

Request for certain information to be kept confidential (Article 63(2) of Regulation (EC) 1107/2009, amended by Regulation (EU) No 2019/1381)

This request pertains to:

- ☐ Application for authorization of an authorization (Art. 33)
☒ Renewal of authorization (Art. 43)
☐ Mutual Recognition (Art. 40)
☐ Application for Technical Equivalence (Art. 38)

Product name (product code): Merpan 80 WDG (MCW-3002)

Active(s) substance(s): Captan 800 WG

Member States: CEU: The Netherlands (zRMS), Austria, Belgium, Czech Republic, Germany, Hungary, Poland, Romania, Slovenia, Slovakia
 SEU: Italy (zRMS), Bulgaria, Croatia, France, Greece, Portugal, Spain

Document	Page No:	Paragraph(s):	Justification	Evaluation of the request by the RMS
dRR Part A		1.2 Appendix 3 Appendix 4	Information considered confidential according to Reg 178/2002 (GFL) as amended by Reg 2019/1381 Art 1 (8): information concerning letter of access is considered confidential as it provides commercial links between a producer or data owner and the applicant. Furthermore, any personal data (names and addresses) of individuals involved in testing on vertebrate studies or in obtaining toxicological information, including laboratories and suppliers test animals and feed items, as per Article 39(e)(2) of Regulation (EC) No 178/2002 and Article 63(g) of Regulation (EC) No 1107/2009 is to be kept confidential	
dRR Part B 1-2,4 dRR Part B 3 dRR Part B 4 dRR Part B 5 dRR Part B 6 dRR Part B 7 dRR Part B 8 dRR Part B 9 dRR Part B10	all	all	All dossier parts submitted along with the application contain personal information that are to be kept confidential according to Article 39(e)(1) of Regulation (EC) No 178/2002. This includes all names of authors, laboratories and geolocations of fields that were used for testing. Exempt from this request are: - the name and address of the applicant. - the names of authors of published or publicly available studies supporting the application. Primarily this request for certain information to be kept confidential is referring to the reference lists under Appendix 1 of each dRR Part and summaries of new studies presented under Appendix 2 of the relevant dRR Parts.	

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dRR Part C			Protection of privacy. Article 4(1)(b) of Regulation 1049/2001: name, address, contact numbers and personal e-mail of applicant and producer. Information considered confidential according to Reg 178/2002 (GFL) as amended by Reg 2019/1381 Art 1 (8): Location, addresses and contact information for manufacturing sites (technical material and preparation) as it provides commercial links between a producer and the applicant as well as sourcing detail. Information deemed to undermine the protection of the commercial interests according to Reg 2019/1381 Art. 7 (5) amending Art 63 of 1107/209 as this would significantly facilitate the approval of competitors product: • Information on the complete composition of a plant protection product; and therefore also the formulation process • Specific assessment which are related to the composition of the product and the active substance (incl non-relevant impurities). • Commercial ties between a producer or importer and the applicant • Information revealing information on the manufacturing and formulation sites	

Company: ADAMA Makhteshim Ltd.
Date: 20 January 2025

Signature:

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