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| REGISTRATION REPORT  Part B  Section 0  Product Background, Regulatory Context and  GAP information |
| Product code: ADM.09250.H.1.A  Product name: **2,4-D 95 SP**  Chemical active substance:  2,4-dichlorophenoxy acetic acid**,** 80.4% or 804 g/kg |
| Central  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (authorization) |
| Applicant: XXXX  Sponsor: XXXX  Submission date: March 2023  Evaluation date: December 2023  MS Finalisation date: March 2024 |

Version history

|  |  |
| --- | --- |
| When | What |
| March 2023 | 1st applicant version |
| December 2023 | Initial version of RR |
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# Product background, regulatory context and GAP information

## Introduction

This is an application from XXXX for the registration of ‘2,4-D 95 SP’ according to Art 33 of Regulation (EC) N° 1107/2009, to be used as an herbicide in spring wheat.

The active substance 2,4-D is approved under Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 891/2014) until 31 December of 2030.

Part of this assessment is based on the ongoing evaluation by the Polish Authority of ADM.3304.H.1.A / Tricera.

### Reason for application

The reason for this application is to achieve an authorisation for the new product ‘2,4-D 95 SP’ in the MS Poland.

An assessment of technical equivalence is not required, but full details of the source (already determined as equivalent in the EU) is given in Part C of this draft registration report.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

### Details of zRMS(s) and concerned MS

Table 0.1‑1: Overview of zRMS and cMS

|  | zRMS, product name and authorization no. (if relevant) | (if relevant) Concerned MS, MS’ product name and authorization number (if applicable) |
| --- | --- | --- |
| Northern zone | Not applicable | Not applicable |
| Central zone | Poland | Poland |
| Southern zone | Not applicable | Not applicable |
| Inter-zonal | Not applicable | Not applicable |

### 

### Regulatory history of the active(s)

#### 2,4-D

Table 0.1‑2: Summary of regulatory history of CAS No: 94-75-7

| Status |  |
| --- | --- |
| Approved in EU | Y |
| Original Inclusion Directive  or  Commission Implementing Regulation | [Commission Implementing Regulation (EU) No 540/2011](https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R0540) |
| RMS | Greece (EL), co-RMS Poland (PL) |
| Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied) | 01.01.2016 |
| Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal) | Not relevant for this submission |
| Date of final Commission (re-registration) deadline (Step 2) | Not relevant for this submission |
| Current expiration of approval | 31.12.2030 |
| Low risk substance or Candidate for Substitution? | N/A |

Issues that need to be considered as part of the EU approval are listed below.

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

(a) must pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;

(b) must pay particular attention to the dermal absorption;

(c) must pay particular attention to the impact on aquatic plants and must ensure that the condition of authorisation include, where appropriate, risk mitigation measures.

The SANCO report for 2,4-D ([SANCO/11961/2014](https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&as_id=394) from 09/10/2015 and revised on 06/10/2017) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An [EFSA Scientific Report](https://www.efsa.europa.eu/en/efsajournal/pub/3812)[[1]](#footnote-1) was made available on 11 September 2014.

Table 0.1‑3: Information on minimum purity of 2,4-D

| EU agreed minimum purity from Inclusion Directive or Implementing regulation | (if different) Minimum purity of active substance used in the product / information on available equivalency report \*, \*\* |
| --- | --- |
| Minimum purity of active substance: 960 g/kg  The maximum contents of free phenols (expressed as 2,4-DCP) shall not exceed 3 g/kg.  The content of dioxins and furans that could be formed as manufacturing by-products shall be maximum 0,01 mg/kg TCDD toxic equivalents. | Minimum purity of active substance (XXXX): 970 g/kg  Equivalence report available: Y  RMS: Greece |

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

\*\*. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

| Endpoint | Active Substance | |
| --- | --- | --- |
| EU agreed endpoint from EFSA scientific report | Endpoint used\* |
| 2,4 DCP – fish acute | No previous study | LC50 = 10 mg/L NOM |
| 2,4-D acid – aquatic macrophyte (*Myriophyllum)* | No previous study | ErC50 = 0.346 mg/L NOM |
| 4-chlorophenol – aquatic macrophyte (*Myriophyllum)* | No previous study | ErC50 = 13.1 mg/L GEO |
| 4-chlorophenol – earthworm chronic | No previous study | NOECcorr = 5 mg/kg dw soil |
| 2,4-D (formulated as 2,4-D 95 SP) – seedling emergence | No previous study | ER50 = 28.69 g a.s./ha |
| 2,4-D (formulated as 2,4-D 95 SP) – vegetative vigour | No previous study | ER50 = 29.4 g a.s./ha |

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

### Regulatory history of the product

Not relevant as the product has not yet been authorised.

## zRMS conclusion

Identity, physicochemical properties and analytical methods:

The two-year study is ongoing. It has to be provided for evaluation in Poland when available. It is required to confirm the two-year shelf life.

Efficacy:

The evaluation of the application for ADM.09250.H.1.A. resulted in the decision to grant the authorization.

Toxicology and health risk:

For the aspect **human health**, the intended use is considered safe – operator has to wear suitable workwear (arms, body and legs covered), protective gloves during mixing/loading and application and face mask/respiratory protection (FP2, P2 and similar) when handling the concentrate.

Residues:

The evaluation of the application for ADM.09250. H.1.A resulted in the decision to grant the authorization. All uses applied for were authorised. An exceedance of the current MRL of 2 mg/kg for 2,4-D as laid down in Reg. (EU) 2022/1363 is not expected. The chronic and the short-term intakes of 2,4-D residues are unlikely to present a public health concern.

Fate and behaviour:

The results of FOCUS groundwater calculation for 2,4-D and its metabolites 2,4-DCP, 2,4-DCA and 4-CP indicated that PECGW values do not exceed the regulatory trigger of 0.1 µg/L at 1 m depth in any of the scenarios.

Ecotoxicology:

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed uses of 2,4-D 95 SP poses acceptable risk to non-target organisms, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from 2,4-D 95 SP applications are required for non-target terrestrial plants.

Uses to be considered safe on the basis of EU methodology:

|  |
| --- |
| Use 1 |

Uses to be considered non-safe on the basis of EU methodology:

|  |
| --- |
| None |

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

|  |
| --- |
| Mammalian Toxicity: all uses – operator has to wear gloves during mixing/loading and application and face mask/respiratory protection (FP2, P2 and similar) when handling the concentrate. |

The following text is to be shortened or to be amended as necessary.

All uses/ GAPs are covered by established MRLs except for use in crop. An application for amending the MRL has been submitted by MS to EFSA EFSA Project Number (if applicable).

zRMS may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

1. ALL intended uses

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | GAP February 2023 |
| PPP (product name/code): | 2,4-D 95 SP / ADM.09250.H.1.A | Formulation type: | SP, Soluble Powder |
| Active substance: | 2,4-D (2,4-dichlorophenoxy acetic acid 80.4%) | Conc. of as: | 950 g/kg |
| Safener: | - | Conc. of safener: | - (c) |
| Synergist: | - | Conc. of synergist: | - (c) |
| Applicant: | XXXX | Professional use: |  |
| Zone(s): | Central | Non professional use: |  |
| Verified by MS: | no |  |  |
|  |  |  |  |
| Field of use: | herbicide |  |  |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Use-No. (e) | Member state(s) | Crop and/ or situation  (crop destination / purpose of crop) | F, Fn, Fpn G, Gn, Gpn or I | Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks:   e.g. g safener/synergist per ha  (f) |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | kg or L product / ha  a) max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min / max |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | |
| 1 | Poland | Spring Wheat | F | Broadleaf Weeds  CENCY, VERPE, BRSNW, THLAR, CAPBP | Overall, Broadcast foliar spray | BBCH 15-25 | 1 | (-) | 0.9328 kg product (2,4-D acid)/ha | 0.75 | 200 -300 | - | - |

|  |  |  |  |
| --- | --- | --- | --- |
| Remarks  table heading: | (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  (b) Catalogue of pesticide formulation types and international coding system CropLife  International Technical Monograph n°2, 6th Edition Revised May 2008  (c) g/kg or g/l |  | (d) Select relevant  (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use. |
|  |  |  |  |
| Remarks  columns: | 1 Numeration necessary to allow references  2 Use official codes/nomenclatures of EU Member States  3 For crops, the EU and Codex classifications (both) should be used; when relevant, the  use situation should be described (e.g. fumigation of a structure)  4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. |  | 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3‑8263-3152-4), including where relevant, information on season at time of application  8 The maximum number of application possible under practical conditions of use must be provided.  9 Minimum interval (in days) between applications of the same product  10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.  13 PHI - minimum pre-harvest interval  14 Remarks may include: Extent of use/economic importance/restrictions |

1. Conclusion on the peer review of the pesticide risk assessment of the active substance 2,4-D. European Food Safety Authority. EFSA Journal 2014; 12(9):3812 https://www.efsa.europa.eu/en/efsajournal/pub/3812 [↑](#footnote-ref-1)