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

**ADDENDUM**

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR MAJOR CHANGE OF NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



NYNA PELLET 25

Product type 14

Difenacoum as included in the Union list of approved active substances

Case Number in R4BP: [BC-NA039818-39]

Evaluating Competent Authority: FR CA

Date: [February 2020]

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *IT* | *-* | 05.05.2010 | Initial assessment : ACTIPELLET-DIFE (In france : NYNA D+ PELLET) |
| NA-BBS | *FR* | *BC-KR027578-12* | 05.07.2017 | National authorisation of same biocidal product : NYNA PELLET 25 |
| NA-RNL | *FR* | *BC-WL033605-25* | 28.03.2019 | Application for renewal of national authorisation |
| NA-MAC | *FR* | BC-NA039818-39 | 16/03/2020 | Major change application :   * Reduction of active substance and some coformulants * Adding categories of users * Packaging modification * Administrative changes |

Table of Contents

[Table of Contents 3](#_Toc2155617)

[*1* CONCLUSION 5](#_Toc2155618)

[*2* ASSESSMENT REPORT 6](#_Toc2155619)

[2.1 Summary of the product assessment 6](#_Toc2155620)

[2.1.1 Administrative information 6](#_Toc2155621)

[**2.1.1.1** Identifier of the product 6](#_Toc2155622)

[**2.1.1.2** Authorisation holder 6](#_Toc2155623)

[**2.1.1.3** Manufacturer(s) of the products 6](#_Toc2155624)

[**2.1.1.4** Manufacturer(s) of the active substance(s) 6](#_Toc2155625)

[2.1.2 Product composition and formulation 7](#_Toc2155626)

[**2.1.2.1** Identity of the active substance 7](#_Toc2155627)

[**2.1.2.2** Candidate(s) for substitution 7](#_Toc2155628)

[**2.1.2.3** Qualitative and quantitative information on the composition of the biocidal product 8](#_Toc2155629)

[**2.1.2.4** Information on technical equivalence 8](#_Toc2155630)

[**2.1.2.5** Information on the substance(s) of concern 8](#_Toc2155631)

[**2.1.2.6** Assessment of endocrine disruption (ED) properties of the biocidal product 8](#_Toc2155632)

[**2.1.2.7** Type of formulation 8](#_Toc2155633)

[2.1.3 Hazard and precautionary statements 8](#_Toc2155634)

[2.1.4 Authorised use(s) 9](#_Toc2155635)

[**2.1.4.1** Use description 9](#_Toc2155636)

[**2.1.4.2** Use-specific instructions for use 9](#_Toc2155637)

[**2.1.4.3** Use-specific risk mitigation measures 9](#_Toc2155638)

[**2.1.4.4** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 9](#_Toc2155639)

[**2.1.4.5** Where specific to the use, the instructions for safe disposal of the product and its packaging 10](#_Toc2155640)

[**2.1.4.6** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 10](#_Toc2155641)

[2.1.5 General directions for use 11](#_Toc2155642)

[**2.1.5.1** Instructions for use 11](#_Toc2155643)

[**2.1.5.2** Risk mitigation measures 11](#_Toc2155644)

[**2.1.5.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 11](#_Toc2155645)

[**2.1.5.4** Instructions for safe disposal of the product and its packaging 11](#_Toc2155646)

[**2.1.5.5** Conditions of storage and shelf-life of the product under normal conditions of storage 11](#_Toc2155647)

[2.1.6 Other information 11](#_Toc2155648)

[2.1.7 Packaging of the biocidal product 11](#_Toc2155649)

[2.1.8 Documentation 12](#_Toc2155650)

[**2.1.8.1** Data submitted in relation to product application 12](#_Toc2155651)

[**2.1.8.2** Access to documentation 12](#_Toc2155652)

[2.2 Assessment of the biocidal product 13](#_Toc2155653)

[2.2.1 Intended use(s) as applied for by the applicant 13](#_Toc2155654)

[2.2.2 Physical, chemical and technical properties 13](#_Toc2155655)

[2.2.3 Physical hazards and respective characteristics 15](#_Toc2155656)

[2.2.4 Methods for detection and identification 16](#_Toc2155657)

[2.2.5 Efficacy against target organisms 18](#_Toc2155658)

[**2.2.5.1** Function and field of use 18](#_Toc2155659)

[**2.2.5.2** Organisms to be controlled and products, organisms or objects to be protected 18](#_Toc2155660)

[**2.2.5.3** Effects on target organisms, including unacceptable suffering 19](#_Toc2155661)

[**2.2.5.4** Mode of action, including time delay 19](#_Toc2155662)

[**2.2.5.5** Efficacy data 19](#_Toc2155663)

[**2.2.5.6** Occurrence of resistance and resistance management 19](#_Toc2155664)

[**2.2.5.7** Known limitations 19](#_Toc2155665)

[**2.2.5.8** Evaluation of the label claims 19](#_Toc2155666)

[**2.2.5.9** Relevant information if the product is intended to be authorised for use with other biocidal product(s) 19](#_Toc2155667)

[2.2.6 Risk assessment for human health 20](#_Toc2155668)

[**2.2.6.1** Assessment of effects on Human Health 20](#_Toc2155669)

[**2.2.6.2** Exposure assessment 30](#_Toc2155670)

[**2.2.6.3** Risk characterisation for human health 42](#_Toc2155671)

[2.2.7 Risk assessment for animal health 46](#_Toc2155672)

[2.2.8 Risk assessment for the environment 46](#_Toc2155673)

[**2.2.8.1** Effects assessment on the environment 46](#_Toc2155674)

[**2.2.8.2** Exposure assessment 59](#_Toc2155675)

[**2.2.8.3** Risk characterisation 63](#_Toc2155676)

[2.2.9 Measures to protect man, animals and the environment 68](#_Toc2155677)

[2.2.10 Assessment of a combination of biocidal products 68](#_Toc2155678)

[2.2.11 Comparative assessment 68](#_Toc2155679)

[**2.2.11.1** Screening phase 68](#_Toc2155680)

[**2.2.11.2** Tier IA 68](#_Toc2155681)

[**2.2.11.3** Tier IB 68](#_Toc2155682)

[**2.2.11.4** Tier II 69](#_Toc2155683)

[**2.2.11.5** Overall conclusion 69](#_Toc2155684)

[*3* Annexes 70](#_Toc2155685)

[3.1 List of studies for the biocidal product 70](#_Toc2155686)

[3.2 Output tables from exposure assessment tools 70](#_Toc2155687)

[3.3 New information on the active substance 70](#_Toc2155688)

[3.4 Residue behaviour 70](#_Toc2155689)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 70](#_Toc2155690)

[3.6 Confidential annex 70](#_Toc2155691)

[3.7 Other 70](#_Toc2155692)

# CONCLUSION

NYNA PELLET 25 product is a type of product 14 for the control of rodents (rats and house mice) based on 0.005% (w/w) difenacoum. The biocidal product is a ready-to-use bait (pellet) , and is currently to be applied indoor, outdoor around buildings, and in open areas by professional users.

This major change application consists in :

* The reduction of active substance and co-formulants
* The addition of the non professional users
* Packaging modifications
* Administratives changes

**Physico-chemical properties**

Physico-chemical properties of the product are considered as acceptable. The product is stable for 2 years at ambient temperature. The product is not classified for the physico-chemical aspect. Analytical methods for the determination of the active substance in the formulation are available and validated.

**Efficacy**

French competent authorities (FR CA) consider that efficacy of the product NYNA PELLET 25 can be validated for the control of rats (*Rattus norvegicus* and *Rattus rattus*) and, house mice (*Mus musculus*), at the claimed application rates, when used indoors and outdoors around buildings by professionals and non-professionals users.

Nevertheless, it is to be noted that only field tests were considered to validate the efficacy of the major change. French competent authorities (FR CA) consider that laboratory tests on all target species with the product NYNA PELLET 25 must be submitted by the applicant at renewal of the authorisation.

**in France only** : The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance difenacoum. Results of the resistance monitoring must be submitted at the renewal of the product.)

**Human health**

The risk is acceptable for professionals when gloves are worn for products in bulk form and without PPE for products in sachets. Gloves are also recommended to prevent rodent-borne disease. Moreover, the mention “do not open the sachet” has to be added in the label of the product*.*

The risk is acceptable for non-professionals.

The risk for the general public is considered covered by the initial assessment.

Product label (“do not open the sachet”) and good practice advise users to prevent access to bait by children, infants and pets.

**Environment**

The major change request is a decrease in the active substance content (from 50 ppm to 25 ppm) and a reduction of 3 coformulants. Therefore, risk assessment for environment is considered covered by the initial assessment.

**GENERAL CONCLUSION :**

**In the frame of the major change application , FR CA considers that the product shall be authorized for the following uses** :

|  |  |  |
| --- | --- | --- |
| **Target organism** | **Application rates** | **Use conditions** |
| Rats (*Rattus Norvegicus, Rattus rattus*) | 100g of bait per bait point every 5-10 meters | Professionals  Indoor, outdoor around buildings and in open areas |
| Non professionnals  Indoor, outdoor around buildings |
| House mice ( *Mus musculus*) | 40g of bait per bait point every 1-2 meters | Professionals  Indoor, outdoor around buildings |
| Non professionnals  Indoor |

# ASSESSMENT REPORT – Minor Change 2019

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| NYNA PELLET 25  DIFEPELLET RAT 25  DIFEPELLET RONGEUR 25  STOP DIFEPELLET 25  SUPP’DIFEPELLET 25 | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | **TRIPLAN** |
| **Address** | **BP 258 LA POSTE FRANCAISE**  **AD500 ANDORRA LA BELLA**  **ANDORRE** |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | NOXIMA |
| **Address of manufacturer** | Carrefour Jean Monnet – Lacroix Saint-Ouen  60201 COMPIEGNE  France |
| **Location of manufacturing sites** | Carrefour Jean Monnet – Lacroix Saint-Ouen  60201 COMPIEGNE  France |

#### 

|  |  |
| --- | --- |
| **Name of manufacturer** | INDUSTRIAL CHIMICA SRL |
| **Address of manufacturer** | Via Sorgaglia 40  l-35020 ARRE (PD)  Italie |
| **Location of manufacturing sites** | Via Sorgaglia 40  l-35020 ARRE (PD)  Italie |

|  |  |
| --- | --- |
| **Name of manufacturer** | DALTA SA |
| **Address of manufacturer** | Zone industrielle RN20-BP6  82270 Montpezat de Quercy  France |
| **Location of manufacturing sites** | Zone industrielle RN20-BP6  82270 Montpezat de Quercy  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | FARMAVIT OOD |
| **Address of manufacturer** | Bul Tsar Boris III, n°63, Office 1  1612 SOFIA  Bulgaria |
| **Location of manufacturing sites** | Indulstriana 2 str  Pleven District  5960 Guliantsi  Bulgaria |

|  |  |
| --- | --- |
| **Name of manufacturer** | SOFAR France |
| **Address of manufacturer** | ZA DU DREVERS BP02  29190 PLEYBEN  France |
| **Location of manufacturing sites** | ZA DU DREVERS BP02  29190 PLEYBEN  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | AEDES PROTECTA |
| **Address of manufacturer** | 75 rue d’Orgemont  95210 SAINT-GRATIEN  France |
| **Location of manufacturing sites** | LIEU DIT DOUILLAC  81310 PARISOT  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | IRIS |
| **Address of manufacturer** | 1126A, Avenue du Moulinas,  Route de Saint-Privat  30340 SALINDRES  France |
| **Location of manufacturing sites** | 1126A, Avenue du Moulinas,  Route de Saint-Privat  30340 SALINDRES  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | HDA |
| **Address of manufacturer** | ZA LA CHARME MENEROL  63200 RIOM  France |
| **Location of manufacturing sites** | ZA LA CHARME MENEROL  63200 RIOM  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | RATOUCY SAS |
| **Address of manufacturer** | 29 Rue de la forêt LOOZE – BP 145  89303 JOIGNY CEDEX  France |
| **Location of manufacturing sites** | 29 Rue de la forêt LOOZE – BP 145  89303 JOIGNY CEDEX  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | EDIALUX |
| **Address of manufacturer** | ZA MACON EST  01750 REPLONGES  France |
| **Location of manufacturing sites** | Chez LARC – ZA de KERAMPAOU  29140 MELGVEN |

|  |  |
| --- | --- |
| **Name of manufacturer** | PROFARM SA |
| **Address of manufacturer** | Industrial Area of Thessaloniki, Entrance A, O.T. 20, Buildings 30 and 53  57022 SINDOS  Greece |
| **Location of manufacturing sites** | Industrial Area of Thessaloniki, Entrance A, O.T. 20, Buildings 30 and 53  57022 SINDOS  Greece |

|  |  |
| --- | --- |
| **Name of manufacturer** | FARMA-CHEM SA |
| **Address of manufacturer** | Industrial Area of Sindos, P.O. BOX 1026 Block 53 Zone C  57022 THESSALONIKI  Greece |
| **Location of manufacturing sites** | Industrial Area of Sindos, P.O. BOX 1026 Block 53 Zone C  57022 THESSALONIKI  Greece |

|  |  |
| --- | --- |
| **Name of manufacturer** | AGROLOGY SA |
| **Address of manufacturer** | P.O. BOX 1089, Industrial Area of Thessaloniki  57022 THESSALONIKI  Greece |
| **Location of manufacturing sites** | P.O. BOX 1089, Industrial Area of Thessaloniki  57022 THESSALONIKI  Greece |

|  |  |
| --- | --- |
| **Name of manufacturer** | AGGRESS |
| **Address of manufacturer** | EL.VENIZELOU 158 A  16341 ATHENES  Greece |
| **Location of manufacturing sites** | ARMA THEBES  3220 OIOTIA  Greece |

#### Manufacturer(s) of the active substance(s)

|  |  |
| --- | --- |
| **Active substance** | Difenacoum |
| **Name of manufacturer** | DR TEZZA S.R.L. |
| **Address of manufacturer** | Via Tre Ponti, 22 37050 - S. Maria di Zevio (VR)  Italy |
| **Location of manufacturing sites** | Via Tre Ponti, 22 37050 - S. Maria di Zevio (VR)  Italy |

### Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012.

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Difenacoum |
| **IUPAC or EC name** | 3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin |
| **EC number** | 259-978-4 |
| **CAS number** | 56073-07-5 |
| **Index number in Annex VI of CLP** | 607-157-00-X |
| **Minimum purity / content** | ≥960 g/kg |
| **Structural formula** |  |

#### Candidate(s) for substitution

Difenacoum does meet the exclusion criteria laid down in Article 5(1)(c) of Regulation (EU) No 528/2012. Difenacoum does meet the conditions laid down in Article 10(1)(a) and (e) of Regulation (EU) No 528/2012 if approved, and is therefore considered as a candidate for substitution.

**Comparative assessment**

A comparative assessement has been carried out at the European level. According to Article 1 of Commission Implementing Decision (EU) 2017/1532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council. In the absence of anticoagulant rodenticides, the use of rodenticides containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms.

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled. Therefore, the authorization of this product will be renewed for 5 years.

#### Qualitative and quantitative information on the composition of the biocidal product[[2]](#footnote-3)

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Difenacoum | 3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin | Active substance | 56073-07-5 | 259-978-4 | 0.0025 (technical) |

#### Information on technical equivalence

Activa S.r.l. is one of the approved Active Suppliers on the Article 95 list.

#### Information on the substance(s) of concern

Substances of concern are not present in the product.

#### Assessment of endocrine disruption (ED) properties of the biocidal product

According to our assessment, none of the co-formulants contained in the product NYNA PELLET 25 are identified as endocrine disruptors.

However, four co-formulants show indications of endocrine activity (please refer to confidential annex).

Based on available information, it is not possible to conclude whether these co-formulants should be considered to have ED properties or not. This should be further assessed in the frame of REACH Regulation. In case these co-formulants are finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

#### Type of formulation

|  |
| --- |
| Ready-to-use bait : pellet |

### Hazard and precautionary statements[[3]](#footnote-4)

**Classification and labelling of the products according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | STOT RE 2 |
| Hazard statement | H373 : May cause damage to organs (blood) through prolonged or repeated exposure. |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H373: May cause damage to the blood through prolonged or repeated exposure. |
| Precautionary statements | P260 - Do not breathe dust.  P314 - Get medical advice/attention if you feel unwell.  P501 - Dispose of contents and container to hazardous or special waste in accordance with national regulation |
|  | |
| Note | **-** |

### Authorised use(s)

#### Use # 1 (Not relevant in France)– House mice – professionals - indoor

Use # 1 (Not relevant in France)– House mice - professionals - indoor

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Mus musculus* (house mice) |
| **Field of use** | Indoor |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | 40 g of bait per bait point. If more than one bait point is needed, the minimum distance between bait points should be of 1 to 2 meters. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3kg.  The product is supplied in individual PE/PP sachets (5-100g) and in bulk.  The sachets (5-100 g) are wrapped in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Metal boxes (5-25kg)  - Bait box in PET/PP/PE/PVC  The product is supplied in bulk in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Sachet (PET/ALU/PET) (5-25kg) packed in cardboard box (5-50kg)  - Metal boxes (5-25kg)  - Pre-filled bait boxes in PET/PP/PE/PVC up to the claimed dose for mice/rats |

##### Use-specific instructions for use[[4]](#footnote-5)

|  |
| --- |
| - The bait station should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait station are intact and to remove rodent bodies. Re-fill bait when necessary.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice. |

##### Use-specific risk mitigation measures

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##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| --- |
| - When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided. |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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|  |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use # 2 (Not relevant in France) – Rats - professionals - indoor

##### Use description

Use # 2 (Not relevant in France) – Rats - professionals - indoor

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including delopment stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field of use** | Indoor |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | 100 g of bait per bait point. If more than one bait point is needed, the minimum distance between bait stations should be of 5-10 meters. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3kg.  The product is supplied in individual PE/PP sachets (5-100g) and in bulk.  The sachets (5-100 g) are wrapped in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Metal boxes (5-25kg)  - Bait box in PET/PP/PE/PVC  The product is supplied in bulk in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Sachet (PET/ALU/PET) (5-25kg) packed in cardboard box (5-50kg)  - Tin-plate boxes (5-25kg)  - Pre-filled bait boxes in PET/PP/PE/PVC up to the claimed dose for mice/rats |

##### Use-specific instructions for use

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| --- |
| - The bait station should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait station are intact and to remove rodent bodies. Re-fill bait when necessary.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice. |

##### Use-specific risk mitigation measures

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##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| - When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided. |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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| - |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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| - |

#### Use # 3 (Not relevant in France)– House mice and rats - professionals - outdoor around buildings

##### Use description

Use # 3 (Not relevant in France) – House mice and rats - professionals - outdoor around buildings

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Mus musculus* (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field of use** | Outdoor around building |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | - 40 g of bait per bait point for mice. If more than one bait point is needed, the minimum distance between bait points should be of 1 to 2 meters.  - 100 g of bait per bait point for rats. If more than one bait point is needed, the minimum distance between bait points should be of 5 to 10 meters. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3kg.  The product is supplied in individual PE/PP sachets (5-100g) and in bulk.  The sachets (5-100 g) are wrapped in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Metal boxes (5-25kg)  - Bait box in PET/PP/PE/PVC  The product is supplied in bulk in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Sachet (PET/ALU/PET) (5-25kg) packed in cardboard box (5-50kg)  - Tin-plate boxes (5-25kg)  - Pre-filled bait boxes in PET/PP/PE/PVC up to the claimed dose for mice/rats |

##### Use-specific instructions for use

|  |
| --- |
| - Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.  - The bait station should be visited for mice at least every 2 to 3 days at the beginning of the treatment and for rats only 5 to 7 days after the beginning of the treatment and at least weekly afterwards (for mice and rats), in order to check whether the bait is accepted, the bait station are intact and to remove rodent bodies. Re-fill bait when necessary.  - Replace any bait in bait station in which bait has been damaged by water or contaminated by dirt. |

##### Use-specific risk mitigation measures

|  |
| --- |
| - Do not apply this product directly in the burrows. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| - When placing bait stations close to surface water (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or drainage systems, ensure that bait contact with water is avoided. |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use # 4 – House mice and/or rats – trained professionnals - indoor

##### Use description

Use # 4 – House mice and rats - trained professionals - indoor

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| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Mus musculus* (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field of use** | Indoor |
| **Application method(s)** | Bait formulations:  - ready-to-use bait to be used in tamper-resistant bait stations  - ready-to-use bait may be used in covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait station |
| **Application rate(s) and frequency** | Rats  - 100 g of bait per baiting point every 5 to 10 meters.  Mice   * 40 g of bait per baiting point every 1 to 2 meters. |
| **Category(ies) of users** | Trained professionals. |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only*** *: minimum pack size of 5 kg)*  The product is supplied in individual PE/PP sachets (5-100g) and in bulk.  The sachets (5-100 g) are wrapped in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Metal boxes (5-25kg)  - Bait box in PET/PP/PE/PVC  The product is supplied in bulk in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Sachet (PET/ALU/PET) (5-25kg) packed in cardboard box (5-50kg)  - Tin-plate boxes (5-25kg)  - Pre-filled bait boxes in PET/PP/PE/PVC up to the claimed dose for mice/rats |

##### Use-specific instructions for use

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| - Remove the remaining product at the end of treatment period.  - Follow any additional instructions provided by the relevant code of best practice. |

##### Use-specific risk mitigation measures

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| - Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.  - Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.  - To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.  - Do not use the product in pulsed baiting treatments. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| - When placing bait points close to water drainage systems, ensure that bait contact with water is avoided. |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use # 5 – Mice and/or rats - trained professionals - outdoor around buildings

##### Use description

Use # 5 – Mice and rats - trained professionals - outdoor around buildings

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| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Mus musculus* (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field of use** | Outdoor around buildings |
| **Application method(s)** | Bait formulations:  - ready-to-use bait to be used in tamper-resistant bait stations  - ready-to-use bait may be used in covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait station |
| **Application rate(s) and frequency** | Rats  100 g of bait per baiting point every 5 to 10 meters.  Mice  40 g of bait per baiting point every 1 to 2 meters. |
| **Category(ies) of users** | Trained professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****in France only*** *:* Minimum pack size of 5 kg)  The product is supplied in individual PE/PP sachets (5-100g) and in bulk.  The sachets (5-100 g) are wrapped in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Metal boxes (5-25kg)  - Bait box in PET/PP/PE/PVC  The product is supplied in bulk in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Sachet (PET/ALU/PET) (5-25kg) packed in cardboard box (5-50kg)  -Tin-plate boxes (5-25kg)  - Pre-filled bait boxes in PET/PP/PE/PVC up to the claimed dose for mice/rats |

##### Use-specific instructions for use

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| - Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.  - Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.  - [When available] Follow any additional instructions provided by the relevant code of best practice. |

##### Use-specific risk mitigation measures

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| - Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.  - Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.  - To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.  - Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.  - Do not use this product in pulsed baiting treatments.  - Do not apply this product directly in the burrows. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| - When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided. |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use # 6 – Rats - trained professionals - Outdoor open areas

##### Use description

Use # 6 – Rats - trained professionals - Outdoor open areas

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| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field of use** | Outdoor open areas |
| **Application method(s)** | Bait formulations:  - ready-to-use bait to be used in tamper-resistant bait stations or in covered and protected baiting points |
| **Application rate(s) and frequency** | Bait products  - 100 g of bait per baiting point every 5 to 10 meters. |
| **Category(ies) of users** | Trained professionals only |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(***in France only** *:* Minimum pack size of 5 kg)  The product is supplied in individual PE/PP sachets (5-100g) and in bulk.  The sachets (5-100 g) are wrapped in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Tin -plate boxes (5-25kg)  - Bait box in PET/PP/PE/PVC  The product is supplied in bulk in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Sachet (PET/ALU/PET) (5-25kg) packed in cardboard box (5-50kg)  - Tin-plate boxes (5-25kg)  - Pre-filled bait boxes in PET/PP/PE/PVC up to the claimed dose for mice/rats |

##### Use-specific instructions for use

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| --- |
| - Protect bait from the atmospheric conditions. Place the bait stations in areas not liable to flooding.  - Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.  - Follow any additional instructions provided by the relevant code of best practice. |

##### Use-specific risk mitigation measures

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| --- |
| - Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.  - To reduce risk of secondary poisoning, search for and remove dead rodents during treatmentat frequent intervals*,* in line with the recommendations provided by the relevant code of best practice.  - Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.  - Do not use this product in pulsed baiting treatments.  - Do not apply this product directly in the burrows |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| --- |
| - When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided. |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use # 7 – House Mice – General public - Indoor

##### Use description

Use # 7 – House Mice – General public - Indoor

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| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Mus musculus* (house mice) |
| **Field of use** | Indoor |
| **Application method(s)** | Bait formulations:  - ready-to-use bait to be used in tamper-resistant bait stations or in covered and protected baiting points |
| **Application rate(s) and frequency** | 40 g of bait per bait point for mice.  If more than one bait point is needed, the minimum distance between bait points should be of 1 to 2 meters. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | Maximum packaging 150g  The product is supplied in individual PE/PP sachets (5-40g) packed in :  - Buckets (PE/PP)  - Bottles/Containers (PE/PP)  - Cardboard boxes  - Films (PE/PP)  - Tin-plate boxes  - Bait boxes PET/PP/PE/PVC |

##### Use-specific instructions for use

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| - The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. |

##### Use-specific risk mitigation measures

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##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use # 8 – Rats – General public - Indoor

##### Use description

Use # 8 – Rats – General public - Indoor

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field of use** | Indoor |
| **Application method(s)** | Bait formulations:  - ready-to-use bait to be used in tamper-resistant bait stations or in covered and protected baiting points |
| **Application rate(s) and frequency** | 100 g of bait per baiting point.  If more than one bait point is needed, the minimum distance between bait points should be of 5 to 10 meters. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Maximum packaging 150g.  The product is supplied in individual PE/PP sachets (5-100g) packed in :  - Buckets (PE/PP)  - Bottle/Containers (PE/PP)  - Cardboard boxes  - Films (PE/PP)  - Tin-plate boxes  - Bait boxes PET/PP/PE/PVC |

##### Use-specific instructions for use

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| - The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. |

##### Use-specific risk mitigation measures

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##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use # 9 – Rats – General public - outdoor around buildings

##### Use description

Use # 9 – Rats – General public – outdoor around buildings

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field of use** | Outdoor around buildings |
| **Application method(s)** | Bait formulations:  - ready-to-use bait to be used in tamper-resistant bait stations or in covered and protected baiting points |
| **Application rate(s) and frequency** | 100 g of bait per baiting point.  If more than one bait point is needed, the minimum distance between bait points should be of 5 to 10 meters. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | Maximum packaging 150g.  The product is supplied in individual PE/PP sachets (5-100g) packed in :  - Buckets (PE/PP)  - Bottles/Containers (PE/PP)  - Cardboard boxes  - Films (PE/PP)  - Tin plate boxes  - Bait boxes PET/PP/PE/PVC |

##### Use-specific instructions for use

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| - Place the bait stations in areas not liable to flooding.  - Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.  - The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. |

##### Use-specific risk mitigation measures

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##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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##### Where specific to the use, the instructions for safe disposal of the product and its packaging

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##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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### General directions for use

#### Instructions for use[[5]](#footnote-6)

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| **FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS**  - Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.  - Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.  - Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.  - The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.  - The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).  - Where possible, bait stations must be fixed to the ground or other structures.  - Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened *(see section 5.3 for the information to be shown on the label)*.  - *[If national policy or legislation requires it]* When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.  - Bait should be secured so that it cannot be dragged away from the bait station.  - Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.  - Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.  Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).  - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.  ***FOR TRAINED PROFESSIONAL ONLY***  *- The* frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.  - If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.  - If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.  ***FOR PROFESSIONNALS ONLY***  ***-*** Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.  -Remove the remaining bait or the bait stations at the end of the treatment period.  - For non-emptiable sachets - Do not open the sachets containing the bait.  Loose pellets-granules, grains:   * Place the bait in the baiting point by using a dosage devise. Specify the methods to minimise dust (e.g. wet wiping). * Decanting is to be avoided. In case decanting cannot be avoided, an RPE of APF 10 has to be used.   **FOR NON PROFESSIONAL USERS**  - Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.  - Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.  - Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.  - Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).  - Where possible, bait stations must be fixed to the ground or other structures.  - Do not open the sachets containing the bait  - Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.  - Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.  - Do not place bait stations near water drainage systems where they can come into contact with water.  - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.  - Remove the remaining bait or the bait stations at the end of the treatment period. |

#### Risk mitigation measures

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| **FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS**  - Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*".  - The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only".  ***FOR TRAINED PROFESSIONAL ONLY***  -Do not use in areas where resistance to the active substance can be suspected.  - Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.  - Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.  - Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.  - Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*.  - ***FOR PROFESSIONAL ONLY***  -To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). *[Where relevant, specify if more frequent or daily inspection is required].*  - Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.  - The product information (i.e. label and/or leaflet) shall clearly show that:   * the product shall not be supplied to the general public (e.g. "for professionals only"). * the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only"). * users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").   - Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.  **FOR NON PROFESSIONAL USERS**  - Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.  - Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).  - The product information (i.e. label and/or leaflet) shall clearly show that:  the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").  users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").  - Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.  - Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.  - Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*. |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| * This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. * Skin contact: Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with warm water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. * Antidote: vitamin K1 (phytomedione). Contact poison treatment specialist for antidote dosage and INR (or PT) monitoring. * Keep the container or label available.   - Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre or emergency telephone number.  - Hazardous to wildlife. |

#### Instructions for safe disposal of the product and its packaging

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| - At the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

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| - Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.  - Store in places prevented from the access of children, birds, pets and farm animals.  - Keep out of reach of children  - Shelf life: 2 years. |

### Other information

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| - Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.  - Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.  - This product contains a bittering agent and a dye. |

### Packaging of the biocidal product

* **MAJOR CHANGE for NYNA PELLET 25 - 2019 (FR CA):**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Sachets PE/PP wrapped in:  -Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  -Cardboard boxes (5-50kg)  Bags/Films PE/PP (5-25kg)  - Tin-plate boxes (5-25kg)  - Bait box in PET/PP/PE/PVC | Rats : 5-10-15-20-  25-30-40-50-75-100g) (Mice : 5-10-15-20-25-30-40g) | PE/PP | / | Professionals users | Yes |
| Buckets-Barrel | 5-30kg | PP/PE | / | Professionals users | Yes |
| paper  bags with or without plastic film PE/PP inside | 5-30kg | Paper bag | / | Professionals users | Yes |
| PE/PP bags | 5-25kg | PE/PP | / | Professionals users | Yes |
| Tin-plate box | 5-25kg | metal (without varnish) | / | Professionals users | Yes |
| Cardboard box | 5-50kg | carton | / | Professionals users | Yes |
| Pre-filled bait boxes | -mouse : 127 x 95 x 35 mm  - rats : 230 x 135 x 85 mm | PET/PP/PE/PVC | / | Professionals users | Yes |
| Sachet | 5-25 kg | PET/Alu/PET | / | Professionals users | Yes |
| Sachets PE/PP wrapped in:  - Buckets (PE/PP)  - Bottles/Containers (PE/PP)  - Cardboard boxes  - Films (PE/PP)  - Tin-plate boxes  - Bait boxes PET/PP/PE/PVC | Rats : 5-  10-15-20-25-30-40-50-75-100g) (Mice : 5-10-15-20-25-30-40g) | PE/PP | / | non – professionals | Yes |

### Documentation

#### Data submitted in relation to product application

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

**Physico-chemical data**

* Validation of the analytical method for the determination of difenacoum in DPA25V1 in compliance with SANCO/3030/99 rev. 4 from 11/07/00
* Validation of the analytical method for the determination of difenacoum in DPE25V1
* Physico-chemical tests before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on DPE25V1
* Analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on DPE25V1 Batch 17-071 Prod.: 03/17

**Efficacy data**

A laboratory test, rodenticide mortality and palatability evaluation, with SD rats, with exposure to **NEO-ACTIPELLET-DIFE (0.0025% w/w Difenacoum).**

A semi field test, rodenticide mortality and palatability evaluation, with *Rattus norvegicus*, with exposure **Bromadiolone 0.0027% w/w Pellet bait.**

A field test was carried out with house mice (***Mus musculus***), with exposure to **NEO-ACTIPELLET-DIFE (0.0025% w/w Difenacoum)**.

A field test was carried out with brown rats (***Rattus norvegicus***), with exposure to **NEO-ACTIPELLET-DIFE (0.0025% w/w Difenacoum)**.

A field test was carried out with black rats (***Rattus rattus***), with exposure to **DPE25V1 (0.0025% w/w Difenacoum)**.

#### Access to documentation

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

The applicant has submitted letters of access for the following data :

- Difenacoum date for Post-Annex I inclusion in Directive 98/8/CE, compliance Directive 2008/81/CE and approval under European Regulation 528/2012

Difenacoum (CAS No: 56073-07-5) data according to the Implementing Regulation 2017/1379 renewing the approval of Difenacoum as an active substance for use in biocidal products (PT-14) under the European Regulation 528/2012

ACTIPELLET-DIFE (PT14) data for Authorisation purpose according to article 32 of European Regulation 528/2012

## Assessment of the biocidal product

### Intended use(s) as applied for by the applicant

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

**Table 1. Use # 1 – House mice and/or Rats – Trained professionals – Indoor**

|  |  |
| --- | --- |
| Product type | PT14 - Rodenticides (Pest control) |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticides |
| Target organism(s) (including development stage) | Mus musculus House mouse Juveniles Mus musculus House mouse Adults Rattus norvegicus Brown rat Juveniles Rattus norvegicus Brown rat Adults Rattus rattus Roof rat Juveniles Rattus rattus Roof rat Adults |
| Field(s) of use | Indoor Indoor |
| Application method(s) | Bait application  Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations  - [Covered and protected baiting points] |
| Application rate(s) and frequency | Rats : 100g of bait per baiting point every 5 to 10 meters. Mice: 40g of bait per baiting point every 1 to 2 meters. - -  Bait products :  Rats :  100g of bait per baiting point every 5 to 10 meters.  Mice :  40g of bait per baiting point every 1 to 2 meters. |
| Category(ies) of users | Industrial Trained professional |
| Pack sizes and packaging material | Minimum pack size of 3kg.  (**In France only** : minimum pack size of 5kg)  The product is supplied in individual PE/PP sachets (5-100g) and in bulk.  The sachets (5-100 g) are wrapped in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Metal boxes (5-25kg)  - Bait box in PET/PP/PE/PVC  The product is supplied in bulk in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Sachet (PET/ALU/PET) (5-25kg) packed in cardboard box (5-50kg)  - Metal boxes (5-25kg)  - Pre-filled bait boxes in PET/PP/PE/PVC up to the claimed dose for mice/rats |

**Table 2. Use # 2 – House mice and/or Rats -– Trained professionals – Outdoor around buildings**

|  |  |
| --- | --- |
| Product type | PT14 - Rodenticides (Pest control) |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticides |
| Target organism(s) (including development stage) | Mus musculus House mouse Juveniles Mus musculus House mouse Adults Rattus norvegicus Brown rat Juveniles Rattus norvegicus Brown rat Adults Rattus rattus Roof rat Juveniles Rattus rattus Roof rat Adults |
| Field(s) of use | Outdoor Outdoor around buildings |
| Application method(s) | Bait application  Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - [Covered and protected baiting points] |
| Application rate(s) and frequency | Rats : 100g of bait per baiting point every 5 to 10 meters. Mice : 40g of bait per baiting point every 1 to 2 meters. - -  Bait products :  Rats :  100g of bait per baiting point every 5 to 10 meters.  Mice :  40g of bait per baiting point every 1 to 2 meters. |
| Category(ies) of users | Industrial Trained professional |
| Pack sizes and packaging material | Minimum pack size of 3kg.  (**In France only** : minimum pack size of 5kg)  The product is supplied in individual PE/PP sachets (5-100g) and in bulk.  The sachets (5-100 g) are wrapped in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Metal boxes (5-25kg)  - Bait box in PET/PP/PE/PVC  The product is supplied in bulk in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Sachet (PET/ALU/PET) (5-25kg) packed in cardboard box (5-50kg)  - Metal boxes (5-25kg)  - Pre-filled bait boxes in PET/PP/PE/PVC up to the claimed dose for mice/rats |

**Table 3. Use # 3 – House mice and/or Rats – Trained professionals – Outdoor open areas and waste dumps**

|  |  |
| --- | --- |
| Product type | PT14 - Rodenticides (Pest control) |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticides |
| Target organism(s) (including development stage) | Rattus norvegicus Brown rat Juveniles Rattus norvegicus Brown rat Adults Rattus rattus Roof rat Juveniles Rattus rattus Roof rat Adults Mus musculus House mouse Juveniles Mus musculus House mouse Adults |
| Field(s) of use | Outdoor Outdoor open areas and waste dumps |
| Application method(s) | Bait application  Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - [Covered and protected baiting points] |
| Application rate(s) and frequency | Rats : 100g of bait per baiting point every 5 to 10 meters. Mice : 40g of bait per baiting point every 1 to 2 meters. - -  Bait products :  Rats :  100g of bait per baiting point every 5 to 10 meters.  Mice :   40g of bait per baiting point every 1 to 2 meters. |
| Category(ies) of users | Industrial Trained professional |
| Pack sizes and packaging material | Minimum pack size of 3kg.  (**In France only** : minimum pack size of 5kg)  The product is supplied in individual PE/PP sachets (5-100g) and in bulk.  The sachets (5-100 g) are wrapped in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Metal boxes (5-25kg)  - Bait box in PET/PP/PE/PVC  The product is supplied in bulk in :  - Buckets/Barrels (PE/PP) (5-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (5-30kg)  - Cardboard boxes (5-50kg)  - Bags/Films PE/PP (5-25kg)  - Sachet (PET/ALU/PET) (5-25kg) packed in cardboard box (5-50kg)  - Metal boxes (5-25kg)  - Pre-filled bait boxes in PET/PP/PE/PVC up to the claimed dose for mice/rats |

**Table 4. Use # 4 – House mice - Professionals - Indoor**

|  |  |
| --- | --- |
| Product type | PT14 - Rodenticides (Pest control) |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticides |
| Target organism(s) (including development stage) | Mus musculus House mouse Juveniles Mus musculus House mouse Adults |
| Field(s) of use | Indoor Indoor |
| Application method(s) | Bait application  Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations |
| Application rate(s) and frequency | Mice: 40g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1 to 2 meters. - -  Bait products :  Mice :  40g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1 to 2 meters. |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | Minimum pack size of 3kg.  The product is supplied in individual PE/PP sachets (5-100g) and in bulk.  The sachets (5-100 g) are wrapped in :  - Buckets/Barrels (PE/PP) (3-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (3-30kg)  - Cardboard boxes (3-50kg)  - Bags/Films PE/PP (3-25kg)  - Metal boxes (3-25kg)  - Bait box in PET/PP/PE/PVC  The product is supplied in bulk in :  - Buckets/Barrels (PE/PP) (3-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (3-30kg)  - Cardboard boxes (3-50kg)  - Bags/Films PE/PP (3-25kg)  - Sachet (PET/ALU/PET) (3-25kg) packed in cardboard box (3-50kg)  - Metal boxes (3-25kg)  - Pre-filled bait boxes in PET/PP/PE/PVC up to the claimed dose for mice |

**Table 5. Use # 5 – Rats - Professionals - Indoor**

|  |  |
| --- | --- |
| Product type | PT14 - Rodenticides (Pest control) |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticides |
| Target organism(s) (including development stage) | Rattus norvegicus Brown rat Juveniles Rattus norvegicus Brown rat Adults Rattus rattus Roof rat Juveniles Rattus rattus Roof rat Adults |
| Field(s) of use | Indoor Indoor |
| Application method(s) | Bait application  Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations |
| Application rate(s) and frequency | Rats : 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters. - -  Bait products :  Rats :  100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters. |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | Minimum pack size of 3kg.  The product is supplied in individual PE/PP sachets (5-100g) and in bulk.  The sachets (5-100 g) are wrapped in :  - Buckets/Barrels (PE/PP) (3-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (3-30kg)  - Cardboard boxes (3-50kg)  - Bags/Films PE/PP (3-25kg)  - Metal boxes (3-25kg)  - Bait box in PET/PP/PE/PVC  The product is supplied in bulk in :  - Buckets/Barrels (PE/PP) (3-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (3-30kg)  - Cardboard boxes (3-50kg)  - Bags/Films PE/PP (3-25kg)  - Sachet (PET/ALU/PET) (3-25kg) packed in cardboard box (3-50kg)  - Metal boxes (3-25kg)  - Pre-filled bait boxes in PET/PP/PE/PVC up to the claimed dose for rats |

**Table 6. Use # 6 – House mice and/or Rats - Professionals - Outdoor around buildings**

|  |  |
| --- | --- |
| Product type | PT14 - Rodenticides (Pest control) |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticides |
| Target organism(s) (including development stage) | Mus musculus House mouse Juveniles Mus musculus House mouse Adults Rattus norvegicus Brown rat Juveniles Rattus norvegicus Brown rat Adults Rattus rattus Roof rat Juveniles Rattus rattus Roof rat Adults |
| Field(s) of use | Outdoor Outdoor around buildings |
| Application method(s) | Bait application  Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. |
| Application rate(s) and frequency | Rats : 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters. Mice: 40g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1 to 2 meters. - -  Bait products :  Rats :  100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters.  Mice :  40g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1 to 2 meters. |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | Minimum pack size of 3kg.  The product is supplied in individual PE/PP sachets (5-100g) and in bulk.  The sachets (5-100 g) are wrapped in :  - Buckets/Barrels (PE/PP) (3-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (3-30kg)  - Cardboard boxes (3-50kg)  - Bags/Films PE/PP (3-25kg)  - Metal boxes (3-25kg)  - Bait box in PET/PP/PE/PVC  The product is supplied in bulk in :  - Buckets/Barrels (PE/PP) (3-30kg)  - Bags (paper bags with or without plastic film in PE/PP inside) (3-30kg)  - Cardboard boxes (3-50kg)  - Bags/Films PE/PP (3-25kg)  - Sachet (PET/ALU/PET) (3-25kg) packed in cardboard box (3-50kg)  - Metal boxes (3-25kg)  - Pre-filled bait boxes in PET/PP/PE/PVC up to the claimed dose for mice/rats |

**Table 7. Use # 7 – House mice - General Public - Indoor**

|  |  |
| --- | --- |
| Product type | PT14 - Rodenticides (Pest control) |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticides |
| Target organism(s) (including development stage) | Mus musculus House mouse Juveniles Mus musculus House mouse Adults |
| Field(s) of use | Indoor Indoor |
| Application method(s) | Bait application  Ready-to-use bait in sachets to be used in tamper-resistant bait stations. |
| Application rate(s) and frequency | Mice: 40g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1 to 2 meters. - -  Bait products:  Mice: 40g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1 to 2 meters. |
| Category(ies) of users | General public (non-professional) |
| Pack sizes and packaging material | Maximum packaging 50g (mice only) and 150g (mice and rats)  The product is supplied in individual PE/PP sachets (5-40g) packed in :  - Buckets (PE/PP)  - Flacons/Containers (PE/PP)  - Cardboard boxes  - Films (PE/PP)  - Metal boxes  - Bait boxes PET/PP/PE/PVC |

**Table 8. Use # 8 – Rats - General Public - Indoor**

|  |  |
| --- | --- |
| Product type | PT14 - Rodenticides (Pest control) |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticides |
| Target organism(s) (including development stage) | Rattus norvegicus Brown rat Juveniles Rattus norvegicus Brown rat Adults Rattus rattus Roof rat Juveniles Rattus rattus Roof rat Adults |
| Field(s) of use | Indoor Indoor |
| Application method(s) | Bait application  Ready-to-use bait in sachets to be used in tamper-resistant bait stations. |
| Application rate(s) and frequency | Rats : 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters. - -  Bait products :  Rats: 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters. |
| Category(ies) of users | General public (non-professional) |
| Pack sizes and packaging material | Maximum packaging 150g.  The product is supplied in individual PE/PP sachets  (5-100g) packed in :  - Buckets (PE/PP)  - Flacons/Containers (PE/PP)  - Cardboard boxes  - Films (PE/PP)  - Metal boxes  - Bait boxes PET/PP/PE/PVC |

**Table 9. Use # 9 – Rats - General Public - Outdoor around buildings**

|  |  |
| --- | --- |
| Product type | PT14 - Rodenticides (Pest control) |
| Where relevant, an exact description of the authorised use | Not relevant for rodenticides |
| Target organism(s) (including development stage) | Rattus norvegicus Brown rat Juveniles Rattus norvegicus Brown rat Adults Rattus rattus Roof rat Juveniles Rattus rattus Roof rat Adults |
| Field(s) of use | Outdoor Outdoor around buildings |
| Application method(s) | Bait application  Ready-to-use bait in sachets to be used in tamper-resistant bait stations. |
| Application rate(s) and frequency | Rats: 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters. - -  Bait products :  Rats:100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters. |
| Category(ies) of users | General public (non-professional) |
| Pack sizes and packaging material | Maximum packaging 150g.  The product is supplied in individual PE/PP sachets  (5-100g) packed in :  - Buckets (PE/PP)  - Flacons/Containers (PE/PP)  - Cardboard boxes  - Films (PE/PP)  - Metal boxes  - Bait boxes PET/PP/PE/PVC |

### Physical, chemical and technical properties

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | PA-U10- METDESCR  Visual method | DPE25V1 | Heterogeneous blue granules in transparent PP bag | Demangel B.2017  Report n° 17-  920010-015 |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa |
| Acidity / alkalinity |  |  |  |  |
| Relative density / bulk density |  |  |  |  |
| Storage stability test – **accelerated storage** | CIPAC MT  46.3 | DPE25V1  DPE25V1 | |  |  |  | | --- | --- | --- | | **Test** | **Initial characterisation** | **After 14 days at 54°C** | | Packaging | transparent plastic bag | transparent plastic bag | | Weight variation (%) | - | -3.9% | | Appearance (Colour, odour and physical state) | Heterogeneous blue pellets | Heterogeneous blue pellets | | Difenacoum active ingredient content validated in section 2.2.4 | 0.00216 % w/w | 0.00212 % w/w | | variation (%) | - | -1.9% | | Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally) | - | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena | | pH value (1% aqueous dilution) | 6.1 | 5.6 | | Relative density | 1.1833 g/mL at 20°C | 1.1851 g/mL at 20°C |   **Appearance and stability of the commercial type Package**   |  |  |  | | --- | --- | --- | | **Test** | **Initial characterisation** | **After 12 weeks at 35°C** | | Packaging (PET/Al/PET) | no modification | no modification | | Weight variation (%) | - | A1: - 0.24% A2: - 0.22% | | Appearance (Colour, odour and physical state) | Blue green (shortcode BLG 6) solid pellet, with characteristic odour | Blue green (shortcode BLG 6)  solid pellet, with characteristic odour | | Difenacoum active ingredient content validated in section 2.2.4 | 0.0027 ± 0.0001 % w/w | 0.0025 ± 0.0001 % w/w | | Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally) | - | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena | | pH value (1% aqueous dilution) | 7.0 at ambient temperature | 6.6 at ambient temperature | | Relative density | 1.3740 g/mL at 20°C | 1.3728 g/mL at 20°C | | Dustiness | 1.1 mg  (nearly dust-free) | 1.2 mg  (nearly dust-free) | | Demangel B.2018  Report n° 17-920010-035  Brioschi M. 2017  Report n°: CH- 197/2017 |
| Particle size distribution, content of dust/fines, attrition, friability | CIPAC  MT178 | DPE25V1 | **Before** the accelerated storage procedure for 14 days at 54±2°C  The attrition resistance of the test item was 100.0%.  **After** the accelerated storage procedure for 14 days at 54±2°C  The attrition resistance of the test item was 100.0%. | Demangel B.2017  Report n° 17-  920010-015 |
| Persistent foaming |  |  |  |  |
| Flowability/Pourability/Dustability | CIPAC  MT178 | DPE25V1 | The test item did not drop spontaneously through the 5-mm sieve after an accelerated storage procedure for 14 days at 54 °C ± 2 °C under pressure.  The mean percentage of the test item, which remained on the 5-mm sieve after 5 liftings, was 66.6% w/w.  The mean percentage of the test item, which remained on the 5-mm sieve after 20 liftings, was 30.5% w/w.  The result obtained was not due to an agglomeration of the granules (caking effect) but due to the size of the granules. The test is not suitable to use, this test is not relevant. | Demangel B.2017  Report n° 17-  920010-015 |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| NYNA PELLET P 25 (DPE25V1) is a ready-to-use rodenticide. The accelerated storage stability data showed that the aspect of the test item and the packaging materials were considered stable after 12 weeks at 35 °C and after 8 weeks at 40°C. Results of the accelerated storage studies can be extrapolate for a stability of product for 2 years at ambient temperature. |

### Physical hazards and respective characteristics

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

### The product NYNA PELLET 25 (Difenacoum 0.005%) was a same product than NYNA D+ PELLET (Difenacoum 0.005%). The flammability and auto-ignition data have been approved for the product NYNA PELLET 25 (Difenacoum 0.005%) according to studies presented for the product NYNA D+ PELLET (Difenacoum 0.005%). The product NYNA D+ PELLET doesn’t present any explosive properties or combustive properties. The product is neither flammable nor auto-flammable at room temperature (Spontaneous ignition temperature 279.6°C).

# Both products contain the same components and their concentrations are identical or reduced by half. For the concentration of active substance, it’s reduced by half in the product NYNA PELLET 25 (Difenacoum 0.0025%) and is compensated by an increase of cereals (not classified). Considering the composition of both biocidal products, results on flammability and self-ignition performed on NYNA D+ PELLET (Difenacoum 0.005%) can be extrapolated to NYNA PELLET 25 (Difenacoum 0.0025%).

### Methods for detection and identification

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

A complete analytical method with validated linearity, specificity, precision and accuracy has been developed to measure the quantity of active ingredient in NYNA PATE 25 (DPA25V1) 0.0025% Difenacoum.

A complementary analytical method for the determination of Difenacoum in NYNA PELLET 25 (DPE25V1) with specificity, accuracy and precision of the method has been conducted.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements**  **precision** | **Linearity** | **Specificity** | **Recovery rate (%)** | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean |
| difenacoum | HPLC-UV | 5.19 µg/mL  N=2 (2 levels of concentrations)  RSD = 1.77%  10.37 µg/mL  N=2 (2 levels of concentrations)  RSD = 1.14%  15.56 µg/mL  N=2 (2 levels of concentrations)  RSD = 1.61%  0.0027% (n=6) RSD = 1.23% | Calibration solutions of the reference items at five concentrations between 5.19 µg/mL to 15.56 µg/mL | A comparison of the chromatograms of the solvent wash, Difenacoum reference material,  Placebo and test item solutions, shows that, following the operating conditions recommended in the analytical method, the Difenacoum peak was well separated and there were no interferences with the Placebo. (y= 156075x-3705  R²= 0.99908) | 0.0027%  (n=6) | 0.0027% | / | Brioschi M. 2017  Report n°: CH-200/2017 |
| difenacoum | HPLC-UV | 0.00256% w/w  n=5  RSD = 0.91% | Calibration solutions of the reference items at five concentrations between 50% and 150% of the expected concentration were analysed.  The response of the detector during the analysis of  Difenacoum was linear within the  range of 0.97 mg/L to 3.04 mg/L (y = 1.03x – 0.0517; r = 0.9993). | Retention time for difenacoum Matches between Reference item and test item,confirming the identity of the analyte.  No interference was observed in the solvent blank, the formulation blank, the reference item and the test item at theretention time of Difenacoum | 1.96  1.94  mg/L (2 levels of concentration n=2) | 97%  98.7% | / | Ricau H. 2016.  Report n° 16-  920010-  006 |
| difenacoum | HPLC-UV | 0.00216% w/w  n=5  RSD = 1.61% | See report of  the study 16-  920010-006 | Retention time for difenacoum Matches between Reference item and test item, confirming the identity of the analyte.  No interference was observed in the solvent blank, the formulation blank, the reference item and the test item at the retention time of Difenacoum | 1.98  2.22(2 levels of concentration n=2) | 103.8%  102.9% | The limit of  determination  and the limit of  detection are  not available | Ricau H. 2017.  Report n° 17-  920010-  018 |

### Efficacy against target organisms

#### Function and field of use

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

The product is a rodenticide (PT14) intended to be used by professional and non-professional users.

Now the applicant requires an authorisation for the same product but containing 0.0025 % w/w difenacoum instead of 0.005 % w/w, for the following uses:

-For professional users: Outdoor around buildings for *Rattus norvegicus* and *Rattus rattus*

Indoor for *Mus musculus.*

-For non-professional users: Outdoor around buildings for *Rattus norvegicus* and *Rattus rattus*

Indoor for *Mus musculus*.

#### Organisms to be controlled and products, organisms or objects to be protected

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

#### Effects on target organisms, including unacceptable suffering

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

#### Mode of action, including time delay

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

#### Efficacy data

New data on efficacy have been provided to prove the efficacy of the product after the reduction of active substance (Difenacoum) from 0.005% w/w to 0.0025% w/w.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| **PT 14** | Non-professional  Professional  Indoor | **NEO-ACTIPELLET-DIFE**  Difenacoum 0.0025% w/w Pellet bait.  **NEO-ACTIPELLET-DIFE** is identical to **NYNA PELLET 25** | *Rattus norvegicus*  10 Rats: 5 males and 5 females. | Laboratory test : Rodenticide mortality and palatability Test  The Challenge diet consists in the Laboratory standard diet. | The animals were placed in transparent polycarbonate cages 43\*27\*18 (h) cm in size, they were divided by sex and treatment group:  Phase I (Pre-Test): one animal/cage-50g of the ground standard diet/24h after every administration the food was replaced/3 days.  Phase II (Test): one animal/cage/ Choice system between 2 bags of test material and challenge diet/24h after every administration the food was replaced/ 4 days.  Phase III (Post-test observation): 3 or 5 animals/cage were put depending on the animal weight according to internal procedure/laboratory diet/14 days/ Animals were weighted daily. | 60% mortality  <20% palatability  The product is NOT PALATABLE.  RI = 2 | Report No: **S-2017-00462-1 SAM** |
| **PT 14** | Non-professional  Professional  Indoor | **Bromadiolone 0.0027% w/w Pellet bait.** | *R. norvegicus*  10 rats (5 females and 5 males) | Semi field trial  Simulation of the natural habitat of rodents under controlled conditions | The test system was held in society in a circular enclosure and free to choose any of the two types of food available (standard feed and test item).  The test consisted of an acclimation period (3 days), followed by a pre-test for assessing the rate of food intake (4 days) and finally the test in which the test item was given during 4 days. Daily observations were carried out from the beginning of the test.  Drinking water, EPA standard feed and the product tested were supplied *ad libitum*. | 100% mortality within 7 days  45% palatability  RI = 4  Read across between this product and NYNA PELLET 25 not accepted (different active substance and composition) to justify the palatability of the new composition. | Report No: **68216-1** |
| **PT 14** | Non-professional  Professional  Indoor | **NEO-ACTIPELLET-DIFE**  Difenacoum 0.0025% w/w Pellet bait.  (Identical to **NYNA PELLET 25**) | *M. musculus*  Overall estimated population: about 50-60 mice. | Field trial on an agricultural habitat (breeding stable for chicken). No rodenticide had been used at the site for at least 6 months.  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment, the food/bait at each station was weighed and replenished, and the consumption was calculated. During the treatment census, searches were conducted for dead and dying mice around the sites. | 8 bait stations and 8 tracking patches were used.  Pre census baiting: 5 days (40 g of maize grain and poultry/pig feed per station per day)  Treatment : 40 g of poisoned test bait in each lockable bait station (total 8 bait stations) during 12 days  Post-baiting: 6 days  (40 g of maize grain and poultry/pig feed per station per day) | Estimated efficacy = 100 %  Pre-baiting plateau = 200.3 g/day  Post-baiting = 0 g  4 mice dead  RI = 1  **Key study** | Trial code: **2032.BCD.SAG17** |
| **PT 14** | Non-professional  Professional  Indoor  Outdoor (around buildings) | **NEO-ACTIPELLET-DIFE**  Difenacoum 0.0025% w/w Pellet bait.  (Identical to **NYNA PELLET 25**) | *R. norvegicus*  Overall estimated population: about 35-45 rats. | Field trial on an agricultural habitat (breeding stable for cows). No rodenticide had been used at the site for at least 3 months.  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment, the food/bait at each station was weighed and replenished, and the consumption was calculated. During the treatment census, searches were conducted for dead and dying rats around the sites. | 8 bait stations and 8 tracking patches were used.  Pre census baiting: 5 days (100 g of maize grain and poultry/pig feed per station per day)  Treatment : 100 g of poisoned test bait in each lockable bait station (total 8 bait stations) during 15 days  Post-baiting: 6 days  (100 g of maize grain and poultry/pig feed per station per day). | Estimated efficacy = 100 %  Pre-baiting plateau = 714 g/day  Post-baiting = 0 g  R.I=1  **Key study** | Trial code: **2035.BCD.SAG17** |
| **PT 14** | Non-professional  Professional  Indoor  Outdoor (around buildings) | **DPE25V1 (NYNA PELLET 25)**  Difenacoum 0.0025% w/w Pellet bait. | *R .rattus*  Overall estimated population: about 45-55 rats. | Field trial on an agricultural habitat (breeding stable for pigs). No rodenticide had been used at the site for at least 3 months.  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment the food/bait at each station was weighed and replenished, and the consumption was calculated. During the treatment census, searches were conducted for dead and dying rats around the sites. | 8 bait stations and 8 tracking patches were used.  Pre census baiting: 14 days (100 g of maize grain and poultry/pig feed per station per day)  Treatment : 100 g of poisoned test bait in each lockable bait station (total 8 bait stations) during 20 days  Post-baiting: 5 days (100 g of maize grain and poultry/pig feed per station per day) | Estimated efficacy = 100 %  Pre-baiting plateau = 720.8 g/day  Post-baiting = 0 g  1dead rat  R.I=1  **Key study** | Trial code: **2098.BCD.SAG17** |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| Regarding submitted laboratory data, requirements and criteria are not compliant with those of the TNsG PT14 / Guidance on the Biocidal Products Regulation - Volume II Efficacy (2017). Indeed, only one laboratory study on *R. norvegicus* has been submitted, and this study demonstrates insufficient efficacy and palatability. Furthermore, laboratory data submitted in the frame of the first authorisation resulted from read across with block baits and paste baits.  However, as field trials demonstrating the efficacy on all target species have been submitted and as application for renewal of the authorisation will be submitted within a short time frame, French competent authorities (FR CA) consider that efficacy of the product NYNA PELLET 25 can be validated for the control of rats (*Rattus norvegicus* and *Rattus rattus*) and house mice (*Mus musculus*), at the claimed application rates. New laboratory studies, for all claimed target organisms, performed with the product NYNA PELLET 25 have to be submitted for the renewal of the authorisation. |

#### Occurrence of resistance and resistance management

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

#### Known limitations

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

#### Evaluation of the label claims

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

French competent authorities (FR CA) assessed that the product NYNA PELLET 25 has shown a sufficient efficacy for the control of rats (*Rattus norvegicus, Rattus rattus*) and house mice (*Mus musculus*).

The application rates validated are the following:

House mice (*M. musculus*): 40 g per baiting point separated by 1-2 m.

Rats (*R. norvegicus* and *R. rattus*): 100 g per baiting point separated by 5-10 m.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

Nevertheless, it has to be noted that only field tests were considered to validate the efficacy of the major change. French competent authorities (FR CA) consider that laboratory tests on all target species with the new product must be submitted by the applicant at renewal of the authorisation.

#### Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The product is not intended to be used with other biocidal products.

### Risk assessment for human health

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

The major change request is a decrease in the active substance content (from 50 ppm to 25 ppm), a reduction of 3 coformulants and modifications of the packagings.

The product NYNA PELLET 25 is pellet bait ready-to-use rodenticide containing 0.0025% of difenacoum. It is presented in bulk or in sachets for professional users and in sachets for non-professional users.

For professional users, 40 to 100 g are in bulk or packaged in individual PE or PP sachet to be used in tamper-resistant bait stations or in covered and protected baiting points.

For non-professional users, 40 to 100 g are packaged in individual PE or PP sachet to be used.

It can be used indoor and outdoor around buildings and open areas.

#### Assessment of effects on Human Health

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

For the major change request, no new data has been submitted. However, a read across with the studies presented in the initial PAR for the product at 0.005% of difenacoum is proposed considering that the change will have no impact on classification because it consists in a decrease of 3 co-formulants not classified and an increase of the bait content.

***Skin corrosion and irritation***

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

***Eye irritation***

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

***Respiratory tract irritation***

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

***Skin sensitization***

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

***Respiratory sensitization (ADS)***

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

***Acute toxicity***

*Acute toxicity by oral route*

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

*Acute toxicity by inhalation*

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

*Acute toxicity by dermal route*

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

***Information on dermal absorption***

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

The major change request is a decrease in the s.a content (from 50 ppm to 25 ppm).

No new data has been submitted. A percutaneous absorption of 0.647% has been set according to the EFSA guidance for Difenacoum based on an *in vitro* study realised on human skin with pellets containing 0.005% Difenacoum[[6]](#footnote-7).

For the risk assessment, a dermal absorption value of 0.647 % is used.

For details, please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56)*.*

***Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)***

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56 ).*

*Conclusion on classification:*

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

Based on the results of the studies, the concentration of the active substance and of the co-formulants contained in the product, a classification STOT RE 2 H373 is needed.

#### Exposure assessment

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

The product NYNA PELLET 25 is pellet bait ready-to-use rodenticide. It is presented in bulk or in sachets for professional users and in sachets for non-professional users.

For professional users, 40 to 100 g are in bulk or packaged in individual PE or PP sachet to be used in tamper-resistant bait stations or in covered and protected baiting points.

For non-professional users, 40 to 100 g are packaged in individual PE or PP sachet to be used.

**Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product**

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | n.a. | Yes | No | n.a. | n.a. | No | n.a. |
| Dermal | n.a. | Yes | Yes | n.a. | n.a. | No | n.a. |
| Oral | n.a. | No | No | n.a. | n.a. | Yes | n.a. |

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Primary dermal exposure during loading and cleaning phases | **Primary dermal exposure**  The product is a ready to used product supplied in pellet bait (in sachets or in bulk); therefore exposure during decanting, loading and cleaning is considered. | Professionals |
| 2. | Primary dermal exposure during loading and cleaning phases | **Primary dermal exposure**  The product is a ready to used product supplied in pellet bait (in sachets PE or PP); therefore only exposure during cleaning is expected due to the presence of sachet. | Non-professionals |
| 3. | Ingestion of product by an toddler | **Secondary exposure**  Oral exposure of toddler by ingestion. | General public - toddler |

***Industrial exposure***

No exposure for industrial users is foreseen.

***Professional exposure***

*Scenario [1] - Primary dermal and exposure during loading and cleaning phases for professional users*

| **Description of Scenario [1]** | | | |
| --- | --- | --- | --- |
| The product is a ready-to-use product in bulk or with sachets. Exposure is determined considering the exposure during loading and cleaning phases for product in bulk form. Exposure during cleaning is considered for product with sachets.  According to the HEEG opinion[[7]](#footnote-8) 10, an exposure phase of 63 loadings and 16 cleanings is considered for pellets.  Dermal exposure is based on a CEFIC study (Chambers *et al*., 2004[[8]](#footnote-9)) and taking into account the HEEG opinion 12[[9]](#footnote-10). As a worst-case, the application dose of 100g for the use against rat is taken into account; the dose for the use against mice being lower, the exposure assessment is considered covered. | | | |
|  | Parameters | Value | References |
| Tier 1 | Concentration of a.s in the product %w/w | 0.0025 | Applicant’s data |
| Amount of grain per bait point (g) | 100 | Applicant’s data |
| Amount of exposure to product (75th percentile) during decanting of 3kg of grain | 52.3 | HEEG opinion 12 |
| Amount of exposure to product (75th percentile) during loading | 2.04 | HEEG opinion 12 |
| Amount of exposure to product (75th percentile) during clean-up (mg) | 3.79 | HEEG opinion 12 |
| Manipulation per day | 63 loading and 16 cleaning | HEEG opinion 10 |
| Dermal absorption value % | 0.647 % | See dermal absorption section |
| Inhalation rate (m3/hour) | 1.25 | Recommendation 14 |
| Body weight | 60 | Recommendation 14 |
| Tier 2 | Gloves protection (solid) | 95% |  |

**Calculations for Scenario [1]** (see annex 3.2)

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [1] - bulk | Tier 1/no PPE | 7.52E-07 | 8.06E-07 | n.a. | 7.92E-07 |
| Scenario [1] - bulk | Tier 2/ gloves | 7.52E-07 | 4.03E-08 | n.a. | 1.56E-06 |
| Scenario [1] - sachet | Tier 1/ no PPE | n.a. | 1.63E-07 | n.a. | 1.63E-07 |

***Non-professional exposure***

*Scenario [2] - Primary dermal exposure during loading and cleaning phases for non-professional users*

| **Description of Scenario [2]** | | | |
| --- | --- | --- | --- |
| The product is a ready-to-use product in PE or PP sachet. With the use of sachet, only exposure during cleaning is expected.  According to the HEEG opinion 10, an exposure phase of 5 loadings and 5 cleanings is considered.  Dermal exposure is based on the HEEG opinion 12: Harmonised approach for the assessment of rodenticides. Inhalation exposure is considered negligible.  As a worst-case, the application dose of 100g for the use against rat is taken into account; the dose for the use against mice being lower, the exposure assessment is considered covered. | | | |
|  | Parameters | Value | References |
| Tier 1 | Concentration of a.s in the product %w/w | 0.0025 | Applicant’s data |
| Amount of grain per bait point (g) | 100 | Applicant’s data |
| Amount of exposure to product (75th percentile) during loading (mg) | 3.57 | HEEG opinion 12 |
| Amount of exposure to product (75th percentile) during clean-up (mg) | 4.52 | HEEG opinion 12 |
| Manipulation per day | 5 loading and 5 cleaning | HEEG opinion 10 |
| Dermal absorption value % | 0.647 % | See dermal absorption section |
| Body weight | 60 | Recommendation 14 |

**Calculations for Scenario [2]** (see annex 3.2)

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [2] | Tier 1/no PPE | n.a. | 6.09E-08 | n.a. | 6.09E-08 |

***Exposure of the general public***

The estimation of general public exposure is considered covered by the initial assessment. *Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake (mg/kg bw/d)** |
| 1. | Professionals - bulk | Tier 1 /No PPE | 7.92E-07 |
| 1. | Professionals - bulk | Tier 2/Gloves | 1.56E-06 |
| 1. | Professionals - sachets | Tier 1 /No PPE | 1.63E-07 |
| 2. | Non-professionals | Tier 1 /No PPE | 6.09E-08 |

#### Risk characterisation for human health

Reference values to be used in Risk Characterisation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | Teratogenicity in rabbit | LOAEL = 0.001 mg/kg bw/day | 600 | 68% | 0.0000011 mg/kg bw/day |
| AELmedium-term | Teratogenicity in rabbit | LOAEL = 0.001 mg/kg bw/day | 600 | 68% | 0.0000011 mg/kg bw/day |
| AELlong-term | Teratogenicity in rabbit | LOAEL = 0.001 mg/kg bw/day | 600 | 68% | 0.0000011 mg/kg bw/day |
| ARfD | Not applicable |  |  |  |  |
| ADI | Not applicable |  |  |  |  |

1 safety factor of 300 and a safety factor of 2 due to extrapolation from LOAEL to NOAEL.***isk for industrial users***

Not applicable

***Risk for professional users***

Systemic effects

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [1]** - bulk | Tier 1 / no PPE | 1.1E-06 | 7.92E-07 | 142% | No |
| **Scenario [1] -** bulk | Tier 2 / gloves | 1.1E-06 | 1.56E-06 | 72.0% | Yes |
| **Scenario [1]** - sachets | Tier 1 /No PPE | 1.1E-06 | 1.63E-07 | 14.9% | Yes |

**Conclusion**

The risk is acceptable for professionals when gloves are worn for products in bulk form and without PPE for products in sachets. Gloves are also recommended to prevent rodent-borne disease. Moreover, the mention “do not open the sachet” has to be added in the label of the product*.*

***Risk for non-professional users***

Systemic effects

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [2]** | Tier 1 | 1.1E-06 | 6.09E-08 | 5.5% | Yes |

**Conclusion**

The risk is acceptable for non-professionals.

***Risk for the general public***

The risk for the general public is considered covered by the initial assessment.

Product label (“do not open the sachet”) and good practice advise users to prevent access to bait by children, infants and pets.

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

***Risk for consumers via residues in food***

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56).*

### Risk assessment for animal health

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

Animal health assessment is covered by the secondary exposure of human health. The baits should be placed in areas which do not allow access to children, infants and pets.

The following RMM is proposed: “Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.”

### Risk assessment for the environment

* **MAJOR CHANGE FOR NYNA PELLET 25 – 2019 (FR CA)**

The major change request is a decrease in the active substance content (from 50 ppm to 25 ppm) and a reduction of 3 coformulants. Therefore, risk assessment for environment is considered covered by the initial assessment.

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56 ).*

#### Effects assessment on the environment

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56 ).*

#### Exposure assessment

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56 ).*

#### Risk characterisation

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56 ).*

### Measures to protect man, animals and the environment

*Please refer to the product assessment report related to renewal of the ACTIPELLET-DIFE (NYNA D+ PELLET in France) product authorisation (IT/2012/00004/AUT) under Regulation UE n° 528/2012 (Case number: BC-TF000470-56 ).*

### Assessment of a combination of biocidal products

NYNA PELLET 25 is not intended to be authorised for the use with other biocidal products.

# Annexes[[10]](#footnote-11)

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| DEMANGEL.B | 2017 | Physico-chemical tests before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on DPE25V1 | No | TRIPLAN |
| DEMANGEL.B | 2018 | Analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on DPE25V1 Batch 17-071 Prod.: 03/17 | No | TRIPLAN |
| RICAU.H | 2016 | Validation of the analytical method for the determination of difenacoum in DPA25V1 in compliance with SANCO/3030/99 rev. 4 from 11/07/00 | No | TRIPLAN |
| RICAU.H | 2017 | Validation of the analytical method for the determination of difenacoum in DPE25V1 | No | TRIPLAN |
| A.Moschetti | 2017 | Rodenticide mortality and palatability evaluation on “neo-actipellet-dife” | Yes | ACTIVA |
|  | 2016 | Efficacy evaluation of bromadiolone 0.0027% w/w, pellet bait. Semi field trial study with rats (*Rattus norvegicus*) | No | ACTIVA |
| I.Rovetto | 2017 | Efficacy evaluation of NEO-ACTIPELLET-DIFE (difenacoum 0.0025% w/w a.i., pellet bait) against House mouse (*Mus musculus L*.) in Italy | Yes | ACTIVA |
| I.Rovetto | 2017 | Efficacy evaluation of NEO-ACTIPELLET-DIFE (difenacoum 0.0025% w/w a.i., pellet bait) against Norway rat (*Rattus norvegicus Berk.*) in Italy | Yes | ACTIVA |
| I.Rovetto | 2018 | Efficacy evaluation of NEO-Efficacy evaluation of DPE25V1 (difenacoum 0,0025% w/w a.i., pellet bait) against Roof rat (*Rattus rattus L.*) in Italy | No | TRIPLAN |

## Output tables from exposure assessment tools

Scenario [1]

|  |  |  |  |
| --- | --- | --- | --- |
| **product:** | | **NYNA PELLET 25** | |
|  |  |  |  |
| **Task / Scenario :** | **Professional** | | |
| **Model used :** | **CEFIC study** | | |
|  |  |  |  |
| **AEL** | **mg/kg bw/day** | **1.10E-06** |  |
|  |  |  |  |
|  |  | Tier 2 | Tier 1 |
| Active substance (% w/w) | 0.0025% | With PPE | Without PPE |
| Body weight (kg) | 60 |  |  |
| Dermal absorption | 0.647% |  |  |
| Amount of grain per bait point | g | 100 | 100 |
| Loading of bait point per day | - | 63 | 63 |
| amount of grain manipulated per day | kg | 6.3 | 6.3 |
| **Dermal exposure** |  |  |  |
| **Decanting phase** | **only if packaging greater than 3 kg** |  |  |
| Amount of exposure to product (75th percentile) during decanting of 3kg of grain | mg | 52.3 | 52.3 |
| Amount of exposure to product (75th percentile) during decanting phase | mg | 109.83 | 109.83 |
| **Dermal systemic dose (a.s)** | **mg/kg bw/day** | **2.96E-07** | **2.96E-07** |
| **Loading phase** |  |  |  |
| Amount of exposure to product (75th percentile) during loading | mg | 2.04 | 2.04 |
| Manipulation per day |  | 63 | 63 |
| **Dermal systemic dose (a.s)** | **mg/kg bw/day** | **3.46E-07** | **3.46E-07** |
| **Cleaning phase** |  |  |  |
| Amount of exposure to product (75th percentile) during clean-up | mg | 3.79 | 3.79 |
| Manipulation per day |  | 16 | 16 |
| **Dermal systemic dose (a.s)** | **mg/kg bw/day** | **1.63E-07** | **1.63E-07** |
| **Combined dermal exposure** |  |  |  |
| **Potential total systemic dose (a.s) via skin** | **mg/kg bw/day** | **8.06E-07** | **8.06E-07** |
| Gloves penetration factor | % | 5% | 100% |
| **Actual total systemic dose (a.s) via skin** | **mg/kg bw/day** | **4.03E-08** | **8.06E-07** |
| **Inhalation exposure** | **only for decanting** |  |  |
| **Decanting phase** |  |  |  |
| Air concentration from decanting | mg/m3 | 9.62 | 9.62 |
| Minute per day (3 min/3kg) | min | 9 | 9 |
| Inhalation rate | m3/hour | 1.25 | 1.25 |
| Inhalation absorption | % | 100% | 100% |
| Inhalation exposure product | mg | 1.80 | 1.80 |
| **Potential systemic dose (a.s) via inhalation** | **mg/kg bw/day** | **7.52E-07** | **7.52E-07** |
| Respiratory Protection Equipement protection factor | - | 1 | 1 |
| **Actual total systemic dose (a.s) via inhalation** | **mg/kg bw/day** | **7.52E-07** | **7.52E-07** |
| **Combined total exposure (inhal +dermal)** |  |  |  |
| **Total systemic dose (a.s) (inhal +dermal)** | **mg/kg bw/day** | **7.92E-07** | **1.56E-06** |
|  |  |  |  |
| %AEL – bulk form |  | 72.0% | 142% |

|  |  |  |  |
| --- | --- | --- | --- |
| **Potential total systemic dose (a.s) via skin** | **mg/kg bw/day** | **1.63E-07** | **1.63E-07** |
| Gloves penetration factor |  | 5% | 100% |
| **Actual total systemic dose (a.s) via skin** | **mg/kg bw/day** | **8.17E-09** | **1.63E-07** |
|  |  |  |  |
| %AEL sachet (PP or PE) |  | 1% | 14.9% |

Scenario [2]

|  |  |  |
| --- | --- | --- |
| **product:** | | **NYNA PELLET 25** |
|  |  |  |
| **Task / Scenario :** | **non-Professional** | |
| **Model used :** | **CEFIC study** | |
|  |  |  |
| **AEL** | **mg/kg bw/day** | **1.10E-06** |
|  |  |  |
|  |  | Tier 1 |
| Active substance (% w/w) | 0.0025% | Without PPE |
| Body weight (kg) | 60 |  |
| Dermal absorption | 0.647% |  |
| Amount of grain per bait point | g | 100 |
| Filling of bait point per day | - | 5 |
| amount of grain manipulated per day | kg | 0.5 |
| **Dermal exposure** |  |  |
| **Cleaning phase** |  |  |
| **Amount of exposure to product (75th percentile) during clean-up** | **mg** | **4.52** |
| **Manipulation per day** |  | **5** |
| **Dermal systemic dose (a.s)** | **mg/kg bw/day** | **6.09E-08** |
| **%AEL sachet (PP or PE)** |  | **5.5%** |

## New information on the active substance

## Residue behaviour

## Summaries of the efficacy studies (B.5.10.1-xx)[[11]](#footnote-12)

## Confidential annex

## Other

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. Please delete as appropriate. [↑](#footnote-ref-3)
3. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-4)
4. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-5)
5. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-6)
6. Jäger M. 2013. ACTIPELLET-DIFE: *in vitro* dermal delivery with human skin. Harlan Cytotest Cell Research GmbH, study number 1503302 of 16 January 2013, GLP. [↑](#footnote-ref-7)
7. HEEG opinion 10: Harmonising the number of manipulations in the assessment of rodenticides (anticoagulants), agreed at TM III 2010 [↑](#footnote-ref-8)
8. J.G. Chambers, P.J. Snowdown « study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits ». Synergy LABORATORIES limited, Thaxted, UK, laboratory report number SYN/1302, 8 March 2004 Sponsor CEFIC/EBPF Rodenticides Data Development Group [↑](#footnote-ref-9)
9. HEEG opinion 12: Harmonised approach for the assessment of rodenticides (anticoagulants), agreed at TMII 2011 [↑](#footnote-ref-10)
10. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-11)
11. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-12)