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 THE MINOR CHANGE OF NATIONAL AUTHORISATION APPLICATION**

(submitted by the evaluating Competent Authority)



**ECOGEL ROACHES**

**ROACHES GEL**

**ROACHES BAIT**

**HUNTER ROACHES GEL**

**TEZA Żel na karaluchy i prusaki**

**Focus żel na karaluchy**

Product type 18

IMIDACLOPRID

Case Number in R4BP: BC-EJ057453-42

Evaluating Competent Authority: Poland

21.11.2023

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# Updated data (June 2022)

Amended sections:

Shelf-life of the product

# Conclusion

ECOGEL ROACHES is an insecticides formulated gel solid containing imidacloprid as active substance. The product is used for the control against cockroaches indoor by general user. The biocidal product ECOGEL ROACHES is authorised in Poland (authorisation number PL/2018/0317/MR/SPB) by NA-BBP procedure, which based on the reference biocidal product MAGNUM GEL CUCARACHAS was evaluated by the Spain Competent Authority (ES CA) (authorisation number: ES/APP(NA)-2017-18-00449).

The Product Assessment Report for the authorisation of MAGNUM GEL CUCARACHAS prepared by the Spain CA (dated June 2013 (updated April 2020)) is considered as applicable for authorisation of the product ECOGEL ROACHES.

**Conditions for the authorisation of the biocidal product ECOGEL ROACHES in Poland:**

An application for a minor change was submitted to CA(PL) as the only concerned MS.

Detailed description of the conditions for the authorisation of this biocidal product   
is presented in the summary of product characteristics (SPC).

Description of all the changes to the product:

* Minor changes referred to in Title 2 of the Annex Regulation (EU) No 354/2013 – change number: 5

### Update the shelf life from 2 years to 4 years.

**Conclusion**

Data for storage stability of 4 years has been submitted to change the currently authorised shelf life of 2 years to 4 years. In addition, the applicant has provided an efficacy trial with bait aged to 4 years.

After the evaluation of both tests, the request is accepted and the relevant documents have been modified. Data are acceptable and therefore a shelf life of 4 years can be granted. This information will be updated in SPC with the sentence: The storage stability if this product in its original packaging is 4 years under normal storage conditions.

**Physical, chemical and technical properties**

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| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| Physical state and nature at 25 °C | PA-U10-METDESCR (visual method) | 2.15% w/w Imidacloprid  Batch E240 | Initially: Gel  After 14 days at 54°C ± 2°C: Gel  After 3 months at 25ºC±2ºC: Gel  After 1 year at 25ºC±2ºC: Gel  After 2 years at 25ºC±2ºC: Gel  After 4 years at 25ºC±2ºC: Gel | Study N° 23120,  Ing. Bernard de RYCKEL, 2017 |
| Colour at 20 °C  Plastic syringe | PA-U10-METDESCR (visual method) | 2.15% w/w Imidacloprid  Batch E240 | Initially: brown  After 14 days at 54°C ± 2°C: Dark brown (small modification of colour)  After 3 months at 25ºC±2ºC: brown  After 1 year at 25ºC±2ºC: dark brown  After 2 years at 25ºC±2ºC: dark brown  After 4 years at 25ºC±2ºC: dark brown | Study N° 23120,  Ing. Bernard de RYCKEL, 2017 |
| Odour at 20 °C  plastic syringe | PA-U10-METDESCR (visual method) | 2.15% w/w Imidacloprid  Batch E240 | Initially: practically odourless  After 14 days at 54°C ± 2°C: Practically odourless  After 3 months at 25ºC±2ºC: practically odourless  After 1 year at 25ºC±2ºC: practically odourless  After 2 years at 25ºC±2ºC: practically odourless  After 4 years at 25ºC±2ºC: practically odourless | Study N° 23120,  Ing. Bernard de RYCKEL, 2017 |
| Storage stability test – **accelerated storage**  **(14 days at 54ºC)** |  |  |  |  |
| Active Ingredient Content | CIPAC MT 46.3.1 | 2.15% w/w Imidacloprid  Batch E240 | Initially: **2.215±0.064% w/w**  After 14 days at 54°C ± 2°C: **2.211 ± 0.047% w/w** Difference: -0.2% | Study N° 23120,  Ing. Bernard de RYCKEL, 2017 |
| Homogeneity of application | A-U10-METAPPLGEL | 2.15% w/w Imidacloprid  Batch E240 | Initially: Amount of product deposited in form of spots of 5 mm diameter (n = 9)  **39.6 mg**  After 14 days at 54°C ± 2°C: Amount of product deposited in form of spots of 5 mm diameter (n = 9)  **39.0 mg** | Study N° 23120,  Ing. Bernard de RYCKEL, 2017 |
| Appearance and stability of the package  (plastic syringe) | PA-U10-METDESCR (visual method) | 2.15% w/w Imidacloprid  Batch E240 | **Initially:**  **Outside aspect:** plastic syringe with applicator tip and a plastic plunger  capacity: 5 g  closing: with a clap clip to protect the applicator tip  colour syringe: opaque white; plunger: red; clap clip: red  intact syringe  no observable sign of test item contamination on the outer surface.  no leak during shaking or turning before and after opening.  no noticeable odour before opening.  **Inside aspect:**  no deformation and no observable alteration of package material by the test item.  **After 14 days at 54°C ± 2°C:**  **Outside aspect:** plastic syringe with applicator tip and a plastic plunger  Capacity: 5 g  closing: with a clap clip to protect the applicator tip  colour: syringe: opaque white; plunger: red; lap clip: red  intact syringe  no observable sign of test item contamination on the outer surface.  no leak during shaking or turning before and after opening.  no noticeable odour before opening.  **Inside aspect :**  no deformation and no observable alteration of package material by the test item  **No modification of appearance or significant pack weight change** | Study N° 23120,  Ing. Bernard de RYCKEL, 2017 |
| Storage stability test – **long term storage at ambient temperature** |  |  |  |  |
| 4 Years storage stability (25ºC)  Active Ingredient Content | CropLife nº 17  HPLC method | 2.15% w/w Imidacloprid  Batch E240 | Initially: **2.215±0.064% w/w**  After 3 months at 25ºC±2ºC:  **2.235± 0.058 % w/w**  Difference: +0.9%  After 1 year at 25ºC±2ºC:  **2.224± 0.025 % w/w or 22.24±0.25g/kg**  Difference: +0.4%  After 2 years at 25ºC±2ºC:  **2.284 ± 0.132 % w/w**  Difference: -0.5%  After 4 years at 25°C ± 2°C: **2.358± 0.001% w/w Difference: +6.46%** | Study N° 23120,  Ing. Bernard de RYCKEL, 2017 |
| Homogeneity of application | PA-U10-METAPPLGEL | 2.15% w/w Imidacloprid  Batch E240 | Initially: Amount of product deposited in form of spots of 5 mm diameter (n = 9)  **39.6 mg**  After 3 months at 25ºC±2ºC: Amount of product deposited in form of spots of 5 mm diameter (n=9)  **35.7 mg**  After 1 year at 25ºC±2ºC: Amount of product deposited in form of spots of 5 mm diameter (n=9) **41.9 mg**  After 2 years at 25ºC±2ºC: Amount of product deposited in form of spots of 5 mm diameter (n=9) **43.8 mg**  After 4 years at 25ºC±2ºC: Amount of product deposited in form of spots of 5 mm diameter (n=9) **35.7 mg** |  |
| Appearance and stability of the package  (plastic syringe) | PA-U10-METDESCR (visual method)  (CropLife n° 17) | 2.15% w/w Imidacloprid  Batch E240 | **Initially:**  **Outside aspect:** plastic syringe with applicator tip and a plastic plunger  capacity: 5 g  closing: with a clap clip to protect the applicator tip  colour syringe: opaque white; plunger: red; clap clip: red  intact syringe  no observable sign of test item contamination on the outer surface.  no leak during shaking or turning before and after opening.  no noticeable odour before opening.  **Inside aspect:**  no deformation and no observable alteration of package material by the test item.  **After 3 months at 25ºC±2ºC:**  **Outside aspect :** plastic syringe with applicator tip and a plastic plunger  capacity: 5 g  closing : with a clap clip to protect the applicator tip  colour: syringe: opaque white; plunger: red; clap clip: red  intact syringe  no observable sign of test item contamination on the outer surface.  no leak during shaking or turning before and after opening.  no noticeable odour before opening.  **Inside aspect :** no deformation and no observable alteration of package material by the test item  **No modification of appearance or pack weight change**  **After 1 year at 25ºC±2ºC:**  **Outside aspect:** plastic syringe with applicator tip and a plastic plunger  capacity: 5 g  closing : with a clap clip to protect the applicator tip  colour: syringe: opaque white; plunger: red; clap clip: red  intact syringe  no observable sign of test item contamination on the outer surface.  no leak during shaking or turning before and after opening.  no noticeable odour before opening.  **Inside aspect:** no deformation and no observable alteration of package material by the test item  **No modification of appearance or pack weight change**  **After 2 year at 25ºC±2ºC:**  **Outside aspect:** plastic syringe with applicator tip and a plastic plunger  capacity: 5 g  closing: with a clap clip to protect the applicator tip  colour: syringe: opaque white; plunger: red; clap clip: red  intact syringe  no observable sign of test item contamination on the outer surface.  no leak during shaking or turning before and after opening.  no noticeable odour before opening.  **Inside aspect:** no deformation and no observable alteration of package material by the test item  **No modification of appearance or pack weight change**  **After 4 year at 25ºC±2ºC:**  **Outside aspect:**  plastic syringe with applicator tip and a plastic plunger  capacity: 5 g  closing: with a clap clip to protect the applicator tip  colour: syringe: opaque white; plunger: red; clap clip: red  intact syringe  no observable sign of test item contamination on the outer surface.  no leak during shaking or turning before and after opening.  no noticeable odour before opening.  **Inside aspect :** no deformation and no observable alteration of package material by the test item  **No modification of appearance or pack weight change** | Study N° 23120,  Ing. Bernard de RYCKEL, 2017 |

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| **Conclusion on the physical, chemical and technical properties of theproduct** |
| The biocidal product ECOGEL ROACHES is based in the active substance Imidacloprid. Imidacloprid 2.15% Gel is a brown gel practically odourless.  The data submitted in the storage stability study shows a storage stability after 3 months, 1 year, 2 years and 4 years.  The most noticeable difference in the content of the active substance is observed after 4 years and is +6.5% (compared to the initial value). However it is not a significant difference.  The is also no significant difference in the homogeneity of application. According to appearance of the test item, small modification of colour appears after 1 year.  The is no modification of appearance or pack weight change.  According to presented data the shelf-life of the product on normal conditions of storage for 4 years is fulfilled. |

**EFFICACY**

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| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | |
| **Test substance** | **Test organism(s)** | **Test method/**  **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Imidacloprid 2.15 % Gel Bait | *Blatta orientalis* | Laboratory bioassay with aged bait.(4 years) Mortality and palatability.  Choice test arena. 2 replicates and control. High and low dose. | Dose: 0.16 mg/m2  Dose: 0.24 mg/m2 Palatable bait. Mean acumulative mortality: >95% in 14 days.  Control: 5.83% | *PROTOCOL: ES0018.E* |
| *Blattella germanica* | Dose: 0.1 2 mg/m2  Dose: 0.16 mg/m2 Palatable bait. Mean acumulative mortality: >95% in 14 days.  Control: 3.75% |
| *Periplaneta Americana* | Dose: 0.1 6 mg/m2  Dose: 0.24 mg/m2 Palatable bait. Mean acumulative mortality: >95% in 14 days.  Control: 2.5% |

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| **Conclusion on the efficacy properties of the product** |
| The applicant has submitted a laboratory test with 4-year-old-bait. We consider clearly demostrated that the product is effective and palatable with 4 year-old-bait. |

Sporządziła:JDN

Data: 2023-06-19