

# FINAL REGISTRATION REPORT

## Part B

### Section 10

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

Detailed summary of the risk assessment

Product code: SHA 7216 A

Product name: CIAZ

Chemical active substances:

Boscalid, 233 g/L

Difenoconazole, 66 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: August 2021

MS Finalisation date: 02/2022; 12/2022

## Version history

When	What
02/2022	Assessmeny by expert
12/2022	Final Registration Report

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## **10 Relevance of metabolites in groundwater**

### **10.1 General information**

According to the simulations performed, the maximum predicted concentrations in leachate water at 1m depth are lower than the regulatory threshold of 0.1 µg/L for Difenoconazole and its metabolites 1,2,4-triazole (CGA 71019) and Difenoconazole alcohol (CGA 205375), demonstrating a negligible risk of contamination of groundwater from the proposed uses. Therefore, no relevance assessment is required.

There are not metabolites from Boscalid.

### **10.2 Relevance assessment of metabolites**

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.

**Comment:**

**boscalid**

According to the Review Report (SANCO/3919 /2007-rev. 5, 21 January 2008) :

**Metabolism in animals:**

“Extensive (< 1 % of absorbed dose excreted as parent via urine or bile), 38 metabolites identified in rat matrices. Major pathway was hydroxylation at the diphenyl moiety and subsequent O-glucuronidation

**Studies performed on metabolites or impurities:**

Para-chlorobenzoic acid (degradation product in aquatic environment): literature survey data indicates that parachlorobenzoic acid exhibits higher acute oral toxicity than boscalid.

No concern from limited in-vitro genotoxicity data.

Acute oral toxicity studies and bacterial reverse mutation assays for impurities 107371, 398794, 4060018 and 4060017 resulted in LD50 values > 2000 mg/kg bw and no evidence for a genotoxic potential”

**difenoconazole**

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required. Studies performed on metabolites:EFSA Journal 2011;9(1):1967 Peer review of the pesticide risk assessment of the active substance difenoconazole

**Metabolism in animals:**

Extensively metabolised, mainly by hydrolysis of the ketal and hydroxylation; also by cleavage of the triazole (1, 2, 4- triazole determined to represent <10% in male rats.

Difenoconazole and its metabolites 1,2,4-triazole (CGA 71019) and Difenoconazole alcohol (CGA 205375), demonstrating a negligible risk of contamination of groundwater from the proposed uses.

Therefore, no relevance assessment for boscalid and difenoconazole is required.

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

## **Appendix 2    Additional information**

Not relevant.