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 APPLICATION**

(submitted by the competent authority)



**ADDENDUM**

SAFWS002

Product type 18

Dinotefuran

Case Number in R4BP: BC-ED091103-63 (NA-MIC)

Competent Authority: BE

Date: 23 April 2024

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**Changes history table**

**Note for the applicant and the competent authority:**

The changes to the PAR are implemented as follows:

- For national authorisation, the changes should be introduced in the PAR *via* an addendum. The addendum will be a standalone document, displaying the same chapters’ structure of the PAR and reporting only the changes under the relevant chapters. At the renewal stage of the national authorisation, the PAR will be consolidated by incorporating the changes;

- For Union authorisation, it is recommended that the changes are introduced in a consolidated PAR and are clearly identified, for example by highlighting them in yellow.

The competent authority should delete this note when finalising the PAR.

*[Provide in the table below the overview of the changes history by compiling all the changes made to the PAR since the initial authorisation. In case the change impacts several sections of the PAR, this can be indicated in the last column “Chapter/page”. ]*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| NA-APP | *Belgium* | BC-CC062809-46 | 20/01/2023 | *First authorisation* |  |
| NA-MIC | *Belgium* | BC-ED091103-63 |  | *Addition of a packaging size.*  *Change in the name of the active substance manufacturer.* |  |
|  |  |  |  |  |  |

# Conclusion

SAFWS002 is a RB Bait (ready for use) biocidal product containing dinotefuran. The product is used as a PT18 by non-professionals for the control of house flies.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the use as RTU window sticker against house flies for indoor use by non-professionals, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in the original Product Assessment Report (PAR) by BE CA dated December 2022. They remain unchanged after this minor change and, hence, reader is referred to this PAR.

Together with this change a modification of the name of the active substance manufacturer was implemented. For detailed information, please refer to the SPC.

# Assessment of the biocidal product

## Packaging

Table 3.1 Packaging

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Folding cardboard (outer packaging) | Folding cardboard (outer packaging) including one or two cards of ca. 90-100 mm x ca. 160-170 mm with 2 stickers (Ø ca. 75 mm) each. Thus, in total 2 or 4 stickers per folding cardboard.  Stickers (geometric shape, or alternatively a butterfly or flower motive) are printed on self-adhesive paper card (carrier), covered with a protective, removable silicon paper. | Cardboard, self-adhesive paper card (carrier), silicone paper | N/A | Non-professional | Yes |

## Physical, chemical, and technical properties

The change in packaging size does not impact the physical, chemical, and technical properties of the biocidal product. As such, no new test data was submitted, not considered necessary. The evaluation and conclusion, as described in the original Product Assessment Report (PAR) by BE CA dated December 2022, remains valid without any change.Physical hazards and respective characteristics

## Physical hazards and respective characteristics

The change in packaging size does not impact the physical hazards and respective characteristics of the biocidal product. As such, no new test data was submitted, not considered necessary. The evaluation and conclusion, as described in the original Product Assessment Report (PAR) by BE CA dated December 2022, remains valid without any change.

## Methods for detection and identification

The change in packaging size does not impact the methods for detection and identification. As such, no new test data was submitted, not considered necessary. The evaluation and conclusion, as described in the original Product Assessment Report (PAR) by BE CA dated December 2022, remains valid without any change.