

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: ADM.3304.H.1A

Product name(s): Tricera

Chemical active substance(s):

2,4-D, 375 g/L (562.5 g/L as 2,4-D EHE)

Clopyralid, 30 g/L

Fluroxypyr, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(composition change)

Sponsor: ADAMA Agan Ltd.

Applicant: Country organisation / representative of ADAMA,
as given in Part A

Submission date: February 2021

MS Finalisation date: September 2021 (initial Core Assessment)

November 2022, updated December 2022 (final Core Assessment)

Version history

When	What
January 2021	Initial dRR Section 10, version reflecting composition change submitted by applicant
September 2021	Initial zRMS assessment (with regard to the proposed composition change). 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 struck through and shaded for transparency.
November 2022	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.
December 2022	Final report (Core Assessment updated following the Applicant's comments). No additional information or assessments after the commenting period.

DATA PROTECTION CLAIM

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A

STATEMENT FOR OWNERSHIP

The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

- from the owner of the data, or
- from a second party that has obtained permission from the owner of the data for this purpose or,
- following expiry of any period of exclusive use, by offering – in certain jurisdictions – mandatory compensation, unless the period of protection of the proprietary data concerned has expired.

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Reviewer comments:

This part of dossier summarizes data related to the relevance of groundwater metabolites to support registration product 'Tricera' (ADM.3304.H.1.A.) according art. 33 of 1107/2009 in Poland.

New composition of the preparation for which authorization is requested is given in the Vol 4. The code for the new composition is ADM.3304.H.1.A.

Both compositions previous one (AG-CDF1-480 EC) and current (ADM.3304.H.1.A.) are formulated as EC formulations, with 2,4-D EHE, clopyralid and fluroxypyr (meptyl) as active substances. The content of the active substances remains the same and the type of formulation does not change. Based on available data (refer Vol. 4) the change in the composition has no impact on the environmental fate behaviour of the active substances and metabolites, thus no new information compared to the previously submitted dossier has been added.

Note: for detail assessment of the relevance of groundwater metabolites please refer to dRR B10 AG-CDF1-480 EC which has been reviewed for the purposes of ongoing registration and also checked its compliance with the current guidelines. Information has been considered as sufficient and appropriate for concluding.

Introduction

This document reviews the information related to the relevance of groundwater metabolites.

2,4-D was reviewed as part of the renewal of approval procedure by the Member States and the Commission and the Commission review report finalised on 13.11.2015 approved 2,4-D in accordance with Regulation (EC) No. 1107/2009 (Regulation 2015/2033).

Clopyralid was included into Annex I of Directive 91/414/EEC according to Commission Regulation (EC) No 451/2000 (renewal of inclusion of the second and third group of active substances in Annex I, see Commission Directive 2006/64/EC of 18 July 2006, Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 that replaced the Directive 2006/64/EC after the application of Regulation 1107/2009, and Commission Implementing Regulation (EU) 2020/421 of 18 March 2020 that fixes the new expiry date of approval to 30/04/2021.

Fluroxypyr was included into Annex I of Directive 91/414/EEC according to Commission Regulation (EC) No 736/2011 (renewal of inclusion of the first group of active substances in Annex I).

However, all the relevant information about this last approval are indicated in Review report for active substance Fluroxypyr (SANCO/111019/201, 17 June 2011), as was evaluated within the assessment of active substance Fluroxypyr.

Where appropriate this document refers to the conclusions of the EU review or the Draft Assessment Report (DAR) of the active substances. This will be where:

- the active substance data is relied upon in the risk assessment of the formulation; *or when*
- the EU review or DAR concluded that additional data/information should be considered at national re-registration.

Note: this Part B document only reviews data (Annex II or Annex III) (Chemical Active or Chemical Product) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New annex II (Chemical active) data have only be included if they were considered essential for the evaluation and in this case a full study summary was be provided. In the case where the formulation has been previously evaluated, at European level, detailed summaries have not been provided.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

The EFSA Report of 2,4-D (EFSA Journal 2014;12(9):3812) that was updated on 21st March 2017, the EFSA report of Clopyralid (EFSA Scientific Report (2005) 50, 1–65,) and the EFSA Report of Fluroxypyr (EFSA Journal 2011;9(3):2091) are considered to provide the relevant review information or a reference to where such information can be found.

For the information on 2,4-D EHE, please refer to the Bridging Report (2018) prepared by the RMS for the a.i. (Greece).

The Annex I Inclusion Directives for the active substances **2,4-D** (Commission Directive 2001/103/EC) gives specific provisions under Part B which need to be considered by the applicant in the preparation of their submission prior to granting an authorisation.

For the implementation of the uniform principles of Regulation (EC) 546/2011, the conclusions of the review report on **2,4-D**, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28. May 2015 shall be taken into account. In this overall assessment:

Member States must pay particular attention to the:

- *Risk to aquatic organisms, terrestrial organisms and consumers in cases of uses above 750 g/ha.*

The Annex I Inclusion Directives for the active substances **Clopyralid** (Commission Directive 2006/64/CE) gives specific provisions under Part B which need to be considered by the applicant in the preparation of their submission prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the active substance Clopyralid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 04. April 2006 shall be taken into account. In this overall assessment member states should pay particular attention to:

- The protection of non target plants and groundwater under vulnerable conditions. Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate.

Fluroxypyr (Commission Implementing Regulation (EU) No 736/2011) gives specific provisions under Part B which need to be considered by the applicant in the preparation of their submission prior to granting an authorisation.

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on **Fluroxypyr**, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.

- Only uses as herbicides may be authorised.

In this overall assessment Member States shall pay particular attention to:

- The potential contamination of groundwater by metabolite Fluroxypyr Pyridinol, when the active substance is applied in regions with alkaline or vulnerable soil and/or with vulnerable climatic conditions.
- The risk to aquatic organisms.

These concerns have, where relevant, been addressed within the current submission in the respective sections.

10 Relevance of metabolites in groundwater

10.1 General information

The present dossier is submitted to support a request for composition change.

The change in the composition has no impact on the environmental fate behaviour of the active substances and metabolites.

In this way no new information compared to the previously submitted dossier is presented.

10.2 Relevance assessment

10.2.1 STEP 2: Quantification of potential groundwater contamination

10.2.1.1 STEP 3, Stage 1: screening for biological activity

No new information compared to the previously submitted dossier is presented.

10.2.1.2 STEP 3, Stage 2: screening for genotoxicity

No new information compared to the previously submitted dossier is presented.

10.2.1.3 STEP 3, Stage 3: screening for toxicity

No new information compared to the previously submitted dossier is presented.

10.2.2 STEP 4: Exposure assessment – threshold of concern approach

No new information compared to the previously submitted dossier is presented.

10.2.3 STEP 5: Refined risk assessment

No new information compared to the previously submitted dossier is presented.