

Linge Agroconsultancy B.V.
[REDACTED]
Oosterhoutsestraat 95
6678 PG OOSTERHOUT GLD

Letter ref. number 201703310293
Handled by [REDACTED]
Telephone number +31 [REDACTED]
Date March 31st 2017

Re Notification of incomplete : V10 20160057 ZTG *Vaststelling
onvolledigheid voor bovengenoemde aanvraag*

Dear [REDACTED]

On February 2nd 2017 the Ctgb received the above application.

The application is incomplete. Please address the following issues:

Fys. Chem.

1. The concentration used for the persistent foaming test has not been specified. The concentration should be specified and cover the highest in-use concentration of 10%.
The label mentions a tank mix should be prepared with synthetic sand. However, this is not covered in the dossier. The phys-chem properties of the tank-mix should be addressed in an amended part B section 1. Special attention should be paid to the possibility of clogging of the spraying equipment due to the synthetic sand and a uniform, distribution of the synthetic sand in the spraying solution. Furthermore, the synthetic sand should be registered as adjuvant.

Efficacy

2. Usually for formulation changes bridging trials are required, using preliminary trials is a deviation from guidelines. For low risk products, with good justification, some deviations may be acceptable. However, there are quite a few changes to the formulation (removal of nicotine, change of buffer), and in addition a change was made from carborundum to synthetic sand. There are also problems with the submitted preliminary trial reports.

Trial reports IIIA 6.1.1-03 (bioassay vx1) and IIIA 6.1.1-04 (bioassay vc1) appear to be incomplete and contain no trial results. Not all reports were checked in detail during product intake, but complete reports have to be submitted for all trials.

Furthermore; In general in the dossier different formulations have been used that either have one or both of the actives, different buffers etc, but within some sections of the DRR and in trial reports it is not clear what formulation was actually tested. It is not clear if any of the trials contain the final product with synthetic sand (the claimed use) and if that use has been tested in both the rubbing and in the spray application.

Bridging trials should be submitted using the claimed product with synthetic sand, due to the low risk nature of the product, the required number of bridging trials may be lowered if supported by non GEP or preliminary trials of sufficient quality that are relevant to the claim.

We request that you submit all missing data in a single batch, digitally.

If you submit this data within four weeks of the date on this letter, your application will be taken into consideration. Additional time needed above this four weeks will be deducted from the maximum stop the clock period of six months for this application.

Additional information about the procedure and applicable legislation is included in the general instructions with the application form. Please find this information at www.ctgb.nl.

If you have questions about this letter, please contact me directly.

Kind regards,

The Board for the Authorisation of Plant Protection Products and Biocides,
for this organisation:
the Secretary/Director,
for this organisation:



In Nederlands

Het Ctgb heeft bovenvermelde aanvraag ontvangen en ingeschreven.

De aanvraag is inhoudelijk onvolledig. Bovengenoemde gegevens ontbreken.

We vragen u alle ontbrekende gegevens in één keer digitaal te leveren. Nadere informatie over de procedure en toepasselijke regelgeving is opgenomen in de instructie bij het aanvraagformulier. Deze kunt u raadplegen op www.ctgb.nl.

Indien u binnen vier weken na dagtekening deze gegevens levert, voorkomt u dat de aanvraag niet in behandeling kan worden genomen.

Als u nog vragen heeft over deze brief, kunt u rechtstreeks met mij contact opnemen.