Summary of product characteristics for a biocidal product

Product name: Harmonix 3D

Product type(s): PT14 - Rodenticides (Pest control)

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Authorisation number: ES/MR(NA)-2020-14-00720

R4BP 3 asset reference number: ES-0024447-0000

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Administrative information

1.1. Trade names of the product

HARMONIX 3D
HARMONIX D
HARMONIX PASTA
HARMONIX FREE
HABITRO PASTA RODENTICIDA

1.2. Authorisation holder

Name and address of the authorisation holder	Name	2022 ENVIRONMENTAL SCIENCE FR SAS
	Address	3, place Giovanni Da Verrazzano 69009 LYON France
Authorisation number	ES/MR(NA)-2020-14-00720	
R4BP 3 asset reference number	ES-0024447-0000	
Date of the authorisation	21/09/2020	
Expiry date of the authorisation	24/07/2025	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Bayer SAS
Address of the manufacturer	16 rue Jean-Marie Leclair, CS 90106 69266 Lyon (Cedex 09) France
Location of manufacturing sites	INDUSTRIALCHIMICA Srl. Via Sorgaglia 40 I-35020 Arre Italy
	Kollant S.r.l., via C. Colombo 7/7 30030 Vigonovo (VE) Italy
	IRIS 1126A, avenue du Moulinas - Route de Saint Privat F- 30340 SALINDRES France

1.4. Manufacturer(s) of the active substance(s)

Active substance	1443 - Cholecalciferol
Name of the manufacturer	Bayer S.A.S
Address of the manufacturer	16 rue Jean-Marie Leclair, CS 90106 69266 Lyon (Cedex 09) France
Location of manufacturing sites	Fermenta Biotech Limited, Village Takoli; P.O. Nagwain District Mandi - 175 121 Himachal Pradesh India
	Fermenta Biotech Limited, Z-109 B & C, SEZ II, Dahej, Taluka - Vagara District Bharuch - 392130 Gujarat India

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Cholecalciferol		Active Substance	67-97-0	200-673-2	0,077

2.2. Type of formulation

RB- Ready-to-use bait: paste

3. Hazard and precautionary statements

Hazard statements	
Precautionary statements	

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 1 – House mouse, Norway rat, Roof rat– Professionals – Indoor

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: Norway rat Development stage: adults and juveniles Scientific name: Rattus rattus Common name: Roof rat Development stage: adults and juveniles Scientific name: Mus musculus Common name: House mouse Development stage: adults and juveniles
Field(s) of use	Indoor Indoor
Application method(s)	Method: - Detailed description: Bait application Ready-to-use bait to be used in tamper-resistant bait stations (See document CA-Nov16-Doc.4.1c-Final on the concept of tamperresistant bait stations.)

Application rate(s) and frequencies	Application Rate: For rats: 100-200 g bait per baiting point depending upon infestation level. For mice: 20 g bait per baiting point depending upon infestation level. Dilution (%): - Number and timing of application: <u>For rats</u>: 100-200 g bait per baiting point depending upon infestation level. If more than one bait station is needed, the minimum distance between bait stations should be 10 - 20 linear metres (in case of a low infestation) and 3 – 10 linear meters (in case of a high infestation). An amount of 200 g of product must be added when bait has been totally consumed within one control interval. <u>For mice</u>: 20 g bait per baiting point depending upon infestation level. If more than one bait station is needed, the minimum distance between bait stations should be 5 - 20 linear metres (in case of a low infestation) and 2 – 5 linear meters (in case of a high infestation). An amount of 20 g of product must be added when bait has been totally consumed within one control interval.
Category(ies) of users	Professional
Pack sizes and packaging material	Bait in individual tea bag sachet, Long fibre paper, 20g Primary Packaging: Tea bag (cellulose), 20g Secondary Packaging: Type of packaging: Bucket, Size/ Volume of the packaging: up to 10 kg for the bucket, up to 10 kg for the inner sachet Material of the packaging: Inner LDPE plastic sachet in a plastic PP Bucket Type of the packaging: Box Size/volume of the packaging: up to 15 kg for the box, up to 10 kg for the inner sachet Material of the packaging: Inner COEX PET/LDPE plastic sachet in a cardboard box Type of the packaging: Bag Size/volume of the packaging: up to 5 kg Material of the packaging: Plastic: COEX PET/PA/LDPE Plastic bag, with handle and reclosable zip

4.1.1 Use-specific instructions for use

Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning.
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.
Determine the extent of documentation in agreement with the customer. A site plan of all baiting points and recordings of the regular inspections constitute the minimum requirements for operations that produce, market, store or sell foodstuffs. In any case, the documentation must include the place, purpose, the biocidal products applied (including the specific amounts) and the person in charge of the rodent control. The documentation has to be kept for a minimum of five years.
The aim of a baiting campaign is to eradicate the target rodents in the infested area/building.
Remove water sources and 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.
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.).
Bait stations have to be mechanically stable and tamper-resistant.
Bait stations have to be designed in a way which prevents the access from non-target organisms as far as possible.
Label all baiting points and bait stations with appropriate warnings. The client has to be informed about all ongoing control measures.
The client is obliged to inform his employees as well as external service providers. If necessary, he has to place additional warnings.
The person in charge of the control measure has to supply the client with sufficient information and generally understandable warnings on the risks of primary or secondary poisoning. The client and the person in charge of the control measure have to agree upon the responsibility for putting the warnings in place. As a minimum requirement, the information material or the respective warnings have to include the following details:
- First measures to be taken in case of poisoning,
- Measures to be taken in case of spillage of the bait and the discovery of dead rodents,
- Name of the product and the active substance(s) incl. concentration
- Contact information of the person in charge of the rodent control,
- Telephone number of a poison information centre and the name of the antidote,
- Date of the beginning of the campaign, i.e. when the baits were deployed first.
Bait should be secured so that it cannot be dragged away from the bait station.
Replace consumed baits at each visit; the uptake of baits has to be documented.

Direct application in burrows:
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.
Remove and dispose spilled and rejected baits and dead rodents in accordance with local requirements in order to prevent primary and secondary poisoning.
The authorisation holder shall recommend how spilled bait shall be remediated.
The baits have to be displayed by hand deeply into the rodents corridors and afterwards every corridor must be closed with the soil previously removed to open the gallery. Grass, straw or paperboard etc. may be used to stabilise the cover, to minimise the risk of consumption by other animals or children.
No use of the biocidal product during times of rainfall.

Permanent baiting:
If possible, it is recommended that the treated area be revisited no later than every 4 weeks to avoid any selection of a resistant population.
Follow additional instructions provided by the Good Practice Manual.

4.1.2 Use-specific risk mitigation measures

Search for and dispose dead rodents in the infested area at each visit to prevent secondary poisoning.
At the beginning of the campaign, visit the bait points at the latest after 1 - 2 days and at least on a weekly basis afterwards. The same applies to baiting campaigns that last for more than 35 days.
3) Bait stations have to be used. Only in areas (e.g. closed cable routes, sub-constructions of e.g. electric appliances or high voltage cabinets, cavities in walls and panellings) which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed
Take the following measures to avoid re-infestation after a successful control:
- Remove potential sources of food and water for rodents (food- and feeding stuff, rubbish, etc.) or make them inaccessible to rodents as far as possible.
- Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.
- As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.
- Do not use the product in pulsed baiting treatments.
- 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.

Do not wash the bait stations with water between applications.
Undamaged bait stations and untouched baits may be reused.
The success of the control measure has to be documented and proven.
The client has to be informed of possible preventive measures against re-infestation.
All relevant documents of the control measures have to be provided to the client as well as responsible authorities upon request.
Permanent baiting is strictly limited to sites with a high potential for re-invasion when other control methods have proven to be insufficient.
The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.
See chapter 5.2

4.1.3 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.

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

See directions for use

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

See directions for use

4.2 Use description

Use 2 - Use # 2 – House mouse, Norway rat, Roof rat– Professionals – Outdoor: around buildings

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: Norway rat Development stage: adults and juveniles Scientific name: Rattus rattus Common name: Roof rat Development stage: adults and juveniles Scientific name: Mus musculus Common name: House mouse Development stage: adults and juveniles

Field(s) of use	Outdoor Outdoor: around buildings
Application method(s)	Method: - Detailed description: Bait application Ready-to-use bait to be used in tamper-resistant bait stations (See document CA-Nov16-Doc.4.1c-Final on the concept of tamperresistant bait stations.)
Application rate(s) and frequencies	Application Rate: For rats: 100-200 g bait per baiting point depending upon infestation level. For mice: 20 g bait per baiting point depending upon infestation level. Dilution (%): - Number and timing of application: <u>For rats</u>: 100-200 g bait per baiting point depending upon infestation level. If more than one bait station is needed, the minimum distance between bait stations should be 10 - 20 linear metres (in case of a low infestation) and 3 – 10 linear meters (in case of a high infestation). An amount of 200 g of product must be added when bait has been totally consumed within one control interval. <u>For mice</u>: 20 g bait per baiting point depending upon infestation level. If more than one bait station is needed, the minimum distance between bait stations should be 5 - 20 linear metres (in case of a low infestation) and 2 – 5 linear meters (in case of a high infestation). An amount of 20 g of product must be added when bait has been totally consumed within one control interval.
Category(ies) of users	Professional
Pack sizes and packaging material	Bait in individual tea bag sachet, Long fibre paper, 20g Primary Packaging: Tea bag (cellulose), 20g Secondary Packaging: Type of packaging: Bucket, Size/ Volume of the packaging: up to 10 kg for the bucket, up to 10 kg for the inner sachet Material of the packaging: Inner LDPE plastic sachet in a plastic PP Bucket Type of the packaging: Box Size/volume of the packaging: up to 15 kg for the box, up to 10 kg for the inner sachet Material of the packaging: Inner COEX PET/LDPE plastic sachet in a cardboard box Type of the packaging: Bag Size/volume of the packaging: up to 5 kg Material of the packaging: Plastic: COEX PET/PA/LDPE Plastic bag, with handle and reclosable zip

4.2.1 Use-specific instructions for use

Protect bait from the weathering (e.g. rain, snow, etc.). 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.
Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning.
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.
Determine the extent of documentation in agreement with the customer. A site plan of all baiting points and recordings of the regular inspections constitute the minimum requirements for operations that produce, market, store or sell foodstuffs. In any case, the documentation must include the place, purpose, the biocidal products applied (including the specific amounts) and the person in charge of the rodent control. The documentation has to be kept for a minimum of five years.
The aim of a baiting campaign is to eradicate the target rodents in the infested area/building.
Remove water sources and food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
The product should 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.).
Bait stations have to be mechanically stable and tamper-resistant.
Bait stations have to be designed in a way which prevents the access from non-target organisms as far as possible.
Label all baiting points and bait stations with appropriate warnings. The client has to be informed about all ongoing control measures.
The client is obliged to inform his employees as well as external service providers. If necessary, he has to place additional warnings.
The person in charge of the control measure has to supply the client with sufficient information and generally understandable warnings on the risks of primary or secondary poisoning. The client and the person in charge of the control measure have to agree upon the responsibility for putting the warnings in place. As a minimum requirement, the information material or the respective warnings have to include the following details:
- First measures to be taken in case of poisoning,
- Measures to be taken in case of spillage of the bait and the discovery of dead rodents,
- Name of the product and the active substance(s) incl. concentration
- Contact information of the person in charge of the rodent control,
- Telephone number of a poison information centre and the name of the antidote,
- Date of the beginning of the campaign, i.e. when the baits were deployed first.
Bait should be secured so that it cannot be dragged away from the bait station.
Replace consumed baits at each visit; the uptake of baits has to be documented.

Direct application in burrows:
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.
Remove and dispose spilled and rejected baits and dead rodents in accordance with local requirements in order to prevent primary and secondary poisoning.
The authorisation holder shall recommend how spilled bait shall be remediated.
The baits have to be displayed by hand deeply into the rodents corridors and afterwards every corridor must be closed with the soil previously removed to open the gallery. Grass, straw or paperboard etc. may be used to stabilise the cover, to minimise the risk of consumption by other animals or children.
No use of the biocidal product during times of rainfall.

Permanent baiting:
If possible, it is recommended that the treated area be revisited no later than every 4 weeks to avoid any selection of a resistant population.
Follow additional instructions provided by the Good Practice Manual.

4.2.2 Use-specific risk mitigation measures

Search for and dispose dead rodents in the infested area at each visit to prevent secondary poisoning.
At the beginning of the campaign, visit the bait points at the latest after 1 - 2 days and at least on a weekly basis afterwards. The same applies to baiting campaigns that last for more than 35 days.
Bait stations have to be used. Only in areas which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed.
Take the following measures to avoid re-infestation after a successful control:
- Remove potential sources of food and water for rodents (food- and feeding stuff, rubbish, etc.) or make them inaccessible to rodents as far as possible.
- Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.
- As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.
Do not use this product in pulsed baiting treatments.
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.
Do not wash the bait stations with water between applications.
Undamaged bait stations and untouched baits may be reused.

The success of the control measure has to be documented and proven.
The client has to be informed of possible preventive measures against re-infestation.
All relevant documents of the control measures have to be provided to the client as well as responsible authorities upon request.
Permanent baiting is strictly limited to sites with a high potential for re-invasion when other control methods have proven to be insufficient.
The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.
See Directions for use

4.2.3 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.

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

See Directions for use

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

See Directions for use

4.3 Use description

Use 3 - Use # 3 – House mouse, Norway rat, Roof rat– Trained professionals – Indoor

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: Norway rat Development stage: adults and juveniles Scientific name: Rattus rattus Common name: Roof rat Development stage: adults and juveniles Scientific name: Mus musculus Common name: House mouse Development stage: adults and juveniles

Field(s) of use	Indoor Indoor
Application method(s)	Method: - Detailed description: Bait application Ready-to-use bait to be used in tamper-resistant bait stations (See document CA-Nov16-Doc.4.1c-Final on the concept of tamperresistant bait stations.)
Application rate(s) and frequencies	Application Rate: For rats: 100-200 g bait per baiting point depending upon infestation level. For mice: 20 g bait per baiting point depending upon infestation level. Dilution (%): - Number and timing of application: <u>For rats</u>: 100-200 g bait per baiting point depending upon infestation level. If more than one bait station is needed, the minimum distance between bait stations should be 10 - 20 linear metres (in case of a low infestation) and 3 – 10 linear meters (in case of a high infestation). An amount of 200 g of product must be added when bait has been totally consumed within one control interval. <u>For mice</u>: 20 g bait per baiting point depending upon infestation level. If more than one bait station is needed, the minimum distance between bait stations should be 5 - 20 linear metres (in case of a low infestation) and 2 – 5 linear meters (in case of a high infestation). An amount of 20 g of product must be added when bait has been totally consumed within one control interval.
Category(ies) of users	Trained professional
Pack sizes and packaging material	Bait in individual tea bag sachet, Long fibre paper, 20g Primary Packaging: Tea bag (cellulose), 20g Secondary Packaging: Type of packaging: Bucket, Size/ Volume of the packaging: up to 10 kg for the bucket, up to 10 kg for the inner sachet Material of the packaging: Inner LDPE plastic sachet in a plastic PP Bucket Type of the packaging: Box Size/volume of the packaging: up to 15 kg for the box, up to 10 kg for the inner sachet Material of the packaging: Inner COEX PET/LDPE plastic sachet in a cardboard box Type of the packaging: Bag Size/volume of the packaging: up to 5 kg Material of the packaging: Plastic: COEX PET/PA/LDPE Plastic bag, with handle and reclosable zip

4.3.1 Use-specific instructions for use

Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning.
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.
Determine the extent of documentation in agreement with the customer. A site plan of all baiting points and recordings of the regular inspections constitute the minimum requirements for operations that produce, market, store or sell foodstuffs. In any case, the documentation must include the place, purpose, the biocidal products applied (including the specific amounts) and the person in charge of the rodent control. The documentation has to be kept for a minimum of five years.
The aim of a baiting campaign is to eradicate the target rodents in the infested area/building.
Remove water sources and 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.
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.).
Bait stations have to be mechanically stable and tamper-resistant.
Bait stations have to be designed in a way which prevents the access from non-target organisms as far as possible.
Label all baiting points and bait stations with appropriate warnings. The client has to be informed about all ongoing control measures.
The client is obliged to inform his employees as well as external service providers. If necessary, he has to place additional warnings.
The person in charge of the control measure has to supply the client with sufficient information and generally understandable warnings on the risks of primary or secondary poisoning. The client and the person in charge of the control measure have to agree upon the responsibility for putting the warnings in place. As a minimum requirement, the information material or the respective warnings have to include the following details:
- First measures to be taken in case of poisoning,
- Measures to be taken in case of spillage of the bait and the discovery of dead rodents,
- Name of the product and the active substance(s) incl. concentration
- Contact information of the person in charge of the rodent control,
- Telephone number of a poison information centre and the name of the antidote,
- Date of the beginning of the campaign, i.e. when the baits were deployed first.
Bait should be secured so that it cannot be dragged away from the bait station.
Replace consumed baits at each visit; the uptake of baits has to be documented.

Direct application in burrows:
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.
Remove and dispose spilled and rejected baits and dead rodents in accordance with local requirements in order to prevent primary and secondary poisoning.
The authorisation holder shall recommend how spilled bait shall be remediated.
The baits have to be displayed by hand deeply into the rodents corridors and afterwards every corridor must be closed with the soil previously removed to open the gallery. Grass, straw or paperboard etc. may be used to stabilise the cover, to minimise the risk of consumption by other animals or children.
No use of the biocidal product during times of rainfall.

Permanent baiting:
If possible, it is recommended that the treated area be revisited no later than every 4 weeks to avoid any selection of a resistant population.
Follow additional instructions provided by the Good Practice Manual.

4.3.2 Use-specific risk mitigation measures

Search for and dispose dead rodents in the infested area at each visit to prevent secondary poisoning.
At the beginning of the campaign, visit the bait points at the latest after 1 - 2 days and at least on a weekly basis afterwards. The same applies to baiting campaigns that last for more than 35 days.
3) Bait stations have to be used. Only in areas (e.g. closed cable routes, sub-constructions of e.g. electric appliances or high voltage cabinets, cavities in walls and panellings) which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed
Take the following measures to avoid re-infestation after a successful control:
- Remove potential sources of food and water for rodents (food- and feeding stuff, rubbish, etc.) or make them inaccessible to rodents as far as possible.
- Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.
- As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.
- Do not use the product in pulsed baiting treatments.
- 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.

Do not wash the bait stations with water between applications.
Undamaged bait stations and untouched baits may be reused.
The success of the control measure has to be documented and proven.
The client has to be informed of possible preventive measures against re-infestation.
All relevant documents of the control measures have to be provided to the client as well as responsible authorities upon request.
Permanent baiting is strictly limited to sites with a high potential for re-invasion when other control methods have proven to be insufficient.
The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.
See Directions for use

4.3.3 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 points close to water drainage systems, ensure that bait contact with water is avoided.

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

See Directions for use

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

See Directions for use

4.4 Use description

Use 4 - Use # 4 – House mouse, Norway rat, Roof rat– Trained professionals – Outdoor: around buildings

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: Norway rat

	Development stage: adults and juveniles Scientific name: Rattus rattus Common name: Roof rat Development stage: adults and juveniles Scientific name: Mus musculus Common name: House mouse Development stage: adults and juveniles
Field(s) of use	Outdoor Outdoor: around buildings
Application method(s)	Method: - Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations (See document CA-Nov16-Doc.4.1c-Final on the concept of tamperresistant bait stations.)
Application rate(s) and frequencies	Application Rate: For rats: 100-200 g bait per baiting point depending upon infestation level. For mice: 20 g bait per baiting point depending upon infestation level. Dilution (%): - Number and timing of application: <u>For rats</u>: 100-200 g bait per baiting point depending upon infestation level. If more than one bait station is needed, the minimum distance between bait stations should be 10 - 20 linear metres (in case of a low infestation) and 3 – 10 linear meters (in case of a high infestation). An amount of 200 g of product must be added when bait has been totally consumed within one control interval. <u>For mice</u>: 20 g bait per baiting point depending upon infestation level. If more than one bait station is needed, the minimum distance between bait stations should be 5 - 20 linear metres (in case of a low infestation) and 2 – 5 linear meters (in case of a high infestation). An amount of 20 g of product must be added when bait has been totally consumed within one control interval.
Category(ies) of users	Trained professional
Pack sizes and packaging material	Bait in individual tea bag sachet, Long fibre paper, 20g Primary Packaging: Tea bag (cellulose), 20g Secondary Packaging: Type of packaging: Bucket, Size/ Volume of the packaging: up to 10 kg for the bucket, up to 10 kg for the inner sachet Material of the packaging: Inner LDPE plastic sachet in a plastic PP Bucket Type of the packaging: Box Size/volume of the packaging: up to 15 kg for the box, up to 10 kg for the inner sachet Material of the packaging: Inner COEX PET/LDPE plastic sachet in a cardboard box Type of the packaging: Bag Size/volume of the packaging: up to 5 kg Material of the packaging: Plastic: COEX PET/PA/LDPE Plastic bag, with handle and reclosable zip

4.4.1 Use-specific instructions for use

Protect bait from the weathering (e.g. rain, snow, etc.). 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.
Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning.
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.
Determine the extent of documentation in agreement with the customer. A site plan of all baiting points and recordings of the regular inspections constitute the minimum requirements for operations that produce, market, store or sell foodstuffs. In any case, the documentation must include the place, purpose, the biocidal products applied (including the specific amounts) and the person in charge of the rodent control. The documentation has to be kept for a minimum of five years.
The aim of a baiting campaign is to eradicate the target rodents in the infested area/building.
Remove water sources and food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
The product should 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.).
Bait stations have to be mechanically stable and tamper-resistant.
Bait stations have to be designed in a way which prevents the access from non-target organisms as far as possible.
Label all baiting points and bait stations with appropriate warnings. The client has to be informed about all ongoing control measures.
The client is obliged to inform his employees as well as external service providers. If necessary, he has to place additional warnings.
The person in charge of the control measure has to supply the client with sufficient information and generally understandable warnings on the risks of primary or secondary poisoning. The client and the person in charge of the control measure have to agree upon the responsibility for putting the warnings in place. As a minimum requirement, the information material or the respective warnings have to include the following details:
- First measures to be taken in case of poisoning,
- Measures to be taken in case of spillage of the bait and the discovery of dead rodents,
- Name of the product and the active substance(s) incl. concentration
- Contact information of the person in charge of the rodent control,
- Telephone number of a poison information centre and the name of the antidote,
- Date of the beginning of the campaign, i.e. when the baits were deployed first.

Bait should be secured so that it cannot be dragged away from the bait station.
Replace consumed baits at each visit; the uptake of baits has to be documented.

Direct application in burrows:
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.
Remove and dispose spilled and rejected baits and dead rodents in accordance with local requirements in order to prevent primary and secondary poisoning.
The authorisation holder shall recommend how spilled bait shall be remediated.
The baits have to be displayed by hand deeply into the rodents corridors and afterwards every corridor must be closed with the soil previously removed to open the gallery. Grass, straw or paperboard etc. may be used to stabilise the cover, to minimise the risk of consumption by other animals or children.
No use of the biocidal product during times of rainfall.

Permanent baiting:
If possible, it is recommended that the treated area be revisited no later than every 4 weeks to avoid any selection of a resistant population.
Follow additional instructions provided by the Good Practice Manual.

4.4.2 Use-specific risk mitigation measures

Search for and dispose dead rodents in the infested area at each visit to prevent secondary poisoning.
At the beginning of the campaign, visit the bait points at the latest after 1 - 2 days and at least on a weekly basis afterwards. The same applies to baiting campaigns that last for more than 35 days.
Bait stations have to be used. Only in areas which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed.
Take the following measures to avoid re-infestation after a successful control:
- Remove potential sources of food and water for rodents (food- and feeding stuff, rubbish, etc.) or make them inaccessible to rodents as far as possible.
- Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.
- As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.
Do not use this product in pulsed baiting treatments.
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.
Do not wash the bait stations with water between applications.
Undamaged bait stations and untouched baits may be reused.
The success of the control measure has to be documented and proven.
The client has to be informed of possible preventive measures against re-infestation.
All relevant documents of the control measures have to be provided to the client as well as responsible authorities upon request.
Permanent baiting is strictly limited to sites with a high potential for re-invasion when other control methods have proven to be insufficient.
The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.
See Directions for use

4.4.3 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.

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

See Directions for use

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

See Directions for use

4.5 Use description

Use 5 - Use # 5 – House mouse, Norway rat, Roof rat– Trained professionals – Outdoor: open areas and waste dumps

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: Norway rat Development stage: adults and juveniles Scientific name: Rattus rattus Common name: Roof rat Development stage: adults and juveniles Scientific name: Mus musculus Common name: House mouse Development stage: adults and juveniles
Field(s) of use	Outdoor Outdoor: open areas and waste dumps
Application method(s)	Method: - Detailed description: Bait application Ready-to-use bait to be used in tamper-resistant bait stations (See document CA-Nov16-Doc.4.1c-Final on the concept of tamperresistant bait stations.) Direct application of ready-to-use bait into the burrowa
Application rate(s) and frequencies	Application Rate: For rats: 100-200 g bait per baiting point depending upon infestation level. For mice: 20 g bait per baiting point depending upon infestation level. Dilution (%): - Number and timing of application: <u>For rats</u>: 100-200 g bait per baiting point depending upon infestation level. If more than one bait station is needed, the minimum distance between bait stations should be 10 - 20 linear metres (in case of a low infestation) and 3 – 10 linear meters (in case of a high infestation). An amount of 200 g of product must be added when bait has been totally consumed within one control interval. <u>For mice</u>: 20 g bait per baiting point depending upon infestation level. If more than one bait station is needed, the minimum distance between bait stations should be 5 - 20 linear metres (in case of a low infestation) and 2 – 5 linear meters (in case of a high infestation). An amount of 20 g of product must be added when bait has been totally consumed within one control interval.

Category(ies) of users	Trained professional
Pack sizes and packaging material	Bait in individual tea bag sachet, Long fibre paper, 20g Primary Packaging: Tea bag (cellulose), 20g Secondary Packaging: Type of packaging: Bucket, Size/ Volume of the packaging: up to 10 kg for the bucket, up to 10 kg for the inner sachet Material of the packaging: Inner LDPE plastic sachet in a plastic PP Bucket Type of the packaging: Box Size/volume of the packaging: up to 15 kg for the box, up to 10 kg for the inner sachet Material of the packaging: Inner COEX PET/LDPE plastic sachet in a cardboard box Type of the packaging: Bag Size/volume of the packaging: up to 5 kg Material of the packaging: Plastic: COEX PET/PA/LDPE Plastic bag, with handle and reclosable zip

4.5.1 Use-specific instructions for use

Protect bait from the weathering (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning.
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.
Determine the extent of documentation in agreement with the customer. A site plan of all baiting points and recordings of the regular inspections constitute the minimum requirements for operations that produce, market, store or sell foodstuffs. In any case, the documentation must include the place, purpose, the biocidal products applied (including the specific amounts) and the person in charge of the rodent control. The documentation has to be kept for a minimum of five years.
The aim of a baiting campaign is to eradicate the target rodents in the infested area/building.
Remove water sources and food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
The product should 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.).
Bait stations have to be mechanically stable and tamper-resistant.
Bait stations have to be designed in a way which prevents the access from non-target organisms as far as possible.
Label all baiting points and bait stations with appropriate warnings. The client has to be informed about all ongoing control measures. The client is obliged to inform his employees as well as external service providers. If necessary, he has to place additional warnings.
The person in charge of the control measure has to supply the client with sufficient information and generally understandable warnings on the risks of primary or secondary poisoning. The client and the person in charge of the control measure have to agree upon the responsibility for putting the warnings in place. As a minimum requirement, the information material or the respective warnings have to include the following details:
- First measures to be taken in case of poisoning,
- Measures to be taken in case of spillage of the bait and the discovery of dead rodents,
- Name of the product and the active substance(s) incl. concentration
- Contact information of the person in charge of the rodent control,
- Telephone number of a poison information centre and the name of the antidote,
- Date of the beginning of the campaign, i.e. when the baits were deployed first.

Bait should be secured so that it cannot be dragged away from the bait station.
Replace consumed baits at each visit; the uptake of baits has to be documented.

Additional elements to be considered for direct application in burrows:
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.
Remove and dispose spilled and rejected baits and dead rodents in accordance with local requirements in order to prevent primary and secondary poisoning.
The authorisation holder shall recommend how spilled bait shall be remediated.
The baits have to be displayed by hand deeply into the rodents corridors and afterwards every corridor must be closed with the soil previously removed to open the gallery. Grass, straw or paperboard etc. may be used to stabilise the cover, to minimise the risk of consumption by other animals or children.
No use of the biocidal product during times of rainfall.

4.5.2 Use-specific risk mitigation measures

Search for and dispose dead rodents in the infested area at each visit to prevent secondary poisoning.
At the beginning of the campaign, visit the bait points at the latest after 1 - 2 days and at least on a weekly basis afterwards. The same applies to baiting campaigns that last for more than 35 days.
Bait stations have to be used. Only in areas which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed.
Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
Do not use this product in pulsed baiting treatments.
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.
Do not wash the bait stations with water between applications.
Undamaged bait stations and untouched baits may be reused.
The success of the control measure has to be documented and proven.
The client has to be informed of possible preventive measures against re-infestation.
All relevant documents of the control measures have to be provided to the client as well as responsible authorities upon request.
Open areas:
Take the following measures to avoid re-infestation after a successful control:
- Remove potential sources of food and water for rodents (food- and feeding stuff, rubbish, etc.) or make them inaccessible to rodents as far as possible.
- Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.
- As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.
See Directions for use

4.5.3 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.

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

See Directions for use

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

See Directions for use

5. General directions for use

5.1. 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.

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.

Where possible, bait stations must be fixed to the ground or other structures.

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.

Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 2.5.3. for the information to be shown on the label).

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

If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait stations to further places and the possibility to change to another bait formulation.

If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents so consider the use of a (anticoagulant) rodenticide, or the use of traps as an alternative control measure.

For the label and / or the leaflet, the authorisation holder has to specify how the equipment (e.g. bait boxes) shall be cleaned and how residues of baits have to be collected. The recommended methods shall lead to minimized exposure.

Bait in sachets: Do not open the sachets containing the bait.

5.2. Risk mitigation measures

Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
Dispose of dead rodents in accordance with local regulations (the disposal method will be specifically described in the national SPC and reflected on the product label).
Dispose of dead rodents to an authorized handler in accordance with current regulations. Incineration is recommended as a treatment method.

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

In case of
- eyes exposure: rinse with plenty of water for at least 15 minutes. Do NOT forget to remove the contact lenses.
- skin exposure: wash with soap and plenty of water, without rubbing.
- oral exposure: rinse mouth and do not induce vomiting unless told to do so by poison control or a health care professional.

Dangerous for the environment

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER

Contact a veterinarian if ingested by a pet.

5.4. 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.
At the end of the treatment deliver the contents and/or its container, as well as the unconsumed bait and dead rodents, to an authorized manager, in accordance with current regulations.
Incineration is recommended as a treatment method.
Prevent skin contact when disposing remains of baits.
The following should be indicated on the label of the bait holders:
- Dispose of the bait holders, at the end of their useful life, through an authorized hazardous waste manager, in accordance with current regulations.
For contact formulations (gel or foam products):
- At the end of the treatment hand over the cleaning wipes to an authorized manager, in accordance with current regulations.

5.5. 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.
Keep away from food, drink and animal feeding stuffs.
Shelf-life: 36 months

6. Other information

Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
The product contains a bittering agent and a dye.
Active ingredient content: 0.077% (w/w) (technical); 0.075% (w/w) (pure).
Trained professional personnel are considered to be applicators of biocide products, who have received specific training in rodent control, in accordance with current legislation.
Professional personnel are considered to be those who carry out their professional activity in the animals' environment or in activities

closely related to their exploitation.