

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: SHA 7273 A

Product name(s): CASINO ROYALE

Chemical active substance(s):

Boscalid, 267g/kg

Pyraclostrobin, 67 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: August 2020

MS Finalisation date: 07/2021; 01/2022

Version history

When	What
July 2021	Draft assessment by zRMS
January 2022	Final Registration Report

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10 Relevance of metabolites in groundwater

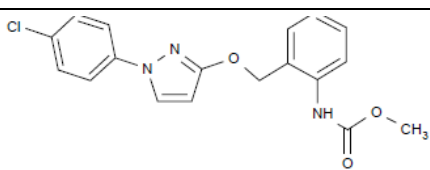
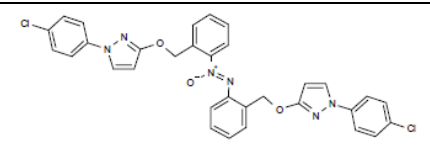
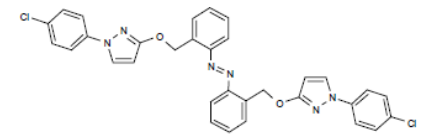
Comment of ZRMS:	Because the process of the renewal of the approval hasn't been finished yet, the assessment of the toxicological relevance of pyraclostrobin metabolites is still underway, in accordance with EU procedures. However, the PEC _{gw} for all metabolites do not exceed the level of 0.1 µg/L.
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10.1 General information

The Pyraclostrobin metabolites BF 500-3, BF 500-6 and BF 500-74 are predicted to occur in groundwater at concentrations below 0.001 µg/L (see Part B8, chapter 8.8 – KCP 9.2.4). Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 is therefore not required.

General information on the metabolites is provided in Table 10.1-1. The impact of the relevance assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the GAP evaluation in chapter 8.8 of the dRR Part B, Section 8 (Environmental fate and behaviour).

Table 10.1-1: General information on the metabolites

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Pyraclostrobin	BF 500-3		Max PEC _{gw} Based on:	< 0.001 µg/L PEARL and PELMO (all scenarios)
	BF 500-6			
	BF 500-7			

10.2 Relevance assessment of metabolites BF 500-3, BF 500-6 and BF 500-7

Not relevant.

10.2.1 STEP 1: Exclusion of degradation products of no concern

Not relevant.

10.2.2 STEP 2: Quantification of potential groundwater contamination

Not relevant.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

Not relevant.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Not relevant.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

Not relevant.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not relevant.

10.2.5 STEP 5: Refined risk assessment

Not relevant.

Appendix 1 Lists of data considered in support of the evaluation

Appendix 2 Additional information

Not relevant.