

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 10 maart 2017 tot wijziging van de toelating van het biocide Propasta / Strong Pasta / MS Rodetox Brodi Paste , toelatingnummer NL-0005220-0000

Addendum to Product Assessment Report

**Propasta / Strong Pasta / MS Rodetox Brodi Paste
NL-0005220-0000**

10 March 2017

Addendum to biocidal product assessment report related to product authorisation under Regulation (EU) 528/2012

Contents

Contents 0

Background..... 1

Packaging of the biocidal product1

Decision..... 1

Background

An application for a minor change was received concerning the packaging of Propaste / Strong Pasta / MS Rodetox Brodi Paste. The minor change was already approved in reference member state Ireland (SAPHIR PASTE; asset no. IE-0000811-0000).

Packaging of the biocidal product

Changes to the packaging type and sizes were applied for:

A PP or HDPE cartridge for use with a caulking gun is added. Sizes of the cartridge are 80g, 150g, 280g, 310g, 400g, 500g.

The applicant did originally not apply in NL for all packagings that have been authorised by the RMS in the original authorisation. Now the applicant wishes authorisation for all packaging type and sizes that have been authorised by the RMS in the original application. This means the following packagings are added:

- Paste bait 10g in PE + PP sachet or loose bait further packed in individual PE sachets (zip pouch); Inner packaging: PE +PP sachet; Outer Packaging: N/A PE sachets (zip pouch) 250g
- Paste bait 10g in PE +PP sachet or loose bait further packed in individual PP pre-baited station into a cardboard case Inner packaging: PP pre-baited station; Outer Packaging: cardboard case 240g or 480g
- Paste bait 10g in PE + PP sachet or loose bait further packed in individual cardboard cases with PE liner; Inner packaging: PE + PP sachet; Outer Packaging: Cardboard case with PE liner 50g, 100g, 120g, 200g, 240g , 250g, 480g, 500g, 520g, 520g, 720g, 750g.

Decision

There is no impact on the risk assessment for human health because the risk assessment was already performed on wax blocks as a suitable worst-case scenario for the application on paste bait.

There is also no impact on the efficacy assessment as no negative impact is to be expected on the palatability or efficacy of the product when applied by caulking gun or because of a change in outer packaging. However, use instructions on the SPC were slightly changed for the application by caulking gun as the use instructions were only specified for sachets.

The new packaging can be authorized based on the packagings evaluated in the original authorisation of the product and extrapolation of the existing PP sachets and buckets evaluated for the original authorisation of the product.