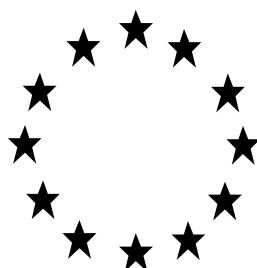


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the evaluating Competent Authority)

**ADDENDUM: Minor Change**



Nonanoic Acid Algaecides

Product type PT2

Nonanoic acid

Case Number in R4BP: BC-NJ019882-30

Evaluating Competent Authority: Austria

**04/08/2023 (Final)**

**PUBLIC**

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**CHANGES HISTORY TABLE**

<b>Application type</b>	<b>refMS</b>	<b>Case number in the refMS</b>	<b>Decision date</b>	<b>Assessment carried out (i.e. first authorisation / amendment / renewal)</b>	<b>Chapter/ page</b>
NA-APP	Austria	BC-NJ019882-30	08/07/2022	<i>First authorisaiton</i>	
NA-ADC	Austria	BC-BS080424-29	21/11/2022	<i>Change (trade names)</i>	SPC
NA-MIC	Austria	BC-NJ019882-30	<i>On-going</i>	<i>Change (pack size, child-proof closure)</i>	SPC

## 1 CONCLUSION

The authorisation holder W. Neudorff GmbH KG has applied for a minor change in accordance with Regulation (EU) No 354/2013 to the authorised product family *Nonanoic Acid Algaecides*. The change relates to modifying the packaging (addition of pack sizes; removal of child-proof closure).

The addition of further pack sizes is a minor change according to Reg.(EU) No. 354/2013, Annex, Title 2, point 7. The criteria for the minor change application are fulfilled because the new range is consistent with the dose rate and instructions for use as approved in the summary of the biocidal product characteristics, there is no change of user category, and the same risk-mitigation measures apply.

The change of the closure is a minor change according to Reg.(EU)No. 354/2013, Annex, Title 2, point 4. The criteria for the minor change application are fulfilled because the new device accurately delivers the required dose for the biocidal product concerned in line with the approved conditions of use, the new device is compatible with the biocidal product, and the change is not expected to adversely affect the exposure.

It is demonstrated that the proposed changes would not adversely affect the conclusions previously reached on the assessment of the biocidal product family *Nonanoic Acid Algaecides*.

**It can be concluded that the conditions of Article 19 1)-4) of regulation (EU) no. 528/2012 are fulfilled and that the product may be authorised with the proposed changes.**

## 2 ASSESSMENT

### 2.1 Background

The authorisation holder W. Neudorff GmbH KG has applied for a minor change in accordance with Regulation (EU) No 354/2013 to the authorised product family *Nonanoic Acid Algaecides*. The application contains a minor change (NA-MIC) related to the packaging sizes and the type of closure.

### 2.2 Description of changes

The following minor change is applied for:

In order to make the production of the according biocidal products more economic and more sustainable the authorisation holder was seeking for amending the packages defined in the current authorisation. The desired change primarily concerns the package sizes and secondly the type of closure of the packages.

The product family consists of two concentrated product formulations (NEU 1170 H EC and NEU 1370 H) and two ready to use formulations (NEU 1170 H AF 31.02 g/L and NEU 1170 H AF 28.0 g/L).

The ready to use formulations are intended for non-professional use only. In case of the concentrated product formulation a larger package size of **up to 20 L** is intended to be added for professional uses, only. In case of the ready to use formulations a range of package sizes (**500 mL up to 5 L**) is intended.

For all package sizes the obligation to equip the packages with **childproof closures** is intended to be **omitted**. The use of childproof lids is intended to be a *recommendation* rather than an *obligation*.

Neither the packaging material nor the product composition are affected in any way by the sought changes.

### 2.3 Evaluation of changes

#### 2.3.1 Identity and physico-chemical properties

The intended packagings of the biocidal products are listed in the table below (Tab. 1). Packaging of the biocidal products according to the PAR of the initial authorisation of the product family is listed in a second table (Tab. 2) thereafter. The proposed additional packagings are deemed to be covered by the available storage studies. The packaging material is the same. Read-across is deemed acceptable.

Furthermore the statement "*Note to the applicant meta SPC 1: The products should have child-proof closure.*" (please consult PAR Chapter 2.1.6 Other information) has to be amended to "*Note to the applicant meta SPC 1: It is recommended to equip the packages with a child-proof closure.*" This is deemed acceptable, as child proof closure is not mandatory according to the human health risk assessment.

**Tab. 1 Intended packagings of the biocidal products**

<b>Meta SPC 1</b>					
<b>Type of packaging</b>	<b>Size/volume of the packaging</b>	<b>Material of the packaging</b>	<b>Type and material of closure(s)</b>	<b>Intended user</b>	<b>Compatibility of the product with the proposed packaging materials (Yes/No)</b>
Bottle with dosing device	500 mL to 1 L	HDPE	HDPE lid	Professional and non-professional	Yes
Canister	5 L to 20 L	HDPE	HDPE lid	professional	Yes
<b>Meta SPC 2</b>					
<b>Type of packaging</b>	<b>Size/volume of the packaging</b>	<b>Material of the packaging</b>	<b>Type and material of closure(s)</b>	<b>Intended user</b>	<b>Compatibility of the product with the proposed packaging materials (Yes/No)</b>
Container with spray cap	500 mL to 5 L	HDPE	HDPE trigger sprayer	professional and non-professional	Yes
<b>Meta SPC 3</b>					
<b>Type of packaging</b>	<b>Size/volume of the packaging</b>	<b>Material of the packaging</b>	<b>Type and material of closure(s)</b>	<b>Intended user</b>	<b>Compatibility of the product with the proposed packaging materials (Yes/No)</b>
Canister	5 L to 20 L	HDPE	HDPE lid	professional	Yes

**Tab. 2 Packagings of the biocidal products according to currently valid authorisation (provided in PAR chapter 2.1.7)**

<b>Meta SPC 1</b>					
<b>Type of packaging</b>	<b>Size/volume of the packaging</b>	<b>Material of the packaging</b>	<b>Type and material of closure(s)</b>	<b>Intended user</b>	<b>Compatibility of the product with the proposed packaging materials (Yes/No)</b>
Dosing bottle Ultima 510 mL	L: 100 mm W: 53 mm H: 233 mm <b>500 mL</b>	HDPE	Neck diameter: outer 35.3 mm inner 23 mm Closure for Dosing bottles HDPE child proof	professional and non- professional	Yes
Dosing bottle Ultima 1020 mL	L: 121 mm W: 63 mm H: 273 mm <b>1000 mL</b>	HDPE	Neck diameter: outer 35.3 mm inner 23 mm Closure for Dosing bottles HDPE child proof	professional and non- professional	Yes
Jerrycan: type 5 SK 5 (UN no. UN 3 H 1 / Y1.9 / 200 / D / BAM 6186 PP)	L: 191 mm W: 152 mm H: 290 mm <b>5 L</b>	HDPE wall thickness: 0.9 - 1.5 mm	Neck diameter: 40 mm Screw cap: No. 50 with tamper evidence Seal: PE foam	professional	Yes
Jerrycan: type 10 SK 4 (UN no. UN 3 H 1 / Y1.6 / 175 / D / BAM 8889 PP)	L: 232 mm W: 192 mm H: 309 mm <b>10 L</b>	HDPE wall thickness: 1.2 - 1.8 mm	Neck diameter: 40 mm Screw cap: No. 50 with tamper evidence Seal: PE foam	professional	Yes
<b>Meta SPC 2</b>					
<b>Type of packaging</b>	<b>Size/volume of the packaging</b>	<b>Material of the packaging</b>	<b>Type and material of closure(s)</b>	<b>Intended user</b>	<b>Compatibility of the product with the proposed packaging materials (Yes/No)</b>

500 mL Container with spray cap	180 x 105 x 45 mm <b>500 mL</b>	HDPE	HDPE trigger sprayer child proof	professional and non-professional	Yes
1L Container with spray cap	230 x 145 x 45 mm <b>1 L</b>	HDPE	HDPE trigger sprayer child proof	professional and non-professional	Yes
3L Container with spray cap	220 x 230 x 90 mm <b>3 L</b>	HDPE	HDPE trigger sprayer child proof	professional and non-professional	Yes
<b>Meta SPC 3</b>					
<b>Type of packaging</b>	<b>Size/volume of the packaging</b>	<b>Material of the packaging</b>	<b>Type and material of closure(s)</b>	<b>Intended user</b>	<b>Compatibility of the product with the proposed packaging materials (Yes/No)</b>
Jerrycan: type 5 SK 5 (UN no. UN 3 H 1 / Y1.9 / 200 / D / BAM 6186 PP)	L: 191 mm W: 152 mm H: 290 mm <b>5 L</b>	HDPE wall thickness: 0.9-1.5 mm	Neck diameter: 40 mm Screw cap: No. 50 with tamper evidence Seal: PE foam	professional	Yes
Jerrycan: type 10 SK 4 (UN no. UN 3 H 1 / Y1.6 / 175 / D / BAM 8889 PP)	L: 232 mm W: 192 mm H: 309 mm <b>10 L</b>	HDPE wall thickness: 1.2-1.8 mm	Neck diameter: 40 mm Screw cap: No. 50 with tamper evidence Seal: PE foam	professional	Yes



### **2.3.2 Authorised use and General directions of use**

Neither authorised uses nor general instructions of use are affected by the sought changes.

### **2.3.3 Efficacy**

The efficacy is not affected by the sought changes.

### **2.3.4 Human Health**

The sought changes do not affect the risk assessment for human health.

### **2.3.5 Environment**

The sought changes do not affect the risk assessment for the environment.

### **3 ANNEX**

#### **3.1 List of studies**

None.

#### **3.2 List of references**

None.

#### **3.3 Confidential information**

None.

#### **3.4 Confidential information restricted to authorities**

None.