

Appendix: List of renewal data in the Renewal Assessment Report of [Cholecalciferol/PT 14], including information on which data is considered 'relevant data' by the evaluating Competent Authority (eCA) [Article 95(7) of Regulation (EU) No 528/2012 (BPR)]¹

When the approval of an active substance/product type combination is renewed, all concerned Article 95 suppliers, who are not the applicants behind the renewal of the approval, will need to submit a letter of access (LoA) to all the relevant renewal data, as identified by the eCA, within 12 months of the renewal in order to comply with Article 95(7) BPR. A failure to do so means removal from the Article 95 list. For further details, please refer to the CA document².

To facilitate data sharing negotiations, information pertaining to the data submitted in support of the active substance/product type renewal with an indication on whether or not the data is considered 'relevant data' by the eCA is published around the same time as the Biocidal Products Committee's opinion. Any confidential or personal information are redacted by the eCA before this information is disseminated on ECHA's website. The identities of the data submitters can be obtained via the inquiry process under Article 62(2) BPR, if not disclosed.

Disclaimer: Please note that the establishment and publication of this list does not mean that the approval of the concerned active substance/product type combination will be renewed in accordance with Article 14(4) BPR. Renewal is contingent on the Commission adopting an implementing act to that effect.

Author(s)	Year	Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner	Data Identified as 'relevant' by the eCA ¹ (Yes/No)
[REDACTED]	2022	3.14 Granulometry (particle size distribution (granulometry))	CHOLECALCIFEROL: PARTICLE SIZE DISTRIBUTION Study report Report No.: ACE-22-124; Study No.: ACE-22-124 AGROCHEMEX ENVIRONMENTAL LTD BASF	Yes	Agro B.V. Arnhem (NL) Freienbach Branch	No

¹ Status: 14/03/2024

² For further information, and criteria of "relevant", please see [CA-Sept20-Doc.7.1.b - Relevant Renewal Data under Article 95_FINAL](#)

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			GLP			
██████████	2022	3.14 Granulometry (particle size distribution (granulometry))	CHOLECALCIFEROL: PARTICLE SIZE DISTRIBUTION Study report Study No.: ACE-22-126 AGROCHEMEX ENVIRONMENTAL LTD	Yes	2022 Environmental Science FR S.A.S GLP	No
Bilani, et al.	2021	8.11 Carcinogenicity (carcinogenicity, other)	Newly-identified Pathways Relating Vitamin D to Carcinogenesis: A Review Reference type not provided in vivo 35: 1345-1354 (2021) GLP information not provided	No	N/A	No
██████████	2022	8.12.3 Medical surveillance data, health records and case reports (health surveillance data)	Medical Surveillance - Fermenta Biotech Ltd, Takoli, Dahej Reference type not provided Source and/or Testing facility not provided Non GLP	Yes	N/A	No
Mahmoodani, F. et al	2017	10.1.1.1.a Abiotic: Hydrolysis as a function of pH and identification of	Degradation studies of cholecalciferol (vitamin D3) using HPLC-DAD, UHPLC-MS/MS and chemical derivatization Publication	No	N/A	No

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		breakdown products (hydrolysis)	Food Chemistry 219 (2017) 373–381 GLP information not provided			
Hosoda, K et al	2015	10.1.1.1.a Abiotic: Hydrolysis as a function of pH and identification of breakdown products (hydrolysis)	Identification and characterization of a vitamin D3 decomposition product bactericidal against Helicobacter pylori Publication Scientific Reports volume 5, Article number: 8860 (2015) GLP information not provided	No	N/A	No
Temova, Z, Rožkar, R	2016	10.1.1.1.a Abiotic: Hydrolysis as a function of pH and identification of breakdown products (hydrolysis)	Stability-Indicating HPLC–UV Method for Vitamin D3 Determination in Solutions, Nutritional Supplements and Pharmaceuticals Publication Journal of Chromatographic Science, Volume 54, Issue 7, 1 August 2016, Pages 1180–1186 GLP information not provided	No	N/A	No
Anon	2021	11 Measures to protect humans, animals and the environment	Safety Data Sheet Cholecalciferol Other company data Source and/or Testing facility not provided GLP information not provided	N/A	N/A	No

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