**BIJLAGE II** bij het besluit d.d. 8 maart 2018 tot verlenging van de toelating van het middel ROZOL PAT’, toelatingnummer NL-0003390-0000

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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR THE RENEWAL OF A NATIONAL AUTHORISATION**



|  |  |
| --- | --- |
| Product identifier in R4BP | ROZOL PAT’ |
| Product type(s):  | 14 (Rodenticide) |
| Active ingredient(s): | Chlorophacinone |
| Case No. in R4BP | BC-UT014438-09 |
| Asset No. in R4BP | NL-0003390-0000 |
| Evaluating Competent Authority | NL (Ctgb) |
| Internal registration/file no |  |
| Date | 09-03-2018 (renewal) |

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APPENDIX: Product assessment report for first authorisation

# Conclusion

**First renewal authorisation:**

Originally, ROZOL PAT’ is authorised as a rodenticide against rats and house mice for the following uses: in and around buildings (professional and non-professional use), open areas (professional use only) and waste dumps (professional use only). For the renewal of the product, the intended uses as a rodenticide against rats and house mice are modified to the following uses: in and around buildings by (trained) professionals and in open areas and waste dumps by trained professionals only. Use of the product by non-professionals is no longer intended. This is due to the fact the product is classified with Repr. 1B after application of the 9th ATP on March 01, 2018. Non-professional use will not be permitted after this date.

The Dutch CA considers the information provided for the first authorisation sufficient for the renewal of the product. Therefore, the first renewal authorisation of ROZOL PAT’ will be as rodenticide against rats and house mice for the following uses: in and around buildings by (trained) professionals and in open areas and waste dumps by trained professionals only.

|  |  |
| --- | --- |
| Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation) | Use(s) appropriate for *further* authorisation (first renewal authorisation) |
| 1 | Rats and house mice (open areas and waste dumps, professionals)  | 1 | House mice and rats (indoor, trained professionals)  |
| 2 | Mice and/or rats (outdoor around buildings, trained professionals) |
| 3 | House mice and rats (outdoor open areas and waste dumps trained professionals)  |
| 2 | Rats and house mice (in and around buildings, professionals and non-professionals) | 4 | House mice and rats (indoor, professionals) |
| 5 | House mice and rats (outdoor around buildings, professionals) |

Some restrictions in usage are necessary to prevent access of children and non-target animals to the product, please refer to the SPC (Summary of product characteristics). Prior to renewing the approval of anticoagulant active substances and renewing the authorisations of the respective products discussions took place at EU-level to harmonise use instructions and risk mitigation measures to the greatest possible extend. As an outcome of these discussions a set of three standard SPCs compiling the relevant sentences for the uses that may be authorised for each of the three user categories (general public, professionals and trained professionals) has been produced (for details please refer to document CA-Nov16-Doc.4.1.b – Final). The SPC for renewal of ROZOL PAT’ has been updated with the relevant sentences accordingly.

**National specific regulations in the Netherlands:**

Due to Dutch national specific regulations in the Netherlands, only trained professionals are allowed to apply rodenticides (no professional use) and additional IPM training is needed for outdoor application of rodenticides (around buildings and food storage locations). The use of first generation anticoagulants is not allowed for brown rats due to resistance issues (derogation based on art 37 BPR). In addition, the use against house mice is restricted to use in buildings and for both house mice and rats use in covered and protected bait points is not allowed. Also, in the Netherlands use of anticoagulants is not approved for open areas and/or waste dumps.

Therefore, in the Netherlands the authorised use of this product will consist of use by trained professionals in buildings against house mice (*Mus musculus*) and black rats (*Rattus* *rattus*), and around buildings and food storage locations against black rats. The only application method of the product in the Netherlands will be in tamper-resistant bait boxes.

|  |  |
| --- | --- |
| Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation in Netherlands) | Use(s) appropriate for *further* authorisation in the Netherlands (first renewal authorisation). |
| 1 | Black rats (*Rattus rattus*) and house mice (*Mus musculus*) (in buildings, professionals) | 1 | Black rats (*Rattus rattus*) and house mice (*Mus musculus*) (indoor, trained professionals) |
| 2 | Black rats (*Rattus rattus*) (outdoor around buildings and food storage locations, trained professionals with additional IPM training) |

# Summary of the product assessment

## Administrative information

### Identifier in R4BP[[1]](#footnote-1)

|  |
| --- |
| ROZOL PAT’ |

### Manufacturer(s) of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | Liphatech SAS |
| **Address of manufacturer** | Bonnel – CS 1000547480Pont du CasseFrance |
| **Location of manufacturing sites** | Production centre, Avenue Jean Serres, ZA Malère47480Pont du CasseFrance |

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

|  |  |
| --- | --- |
| **Active substance** | Chlorophacinone |
| **Name of manufacturer** | Liphatech SAS |
| **Address of manufacturer** | Bonnel – CS 1000547480Pont du CasseFrance |
| **Location of manufacturing sites\*** | LIPHATECH S.A.S at AlzChem Trostberg GmbH - Chemie Park Trostberg Dr Albert Frank Strasse 3283308TrostbergGermany |

\* The location of the manufacturing location is confirmed by the eCA of the active substance.

## Composition and formulation

### Qualitative and quantitative information on the composition

Table 1

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| --- | --- | --- | --- | --- | --- |
| Chlorophacinone | Chlorophacinone | Active substance | 3691-35-8 | 223-003-0 | 0.005(pure) |
|  |  | Non-active substance |  |  | Refer to Confidential Annex 4.1 |

* The product contains a bittering agent and a dye.
* Information on the full composition is provided in the confidential[[2]](#footnote-2) annex (see chapter 4).
* According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

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

No substance of concern was identified upon initial assessment (the application for authorisation was submitted and the assessment took place before the Biocidal Products Regulation 528/2012 entered into force).

### Candidate(s) for substitution

No candidate for substitution was identified upon initial assessment (the application for authorisation was submitted and the assessment took place before the Biocidal Products Regulation 528/2012 entered into force).

Now that the Biocidal Products Regulation 528/2012 entered into force, the following substance(s) was/were identified as candidate(s) for substitution upon this renewal:

* Chlorophacinone

Chlorophacinone meets the exclusion criteria according to Article 5(1) BPR. Because the following exclusion criteria are met:

* toxic for reproduction category 1B

And therefore, Chlorophacinone also meets the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

### Type of formulation

|  |
| --- |
| RB - Ready-to-use bait: paste |

## Classification and Labelling according to the Regulation (EC) No 1272/2008[[3]](#footnote-3)

Table 2

| ClassificationHazard classes, Hazard categories | Hazard statements |
| --- | --- |
| Repr. 1B | H360D  |

Table 3

| Labelling | Code | Pictogram / Wording |
| --- | --- | --- |
| Pictograms | GHS08 |  |
| Signal word | - | Danger |
| Hazard statements | H360D | May damage the unborn child. |
| Supplemental hazard information |  |  |
|  |  |
| Supplemental label elements |  |  |
|  |  |
| Precautionary statements |  |  |
| P201 | Obtain special instructions before use. |
|  |  |
|  |  |
| P280 | Wear protective gloves. |
| P308+P313 | IF exposed or concerned: Get medical advice/attention. |
| P501 | Dispose of contents and container according to local regulations |
| Note | - |  |

## Use(s) appropriate for further authorisation

For national specific regulations in the Netherlands see conclusions.

### Use 1 appropriate for further authorisation – House mice and rats - trained professionals – indoor

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | - |
| Target organism(s) (including development stage) | *Mus musculus* (House mouse – all development stages)*Rattus rattus* (Black/roof rat – all development stages)*Rattus norvegicus* (Brown rat – all development stages) |
| Field(s) of use | Indoor |
| Application method(s) | Bait application:-Ready-to-use bait to be used in tamper-resistant bait stations.-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 stations) |
| Application rate(s) and frequency | Mice: 30-50 g of bait per bait station. Rats: 100-200 g of bait per bait station.  |
| Category(ies) of users | Trained professionals  |
| Pack sizes and packaging material | Paper bag or PP sachet: 10 to 40 g paste, further packed in:- PP bucket with lid 3-20 kg- Cardboard carton with integral plastic (PP/PE) bag  3-20 kg- Plastic (PP/PE) pouch 3- 20 kg- Carton containing prefilled PP/HDPE/PS bait stations 3-10 kg |

#### Use-specific instructions for use

|  |
| --- |
| Remove the remaining product at the end of treatment period. - 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.).- *[When available]* Follow any additional instructions provided by the relevant code of best practice.- 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.  |

#### Use-specific risk mitigation measures

|  |
| --- |
| - 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 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 only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals 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.[- 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. |

#### 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

|  |
| --- |
|  See general directions for use. |

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

|  |
| --- |
| See general directions for use. |

### Use 2- Mice and/or rats – trained professionals – outdoor around buildings

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | - |
| Target organism(s) (including development stage) | *Mus musculus* (House mouse – all development stages)*Rattus rattus* (Black/roof rat – all development stages)*Rattus norvegicus* (Brown rat – all development stages) |
| Field(s) of use | Outdoor around buildings  |
| Application method(s) | Bait application:-Ready-to-use bait to be used in tamper-resistant bait stations.-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 stations)-Direct application of ready-to-use bait into the burrow |
| Application rate(s) and frequency | Mice: 30-50 g of bait per bait station. Rats: 100-200 g of bait per bait station.  |
| Category(ies) of users | Trained professionals  |
| Pack sizes and packaging material | Paper bag or PP sachet: 10 to 40 g paste, further packed in:- PP bucket with lid 3-20 kg- Cardboard carton with integral plastic (PP/PE) bag  3-20 kg- Plastic (PP/PE) pouch 3- 20 kg- Carton containing prefilled PP/HDPE/PS bait stations 3-10 kg |

#### Use-specific instructions for use

|  |
| --- |
| Remove the remaining product at the end of treatment period. - 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.).- *[When available]* Follow any additional instructions provided by the relevant code of best practice.- 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. - 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.- Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.Burrow baiting:- Baits must be placed to minimise the exposure to non-target species and children.- Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.- [*When available*] Follow any additional instructions provided by the relevant code of best practice. |

#### Use-specific risk mitigation measures

|  |
| --- |
| - 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 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 only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals 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.[- 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. |

#### 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 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

|  |
| --- |
|  See general directions for use. |

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

|  |
| --- |
| See general directions for use. |

### Use 3- House mice and rats – trained professionals – Outdoor open areas & waste dumps

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | - |
| Target organism(s) (including development stage) | *Rattus rattus* (Black/roof rat – all development stages)*Rattus norvegicus* (Brown rat – all development stages)Mus musculus (House mice – all development stages) |
| Field(s) of use | Outdoor open areas (rats)Outdoor waste dumps (brown rats only)  |
| Application method(s) | Bait application:-Ready-to-use bait to be used in tamper-resistant bait stations.-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 stations)-Direct application of ready-to-use bait into the burrow |
| Application rate(s) and frequency | Mice: 30-50 g of bait per bait station. Rats: 100-200 g of bait per bait station.  |
| Category(ies) of users | Trained professionals  |
| Pack sizes and packaging material | Paper bag or PP sachet: 10 to 40 g paste, further packed in:- PP bucket with lid 3-20 kg- Cardboard carton with integral plastic (PP/PE) bag  3-20 kg- Plastic (PP/PE) pouch 3- 20 kg- Carton containing prefilled PP/HDPE/PS bait stations 3-10 kg |

#### Use-specific instructions for use

|  |
| --- |
| - Remove the remaining product at the end of treatment period. - 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.).- *[When available]* Follow any additional instructions provided by the relevant code of best practice.- 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. - 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.- Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.Burrow baiting:- Baits must be placed to minimise the exposure to non-target species and children.- Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.- [*When available*] Follow any additional instructions provided by the relevant code of best practice. |

#### Use-specific risk mitigation measures

|  |
| --- |
| - 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 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 only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals 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.[- 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. |

#### 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 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

|  |
| --- |
|  See general directions for use. |

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

|  |
| --- |
| See general directions for use. |

### Use 4 appropriate for further authorisation –House mice and rats – professionals – indoor

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use |  |
| Target organism(s) (including development stage) | *Mus musculus* (House mouse – all development stages)*Rattus rattus* (Black/roof rat – all development stages)*Rattus norvegicus* (Brown rat – all development stages) |
| Field(s) of use | Indoor |
| Application method(s) | Bait applicationReady-to-use bait to be used in tamper-resistant bait stations.  |
| Application rate(s) and frequency | Mice: 30-50 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 1-3 meters.Rats: 100-200 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 4-10 meters. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | Paper bag or/PP sachet: 10 to 40 g paste, further packed in:- PP bucket with lid 3-20 kg- Cardboard carton with integral plastic (PP/PE) bag 3-20 kg-- Plastic (PP/PE) pouch  3-20 kg- Carton containing prefilled PP/HDPE/PS bait stations 3- 10 kg |

#### Use-specific instructions for use

|  |
| --- |
| - 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.- Bait stations should be placed in the immediate vicinity of places where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).- The bait stations should be visited at least every 2 to 3 days (for use against mice) at the beginning or only 5 to 7 days after the beginning (for use against rats) 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.- Remove the remaining bait or the bait stations at the end of the treatment period. |

#### Use-specific risk mitigation measures

|  |
| --- |
| - To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week).- 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 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.- Do not wash the bait stations with water between applications. |

#### 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

|  |
| --- |
|  See general directions for use. |

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

|  |
| --- |
|  See general directions for use. |

### Use 5 appropriate for further authorisation –House mice and rats – professionals – outdoor around buildings

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use |  |
| Target organism(s) (including development stage) | *Mus musculus* (House mouse – all development stages)*Rattus rattus* (Black/roof rat – all development stages)*Rattus norvegicus* (Brown rat – all development stages) |
| Field(s) of use | Outdoor around buildings |
| Application method(s) | Bait applicationReady-to-use bait to be used in tamper-resistant bait stations.  |
| Application rate(s) and frequency | Mice: 30-50 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 1-3 meters.Rats: 100-200 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 4-10 meters. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | Paper bag or/PP sachet: 10 to 40 g paste, further packed in:- PP bucket with lid 3-20 kg- Cardboard carton with integral plastic (PP/PE) bag 3-20 kg-- Plastic (PP/PE) pouch  3-20 kg- Carton containing prefilled PP/HDPE/PS bait stations 3- 10 kg |

#### Use-specific instructions for use

|  |
| --- |
| - 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.- Bait stations should be placed in the immediate vicinity of places where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).- The bait stations should be visited at least every 2 to 3 days (for use against mice) at the beginning or only 5 to 7 days after the beginning (for use against rats) 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.- Remove the remaining bait or the bait stations at the end of the treatment period.- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). 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. |

#### Use-specific risk mitigation measures

|  |
| --- |
| - To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week).- 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 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").

- Do not apply this product directly in the burrows.-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.- Do not wash the bait stations with water between applications. |

#### 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 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

|  |
| --- |
|  See general directions for use. |

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

|  |
| --- |
|  See general directions for use. |

## General directions for use

### Instructions for use

|  |
| --- |
| - Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.- 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.- Where possible, bait stations must be fixed to the ground or other structures. - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.*-[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 along the baits.-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.Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened *(see section 5.3 of the SPC for the information to be shown on the label)*.-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. -When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product. 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.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.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 rodents 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.In sachets: Do not open the sachets containing the bait. |

### Risk mitigation measures

|  |
| --- |
| - Do not use this product in pulsed baiting treatments.- 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 [*in accordance with the applicable code of good practice, if any*].- 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].Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder with the product information). |

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

|  |
| --- |
| - 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.- Antidote: Vitamin K1 administered by medical/veterinary personnel only.    - In case of:- Dermal exposure, wash skin with water and then with water and soap. - Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes. - Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label [insert country specific information]. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information]- 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 [insert national phone number]".- Hazardous to wildlife |

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

|  |
| --- |
| - At the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label]. |

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

|  |
| --- |
| - 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.- Shelf life: 2 years |

### Other information

|  |
| --- |
| - 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. |

# Assessment of the product

## Use(s) considered appropriate for authorisation after former assessment

The following information is based on the PAR (updated version) realised by NL-CA (Ctgb) as reference MS for the initial authorisation of the product and does not contain Dutch national-specific elements.

### Use 1 –Professional

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | *Mus musculus* (House mouse – juveniles and adults)*Rattus rattus* (Black/roof rat – juveniles and adults)*Rattus norvegicus* (Brown rat – juveniles and adults) |
| Field(s) of use |  In and around buildings, open areas and waste dumps |
| Application method(s) | Covered application, preferably in tamper-resistant bait stations |
| Application rate(s) and frequency |  Rats: 100 to 200 g bait per bait station. Bait points placed at 4 to 10 meter distance of each other.Mice: 30 to 50 g bait per bait station. Bait points placed at 1 to 3 meter distance of each other. |
| Category(ies) of users | Trained professionals |
| Pack sizes and packaging material | Paper bag or PP sachet: 10 to 40 g paste further packed in:PP bucket with lid 3-20 kgCardboard carton with integral plastic (PP/PE) bag  3-20 kgPlastic (PP/PE) pouch  3- 20 kgCarton containing prefilled PP/HDPE/PS bait stations 3- 10 kg |

### Use 2 – Non-Professional

Remark from applicant: this use is not supported anymore because of the classification (H360D) of the product in application to the 9th ATP to CLP.

## Physical, chemical and technical properties

Neither new data was provided nor had new guidance to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding physical, chemical and technical properties remains valid.

## Physical hazards and respective characteristics

Neither new data was provided nor had new guidance to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

## Methods for detection and identification

Neither new data was provided nor had new guidance to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

## Efficacy against target organisms

Neither new data was provided nor had new guidance to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding efficacy against target organisms remains valid.

###  Occurrence of resistance

Resistance to the first generation anticoagulants has been widely reported in both *Rattus norvegicus* and *Mus domesticus* since the late 1950's. The incidence of resistance to first generation anticoagulants in areas in which it is established is commonly 25-85%. For a **status report** on the resistance situation for anticoagulants in Europe please refer to the following document:

RACC guidelines on Anticoagulant Rodenticide Resistance Management (October 2016).

This document provides guidance to advisors, national authorities, professionals, practitioners and others on the nature of anticoagulant resistance in rodents, the identification of anticoagulant resistance, strategies for rodenticide application that will avoid the development of resistance and the management of resistance where it occurs. To download the latest version visit: [www.rrac.info](http://www.rrac.info)/releases

## Risk assessment for human health

### Assessment of effects of the active substance on human health

Neither new data was provided nor had new guidance to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding effects of the active substance on human health remains valid.

Considering the Regulation 2016/1179, the harmonised classification of chlorophacinone is the following:

|  |
| --- |
| Classification under regulation (EC) 1272/2008 |
| Acute Tox 1 – H300 ; H310 ; H330STOT RE 1 – H372 (blood)Repr. 1B – H360Repr. 1B; H360D: C ≥ 0,003 %STOT RE 2; H373: 0,01 % ≤ C < 0,1 %STOT RE 1; H372: C ≥ 0,1 % |

Based on the results of the studies, the concentration of the active substance (0.005%) and of the compounds contained in the product and according to the above classification, the following classification is required:

* Repr. 1B - H360D: May damage the unborn child

### Assessment of effects of the product on human health

For the previous authorisation the dermal absorption value of 1.7 % has been used based on the study by Hardwick and Russell (2003). **For the renewal, the following new guidance was taken into account for the re-assessment:**

* EFSA GD on dermal absorption (2012): *EFSA Panel on Plant Protection Products and their Residues (PPR); Guidance on Dermal Absorption.EFSA Journal 2012;10(4):2665. [30 pp.] doi:10.2903/j.efsa.2012.2665.*

**Re-assessment of the relevant data:**

Taking the new EFSA guidance on dermal absorption into account the data already submit was re-assessed: The *in vitro* human dermal penetration study (Hardwick and Russell, 2003) was performed on a moistened 50 mg/Kg wheat bait formulation and on a 2 g/kg tracking powder formulation. The results are presented in the table below.

|  |  |  |
| --- | --- | --- |
| **compartment** | **chlorophacinone (%)****wheat bait** | **chlorophacinone (%)****tracking powder** |
| Receptor Fluid | 0.440 ± 0.631 | 0.093 ± 0.125 |
| Residual Skin | 55.15 ± 51.38 | 1.006 ± 1.602 |
| Skin Wash | 47.81 ± 53.60 | 92.29 ± 7.118 |
| Tape strips (epidermis) | 0.236 ± 0.180 | 0.301 ± 0.154 |
| Cell Wash | 0.123 ± 0.275 | 1.277 ± 2.191 |
| receptor fluid + residual skin + tape strips + cell wash | 0.799 ± 0.719 \*\*  | 2.583 ± 3.891 |
| Recovery | 103.8 ± 14.66 | 94.97 ± 5.433 |

\*\* Residual skin values were not used as the wheat bait was not eliminated by washing due to high adhesion of particles.

Conclusion in the CAR was as following: Total absorption of 14C- Chlorophacinone (tracking powder) including receptor fluid (0.1%), residual skin levels (1.0%) and tape stripping values (0.3%) was 1.4**%.** The study with wheat flour formulation showed 0.44 % in receptor fluid, and 0.236% in tape strips (total 0.676%) and residual skin values was not used due to high adhesion of particles not eliminated by washing; if it is assumed that a similar residual skin value (1.0%) is appropriate then total absorption is circa 1.7**%**. This last value was adopted as the best estimation of dermal absorption.

According to the new EFSA guidance (2012), when the standard deviation is >25% of the mean, the mean value requires correction for the level of variation between replicates. Tape stripping was performed, and the values of the individual tape strips were not reported individually. Therefore, the tape strips will be included in the absorbed dose.

When these points are accounted for, the dermal absorption is re-calculated to be 6.47% (2.58+3.89) for test with tracking powder, which is rounded to 6% for risk assessment. The dermal absorption with wheat bait is not determined because it is not possible to determine standard deviation for absorbed amount without reliable data in residual skin value. Nevertheless the value with tracking powder represents the worse case as the absorbed value (receptor fluid + residual skin + tape strips + cell wash) of tracking powder is higher than that with wheat bait.

### Exposure assessment

ROZOL PAT’ is supplied ready for use in paper bag/PP sachets which are not intended to be opened by the user. The product is placed in position by hand. As a ‘worst case’ scenario dermal exposure whilst handling unopened bait has been assessed in accordance with HEEG Opinion 12. Actual exposure to professional users loading bait boxes, however, is expected to be significantly lower than the values in accordance with HEEG Opinion 12 for ROZAL PAT’ due to the presence of sachet. The level of reduction due to the sachets is currently under debate in the BPC Working Group Human Health (WG IV, 2017). For this risk assessment 50% reduction is applied from the use of paper/PP sachet, in accordance with the discussion during the WG IV, 2017.

Once in place, the product packaging will be damaged by rodents as they feed and the paste bait

will be exposed. Dermal exposure to paste is therefore possible during clean-up operations, but this

will be limited to the hands and exposure to other parts of the body is negligible.

**Results of assessment**

|  |
| --- |
| **Professional user exposure whilst loading bait stations**  |
| **Product and intended use** | **Exposure scenario** | **PPE** | **Inhalational uptakeExposure (mg/m3)** | **Dermal uptakeExposure (mg b.p / manipulation)** |
|  ‘Rozol PAT’In and around buildings for the control of rodents | Loading 60 bait points per day.20 sachets per bait point (20 sachets x 10 g of bait). | Gloves | Not applicable. | 55.58 mg product (adapted 75th percentile potential dermal exposure value) by taking 50% reduction by sachet into account |
| **Dermal Exposure** |
| Measured value for amount of product on gloves: | 55.58 mg product/bait point during loading |
| Amount of red paste on gloves during disposal: | 55.58 mg x 60 = 3334.8 mg |
|  |  |
| Concentration of chlorophacinone in product: | 0.005 % w/w |
| Amount of chlorophacinone on gloves: | 0.16674 mg/day |
| Protection factor (chemical resistant gloves): | 95% |
| Amount of chlorophacinone on skin: | 0.00834 mg/day |
| Dermal absorption of chlorophacinone | 6% |
| Systemic exposure of chlorophacinone | 0.00050 mg/day |
| Operator body weight: | 60 kg |
| **Systemic exposure to chlorophacinone during the loading of bait boxes:** | **8.34 x10-6 mg/kg bw/day** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product and intended use** | **Exposure scenario** | **PPE** | **Inhalational uptakeExposure (mg/m3)** | **Dermal uptakeExposure (mg b.p / manipulation)** |
| ‘Rozol PAT’In and around buildings for the control of rodents | Cleaning the remains of 15 bait points/day | Gloves | Not applicable. | 5.70 mg product/manipulation (75th percentile potential dermal exposure value) when cleaning bait boxes and disposing of the unwanted bait. |
| **Dermal Exposure** |
| Amount of product on gloves: | 5.70 mg product/bait point during disposal |
| Total amount of paste on gloves: | 5.70 mg x 15 = 85.5 mg |
|  |  |
| Concentration of chlorophacinone in product: | 0.005 % w/w |
| Amount of chlorophacinone on gloves: | 0.004275 mg/day |
| Protection factor (chemical resistant gloves): | 95% |
| Amount of chlorophacinone on skin: | 0.000214 mg/day |
| Dermal absorption of chlorophacinone: | 6% |
| Systemic exposure of chlorophacinone: | 0.0000128 mg/day |
| Operator body weight: | 60 kg |
| **Systemic exposure to chlorophacinone during disposal/cleaning of bait boxes:** | **2.14x10-7 mg/kg bw/day** |

### Risk characterisation for human health

#### Risk for professional users

**Professional users**

The results are summarised in the table below.

**Risk assessment for professional operators handling ‘Rozol PAT’**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Operation** | **PPE** | **Exposure path** | **Body dose (mg/kg bw/day)** |  | **Repeated dose toxicity AEL: 0.000017 mg/kg bw/dayNOAEL: 0.005 mg/kg bw/day** |
|  |  | **%AEL** |
| Cleaning 15 bait points/day in/around buildings | Gloves | Dermal | 2.14x 10-7 |  |  | 1.3 |
| Loading 60 bait points  | Gloves | Dermal | **8.34 x10-6** |  |  | 49.1 |
| Combined exposure to an individual both cleaning (15) and loading (60) bait stations | Gloves | Dermal | 8.55 x 10-6 |  |  | 50.3 |

**Overall assessment of the risk to professionals - active substance in biocidal products**

The exposure level of a protected (chemical resistant gloves) professional was calculated to be 50.3% AEL. For the exposure assessment reduction of 50% in exposure level was accounted for because the bait is packaged in sachets. As discussed during the WG IV, 2017, the reduction in exposure level from the use of plastic sachet is likely to be higher than 50%. Furthermore, the assessment is considered worst case as it is based on the smallest pack size leading to a highest number of contacts required to load the bait box.

The risk to protected (gloves) (trained) professional workers handling ‘Rozol PAT’ containing chlorophacinone for the control of rats and mice is therefore considered to be acceptable.

#### Risk for the general public

 The use by the general public (non-professionals) is not supported at renewal.

Neither new data was provided nor new guidance had to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding risks for consumers via for the general public via indirect contact remain valid.

Based on the former assessment the following risk mitigations are included:

- 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 [in accordance with the applicable code of good practice, if any].

- 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.

- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.

- Store in places prevented from the access of children, birds, pets and farm animals.

#### Risk for consumers via residues in food

Neither new data was not provided nor new guidance had to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid.

Based on the former assessment the following risk mitigations are included:

- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

#### Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product[[4]](#footnote-4)

#### Summary of risk characterisation

The risk to professional workers handling ‘Rozol PAT’ containing chlorophacinone for the control of rats and mice is considered to be acceptable for all considered scenarios for the protected (gloves) (trained) professional. The conclusion for secondary exposure, as well as the required RMMs remain unchanged.

## Risk assessment for animal health

Neither new data was provided nor new guidance had to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding animal health remains valid.

## Risk assessment for the environment

Neither new data was provided nor new guidance had to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding the environment remains valid.

Please note, that in the previous PAR for Rozol Pat’ it was concluded: Due to very low soil concentrations, the restricted use pattern, the low water solubility (0.13 mg/L) and the strong adsorption of the active substance to soil, chlorophacinone is not considered to leach to groundwater and hence no PECgroundwater was calculated.

The initial assessment did not include a quantitative risk assessment for the groundwater. A groundwater assessment should always be performed for rodenticides, also in cases when only hot spot applications are considered (see ENV 113, TAB version 1.3, August 2017)

The PECgroundwater is calculated according to equation 68, chapter 2.3.8.6, Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B (2015) as a first worst-case estimation.

With regard to Tier I as a worst case, the local concentration in pore water (PEClocal, agr.soil,porew) would have to be considered. Due to the high discrepancies between the measured Koc and the Koc calculated from the Kow (15,600 - 135,000 L/kg), the partitioning method was determined to be not accurate here. In the assessment report, PECporewater was calculated for the scenario bait boxes ‘in and around buildings’. It must be noted that the type of formulation (wax blocks) of the product assessed in the CAR was different than the formulation type (paste) of Rozol Pat’. In the CAR, the highest PECsoil ­was found for the scenario ‘open areas’, as compared to ‘in and around buildings’ and ‘waste dumps’. The resulting worst-case PECporewater calculated in the CAR, for open areas, was repeated here.

PECporewater ~ 0.6 E-06 mg/L

**Conclusion:** The value obtained for the concentration of chlorophacinone in porewater resulting from the use in open areas, is far below the trigger for drinking water of 0.0001 mg/L. Therefore, it may be concluded that based on a worst case Tier I estimation there is no risk for groundwater to be expected from the use of chlorophacinone in Rozol Pat’.The table below summarises the risks for the receiving environmental compartments that have been identified as potentially exposed during the use of the product for the different intended uses of the product.

Risks for the foreseeable routes of entry into the environment on the basis of the intended uses, calculated in original authorisation

| **Intended use** | **Risk for environmental compartments exposed** |
| --- | --- |
| **STP1** | **Freshwater2** | **Soil** | **Air** | **Primary and secondary poisoning of birds and mammals** |
| In and around buildings | n.r. | n.r. | No | No | **Yes** |
| Open areas | n.r. | n.r. | **Yes** | No | **Yes** |
| Waste dumps | n.r. | n.r. | No | No | **Yes** |

 1 Sewage Treatment Plant, 2 Including sediment, 3 Including groundwater; n.r. = not relevant

Exposures to the STP and subsequently surface water after cleaning operations at the end of a campaign for the scenario ‘in and around buildings’ or direct emissions to surface water by run-off or otherwise, for the other two scenarios, were considered negligible in the previous assessment (according to the ESD). A risk was found for soil for the use ‘open areas’. The PEC/PNEC ratio for primary and secondary poisoning for birds and mammals resulting from all intended uses widely exceeds 1, showing the need for implementation of use restrictions and RMMs to minimise the risk. In NL this means a restriction to the use by (trained) professionals as part of Integrated Pest Management (IPM) principles. For further measures to protect animals and the environment we refer to the SPC which shall be duly taken into consideration for a clear labelling of Rozol Pat’.

## Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

## Comparative assessment

The NL CA for biocides has processed an application for renewal for the biocidal product Rozol Pat’ which contains the active substance chlorophacinone. The active substance chlorophacinone meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR (for details see chapter 2.2.3).

Therefore, in line with Article 23 (1) BPR a comparative assessment for the product Rozol Pat’ has to be conducted.

At the 60th meeting of representatives of Members States Competent Authorities for the implementation of BPR held on 20 and 21 May 2015, all Member States submitted to the Commission a number of questions to be addressed at Union level in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides'). The questions submitted were the following:

(a) Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?;

(b) For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?;

(c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?;

d) Are these alternatives sufficiently effective?;

(e) Do these alternatives present no other significant economic or practical disadvantages?

The information addressing these questions is provided in the Annex of the Commission Implementing Decision (EU) 2017/1532 According to Article 1 of Commission Implementing Decision (EU) 2017/1532 the NL CA considered the information in the Annex during the comparative assessment of anticoagulant rodenticide biocidal products.

**Conclusion**

Based on the information provided in the Annex of the Commission Implementing Decision (EU) 2017/1532 the NL CA came to the conclusion that 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. These products also showed some significant practical or economical disadvantages for the relevant uses.

The opinion also considered a number of non-chemical control or prevention methods ("non-chemical alternatives"), which may provide sufficient efficacy in certain circumstances on their own or in a combination of them. However, there is insufficient scientific evidence to prove that those non-chemical alternatives are sufficiently effective according to the criteria established in agreed Union guidance (1) with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled.

Therefore, the authorisation of the product Rozol Pat’ will be renewed for 5 years.

APPENDIX:

Product Assessment Report for first authorisation

Rozol PAT’

Amendment d.d. 06-12-2013

|  |  |
| --- | --- |
| Internal registration/file no: | 20110651 |
| Authorisation/Registration no: | 13974N |
| Granting date/entry into force of authorisation/ registration: | 08-03-2013Amendment of authorisation: 06-12-2013 |
| Expiry date of authorisation/ registration: | 30-06-2016 |
| Active ingredient: | Chlorophacinone |
| Product type:  | PT14 |

Biocidal product assessment report related to product authorisation under Directive 98/8/EC

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# General information about the product application

## Applicant

|  |  |
| --- | --- |
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|  |  |
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## Current authorisation holder[[5]](#footnote-5)

Liphatech S.A.S.

## Proposed authorisation holder

|  |  |
| --- | --- |
| **Company Name:** | Liphatech S.A.S. |
| **Address:** | Bonnel BP 3 |
| **City:** | Pont du Casse |
| **Postal Code:** | 47480 |
| **Country:** | France |
| **Telephone:** | +33 563 693 570 |
| **Fax:** | +33 553 479 501 |
| **E-mail address:** | corg@liphatech.fr |
| **Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):** | Not applicable |

## Information about the product application

|  |  |
| --- | --- |
| **Application received:** | 04-07-2011 |
| **Application reported complete:** | 29-01-2013 |
| **Type of application:** | First authorisation |
| **Further information:** | The authorisation has been changed on 06-12-2013 due to new scientific information. In the section on efficacy the amendments are explained. |

## Information about the biocidal product

### General information

|  |  |
| --- | --- |
| **Trade name:** | Rozol Pat’ |
| **Manufacturer’s development code number(s), if appropriate:** | CLOPA0,0050\_01F\_F01265\_00 |
| **Product type:** | 14 |
| **Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):** | Chlorophacinone 0.0050% |
| **Formulation type:** | RB |
| **Ready to use product (yes/no):** | Yes |
| **Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no);****If yes: authorisation/registration no. and product name:****or****Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):** | No |

### Information on the intended use(s)

Below is the intended use as applied for by the applicant at the start of the evaluation. These uses/claims have been adapted during the evaluation.

See SPC for the final authorised use.

|  |  |
| --- | --- |
| **Overall use pattern (manner and area of use):** | Rozol Pat’ is a blue rodenticide paste bait used for the control of rats and mice - in and around buildings (professional and non-professional use)- in open areas and waste dumps (professional use only).The paste is contained in a sachet which is not opened by the operator.Details of use are shown in Table 2.5.3.1 |
| **Target organisms:** | *Rattus norvegicus* (Norway rat, Brown rat) *Rattus rattus* (Black rat) *Mus musculus* (House mouse) |
| **Category of users:** | Professional and non-professional |
| **Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:** | Rats: **up to 200 g** bait per bait station. Bait points placed at **4 to 10** meter distance of each other.Mice: **up to 100 g** bait per bait station. Bait points placed at **1 to 3** meter distance of each other. |
| **Potential for release into the environment (yes/no):** | Yes |
| **Potential for contamination of food/feedingstuff (yes/no)** | No |
| **Proposed Label:** | Translation of the final Dutch labels, see Annex 9. |
| **Use Restrictions:** | Not for use in sewers. |

### Information on active substance(s)

|  |  |
| --- | --- |
| **Active substance chemical name:** | chlorophacinone |
| **CAS No**: | 3691-35-8 |
| **EC No:** | 223-003-0 |
| **Purity (minimum, g/kg or g/l):** | >97.8% |
| **Inclusion directive:** | 2009/99/EG, d.d. 4 augustus 2009 |
| **Date of inclusion:**  | 1 July 2011 |
| **Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):**  | Yes |
| **CONFIDENTIAL: this information should not be disclosed to third parties** |
| **Manufacturer of active substance(s) used in the biocidal product:** |  |
| **Company Name:** | Liphatech S.A.S. at AlzChem Trostberg GmbH |
| **Address:** | Chemie Park Trostberg, Dr Albert Frank strasse 32 |
| **City:** | Trostberg |
| **Postal Code:** | 83308 |
| **Country:** | Germany |
| **Telephone:** | +33 5 53 69 36 30 |
| **Fax:** | +33 5 53 69 81 81 |
| **E-mail address:** | corg@liphatech.fr |

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

No substances of concern are present in the active substance/formulation.

## Documentation

### Data submitted in relation to product application

New studies concerning the product Rozol Pat’ have been submitted with respect to physical-chemical properties, analytical methods and efficacy of the product. The studies are listed in Annex 2.

### Access to documentation

The applicant does not need to provide a letter of access as the applicant is also notifier of the dossier on the active substance chlorophacinone placed on Annex I of the Biocides Directive 98/8/EC.

# Summary of the product assessment

## Identity related issues

|  |  |
| --- | --- |
| Trade name | Rozol Pat’ |
| Active ingredient | Purity (%w/w) | CAS No. | EC No. | Content (%) |
| Chlorophacinone | >97.8% | 3691-35-8 | 223-003-0 | 0.005 (pure active) |
| Remark: chlorophacinone is present as the racemic mixture of the two enantiomersNo substance of concern is found in Rozol Pat’. |

## Classification, labelling and packaging

### Harmonised classification and labelling of the biocidal product

**Proposal for the classification and labelling of the formulation concerning physical chemical properties**

Classification and labeling of the formulation concerning physical chemical properties is not required.

Supported shelf life of the formulation: three years in PP.

**Proposal for the classification and labelling of the formulation concerning**

**toxicological properties**

Proposed classification based on Directive 1999/45/EC

**Human toxicology:**

**Professional and non-professional users:**

|  |
| --- |
| Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances): |
| - |
| Symbol: | - | Indication of danger: | - |
| R phrases | - | - |
| S phrases | S2 | Keep out of the reach of children |
| Special provisions:DPD-phrases | - | - |
| Child-resistant fastening obligatory? | no |
| Tactile warning of danger obligatory? | no |

|  |
| --- |
| Explanation: |
| Hazard symbol: | - |
| Risk phrases: | - |
| Safety phrases: | S46 is not indicated according to Annex VI of Directive 67/548/EEC, as the product is not classified as dangerous. |
| Other: | - |

Proposed classification based on Regulation EC 1272/2008

Human toxicology:

|  |  |
| --- | --- |
| **Signal word:** | - |
| **Pictogram:** | - |
|  | **Hazard class-and-Category** | **Code** | **Hazard statement** |
| **Hazard statements:** | - | - | - |
| **Precautionary statements:** |  | P102 | Keep out of reach of children |

|  |
| --- |
| Explanation: |
| Pictogram: | - |
| H-statements: | - |
| P-statements: | The P-statement is chosen based on the specific restrictions for the inclusion of clorophacinone in Annex I of the Directive 98/8/EC.  |

**Proposal for the classification and labelling of the formulation concerning environmental properties**

Classification and labelling of the formulation concerning environmental properties is not required.

### Packaging of the biocidal product

**Professional use**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outer packaging type applied for** | **Inner packaging type applied for** | **Packaging sizes evaluated**  | **Packaging sizes authorised in NL\*** |
| PP bucket with lid | Paper bag/PP sachet: 10 to 40 g | Up to 20 kg | 800g to 20 kg |
| Cardboard carton with integral plastic (PP/PE) bag  | Paper bag/PP sachet: 10 to 40 g | Up to 20 kg | 800g to 20 kg |
| Plastic (PP/PE) container | Paper bag/PP sachet: 10 to 40 g | Up to 1.5 kg | 800 g to 1.5 kg |
| Plastic (PP/PE) pouch | Paper bag/PP sachet: 10 to 40 g | Up to 20 kg | 800 g to 1 kg |
| Carton containing prefilled PP/HDPE/PS bait stations | Paper bag/PP sachet: 10 to 40 g | Up to 10 kg | 800g to 10 kg |

\*Member state specific regulations only allow pack sizes of up to 200 g. for non-professional use and from 800 g. for professional use, concerning authorisation of rodenticides in the Netherlands.

**Non-professional use**

**(not accepted in NL)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outer packaging type applied for** | **Inner packaging type applied for** | **Packaging sizes evaluated**  | **Packaging sizes authorised in NL** |
| PP bucket with lid | Paper bag/PP sachet: 10 to 40 g | Up to 5 kg | - |
| Cardboard carton with integral plastic (PP/PE) bag  | Paper bag/PP sachet: 10 to 40 g | Up to 4 kg | - |
| Plastic (PP/PE) container | Paper bag/PP sachet: 10 to 40 g | Up to 4 kg | - |
| Plastic (PP/PE) pouch | Paper bag/PP sachet: 10 to 40 g | Up to 4 kg | - |
| Carton containing prefilled PP/HDPE/PS bait stations | Paper bag/PP sachet: 10 to 40 g | Up to 3 kg | - |

-

## Physico/chemical properties and analytical methods

The applicant is owner of the Annex I dossier. The physico/chemical properties for the active substance chlorophacinone are detailed in the Annex I dossier, Doc IIIA, Section 3.

The methods for the active substance chlorophacinone, the impurities and the enantiomeric ratios of the active substance in the technical active substance are detailed in the Annex I dossier, Doc IIIA, Section 4.1.

### Physico-chemical properties

The product is not the representative product included in the CA report to support the inclusion of chlorophacinone in annex I of Directive 98/8/EC. The applicant has submitted the following studies.

For some endpoints data of other products has been used. The compositions of these products are comparable to Rozol Pat’ and allow for acceptable extrapolation.

Table 1: Physico-chemical properties of the biocidal product:

|  | Method | Purity/Specification | Results | Reference |
| --- | --- | --- | --- | --- |
| Physical state and nature | Visual | Blue paste: F01265, Batch: F1265, Nominal: 50 mg/kg | Paste | Caruel, H.(2008)IIIB 3.1.1-01Non-GLP |
| Colour | Visual | Blue paste: F01265, Batch: F1265, Nominal: 50 mg/kg | Blue | Caruel, H.(2008)IIIB 3.1.2-01Non-GLP |
| Odour | Olfactory | Blue paste: F01265, Batch: F1265, Nominal: 50 mg/kg | Cereal odour | Caruel, H.(2008)IIIB 3.1.1-01Non-GLP |
| Explosive properties | Expert statement | Blue paste: F01265, Nominal: 50 mg/kg | Not explosive | Curl, M and Wright, E.(2011a)IIIB 3.2-01Non-GLP |
| Oxidizing properties | Expert statement | Blue paste: F01265, Nominal: 50 mg/kg | Not oxidising | Curl, M and Wright, E.(2011b)IIIB 3.3-01Non-GLP |
| Flash point  | n.a. |
| Autoflammability  | There are no auto-flammable components in the formulation. |
| Other indications of flammability | EEC A10(flammability of solids) | Study conducted with an alternative paste formulation F00060 | F00060 paste is not flammable and blue paste F01265 containing chlorophacinone will also not be flammable, based on their comparable compositions. | Demangel, B.(2008a)IIIB 3.4-01GLP |
| Acidity / Alkalinity | CIPAC MT31.2 | Study conducted with an alternative paste formulation F00060 | F00060 paste has an acidity of 0.08% m/m H2SO4. Blue paste F01265 will have a similar acidity. | Demangel, B.(2008b)IIIB 3.5-01GLP |
| Relative density / bulk density | Pyknometer method using displacement | Study conducted with an equivalent paste (LR363, Lot 8390) | F00060 paste has a density of 1.1444 g/mL at 25°C and blue paste F01265 will have a similar density. | Zobel, M.(2007)IIIB 3.6-01GLP |
| Storage stability – stability and shelf life | Longterm stability study 25°C – 2 years | blue Paste F1265\_00.Batch F1265.Nominal 50 mg/kg. | Content of a.s.:Initial: 51.61 mg/kgFinal: 47.53 mg/kgThe active substance content content showed an acceptable decrease, aspect of test item and packaging and pH did not change significantly after storage at 25°C for 2 years. Test was performed in PP packaging. | Caruel, H.(2011)IIIB 3.7-02GLP |
| Effects of temperature  | Accelerated stability study 40°C – 8 weeks | Blue paste F01265\_00Batch F1265Nominal content 50 mg/kg | Content of a.s.:Initial: 50.08 mg/kgFinal: 51.55 mg/kgThe active substance content remained stable, aspect of test item and packaging and pH of dispersion did not change significantly. Test was performed in PP packaging. | Caruel, H.(2010)IIIB 3.7-01GLP |
| Effects of light | The product will not be exposed to direct (sun)light. |
| Reactivity towards container material  | Longterm stability study 25°C – 2 years | blue Paste F1265\_00.Batch F1265.Nominal 50 mg/kg. | Packaging: PP boxstable for 2 years. | Caruel, H.(2011)IIIB 3.7-02GLP |
| Accelerated storage stability 54°C - 2 weeks | Chlorophacinone paste. Batch F2914.a.i.: 48.68 mg/Kg | No damage and no alteration in PE and PP sachet or in paper, non-woven film. | Deslux, R. (2012), IIIB 3.7-03 |
| Technical characteristics in dependence of the formulation type | n.a. |
| Compability with other products | This ready to use paste preparation is not intended to be used or mixed with other products. |
| Surface tension | n.a. |
| Viscosity | n.a. |
| Particle size distribution | n.a. |

### Analytical methods

|  |  |
| --- | --- |
|  | Principle of method |
| Technical active substance as manufactured:  | HPLC-UV (CA report chlorophacinone) |
| Impurities in technical active substance:  | Confidential information (CA report chlorophacinone) |
| active substance in the formulation: | HPLC-UV after extraction. Method is validated for the product. Specificity, linearity, repeatability and recovery rate have been tested.  |

## Risk assessment for Physico-chemical properties

The product is not oxidising, not explosive, not highly flammable and not expected to be corrosive. Risks regarding physical and chemical properties of the product are not expected.

## Effectiveness against target organisms

### Function

Rozol Pat’ is a rodenticide (PT14) based on 0.005% w/w chlorophacinone. The product is applied for as a product for both professional and non-professional use.

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

In the application the following target organisms were indicated:

Rozol Pat’ paste bait is used to control:
*Rattus norvegicus* (Norway rat/Brown rat)*\*
Rattus rattus* (Roof rat/Black rat)
*Mus musculus* (House mouse)

Professional use: the control of rats and mice in and around buildings, in open areas and waste dumps.

Non-professional use: the control of rats and mice in and around buildings\*.

Rozol Pat’ paste bait is used to protect human food and animal feedstuffs and for general hygiene purposes.

*\*The uses and claims as applied for by the applicant differ from the authorised use. See SPC for final authorised uses.*

### Effects on target organisms

Chlorophacinone is a first-generation anticoagulant rodenticide. It disrupts the normal blood clotting mechanisms resulting in increased bleeding tendency and, eventually, profuse haemorrhage and death. Effectiveness of the active substance depends on exposure (i.e. consumption of the bait by the target organism). For effective and comprehensive control of rats and mice, a bait concentration of 50 mg active /kg bait is proposed.

Rozol Pat’ differs from the products described in the CAR of chlorophacinone since the bait is a paste. Therefore, the studies presented in the CAR are not applicable and new laboratory and field studies have been conducted with mice and rats using paste bait formulations containing 50 mg/kg chlorophacinone. The results are described in Section IIIB 5.10.2 and are summarised in table 2.5.3.0 below.

Besides these efficacy studies two studies have been provided showing that the warfarine sensitive strains of *R. norvegicus* and *M. musculus* were suitably sensitive to warfarine (IIIB 5.10.2-8 and IIIB 5.10.2-9). Furthermore, studies have been provided showing that neither the packaging of a block bait in either polyethylene or polypropylene film, nor the addition of the bittering agent denatonium benzoate (0.01% or 0.001%) to a rodenticide green block formula had any effect on the palatability of the bait (IIIB 5.10.2-6 and 7).

**Table 2.5.3.0: Efficacy of the active substance from its use in the biocidal product – paste bait formulations**

| Test substance | Test organism(s) | Test system / concentrations applied / exposure time | Test results: effects, mode of action, resistance\* | Reference |
| --- | --- | --- | --- | --- |
| Blue paste F01265\_00 | House Mouse*Mus musculus* (wild strain, sensitive to warfarin) | Laboratory study, using bait aged for 4 months, single free-choice test with a total of 20 mixed sex animals, 4 day exposure.Test Method: EPPO PP1/214(1) | Palatability of the treated bait was greater than the reference diet in the test diet (attractivity value = 0,66) . Efficacy was 85% occurring between 7 and 14 days after initial consumption. | IIIB5.10.2-03 |
| Blue pasteF01265\_00 | House Mouse *Mus musculus* (wild strain, sensitive to warfarin) | Laboratory study, using bait aged for 3 years, single free-choice test with a total of 23 mixed sex animals, 4 day exposure.Test method: EPPO PP1/214(1) | Palatability of the treated bait was superior to the reference diet (attractivity value = 0,74). Efficacy was 91% occurring between 4 and 15 days after initial consumption. | IIIB5.10.2-12 |
| Red blockF00507 (active: 50mg/kg chlorophacinone) | House Mouse *Mus musculus*(wild strain) | Field study conducted at 2 sites, in and around agricultural buildings with high mice activity. Bait stations contained 40g bait at 16 locations at site 1 and 12 location at site 2. The number of mice estimated on the maximum food intake recorded during treatment was 263 (site 1) and 108 mice (site 2). Assessments were conducted throughout the duration of the trial at 1- 4 day intervals. During each assessment the food/bait at each station was weighed and replenished, and the amount consumed was calculated. During the treatment, searches were conducted for dead and dying mice in and around the site. The duration of the whole test (incl pre- and post-treatment) was 59-66 days.  | Based on consumption estimates the efficacy under field conditions was 95.5%. (site 1) and 92.6% (site 2). Mortality was observed from 6 to 20 days at site 1 (70 dead mice) and from 4 to 20 days at site 2 (21 dead mice), with the cause of death confirmed as bait consumption with signs of intra-peritoneal bleeding. The block bait tested was effective under field conditions against mice when in competition against natural food sources and other environmental factors. | IIIB5.10.2-10 |
| Blue pasteF01265\_00 | House Mouse*Mus musculus*(wild strain) | Field study conducted at 1 site, in and around agricultural buildings with high mice activity. Bait stations contained 40g bait at 24 locations (20 in building, 4 around building), positioned at a distance of 2 to 15 m between stations. The number of mice estimated on the maximum food intake recorded during treatment was 126. Assessments were conducted throughout the duration of the trial at 1- 4 day intervals (one 7 day interval at end of baiting phase). During each assessment the food/bait at each station was weighed and replenished, and the amount consumed was calculated. During the treatment, searches were conducted for dead and dying mice in and around the site. Pre baiting: 22 days. Baiting: 25 days. Post-baiting: 7 days. | Based on consumption estimates the efficacy under field conditions was 98.4%. Mortality was observed during baiting from day 6 on (42 dead mice during baiting, 3 during post-baiting), with the cause of death confirmed as bait consumption with signs of intra-peritoneal bleeding. The paste bait tested was effective under field conditions against mice when in competition against natural food sources and other environmental factors. | IIIB 5.10.2-13 |
| Blue paste F01265\_00 | Rat*Rattus norvegicus*(wild strain, sensitive to warfarin) | Laboratory study, using bait aged for 17 months, two free-choice tests with a total of 20 mixed sex animals, 4 day exposure.Test Method: EPPO PP1/214(1) | Palatability of the treated bait was equivalent to or similar to the reference diet (attractivity value = 0,45 and 0,42). Efficacy was 96% occurring between 7 and 11 days after initial consumption. | IIIB5.10.2-02 |
| Blue paste F01265\_00 | Rat*Rattus norvegicus*(wild strain, sensitive to warfarin) | Laboratory study, using bait aged for 3 years, single free-choice test with a total of 10 mixed sex animals, 4 day exposure.Test Method: EPPO PP1/214(1) | Palatability of the treated bait was equivalent to the reference diet (attractivity value = 0,47). Efficacy was 90% occurring between 7 and 14 days after initial consumption. | IIIB5.10.2-11 |
| Blue paste F01265\_00 | Rat*Rattus norvegicus*(wild strain) | Field study conducted at 2 farm sites in France in and around buildings. The number of rats calculated on the maximum food intake recorded before treatment was 59 for site 1 and 40 for site 2.Bait stations (12 on site 1 and 10 on site 2) were positioned where high levels of rodent activity were identified and were positioned 2-15 metres apart. Each bait contained 150 g paste (applied in sachets containing 10 g of blue paste).Assessments were conducted throughout the trial and were done every 1-4 days; baits were weighed and replenished, then the amount consumed was calculated.The duration of the whole test was 64 days for site 1 and 67 days for site 2. | Based on consumption estimates the efficacy under field conditions was 97,6% Mortality was observed from 4 to 11 days at site 1 (12 dead rats) and from 5 to 14 days at site 2 (7 dead rats), with the cause of death confirmed as bait consumption with signs of intra-peritoneal bleeding. The paste bait tested was effective under field conditions against rats when in competition against natural food sources and other environmental factors. | IIIB5.10.2-04 |
| Blue paste F01265\_00 | Rat*Rattus rattus*(wild strain, sensitive to warfarin) | Laboratory study, using bait aged for 17 months, two free-choice tests with a total of 20 mixed sex animals, 4 day exposure.Test Method: EPPO PP1/214(1) | Palatability of the treated bait was greater than that of the reference diet in each test (attractivity value = 0,66 and 0,63).Efficacy was 90% occurring between 7 and 14 days after initial consumption. | IIIB5.10.2-01 |
| Blue paste F01265\_00 | Rat*Rattus rattus*(wild strain) | Field study conducted at 2 farm sites in France in and around buildings. The number of rats calculated on the maximum food intake recorded before treatment was 65 for site 1 and 51 for site 2.Bait stations (12 on each site) were positioned where high levels of rodent activity were identified and were positioned 2-15 metres apart. Each bait contained 150 g paste (applied in sachets containing 10 g of blue paste) .Assessments were conducted throughout the trial and were done every 1-4 days; baits were weighed and replenished, then the amount consumed was calculated.The duration of the whole test was 67 days for site 1 and 57 days for site 2. | Based on consumption estimates the efficacy under field conditions was 98%. Mortality was observed from 4 to 34 days at site 1 (9 dead rats) and from 4 to 18 days at site 2 (8 dead rats), with the cause of death confirmed as bait consumption with signs of intra-peritoneal bleeding. The paste bait tested was effective under field conditions against rats when in competition against natural food sources and other environmental factors. | IIIB5.10.2-05 |

\* Efficacy laboratory study = mean mortality of male and female animals tested (in %); Efficacy of field study = (Ipre-Ipost)/Ipre\*100% (Ipre = mean (stabilized) intake in pre-baiting period, Ipost=mean daily intake in post-baiting period); Palatability (=attractivity of the bait) is expressed as the attractivity value calculated as A/(A+B) (A = amount of test bait consumed, B = amount of standard bait consumed).

These tests show the efficacy of the Blue paste F01265\_00 in laboratory choice tests and field tests against all the target organisms and the efficacy of Red bait block F00507 against *M. musculus* in the field. F00507 is a red bait block containing 50 mg/kg chlorophacinone. Blue paste F01265\_00 is identical to Rozol Pat’. Note that during product authorisation, the applicant has amended the study reports with reference IIIB5.10.2-01 to 05; the tested product has been amended from green paste F00871\_02 to blue paste F01265\_00.

Lab studies:

Efficacy and palatability of the product has been sufficiently demonstrated in laboratory choice tests for *R. norvegicus* and *R. rattus* (90-96% mortality). Although the efficacy of the product was somewhat lower for *M. musculus* in the choice test using bait aged for 4 months (85%, IIIB 5.10.2-03), the efficacy is shown to be sufficient (91% mortality) in the choice test using bait aged for 3 years. It is therefore concluded that efficacy has been sufficiently demonstrated in laboratory mortality and palatability tests for all the target organisms.

The studies also show that the palatability of the product is still sufficient after a storage period of 3 years.

Field studies:

A field study with a block rodenticide containing 50 mg/kg chlorophacinone was provided. This study showed a high efficacy of the block rodenticide against mice in the field. However, a field study with a block rodenticide is not representative for the palatability of a gel in sachets.

Also field studies with Blue paste F01265\_00 were provided. Blue paste F01265\_00 is identical to Rozol Pat’. The efficacy of the product in these field tests has been sufficiently demonstrated for *R. rattus,* *R. norvegicus* and *M. musculus* (98% mortality for all target organisms).

Note that for mice the application rate in the field study is lower than the application rate proposed by the applicant (see Table 1.5.2). Moreover, the Competent Authority NL is of the opinion that for both rats and mice a minimum application rate should be stated, based on expert opinion these have been determined at 100g for rats and 30 g for mice.

It can be concluded that Rozol Pat’ is effective in controlling *R. rattus,* *R. norvegicus* and *M. musculus* at a use dosage of 100-200 g bait per bait point for rats (distance of 4-10 m between bait points) and 30-50 g bait per bait point for mice (distance of 1-3 m between bait points).

**2.5.3.1 Dose**

The active substance is incorporated into a paste bait at a concentration of 50 mg/kg and used by both professional and non-professional users. Each sachet contains 10 to 40 gram of product. A box contains sachets of one weight.

Table 2.5.3.1: Summary of use pattern for chlorophacinone paste bait for professional and amateur users

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Recommended Application rate for one bait point/baiting point intervals**# | **Frequency of controls**  | **Checking / Replenishing**  | **Time of treatment and place of application**  |
| **Non-professional users** |
| Mice | 30 to 50 g of paste in one or more sachets per bait station. Place 1 station every 1 to 3 m | Dispose the product and check 3 days after first application, then regularly once a week or 15 days  | At each check, re-apply the bait if only a part of the bait is consumed. In case all bait is eaten, refill the station and use more bait stations and/or increase the control frequency. | All yearIn & around buildings. |
| Rats:Brown & Black | 100 to 200 g of paste in 2 or more sachets per bait station. Place 1 station every 4 to 10 m. | Dispose the product and check 3 days after first application, then regularly once a week or 15 days | At each check, re-apply the bait if only a part of the bait is consumed. In case all bait is eaten, refill the station and use more bait stations and/or increase the control frequency.  |
| **Professional users\*** |
| Mice | High infestation30 to 50 g of paste in one or more sachets per bait station. Place 1 station every 1 to 1.5 m | Dispose the product and check 3 days after first application, then regularly once a week or 15 days | At each check, re-apply the bait if only a part of the bait is consumed. In case all bait is eaten, refill the station and use more bait stations and/or increase the control frequency. | All yearIn & around buildingsIn open areasIn waste dumps. |
| Low infestation30 to 50 g of paste in one or more sachets per bait station. Place 1 station every 2 to 3 m | Dispose the product and check 3 days after first application, then regularly once a week or 15 days | At each check, re-apply the bait if only a part of the bait is consumed. In case that all bait is eaten at a bait station, refill the bait station and use more bait stations and/or increase the control frequency. |
| Rats:Brown & Black | High infestation100 to 200 g of paste in 2 or more sachets per bait station. Place 1 station every 4 to 5 m. | Dispose the product and check 3 days after first application, then regularly once a week or 15 days | At each check, re-apply the bait if only a part of the bait is consumed. In case that all bait is eaten at a bait station, refill the bait station and use more bait stations and/or increase the control frequency. | All yearIn & around buildingsIn open areasIn waste dumps. |
| Low infestation100 to 200 g of paste in 2 or more sachets per bait station. Place 1 station every 8 to 10 m. | Dispose the product and check 3 days after first application, then regularly once a week or 15 days | At each check, re-apply the bait if only a part of the bait is consumed. In case that all bait is eaten, refill the station and use more bait stations and/or increase the control frequency. |

\*: Since it is also possible that the professional user will identify a medium infestation the RMS proposes to put only the shortest and longest distance on the label (1 to 3 m for mice, 4 to 10 m for rats) and let the professional user decide what distance is most appropriate.
# In case of a black rat infestation, preferably higher bait points should be chosen.

* + - 1. **Mode of action**

Chlorophacinone is a first-generation anticoagulant rodenticide. It disrupts the normal blood clotting mechanisms resulting in increased bleeding tendency and, eventually, profuse haemorrhage and death. As with other anticoagulant rodenticides, the active substance is a vitamin K antagonist. It interferes with the regeneration of prothrombin, disturbing the normal blood clotting mechanisms and causing an increased tendency to haemorrhage. The site of action is the liver, where several of the blood coagulation precursors undergo vitamin K dependent post translation processing before they are converted into the respective pro-coagulant zymogens. The point of action appears to be the inhibition of K1 epoxide reductase. Rodents usually die within three to six days of the first consumption. Clinical symptoms may be observed around one to two days before death.

* + - 1. **Limitations**

**The original information provided in the PAR of 22nd March 2013**

The product is not recommended for the concomitant use with other specific biocidal products (5.11.3).

For the authorisation of rodenticides for controlling rats, the RMS, the Netherlands, is of the opinion that the general public is not able to use rodenticides against rats in a correct way. Incorrect use can cause resistance in rats which will increase problems of controlling rats in the future. Furthermore, in the Netherlands the control of rats and use of rodenticides against rats is restricted to licensed professional users and rodenticides against rats have never been used by the general public. Therefore the authorisation of rodenticides for controlling rats in the Netherlands is restricted to licensed professional users only due to national policy.

**New limitations added to the PAR of 1st November 2013**

Due to the widespread occurrence of resistance in brown rats in the Netherlands against first-generation anti-coagulants, including chlorophacinone (see paragraph 2.5.3.4) and the risk of further development of cross-resistance in brown rats against second-generation anti-coagulants the use of this product against brown rats is not authorised in the Netherlands.

Due to the risks of further spread of resistance to first-generation anti-coagulants including chlorophacinone in house mice and the risk of further development of cross-resistance in house mice against second-generation anti-coagulants, the use of Rozol Pat’ by non-professionals is not authorised in the Netherlands.

Non-professionals are normally allowed to control house mice in the Netherlands with anticoagulants. House mice and brown rats, however, often occur together and it cannot be excluded that non-profs will apply bait products in regions with resistant brown rat populations. Even when the product is intended for mice it can be expected that brown rats in the neighbourhood will eat from the bait and in this way remain selection pressure for the resistance genes in rats.

It is not feasible to expect from non-profs that they will be able to monitor resistance and apply a resistance management strategy. Moreover, it is not possible to inform non-professionals on the presence of resistance in certain populations and regions. Ctgb has therefore decided to restrict the use of Rozol Pat' to professional use only.

Professional users will be able to monitor resistance and apply resistance management strategies. It is also possible to inform professionals on regional differences in rodent resistance.

* + - 1. **Resistance**

**The original information provided in the PAR of 22nd March 2013**

There have been cases of resistance to first generation anticoagulants including chlorophacinone in some EU member states. Nevertheless, the resistance is not widespread and chlorophacinone remains effective in most of the rodent control situations.

**New information provided on resistance for the adapted PAR of 1st November 2013**

Shortly after the authorisation of Rozol Pat' (13974N) on the 22nd March2013, an appeal was made to the CA NL by a specialist and by a professional user organisation that the authorisation of Rozal Pat’ for the Dutch market should be reconsidered as the product is based on chlorophacinone to which widespread resistance in brown rats was present in NL. Also resistance of house mice to chlorophacinone in the Netherlands appeared to be already reported in the 1970s (Bosman, 1978).

In May 2013 also the results of a new study investigating the anticoagulant resistance of the brown rat in the Netherlands became available (WUR, 2013)1. In this report samples of rat droppings collected throughout the Netherlands in 2012 were analysed for the presence of resistance genes. Although the number of samples that were included in the study was limited (n=169), it was clear that overall 25% of the brown rats are resistant based on two different mutations Tyr139Cys and Tyr139Phe, in the report referred to as the German resistance gene and the French resistance gene. The resistance rates vary between different regions in the Netherlands. In particular in the region Twente in the eastern part of the Netherlands all samples were found to be resistant. But resistance is also spread over a considerable part of the country, in particular in the eastern, central and southern region and the city of Rotterdam. Moreover, the resistant rats seem to be spreading over the country. The resistance situation in the population of black rats and house mice was not investigated and is not clear at the moment. The study report mentions that it is not clear how the resistance genes and the rates of homozygosity /heterozygosity affect the resistance against the authorised active substances in the Netherlands.

However, from studies in the UK, Germany and France (RRAG, 2010; Buckle and Prescott, 2012; Prescott et al., 2010; Grandemange et al, 2010) it is known that brown rats carrying the mutations found in the Netherlands are resistant to the first generation anticoagulants among which warfarin, chlorophacinone and coumatetralyl. It was concluded that applying products based on these active substances in a population in which these resistance genes are present will accelerate the selection for homozygous resistance in this population and will make such a populations very difficult to control.

Also cross-resistance with the second generation anticoagulants bromadiolon and difenacoum is described in rat populations with these resistance genes. As a consequence products based on these active substances are found to be less effective in these populations (e.g. Buckle et al., 2013; RRAG, 2010).

In May 2013 also an extensive overview over the resistance development to Vitamin K anticoaglants (VKA’s) in rodents in Europe was presented in a draft report that was discussed at the 51st CA-meeting (CA-meeting 51, circabc.europa.eu). This report confirms the concerns on cross resistance between first and second generation anticoagulants in rodents, in particular for the brown rat. For the situation of resistance in black rats and house mice to anticoagulants less information is available, but resistance has been reported in several countries and there is also reason for concern of further development of resistance and cross-resistance to VKA’s in these species, but the situation is not as critical as for brown rats. In practice brown rats and black rats do not occur at the same location but both species may coexists with house mice populations. In the Netherlands resistance of house mice to chlorophacinone has been reported in the 1970s (Bosman, 1978)

As a consequence of the new information provided on the spread of resistant brown rats in our country and considering the risk on cross-resistance form first-generation anti-coagulants to second-generation anticoagulants bromadiolon en difenacoum, the CA NL does not consider products based on chlorophacinone suitable for the control of brown rats in the Netherlands. Ctgb therefore has decided to exclude the control of brown rats from the label claim of Rozol Pat’ in NL and restrict the use of Rozol Pat' to the control of black rats and mice only in the Netherlands.

Non-professionals are only allowed to control house mice in the Netherlands. House mice and brown rats often occur together and it cannot be excluded that non-profs will apply bait products in regions with resistant brown rats. It is not feasible to expect from non-professionals that they will be able to monitor resistance and apply a resistance management strategy. Moreover, it is not possible to inform non-professionals on the presence of resistance in certain populations/regions. The CA NL has therefore decided to restrict the use of Rozol Pat' to professional use only.

Professional users will be able to monitor resistance and apply resistance management strategies. Ctgb believes that it is also possible to inform professionals on regional differences in resistance. The possibility of other risk mitigation measures such as the French resistance monitoring system, in which the authorisation holders will have to report resistance reported by users every two years to the competent authorities have been discussed. In the Netherlands such a system is not in place and cannot be created on short term for just this product. Moreover, Ctgb strongly doubts whether such a system will be effective in the Dutch situation in which resistance is already present in brown rat populations throughout the country.

In response to the considerations above, the applicant has provided a statement with arguments on the further development of resistance and of cross-resistance to second-generation VKA’s by the use of Rozol Pat’. The main argument of the applicant is that use of a first generation VKA, such as Rozol Pat’ may be useful to control micro populations of non-resistant rats and even be used to reduce resistance levels in resistant rat populations by removing selection pressure. Also the occurrence and the mechanism of cross resistance is disputed.

In the Netherlands micro populations of non-resistant rats have not been found and are not likely to be present because of the short distances between farms and the high selection pressure by use of VKA’s (WUR, 2013). In Denmark, the strategy of using first and second generation VKA’s in alternation (warfarin, then coumatetralyl, followed by difenacoum) has resulted in extremely high levels of resistance of rats, even to difenacoum, in most of the country (Lodal, 2001). Another strategy would be a major shift towards the use of newer second generation VKA’s (brodifacoum, difethialone), hoping that moving from chlorophacinone or warfarin to one of these AVK’s represents a change that cannot result in an adaptation of the rat population. This is the strategy that is currently used in the Netherlands, but we now also see that resistant rats are further spreading throughout the country.

Although lowering AVK selection pressure could potentially result in a return of susceptible animals (as there might be a biological cost associated with resistance) this is still highly hypothetical. In such a situation, second generation AVKs could function as treatment against resistant populations and first generation could be used in those cases where no resistance is suspected, which is rare in the Netherlands. Because of the current state of knowledge, i.e. resistance is found all over the Netherlands and it is not clear where susceptible populations can be found,this strategy is currently not our choice.

The use of Rozol Pat’ to control brown rats in the Netherlands is therefore is not authorised by CA NL as it is not sufficiently effective to control brown rats, may lead to bioaccumulation in predators by the occurrence of partly poisoned rats and will also lead, to our opinion, to further development of resistance and cross-resistance to second generation VKA’s in brown rat populations. Also the use of Rozol Pat’ by non-professionals will not be authorised for the Netherlands by the CA NL.

Rozol Pat’ is authorised to be used to control black rats and house mice in buildings by professionals only in the Netherlands.

The situation on resistance in rodents in other EU countries may differ from the Dutch situation. It is therefore up to the different CA’s of the EU countries to take their own decision in the authorisation of Rozol Pat’ to control brown rats, black rats and house mice by professionals and non-professional in and around buildings, in open areas and waste dumps. Rozol Pat’ should not be used in areas where resistance against chlorophacinone is present in rats or mice, to prevent spreading of resistant populations.

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**2.5.3.4.1 Resistance management strategy**
A management strategy to minimise the likelihood of resistance to the active substance developing in the target species was provided by the applicant. It consists of the following three components:

Firstly, in general ineffective use of chlorophacinone rodenticides is often misdiagnosed as resistance. The success of a control campaign is often dependant on how the control measures are conducted in practice. It is therefore most important to select an appropriate control strategy. An effective control programme needs to consider the following aspects:

* Identification of target organism and selection of an appropriate product.
* Correct positioning of bait stations.
* Attractiveness of bait selected/competition with abundant food sources.
* Baiting for an adequate time.
* Understanding the extent and area of infestation to ensure an adequate amount is used over a sufficient area.
* Immigration from neighbouring populations.

Secondly, to avoid the development of resistance in susceptible rodent populations the following points should be adopted for all control programmes:

* Use chlorophacinone rodenticides. Ensure that all baiting points are inspected weekly and old bait replaced where necessary.
* Undertake treatment according to the label until the infestation is completely cleared.
* On completion of the treatment remove all unused baits.
* Do not use chlorophacinone rodenticides as permanent baits routinely. Use permanent baits only where there is a clear and identified risk of immigration or introduction or where protection is afforded to high risk areas.
* Monitoring of rodent activity should be undertaken using visual survey, through the use of non-toxic placebo monitors or by other effective means.
* Record details of treatment.
* Where rodent activity persists due to problems other than resistance, use alternate baits or baiting strategy, extend the baiting programme or apply alternate control techniques to eliminate the residual infestation (sub-acute rodenticides, gassing or trapping).
* Ensure that complete elimination of the infestation is achieved.
* As appropriate during the rodenticide treatment apply effective Integrated Pest Management measures (remove alternate food sources, remove water sources, remove harbourage and proof susceptible areas against rodent access).

Thirdly, when resistance to chlorophacinone is suspected or identified, the following should be conducted:

* Where rodent infestations containing resistant individuals are identified, immediately use an alternate anticoagulant of the same potency. If in doubt, seek expert advice on the local circumstances.
* Alternatively use an acute or sub-acute but non-anticoagulant rodenticide.
* In both cases it is essential that complete elimination of the rodent population is achieved. Gassing or fumigation may be useful in specific situations.
* Apply thorough Integrated Pest Management procedures (environmental hygiene, proofing and exclusion).
* Do not use anticoagulant rodenticides as permanent baits as routine. Use permanent baits only where there is a clear and identified risk of immigration or introduction or where protection is afforded to high risk areas.
* Record details of treatment.

Where individual infestations are found to be resistant or contain resistant individuals it is possible that the resistance extends further to neighbouring properties:

* Where there are indications that resistance may be more extensive than a single infestation, apply area or paste control rodent programmes.
* The area under such management should extend at least to the area of known resistance and ideally beyond.
* These programmes must be effectively co-ordinated and should encompass the procedures identified above.

The use of differing bait formulations is an integral part of the resistance avoidance plan and as such, paste bait formulations provide suitable alternate preparations of anticoagulant rodenticide. In NL professionals always need to be certificated as a pest controller. These professionals are educated in the above described resistance management strategies. It can not be expected that non-professionals have any knowledge on resistance management.

**2.5.3.5 Humaneness**The use of chlorophacinone as a rodenticide could cause suffering of vertebrate target organisms. The use of anti-coagulant rodenticides is necessary as there are at present no other valuable measures available to control the rodent population in the European Union. Rodent control is needed to prevent disease transmission, contamination of food and feeding stuffs and structural damage.

It is recognised that anticoagulants like chlorophacinone do cause pain in rodents but it is considered that this is not in conflict with the requirements of Art. 5.1 of the BPD “to avoid unnecessary pain and suffering of vertebrates”, as long as effective, but comparable less painful alternative biocidal substances or biocidal products or even non-biocidal alternatives are not available.

**2.5.4 Evaluation of the label claim**

The applicant has provided a Dutch label (WG/GA). This has been adapted to our standards. For the convenience of the competent authorities authorising this product through mutual recognition, the Dutch labels, translated in English, are added to the PAR in annex 9.

Field of use

Efficacy is claimed for indoor and outdoor use. However, authorisation for this product in NL is only allowed for indoor use for environmental reasons (see 2.8). The Dutch label (WG/GA) has been adapted accordingly.

Target species

The Ca NL has decided not to authorize the use of Rozol Pat’ to control brown rats in NL due to the spread of the resistant brown rats in the Netherlands and the cross-resistance among the first-generation anti-coagulants and between the first- and second-generation anti-coagulants. The Dutch label (WG/GA) has been adapted accordingly.

The organisms claimed to be controlled by non-professionals are brown rats, black rats and mice. However, the authorisation to use rodenticides for controlling rats in the Netherlands is restricted to licensed professional users only due to national policy. The Dutch label (WG/GA) has been adapted accordingly

Non-professionals are allowed to control only the house mice in the Netherlands. House mice and brown rats often occur together and it cannot be excluded that non-profs will apply bait products in regions with resistant brown rats, thus continuing selection pressure on resistant brown rats. It is not feasible to expect from non-professionals that they will be able to monitor resistance and apply a resistance management strategy. Moreover, it is not possible to inform non-professionals on the presence of resistance in certain populations/regions. Therefore the use of Rozol Pat' for control of house mice is restricted to professional use only. The Dutch label (WG/GA) has been adapted accordingly

Use instructions

Based on the data of the field studies, the use dosages for mice have been adapted to 30 – 50 g bait per bait point and for rats to 100 – 200 g bait per bait point (see also Table 2.5.3.4).

Resistance management

In the PAR a resistance management strategies is outlined. A short remark on resistance is added to the Dutch label (WG/GA): For the active substance chlorophacinone present in the product, there is a risk that mice and rats may develop resistance and in some parts of the Netherlands resistance is already present. This product should therefore not be used in cases in which resistance is likely, for example in cases in which earlier treatment with a chlorophacinone containing product did not result in a clear reduction of the population. Always contact with the appropriate authorities to check for the latest knowledge on occurrence of resistance.

## Exposure assessment

### Description of the intended use(s)

Rozol Pat’ is a ready-to-use rodenticide paste bait in sachets based on 0.005% w/w chlorophacinone. The product applied for is for both professional and non-professional use. Professional use is restricted to the control of rats and mice in and around buildings, in open areas and waste dumps. Non-professional use is restricted to the control of rats and mice in and around buildings. Baits should preferably be placed in tamper-resistant bait stations. For rats 100 to 200 g bait should be placed per bait station, which should be positioned at 4 to 10 meter distance of each other. For mice 30 to 50 g bait should be placed per bait station, which should be positioned at 1 to 3 meter distance of each other. After disposal of the product the bait should be checked regularly: first check 3 days after application, then every week or 15 days.

### Assessment of exposure to humans and the environment

For the product Rozol Pat’ to be used by professionals and non-professionals for the control of rats and mice in and around buildings, in open areas and around waste sites with the purpose of protecting human food and animal feedstuffs, and for general human hygiene no new studies have been provided. The environmental exposure and risk assessment of the biocidal product blue paste F01265 bait containing 50 mg/kg chlorophacinone (Rozol Pat’) from the applicant was examined appropriately according to standard requirements. The product was not a reference product in the EU-review program for inclusion of the active substance in Annex I of Directive 98/8/EC. For the environmental exposure and risk assessment of Rozol Pat’, the applicant considers the EUBEES 2 scenario for blocks to be appropriate for paste baits.

The applicant has submitted an effect and exposure assessment for Rozol Pat’. The RMS NL has updated this risk assessment for the environmental aspect. For authorisation purposes the risk assessment of Rozol Pat’ performed by the applicant is included in this Product Authorisation Report.

Environmental exposure to soil occurs when Rozol Pat’ is deployed outdoor. Non-target vertebrates may be exposed to Rozol Pat’ either directly by ingestion of exposed paste (primary poisoning) or indirectly by ingestion of the carcasses of target rodents that contain chlorophacinone residues (secondary poisoning). See for more detail section 2.8 below.

## Risk assessment for human health

Rozol Pat’ is not a reference product of the CAR for chlorophacinone; however, the risk assessment in the CAR was performed for a related product Product P1 – Red blocks containing 50 mg chlorophacinone/kg. Based on the composition the results of the studies with this product are considered to be applicable for Rozol Pat’.

No new studies with Rozol Pat’ have been submitted with respect to toxicological properties of the product.

### Hazard potential

#### Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR. The threshold limits and labelling regarding human health risks listed in Annex 4 „Toxicology and metabolism” must be taken into consideration.

#### Toxicology of the substance(s) of concern

The biocidal product does not contain substances of concern.

#### Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The product was not a reference product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC. For the toxicology of Rozol Pat’ the applicant submitted data of the comparable product Product P1 – Red blocks containing 50 mg chlorophacinone/kg, which was evaluated in the CAR. Both products contain the equal amounts of the active substance, and the concentrations of other co-formulants are comparable. Based on this the studies on Product P1 – Red blocks containing 50 mg chlorophacinone/kg are considered to be suitable for the risk assessment of Rozol Pat’. No new information is required.

The basis for the health assessment of the biocidal product is laid out in Annex 5 ”Toxicology – biocidal product”.

### Exposure

The biocidal product Rozol Pat’ contains the active substance chlorophacinone (pure: 0.050 g/kg). Rozol Pat’ bait is a ready-to use paste bait for the control of black and brown rats and mice in and around buildings, waste dump places and open areas with the purpose of protecting human food and animal feedstuffs, and for general human hygiene. Rozol Pat’ is supplied in ready to use sachets (weight: 5-40 g) which are not intended to be opened by the user.

The product is intended for both professional and non-professional use. However, non-professional use against rats is not permitted in the Netherlands by specific national policy.

The potential for exposure to chlorophacinone paste baits is summarised in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure path** | **Industrial use** | **Professional use** | **General public** | **Via the environment** |
| Inhalation | Not relevant | Not relevant | Not relevant | Negligible |
| Dermal | Not relevant | Potentially significant | Potentially significant | Negligible |
| Oral | Not relevant | Negligible | Negligible | Negligible |

**Inhalation exposure**

Chlorophacinone is not volatile and Rozol Pat’ bait is a non-dusty cereal based paste formulation containing the active substance chlorophacinone which is not volatile. Therefore, the risk of inhalation exposure to chlorophacinone for professional or amateur users during use is not considered a relevant exposure path. Similarly, for non-users, the risk of inhalation exposure to residues during or after application via the environment is considered to be negligible.

**Dermal exposure**

Rozol Pat’ is supplied ready for use in sachets which are not intended to be opened by the user. The product is placed in position by hand; however dermal exposure during application can be excluded due to the presence of the packaging. Once in place the product packaging will be damaged by rodents as they feed and the paste bait will be exposed. Dermal exposure to paste is therefore possible during clean-up operations, but this will be limited to the hands and exposure to other parts of the body is negligible. Children could potentially be the group most at risk as they may play inside or around buildings where baits have been placed. However, product labels and good practice advise users to prevent access to bait by children.

**Oral exposure**

Rozol Pat’ bait is not likely to reach the mouth of professional or amateur users. Therefore, the risk during use is considered to negligible. To prevent dermal-oral uptake, the following sentence is included in the WG/GA (instruction of use) ”Wash hand after use”. Similarly, for non-users, risk of oral exposure to residues during or after application is considered to be negligible. Children or infants may play close to the floor where baits have been placed indoors. However, product labels and good practice advise users to prevent access to bait by children. Rozol Pat’ bait also contains a bittering agent to prevent infants from ingesting bait.

#### Exposure of professional users

In Annex 6 „Safety for professional operators“, the results of the exposure calculations for the active substance and the substance of concern for the professional user are laid out.

The exposure assessment to Rozol Pat’ has been performed by the applicant by considering three exposure scenarios: bait placement in and around buildings, application around waste dumps and application in open areas.

Rozol Pat’ is supplied in sachets ready to use by professional users. A maximum dose of 200 g for rats and 100 g for mice is used per one bait point. As a worst-case, a maximum application of 6 sachets of 40 g per one bait point is considered. As the product is supplied in ready to use sachets, dermal exposure during loading is considered to be negligible. Once in place the product packaging will be damaged by rodents as they feed and red paste bait will be exposed. Dermal exposure to paste is therefore possible during clean-up operations but will be limited to the hands and exposure to other parts of the body is negligible.

According to HEEG opinion (2010) on the number of manipulations in the assessment of rodenticides (anticoagulants) a maximum of 75 manipulations per day per person is assumed (placing of 60 bait stations per day and cleaning of 15 bait stations per day). This corresponds to the maximum handling of 75 x 6 x 40 = 18 kg product/day, or 18 x 0.05 = 900 mg chlorophacinone handled per day. This scenario has been considered by the applicant for bait placement in and around buildings.

Two additional exposure scenario’s for professional user have been considered by the applicant: aplication around waste dump (landfill) perimeters for control of rodents and application in open areas for control of rodents. In the first scenario, as a worst case a maximum of 50 bait points treated per day plus remains of 50 bait points collected is considered, which corresponds to 100 x 6 x 40 = 24 kg product/day, or 24 x 0.05 = 1200 mg chlorophacinone handled per day. In the second scenario a maximum of 30 bait points treated per day is assumed, corresponding to 30 x 6 x 40 = 7.2 kg product/day, or 360 mg chlorophacinone handled per day.

The same exposure scenarios (bait placement in and around buildings, application around waste dumps and application in open areas) were considered in the CAR of chlorophacinone; however, as a worst-case approach, the assessment of the product (Product P1 – Red blocks containing 50 mg chlorophacinone/kg) without protective sachets was performed. Therefore dermal exposure during loading was also taken into account in the CAR, leading to overall higher total exposure estimates. The number of manipulations considered in the CAR were 75 treated and 75 collected bait points per day for the applications in and around buildings and around waste dumps, and 75 treated and none collected for the application in open area. Although the numbers of manipulations considered in the CAR represent a more worst-case approach, taking into account the advised maximal number of manipulations according to the HEEG opinion (2010) the numbers of manipulations proposed by the applicant are considered acceptable.

The applicant has submitted two operator exposure studies using wax block bait which is considered to be a suitable surrogate for blue paste bait in a clean-up/disposal scenario. The studies were conducted using Racumin Ready Bait (cracked wheat) containing 0.031% w/w coumatetralyl and Storm Secure 20G containing 0.0056% w/w flocoumafen. These studies were also assessed in the CAR of chlorophacinone. Following clean-up of 5 wax block residues from a single bait station, the mean residue on hands was 3.41 mg product equivalents/sample. The corresponding residues for cleaning up bait stations containing residues from 6 paste sachets and disposing of the unwanted bait will be (3.41 / 5) x 6 = 4.09 mg product equivalent/sample.

Operator body weight is assumed to be 60 kg. The dermal penetration of chlorophacinone is considered to be 1.7%.

The total systemic exposure to chlorophacinone of professional operators cleaning up Rozol Pat’ bait considered 75 manipulations per day according to HEEG (2010) is estimated at 8.70 x 10-7 mg chlorophacinone/kg bw/day without PPE. For two additional scenarios (application around waste dump and application in open area) considered by the applicant the total systemic exposure of 2.89 x 10-6 mg chlorophacinone/kg bw/day and 1.74 x 10-6 mg chlorophacinone/kg bw/day without PPE is estimated.

For professional users the use of gloves can be expected. Gloves are assumed to reduce the exposure of hands by 90%. This results in the total systemic exposure of 8.70 x 10-8, 2.89 x 10-7 and 1.74 x 10-7 mg chlorophacinone/kg bw/day for three described scenarios, respectively.

#### Exposure of non-professional users and the general public

In Annex 7 “Safety for non-professional operators and the general public”, the results of the exposure calculations for the active substance and the substance of concern for the non-professional user and the general public are laid out.

The exposure assessment to Rozol Pat’ has been performed by the applicant.

According to HEEG opinion (2010) on the number of manipulations in the assessment of rodenticides (anticoagulants) a maximum of 10 manipulations per day per person (5 loading bait stations per day and 5 cleaning bait stations per day) is proposed for non-professional user. This corresponds to the maximum handling of 10 x 6 x 40 = 2.4 kg product/day, or 2.4 x 0.05 = 120 mg chlorophacinone handled per day.

As the product is supplied in ready to use sachets, dermal exposure during loading is considered to be negligible. Once in place the product packaging will be damaged by rodents as they feed and the red paste bait will be exposed. Dermal exposure to paste is therefore possible during clean-up operations but will be limited to the hands and exposure to other parts of the body is negligible.

The same number of manipulations was considered in the CAR of chlorophacinone for non-professional users. However, as a worst-case approach, the assessment of the product (Product P1 – Red blocks containing 50 mg chlorophacinone/kg) without protective sachets was performed. Therefore dermal exposure during loading was also taken into account in the CAR, leading to overall higher total exposure estimates.

Non-professional users are assumed not to wear protective gloves (or other protective clothing) when handling the products. Operator body weight is assumed to be 60 kg. The dermal penetration of chlorophacinone is considered to be 1.7%.

Exposure assessment was evaluated based on the submitted operator exposure studies. Following clean-up of 5 wax block residues from a single bait station, the mean residue on hands was 3.41 mg product equivalents/sample. The total systemic exposure to chlorophacinone of non-professional operators cleaning up Rozol Pat’ bait in and around buildings is estimated at 2.89 x 10-7 mg/kg bw/day**.**

Indirect exposure to ROZOL PAT due to the ingestion of a bait by an infant has been considered. It is assumed that an infant may ingest 10 mg of product treated with repellent, such as blue paste. Body weight is assumed to be 10 kg for infants. Total indirect systemic exposure to chlorophacinone following the ingestion of ROZOL PAT bait is estimated at 0.00005 mg/kg bw/day for infants. However, Rozol Pat’ bait contains bittering agent which would cause any person to immediately expel it from the mouth by reflex action. Furthermore, product labels and good practice advise users to prevent access to bait by children.

#### Exposure to residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely. Therefore the risk for consumers to residues from food is considered negligible.

### Risk Characterisation

With proper use in accordance with regulations harmful effects on the health of users and third parties are not expected. The estimated exposures for the intended use are compared to the respective systemic AEL.

The AELs of 0.000017 mg/kg bw/day for repeated exposure and of 0.000033 mg/kg bw/day for acute exposure have been set in the CAR of chlorophacinone.

#### Risk for Professional Users

The following total systemic exposures to chlorophacinone have been estimated for professional users for three exposure scenarios (application in and around buildings, application around waste dump and application in open areas):

Without PPE: 8.70 x 10-7, 2.89 x 10-6 and 1.74 x 10-6 mg chlorophacinone/kg bw/day, respectively

With PPE (gloves), considering 90% reduction: 8.70 x 10-8, 2.89 x 10-7 and 1.74 x 10-7 mg chlorophacinone/kg bw/day

Professional operators are considered to be exposed to the product regularly, therefore the AEL for repeated exposure of 0.000013 mg/kg bw/day is considered. The estimated exposure levels correspond to the following percentages of AELlong-term:

Without PPE: 5.1%, 17.0% and 10.2%, respectively.

With PPE (gloves, 90% reduction): 0.51%, 1.70% and 1.02%, respectively

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected professional operator, after dermal and respiratory exposure to chlorophacinone as a result of the application of Rozol Pat’.

#### Risk for non-professional users and the general public

The total systemic exposure to chlorophacinone of non-professional operators cleaning up Rozol Pat’ bait in and around buildings is estimated at 2.89 x 10-7 mg/kg bw/day. Non-professional users are considered not to be exposed to the product on a regular basis, therefore repeated exposure is considered to be not relevant for them and the AEL for acute exposure of 0.000033 mg/kg bw/day is considered. The estimated exposure level of 2.89 x 10-7 corresponds to 0.88% of AELacute.

Total indirect systemic exposure to chlorophacinone following the ingestion of Rozol Pat’ bait is estimated at 0.00005 mg/kg bw/day for infants. Such exposure is considered to occur only incidently, therefore the AEL for acute exposure of 0.000033 mg/kg bw/day is considered. The estimated exposure corresponds to 151.5% of AELacute. The risk to infants thus appears to be of concern. According to DOC I of CAR on chlorophacinone the products containing chlorophacinone are required to carry precautionary phrases on the label to mitigate the risk of secondary human exposure. These include:

* “Baits must be securely deposited in a way so as to minimise the risk of consumption by non-target animals or children. Where possible, secure baits so that they cannot be dragged away”.
* “Keep out of reach of children”

If these safety measures are taken into account, the risks of infant exposure due to the ingestion of bait are considered to be mitigated.

Based on the risk assessment, it can be concluded that no adverse health effects are expected from indirect exposure to chlorophacinone as a result of use of Rozol Pat’.

#### Risk for consumers via residues

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely and is considered negligible (see 2.7.2.3).

## Risk assessment for the environment

Production of chlorophacinone and formulation of paste baits at the manufacturing sites takes place in closed systemsProduction and formulation systems have air treatment and all liquid effluent is stored in liquid waste storage tanks and disposed of to specialist dangerous waste processors. Contaminated solid waste is stored in dedicated containers and incinerated in a special incinerator. Consequently environmental exposure *via* manufacture, formulation, distribution and storage is considered negligible.

Consideration in the following text is confined to environmental releases following the use of Rozol Pat’ containing 50 mg chlorophacinone/kg in the scenario in and around buildings, in open areas and around waste sites. Rozol Pat’ is a ready-to-use product and further dilution prior is not foreseen.

The risk characterisation for the environment is based on proprietary product information, authoritative guidance documents describing good application practice (Crop Life International, Rodenticide Resistance Action Committee, Technical Monograph; UK Health and Safety Executive, 1999; UK Health and Safety Executive, 2003), on the EUBEES 2 ‘Emission scenario document for biocides used as rodenticides’ (Larsen, 2003), hereafter referred to as EUBEES 2, and on the Technical Guidance Document (TGD; ECB 2003).

The risk characterisation and the underlying assumptions presented here are also confirmed in the Assessment Report for chlorophacinone (Product Type 14).

Application of Rozol Pat’ containing 50 mg/kg chlorophacinone is confined to rodent control in the scenario in and around buildings, in open areas and around waste sites.

No studies were submitted with the product authorisation application for the active substance or for the product that were not already evaluated during the Annex I active review stage or studies. Detailed data on the fate and distribution of chlorophacinone in the environment and the effect of the active substance on environmental organisms can be consulted in Doc IIA of the revised final draft Assessment Report (December 2008) for chlorophacinone (PT14). The PNEC derivation is also described in detail in the Assessment Report for Chlorophacinone (Product Type 14) and included inthe table below.

**Summary of the PNECs derived for chlorophacinone in the different compartments**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Compartment | Organism | Endpoint | AF | PNEC |
| Aquatic | Fish (*O. mykiss*) | LC50 (96 h) = 0.45 mg a.s/l | 1,000 | 0.00045 mg a.s/l |
| STP | Microorganisms from an activated sludge | NOEC > 344 mg/l water solubility limit | 10 | 34.4 mg/l |
| Sediment | Sediment-dwelling organisms | Covered by the aquatic compartment |
| Soil | Earthworm (*E. foetida*) | LC50 > 340 mg a.s/kg dry soil\* | 1,000 | 0.30 mg a.s/kg wwt soil\*\* |
| Terrestrial | Birds (*C. virginianus*) | 5-d LD50 = 17.3 mg/kg bw LC50 = 95 mg a.s/kg food | 3,000 | 0.0058 mg/kg bw0.03 mg a.s/kg food |
| Terrestrial | Mammals (*Rattus norvegicus*) | NO(A)EL =0.005 mg a.s/kg bwNOEC = 0.1 mg a.s/kg food | 90 | 0.000056 mg/kg bw0.0011 mg a.s/kg food\*\*\* |

\* based on nominal concentrations and for a standard soil of 3.4% o.m. content.

\*\* No test on plants has been requested according to TM’s decision.

\*\*\* For species with a food ingestion ratio of about 0.15 (ingestion up to 15% of their body weight as food per day)., (see complementary document prepared by the RMS Suárez E. *et al*., 2008. Assessing the environmental risk for primary and secondary poisoning in birds and mammals of the rodenticide chlorophacinone. INIA-MARM report. July 2008).

### Exposure Assessment

An environmental exposure assessment has been conducted based on the fate and distribution properties of the active substance, chlorophacinone, as determined from laboratory studies. The predicted environmental concentration (PEC) of chlorophacinone has been estimated, where appropriate, in various environmental compartments (surface water, groundwater, sediment, air and soil) following realistic worst case and, where appropriate, normal case usage scenarios.

The following PEC values are based on proprietary product information[[6]](#footnote-6) and on the EUBEES 2 ‘Emission scenario document for biocides used as rodenticides’ (Larsen, 2003)

These PEC values and the underlying assumptions are also confirmed in the revised final draft Assessment Report for chlorophacinone (Product Type 14).

#### Fate and distribution in the environment

The environmental fate and behaviour of the active substance chlorophacinone is summarised in the Assessment Report for chlorophacinone (Product Type 14).

#### PEC in surface water, ground water and sediment

The PEC of chlorophacinone in surface water, groundwater and sediment is considered for uses in and around buildings, in open areas and around waste sites. Contamination of surface water or sediment with chlorophacinone from the placing of Rozol Pat’ in these areas is highly unlikely. Negligible exposure of surface water under these circumstances is also stated in the EUBEES 2 emission scenario document. In the Netherlands, however, it is well known that rats live near surface waters and that therefore also rodenticide campaigns may occur near these surface waters. Agreed scenarios to calculate the exposure in surface water from leaching of rodenticides are lacking, therefore risk mitigation measures derived from CLP characteristics of the active substance are set in place.

Furthermore, due to the likely low soil concentrations the restricted use patterns and the strong adsorption of the active substance to soil, it is considered that chlorophacinone will not move to groundwater in significant quantities.

#### PEC in air

For chlorophacinone, the estimated half-life for the hydroxyl reaction in air is 14.3 hours, the vapour pressure as determined by OECD 104 is 4.76·10-4 Pa (22.8°C) and the Henry's law constant is 0.013725 Pa.m3.mol-1 (based on a water solubility of 13.0 mg a.s/l). Therefore chlorophacinone is not expected to volatilise to air in significant quantities following use in any of the usage scenarios (i.e. in and around buildings, open areas and waste dumps) and the potential concentration of chlorophacinone in air is considered to be negligible.

#### PEC in soil

The PECs of chlorophacinone in soil arising from the various usage scenarios are considered, as follows:

**In and around buildings**

The PEC of chlorophacinone in soil is considered for uses in and around buildings as follows:

Exposure of the terrestrial compartment (soil) will occur when Rozol Pat’ is deployed outdoors. EUBEES 2 considers a scenario that entails outdoor baiting with bait blocks around a farm building. In this situation, exposure is assumed to arise through a combination of transfer (direct release) and deposition *via* urine and faeces (disperse release) onto soil. The EUBEES 2 scenario for blocks is considered to be appropriate for paste baits.

Direct release is estimated to amount to 1.0% of the total bait deployment during the entire campaign, concentrated within 10 cm of the individual secured bait points. However, since Rozol Pat’ is applied in packaging, the release is anticipated to be lower and a direct release of 0.1% is assumed to be more realistic.Similarly, EUBEES 2 considers that 90% of the total amount of rodenticide consumed by the target rodents over the duration of the outdoor baiting campaign enters soil *via* urine and faeces.

The maximum application rate for Rozol Pat’ containing 50 mg chlorophacinone/kg entails the deployment of 240 g bait in each of ten secured bait points spaced 5 m apart against a 55 m length of external wall. EUBEES 2 assumes that direct release is concentrated in a 10 cm strip in front of and to both sides of each bait point (0.09 m2). Based on penetration to a depth of 10 cm and a bulk soil density of 1700 kg/m3, the mass of soil affected by the direct release around each secured bait point is 15.3 kg. To estimate the concentration of chlorophacinone in soil arising from disperse release, it is assumed that most of the activity of the target rodents is confined to a strip of ground running along the length of the baited wall and extending to 10 m in front of it (presenting an area of 550 m2). Based on the depth and soil density values, the mass of soil receiving disperse inputs is 93,500 kg.

EUBEES 2 considers two levels of baiting. In the first, described as the “realistic worst-case”, the campaign lasts 21 days and secured bait points (initially filled on day 1 and repeatedly and completely emptied by the target rodents) are refilled on days 3, 7, 14 and 21. In the other, “typical” scenario, bait consumption progressively declines as the campaign proceeds, such that the replenishments made on days 3, 7, 14 and 21 represent 100%, 25-50%, 10% and 0%, respectively, of the quantity initially deployed on day 1. It should be noted that the “typical” scenario is more representative of the consumption pattern for a potent anticoagulant rodenticide such as chlorophacinone, as demonstrated by field studies.

In both scenarios, the direct and disperse chlorophacinone releases (Elocalsoil, mg) to the relevant soil surfaces may be calculated according to:

Elocalsoil = Qprod × Fcprod × Nsites × Nrefill × Frelease, soil,

where:

Qprod = weight of Rozol Pat’ (240 g) per secured bait point;
Fcprod = concentration of chlorophacinone in the paste bait (0.050 mg/g);
Nsites = number of secured bait points (10);
Nrefill = number of refills during the campaign (5 in “realistic worst-case” and 1.5 in “typical” scenario)
Frelease, soil = fraction released to soil (0.001 for direct release and 0.9 for disperse release).

**Concentrations of chlorophacinone in soil following baiting around buildings with Rozol Pat’**

|  |  |  |  |
| --- | --- | --- | --- |
| **Baiting scenario (EUBEES 2)** | Direct release(mg/0.09 m2) | Disperse release(mg/550 m2) | PECsoil (mg chlorophacinone/kg ww)a |
| meanb | maxc |
| Realistic worst-case | 0.60 | 540.0 | 0.0058 | 0.0097 |
| Typical | 0.18 | 162.0 | 0.0017 | 0.0029 |
| a based on uniform distribution to 10 cm depth and wet soil bulk density of 1.7 g/cm3;b disperse release applied to total area (550 m2);c direct + disperse release within 10 cm in front of and to sides of each bait point. |

Clocal concentrations (PECsoil, mg chlorophacinone/kg wet soil) have been calculated as indicated below. The mass of soil affected by the direct release around each secured bait point is 15.3 kg; the soil affected by indirect release around 10 bait stations is 93,500 kg.

**Realistic worst-case (values for typical case shown in brackets)**:

Direct release: Clocal, direct =  = 0.0039 mg/kg (0.0012 mg/kg ww);

Indirect release: Clocal, indirect =  = 0.0058 mg/kg (0.0017 mg/kg ww);

Maximum concentration in soil: Clocal, direct + Clocal, indirect = 0.0097 mg/kg (0.0029 mg/kg ww).

**Open areas**

Paste baits are applied in open areas by inserting them inside the openings of the tunnels of the target rodents and, according to the scenario presented in EUBEES 2, two such treatments would typically be applied in the space of six days. Bait deployment comprising 6 × 40 g pastes per application per tunnel entrance is considered in this assessment as a worst-case compared to the 100 g bait application suggested in EUBEES 2. Based on a tunnel of 8 cm diameter, worst-case soil exposure is assumed to occur to a depth of 10 cm from the contact half (*i.e*. the burrow floor) of a 30 cm tunnel section in which the bait is placed. This section of tunnel floor is assumed to receive an input corresponding to 5% of the product during application and a further 20% as the bait is consumed.

**Concentrations of chlorophacinone in soil following baiting in open areas with paste bait**

|  |  |  |  |
| --- | --- | --- | --- |
| **Baiting scenario (EUBEES 2)** | Chlorophacinone applied(mg)a | Total direct deposition(mg)b | PECsoil(mg chlorophacinone/kg ww)c |
| Worst-case | 24.0 | 6.0 | 0.415 |
| a based on 2 × (6 × 40 g) pastes containing 50 mg chlorophacinone/kg;b based on inputs during application and consumption giving a combined deposition of 25%;c based on uniform distribution in a semi-cylinder of soil of 4 cm and 14 cm inner and outer radius, respectively, 30 cm length (volume: 8,500 cm3) and a wet soil bulk density of 1.7 g/cm3. |

The predicted concentration of 0.415 mg chlorophacinone/kg soil represents the worst-case in the immediate vicinity of each bait application. However, since paste baits are supplied in sachets, the extent of release of chlorophacinone into the floor of the tunnel is likely to be considerably less than the 25% suggested in EUBEES 2. Moreover, as the target rodents will eat and translocate portions of edible baits, and since much of the active substance will subsequently be excreted over a wide area outside the tunnel network, soil concentrations elsewhere will be considerably lower.

**Waste dumps**

Paste baits are deployed around the perimeter of waste-dumps and land-fill sites to control populations of rats. EUBEES 2 suggests a worst-case scenario in the event of an infestation outbreak that entails 40 kg of paste protected and distributed over an area of 1 ha, with a total of seven such applications per year. In this situation, soil exposure is assumed to arise through a combination of deposition via urine and faeces plus the rodenticide contained in the carcasses of poisoned target rodents. The EUBEES 2 scenario for blocks is considered to be appropriate for paste baits. In general, ninety percent of the total amount of rodenticide consumed by the target rodents over the duration of each baiting campaign is assumed to enter soil over the 1 ha surface.

According to the worst-case scenario, the total chlorophacinone release (Elocalsoil, mg) to the soil surface may be calculated according to:

Elocalsoil = Qprod × Fcprod × Napp × Frelease, soil,

Where:

Qprod = the total weight of paste (40 kg)
Fcprod = the concentration of chlorophacinone in the paste product (50 mg/kg)
Napp = the number of applications (7)
Frelease, soil = the fraction released to soil (0.9).

**Worst-case concentration of chlorophacinone in soil following baiting around waste dumps/landfills with bait pastes**

|  |  |  |
| --- | --- | --- |
| **Baiting scenario** | Release to soil(mg chlorophacinone/ha) | PECsoil(mg chlorophacinone/kg ww)a |
| Worst-case (EUBEES 2)b | 12600 | 0.0074 |
| a based on uniform distribution to 10 cm depth and wet soil bulk density of 1.7 g/cm3;b based on seven applications of chlorophacinone in pastes/year. |

#### Non compartment specific exposure relevant to the food chain (secondary poisoning)

The exposure of chlorophacinone directly to non-target birds and mammals and indirectly via target rodent carcasses (secondary poisoning) is quantified in section 2.8.2. These exposure routes to non-target vertebrates are not considered to have consequences for widespread contamination of environmental compartments.

### Risk Assessment

The risk characterisation and the underlying assumptions presented here are also confirmed in the Assessment Report for chlorophacinone (Product Type 14).

#### Aquatic compartment (incl. sediment)

Contamination of surface water or sediment with chlorophacinone following the use of Rozol Pat’ in and around buildings, open areas and around waste dumps is highly unlikely. Negligible exposure of surface water is also stated in the EUBEES 2 emission scenario document. Furthermore, due to the likely low concentrations in soil the restricted usage patterns and the strong adsorption of the active substance to soil, it is considered that chlorophacinone will not move to groundwater in significant quantities. Therefore, chlorophacinone concentrations in surface waters have not been calculated and, since exposure is expected to be negligible, PEC/PNEC quotients are not presented. The use of Rozol Pat’ represents a very low risk to aquatic and sediment-dwelling biota and no further assessment of risk is necessary.

In the Netherlands, however, it is well known that rats live near surface waters and that therefore also rodenticide campaigns may occur near these surface waters. Agreed scenarios to calculate the exposure in surface water from leaching of rodenticides are lacking, therefore risk mitigation measures derived from CLP characteristics of the active substance are set in place.

#### Atmosphere

For chlorophacinone, the estimated half-life for the hydroxyl reaction in air is 14.3 hours, the vapour pressure as determined by OECD 104 is 4.76·10-4 Pa (22.8°C) and the Henry's law constant is 0.013725 Pa.m3.mol-1 (based on a water solubility of 13.0 mg a.s/l). Therefore chlorophacinone is not expected to volatilise to air in significant quantities following use in any of the usage scenarios (i.e. in and around buildings, open areas and waste dumps) and the potential concentration of chlorophacinone in air is considered to be negligible.

#### Terrestrial compartment

Soil exposure occurs both through a combination of direct and indirect releases from the use of Rozol Pat’ in the scenario “in and around buildings”, in open areas and around waste sites.

**In and around buildings**

Exposure of the terrestrial compartment (soil) will occur when Rozol Pat’ is deployed outdoors.

EUBEES 2 considers a scenario that entails outdoor baiting with paste bait around a farm building. In this situation, exposure is assumed to arise through a combination of transfer (direct release) and deposition *via* urine and faeces (disperse release) onto soil. The EUBEES 2 scenario for blocks is considered to be appropriate for paste baits. Direct release is estimated to amount to 1.0% of the total bait deployment during the entire campaign, concentrated within 10 cm of the individual secured bait points. However, since Rozol Pat’ is applied in packaging, the release is anticipated to be lower and a direct release of 0.1% is assumed to be more realistic.Similarly, EUBEES 2 considers that 90% of the total amount of rodenticide consumed by the target rodents over the duration of the outdoor baiting campaign enters soil *via* urine and faeces.

The maximum application rate for Rozol Pat’ containing 50 mg chlorophacinone/kg entails the deployment of 240 g bait in each of ten secured bait points.

EUBEES 2 considers two levels of baiting. In the first, described as the “realistic worst-case”, the campaign lasts 21 days and secured bait points (initially filled on day 1 and repeatedly and completely emptied by the target rodents) are refilled on days 3, 7, 14 and 21. In the other, “typical” scenario, bait consumption progressively declines as the campaign proceeds, such that the replenishments made on days 3, 7, 14 and 21 represent 100%, 25-50%, 10% and 0%, respectively, of the quantity initially deployed on day 1. It should be noted that the “typical” scenario is more representative of the consumption pattern for a potent anticoagulant rodenticide such as chlorophacinone.

The risks to the terrestrial environment posed by contamination of soil by chlorophacinone following “realistic worst-case” and “typical” outdoor use of Rozol Pat’ are assessed by calculating ratios of PEC/PNEC, as indicated below. As stated above, the “typical” pattern is the one more likely to apply to an efficient anticoagulant rodenticide such as chlorophacinone.

PECsoil/PNECsoil for soil-dwelling invertebrates exposed to chlorophacinone following outdoor use of bait pastes around buildings

|  |  |  |  |
| --- | --- | --- | --- |
| **Baiting scenario (EUBEES 2)** | maximum PECsoil (mg chlorophacinone/kg ww) | PNECsoil (mg chlorophacinone/kg ww) | PEC/PNEC ratio |
| Realistic worst-case | 0.0097 | 0.30 | 0.03 |
| Typical | 0.0029 | 0.30 | 0.01 |

The PEC/PNEC ratios are less than 1.0, indicating that the exposure to chlorophacinone that arises following the use of Rozol Pat’ in and around buildings presents no unacceptable risks to soil-dwelling invertebrates.

**Open areas**

Rozol Pat’ is applied in open areas by inserting them inside the openings of the tunnels of the target rodents and, according to the scenario presented in EUBEES 2, two such treatments would typically be applied in the space of six days. Bait deployment comprising 6 × 40 g pastes per application per tunnel entrance is considered in this assessment as the closest practical approximation to the 100 g bait application suggested in EUBEES 2. Based on a tunnel of 8 cm diameter, worst-case soil exposure is assumed to occur to a depth of 10 cm from the contact half (*i.e*. the burrow floor) of a 30 cm tunnel section in which the bait is placed. This section of tunnel floor is assumed to receive an input corresponding to 5% of the product during application and a further 20% as the bait is consumed.

The predicted concentration of 0.415 mg chlorophacinone/kg ww soil represents the worst-case in the immediate vicinity of each bait application.

**PECsoil/PNECsoil for soil-dwelling invertebrates exposed to chlorophacinone following use of paste bait in rodent tunnels in open areas**

|  |  |  |  |
| --- | --- | --- | --- |
| **Baiting scenario (EUBEES 2)** | PECsoil (mg chlorophacinone/kg ww) | PNECsoil (mg chlorophacinone/kg ww) | PEC/PNEC ratio |
| Worst-case | 0.415 | 0.30 | 1.4 |

The PEC/PNEC ratios calculated indicate a marginal risk based on the PEC that represents a localised “hotspot” of contamination near the entrance of each baited tunnel.

**Waste dumps**

Paste baits are deployed around the perimeter of waste-dumps and land-fill sites to control populations of rats. EUBEES 2 suggests a worst-case scenario in the event of an infestation outbreak that entails 40 kg of paste protected inside bait boxes distributed over an area of 1 ha, with a total of seven such applications per year. In this situation, soil exposure is assumed to arise through a combination of deposition via urine and faeces plus the rodenticide contained in the carcasses of poisoned target rodents. The EUBEES 2 scenario for blocks is considered to be appropriate for paste baits. In general, ninety percent of the total amount of rodenticide consumed by the target rodents over the duration of each baiting campaign is assumed to enter soil over the 1 ha surface.

The risks to earthworms posed by contamination of soil by chlorophacinone following the “worst-case” use of pastes at waste dumps and landfill sites are assessed by calculating ratios of PEC/PNEC, as indicated below.

**PECsoil/PNECsoil for soil-dwelling invertebrates exposed to chlorophacinone following use of paste bait at waste dumps and landfill sites**

|  |  |  |  |
| --- | --- | --- | --- |
| **Baiting scenario** | PECsoil (mg chlorophacinone/kg ww) | PNECsoil (mg chlorophacinone/kg ww) | PEC/PNEC ratio |
| Worst-case (EUBEES 2) | 0.0074 |  0.30 |  0.025 |

The PEC/PNEC ratio is less than 1.0 under the worst case suggested by EUBEES 2. The exposure to chlorophacinone that arises from the use of Rozol Pat’ at waste dumps and landfill sites therefore presents no unacceptable risks to soil organisms.

#### Non compartment specific effects relevant to the food chain (primary and secondary poisoning)

Non-target vertebrates (birds and mammals) may be exposed to Rozol Pat’ containing chlorophacinone either directly by ingestion of exposed paste (primary poisoning) or indirectly by ingestion of the carcasses of target rodents that contain chlorophacinone residues (secondary poisoning).

Based on toxicity data chlorophacinone is very toxic and presents a hazard to birds and non-target mammals.

The Emission Scenario Document for Biocides used as Rodenticides (EUBEES 2) presents exposure scenarios and assessments which give a basis for evaluating the primary and secondary poisoning risk to non-target animals. It is proposed to introduce tiered approaches for assessing the risks through both primary and secondary poisoning and to derive different PECs for each step.

**Exposure scenarios for quantification of primary and secondary poisoning according to EUBEES 2**

|  |  |  |
| --- | --- | --- |
|  | **Primary poisoning** | **Secondary poisoning** |
| Tier 1 | Risk is quantified as the ratio between the concentration in the food for the non-target organism (PECoral) and the predicted no-effect-concentration for oral intake for the non-target organism (PNECoral) | Risk is quantified as the ratio between the concentration in the rodent immediately after a last meal on day 5 (EC5) and the predicted no-effect-concentration for oral intake for the non-target organism (PNECoral)  |
| Tier 2 | Risk is quantified as the ratio between the estimated daily intake of a compound (ETE) and the predicted no-effect-concentration for oral intake for the non-target organism (PNECoral).For the long-term exposure the estimated concentration of the active substance in the animal can be calculated and compared with the NOAEL. | Risk is quantified as the ratio between the estimated concentration in predatory mammals or birds and the no-observed-adverse-effect levels (NOAEL) for the organism. |

Object of a quantitative risk assessment will be:

• Primary poisoning, Tier 1

• Primary poisoning, Tier 2 for 5 day exposure

• Secondary poisoning; Tier 1 for long-term exposure

• Secondary poisoning; Tier 2 for long-term exposure

Object of a qualitative risk assessment will be:

• Primary poisoning, Tier 2 for 1 day exposure

• Secondary poisoning; Tier 1 for short-term exposure

The primary and secondary poisoning assessment has further on been conducted in accordance with the newly developed guidance document on the PNECoral derivation for the primary and secondary poisoning assessment of anticoagulant rodenticides, which has been adopted by the Competent Authorities and published on JRC IHCP’s biocides website. It describes a quantitative risk assessment for the long-term exposure situation regarding primary and secondary poisoning with anticoagulant rodenticides and what PNECoral to be used for this assessment. As at the moment no guidance is available on how to derive a PNECoral for an acute exposure situation, only a qualitative risk assessment for the acute primary and secondary poisoning situations is carried out.

Regarding the qualitative assessment only a description of the toxicity of the substance compared to the possible single uptake is presented instead of carrying out a quantitative risk assessment. It is important to stress that this qualitative assessment is a simple comparison of the acute exposure situation with single dose LD50 values. It is not intended to be used for risk characterisation; no PNECoral shall be derived and hence no PEC/PNEC ratio can be established. This comparison gives only a first indication of the acute toxicity of the substance. Regarding the long-term exposure situation a quantitative risk assessment of the primary and secondary poisoning situation is carried out. However, it is not possible to quantify primary or secondary exposure accurately, given highly variable factors such as the specific locality of a rodent control campaign, whether there are non-target scavengers or predators present, whether predators will catch many rodents and whether such rodents will contain high levels of chlorophacinone. Because of many uncertainties the following assessments of risk should be considered as a worst case.

Chlorophacinone is presented in a matrix of cereal flour bound together with hydrogenated vegetable fat. Presentation of chlorophacinone in this processed matrix has the benefit of reducing the appeal of the bait to non-target organisms that would otherwise readily consume loose chlorophacinone-treated cereal grains (Marsh, 1985). Marsh noted that modification of cereal grains by rolling and milling reduces their acceptance by birds that would readily consume them in their natural state.

Rozol Pat’ is individually packaged in sachets and is deployed with the wrapping intact. This reduces the appeal to non-target vertebrates that rely predominantly on visual rather than olfactory recognition of potential food items. It is known that visual stimuli are particularly important to birds in the selection of novel foods and sachets containing paste are likely not to be visually appealing to birds as food, based on their shape, texture and colour (WHO, 1995). Inclusion of a blue dye in chlorophacinone paste bait is likely to reduce its appeal as a potential food item still further.

Gemmeke (2000)[[7]](#footnote-7) noted that pigeons, Japanese quails, various crows, jackdaws, magpies and pheasants presented with a choice of natural and dyed seeds of various crop species all preferred the untreated option, and that seeds artificially coloured green, grey, black, pink, blue, violet and brown-violet were either untouched or only eaten in small (*ca*. 10%) amounts. Similarly, Moran (1999)[[8]](#footnote-8) found that pigeons and partridges preferred undyed grains of their favoured seeds (whole-grain wheat and sorghum, respectively), but that pigeons showed no colour discrimination when only the seeds of a species normally avoided were available. Although species, sex and even individual preferences will modulate the response of birds to colour, there is evidence from the literature that colours in the middle of the visible colour spectrum range are generally better deterrents than other colours. For example, Marsh (1985)[[9]](#footnote-9), (citing Kalmbach (1943)[[10]](#footnote-10), Kalmbach and Welch (1946)[[11]](#footnote-11), Caithness and Williams (1971)[[12]](#footnote-12), Pank, (1976)[[13]](#footnote-13) and Brunner and Coman (1983)[[14]](#footnote-14)) reported that green and yellow were particularly effective colours for discouraging intake of rodenticidal baits and suggested that the deterrent effect of the colorant may in some cases be a visual cue coupled with taste-conditioned aversion. However, EUBEES 2 states clearly that it is impossible to quantify the effect of the coloured bait and that colour preferences vary between species and may change depending on the context (e.g. depending on the hunger of the animals). Birds are therefore not considered to be at low risk of primary poisoning, although the worst case scenarios described below may over-estimate uptake for birds. However, this can not be quantified and will not be considered in the primary poisoning risk assessment. As paste in sachets seems to have a very low likelihood to be ingested by birds the default value for the avoidance factor of 1 from EUBEES 2 is lowered to 0.5 for this product type.

Primary poisoning of mammals is included in this assessment since non-target mammals are less reliant solely on visual stimuli in identifying potential food and may ingest paste bait.

A secondary poisoning risk assessment was carried out for birds and mammals for the use scenario “in and around buildings”.

**PNECoral derivation for primary and secondary poisoning**

In EUBEES 2 no guidance is given on how to derive the PNECoral values. The PNECoral derivation described in the TGD for the secondary poisoning assessment considers the oral intake of a chemical via fish or worms and a long-term exposure situation. No guidance is given regarding primary poisoning. In EUBEES 2 it is mentioned that both an acute and a long-term risk assessment should be conduced for anticoagulant rodenticides, because although the mode of action is generally chronic, some anticoagulant rodenticides (including rodenticides containing chlorophacinone) have substantial acute toxicity. But comparing an acute poisoning incident, which represents a single uptake of the anticoagulant rodenticide by a non-target mammal or a bird, to a PNECoral which has been derived in accordance with the TGD, considerably overestimates the risk due to the choice of long-term studies as a basis for deriving the PNECoral. The TGD does not give guidance on how to derive acute PNECoral in addition to the long-term PNECoral. Nothing is stated on the choice of studies, endpoints and assessment factors.

Therefore the acute primary and secondary poisoning risk assessment for the food chains rodenticide (bait) → rodenticide-eating mammal or bird (primary poisoning) and the food chain rodenticide (bait) → rodent → rodent-eating mammal or bird (secondary poisoning) is only assessed in a qualitative, and not in a quantitative way. It is important to stress that this qualitative assessment is not intended to be used for the risk characterisation of primary and secondary poisoning of rodenticides and shall not be used for a comparative assessment. This comparison should only give a first indication of the acute toxicity of the substance. Regarding the long-term exposure situation a quantitative risk assessment is carried out. The risk characterisation for the primary and secondary poisoning risk assessment is based on the long-term exposure situation as described in EUBEES and on PNECoral values which are derived according to the TGD. The PNECsoral used for primary and for secondary poisoning are the same, as is anticipated that chlorophacinone taken up via chlorophacinone containing products is as toxic and equal available to non-target animals as chlorophacinone taken up via poisoned rodents.

**PNECoral related to the concentration in the food**

For primary and secondary poisoning at Tier 1 the PNECoral is related to the food concentration [mg/kg food] and values for PNEC oral were derived according to the TGD.

**Birds:**

Based on the 5-days short-term dietary LC50 study performed by several authors, in Bobwhite quail (*Colinus virginianus*), the 5‑days LC50 of chlorophacinone is 95 mg a.s/kg food.

According to the Risk Assessment TGD the oral assessment factor (AForal) for extrapolation of bird toxicity data in a 5-day dietary assay is 3,000. PNECoral (bird) = 95/3000 = 30 μg/kg food.

Birds in a 90-day reproduction study with no GLP (Ri=3) resulted in a NOEC of 0.1 mg/kg food with AForal of 30 would result in PNECbirds of 1/30 = 0.03 mg a.s/kg food based on mortality. This result is considered as additional information which supports the PNEC calculated with the former AF of 3,000 (short-term dietary studies) for birds. This information is confirmed by the extrapolation from the difenacoum data.

PNECoral (bird) = 30 μg/kg food.

**Mammals:**

Results (NOAEL) from the repeated dose toxicity studies are used for PNECoral derivation. In principle the lowest NOAEL should be used to derive a PNECoral, predator. Rat was the most sensitive species to chlorophacinone. It seems justified to use this value for the PNECoral derivation for mammals, even though it is the target organism, as the effect mechanism of chlorophacinone is not target specific but general for warm blood organisms

Rat: NOAEL (77-112 days, repeated dose) = 5 μg/kg bw; Conversion factor 20; Assessment factor 90.

PNECoral (mammal) = 1.1 μg/kg food

For dogs there is a non-valid single dose study available with a LD50 much lower than 2 mg/kg bw as all animals died in this study. The study results suggest that dogs might be orally more sensitive than rats, as higher mortality is observed at similar or lower doses than in the rat studies. However, a higher sensitivity of dogs cannot be definitively concluded as dogs were fed with a vitamin K deficient diet, which might influence the potency of the administered chemical. In any case, there is no evidence that the rat is more sensitive that other mammal species.

The PNEC for dogs is therefore set equal to the PNECoral (mammal) = 1.1 µg/kg food

**PNECoral – Related to dose**

At Tier 2 of the primary and the secondary poisoning assessment the PECoral is related to the dose [mg/kg bodyweight] and therefore PNECoral has also to be expressed on the basis of the dose. For converting the PNECoral values from a concentration in food [mg/kg food] to a dose related PNECoral [mg/kg body weight], and vice versa, the following equation can be used, if necessary:

Daily dose [mg/kg bw day] = conc. in food [mg/kg] \* daily food consumption [g/bird day]/body weight [g]

**Birds:**

Based on the 5-days short-term dietary LD50 study, performed by several authors, in Bobwhite quail (*Colinus virginianus*), the 5‑days LD50 of chlorophacinone is 17.3 mg a.s/kg bw.

According to the Risk Assessment TGD the oral assessment factor (AForal) for extrapolation of bird toxicity data in a 5-day dietary assay is 3,000. This information is confirmed by the extrapolating the data from difenacoum.

PNECoral (bird) = 5.8 μg/kg bw.

**Mammals:**

Results (NOAEL) from the repeated dose toxicity studies are used for PNECoral derivation. In principle the lowest NOAEL should be used to derive a PNECoral, predator. Rat was the most sensitive species to chlorophacinone. It seems justified to use this value for the PNECoral derivation for mammals, even though it is the target organism, as the effect mechanism of chlorophacinone is not target specific but general for warm blood organisms.

Rat: NOAEL (77-112 days, repeated dose) = 5 μg/kg bw; Assessment factor 90

PNECoral (mammal) = 0.056 μg/kg bw

For dogs the same PNEC was used considering the insufficient data available.

**Primary poisoning**

**In and around buildings**

Non-target birds and mammals may encounter paste bait containing chlorophacinone if they are small enough to be able to reach the bait, or because the bait is inadequately safeguarded or a secured bait point has become damaged, or by finding pieces of paste which have been removed by target rodents. However, good practice requires that control sites are checked regularly during baiting campaigns and that damaged points have to be repaired or replaced and that spilt bait is removed.

A primary poisoning assessment for mammals and birds has been carried out. Regarding birds, the avoidance factor for the paste formulation has been lowered as paste in sachets is unlikely to be consumed by birds. Dyed bait blocks and pellets might not appeal to birds as a source of food as well. However, as indicated in the EUBEES 2 document colour preferences vary between species and may change depending on the context. Therefore, as a worst case approach, primary poisoning is considered.

**Tier 1 risk assessment**

Quantities of paste bait (40 g size) are placed at secured bait points in and around buildings. Based on the maximum number used (6) and the concentration of active substance (50 mg/kg), the following table indicates various amounts of chlorophacinone that may be taken from a bait point. These provide chlorophacinone ingestion estimates for a first tier, estimate of exposure to non-target mammals.

**Quantities of chlorophacinone in paste bait potentially accessible to non-target vertebrates following deployment at secured bait points in and around buildings**

|  |  |  |  |
| --- | --- | --- | --- |
| **Maximum paste size and maximum number per bait point** | Maximum weight of chlorophacinone per bait point (mg) | **Proportion of bait point contents accessible (%)** | **Chlorophacinone potentially ingested by non-target vertebrates (mg) ≡ PECoral** |
| 40 g × 6 (rat control) | 12.0 | 100 | 12.0 |
| 50 | 6.0 |
| 40 | 4.8 |
| 30 | 3.6 |
| 20 | 2.4 |
| 10 | 1.2 |

As an absolute worst case the risk at this tier is quantified as the ratio between the concentration of chlorophacinone in food and the PNECoral. It is assumed that non-target animals have direct access to an unlimited amount of formulated product. Chlorophacinone concentration in the bait is 50 mg/kg and hence the PECoral is 50 mg/kg food. The PNECoral for birds is 30 μg/kg food, the PNECoral (mammal and dog) is 1.1 μg/kg food. The PEC/PNEC values are rounded values. There are many uncertainties related to the calculation of PEC/PNEC values. Moreover, the PEC/PNEC values are very high. Therefore, not the exact numbers have been presented but rounded figures (e.g. 45,000 instead of 45,455).

Mammals: PEC/PNEC ≈ 45,000

Dogs: PEC/PNEC ≈ 45,000

Birds: PEC/PNEC ≈ 1,700

This conservative approach clearly highlights a high risk to birds and non-target mammals if chlorophacinone containing products are freely consumed. This risk characterisation has been carried out with the PNECoral values representative for a long-term exposure situation.

**Tier 2 risk assessment: Acute effects**

At Tier 2 a refinement of the Tier 1 is made by assessing the amount of food ingested by non target animals by the equation:

ETE = (FIR/BW) \* C \* AV \* PT \* PD (mg chlorophacinone/kg bw/day),

- where ETE is the estimated theoretical exposure to the active substance, FIR is the non-target mammal food intake [g/d] (fresh weight), BW is bodyweight [g], C is the concentration of active substance in the fresh diet 50 mg/kg (paste), AV is the avoidance factor (default 1.0 = no avoidance; AV = 0.5 for birds when product is paste), PT is the fraction of diet obtained in the treated area (default 1.0) and PD is the fraction of food type in the diet (default 1.0).

This is a worst case scenario as it assumes that the entire food of the non-target animals (except for birds) is the bait (PD = 1) and that AV and PT are both 1. The concentration of chlorophacinone in the products is 50 mg/kg. In a second step for mammals AV is 0.9, PT is 0.8 and PD is 1 to represent a more realistic worst case situation. For birds AV is set to 0.5 at both steps as the product is a paste in a sachet as this product is less likely to be consumed by birds than bait blocks. The ETE is estimated for one day without taking excretion into account. Data on bodyweight is taken from EUBEES 2, if not otherwise stated.

**ETE (1 day) for non-target mammals and birds ingesting paste bait containing chlorophacinone without excretion**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Non-target mammal** | **Typical bodyweight (g)** | **Daily mean food intake(g dry weight/day)3** | **ETE after one meal [mg/kg bw]**Step 11 | **ETE after one meal [mg/kg bw]Step 21** |
| Dog | 10,000a | 456 | 2.28 | 1.82 |
| Cat  | 3,000 2 | 170 | 2.83 | 2.27 |
| Pig  | 25,000 | 969 (600) 5 | 1.20 6 | 0.96 |
| General non target mammal  | 5,700 4 | 287 | 2.52 | 2.01 |
| Tree sparrow  | 22 | 7.6 | 8.64 | 6.91 |
| Chaffinch  | 21.4 | 6.42 | 7.50 | 6.00 |
| Woodpigeon  | 490 | 53.1 | 2.71 | 2.17 |
| Pheasant  | 953 | 103 | 2.69 | 2.16 |
| 1 Step 1: AV, PT and PD = 1; Step 2: AV = 0.9, PT = 0.8 and PD = 1 (both steps for birds AV = 0.5),2 Mean bodyweight from chlorophacinone dossier. 3 From EUBEES 2, Section 3.2.1., logFIR = 0.822 logBW - 0.629. 4 From EUBEES 2, Table 3.5 (weight of a fox is anticipated) 5 EUBEES 2 give an upper limit of 600 g for daily meal. 6 based on FIR calculated with 600 g  |

**Comparison of ETE (1 day) for non-target mammals and birds, without excretion, with LD50 values**

|  |  |  |  |
| --- | --- | --- | --- |
| **Non-target mammal** | **ETE [mg/kg bw]****Step 1** | **ETE [mg/kg bw]****Step 2** | **LD50 mammals/birds** **[mg/kg bw]**  |
| Dog  | 2.28 | 1.82 | << 2 (dog)  |
| Cat  | 2.83 | 2.27 | 3.15 (male rat)1 |
| Pig  | 1.20 6 | 0.96 | 3.15 (male rat)1  |
| General non target mammal2 | 2.52 | 2.01 | 3.15 (male rat)1  |
| Tree sparrow  | 8.64 | 6.91 | 257 (quail)3  |
| Chaffinch  | 7.50 | 6.00 | 257 (quail)3  |
| Woodpigeon  | 2.71 | 2.17 | 257 (quail)3  |
| Pheasant  | 2.69 | 2.16 | 257 (quail)3  |
| 1 single dosage 21 days post exposure period (no valid LD50 for cat / pig available)2 Body weight of a fox was chosen 3 single dosage 30 days post exposure |

Taking into account excretion in non-target animals, assuming a default elimination factor of 0.3 according to EUBEES 2, the following values for ETE at step 1 and 2 can be calculated.

**Comparison of ETE (1 day) for non-target mammals and birds, consideration excretion, with LD50 values**

|  |  |  |  |
| --- | --- | --- | --- |
| **Non-target mammal** | **ETE [mg/kg bw]****Step 1** | **ETE [mg/kg bw]****Step 2** | **LD50 mammals/birds** **[mg/kg bw]**  |
| Dog  | 1.60 | 1.28 | << 2 (dog)  |
| Cat  | 1.98 | 1.59 | 3.15 (male rat)1 |
| Pig  | 0.84 | 0.67 | 3.15 (male rat)1 |
| General non target mammal2 | 1.76 | 1.41 | 3.15 (male rat)1 |
| Tree sparrow  | 6.05 | 4.84 | 257 (adult quail)3  |
| Chaffinch  | 5.25 | 4.20 | 257 (adult quail)3  |
| Woodpigeon  | 1.90 | 1.52 | 257 (adult quail)3 |
| Pheasant  | 1.89 | 1.51 | 257 (adult quail)3 |
| 1 single dosage 21 days post exposure period (no valid LD50 for cat / pig available)2 Body weight of a fox was chosen 3 single dosage 30 days post exposure |

As no acute PNECoral could be derived the exposure concentrations are only compared in a qualitative way with acute LD50 values. It is clear from the above two tables that for birds values for ETE are after one meal do not exceed the lowest single dosage LD50 for birds of 257 mg/kg bw. For mammals except for dogs (step 1) ETE is below the single dose LD50 value of << 2 mg/kg bw. However, this qualitative assessment is a simple comparison of the acute exposure situation with single dose LD50 values and the conclusion should not be that the substance is not acutely toxic or "unproblematic" with regard to the acute primary poisoning situation of mammals. A comparison has been made with a single dose LD50 without applying an assessment factor. This comparison is not intended to be used for risk characterisation as no PNECoral has been derived and hence no PEC/PNEC ratio can be established.

**Tier 2 risk assessment - long-term effects**

EUBEES 2 suggests a long-term scenario for 5 days of exposure and considering elimination (excretion). The principle in the calculations is for the first 5 days that the animal eats the same daily amount and eliminates 30 % of its content of residues (default value). Therefore, the concentration of residues on day 5 is calculated stepwise:

EC=ETE\*(1-EL), where EL is the fraction eliminated

EC1 = ETE

EC2 = ETE \* (1 - 0.3)

EC3 = (EC2 + ETE) \* (1 - 0.3)

EC4 = (EC3 + ETE) \* (1 - 0.3)

EC5 = (EC4 + ETE) \* (1 - 0.3)

Elimination factors are only available for rats. They indicate an elimination of approximately 26 % per day during the first 3 days after dosing. For simplification an elimination factor of 0.3 is used for the entire time, in accordance with EUBEES 2, and this elimination rate is used for all animals. However, this is only a preliminary approach as the elimination rates in other animals but rats might be different. This approach may under- or overestimate the concentration in the non target animals. In a first step, AV, PT and PD all are 1.

In a second approach AV and PT can be reduced (AV = 0.9 for mammals and 0.5 for birds, PT = 0.8 and PD = 1) to represent a more realistic worst case. Results of the long term PEC/PNECoral ratios for non-target animals exposed to paste containing 50 mg chlorophacinone /kg in the scenario “in and around buildings” are presented in the Table below. The ETE was calculated including an elimination factor of 0.3 per day from body residues. The expected concentration of chlorophacinone in the animals after 5 days after excretion is calculated. There are many uncertainties related to the calculation of PEC/PNEC values. Moreover, the PEC/PNEC values presented in the table below are very high for mammals (up to 238,000) and for birds (up to 4,100).

**Long term PEC/PNECoral for non-target mammals and birds**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Non-target** **mammal**  | **EC5 Step 11 [mg/kg bw]** | **EC5 Step 22 [mg/kg bw]** | **PNECoral****[μg/kg bw]** | **PEC/PNEC****Step 11** | **PEC/PNEC****Step 22** |
| Dog  | 6.3 | 5.06 | 0.056 | 113,000 | 90,000 |
| Cat  | 13.3 | 10.7 | 0.056 | 238,000 | 191,000 |
| Pig  | 3.33 | 2.66 | 0.056 | 60,000 | 47,500 |
| Non target mammal3 | 11.8 | 9.47 | 0.056 | 211,000 | 169,000 |
| Tree sparrow  | 23.95 | 19.16 | 5.8 | 4,100 | 3,300 |
| Chaffinch  | 20.80 | 16.64 | 5.8 | 3,600 | 2,900 |
| Woodpigeon  | 7.51 | 6.01 | 5.8 | 1,300 | 1,040 |
| Pheasant  | 7.47 | 5.98 | 5.8 | 1,300 | 1,030 |
| 1 AV, PT and PD = 1; AV of 0.5 for birds2 AV = 0.9, PT = 0.8 and PD = 1; AV of 0.5 for birds3 Body weight of a fox was chosen |

**Conclusion primary poisoning**

When comparing the concentration of chlorophacinone in food with the PNECoral a high risk can be identified. Regarding the short-term exposure at Tier 2, ETE values after 1 day for birds and for non-target mammals do not exceed the LD50 value for birds and mammals both without and with excretion. Concerns exist as to the risk for dogs feeding on bait. The toxicity test used for the comparison, however, was done with dogs feeding on a vitamin K deficient diet, possibly causing oversensitivity to anticoagulants.

ETE values after 5 days intake of chlorophacinone (long-term exposure) are higher than those after a single day of exposure. Even though excretion from the non-target animal is anticipated accumulation of chlorophacinone in the non-target animals outweigh loss of chlorophacinone in non-target animals due to excretion. For the long-term assessment all PEC/PNECoral ratios are far above one. Mammals are at considerably at greater risk than birds with respect to primary poisoning according to the EUBEES 2 default scenarios. In general small animals have a higher risk than large ones.

**The worst-case PEC/PNEC ratio for birds at step 1 is about 4,120 (sparrow) and about 238,000 for mammals (cat).**

**The worst-case PEC/PNEC ratio for birds at step 2 is about 3,300 (sparrow) and about 191,000 for mammals (cat).**

Worst case assumptions have been made. It was assumed that the non-target animals have fed entirely, respectively mostly, on chlorophacinone containing products (PT was 1 and 0.8, respectively) and that no avoidance (AV = 1) respectively little avoidance (AV = 0.9) for mammals. For birds the avoidance factor for paste was set to 0.5. Consumption of these quantities of chlorophacinone containing products is clearly a worst case and the risk in reality might probably not be as high as presented in these scenarios.

Based on the maximum recommended baiting regime that entails deployment of 240 g paste per secured bait point, the daily food intakes of 456, 170 and 600 g for dogs, cats and pigs correspond to the contents of 1.9, 0.71 and 2.5 bait points, respectively. However, as the PEC/PNEC ratio for dogs is above 10,000 the PEC/PNECoral value below 1 for dogs would only be achieved for a single meal if the daily intake of paste by dogs was less than 0.01 % of its daily food requirement (<0.05 g bait per day for dogs). This is much less than the weight of one sachet (40 g) of which 6 are placed in one bait point. As the EC5 is higher than the EC1 (ETE after 1 day) these values would be lower for the long-term assessment.

Based on the recommended baiting regime that entails deployment of a maximum of 240 g paste per secured bait point, the daily food intakes of 7.6, 6.42, 53.1 and 102.7 g for *P. montanus*, *F. coelebs*, *C. palumbus* and *P. colchicus* (values from table 3.1 EUBEES 2) correspond to the contents of at least 0.03, 0.027, 0.22 and 0.43 full bait boxes, respectively. It is unlikely that such amounts of bait would be available to the larger birds whereas smaller species may be able to reach bait inside the bait boxes by entering through the access hole, simply on the basis of their size. However, PEC/PNEC ratios for bigger birds are above 1,000 and for smaller birds above 2,800. Values below 1 for the different bird species would only be achieved if the daily intake of bait blocks/pellets/paste by birds were below 0.1 % of their daily food requirement. That means that for example a chaffinch (*F. coelebs*) had to eat less than 7 mg bait in order not to be at risk.

Gemmeke (2000) noted that pigeons, Japanese quails, various crows, jackdaws, magpies and pheasants presented with a choice of natural and dyed seeds of various crop species all preferred the untreated option, and that seeds artificially coloured green, grey, black, pink, blue, violet and brown-violet were either untouched or only eaten in small (ca. 10%) amounts. According to Harrison et al. (1988), wild birds presented with a selection of foods resembling wheat-based rodenticide baits were generally indifferent to whole, non-coloured wax blocks and consumption amounted to less than 5% of the quantity offered. Considering these figures it becomes clear that birds have a very high risk of primary poisoning even if paste is only a very low share of their daily food intake.

Comparing the quantities of chlorophacinone potentially accessible to non-target vertebrates at one bait point directly with the food based PNECoral of 30 μg/kg food birds are at high risk even if they eat only 1 % of the bait at one bait point.

A potential risk of primary poisoning could clearly be identified both for non-target mammals and for birds. Relatively high assessment factors applied to long-term test results for the derivation of PNECoral and the high toxicity of chlorophacinone to mammals and birds led to a high risk. It is evident that this risk can occur if these animals have free access to products containing chlorophacinone, which is the case for baiting around buildings but probably not for baiting within buildings.

**Possible measures to reduce the risk of primary poisoning to non-target animals**

Chlorophacinone is both highly and non-selectively toxic to vertebrates and the attempt to refine the primary and secondary assessments to demonstrate acceptable risks to birds and non-target mammals with the tools currently available will prove fruitless.

Information regarding risk reduction measures is presented in chapter 2.8.3 “Possible measures to reduce the risk of primary and secondary poisoning to non-target animals”.

**Secondary poisoning**

In accordance with the EUBEES 2, the following assessment of secondary poisoning takes into account the levels of chlorophacinone residues in target rodents, based on its concentration in the bait, feeding (chlorophacinone intake) and excretion (chlorophacinone elimination) rates of target rodents, as well as the period over which the bait is eaten before the effects of poisoning inhibit further feeding. These combined factors form the basis of exposure to predators and scavengers upon which to assess risk.

Rodents targeted by indoor and outdoor baiting campaigns are likely to roam outdoors and within the hunting ranges of predatory birds and mammals. Target animals that succumb to the effects of anticoagulant rodenticides and die whilst foraging outdoors may be found and ingested by scavenging vertebrates. A potential for secondary poisoning of birds and mammals therefore exists, even (though to a lesser extent) on occasions when the deployment of paste bait containing chlorophacinone is confined to the interiors of buildings.

However, the extent of possible exposure of predators and scavengers to live prey and carcasses containing rodenticide residues is uncertain. EUBEES 2 cites two published reports of cage and enclosure studies in which the authors observed behavioural changes in poisoned rodents that would appear to increase their susceptibility to predation during daytime and also the likelihood that fatal haemorrhage would occur while the rodents were away from shelter, leaving their carcasses exposed to scavengers. On the other hand, these predictions are contradicted by reports of observations made before, during and after anticoagulant baiting programmes conducted in and around farm buildings, where carcasses found by systematic searches were predominantly either indoors or concealed beneath cover (*e.g*. under haystacks)[[15]](#footnote-15). Bodies representing only 4% of an estimated initial rat population were found away from cover in one study and (in the absence of evidence of further activity) the majority of the remaining, unrecovered population was assumed to have died underground in a system of burrows.

In accordance with EUBEES 2 guidance, the following assessment of secondary poisoning takes into account the levels of chlorophacinone residues in target rodents, based on its concentration in paste bait, feeding (chlorophacinone intake) and excretion (chlorophacinone elimination) rates of target rodents, as well as the period over which the bait is eaten before the effects of poisoning inhibit further feeding. These combined factors form the basis of exposure to predators and scavengers upon which to assess risk.

The chlorophacinone residue concentration in rodents is based on the following equation:

n

* where ECn is the estimated residue concentration in the rodent on day n, ETE is the estimated theoretical exposure as defined above for primary poisoning for mammals and EL is the fraction of residue eliminated from the target rodent per day.

The ETE values for rodents (mice and rats) are based on three theoretical levels of ingestion of paste bait constituting 100%, 50% and 20% of the daily food intake (to allow for various intakes of alternative foods), a FIR/kg bw of 0.1 for rats and mice and a concentration of chlorophacinone in paste bait equal to 50 mg/kg. The ETE values are therefore 5.0, 2.5, 1.00 mg chlorophacinone/kg bw for levels of bait consumption equivalent to 100%, 50% and 20% of daily food intake, respectively.

The default rate of elimination of residues from the bodies of target rodents is 30% per day (faecal route only). The elimination of residues has been measured from a pair of male rats fed with approximately 5.0 mg chlorophacinone/kg bw. Severe haemorrhaging occurred and the test rats eventually died. No significant metabolites of chlorophacinone were identified and so the faecal radioactivity may be assumed to be parent chlorophacinone only. The default daily elimination rate of 30% for anticoagulant rodenticides prescribed by EUBEES 2 is in general accordance with the mean values measured for chlorophacinone, which averaged 33.5% over the first three days and ranged from 37.6% for day 1 to 52.8% for day 2.

Elimination of chlorophacinone residues (14C-equivalents) from male rats

|  |  |
| --- | --- |
| **Sampling time (days)** | **Radioactivity excreted (mean % of applied, estimated dose approximately 5.0 mg/kg bw1)** |
| **Urine** | **Faeces** | **Volatiles** | **Total** |
| 1 | 0.383 | 37.19 | 0.025 | 37.6 |
| 2 | 0.241 | 52.54 | 0.013 | 52.8 |
| 3 | 0.082 | 10.08 | 0.004 | 10.2 |
| 4 | 0.052 | 1.8 | 0.006 | 1.9 |
| Cumulative 3 day total | 0.706 | 99.81 | 0.042 | 100.6 |
| Cumulative 4 day total | 0.758 | 101.61 | 0.048 | 102.4 |
| 1 Based on individual doses of 1.43 and 1.28 mg 14C‑chlorophacinone per animal, individual bw not stated, range 200 to 250 g. |

The residue levels are also based on an assumption that ingestion of chlorophacinone in paste bait occurs consistently during the first five days of baiting and that feeding (including bait ingestion) ceases on day 6, followed by death on day 7. However, the time to death under more realistic conditions may differ from that observed in the laboratory if the target rodents have unrestricted access to alternative food(s). EUBEES 2 considers three levels of bait consumption by target rodents, expressed in terms of bait ingestion as a percentage of total daily food intake. A level of 20% is regarded as the minimum for effective bait formulated to appeal to target rodents, whilst 100% represents the realistic worst-case view. In the presence of other, competing food sources (presumed to be present to allow a population of target rodents to become established), an intake of around 50% may be more likely.

Residues of chlorophacinone in target rodents from the ingestion of paste bait at different times during a control campaign, calculated according to EUBEES 2 (Frodent = 1)

|  |  |
| --- | --- |
| Time | **Residues of chlorophacinone in target rodent (mg/kg bw)** |
| **20% bait consumption** | **50% bait consumption** | **100% bait consumption** |
| Day 1, after first meal | 1.000 | 2.500 | 5.000 |
| Day 2 before new meal | 0.700 | 1.750 | 3.500 |
| Day 5 after last meal1 | 2.773 | 6.933 | 13.866 |
| Day 7 (mean time to death)2 | 1.359 | 3.397 | 6.794 |
| 1 TIER 1 short-term (Frodent = 1)2 TIER 1 long-term (Frodent = 0.5) |

Calculated residue patterns suggest that levels increase following each daily intake until day 5, after which the rodents are assumed to eat no more bait, but to continue to excrete residues at approximately 30% per day, resulting in a reduction of residues by approximately half between the last intake on day 5 and death on day 7.

However, comparison with semi-field data shows these calculated values to be greatly overestimated. Two studies were conducted to determine the effects of secondary exposure to chlorophacinone on *Pica pica* and *Mustela putorius furo*. In each case a different population of rats was first fed on a diet that comprised exclusively bait pellets containing 50 mg chlorophacinone/kg. Bait consumption as a proportion of food intake by the rats was therefore 100%. The primary feeding phase continued for 5 days, after which all survivors were euthanised and stored frozen together with carcasses of rats that had succumbed earlier. Four rat carcasses were randomly selected in each study, individually homogenised and analysed to determine residues of chlorophacinone, whilst the remaining carcasses were used as the exposure vehicle for the magpies and ferrets. Measured whole-rat concentrations of chlorophacinone at a time coinciding – according to EUBEES 2 - with the occurrence of peak levels following the last meal on day 5, ranged from 0.2107 to 0.9272 mg/kg bw (mean: 0.467 mg/kg bw) in the first study and from 0.175 to 0.805 mg/kg bw (mean: 0.453 mg/kg bw) in the second. The highest measured concentration corresponds to just 6.7% of the value of 13.866 mg/kg bw predicted for the same time point according to EUBEES 2. In the table below and in the following assessments, the various concentrations of chlorophacinone in target rodents on day 5 and day 7 have therefore been lowered *pro rata* to reflect real, measured residues.

Residues of chlorophacinone in target rodents from the ingestion of paste bait at different times during a control campaign, based on the maximum residue level measured in rats (Frodent is 1)

|  |  |
| --- | --- |
| Time | **Residues of chlorophacinone in target rodent (mg/kg bw)** |
| **20% bait consumption** | **50% bait consumption** | **100% bait consumption** |
| Day 5 after last meal1 | 0.185 | 0.464 | 0.927 |
| Day 7 (mean time to death)2 | 0.093 | 0.232 | 0.464 |
| 1 Based on 0.9272 mg/kg bw measured after 100% bait consumption for 5 days;2 Based on excretion of 30% per day and a reduction of approximately 50% between days 5 and 7. |

**Tier 1 risk assessment for short-term secondary poisoning**

The figures presented in the table above are rather qualitatively compared to the lowest LC50 value for birds. For mammals no such qualitative comparison has been carried out because no short-term LC50 values are available. The LC50 for birds is 95 mg/kg food (Bobwhite quail). This LC50 for birds is higher than the 5 days residue values in target rodents for all bait consumptions (20, 50 and 100 %). Also after one single meal the residue values for 50 and 100 % bait consumption are below the LC50 value for birds. This highlights the low acute toxicity of chlorophacinone to birds.

**Tier 1 risk assessment for long-term secondary poisoning**

For a more long-term exposure it is assumed that the rodents have fed entirely on rodenticide (PD = 1) and that the non-target animals consume 50 % of their daily intake on poisoned rats (Frodent = 0.5).

Residues of chlorophacinone in target rodents from the ingestion of paste bait at different times during a control campaign, based on the maximum residue level measured in rats (Frodent = 0.5)

|  |  |
| --- | --- |
| Time | **Residues of chlorophacinone in target rodent (mg/kg bw)** |
| **20% bait consumption** | **50% bait consumption** | **100% bait consumption** |
| Day 5 after last meal1 | 0.093 | 0.232 | 0.463 |
| Day 7 (mean time to death)2 | 0.046 | 0.116 | 0.232 |
| 1 Based on 0.9272 mg/kg bw measured after 100% bait consumption for 5 days;2 Based on excretion of 30% per day and a reduction of approximately 50% between days 5 and 7. |

As discussed previously, there are many uncertainties related to the calculation of PEC/PNEC values. Moreover, the PEC/PNEC values presented in the tables below are very high.

Tier 1 estimate of PECoral/PNECoral for predatory or scavenging birds ingesting target rodents (on day 5 and day 7 of a control campaign) containing chlorophacinone obtained from areas in and around buildings, Frodent = 0.5

|  |  |
| --- | --- |
| **Avian predator/scavengerPECoral/PNECoral - day 5 (maximum rodent residue levels)** | **Avian predator/scavengerPECoral/PNECoral - day 7** |
| **bait = 20% of rodents’ food intake/day** | **bait = 50% of rodents’ food intake/day** | **bait = 100% of rodents’ food intake/day** | **bait = 20% of rodents’ food intake/day** | **bait = 50% of rodents’ food intake/day** | **bait = 100% of rodents’ food intake/day** |
| 3.1 | 7.7 | 15.5 | 1.5 | 3.9 | 7.7 |
| PNECoral = 0.030 mg/kg food |

Tier 1 estimate of PECoral/PNECoral for predatory or scavenging mammals ingesting target rodents (on day 5 and day 7 of a control campaign) containing chlorophacinone obtained from areas in and around buildings, Frodent = 0.5

|  |  |
| --- | --- |
| **Mammalian predator/scavengerPECoral/PNECoral - day 5 (maximum rodent residue levels)** | **Mamalian predator/scavengerPECoral/PNECoral - day 7** |
| **bait = 20% of rodents’ food intake/day** | **bait = 50% of rodents’ food intake/day** | **bait = 100% of rodents’ food intake/day** | **bait = 20% of rodents’ food intake/day** | **bait = 50% of rodents’ food intake/day** | **bait = 100% of rodents’ food intake/day** |
| 84 | 211 | 421 | 42 | 105 | 211 |
| PNECoral = 0.0011 mg/kg food |

The above PECoral/PNECoral quotients ranging from 1.5 to 15.5 for birds and from 42 to 421 for mammals assume that rodents containing chlorophacinone residues are wholly ingested by predatory or scavenging birds which feed on target rodents. The Tier 1 PECoral/PNEC oral quotients presented above are all above 1. However, it is not certain that the sensitivity of predatory bird species is adequately represented by the PNECoral of 30 µg/kg food derived from a study conducted with bobwhite quail. In addition, there is also evidence that secondary poisoning by anticoagulant rodenticides has been implicated in the deaths of raptorial birds in the wild, albeit not necessarily arising from the uses of chlorophacinone paste bait considered in this assessment, or from uses compliant with current recommended good practice. In view of these uncertainties a refined Tier 2 assessment is set out below, based on representative avian species.

**Tier 2 risk assessment for secondary poisoning**

In a manner similar to the second tier primary poisoning calculations the concentrations in the relevant predatory mammals and birds can be calculated. In the following table the expected values for uptake of chlorophacinone by a mammal predator or a bird of prey are presented after a single day of exposure and the expected concentration in the non-target animals are presented. It is assumed that rodents fed 100 % on rodenticide (PD = 1) and that predators fed 50 % on poisoned rodents (Frodent = 0.5). The residue of chlorophacinone at day 5 after the last meal is 0.927 mg/kg food. As Frodent in this scenario is 0.5 instead of 1 the residue of chlorophacinone at day 5 after the last meal is 0.464 mg/kg food. The bodyweights and food intake data of raptorial species are drawn from EUBEES 2.

The refined, tier 2 estimate of risk considers exposure of relevant species of avian and mammalian predators, based on their bodyweights and food intakes (table below). The following three tables assume that 50% of the diet of each bird and mammal species on a single day consists of rodents containing chlorophacinone. In each case, chlorophacinone paste baits have contributed either 100%, 50% or 20% of the daily food intake of the rodents eaten by the birds.

Estimated intakes and concentrations of chlorophacinone (CPN) predatory and scavenging birds and mammals ingesting target rodents, assuming poisoned rodents comprise 50% of a bird‘s diet and that paste bait contributed 100% of the target rodents’ daily food intake

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Non-target avian or mammalian predator** | **Mean body weight (g)** | **Daily food intake (g/day)** | **Normal susceptible rodents caught on day 5, just after their last meala** | **Normal susceptible rodents caught on day 7, two days after their last mealb** |
| **CPN consumed (mg)** | **CPN in predator (mg/kg bw)** | **CPN consumed (mg)** | **CPN in predator (mg/kg bw)** |
| **Birds** |  |  |  |  |  |  |
| Tyto alba | 294 | 72.9 | 0.034 | 0.115 | 0.017 | 0.058 |
| *Falco tinnunculus* | 209 | 78.7 | 0.036 | 0.175 | 0.019 | 0.091 |
| *Athene noctua* | 164 | 46.4 | 0.022 | 0.131 | 0.011 | 0.067 |
| *Strix aluco* | 426 | 97.1 | 0.045 | 0.106 | 0.023 | 0.054 |
| **Mammals** |  |  |  |  |  |  |
| *Vulpes vulpes* | 5,700 | 520.2 | 0.241 | 0.042 | 0.121 | 0.021 |
| *Mustela putorius* | 689 | 130.9 | 0.061 | 0.088 | 0.030 | 0.044 |
| *Mustela erminea* | 205 | 55.7 | 0.026 | 0.126 | 0.013 | 0.063 |
| *Mustela nivalis* | 63 | 24.7 | 0.011 | 0.182 | 0.006 | 0.091 |
| Dogs | 10,000 | 456 | 0.211 | 0.021 | 0.106 | 0.011 |
| a Based on a rodent containing 0.927 mg chlorophacinone/kg (100% of their diet is paste bait).b Based on a rodent containing 0.473 mg chlorophacinone/kg (100% of their diet is paste bait). |

Estimated intakes and concentrations of chlorophacinone (CPN) in predatory and scavenging birds and mammals ingesting target rodents, assuming poisoned rodents comprise 50% of a bird‘s diet and that paste bait contributed 50% of the target rodents’ daily food intake

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Non-target avian or mammalian predator** | **Mean body weight (g)** | **Daily food intake (g/day)** | **Normal susceptible rodents caught on day 5, just after their last meala** | **Normal susceptible rodents caught on day 7, two days after their last mealb** |
| **CPN consumed (mg)** | **CPN in predator (mg/kg bw)** | **CPN consumed (mg)** | **CPN in predator (mg/kg bw)** |
| **Birds** |  |  |  |  |  |  |
| Tyto alba | 294 | 72.9 | 0.017 | 0.057 | 0.009 | 0.031 |
| *Falco tinnunculus* | 209 | 78.7 | 0.018 | 0.087 | 0.009 | 0.043 |
| *Athene noctua* | 164 | 46.4 | 0.011 | 0.066 | 0.005 | 0.030 |
| *Strix aluco* | 426 | 97.1 | 0.023 | 0.053 | 0.012 | 0.028 |
| **Mammals** |  |  |  |  |  |  |
| *Vulpes vulpes* | 5,700 | 520.2 | 0.121 | 0.021 | 0.060 | 0.011 |
| *Mustela putorius* | 689 | 130.9 | 0.030 | 0.044 | 0.015 | 0.022 |
| *Mustela erminea* | 205 | 55.7 | 0.013 | 0.063 | 0.006 | 0.031 |
| *Mustela nivalis* | 63 | 24.7 | 0.006 | 0.091 | 0.003 | 0.045 |
| Dogs | 10,000 | 456 | 0.106 | 0.011 | 0.053 | 0.005 |
| a Based on a rodent containing 0.464 mg chlorophacinone/kg (50% of their diet is bait block).b Based on a rodent containing 0.237 mg chlorophacinone/kg (50% of their diet is bait block). |

Estimated intakes and concentrations of chlorophacinone (CPN) in predatory and scavenging birds and mammals ingesting target rodents, assuming poisoned rodents comprise 50% of a bird‘s diet and that paste bait contributed 20% of the target rodents’ daily food intake

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Non-target avian or mammal predator** | **Mean body weight (g)** | **Daily food intake (g/day)** | **Normal susceptible rodents caught on day 5, just after their last meala** | **Normal susceptible rodents caught on day 7, two days after their last mealb** |
| **CPN consumed (mg)** | **CPN in predator (mg/kg bw)** | **CPN consumed (mg)** | **CPN in predator (mg/kg bw)** |
| **Birds** |  |  |  |  |  |  |
| Tyto alba | 294 | 72.9 | 0.007 | 0.023 | 0.003 | 0.010 |
| *Falco tinnunculus* | 209 | 78.7 | 0.007 | 0.035 | 0.004 | 0.019 |
| *Athene noctua* | 164 | 46.4 | 0.004 | 0.026 | 0.002 | 0.012 |
| *Strix aluco* | 426 | 97.1 | 0.009 | 0.021 | 0.005 | 0.012 |
| **Mammals** |  |  |  |  |  |  |
| *Vulpes vulpes* | 5,700 | 520.2 | 0.048 | 0.008 | 0.024 | 0.004 |
| *Mustela putorius* | 689 | 130.9 | 0.012 | 0.018 | 0.006 | 0.009 |
| *Mustela erminea* | 205 | 55.7 | 0.005 | 0.025 | 0.003 | 0.013 |
| *Mustela nivalis* | 63 | 24.7 | 0.002 | 0.036 | 0.001 | 0.018 |
| Dogs | 10,000 | 456 | 0.042 | 0.004 | 0.021 | 0.002 |
| a Based on a rodent containing 0.186 mg chlorophacinone/kg (20% of their diet is bait block).b Based on a rodent containing 0.095 mg chlorophacinone/kg (20% of their diet is bait block). |

It has to be stated that the values in the three tables above represent only a single day of exposure. Poisoned rodents are likely to be available for at least several days during a rodenticide treatment, and a predator could therefore be exposed over several days. In principle, exposure should be estimated over several days because of the chronic mode of action of anticoagulant rodenticides (a low dose over several days may be more toxic than a higher dose on one day). Therefore the values in these tables do not necessarily represent a realistic worst case situation.

As discussed previously, there are many uncertainties related to the calculation of PEC/PNEC values.

Tier 2 estimates of PECoral/PNECoral for predatory and scavenging birds and mammals ingesting target rodents (as 50% of their diet) containing chlorophacinone obtained from areas in and around buildings

|  |  |  |  |
| --- | --- | --- | --- |
| **Non-target avian predator/ scavenger** | **PECoral/PNECoral(rodent ingesting paste bait at 20% of daily requirement)** | **PECoral/PNECoral(rodent ingesting paste bait at 50% of daily requirement)** | **PECoral/PNECoral(rodent ingesting paste bait at 100% of daily requirement)** |
| **Rodent caught on day 5** | **Rodent caught on day 7** | **Rodent caught on day 5** | Rodent caught on day 7 | **Rodent caught on day 5** | **Rodent caught on day 7** |
| **Birds** |  |  |  |  |  |  |
| *Tyto alba* | 4.0 | 2.0 | 9.9 | 5.0 | 19.8 | 9.9 |
| *Falco tinnunculus* | 6.0 | 3.0 | 15.0 | 7.5 | 30.1 | 15.0 |
| *Athene noctua* | 4.5 | 2.3 | 11.3 | 5.7 | 22.6 | 11.3 |
| *Strix aluco* | 3.6 | 1.8 | 9.1 | 4.6 | 18.2 | 9.1 |
| **Mammals** |  |  |  |  |  |  |
| *Vulpes vulpes* | 151 | 76 | 378 | 189 | 755 | 378 |
| *Mustela putorius* | 314 | 157 | 786 | 393 | 1572 | 786 |
| *Mustela erminea* | 450 | 225 | 1124 | 562 | 2249 | 1124 |
| *Mustela nivalis* | 649 | 325 | 1623 | 811 | 3245 | 1623 |
| Dogs | 75 | 38 | 189 | 94 | 377 | 189 |
| Birds PNECoral = 0.0058 mg/kg bw.Mammals PNECoral = 0.000056 mg/kg bw. |

Based on the assumption that 50% of a predatory bird’s diet consists of rodents that contain the maximum estimated quantity of chlorophacinone residues, the risk assessment indicates uncertainty in some instances: *i.e*. the PECoral/PNECoral exceeds 1.0, in all cases even if a rodent has eaten only 20% for 5 days followed by non eating period of 2 days.

**Summary secondary poisoning**

There is clearly a high risk of secondary poisoning of non-target mammals and birds. The risk is slightly higher for mammals than for birds and small animals have a higher risk than large animals.

Regarding the short-term exposure at Tier 1, the concentrations of chlorophacinone in the target rodents, assuming 50 % bait consumption, are higher than the lowest LC50 value for birds.

For the long-term situation at Tier 1 and 2 all PEC/PNEC ratios are clearly above 1.

**The worst-case PEC/PNEC ratios at Tier 1 are about 15.5 for birds and 421 for mammals. The worst-case PEC/PNEC ratio for birds at Tier 2 is about 30 (kestrel) and 3200 for mammals (weasel).**

For Tier 1 of the long-term scenario it was assumed that the rodents have fed entirely on rodenticide and that the non-target animals consume 50 % of their daily intake on poisoned rats. These assumptions led to a high risk, but even if the rodents have fed only 20 % of their daily intakes by rodenticide and non-target animals consume 50 % of their daily intake on poisoned rats the risk quotients are still over 1 for birds (3.1) and high (84) for other non-target mammals).

At Tier 2 an approach based on the body burden of chlorophacinone in the non-target animals was conducted. At this tier values only for a single day of exposure were calculated. PEC/PNEC ratios for all species are clearly above 1 even though these values do not necessarily represent a worst case because ingestion of poisoned rat over a few days was not considered.

The apparent risks indicated above may, on the other hand, be overestimated because it takes not into account behavioural factors. For example, many birds of prey will not take dead rodents and this may therefore reduce exposure to species such as owls, although some species prey principally on dead animals. Smaller owls such as *Athene noctua* will take only smaller rodents and not large rats, as assumed above in the risk calculations, and so their exposure will be reduced. Many rodents will be caught by predators at times when they do not contain the relatively high levels of chlorophacinone. However, as shown above, even if the rodents have fed only 20 % of their daily intakes by rodenticide, non-target animals are still at high risk. The majority of the chlorophacinone residues are concentrated in the liver and to a lesser extent in the fat tissues. This may reduce exposure to some, but not all birds, which selectively pick at flesh and discard offal during feeding. For example, Tkladec and Rychnovsky (1990), cited by Luttik et al. (1999), observed that kestrels and weasels do not eat the guts of prey, thus avoiding the tissues containing the highest concentrations of rodenticide residues. On the other hand the PEC/PNEC ratios do not include the possibility of recurrent exposure. Many predatory birds are territorial and may therefore actively hunt in areas where they have experienced good success, even feeding young birds with contaminated prey.

In the context of a scenario that involves baiting in and around houses several of the predators considered above would be relatively exotic in many situations. Species more likely to be encountered are mixed-diet scavengers of the crow family and gulls (e.g. *Pica pica*, *Corvus corone* *corone* and *Larus ridibundus*) that feed opportunistically on carrion[[16]](#footnote-16) and which are likely to consume the bodies of target rodents whenever they are accessible. A significant difference between these scavengers and the predators considered previously is that whereas the raptors tend to be solitary in habit, corvids and gulls are generally gregarious and several birds may consequently pick at the same carcass. Hence, the available carrion may contribute to a smaller extend to the food intake of an individual bird.

As is the case with birds, the risk to non-target mammals may also be overestimated because they do not take behavioural factors into account. Based on five studies of the abundance of different animals among the gut contents of *E. erminia*, rodent species contributed a mean of 26% of the diet (Gurney et al. 1997) and many of these would not be considered to be target rodents in an indoor baiting scenario. This will effectively reduce the risk; however, only for indoor and not for outdoor baiting. In another study, 32% of the diet of *M. putorius* consisted of rodents. The abundance of rodents in the diet of *M. nivalis* is relatively higher than for other mustelid species, but is still less than 100%. Although mustelids are at greatest risk from secondary poisoning, the fact that their diet is not entirely composed of rodents, and that the rodents that are eaten are not exclusively those encountered in and around buildings, reduces the apparent risk. However, as shown above, even if the rodents have fed only 20 % of their daily intakes by rodenticide non-target animals are still at high risk.

**Open areas**

Primary poisoning

The primary poisoning risks to birds and mammals from ingestion of Rozol Pat’ is assumed to be similar in open areas as compared with the risk for birds and mammals in and around buildings non-target animals may enter treated areas even if openings are covered and may consume bait.

It is not possible to quantify the amount of bait that may be exposed for ingestion by non-target birds and mammals. The levels of risk are adequately covered by the assessments made above for various amounts of red paste bait directly ingested following use in and around buildings.

Secondary poisoning

The secondary poisoning risks to birds and mammals following the use of paste bait containing chlorophacinone in open areas are adequately quantified for uses in and around buildings.

**Waste dumps**

Primary poisoning

The primary poisoning risks to birds and mammals from ingestion of paste containing chlorophacinone are assumed to be similar to those indicated above for uses in and around buildings. Although the paste bait on waste dumps will initially be deployed in sachets, it is possible that pieces of bait will be dropped following uptake by target rodents, in places where they may become accessible to non-target birds and mammals.

The levels of risk are considered to be adequately represented by the assessments made above for various amounts of Rozol Pat’ directly ingested following use in and around buildings.

Secondary poisoning

The secondary poisoning risks to birds and mammals following the use of paste bait containing chlorophacinone in waste dumps are adequately quantified for uses in and around buildings.

### Possible measures to reduce the risk of primary and secondary poisoning to non-target animals

Chlorophacinone is both highly and non-selectively toxic to vertebrates and, as previously stated, attempts to refine the primary and secondary assessments to demonstrate acceptable risks to birds and mammals with the tools currently available are proven fruitless. Whilst the approved procedure for estimating theoretical exposure of chemicals and plant protection products allows account to be taken of such factors as avoidance of contaminated food items, there is no approved mechanism for adjusting risk assessments quantitatively to take into account practices and intervention specifically intended to minimise the potential for primary and secondary poisoning of non-target vertebrates.

Careful management of anticoagulant rodenticides is understood by the manufacturing industry and by pest-control professionals to be essential to eliminate or reduce to a minimum the opportunity for exposure of non-target species whilst maximising necessary impact on the target rodents. These measures are described in good practice guidance documents, in training courses and on the labels of the products themselves. They are listed below, among a number of other important mitigating factors that need to be taken into account in the risk assessment for paste bait containing chlorophacinone.

The more direct the delivery of paste containing chlorophacinone to the target animals and the faster their consumption, the shorter the eradication campaign and ultimately the smaller the opportunity for non-target species to discover and ingest the bait. The secured bait points selected for deployment of bait in and around buildings are therefore placed where they are most likely to be encountered exclusively by the target organisms (e.g. on habitual rat-runs), thus maximising exposure of the target rodents and minimising unintended exposure of other non-target vertebrates.

According to recommended practice, baiting campaigns with anticoagulant rodenticides continue until uptake monitoring indicates that eradication of the target rodent population has been achieved, at which point all remaining bait is retrieved and destroyed or securely disposed off. Elimination of residual bait in this way has two benefits: Firstly it removes the potential for unintended exposure of non-target animals in the absence of competition from rats and mice, thus reducing the risk of primary poisoning, and secondly it reduces the likelihood of resistance (i.e. immunity to a particular active substance) developing among the target rodents. In order to minimise the likelihood of target rodents developing resistance to second-generation anticoagulant rodenticides long-term deployment of bait as a preventative control measure is not recommended.

Resistance has the obvious consequence that rodenticide deployment will fail to elicit the desired response among the target rodent population. If not promptly recognised, it may also lead to extended baiting programmes that result in extended opportunities for accidental primary poisoning of non-target animals. It may also result in a population of rodents that continue to feed on bait and maintain maximal levels of rodenticide in their tissues, thus exposing predators to a heightened risk of secondary poisoning. However, guidance documents warn against this possibility and indicate the need to monitor bait uptake in case it exceeds the expected pattern and to cease ineffectual baiting as soon as resistance is suspected.

Knowledge of the site in which the control campaign is to be conducted also entails taking into account the presence of or possible access by non-target animals and selecting appropriate baits and degrees of bait point protection that minimise the potential for unintended exposure to occur. However, only professionals are supposed to retrieve remaining bait and destroy it in a safe way. Non-professionals are not expected to follow this practice.

Good practice guidance reinforced by product labelling, demands also that site inspections have to be made regularly during baiting campaigns. One of the objectives of these inspections is to search for carcasses of target rodents that must then be collected and disposed off in a manner (e.g. incineration or burial at sufficient depth) that ensures they remain inaccessible to scavengers. This significantly reduces the levels of exposure and the risk of secondary poisoning. Good practice also requires that residents and/or workers in and around the baited area are alerted to the hazards posed by baits and carcasses containing rodenticide, so that they may also take appropriate measures to prevent non-target animals being exposed to and/or consuming poisoned rodents.

Products containing chlorophacinone are placed at secured bait points. The type of secured bait point suitable for a given situation is determined on a case-by-case basis, taking into account such factors as shielding from sunlight and moisture necessary to maintain bait integrity and the level of security required to prevent access to and/or interference by non-target animals, children etc. Where adequate protection is provided by parts of buildings (e.g. cellars, lofts), a secured bait point may simply comprise a tray shielded by an object such as a roofing tile. Bait points that incorporate a degree of physical obstruction to restrict access – termed bait stations - are used in more sensitive environments where there are non-target animals that may otherwise be unintentionally exposed. In particularly sensitive locations the bait is contained in bait boxes; high-security bait stations comprising weather-proof, tamper-proof, rigid casings. Good practice requires as well that these points are regularly checked for damage during inspection visits and repaired or replaced, as appropriate, to prevent access to bait by non-target animals. This might reduce the risk of primary poisoning. The use of dyed bait might further reduce the risk of primary poisoning of birds.

Good practice should require that bait boxes, containing bait in a chamber not directly accessible from the access hole, be used in locations where preliminary site assessment has identified a potential for avian exposure. This reduces both the visibility of the bait and the ability of larger birds to access it simply by putting their head and neck through the entrance hole. For these birds the availability of bait is thus effectively reduced to those pieces of paste translocated and dropped by the target rodents, and good practice requires that these be retrieved on regular inspection visits.

To conclude, the true primary and secondary poisoning risks posed to non-target animals and birds by chlorophacinone containing products might be lower than those indicated in the quantitative assessment of risk as a result of the many mitigating factors listed above. The most significant reductions in exposure and risk are achieved by restricting its use to treatment campaigns of limited duration, limiting access of non-target animals to the bait and removing unused bait and dead and moribund rodents during a baiting campaign to minimise the opportunity of primary secondary exposure of non-target animals. However, it has to be stated that only professionals are expected to follow these instructions.

Despite the possible risk mitigation measures listed above, the Dutch CA is of the opinion that the use of Rozol Pat’ needs to be restricted to indoor use only for authorisation in the Netherlands. To the opinion of Ctgb, the evidence for the effectiveness of the risk mitigation measures listed above is weak and therefore, Ctgb does not allow for outdoor use of this product based on chlorophacinone, also not with these specific risk mitigation measures.

## Measures to protect man, animals and the environment

The information submitted covering the requirements as described in the TNsG on Data Requirements, common core data for the product, section 8, points 8.1 to 8.8 should be assessed and summarised here.

The instructions for use must contain the following indications:

* Prevent access to bait by children and non-target animals
* Keep out of reach of children
* Baits must be securely deposited in a way so as to minimise the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away
* When tamper resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.

Antidote vitamin K1 (under medical supervision).

For the measures to protect animals and the environment we refer to the “elements to be taken into account by Member States when authorising products” from the Assessment Report and inclusion directive 2009/92/EC for chlorophacinone which shall be duly taken into consideration for a clear labelling of Rozol Pat’.

The instructions for use must contain the following indications:

* The size of the package placed on the market should be proportionate to the duration of the treatment and appropriate to the pattern of use of particular user groups.
* Product design and use restrictions should be optimised in order to ensure sufficient and efficient rodent control while at the same time minimizing the risk for primary poisoning. This could include the use of tamper resistant bait boxes and the need to secure the baits so that rodents cannot remove the bait from the bait box. It could also include regular check of the bait points for damage and to repair or replace, as appropriate.
* The restriction of products to specific areas and manners of use and also restrictions of products to professionals or trained professionals only, should be considered.
* Baits must be securely deposited in a way so as to minimise the risk of consumption by non-target animals or children. Where possible, secure baits so that they cannot be dragged away.
* Search for and remove dead rodents at frequent intervals during treatment, at least as often as when baits are checked and/or replenished. Dispose of dead rodents in accordance with local requirements.
* Do not use anticoagulant rodenticides as permanent baits. In most cases treatment with this product should have achieved control within 35 days. Should activity of house mice, brown or black rats continue beyond this time, the likely cause should be determined and measures should be taken.
* Remove all baits after treatment and dispose of them in accordance with local requirements.
* Adequate safety instructions (including use of appropriate personal protective equipment) should be provided in the use instructions.
* The population size of the target rodent should be evaluated before a control campaign. The number of baits and the timing of the control campaign should be in proportion to the size of infestation.
* A complete elimination of rodents in the infested area should be achieved.
* It is recommended to develop and implement an Integrated Pest Management system (IPM). Relevant IPM issues are:
- Measures for the prevention and/or suppression of harmful organisms;
- Adequate methods and tools for monitoring of harmful organisms;
- Preference of non-chemical methods;
- Target-specificity and minimisation of impact on non-target organisms, health and the environment;
- Reduction to use of minimum necessary level;
- Application of strategies on anti-resistance;
- Check of success on the basis of records, monitoring and documentation.
* The use instruction of products should contain guidance on resistance management for rodenticides.
* Resistant management strategies should be developed, and chlorophacinone should not be used in an area where resistance to this substance is suspected.

The authorisation holder shall report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management.

# Proposal for decision

The Dutch CA considers that sufficient data have been provided to verify the outcome and conclusions, and permits the authorisation of Rozol Pat’.

Rozol Pat’ has been applied for and evaluated as a rodenticide against rats and mice for the following use patterns: in and around buildings (professional and non-professional use), open areas (professional use only) and waste dump perimeters (landfill) (professional use only).

Amendment 6-12-2013

Based on the assessment, it is concluded by the Dutch CA that Rozol Pat’ can be safely used by professional users for the control of black rats and house mice in buildings.

**ANNEXES CONTAIN CONFIDENTIAL DATA: This information should not be disclosed to third parties**

# Annexes:

1. **Summary of product characteristics**
2. **List of studies reviewed**
3. **Analytical methods residues – active substance**
4. **Toxicology and metabolism –active substance**
5. **Toxicology – biocidal product**
6. **Safety for professional operators**
7. **Safety for non-professional operators and the general public**
8. **Translation of Dutch label**

## Annex 1: Summary of product characteristics

**(a) Product trade name:** Rozol Pat’

|  |
| --- |
| **(b) (i) Qualitative and quantitative information on the composition of the biocidal product** |
| **Active substance(s)** | **Contents** |  |
| **Common name** | **IUPAC name** | **CAS number** | **EC number** | **Concentration** | **Unit** | **w/w (%)** | **Minimum purity****(% w/w)** | **Same source as for Annex I inclusion** |
|  |  |  |  |  |  |  |  |  |
| chlorophacinone | 2-[2-(4-chlorophenyl)-2-phenylacetyl]indan-1,3-dione | 3691-35-8 | 223-003-0 | 0.05 | g/L | 0.0050 | 97.8 | [x]  **yes** [ ]  **no** |
|  |  |  |  |  |  |  |  |  |
| **Co-formulants** | **Contents** |  |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Concentration** | **Unit** | **w/w (%)** | **Classification** | **Substance of concern** |
|  |  |  |  |  |  |  |  |  |
| Propylene glycol | propane-1,2-diol | Solvent | 57-55-6 | 200-338-0 |  |  | 0.787 | **-** | [ ]  **yes** [x]  **no** |
| Polyethylene glycol 300 | Poly(oxy-1,2-ethanediyl),α-hydro-ω-hydroxy-ethane-1,2-diol, ethoxylated | Solvent | 25322-68-3 | 500-038-2 |  |  | 0.223 | **-** | [ ]  **yes** [x]  **no** |
| Blue food dye E133 | disodium2-[[4-[ethyl-[(3-sulfonatophenyl)methyl]amino]phenyl]-[4-[ethyl-[(3-sulfonatophenyl)methyl]azaniumylidene]cyclohexa-2,5-dien-1-ylidene]methyl]benzenesulfonate | Dye | 3844-45-9 | 223-339-8 |  |  | 0.022 | **-** | [ ]  **yes** [x]  **no** |
| Denatonium benzoate | phenylmethyl-[2- [(2,6-dimethylphenyl)amino]- 2-oxoethyl]-diethylammonium benzoate | Bittering agent | 3734-33-6 | 223-095-2 |  |  | 0.005 | Xn R20/22, R38, R41 | [ ]  **yes** [x]  **no** |
| Oat flour | **-** | Holder | - | **-** |  |  | 74.93 | **-** | [ ]  **yes** [x]  **no** |
| Wheat flour | **-** | Holder | - | **-** |  |  | 1.97 | **-** | [ ]  **yes** [x]  **no** |
| water | water | Solvent | 7732-18-5 | 231-791-2 |  |  | 0.015 | **-** | [ ]  **yes** [x]  **no** |
| Butylated hydroxytoluene | 2,6-bis(1,1-dimethylethyl)-4-methylphenol | Preservative | 128-37-0 | 204-881-4 |  |  | 0.02 | **-** | [ ]  **yes** [x]  **no** |
| EDTA | calcium disodium2-[2-[bis(carboxylatomethyl)amino]ethyl-(carboxylatomethyl)amino]acetate | Preservative | 62-33-9 | 200-529-9 |  |  | 0.01 | **-** | [ ]  **yes** [x]  **no** |
| Vegetal fat | Fatty acids, soya, Me esters | Binder | 68919-53-9 | 272-898-4 |  |  | 22 | **-** | [ ]  **yes** [x]  **no** |
| Potassium citrate | tripotassium 2-hydroxypropane-1,2,3-tricarboxylate | Preservative | 866-84-2 | 212-755-5 |  |  | 0.01 | **-** | [ ]  **yes** [x]  **no** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  | **Sum** | **0.0** |  | **100.0** |  |

**(b) (ii) Is the product identical to the representative product, assessed for the purpose of the Annex I inclusion?**

[ ]  **yes ■ no** [ ]  **unknown**

**If not, briefly describe the difference.**

Different dye, different binder, different attractant

**(b) (iii) Does the biocidal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?**

[ ]  **yes ■ no**

If yes, does the product comply with Directive 2001/18/EC?

[ ]  **yes** [ ]  **no**

A copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive was provided.

1. Manufacturer(s) of the active substance(s) (name(s) and address(es) including location of plant(s))

Name of the active substance: chlorophacinone

Manufacturer

Company Name: Liphatech S.A.S. at AlzChem Trostberg GmbH

Address: Chemie Park Trostberg,

 Dr Albert Frank strasse 32

City: Trostberg

Postal Code: 83308

Country: Germany

Telephone: +33 5 53 69 36 30

Fax: +33 5 53 47 95 01

E-Mail: corg@liphatech.fr

Intra-Community VAT number or, for non EU companies, company registration number: FR91442688206

Manufacturing site same address.

1. Formulator(s) of the biocidal product (name(s) and address(es) including location of plant(s))

Formulator

Company Name: Liphatech S.A.S.

Address: Production centre,Av Jean Serres, ZA Malère

City: Pont du Casse

Postal Code: 47480

Country: France

Telephone: +33 5 53 69 36 30

Fax: +33 5 53 47 95 01

E-Mail: corg@liphatech.fr

Intra-Community VAT number or, for non EU companies, company registration number: FR91442688206

Formulation site same address.

***Physical state and nature of the biocidal product:***

1. Type of formulation: RB
2. Ready-to-use product: [ ] no **■** yes

***Classification and labelling statements of the biocidal product:***

1. Product classification: -
2. Risk and Safety Phrases:

Professionals: S2

Non-Professionals: S2

In NL the use is restricted to professional users.

1. Product classification according to GHS: -
2. Hazard statement according to GHS: P102 Keep out of reach of children

***Intended uses and efficacy:***

1. PT: PT 14 (Rodenticides)
2. Target harmful organisms: *Rattus norvegicus,* (Norway rat, Brown rat) *Rattus rattus* (Black rat) *Mus musculus* (House mouse)

 In NL the use is restricted to black rats and house mice

1. Development stage of target organisms: Juveniles and adults
2. Function/mode of action: Anticoagulant, bait product
3. Field of use: In and around buildings, in open areas and waste dumps. In NL field of use is restricted to use in buildings
4. Application aim: It is used to protect human food and animal feedstuffs and for general hygiene purposes.
5. User category: Professional and non-professional. In NL the use against black rats and house mice is restricted to professional use for reasons of resistance management (see 2.5.4 for explanation).
6. Application method[[17]](#footnote-17): Covered application, preferably in tamper-resistant bait stations

***Directions for use:***

1. Manner and area of use:

See "intended uses and efficacy" section above for information on target organisms, mode of action, field of use, application aim, user category and application method.

1. Conditions of use:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Recommended Application rate for one bait point/baiting point intervals**# | **Frequency of controls**  | **Checking / Replenishing**  | **Time of treatment and place of application1**  |
| **Non-professional users** |
| Mice | 30 to 50 g of paste in one or more sachets per bait station. Place 1 station every 1 to 3 m | Dispose the product and check 3-4 days after first application, then regularly once a week or 15 days  | At each check, re-apply the bait if only a part of the bait is consumed. In case all bait is eaten, refill the station and use more bait stations and/or increase the control frequency. | All yearIn & around buildings. |
| Rats:Brown & Black | 100 to 200 g of paste in 2 or more sachets per bait station. Place 1 station every 4 to 10 m. |
| **Professional users** |
| Mice | 30 to 50 g of paste in one or more sachets per bait station. Dispose 1 station every 1 to 3 m | Dispose the product and check 3-4 days after first application, then regularly once a week or 15 days | At each check, re-apply the bait if only a part of the bait is consumed. In case all bait is eaten, refill the station and use more bait stations and/or increase the control frequency. | All yearIn & around buildingsIn open areasIn waste dumps. |
| Rats:Brown & Black | 100 to 200 g of paste in 2 or more sachets per bait station. Dispose 1 station every 4 to 10 m. |

1 In NL field of use is restricted to use in buildings

1. Instructions for safe use of the product

See paragraph 2.9

1. Particulars of likely direct or indirect adverse effects and first aid instructions

Rozol Pat’ is a rodenticide containing chlorophacinone (0.005%) as an active substance. Chlorophacinone is a first-generation anticoagulant rodenticide. It disrupts the normal blood clotting mechanisms resulting in increased bleeding tendency and, eventually, profuse haemorrhage and death.

Clinical symptoms: nose bleed, gum bleed, bloody saliva, extravasation, sudden or unusual internal pain.

If in contact with eyes:

Keep the eye open and wash slowly and carefully with water during 15-20 minutes

Remove eventual contact lenses after the first 5 minutes and continue washing

Pay attention to possible symptoms mentioned above.

If inhaled:

The product is a non-dusty bait. Inhaling is not considered a relevant route of exposure

If in contact with skin:

Remove contaminated cloths. Wash before re-use.

Wash the skin immediately with water and soap.

Pay attention to possible symptoms mentioned above.

If swallowed:

Wash your mouth with plenty of water

If swallowed, get medical advise immediately. Show the packaging, label or the safety data sheet.

Do not induce vomiting, unless advised by a medical specialist.

Do not administer anything by mouth, if the person is unconscious.

Antidote vitamin K1 (under medical supervision).

For the directions for use regarding the environmental aspect we refer to sections 2.9 and 3 of the PAR.

1. Instructions for safe disposal of the product and its packaging

See MSDS.

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

The specified shelf life is three year in the original PP packaging, which is supported by ambient temperature storage stability data.

1. Additional information:

In the PAR resistance management strategies are outlined. A remark on resistance should be added to the Label. We propose to add a different remark for professional and non-professional use since non-professionals are not expected to have knowledge on resistance (see annex 9). It should be noted that non-professional use is not allowed for in the Netherlands.
For professional use:
For the active substance in this product, chlorophacinone, there is a risk of development of resistance and in some parts of the Netherlands resistance in rats and mice is already present. Therefore, this product should not be used in cases where resistance against chlorophacinone is known or presumed, for instance in cases where the last treatment with chlorophacinone containing products did not results in a reduction of the population. Always contact with the appropriate authorities to check for the latest knowledge on occurrence of resistance.
For non-professional use (not accepted in NL):
If 28 days after the start of the treatment the control of mice is not sufficient, a professional in pest control should be consulted.

## Annex 2: List of studies reviewed

##### List of new data[[18]](#footnote-18) submitted in support of the evaluation of the active substance

No new date is submitted in support of the evaluation of the active substance.

##### List of new data submitted in support of the evaluation of the biocidal product

| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of Access** | **Data protection claimed** |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  | **Yes**  | **No** | **Yes**  | **No** |
| IIIB3.1.1-01 |  | Caruel, H. | 2008 | Chlorophacinone Blue Paste 50 mg/kg, CLOPA0,0050\_01F\_F01265\_00 Appearance, Colour, Odour.Centre R&D De Sangosse, Pont du Casse, France.Study code: CLO0812C.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| IIIB3.1.2-01 |  | Caruel, H. | 2008 | Chlorophacinone Blue Paste 50 mg/kg, CLOPA0,0050\_01F\_F01265\_00 Appearance, Colour, Odour.Centre R&D De Sangosse, Pont du Casse, France.Study code: CLO0812C.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| IIIB3.1.3-01 |  | Caruel, H. | 2008 | Chlorophacinone Blue Paste 50 mg/kg, CLOPA0,0050\_01F\_F01265\_00 Appearance, Colour, Odour.Centre R&D De Sangosse, Pont du Casse, France.Study code: CLO0812C.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| IIIB3.2-01 |  | Curl, M and Wright, E. | 2011a | Expert Statement on the Explosive Properties of Chlorophacinone Blue Paste 0.005% Bait Formulation. TSGE, Knaresborough, UK.Study No: 12-1-17\_F01265\_00\_Exp,Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| IIIB3.3-01 |  | Curl, M and Wright, E. | 2011b | Expert Statement on the Oxidising Properties of Chlorophacinone Blue Paste 0.005% Bait Formulation. TSGE, Knaresborough, UK.Study No: 12-1-17\_F01265\_00\_Oxp,Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| IIIB3.4-01 |  | Demangel, B. | 2008a | Flammability of Solids on Difethialone Paste – F00060\_01,Defitraces, Brindas, FranceStudy number 08-912021-002GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| IIIB3.5-01 |  | Demangel, B. | 2008b | Free Acidity or Alkalinity on Difethialone Paste – F00060\_01,Defitraces, Brindas, FranceStudy number 08-912021-003GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| IIIB3.6-01 |  | Zobel, M.L. | 2007 | Density Determination of DFN Paste 0601Liphatech Inc, Milwaukee, WI, USA.Study code: 06083.GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| IIIB3.7-01 |  | Caruel, H. | 2009 | Chlorophacinone blue paste 50 mg/kg – Accelerated Storage Stability (40°C – 8 weeks), CLOPA0,0050\_01F\_F01265\_00.Centre R&D De Sangosse, Pont du Casse, France.Study code: CLO00903C.GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| IIIB3.7-02 |  | Caruel, H. | 2011 | Chlorophacinone blue paste 50 mg/kg –Storage Stability (25°C – 2 Years), CLOPA0,0050\_01F\_F01265\_00.Centre R&D De Sangosse, Pont du Casse, France.Study code: CLO00903D.GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| IIIB3.7-03 |  | Deslux,R. | 2012 | Chlorophacinone bait compatibility packaging study (54°C, 14days)Centre R&D De Sangosse, Pont du Casse, France.Study code: CLO1203A.GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| IIIB4.1-01 |  | Caruel, H. | 2009 | Chlorophacinone Paste 50 mg/kg - Analytical method validation.CLOPA0,0050\_01F\_F01265\_00Centre R&D De Sangosse, Pont du Casse, France.Study code: CLO0903F.GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| 5 | IIIB5.10.2-01 | Berny, P. | 2010a | Study on the Efficacy and Palatability of a Paste at 50 mg/kg of Chlorophacinone in the Rat, Rattus rattus, Wild Strain, sensitive to Warfarin.ENVL, Marcy L’Etoile, France.Study code: RE/1003/CPN/paste/Rr/S.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| 5 | IIIB5.10.2-02 | Berny, P. | 2010b | Study on the Efficacy and Attractivity of a Paste at 50 mg/kg of Chlorophacinone in the Rat, *Rattus* *Norvegicus*, Wild Strain, sensitive to Warfarin.ENVL, Marcy L’Etoile, France.Study code: RE/1004/CPN/paste/Rn/S.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| 5 | IIIB5.10.2-03 | Berny, P. | 2010c | Study on the Efficacy and Palatability of a Paste at 50 mg/kg of Chlorophacinone in the House Mouse, Mus Musculus, Wild Strain, sensitive to Warfarin.ENVL, Marcy L’Etoile, France.Study code: RE/1006/CPN/paste/Mm/S.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| 5 | IIIB5.10.2-04 | Berny, P. | 2010d | Evaluation of the efficacy of a paste rodenticide containing 50 mg/kg chlorophacinone for the control of brown rat infestations in and around agricultural buildings.ENVL, Marcy L’Etoile, France.Study code: Report FSR-1001.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| 5 | IIIB5.10.2-05 | Berny, P. | 2010e | Evaluation of the efficacy of a paste rodenticide containing 50 mg/kg chlorophacinone for the control of black rat infestations in and around agricultural buildings.ENVL, Marcy L’Etoile, France.Study code: Report FSR-1002.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| 5 | IIIB5.10.2-06 | Berny, P. | 2005b | Study on the Impact of Denatonium Benzoate Variation Concentration on the Palatability of a Rodenticide Block Formula in the Rat, Rattus Norvegicus, Wild Strain.ENVL, Marcy L’Etoile, France.Study code: RE/0404/BDN/Block/Rn.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| 5 | IIIB5.10.2-07 | Berny, P. | 2005c | Study on the Impact of Packaging on the Attractivity of a Block in the Rat, Rattus Norvegicus, Wild Strain.ENVL, Marcy L’Etoile, France.Study code: RE/0314/Pack/R225/Block/Rn.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| 5 | IIIB5.10.2-08 | Berny, P. | 2003 | Selection of House Mouse Strains, Mus Musculus According to Their Degree of Resistance to an Anticoagulant of 1st Generation: Warfarin.ENVL, Marcy L’Etoile, France.Study code: RE/SOU/0202.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| 5 | IIIB5.10.2-09 | Berny, P. | 2002 | Selection of Rat Strains, Rattus Norvegicus According to Their Degree of Resistance to an Anticoagulant of 1st Generation: Warfarin.ENVL, Marcy L’Etoile, France.Study code: RE/SOU/0201.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| 5 | IIIB5.10.2-10 | Berny, P. | 2010f | Evaluation of the efficacy of a block rodenticide containing 50 mg/kg chlorophacinone for the control of house mice infestations in and around agricultural buildings.ENVL, Marcy L’Etoile, France.Study code: Report FSR-1003.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| 5 | IIIB5.10.2-11 | Berny, P. | 2011 | Study on the Efficacy and Attractivity of a Paste at 50 mg/kg of Chlorophacinone in the Rat, *Rattus* *Norvegicus*, Wild Strain, sensitive to Warfarin.ENVL, Marcy L’Etoile, France.Study code: RE/1114/CPN/paste/Rn/S.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| 5 | IIIB5.10.2-12 | Berny, P. | 2011b | Study on the Efficacy and Palatability of a Paste at 50 mg/kg of Chlorophacinone in the House Mouse, Mus Musculus, Wild Strain, sensitive to Warfarin.ENVL, Marcy L’Etoile, France.Study code: RE/1116/CPN/paste/Mm/S.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |
| 5 | IIIB5.10.2-13 | Grancher, D. | 2012 | Evaluation of the efficacy of a paste rodenticide containing containing 50 mg/kg chlorophacinone for the control of Mus musculus infestations in and around agricultural buildings. One trial, 1 site: Rhone; France, 2012.Report number FSR-1201.Non-GLP, Unpublished. | Liphatech | [ ]  | [ ]  | [x]  | [ ]  |

## Annex 3: Analytical methods residues – active substance

**Chlorophacinone**

The analytical methods for residues are taken from the CA report to support the inclusion of chlorophacinone in annex I of Directive 98/8/EC.

Please note that the following further information is demanded: Preliminary results of an analytical method for the determination of chlorophacinone in food and feedingstuffs showed that the method was partially acceptable for some of the matrices; however a fully validated method should be necessary when applying for authorisation of the biocidal product at national level for the first time after Annex I Inclusion.

**Analytical methods for residues**

|  |  |
| --- | --- |
| Soil (principle of method and LOQ) (Annex IIA, point 4.2) | Soil is extracted by shaking with aqueous methanol. Determination of the filtered and diluted extract is by reverse-phase LC-MS/MS (monitored ions 373.4/201.2 m/z). A Luna C-8 column is used with acetonitrile/water/ammonium acetate (gradient) mobile phase. The limit of determination is 0.01 mg/kg (defined as the lowest concentration at which acceptable recovery has been demonstrated). |
| Air (principle of method and LOQ) (Annex IIA, point 4.2) | Air is passed through Tenax absorption tubes which are eluted with acetonitrile. Determination is by reverse-phase HPLC, Luna C-8 column with acetonitrile/water/ ammonium acetate (gradient) mobile phase. The limit of determination is 0.03 μg/m3 (defined as the lowest concentration at which acceptable recovery has been demonstrated). |
| Water (principle of method and LOQ) (Annex IIA, point 4.2) | Water is extracted by partition into dichloromethane. The extract is evaporated to dryness and reconstituted in aqueous methanol. Determination is by reverse-phase LC-MS/MS (monitored ions 373.4/201.2 m/z). A Luna C-8 column is used with acetonitrile/water/ ammonium acetate (gradient) mobile phase. The limit of determination is 0.05 μg/L (defined as the lowest concentration at which acceptable recovery has been demonstrated). |
| Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2) | BloodBlood is diluted with methanol. Phosphate buffer, a mixture of ethanol/ethyl acetate and trichloroacetic acid solution is added. The sample is shaken and the organic phase removed. The sample is re-extracted with ethanol/ethyl acetate. The combined organic extracts are evaporated to dryness and reconstituted in methanol prior to determination. Determination is by HPLC with a Thermo Hypersil Keystone column and ammonium acetate/methanol (gradient) mobile phase (two ion transitions monitored 373>201 and 375>203). The limit of determination is 0.05 mg/L (defined as the lowest concentration at which acceptable recovery has been demonstrated).LiverLiver is blended with phosphate buffer (pH 5.5) and a mixture of ethanol and ethyl acetate (1+19, v/v). A solution of trichloroacetic acid is added and the sample is blended again. Clean-up of the centrifuged extract is by GPC. Determination is by HPLC with Thermo hypersil keystone column and ammonium acetate/methanol (gradient) mobile phase (two ion transitions monitored 373>201 and 375>203). The limit of determination is 0.05 mg/L (defined as the lowest concentration at which acceptable recovery has been demonstrated). |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1) | Samples are extracted by blending twice with methanol (meat and lemon) or methanol/water (oil-seed rape). After centrifugation the samples are diluted with methanol/water. Determination is by HPLC/MS-MS LOQ: 0.01 mg/kg |

## Annex 4: Toxicology and metabolism –active substance

**Chlorophacinone**

##### ***Threshold Limits and other Values for Human Health Risk Assessment***

| **Summary**  |
| --- |
|  | Value | Study | SF |
| AEL long-term | 0.000017 mg/kg bw/day | 90 day rat oral toxicity study | 300 |
| AEL medium-term | 0.000017 mg/kg bw/day | 90 day rat oral toxicity study | 300 |
| AEL acute  | 0.000033 mg/kg bw/day | Teratogenicity rabbit study | 300 |
|  |
| Inhalative absorption | No data |
| Oral absorption | 100%  |
| Dermal absorption | 1.7% |
| **Classification**  |
| with regard to toxicological data(according to the criteria in Dir. 67/548/EEC)\* | T+R26/27/28, R48/23/24/25, R61S1/2, S36/37, S45 |
| with regard to toxicological data(according to the criteria in Reg. 1272/2008) | Pictograms: GHS06, GHS08Signal word: DangerAcute Toxic Cat. 1, H300; H310; H330; STOT RE Cat. 1, H370; Repr. Cat. 1B, H360 |

|  |  |  |
| --- | --- | --- |
| Specific concentration limits\* | C ≥ 0.5%0.25% ≤ C < 0.5%0.025% ≤ C < 0.25%0.0025% ≤ C < 0.025%  | T+; R61-26/27/28 - T; R48/23/24/25T+; R26/27/28 – T; R48/23/24/25T; R23/24/25 – T; R48/23/24/25Xn; R20/21/22 – R48/20/21/22 |

\* The following information with regard to classification and labelling is included in the CAR:

The classification for human health effects of chlorophacinone is in May 2007 still under discussion. For anticoagulant rodenticides, regarding human health effects, a provisional classification with R61 was decided in November 2006 by the C & L, but without a final decision on the category to be used (Repr. Cat.1 or Repr. Cat. 2). The proposed classification for chlorophacinone for acute and repeated dose toxicity was agreed in May 2007. At that moment, the provisionally classification for reprotoxicity was not confirmed as the TC C&L decided to await further results from studies on anticoagulant rodenticides before finalising the discussion on reprotoxicity. Specific concentration limits for chlorophacinone are proposed, but there are still under consideration.

\*\* Chlorophacinone is included in the Registry of submitted Harmonised Classification and Labelling intentions (see www.echa.eu); however, no final conclusion on the classification has been reached yet. The current classification is the self-classification of the RMS (The Netherlands) based on the human toxicological data provided in the CAR of chlorophacinone, and proposed classification according to Directive 67/548/EEC.

## Annex 5: Toxicology – biocidal product

**Rozol Pat’**

|  |
| --- |
| General information |
| Formulation Type | Paste bait |
| Active substance(s) (incl. content) | Chlorophacinone, 0.005% |
| Category | PT14 |

| Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3) |
| --- |
| Rat LD50 oral (OECD 420) | > 2000 mg/kg bw |  |  |  |
| Rat LD50 dermal (OECD 402) | > 2000 mg/kg bw |  |  |  |
| Rat LC50 inhalation (OECD 403) | No classification\* |  |  |  |
| Skin irritation (OECD 404) | Not irritating  |  |  |  |
| Eye irritation (OECD 405) | Not irritating |  |  |  |
| Skin sensitisation (OECD 429; LLNA) | Not sensitizing |  |  |  |

\* An inhalation study of the product is not required. The product contains a small percentage of active

ingredient and is classed as nearly dust free. The active substance is not volatile. The physical nature of the product is such that inhalation of volatiles or dust is highly improbable.

|  |
| --- |
| Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9) |
| Directive 1999/45/EC | S2 |
| Regulation 1272/2008/EC | P102 |

## Annex 6: Safety for professional operators

**Rozol Pat’**

Exposure assessment

| Exposure scenarios for intended uses (Annex IIIB, point 6.6 )  |
| --- |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Product and intended use | Exposure scenario | PPE | Inhalational uptakeExposure (mg/m3) | Dermal uptakeExposure (mg/m2) |
| Rozol Pat’In and around buildings for the control of rodents | Cleaning the remains of 15 bait points/day6 sachets per bait point.Loading product is not relevant due to protective packaging | Gloves | Not considered for cleaning since negligible measured residues present during cleaning of bait boxes in pilot exposure study. | Measured as 4.09 mg product/gloves (geometric mean value) when cleaning up a bait box containing 6 sachets and disposing of the unwanted bait.Assume negligible amount of bait is consumed. |
| Dermal Exposure |
| Measured value for amount of product on gloves: | 4.09 mg product/bait point during disposal |
| Amount of blue paste on gloves during disposal: | 4.09 mg x 15 = 61.35 mg |
| Total amount of blue paste on gloves: | 61.35 mg |
| Concentration of chlorophacinone: | 50 mg/kg |
| Amount of chlorophacinone on gloves: | 50 x 61.35 ÷106 mg = 3.07 x 10-3 mg/day |
| Reduction in exposure from gloves: | 90% |
| Amount of chlorophacinone on skin: | 3.07 x 10-3 x (10 ÷ 100) mg = 3.07 x 10-4 mg/day |
| Dermal absorption of chlorophacinone: | 1.7% |
| Systemic exposure of chlorophacinone: | 5.22 x 10-6 mg/day |
| Operator body weight: | 60 kg |
| Dermal exposure of chlorophacinone during disposal: | 8.70 x 10-8 mg/kg bw/day |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Product and intended use | Exposure scenario | PPE | Inhalational uptakeExposure (mg/m3) | Dermal uptakeExposure (mg/m2) |
| Rozol Pat’ Around waste sites for the control of rodents | Cleaning up 50 bait points/ day.6 sachets per bait point.Loading product is not relevant due to protective packaging | Gloves | Not considered for cleaning since negligible measured residues present during cleaning of bait boxes in pilot exposure study. | Measured as 4.09 mg product/gloves (geometric mean value) when cleaning up a bait box containing 6 sachets and disposing of the unwanted bait.Assume negligible amount of bait is consumed. |
| Dermal Exposure |
| Measured value for amount of product on gloves: | 4.09 mg product/bait point during disposal |
| Amount of blue paste on gloves during disposal: | 4.09 mg x 50 = 204.5 mg |
| Concentration of chlorophacinone: | 50 mg/kg |
| Amount of chlorophacinone on gloves: | 50 x 204.5 ÷106 mg = 0.0102 mg/day |
| Reduction in exposure from gloves: | 90% |
| Amount of chlorophacinone on skin: | 0.010 x (10 ÷ 100) mg = 1.02 x 10-3 mg/day |
| Dermal absorption of chlorophacinone: | 1.7% |
| Systemic exposure of chlorophacinone: | 1.73 x 10-5 mg/day |
| Operator body weight: | 60 kg |
| Dermal exposure of chlorophacinone during disposal: | 2.89 x 10-7 mg/kg bw/day |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Product and intended use | Exposure scenario | PPE | Inhalational uptakeExposure (mg/m3) | Dermal uptakeExposure (mg/m2) |
| Rozol Pat’Open areas for control of rodents. | Cleaning up 30 bait points/ day.6 sachets per bait point.Loading product is not relevant due to protective packaging | Gloves | Not considered for cleaning since negligible measured residues present during cleaning of bait boxes in pilot exposure study. | Measured as 4.09 mg product/gloves (geometric mean value) when cleaning up a bait box containing 6 sachets and disposing of the unwanted bait.Assume negligible amount of bait is consumed. |
| Dermal Exposure |
| Measured value for amount of product on gloves: | 4.09 mg product/bait point during disposal |
| Amount of blue paste on gloves during disposal: | 4.09 mg x 30 = 122.7 mg |
| Concentration of chlorophacinone: | 50 mg/kg |
| Amount of chlorophacinone on gloves: | 50 x 122.7 ÷106 mg = 6.135 x 10-3 mg/day |
| Reduction in exposure from gloves: | 90% |
| Amount of chlorophacinone on skin: | 6.135 x 10-3 x (10 ÷ 100) mg = 6.135 x 10-4 mg/day |
| Dermal absorption of chlorophacinone: | 1.7% |
| Systemic exposure of chlorophacinone: | 1.04 x 10-5 mg/day |
| Operator body weight: | 60 kg |
| Dermal exposure of chlorophacinone during disposal: | 1.74 x 10-7 mg/kg bw/day |

Primary exposure of professionals

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Exposure scenario  | Component | CAS | Dermal Total [mg/day] (no PPE) | Dermal Total [mg/kg/d] (no PPE) | Dermal Total [mg/day] (gloves, 90% reduction) | DermalTotal [mg/kg/d] (gloves, 90% reduction) | InhalationExposure [mg/m³] |
| Application in and around buildings  | Chlorophacinone | 3691-35-8 | 5.22 x 10-5 | 8.70 x 10-7 | 5.22 x 10-6 | 8.70 x 10-8 | -  |
| Application around waste sites for the control of rodents | Chlorophacinone | 3691-35-8 | 1.73 x 10-4 | 2.89 x 10-6 | 1.73 x 10-5 | 2.89 x 10-7 | - |
| Application in open areas | Chlorophacinone | 3691-35-8 | 1.04 x 10-4 | 1.74 x 10-6 | 1.04 x 10-5 | 1.74 x 10-7 | - |

Risk assessment

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Exposure scenario | Component | CAS | AEL [mg/kg/d] | Absorption | Inhal ext[mg/m3] | Derm ext[mg/kg/d] | RCR total |
| inh | derm | Act. Expo | RCR | Act. Expo | RCR |
| Application in and around buildings | Chlorophacinone | 28772-56-7 | 0.000017 | No data | 1.7% | **-** | **-** | 8.70 x 10-7 | 5.1% | 5.1% |
| Application around waste sites for the control of rodents | Chlorophacinone | 28772-56-7 | 0.000017 | No data | 1.7% | **-** | **-** | 2.89 x 10-6 | 17.0% | 17.0% |
| Application in open areas | Chlorophacinone | 28772-56-7 | 0.000017 | No data | 1.7% | **-** | **-** | 1.74 x 10-6 | 10.2% | 10.2% |

## Annex 7: Safety for non-professional operators and the general public

**Rozol Pat’**

Non-professional use is not accepted in The Netherlands.

| General information |
| --- |
| Formulation Type | Paste bait |
| Active substance(s) (incl. content) | Chlorophacinone (0.005%) |
| Category | PT14 |
| Authorisation number | - |

| **Chlorophacinone** |
| --- |

| Data base for exposure estimation |
| --- |
| according to | Appendix: Toxicology and metabolism – active substance/CAR |

| Exposure scenarios for intended uses (Annex IIIB, point 6.6 )  |
| --- |
| Primary exposure | Non-professional users, application in and around buildings for the control of rodents |
| Secondary exposure, acute | Infant, ingesting a bait |
| Secondary exposure, chronic | -  |

Non-professional users:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product and intended use** | **Exposure scenario** | **PPE** | **Inhalational uptakeExposure (mg/m3)** | **Dermal uptakeExposure (mg/m2)** |
| Rozol Pat’In and around buildings for the control rodents | Cleaning the remains of 5 bait points per day. 6 sachets per bait point.Loading is not relevant due to protective packaging | None | Not considered for cleaning since negligible measured residues present during cleaning of bait boxes in pilot exposure study. | Measured as 4.09 mg product/gloves (geometric mean value) when cleaning up a bait box containing 6 sachets and disposing of the unwanted bait. |
| **Dermal Exposure** |
| Measured value for amount of product on hands: | 4.09 mg product/bait point during disposal |
| Amount of blue paste on hands during disposal: | 4.09 mg x 5 = 20.45 mg |
| Total amount of blue paste on hands: | 20.45 mg |
| Concentration of chlorophacinone: | 50 mg/kg |
| Amount of chlorophacinone on hands: | 50 x 20.45 ÷106 mg = 1.02 x 10-3 mg/day |
| Amount of chlorophacinone on skin: | 1.02 x 10-3 mg/day |
| Dermal absorption of chlorophacinone: | 1.7% |
| Systemic exposure of chlorophacinone: | 1.73 x 10-5 mg/day |
| Operator body weight: | 60 kg |
| **Dermal exposure of chlorophacinone during disposal:** | **2.89 x 10-7 mg/kg bw/day** |

Indirect exposure: infants ingesting a bait:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product and intended use** | **Exposure scenario** | **Inhalational uptake** | **Dermal uptake** | **Oral uptake** |
| **Exposure concentration(mg/m3)** | **Exposure concentration (mg/m2)** | **Exposure concentration (mg/event)** |
| Rozol Pat’In and around buildings for control of rats and mice | Non-users (adults, children and infants) will not be present during application.Infants may ingest part of the paste. | None. | Not applicable. | Assumed in EU guidance to be equivalent to 10 mg wax (infants) for transient mouthing of poison bait treated with repellent. |
| **1. ORAL EXPOSURE ASSESSMENT FOR INFANTS BASED ON DEFAULT VALUES** |
| Default value for amount of product ingested : | 10 mg |
| Concentration of chlorophacinone : | 50 mg/kg |
| Amount of chlorophacinone ingested : | 10 x 50 ÷ 106 mg = 0.00050 mg |
| Systemic exposure of chlorophacinone : | 0.00050 mg/day |
| Body weight : | 10 kg |
| Systemic exposure : | 0.000050 mg/kg bw/day |

Non-professional users, application in and around buildings for the control of rodents

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario**  | **Component** | **CAS** | **Dermal Total [mg/day]**  | **Dermal Total [mg/kg/d]**  | **InhalationExposure [mg/m³]** |
| Application in and around buildings  | Chlorophacinone | 3691-35-8 | 1.73 x 10-5 | 2.89 x 10-7 | -  |

Secondary exposure, infants ingesting a bait

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure scenario**  | **Component** | **CAS** | **OralTotal [mg/day]**  | **Oral Total [mg/kg/d]**  |
| Ingestion of a bait  | Chlorophacinone | 3691-35-8 | 0.00050 | 0.000050 |

Risk assessment

Non-professional users, application in and around buildings for the control of rodents

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Exposure scenario | Component | CAS | AEL [mg/kg/d] | Absorption | Inhal ext[mg/m3] | Derm ext[mg/kg/d] | RCR total |
| inh | derm | Act. Expo | RCR | Act. Expo | RCR |
| Non-professional users, application in and around buildings | Chlorophacinone | 3691-35-8 | 0.000033  | No data | 1.7% | - | - | 2.89 x 10-7 | 0.88% | 0.88% |

Indirect exposure: infants ingesting a bait:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | Component | CAS | AEL [mg/kg/d] | Oral exposure[mg/kg/d] | RCR ges |
| Act. Expo | RCR |
| Secondary exposure, infants ingesting a bait | Chlorophacinone | 3691-35-8 | 0.000033 | 0.000050 | 384.6% | 151.5% |

Conclusion:

Exposure of non-professionals and the general public to the biocidal product containing chlorophacinone as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

1. [↑](#footnote-ref-1)
2. Access level: “Restricted” to applicant and authority [↑](#footnote-ref-2)
3. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. [↑](#footnote-ref-3)
4. [Please, refer to Guidance for Human Health Risk Assessement, Volume III, Part B - to characterise the risk in case of exposure to several active substances or substances of concern within a product] [↑](#footnote-ref-4)
5. Applies only to existing authorisations [↑](#footnote-ref-5)
6. Larsen, J. (2003). Emission scenario document for biocides used as rodenticides. Supplement to the methodology for risk evaluation for biocides, CA‑Jun03‑Doc.8.2‑PT14. Report prepared in the context of the EU project entitled “Gathering, review and development of environmental emission scenarios for biocides” (EUBEES 2). [↑](#footnote-ref-6)
7. Gemmeke, H. (2000). Fraßabschreckende Wirkung von gefärbtem Saatgut auf Vögel. http://www.bba.de/oekoland/oeko3/voegel.htm [↑](#footnote-ref-7)
8. Moran, S. (1999). Rejection of dyed field rodent baits by feral pigeons and chukar partridges. *Phytoparasitica* **27** (1): 9-17 [↑](#footnote-ref-8)
9. Marsh, R.E. (1985) Techniques used in rodent control to safeguard nontarget wildlife. [↑](#footnote-ref-9)
10. Kalmbach, E.R. 1943. Birds, rodents and colored lethal baits. Transactions of the North American Wildlife Conference, 8: 408-416. [↑](#footnote-ref-10)
11. Kalmbach, E.R. and Welch, J.F. (1946). Colored rodent baits and their value in safeguarding birds. *J. Wildlife Management*, 10: 353-360. [↑](#footnote-ref-11)
12. Caithness, T.A. and Williams, G.R. (1971). Protecting birds from poisoned baits. New Zealand Department of Internal Affairs, Wildlife Publication No. 129. [↑](#footnote-ref-12)
13. Pank, S. (1976). Effects of seed and background colours on seed acceptance by birds. *J. Wildlife Management*, **40**: 769-774. [↑](#footnote-ref-13)
14. Brunner, H. and Coman, B.J. (1983). The ingestion of artificially coloured grain by birds, and its relevance to vertebrate pest control. *Australian Wildlife Research* **10**: 303-310. [↑](#footnote-ref-14)
15. Harrison, E.G., Porter, A.J. and Forbes, S. (1988). Development of methods to assess the hazards of a rodenticide to non-target vertebrates. Proceedings of the British Crop Protection Symposium.

Fenn, M.G.P., Tew, T.E. and MacDonald, D.W. (1987). Rat movements and control on an Oxfordshire farm. *J. Zoology, London*. **213**, 745-749. [↑](#footnote-ref-15)
16. Handbook of the Birds of Europe, the Middle East and North Africa. The Birds of the Western Palearctic (Cramp, S. and Perrins, C.M.: Eds.) Vols. III and VIII. Oxford University Press. [↑](#footnote-ref-16)
17. Indicate how the product will be applied (e.g. brush, spray, dipping, bait, etc). Where the product is to be used by more than one user category, indicate the application method(s) intended for each user category. [↑](#footnote-ref-17)
18. Data which have not been already submitted for the purpose of the Annex I inclusion. [↑](#footnote-ref-18)