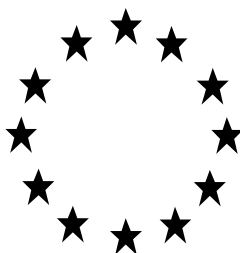


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the eCA)

ADDENDUM: Minor Change



Night & Day Family

Product type PT 18

Transfluthrin

Asset Number in R4BP: NL-0016419-0000

Evaluating Competent Authority: The Netherlands

Date: 13/01/2022

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BACKGROUND

(Minor change application)

With this minor change application the Authorisation holder requests the change of the directions for use to the recently authorised product, Night & Day Family (Non-Professional Use), NL-0016419-0000, for which NL acted as the rMS.

The electrical devices safety instruction in section 5.2 of the SPC (titled – IMPORTANT SAFETY INSTRUCTIONS) gets regularly updated which makes the current version in the approved SPC outdated.

This has proved very problematic with some authorities as they refuse to accept an updated version of the text, citing it must first be changed in the SPC approved by RefMS. Although the 'electrical devices safety instruction' is out of scope for a biocide competent authority and could independently be updated as it is not governed by the BPR.

Therefore, to avoid similar situation with future updates of the safety instruction, we would like it to be removed from the SPC.

Here is the text we are requesting to be removed from the SPC, section 5.2.

IMPORTANT SAFETY INSTRUCTIONS: Instructions to avoid the hazards of fire, toxicity, electric shock, or injury. PLEASE READ BEFORE USING AND SAVE THESE IMPORTANT SAFETY INSTRUCTIONS. WARNING: when using electrical appliances, basic precautions should always be followed including the following: CAUTION: to reduce risk of injury and prevent play, children shall not use product. Close supervision is necessary when a product is used near children 8 years and above or persons with special needs. For safe use, plug only into properly functioning wall outlets where device is ventilated and cannot contact bed covering or other material. Do not use with extension cords or multi-plugs. Do not immerse in water. Do not insert anything into outlet above it. Use only (Brand Name) refills in (Brand Name) holders. These instructions are available at [website]

DECISION

Efficacy

NL CA agrees with the removal of the mentioned text in section 5.2. Removal of the text has no influence on the efficacy assessment of the product family.

Human health

NL CA agrees with the removal of the mentioned text in section 5.2. Removal of the text has no influence on the human health risk assessment of the product family.