSE evaluator notes that the Applicant used the default soil organic carbon content of 1.5%. The HSE evaluator also notes that, since the $PEC_{soil,\ twa}$ was required for the ecotoxicology assessment (Vol. 3 CP B.9.2.), it was more appropriate to use the measured organic carbon content value for the Denmark soil in this calculation (1.13%). The HSE evaluator checked the Applicant's modelling by running the ESCAPE model using the same Denmark FOMC model parameters with the measured soil organic carbon, but notes that this made a negligible difference over 100 days of simulation, and no difference to values up to 50 days after application. As such, the HSE evaluator accepted the Applicant's PEC_{soil} modelling for the Denmark soil.

Table 8.2.2 displays the values used as inputs for the two sets of PEC_{soil} calculations.

Table 8.2.2 Input values used by the HSE evaluator to derive PEC_{soil} values for cinmethylin.

Excel Calculator Inputs (Texas soil)		
Parameter	**Value**	**Comments**
Soil DT_{50}	53.9 d	SFO fit.
ESCAPE Inputs (Denmark soil)		
Parameter	**Value**	**Comments**
Soil DT_{90}	207.6 d	FOMC fit.
α	1.919	
β	89.45	
Soil depth	5 cm	Default value.
Soil density	1.5 g cm^{-3}	Default value.
Soil organic content	1.5% [a]	Used to calculate porewater concentration. Default value.
Field capacity	29.2 %	Default value.
Wilting point	6.4 %	Default value.
Temperature	20 ºC	Default value.
Tillage depth	5 cm	Default value for application patterns not requiring immediate incorporation.

[a] The HSE evaluator notes that the correct value to use would be 1.13%, as measured in the terrestrial field dissipation study (see CA Section 8.1.2.2.1). However, the HSE evaluator concluded that there was no difference in PEC_{soil} calculations up to 50 days after application, and a negligible difference in PEC_{soil} calculations arose after 100 days when using the measured organic carbon value. Therefore, the HSE evaluator accepted the Applicant's use of the default value of 1.5%.

RESULTS

The HSE evaluator compared the two sets of PEC_{soil} values based on the Texas and Denmark soils. For the ecotoxicology assessment, the worst case value for the 21 day time-weighted average PEC_{soil} was required. The HSE evaluator notes that the Texas soil provided the worst case out of the two soils; therefore, the PEC_{soil} values reported in the following section derive from the modelling of the Texas soil. For clarity, the exposure assessment based upon the Denmark soil has not been presented.

Table 8.2.3 shows the PEC_{soil} values calculated by the HSE evaluator for cinmethylin based on the worst case scenario of 0% crop interception arising from a pre-emergence application.

Table 8.2.3 PEC$_{soil}$ of cinmethylin following single application to winter cereals and winter oilseed rape, calculated for 5 cm soil depth and a bulk density of 1.5 g/cm^3. Crop interception was assumed to be 0%.

	Crop	Winter cereals		Winter oilseed rape	
	Application rate	1 x 500 g a.s. ha^{-1}		1 x 250 g a.s. ha^{-1}	
	Time [d]	PEC$_{soil,act}$ [mg kg^{-1}]	PEC$_{soil,twa}$ [mg kg^{-1}]	PEC$_{soil,act}$ [mg kg^{-1}]	PEC$_{soil,twa}$ [mg kg^{-1}]
Global max.	0	0.667	-	0.333	-
Short-term	1	0.658	0.662	0.329	0.331
	2	0.650	0.658	0.325	0.329
	4	0.633	0.650	0.317	0.325
Long-term	7	0.609	0.638	0.305	0.319
	14	0.557	0.610	0.278	0.305
	21	0.509	0.584	0.254	0.292
	28	0.465	0.560	0.233	0.280
	48	0.360	0.497	0.180	0.249
	100	0.184	0.375	0.092	0.188

Derived from SFO DT$_{50}$ = 53.9 d

The HSE evaluator assessed the Applicant's formulation PEC$_{soil}$ derivation by checking the values provided in the Excel PEC$_{soil}$ calculator. The HSE evaluator agrees with the input values and resulting formulation PEC$_{soil}$ values; these are presented in Table 8.2.4 below.

Table 8.2.4 PEC$_{soil}$ for the formulation BAS 684 03 H following a single application to winter cereals and winter oilseed rape, as supplied by the Applicant.

Crop	Application rate of formulation [L ha^{-1}]	Formulation density [g L^{-1}]	Crop interception [%]	Effective soil load [g ha^{-1}]	PEC$_{soil,max}$ [mg kg^{-1}]
Winter cereals	0.666	1000	0	666	0.888
	0.333			333	0.444

B.8.3. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUND WATER (PEC_{GW})

Report	Gutierrez and He, 2018
Title	Predicted environmental concentrations of BAS 684 H in groundwater following application to winter wheat and winter oilseed rape
Document ID	2017/1217978
Guidelines	FOCUS (2000). FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS groundwater scenarios workgroup, EC document reference SANCO/321/2000 rev. 2, 202 pp. FOCUS (2014a). Assessing potential for movement of active substances and their metabolites to groundwater in the EU. Report of the FOCUS Groundwater Work Group, EC Document Reference SANCO/13144/2010 version 1, 604 pp. FOCUS (2014b). Generic guidance for Tier 1 FOCUS ground water assessments, v. 2.2
GLP	No

Previous evaluation	None – new evaluation
HSE Evaluator comments	This study utilised endpoints which are not agreed with by the HSE evaluator. For this reason, the results obtained in this study are not accepted and therefore to avoid any potential confusion the results have not been presented. Instead, the HSE evaluator's own modelling has been presented, though it is noted that the results were in agreement with the Applicant's.

INTRODUCTION

The Applicant conducted modelling to calculate predicted environmental concentrations in groundwater (PEC_{gw}) for cinmethylin following a single application of either 500 g a.s./ha or 250 g a.s./ha to winter wheat (pre-emergence or post-emergence) and 250 g a.s./ha to winter oilseed rape (pre-emergence or post-emergence). Table 8.3.1 summarises the GAP for cinmethylin. The calculations were performed by the Applicant according to the recommendations of the FOCUS working groups on groundwater scenarios using the models FOCUS-PEARL 4.4.4, FOCUS-PELMO 5.5.3 and FOCUS-MACRO 5.5.4.

Table 8.3.1 Agricultural use pattern of cinmethylin

Crop	**Winter wheat**				**Winter oilseed rape**	
Crop growth stage [BBCH]	00-08	09-29	00-08	09-29	00-08	09-18
Max. no. of applications [-]	1	1	1	1	1	1
Application rate [g a.s. ha^{-1}]	500	500	250	250	250	250
Application method [-]	Spray	Spray	Spray	Spray	Spray	Spray

PEC_{gw} calculations were performed for all FOCUS groundwater scenarios parameterised for the $FOCUS_{gw}$ crops winter cereals and winter oilseed rape, considering an application rate of 500 g a.s./ha for winter cereals, covering the uses with 250 g a.s./ha, and 250 g a.s./ha for oilseed rape. The Applicant considered pre-emergence application for both crops as the worst case of the scheduled application covering later uses. No crop interception was considered in accordance with the guidance of the FOCUS groundwater scenarios workgroup. Continuous cropping over a period of 26 years was assumed and annual application of cinmethylin was taken into account according to FOCUS.

The HSE evaluator assessed the methods and endpoints used by the Applicant to derive PEC_{gw} values. The HSE evaluator agreed with the procedures followed but noted that the endpoints used by the Applicant were incorrect. As such, the HSE evaluator repeated all modelling with the correct endpoints and notes that the different endpoints did not change the results or conclusion due to the PEC value being sufficiently low that there was a large margin of safety.

METHODS

Endpoints used

For the soil degradation rates, the Applicant utilised the EFSA $DegT_{50}$ endpoint selector tool and concluded that the normalised field DT_{50} value should be used. The HSE evaluator agrees with this conclusion; refer to CA Section 8.1 for discussion of the process followed. However, the geometric mean DT50 was derived from six field soils when 11 were available. As such, the Applicant's soil DT50 was incorrect and this has not been reported. The correct values as used by the HSE evaluator are reported in Table 8.3.2.

The Applicant investigated the sorption behaviour of cinmethylin in eight soils, however, following study evaluation, the HSE evaluator rejected three of the soils, giving a total of five soils for deriving the sorption endpoints. As a result, the Applicant's sorption values were incorrect; the correct values as used by the HSE evaluator are reported in the table below.

K_{foc} values do not correlate with soil pH (refer to CA Section 8.1). Additionally, no pH dependence was observed in the degradation of cinmethylin (see CA section 8.1.3.1.1). Therefore, it was not necessary to consider pH dependence in this assessment.

Table 8.3.2 Endpoints used for the calculation of PEC_{gw} for cinmethylin.

Endpoint	**Unit**	**cinmethylin**
$DT_{50,soil}$ (SFO)	d	11.1 [a]
$K_{f,oc}$	mL/g	317.8 [b]
$K_{f,om}$	mL/g	184.3 [c]
1/n	-	0.97 [d]

[a] Geometric mean of normalised field DT_{50} (n = 11; 20°C, pF2)
[b] Geometric mean
[c] Calculated as $K_{om} = K_{oc}/1.724$
[d] Arithmetic mean

Modelling approach

The Applicant conducted the leaching assessment for cinmethylin in accordance with the guidance of the FOCUS groundwater working group. The leaching assessment was conducted for Tier 1 of the tiered assessment scheme: PEC_{gw} modelling assessments carried out with basic data in combination with standard FOCUS scenarios or standard national groundwater scenarios.

The Applicant utilised FOCUS-PEARL 4.4.4, FOCUS-PELMO 5.5.3 and FOCUS-MACRO 5.5.4 to simulate the leaching behaviour of cinmethylin.

In accordance with FOCUS, the 80th percentile annual average leachate concentrations at 1 m depth out of a 20-year simulation period are reported as relevant values for the leaching assessment.

Application scenarios

The Applicant performed PEC_{gw} calculations for all FOCUS groundwater scenarios parameterized for the $FOCUS_{gw}$ crops ‘winter cereals’ and ‘winter oilseed rape’. The HSE evaluator notes that, for the UK only assessment, five of the nine application scenarios were not necessary. Therefore, the HSE evaluator has only assessed the following scenarios, most relevant to UK conditions: Châteaudun, Hamburg, Kremsmünster and Okehampton.

The Applicant considered an application rate of 500 g a.s./ha for winter cereals (covering the uses with 250 g a.s./ha) and 250 g a.s./ha for oilseed rape. Pre-emergence application was considered by the Applicant to be the worst case scenario for both crops, covering later uses. No crop interception was considered in accordance with the guidance of the FOCUS groundwater scenarios workgroup (FOCUS, 2014a).

For the modelling, continuous cropping over a period of 26 years was assumed and annual application of cinmethylin was taken into account according to FOCUS (2014a; 2014b). The 26-year cropping period consists of ‘warm-up-period’ from year 1 to year 6 and the period from year 7 to year 26 that is considered for deriving the 80th percentile leachate concentrations.

The application dates were selected by the Applicant based on the recommendations given by the AppDate tool, which calculates appropriate application dates for the relevant crops defined for the different FOCUS scenarios based on crop BBCH growth stage (Klein, M., 2010. AppDate. Estimation of application dates based on crop development – Fraunhofer Institut Molekularbiologie und Angewandte Ökologie, Schmallenberg, Germany. Version 3.00 (09 Nov 2017)). The Applicant defined the pre-emergence application as 10 days before emergence for winter cereals and 7 days before emergence for winter oilseed rape.

The HSE evaluator verified the pre-emergence application dates using AppDate and agreed with all application dates selected by the Applicant. A summary of the application scenarios and application dates considered for the PEC_{gw} calculations is given in Table 8.3.3.

Table 8.3.3 Worst-case application scenarios of cinmethylin applied to winter cereals and winter oilseed rape considered for the PEC_{gw} calculations.

Pre-emergence application		
Crop	**Winter wheat**	**Winter oilseed rape**
$FOCUS_{gw}$ crop	**Winter cereals**	**Winter oilseed rape**
Crop growth stage at first application (BBCH)	00	00
Max. no. of applications (-)	1	1
Minimum application interval (d)	-	-
Application rate (g a.s./ha)	500	250
Interception (%)	0	0
Amount reaching the soil surface (g a.s./ha)	500	250
Total yearly soil load (g a.s./ha)	500	250
Scenario	**Application dates**	
Châteaudun	16th Oct (289) [a]	31st Aug (243) [a]
Hamburg	22nd Oct	26th Aug
Kremsmünster	26th Oct	26th Aug
Okehampton	07th Oct	7th Aug

[a] In brackets: Julian day used for FOCUS-MACRO calculations

The HSE evaluator notes that, on occasion, higher groundwater concentrations can occur with spring applications. To ensure the PEC_{gw} values being reported were representative of the worst case leachate concentrations, the HSE evaluator conducted additional modelling using PELMO with spring application dates, retaining a 0% crop interception to derive worst case values. Application timings were derived using AppDate and a representative BBCH growth stage of 25. The HSE evaluator chose to test the spring applications using PELMO only as an initial test to see whether the PEC values were higher in the autumn or spring scenario. Further modelling would have been if the values were similar enough to warrant investigation or exceeded the trigger of 0.001 µg/L. In this instance, all values were significantly below 0.001 µg/L, therefore according to Section 8 of the Working Document of the Central Zone in the Authorisation of Plant Protection Products (v.1.1, June 2018), further modelling using MACRO and PEARL is not necessary.

Table 8.3.4 Spring application scenarios of cinmethylin applied to winter cereals and winter oilseed rape considered for the PEC_{gw} calculations using PELMO.

Spring application		
Crop	**Winter wheat**	**Winter oilseed rape**
$FOCUS_{gw}$ crop	**Winter cereals**	**Winter oilseed rape**
Crop growth stage at first application (BBCH)	09-29	09-18
Max. no. of applications (-)	1	1
Minimum application interval (d)	-	-
Application rate (g a.s./ha)	500	250
Interception (%)	0	0
Amount reaching the soil surface (g a.s./ha)	500	250
Total yearly soil load (g a.s./ha)	500	250
Scenario	**Application dates**	
Châteaudun	14th Feb	1st Mar
Hamburg	15th Feb	11th Jan
Kremsmünster	15th Feb	11th Jan
Okehampton	6th Feb	8th Jan

Summary of input parameters

The substance specific input parameters for cinmethylin and further parameters, which are set to standard assumptions based on recommendations in specific guidance documents, are given in Table 8.3.5.

Table 8.3.5 Overview of input parameters used by the HSE evaluator for cinmethylin used for the leaching simulation models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4.

Input parameter	Unit	Value	Remarks
PHYSICO-CHEMICAL PARAMETERS			
Molecular mass	(g/mol)	274.4	Phys-chem. properties
Water solubility (20°C, pH7)	(mg/L)	58.0	Phys-chem. properties
Molar enthalpy of dissolution	(kJ/mol)	27	FOCUS recommendation
Saturated vapor pressure (20°C)	(Pa)	8.1×10^{-3}	Phys-chem. Properties
Molar enthalpy of vaporization	(kJ/mol)	95	FOCUS recommendation
Diffusion coefficient in water (20°C) PEARL MACRO	 (m²/d) (m²/s)	 4.3×10^{-5} 5×10^{-10}	FOCUS recommendation
Diffusion coefficient in gas (20°C) PEARL PELMO	 (m²/d) (cm²/s)	 0.43 0.05	FOCUS recommendation
DEGRADATION PARAMETERS			
DT_{50} soil at reference conditions (20°C, pF2)	(d)	11.1	Geometric mean of normalised field values (n = 11)
PELMO transformation rate to SINK [a]	(d)	0.06245	Calculated as $\ln(2)/DT_{50}$
Molar activation energy (PEARL)	(kJ/mol)	65.4	EFSA recommendation
Q_{10} (PELMO)	(-)	2.58	EFSA recommendation
Temperature correction exponent (MACRO)	(K)	0.0948	EFSA recommendation
Exponent of moisture correction function PEARL, PELMO MACRO	 (-)	 0.7 0.49	FOCUS recommendation
SORPTION PARAMETERS			
$K_{f,oc}$	(mL/g)	317.8	Geometric mean (n = 5)
$K_{f,om}$	(mL/g)	184.3	Calculated as $K_{om} = K_{oc}/1.724$
Freundlich exponent 1/n	(-)	0.97	Arithmetic mean (n = 5)
Method of subroutine description	(-)	pH independent	-
CROP RELATED PARAMETERS			
TSCF (crop uptake)	(-)	0	FOCUS recommendation

[a] Transformation rate was calculated automatically by PELMO based on the DT_{50}.

RESULTS

The results of the PEC_{gw} calculations for cinmethylin are presented in Table 8.3.6. The Applicant reported that 80th percentile of the predicted annual leachate concentrations was below 0.001 µg/L in all tested scenarios; the HSE evaluator's modelling with corrected soil degradation rates and sorption parameters corroborated this outcome and so the HSE evaluator agrees that the contamination of groundwater with cinmethylin above 0.1 µg/L on an annual average basis is highly unlikely following application of cinmethylin to winter wheat and winter oilseed rape according to the proposed GAP.

Table 8.3.6 80th percentile annual leachate concentrations of cinmethylin following pre-emergence or spring application to winter cereals and winter oilseed rape.

Crop	Scenario	PEC_{gw} (µg/L)			
		PEARL 4.4.4	PELMO 5.5.3 [a]		MACRO 5.5.4
			Pre-em.	Spring	
Winter cereals	Châteaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	- [b]
	Kremsmünster	<0.001	<0.001	<0.001	
	Okehampton	<0.001	<0.001	<0.001	
Winter oilseed rape	Châteaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	- [b]
	Kremsmünster	<0.001	<0.001	<0.001	
	Okehampton	<0.001	<0.001	<0.001	

[a] The Applicant considered pre-emergence application scenarios in all three models. The HSE evaluator decided to run an additional set of scenarios considering a spring application covering the later growth stages in the GAP table (BBCH 09-29 for winter wheat, 09-18 for winter oilseed rape)
[b] Scenarios not defined for the model

CONCLUSION

The Applicant calculated PEC_{gw} for cinmethylin according to the guidance of the FOCUS groundwater working group. The PEC_{gw} value for cinmethylin was calculated to be significantly below 0.001 µg/L in all FOCUS scenarios. The HSE evaluator agrees with this value and concludes that the use of cinmethylin is not likely to pose unacceptable risks to shallow groundwater when applied in compliance with label recommendations.

B.8.4. FATE AND BEHAVIOUR IN WATER AND SEDIMENT

B.8.4.1. **Aerobic mineralisation in surface water**

No studies were performed with the formulation BAS 684 03 H. The aerobic mineralisation of cinmethylin in surface water is sufficiently addressed by the information given in CA Section B.8.2.2.2.

B.8.4.2. **Water/sediment study**

No water/sediment studies were performed with the formulation BAS 684 03 H. The behaviour of cinmethylin in water/sediment systems is sufficiently addressed by the information given in CA Section B.8.2.2.3.

B.8.4.3. **Irradiated water/sediment study**

No irradiated water/sediment studies were performed with the formulation BAS 684 03 H. The behaviour of cinmethylin in water/sediment systems is sufficiently addressed by the information given in CA Section B.8.2.2.3.

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

Report 1	He, 2018
Title	Predicted environmental concentrations of BAS 684 H and its metabolites in surface water and sediment following application to winter wheat and winter oilseed rape
Document ID	2017/1217979
Guidelines	FOCUS Surface Water Scenarios (2001) SANCO/4802/2001 rev. 2, FOCUS Surface Water (2015) Generic guidance v. 1.4, FOCUS Landscape and Mitigation (2007) SANCO/10422/2005 v. 2 Vol. 1 and 2
GLP	No

Previous evaluation	None – new evaluation
HSE Evaluator comments	This study calculated PEC values in accordance with the FOCUS procedure followed for European applications. As the cinmethylin application is a UK only application, this report and the subsequent modelling is irrelevant to the UK application. **This study is not relied upon for deriving UK specific endpoints and has not been evaluated.**

Report 2	Pfeiffer, 2018
Title	dRR Part B, Section 8, Environmental Fate: National Addendum UK
Document ID	2018/1032944
Guidelines	UK National Requirements – HSE, 2016. Data Requirements Handbook.
GLP	No

Previous evaluation	None – new evaluation
HSE Evaluator comments	This addendum calculated PEC values in accordance with the UK national requirements for spray drift and drain flow. The study utilised endpoints which are not agreed with by the HSE evaluator, though this only affected some of the modelling. For this reason, the results obtained in this addendum are not accepted (except for PEC_{sw} formulation) and therefore to avoid any potential confusion the results have not been presented. Instead, the HSE evaluator's own modelling has been presented. For PEC_{sw} formulation, the Applicant's modelling is presented.

Report 3	Kubitza and Garcia, 2020
Title	Response to CRD's RAC derivation for aquatic invertebrate during the evaluation of Luximo (cinmethylin, BAS 684 H)
Document ID	2020/2088346
Guidelines	UK National Requirements – HSE, 2016. Data Requirements Handbook.
GLP	No

Previous evaluation	None – new evaluation
HSE Evaluator comments	Update July 2020: The Applicant supplied additional higher tier drainflow modelling to address a request for additional information regarding the ecotoxicology assessment. The HSE evaluator has added the additional drainflow modelling here with a full evaluation and consideration starting on page 28.

INTRODUCTION

The Applicant submitted a study calculating PEC_{sw} and PEC_{sed} according to the national requirements of the UK (Draft Registration Report Part B, Section 8, Environmental Fate: National Addendum UK; DocID 2018/1032944). The HSE evaluator disagreed with a number of the chosen endpoints as they did not consider the full data set available in terms of field dissipation studies; the HSE evaluator also disagreed with the sorption parameters applied by the Applicant as they did not exclude three soils that did not pass quality checks (see Vol. 3 CA section B.8). As a result, the HSE evaluator has decided to carry out an independent surface water assessment using fully validated endpoints.

METHODS

This section covers methodology and details that are relevant for all surface water assessments. Following this, sections will, in turn, discuss spray drift and drain flow separately, covering the methods and results for each assessment.

The predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated for cinmethylin and the formulation BAS 684 03 H and its metabolites M684H001 and M684H003 in a series of modelling studies using standard methodology according to national requirements of the UK. For spray drift, a single tier approach was applied; for drain flow, a two-tier approach was used that included a worst-case pesticide loading at Tier 1, with Tier 2 refining this using the WEBFRAM risk assessment tool.

Decisions on acceptable and unacceptable risk were determined based upon whether the calculated PEC exceeded the regulatory acceptable concentration (RAC), calculated from ecotoxicological studies. The RACs for cinmethylin and its metabolites are shown in Table 8.5.1. For cinmethylin, it is noted that two RACs were considered: one based on an aquatic plant, one based on an aquatic invertebrate. This was at the request of the ecotoxicology specialist assessor; for further information on RACs, please refer to Volume 3 CP Part B.9.

Table 8.5.1 RACs for cinmethylin and its metabolites based on the ecotoxicology assessment (see CA section B.9.4)

Test substance	Test species	RAC (µg/L)
Cinmethylin (a.s.)	*Lemna spp.*	8.88
	Chironomus lugubris	20.6
BAS 684 03 H (formulation)	*Lemna spp.*	16.7
M684H001 (metabolite)	*Lemna spp.*	7830
M684H003 (metabolite)	*Lemna spp.*	1000

The use of cinmethylin in two crops (winter cereals and winter oilseed rape) was assessed according to the GAP, as summarised in Table 8.5.2. The HSE evaluator notes that there are two uses for cinmethylin in winter cereals; however, through this assessment only the critical GAP of 1 application of 500 g a.s./ha has been considered.

The HSE evaluator notes that a surface water assessment for winter oilseed rape has not been conducted. The application rate for this crop is 50% of the application rate for winter wheat and winter barley; furthermore, the application timings would be slightly earlier with winter oilseed rape, due to earlier drilling of seed. As a result, the HSE evaluator concluded that it was appropriate to risk envelope the winter oilseed rape crop as the risk assessment is covered by the critical GAP of 1 application of 500 g a.s./ha.

Table 8.5.2 Application pattern used for $PEC_{sw/sed}$ calculations of cinmethylin

Individual Crop	Application					Amount reaching the soil per application
	Rate per Season	Number of Applications	Interval	Plant Interception	BBCH Stage	
	[g a.s./ha]		[days]	[%]		[g a.s./ha]
Winter cereals	500	1	-	0	00-29	1 × 500
	250	1	-	0	00-29	1 × 250
Winter oilseed rape	250	1	-	0	00-18	1 × 250

Tier 1 – Standard assessments for drift and drainage

Table 8.5.3 provides a summary of the input parameters related to cinmethylin and its metabolites used by the HSE evaluator for the $PEC_{sw/sed}$ calculations in both spray drift and drainage assessments.

Table 8.5.3 Input parameters related to the application pattern for $PEC_{sw/sed}$ calculations of cinmethylin and its metabolites.

Compound	Cinmethylin	M684H001	M684H003
Molecular weight (g/mol)	274.4	304.4	170.3
$K_{f,oc}$ (mL/g)	317.8 (geometric mean, n = 5) [a] 510.1, 284.3, 266.5, 270.2, 310.8 [b]	-[c]	-[c]
1/n (-)	1.0, 0.96, 0.94, 0.98, 0.96 0.97 (arithmetic mean) [b]	-[c]	-[c]
$DT_{50,soil}$ (d)	11.1 [a] 29.9, 47.0, 15.3, 5.4, 8.0, 13.9, 18.3, 6.8, 9.9, 3.7, 5.2 (normalised field) [b]	-[c]	-[c]
$DT_{50,water}$ (d)	8.8 (maximum, $DisT_{50}$, n = 2)	-[d]	-[d]
Maximum occurrence observed (% AR)	Water: -[e] Sediment: 55.9 (DAT 56, water/sediment study)	Water: 11.4 (DAT 28, water/sediment study) Sediment: 3.8 (DAT 28, water/sediment study)	Water: 11.1 (DAT 15, indirect photolysis study) Sediment: 0.001 (default, not detected)
Adjusted application rate (g/ha) [f]	-[e]	63.213	34.466

DAT = days after treatment
[a] No DT_{50} soil needed for the standard drainage assessment, since no degradation after the application was assumed as worst-case approach. Geometric mean DT_{50} used for higher tier drainage assessment with MACRO.
[b] Individual data points used for higher tier drainage assessment with WEBFRAM. These values are coupled between K_{foc} and 1/n, ie the first K_{foc} corresponds with the first 1/n value. Arithmetic mean (1/n) and geomean (DT_{50}) used for higher tier drainage assessment with MACRO.
[c] Not required; assessment as a soil metabolite entering surface water is not triggered by levels in soil studies.
[d] Not required; total residue approach
[e] Not relevant for parent substance
[f] Application rates were based on 500 g a.s./ha, adjusted for maximum formation of metabolite in water and corrected for the molecular weight difference (metabolite mol. wt. / parent mol. wt.)

SPRAY DRIFT ASSESSMENT

Methods

For spray drift, the Applicant considered a standard, static water body of 100 m length, 1 m width and 30 cm depth for all calculations.

As cinmethylin is a volatile substance (vapor pressure of 8.1 x 10^{-3} Pa) and in exceedance of the trigger for the short-range exposure assessment according to FOCUS Air (2008), the Applicant considered deposition on the water surface following volatilisation from soil and plants.

The Applicant measured the deposition following volatilisation in a semi-field study with outdoor and wind tunnel experiments (further details in CA Section 8.3.2/1). In this study, cinmethylin was applied as the formulation BAS 684 03 H to a well-developed summer barley crop, and the deposition of cinmethylin was measured. The HSE evaluator notes that this application pattern is not representative of cinmethylin use as the proposed use is on pre- and post-emergence crops; however, this did not justify rejecting these deposition data.

Maximum accumulated deposition rates were reached 48 hours after application, decreasing from 0.82% of applied cinmethylin at 1 m downwind to 0.17% of applied cinmethylin at 20 m downwind. For the purpose of this drift assessment, the Applicant added the 48-hour deposition rates from the wind tunnel study to the Rautmann standard drift rates for the buffer distances of 3 and 5 metres.

The HSE evaluator agrees with the Applicant's approach of including the peak deposition rates with the standard 90th percentile drift values for single applications. Table 8.5.4 outlines the drift values used for the spray drift assessment.

Table 8.5.4 Application pattern used for PEC_{sw} calculations of cinmethylin, the metabolites M684H001 and M684H003 and the formulation BAS 684 03 H.

Buffer distance (m)	**1**	**3**	**5**
90th percentile drift value for single application according to Rautmann (%)	2.77	0.95	0.57
Deposition after 48 hours from wind tunnel study (% of applied) [a]	- [b]	0.56	0.43
Total drift incl. deposition (%)	**2.77**	**1.51**	**1.00**

[a] Deposition rates are based on the application of the formulation BAS 684 03 H.
[b] No deposition after volatilisation has to be be taken into account at 1 m minimum distance following the recommendations of FOCUS Air (2008)

The Applicant used the HSE CRD $PEC_{sw\text{-}sed}$ (spray drift) Excel spreadsheet to determine the PECs related to spray drift for cinmethylin and the metabolites M684H001 and M684H003. The HSE evaluator assessed the data input by the Applicant and the subsequent results. For the metabolites, the HSE evaluator could not replicate the values presented by the Applicant regarding maximum occurrence on a molar basis. As a result, these have not been reported here and the HSE evaluator repeated all modelling for the parent and metabolites using the maximum occurrence in sediment for the parent, and maximum metabolite formation in water for the metabolites (See Table 8.5.3). For the metabolites, the parent application rate was adjusted based on maximum metabolite formation in water and the molecular weight correction. The application rates used for modelling are presented in Table 8.5.3.

For the formulation PEC_{sw} calculations, the HSE evaluator agreed with the process and values used by the Applicant. Standard Rautmann spray drift values were applied without the additional deposition via volatilisation as the latter process was based on deposition following 48 hours and not immediately.

Results

The HSE evaluator agreed with the spray drift assessment conducted by the Applicant for cinmethylin. The results are presented in Table 8.5.5 and demonstrate that the maximum PEC_{sw} does not exceed the RAC when considering a 1 m buffer zone.

Table 8.5.5 Maximum PEC_{sw} and PEC_{sed} for cinmethylin, M684H001 and M684H003 following a single application of 500 g a.s./ha to field crops – pre-emergence, post-emergence and spring application.

Entry pathway	Buffer zone (m)	Cinmethylin		M684H001		M684H003	
		$PEC_{sw,max}$ (µg/L)	$PEC_{sed,max}$ (µg/kg)	$PEC_{sw,max}$ (µg/L)	$PEC_{sed,max}$ (µg/kg)	$PEC_{sw,max}$ (µg/L)	$PEC_{sed,max}$ (µg/kg)
Spray drift	1	4.617	11.911	0.584	0.898	0.318	n/a [a]
Spray drift incl. deposition after volatilisation	3	2.517	6.493	- [b]	- [b]	- [b]	- [b]
	5	1.667	4.30	- [b]	- [b]	- [b]	- [b]

[a] Not measured in sediment.
[b] Not calculated because the metabolites passed the risk assessment with a 1 m buffer zone.

The Applicant also supplied a calculation of PECs for the formulation BAS 684 03 H. The results are presented in Table 8.5.6. The ecotoxicology assessment indicated that the calculation of PEC values for buffer zones was not necessary for the formulation. See Section CP B.9.4 for further information.

Table 8.5.6 Maximum PEC_{sw} for formulation BAS 684 03 H for the pre-emergence use of 0.666 L product/ha in winter cereals.

Buffer distance (m)	Application rate of formulation (L/ha)	Formulation density (g/mL)	Application rate of formulation (g/ha)	Drift rate (%)	Formulation $PEC_{sw,max}$ (µg/L)
1	0.666	1.0 [a]	666	2.77	6.149
5				0.57	1.265

[a] Density value from CA Volume 3, Section B.8.2.14.

DRAINFLOW ASSESSMENT

Methods

For the drainage assessment, the Applicant initially followed the Tier 1 drainage assessment, which assumes that, following a rainfall event, a proportion of cinmethylin in a given hectare will be lost in 10 mm of drainflow (equivalent to 100,000 L water). The proportion of compound lost is assumed to be dependent on its soil adsorption (K_{oc}). This water is then added to a ditch containing 30,000 L water (consistent with the standard water body used in the drift assessment), to give a final volume of 130,000 L.

The Applicant calculated the initial PEC_{sw} via drainage for cinmethylin. The Applicant did not calculate PECs via drainage for the metabolites formed in the water-sediment study as they are not relevant in soil. However, the HSE evaluator notes the metabolites could form once the parent has reached surface waters and that by considering these metabolites in the drainflow assessment, the assessment has taken a conservative approach. As a result, the HSE evaluator conducted their own assessment of PEC_{sw} via drainage for the metabolites M684H001 and M684H003 by correcting the Tier 1 parent PEC values based on molecular weight and the metabolite maximum occurrence in water.

As cinmethylin failed the Tier 1 drainage assessment, the Applicant also submitted a higher tier drainage assessment using WEBFRAM. Three different application scenarios were considered for the calculations based on representative growth stages (pre-emergence, post-emergence, spring application). The Applicant chose application dates for these representative stages by using the tool AppDate and selecting the D2 (Brimstone) scenario to suggest dates for the FOCUS crop “winter cereals”. The HSE evaluator notes that the D2 scenario is appropriate for this use as it is based on the data on which the UK Tier 1 drainage assessment is based.

The HSE evaluator checked the representative application dates and accepts the decisions made. The HSE evaluator notes that, for the spring application, it would be expected that crops would have advanced beyond the BBCH stage 11-19 chosen by the Applicant, and would have reached at least BBCH 25 by 30 March. However, the HSE evaluator accepts that the earlier growth stage class chosen by the Applicant represents a more worse case crop interception scenario. Therefore, all application dates and input parameters presented in Table 8.5.7 below were accepted as appropriate by the HSE evaluator.

Table 8.5.7 Input parameters related to the calculation of PEC_{sw} via drainage for cinmethylin. These values were used by the Applicant and deemed appropriate by the HSE evaluator.

Plant protection product	BAS 684 03 H		
Crop	Field crops (Tier 1), winter wheat and winter barley (Tier 2)		
Application rate (g as/ha)	500 [a]		
Number of applications / interval (days)	1 / -		
Representative growth stages (-)	Pre-emergence	Post-emergence	Spring application
Application timing (No. of days until drainage period) (days) [b]	0	0	0
Max. crop interception (%) [b]	0	0	20
Interception class implemented in WEBFRAM (-) [c]	No crop present	No crop present	BBCH 11-19
Interception rate according to WEBFRAM (Mean ± standard deviation; %) [c]	0	0	15.4 ± 12.7 [d]
Application dates (-) [c]	15th Oct	01st Nov	30th Mar

[a] In the context of a risk envelope approach, lower application rates have been covered by the highest application rate
[b] Relevant for Tier 1 drainage calculations only
[c] Relevant for Tier 2 drainage calculations only
[d] Interception rate applied is for winter barley, representing a conservative approach to interception rate.

The Applicant's modelling approach covered a total of 12 modelling scenarios, comprising four soils that correspond to the default scenario assumptions for winter cereals in WEBFRAM (Denchworth, Hanslope, Brockhurst and Clifton), across three climate categories (dry, medium and wet). Table 8.5.8 summarises the Applicant's modelling setup in WEBFRAM; the HSE evaluator notes that these setup criteria were also used for the evaluator's own WEBFRAM modelling.

Table 8.5.8 Model setup in WEBFRAM used by the Applicant and the HSE evaluator.

WEBFRAM module	Option selected in WEBFRAM
Select Model	Aquatic Model
Aquatic Model Overview	Probabilistic calculation of risk to aquatic organisms → Chronic Risk Assessment
Options for probabilistic calculation of chronic risk to aquatic organisms	Measure of Exposure → Calculate a distribution for the initial concentration in surface water arising from drainflow
	Measure of Effects → Enter a single value for a measure of effects → Enter Single Toxicity Value = 8.877 µg L^{-1} (based on EC_{50} of 88.77 µg L^{-1} for *Lemna*) or 20.6 µg L^{-1} (based on LR_{50} of > 2060 µg L^{-1} for *Chironomus*)
Exposure Data via Drainage - Application Type	Select the crop type: Winter wheat /winter Barley Single Application
Exposure Data via Drainage - General Information	Select a Crop Type and Growth Stage → see Table 8.4.5. Spray to Drain Flow: 0 days [a] Taxonomic Group: Plants (for *Lemna*) or Invertebrates (for *Chironomus*)
Modelling Options	Assume instantaneous sorption equilibrium No relationship between sorption, degradation and pH
Degradation and sorption data	See Table 8.4.3.
Calculation Parameters Exposure Data via Drain Flow Output Options	Set to default values Variability: 1000 Uncertainty: 250 Percentile (%) of the exposure distribution for output results (Percentile 1): 90 Confidence intervals (Interval 1): 95

[a] As a worst-case approach, 0 days between the spray event and the start of drain flow were chosen.

Results

Tier 1

The HSE evaluator repeated the Applicant's first tier drainflow modelling with the correct K_{FOC} value and notes that the results were the same as those supplied by the Applicant for cinmethylin. For the metabolites M684H001 and M684H003, the HSE evaluator conducted their own calculations to derive PEC_{sw} values based on the PEC values derived for cinmethylin, corrected for the difference in molecular weight and maximum occurrence in water from the water/sediment study.

Table 8.5.9 summarises these results for each application scenario and demonstrates that, during drainflow periods, PEC_{sw} exceeds both of the cinmethylin RACs. Therefore, the exposure assessment moves onto the higher tier assessment for cinmethylin. For the metabolites M684H001 and M684H003, the RACs (7830 µg/L and 1000 µg/L respectively) were not exceeded. Therefore, no further exposure assessment at higher tier was necessary.

Table 8.5.9 Maximum PEC_{sw} via drainflow for cinmethylin following a single application to field crops.

Entry pathway	Substance	Pre-emergence Post-emergence		Spring application	
		$PEC_{sw,max}$ (µg/L)	$PEC_{sed,max}$ (µg/kg)	$PEC_{sw,max}$ (µg/L)	$PEC_{sed,max}$ (µg/kg)
Drainage – Tier 1	Cinmethylin	26.923	69.462	21.538	55.569
	M684H001	3.404	5.236	2.723	4.189
	M684H003	1.856	n/a	1.485	n/a

n/a – not applicable due to metabolite not being detected in sediment.

Higher tier drainflow assessment

The HSE evaluator repeated the Applicant's modelling in WEBFRAM using the correct range of field $DegT_{50}$ values (as reported in Table 8.5.3) and correct K_{FOC} values. The resulting values differed slightly to the Applicant's, therefore the results presented in the following tables are the HSE evaluator's own. As there are two RACs that have been evaluated, the following results tables include exceedance statistics for each RAC.

Tables 8.5.9 – 10 present the median exceedance probabilities for all scenarios following application to winter wheat and winter barley respectively. Summaries of threshold exceedances are presented for winter wheat and winter barley in Tables 8.5.11 – 12 respectively.

When considering the *Lemna* RAC of 8.88 µg/L, median exceedance probabilities did not exceed 1.2% where cinmethylin was applied to winter wheat and did not exceed 18% in winter barley. For winter wheat, the Hanslope scenario proved most sensitive, while in winter barley the Denchworth scenario was most sensitive.

When considering the *Chironomus* RAC of 20.6 µg/L, the median exceedance probability was 0% where cinmethylin was applied to winter wheat, and did not exceed 0.2% in winter barley. For winter wheat, all scenarios demonstrated a 0% exceedance probability, while in winter barley the most sensitive scenario was the Hanslope wet scenario, with exceedances no higher than 1.84%.

Table 8.5.9 Median exceedance probabilities (%) for each scenario following application of cinmethylin to winter wheat.

Climate scenario	Soil class			
	Denchworth	**Hanslope**	**Brockhurst**	**Clifton**
***Lemna* RAC (8.88 µg/L)**				
Pre-emergence (15 October)				
Dry	0.0	0.147	0.0	0.0
Medium	0.164	0.469	0.0	0.0
Wet	0.366	0.898	0.0	0.0
Post-emergence (1 November)				
Dry	0.122	0.404	0.0	0.0
Medium	0.352	0.868	0.0	0.0
Wet	0.567	1.20	0.0	0.0
Spring application (30 March)				
Dry	0.365	0.709	0.0	0.0
Medium	0.469	1.01	0.0	0.0
Wet	0.593	1.16	0.0	0.0
***Chironomus* RAC (20.6 µg/L)**				
Pre-emergence (15 October)				
Dry	0.0	0.0	0.0	0.0
Medium	0.0	0.0	0.0	0.0
Wet	0.0	0.0	0.0	0.0
Post-emergence (1 November)				
Dry	0.0	0.0	0.0	0.0
Medium	0.0	0.0	0.0	0.0
Wet	0.0	0.0	0.0	0.0
Spring application (30 March)				
Dry	0.0	0.0	0.0	0.0
Medium	0.0	0.0	0.0	0.0
Wet	0.0	0.0	0.0	0.0

Table 8.5.10 Median exceedance probabilities (%) for each scenario following application of cinmethylin to winter barley.

Climate scenario	Soil class			
	Denchworth	**Hanslope**	**Brockhurst**	**Clifton**
***Lemna* RAC (8.88 µg/L)**				
Pre-emergence (15 October)				
Dry	1.88	1.97	0.0	0.0
Medium	7.19	4.39	0.0	0.0
Wet	13.30	6.89	0.0	0.0
Post-emergence (1 November)				
Dry	10.50	4.59	0.0	0.0
Medium	15.30	6.51	0.0	0.0
Wet	17.80	7.72	0.0	0.0
Spring application (30 March)				
Dry	10.70	4.56	0.0	0.0
Medium	15.10	6.61	0.0	0.0
Wet	18.0	7.82	0.0	0.0
***Chironomus* RAC (20.6 µg/L)**				
Pre-emergence (15 October)				
Dry	0.0	0.17	0.0	0.0
Medium	0.12	0.65	0.0	0.0
Wet	0.27	1.34	0.0	0.0
Post-emergence (1 November)				
Dry	0.33	1.06	0.0	0.0
Medium	0.42	1.51	0.0	0.0
Wet	0.51	1.84	0.0	0.0
Spring application (30 March)				
Dry	0.34	1.07	0.0	0.0
Medium	0.45	1.54	0.0	0.0
Wet	0.52	1.80	0.0	0.0

Table 8.5.11 Summary of threshold exceedance for cinmethylin considering all years, scenarios, and cropping area for winter wheat.

Application scenario	Proportion of cropped area where exceedances occur [%]	Proportion of cropped area with zero exceedance [%]	Proportion of undrained area [%]	Overall exceedance [%]
Lemna **RAC (8.88 µg/L)**				
Pre-emergence	24.1	39.0	36.8	**0.057**
Post-emergence	28.6	34.5	36.8	**0.128**
Spring application	28.6	34.5	36.8	**0.196**
Chironomus **RAC (20.6 µg/L)**				
Pre-emergence	0.0	63.1	36.8	**0.0**
Post-emergence	0.0	63.1	36.8	**0.0**
Spring application	0.0	63.1	36.8	**0.0**

Table 8.5.12 Summary of threshold exceedance for cinmethylin considering all years, scenarios, and cropping area for winter barley.

Application scenario	Proportion of cropped area where exceedances occur [%]	Proportion of cropped area with zero exceedance [%]	Proportion of undrained area [%]	Overall exceedance [%]
Lemna **RAC (8.88 µg/L)**				
Pre-emergence	19.2	35.0	45.6	**0.71**
Post-emergence	19.2	35.0	45.6	**1.41**
Spring application	19.2	35.0	45.6	**1.41**
Chironomus **RAC (20.6 µg/L)**				
Pre-emergence	17.2	37.0	45.6	**0.06**
Post-emergence	19.2	35.0	45.6	**0.20**
Spring application	19.2	35.0	45.6	**0.20**

Higher tier drainflow assessment: July 2020 update

In the original higher tier drainflow assessment, the risk assessment using Webfram passed based on the aquatic plant RAC based on *Lemna spp*. However, due to stricter risk assessment criteria for aquatic invertebrates, there was uncertainty over the risk assessment for *Chironomus* using Webfram, in particular the degree to which predicted environmental concentrations for cinmethylin exceeded the RAC. The Applicant was asked to address this; in response, the Applicant submitted additional MACRO higher tier drainflow modelling as this gives an explicit presentation of the maximum predicted concentration for each modelled year along with the number of years where predicted concentrations exceed the RAC.

The Applicant supplied modelling conducted using MACRO v.4.3 and the HSE Excel tool based on the application of cinmethylin to winter cereals in the pre-emergence and spring application scenarios.

The HSE evaluator evaluated the Applicant's modelling by checking the input parameters and the subsequent results. The HSE evaluator notes that the Applicant's selection of application dates for each application timing were consistent with previous modelling. The HSE evaluator agreed with the substance and application input parameters used by the Applicant. The HSE evaluator validated the Applicant's modelling by using the same input parameters to run the Denchworth Medium drainflow scenario. The HSE evaluator's modelling results were identical to the Applicant's for the maximum daily cinmethylin concentration in the ditch for each of the 30 scenario years; therefore, the HSE evaluator accepted the Applicant's higher tier drainflow modelling for the pre-emergence and spring application scenarios. The Applicant's results are presented below.

In addition to the pre-emergence and spring application scenarios, the HSE evaluator has modelled the post-emergence application scenario to ensure that the worst case scenario has been considered. The results of this modelling are also presented below.

Table 8.5.13 Input parameters related to the higher tier drainflow assessment of cinmethylin using MACRO. Unless otherwise stated, these values were used by the Applicant and accepted by the HSE evaluator.

Plant protection product	BAS 684 03 H		
MACRO crop	Winter cereals		
Application rate (g as/ha)	500 [a]		
Number of applications / interval (days)	1 / -		
DT_{50} (d)	11.1		
K_{oc} (mL/g)	317.8		
1/n	0.97		
Representative growth stages (-)	Pre-emergence	Post-emergence [b]	Spring application
Max. crop interception (%)	0	0	15
Application dates (-)	15th Oct	01st Nov	30th Mar

[a] In the context of a risk envelope approach, lower application rates have been covered by the highest application rate
[b] input parameters used by the HSE evaluator

For each cinmethylin application timing, the maximum cinmethylin concentration has been presented for each modelling scenario along with the number of years in which the PEC exceeded the RAC on at least one day.

Table 8.5.14 The number of years in which the concentration of cinmethylin in surface water exceeds the RAC in a 30 year MACRO simulation following application of BAS 684 03 H to winter cereals.

Climate scenario	Soil class			
	Denchworth	Hanslope	Brockhurst	Clifton
***Chironomus* RAC (20.6 µg/L)**				
Pre-emergence (15 October) [a]				
Dry	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Medium	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Wet	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Post-emergence (1 November) [b]				
Dry	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Medium	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Wet	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Spring application (30 March) [a]				
Dry	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Medium	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Wet	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
***Lemna* RAC (8.88 µg/L)**				
Pre-emergence (15 October) [b]				
Dry	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Medium	1/30 (3%)	0/30 (-)	0/30 (-)	0/30 (-)
Wet	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Post-emergence (1 November) [b]				
Dry	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Medium	1/30 (3%)	0/30 (-)	0/30 (-)	0/30 (-)
Wet	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Spring application (30 March) [b]				
Dry	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Medium	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)
Wet	0/30 (-)	0/30 (-)	0/30 (-)	0/30 (-)

[a] Modelling undertaken by the Applicant and validated by the HSE evaluator
[b] Modelling undertaken by the HSE evaluator

When considering all scenarios and use patterns for cinmethylin, there were no exceedances of the *Chironomus* RAC. When considering the results compared to the *Lemna* RAC, one scenario led to exceedances of the RAC in the pre-emergence and post-emergence application scenarios; in both cases, the RAC was exceeded in one year out of 30 in the Denchworth Medium scenario:

- Pre-emergence: 10.709 µg/L
- Post-emergence: 9.825 µg/L

The HSE evaluator concludes that these additional results are suitable for use in risk assessment.

CONCLUSION

Regarding exposure via spray drift, the PEC_{sw} spray drift value does not exceed either RAC when considering drift into surface waters at a 1 metre buffer distance. Additionally, the RAC is not exceeded for the formulation BAS 684 03 H at a 1 metre buffer distance.

When considering exposure via drainflow, where a RAC is based on the effects against aquatic plants, a maximum of 60% exceedance for any single scenario cannot be breached (HSE Data Requirements Handbook; HSE, 2016). Additionally, the overall rate of exceedance must be less than 10%. Based on the presented results from Webfram, the application of cinmethylin to winter barley and winter wheat fulfils these criteria by not exceeding 18% in any single scenario. Based on the results from MACRO, these criteria are fulfilled by not exceeding 3% in any single scenario, with only one scenario (Denchworth medium) leading to exceedance of the RAC.

When considering a fish or invertebrate RAC, there can be no exceedances of the RAC. Based on the new modelling supplied by the Applicant for considering the *Chironomus* RAC, the HSE evaluator confirms that there are no exceedances of the RAC following application of cinmethylin to winter cereals. For the metabolites M684H001 and M684H003, the PEC_{sw} via spray drift and Tier 1 PEC via drainage do not exceed the RAC.

The conclusion on the aquatic risk assessment is presented in Part B.9.

B.8.6. FATE AND BEHAVIOUR IN AIR

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

The vapour pressure of cinmethylin was determined as 8.1×10^{-3} Pa at 20°C (refer to CA Section 2).

An outdoor wind tunnel study was performed with BAS 684 03 H to evaluate the volatilisation, short range transport and deposition of volatilised cinmethylin (refer to CA Section B.8.3.2.1; KCA 7.3.2/1). Deposition peaked at 0.56% of applied cinmethylin at 3 m downwind 48 hours after application, with this value decreasing with time and distance from the sprayed area. The results of this study were used as modelling input for the determination of PEC_{sw} via spray drift, with deposition values added to the Rautmann spray drift values (See Section B.8.5 of the present document).

B.8.6.2. **Predicted environmental concentrations from airborne transport**

The atmospheric half life of cinmethylin was determined to be below the trigger of 2 days. As a result, exposure and long-range transport are not anticipated for cinmethylin in air. Therefore, no calculation of PEC from airborne transport was conducted.

B.8.7. PREDICTED ENVIRONMENTAL CONCENTRATIONS FROM OTHER ROUTES OF EXPOSURE

No further routes of exposure are expected to be of any relevance to cinmethylin.

B.8.8. References relied on

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	Previous evaluation
KCP 9.1.3/1	He W.	2018 a	Predicted environmental concentrations of BAS 684 H in soil following application to winter wheat and winter oilseed rape 2017/1217977 Dr. Knoell Consult GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF	None – new active substance
KCP 9.2.4/1	Mendet Gutierrez A.A., He W.	2018 a	Predicted environmental concentrations of BAS 684 H in groundwater following application to winter wheat and winter oilseed rape 2017/1217978 Dr. Knoell Consult GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF	None – new active substance
KCP 9.2.5/1	He W.	2018 b	Predicted environmental concentrations of BAS 684 H and its metabolites in surface water and sediment following application to winter wheat and winter oilseed rape 2017/1217979 Dr. Knoell Consult GmbH, Mannheim, Germany Fed.Rep.	No	No	Not applicable	BASF	None – new active substance

			no Unpublished					
KCP 9.2.5/2	Pfeiffer	2018a	dRR Part B, Section 8, Environmental Fate: National Addendum UK	No	No	Not applicable	BASF	None – new active substance
KCP 9.2.5	Kubitza and Garcia	2020	Response to CRD's RAC derivation for aquatic invertebrate during the evaluation of Luximo (cinmethylin, BAS 684 H)	No	No	Not appliable	BASF	None – new active substance