



CTGB
Postbus 8030
6710 AA Ede
The Netherlands

30 January 2025

Re: Art. 43 application for Royal Malvin 80 WG (6782 N), application number 20201681 NLRG

Dear Madam, Sir,

We hereby submit the Art. 43 dossier for our product Royal Malvin 80 WG (Captan 800 g/kg WG), following the Renewal of the active substance Captan by 1 November 2024 (Regulation (EU) 2024/2186). The Netherlands are concerned Member State in this procedure.

However, as the Renewal Regulation of captan led to conditions and restrictions which could not be foreseen by the Applicant, it is not possible to have a complete dossier available by the dossier submission timing for the products based on the active substance Captan (i.e. by 31 January 2025), a request for a Cat. 4 claim was made to zRMS Austria. Austria accepted this Cat. 4 claim and has notified the concerned Member States of this acceptance.

Therefore, with this submission, only the information which is already available is submitted, as the dRR (Parts A, B and C), as well as the studies that are still to be generated, will be submitted in Q2 2027 (phase 2), as agreed with zRMS Austria.

Also we can not submit the proposed GAP and Instructions for Use yet. Following the EU Renewal process, the endpoints for the long-term toxicity to mammals and acute toxicity to aquatic organism have been decreased importantly. Therefore, the current GAP will need to be modified to pass the risk assessment. In addition, 2 important restrictions have been set in the captan renewal:

- No application during the flowering period.
- Use of precision equipment that allow a 61% reduction of exposure

Pending further generation of Category 4 studies (residue and efficacy trials), the necessary changes in the GAP are currently not completely defined. The revised GAP and Instructions for use will be submitted with the complete dRR during the phase 2 of the article 43 submission.

This submission contains (in the Ctgb electronic dossier format):

- Application form G (NL=cMS)
- A statement confirming that the authorized plant protection product and uses are in compliance with the restrictions and conditions in the active substance renewal regulation.
- All currently available studies

Regarding the available studies, please note that Royal Malvin 80 WG was one of the representative products during the EU Renewal of captan. With this submission, only studies which have been finalized and have not been submitted before at EU-level are included.

As part of the available studies, also a number of fish toxicity studies with the active substance captan are submitted (vertebrate studies). These studies were performed for the purpose of the EU review, but were not accepted anymore as the evaluation was already too far progressed. The studies will be necessary to achieve an acceptable risk assessment and have therefore been included in this submission.

We remain at your disposal for any questions you may have regarding this dossier and wish you a good receipt.

With kind regards,

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Appendix: Ctgb dossier format with all available information