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)



**Ratimor brodifacoum trutka granulowana**

**Zudlan brodifakum granulat**

**Zudwiz brodifakum granulat**

**Extrat brodifakum granulat**

**Bioxi brodifakum granulat**

**Mumia brodifakum granulat**

Product type 14 Rodenticide

BRODIFACOUM as included in the Union list of approved active substances

Case Number in R4BP: BC-HN074090-4

Evaluating Competent Authority: Poland

Date:

28.11.2023 r.

# Updated data (August 2023)

Amended sections:

Packaging of the biocidal product

# Background

Ratimor brodifacoum trutka granulowana is a rodenticide formulated as pellet bait containing brodifacoum as active substance. The product is used for control of rodent pests in and around buildings (professional and general public). The biocidal product Ratimor brodifacoum trutka granulowana is authorised in Poland by NA-BBS procedure (case number BC-VE066569-19, authorisation number PL/2022/0504/MR/SBP). The reference biocidal product ACTIPELLET-BROD was evaluated by the Poland Competent Authority (PL CA) for the authorization in Poland (authorisation number: PL/2019/0375/MR), based on NEO-Actipellet-Brod evaluated by Italy CA.

The Product Assessment Report for the authorisation of NEO-Actipellet-Brod prepared by the Italy CA (dated June 2017) is considered as applicable for authorisation of the product Ratimor brodifacoum trutka granulowana.

**Conditions for the authorisation of the biocidal product Ratimor brodifacoum trutka granulowana in Poland:**

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

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: 7 (changes relate to each category of users)

**For general public against mice:**

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| Packaging sizes and packaging materials | **The maximum pack size is 50g.**  1. Edible paper tea-bag sachets (10 g - 20 g) packed in: -  -polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard,  - polyethylene (PE) or polypropylene (PP) pack,  - natron bag,  - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid,  - PE or PP buckets with lid,  - cardboard boxes with PE or PP bag or liner,  - pre-filled or refillable tamper-resistant HDPE or polypropylene mouse bait station (20g-40g). Bait stations packed in cardboard outer or plastic heat-sealed container or thermally sealing foil.  2. Bait in PP/paper film sachets, PET/PE film sachets, PE/paper film sachets or PE/aluminised film sachets (10 g - 40 g) packed in:  - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack.  - PE or PP packs,  - HDPE container,  - Natron bag,  - PP woven sack,  - Pail (PP) or bucket (PP or PE) with lid,  - PP or PE tub,  - Prefilled or refillable tamper-resistant HDPE or PP mouse bait station (20g-40g). Bait stations packed in cardboard outer or plastic heat-sealed container or thermally sealing foil  - PET/PE, PP/PE or paper/PE pouch,  - Cardboard or fibre-board pack with PE or PP bag or liner  - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid.  3. Other packaging:  - loose bait in tray (20g-40g) prefilled or refillable tamper-resistant bait station, packed in cardboard outer or plastic heat-sealed container or thermally sealing foil,  - loose bait in tray (20g-40g) (PVC or polystyrene or polypropylene or PET) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) to be used with bait station. |

**For general public against rats:**

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| Packaging sizes and packaging materials | **The maximum pack size is 150g.**  1. Edible paper tea-bag sachets (10 g - 20 g) packed in: -  -polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard,  - polyethylene (PE) or polypropylene (PP) pack,  - natron bag,  - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid,  - PE or PP buckets with lid,  - cardboard boxes with PE or PP bag or liner,  - pre-filled or refillable tamper-resistant HDPE or polypropylene mouse bait station (100g-150g). Bait stations packed in cardboard outer or plastic heat-sealed container or thermally sealing foil.  2. Bait in PP/paper film sachets, PET/PE film sachets, PE/paper film sachets or PE/aluminised film sachets (10 g - 40 g) packed in:  - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack.  - PE or PP packs,  - HDPE container,  - Natron bag,  - PP woven sack,  - Pail (PP) or bucket (PP or PE) with lid,  - PP or PE tub,  - Prefilled or refillable tamper-resistant HDPE or PP mouse bait station (100g-150g). Bait stations packed in cardboard outer or plastic heat-sealed container or thermally sealing foil  - PET/PE, PP/PE or paper/PE pouch,  - Cardboard or fibre-board pack with PE or PP bag or liner  - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid.  3. Other packaging:  - loose bait in tray (100g-150g) prefilled or refillable tamper-resistant bait station, packed in cardboard outer or plastic heat-sealed container or thermally sealing foil,  - loose bait in tray (100g-150g) (PVC or polystyrene or polypropylene or PET) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) to be used with bait station. |

**For professional use against mice:**

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| Packaging sizes and packaging materials | **The minimum pack size is 1 kg.**  **The maximum pack size is 25 kg.**   1. Bait in sachets (polypropylene/paper film, PET/polyethylene film, polyethylene/paper film, polyethylene/aluminised film) 10 g, 25 g, 30 g, 40 g supplied in the following outer packs:   -Sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box. Up to 20 kg,  -PE or PP packs. Up to 25 kg.  -HDPE container. Up to 25 kg.  -Natron bag. Up to 25 kg.  -Polypropylene woven sack up to 25 kg,  -Polypropylene pail or PP or PE, up to 20 kg,  -Prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station (20g-40g), Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil Up to 20 kg.  -PET/polyethylene, polypropylene/polyethylene or paper/polyethylene pouch. Up to 10 kg,  -Jerry can (PP), with tamper-evident screw-top lid, up to 10 kg,  - Cardboard or fibreboard with PE or PP bag or liner, up to 20 kg,  -Plastic bags (polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE) with natron bag or PP/HDPE buckets with lid or cardboard or fibreboard boxes, up to 25 kg,  -Bait (40 g) in trays (PVC or polystyrene or polypropylene or PET) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) supplied in the following outer packs: Single-use or multi-use tamper-proof HDPE or PP bait station, packed in cardboard outer or plastic heat-sealed container or thermo seal foil, up to 20 kg.   1. Loose bait packed in:   -Polyethylene (PE)-lined polypropylene (PP) sack or multi-ply paper sack, up to 10 kg.  -PE or PP packs up to 10 kg.  -Natron bag up to 10 kg.  -PP or PE bucket with lid up to 10 kg.  -Cardboard or fibreboard or carton boxes with PE or PP bag or liner. Up to 10 kg.  - Plastic bags (polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE) with natron bag or PP/HDPE buckets with lid up to 10 kg. |

**For professional use against rats:**

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| Packaging sizes and packaging materials | **The minimum pack size is 1 kg.**  **The maximum pack size is 25 kg.**   1. Bait in sachets (polypropylene/paper film, PET/polyethylene film, polyethylene/paper film, polyethylene/aluminised film) 10 g, 25 g, 30 g, 40 g, 50g, 100g, 200g supplied in the following outer packs:   -Sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box. Up to 20 kg,  -PE or PP packs. Up to 25 kg.  -HDPE container. Up to 25 kg.  -Natron bag. Up to 25 kg.  -Polypropylene woven sack up to 25 kg,  -Polypropylene pail or PP or PE, up to 20 kg,  -Prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station (up to 200g), Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil Up to 20 kg.  -PET/polyethylene, polypropylene/polyethylene or paper/polyethylene pouch. Up to 10 kg,  -Jerry can (PP), with tamper-evident screw-top lid, up to 10 kg,  - Cardboard or fibreboard with PE or PP bag or liner, up to 20 kg,  -Plastic bags (polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE) with natron bag or PP/HDPE buckets with lid or cardboard or fibreboard boxes, up to 25 kg,  -Bait (up to 200 g) in trays (PVC or polystyrene or polypropylene or PET) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) supplied in the following outer packs: Single-use or multi-use tamper-proof HDPE or PP bait station, packed in cardboard outer or plastic heat-sealed container or thermo seal foil, up to 20 kg.   1. Loose bait packed in:   -Polyethylene (PE)-lined polypropylene (PP) sack or multi-ply paper sack, up to 10 kg.  -PE or PP packs up to 10 kg.  -Natron bag up to 10 kg.  -PP or PE bucket with lid up to 10 kg.  -Cardboard or fibreboard or carton boxes with PE or PP bag or liner. Up to 10 kg.  - Plastic bags (polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE) with natron bag or PP/HDPE buckets with lid up to 10 kg. |

New packagings are consistent with packaging material as approved in the summary of the biocidal product characteristics. There is no change of user category. The same risk-mitigation measures apply.

The addition of a new materials of packaging is considered acceptable.

**Conclusion of physical, chemical and technical properties**

*According to Guidance on the Biocidal Products Regulation: Volume I Parts A+B+C Version 2.1 March 2022 and Technical Monograph No17 (3rd edition) Guidelines for specifying and managing shelf life and expiry date of crop protection products the change of packaging carried out by the applicant is possible between all types of packaging materials as long they are waterproof or have waterproof lining or where the formulation is not moisture sensitive. Therefore the new data to confirm the stability of the product in new packaging is not required.*

Detailed description of the conditions for this minor change is presented in the summary of product characteristics (SPC) and includes Poland’s national requirements.