Addendum to Product Assessment Report

**Product names:**

**Entfloher – Non-Professional Use** NL-0015509-0000

07 12 2020

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

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# Background

(Minor change application)

With this minor change application the Authorisation holder requests the change of the packaging size range by adding an additional packaging size to the recently authorised product, Entfloher (Non-Professional Use), NL-0015509-0000, for which NL acted as the rMS.

The new packaging size range is consistent with the dose rate (250 mL of the product is sufficient for the treatment of 80 m2. This amount corresponds to a spraying time of 2 seconds per m2) and instructions for use as approved in the summary of the biocidal product characteristics.

— No change of user category

— The same risk-mitigation measures apply

The reason for this request is that a 400 mL packaging size would be a more sustainable option reducing also costs in terms of less packaging, less transport, which is possible due to the product’s shelf-life is being at least 3 years.

A grouped application will be submitted with NL as rMS and with the following MSs as cMS:

• DE

Update of the SPCs:

With this minor change application the following updated SPCs will be submitted:

• xml SPC NL (RefMS SPC in English)

• xml SPC DE (cMS SPC in German)

# Decision

A packaging size of 400 ml is added to the already authorised packaging of 250 ml pressurized metal can (aluminium or tin plate) with a Bag-on-Valve System using compressed air as propellant.

For details on the assessment, please refer to the appendix. Changes/additions to the original evaluation are highlighted in yellow.

# Appendix

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



Entfloher

Product type 18

Active substance: Permethrin and pyriproxyfen as included in the Union list of approved active substances

Asset Number: NL-0015509-0000

Evaluating Competent Authority: NL

Date: December 2020

# ASSESSMENT REPORT

# Summary of the product assessment

### Authorised use(s)

#### Use description

Table 1. Use # 1 – insecticide-general public-indoor – pet areas

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** | Insecticide / acaricide |
| **Target organism (including development stage)** | *Ctenocephalides-* Fleas- eggs & larvae |
| **Field of use** | Indoors; in small areas where pets (dogs and cats), mainly remain, including pet bedding, carpets, or cushions |
| **Application method(s)** | spraying |
| **Application rate(s) and frequency** | 250 mL product/80 m2. This amount corresponds to a spraying time of 2 seconds per m2.  Apply spraying from 30 cm distance onto preferred places of the fleas until the surface is slightly moistened.  Maximum two applications per year.  Residual efficacy is up to 24 weeks. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | 250 mL pressurized metal can (aluminium or tin plate) with a Bag-on-Valve System using compressed air as propellant  400 mL pressurized metal can (aluminium or tin plate) with a Bag-on-Valve System using compressed air as propellant |

### General directions for use

#### Instructions for use

|  |
| --- |
| Apply the product as soon as the first fleas are identified.  Clean area before using the product.  Apply spraying from 30 cm distance onto preferred places of the fleas until the surface is slightly moistened.  Spraying is done for 2 seconds per m2.  After application leave the room immediately.  After application ensure adequate ventilation.  After contact with Entfloher the killing effect immediately starts.  Humans and domestic animals may not enter the room at least for an hour after the application.  Where possible, combine the treatment with non-chemical measures.  The infestation should be monitored to see whether the treatment is sufficient.  Products should always be used in accordance with label recommendations.  250 mL of product is sufficient for the treatment of 80 m2.  If the problem persists, contact a professional pest control operator.  Do not apply on wet washable surfaces or materials. |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Can | 250, 400 mL | Aluminium or tin plate can (outer)  Bag of aluminium (inner)  Propellant of the bag-on-valve system consist of compressed air. | Aerosol valve with a bag welded on to it and positioned in the can | General public (non-professional) | Yes |