

# ORIGINAL



**ICB PHARMA**

**Jaworzno, 26.09.2018**

**Tomasz Świętosławski**

**Paweł Świętosławski Sp. J.**

**Ul. Moździerzowców 6 a**

**43-602 Jaworzno, POLAND**

## **ICB STATEMENT FOR URPL DECISION - PROVECTA**

ICB Pharma informs, that regarding PROVECTA the following inquiry has been sent to Polish Competent Authority, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products:

*"Shall the product, which direct mode of action relies on physical immobilization of pest insects, be regarded as biocidal product in the light of Article 3.1 (a) of Biocidal Product Regulation (EU 528/2012)?"*

After answering the Authorities with requested additional clarifications, their final position for original inquiry is provided in the attached statement (sworn translation).

**COMPANY ADDRESS:**

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NIP: 632-17-97-732  
REGON: 276916802  
KRS: 0000150038

Attachments:

1. Sworn translation of the decision of Polish Competent Authority regarding biocidal products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products dated 21st September, 2018.

Yours faithfully,



Tomasz Świętosławski (CEO)



Paweł Świętosławski (CEO)

REFERENCE NUMBER 1409/2018

The POLISH CHAMBER OF FOREIGN TRADE hereby certifies that Mr. Świętosławski T. Świętosławski and Mr. Świętosławski P. Świętosławski are authorised to sign on behalf of ICB Pharma Tomasz Świętosławski Paweł Świętosławski sp. z o.o. and that their signatures are authentic.

Katowice 01.10.2018




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Małgorzata Nowińska

*Sworn Translation from Polish into English*

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Office for Registration of Medicinal Products, Medical Devices and Biocides

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Tax Identification Number (NIP) 521-32-14-182, National Business Registry Number (REGON) 015249601

DEPARTMENT OF INFORMATION ON BIOCIDES AND PRODUCTS SUBJECT TO BIOCIDAL ACTIVITY

Warszawa, [Stamp that reads: 2018-09-21]

UR.DIB.IBI.462.1.0397.2018.M.J

Mr. Grzegorz Żmijowski  
ICB Pharma  
grzegorz.zmijowski@icbpharma.com

In reply to your mail from September 17, 2018 regarding request for indication whether the product designed for immobilization of insects is subject to definition as biocide, I hereby inform you as follows. With respect to the information presented in mails from 21.03.2018, 23.08.2018, 17.09.2018 responses by the Registration Office (documents no. UR.DIB.IBI.462.1.0136.2018.MJ.1, UR.DIB.IBI.462.1.0136.2018.MJ.1) and further explanations presented, the Registration Office hereby informs that the product designed for immobilization of insects (through physical activity) does not fulfill the criteria of the definition of biocide included in the resolution 528/2012 and does not require registration in Office for Registration of Medicinal Products, Medical Devices and Biocides.

[Stamp that reads: DEPARTMENT FOR INFORMATION ON BIOCIDES AND PRODUCTS SUBJECT TO ACTIVITY OF BIOCIDAL ACTIVIT, Elżbieta Buchmiej]

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[logo that reads: niepodległa, 100<sup>th</sup> anniversary of restoration of independence]

I, Małgorzata Kostrowska, Sworn English Translator, entered into the list of sworn translators kept by the Minister of Justice Entry No./313/07, do hereby certify that the above document is a true and lawful translation of the document prepared in Polish.  
Translation No. 5827/2018  
Date: 26.09.2018

*Kes*

