

# REGISTRATION REPORT

## Part B

### Section 10

#### **Assessment of the relevance of metabolites in groundwater**

Detailed summary of the risk assessment

Product code: CA3573

Product name(s): Carnadine/Kestrel

Chemical active substance:

Acetamiprid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(Re-authorisation acc. to Art. 43)

Applicant: Nufarm Europe GmbH

Submission date: July 2020

MS Finalisation date: November 2020 (initial Core Assessment)

November 2021, January 2022 (final Core Assessment)

## Version history

When	What
July 2020	Version 1.0 (application)
November 2020	Evaluation by the zRMS (re-authorization)  The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are <del>struck through and shaded for transparency</del> .
November 2021	Final report (Core Assessment updated following the commenting period)  No additional information or assessments after the commenting period.
January 2022	Final report (Core Assessment after additional round of the commenting period)  No additional information or assessments after the commenting period.

## Table of Contents

10	Relevance of metabolites in groundwater.....	4
10.1	General information.....	4
Appendix 1	Lists of data considered in support of the evaluation .....	5
Appendix 2	Additional information .....	7

### Reviewer comments:

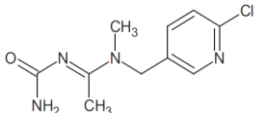
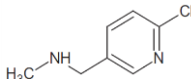
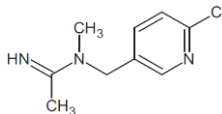
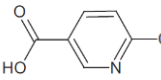
This part of dossier has been prepared to support the re-registration of the insecticide product CA3573 / Carnadine/Kestrel and summarizes the data related to the relevance of metabolites in groundwater. All data contained in this document has been evaluated for the purposes of ongoing re-registration. The information contained in dRR Part B10 has been accepted and considered as sufficient and appropriate for risk assessment.

## 10 Relevance of metabolites in groundwater

### 10.1 General information

The metabolites IM-1-2, IM-1-4, IM-1-5 and IC-0 are not predicted to occur in groundwater at concentrations above 0.1 µg/L. Calculated  $PEC_{gw}$  for IM-1-2, IM-1-4 and IC-0 are < 0.001 µg/L in all scenarios. The maximum  $PEC_{gw}$  for IM-1-5 was < 0.1 µg/L (for details, please refer to Section 8 of the Central Core for Acetamiprid 200 SL / Carnadine). Assessment of the relevance of these metabolites according to the step-wise procedure of the EC guidance document SANCO/221/2000 – rev.10 is therefore not required, and no further information is provided in this document. General information on the metabolites is provided in Table 10.1-1.

**Table 10.1-1: General information on the metabolites of acetamiprid**

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Acetamiprid	IM-1-2		Max $PEC_{gw}$	< 0.001 µg/L
			Based on:	FOCUS PEARL 4.4.4., FOCUS PELMO 5.5.3., all scenarios *
	IM-1-4		Max $PEC_{gw}$	< 0.001 µg/L
			Based on:	FOCUS PEARL 4.4.4., FOCUS PELMO 5.5.3., all scenarios *
	IM-1-5		Max $PEC_{gw}$	0.089 µg/L
			Based on:	FOCUS PEARL 4.4.4., Hamburg, Apples
	6-Chloronicotinic Acid (IC-0) (IV-0)		Max $PEC_{gw}$	< 0.001 µg/L
			Based on:	FOCUS PEARL 4.4.4., FOCUS PELMO 5.5.3., all scenarios *

\* No calculations with FOCUS MACRO were done since the  $PEC_{gw}$  calculated with PEARL and PELMO were all < 0.001 µg/L.

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and 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	Owner
-	-	-	-	-	-

### List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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	Owner
-	-	-	-	-	-

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

**List of data relied on not submitted by the applicant but necessary for evaluation**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

## **Appendix 2    Additional information**

Not required.