

Summary of product characteristics for a biocidal product

Product name: Selontra

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

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Authorisation number: 2806-1

R4BP 3 asset reference number: BG-0023577-0000

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Administrative information

1.1. Trade names of the product

Selontra
Relpexa

1.2. Authorisation holder

Name and address of the authorisation holder	Name	BASF EOOD
	Address	Crop protection division 118 Bulgaria Blvd, fl.1, Abacus Business Center 1618 Sofia Bulgaria
Authorisation number	2806-1	
R4BP 3 asset reference number	BG-0023577-0000	
Date of the authorisation	05/06/2020	
Expiry date of the authorisation	27/04/2025	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	BASF Agro B.V. Arnhem (NL) - Freienbach Branch
Address of the manufacturer	Huobstrasse 3 8808 Pfäffikon SZ Switzerland
Location of manufacturing sites	BASF plc, St. Michaels Industrial Estate WA8 8TJ Widnes, Cheshire United Kingdom

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

Active substance	1443 - Cholecalciferol
Name of the manufacturer	BASF Agro B.V. Arnhem (NL) - Freienbach Branch
Address of the manufacturer	Huobstrasse 3 8808 Pfäffikon SZ Switzerland
Location of manufacturing sites	Fermenta Biotech Limited, Village Takoli, P.O. Nagwain Distt. Mandi - 175 121 Himachal Pradesh 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	0,075

2.2. Type of formulation

RB - Bait (ready for use)

3. Hazard and precautionary statements

Hazard statements	
Precautionary statements	

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 1 - House mice - professionals - indoor

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: House mouse Development stage: Adults and juveniles
Field(s) of use	Indoor
Application method(s)	Bait application - Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequencies	Mice: 20 - 40 g (1 or 2 units) of bait every 1-2 metres. - - The number of bait points used depends on the pest pressure at the site where the product is to be used: Mice: 20 - 40 g (1 or 2 units) of bait every 1-2 metres.
Category(ies) of users	Professional
Pack sizes and packaging material	Up to 10 kg in PP or HDPE or PET or PE or LDPE buckets with lids and re-closable pots. Up to 10 kg in PP or HDPE or PET or PE or LDPE lined re-closable container such as a pot, tin or cardboard carton, also lacquered tins. Pre-filled PP or PE or LDPE bait boxes overpacked in up to 10 kg in PP, PET or PE re-closable container or re-closable cardboard carton.

4.1.1 Use-specific instructions for use

Bait may only have to be placed for 7 days to achieve control provided that sufficient bait for the size of the infestation is placed on day 1 of the treatment. Inspect baits 1-2 days after the first placement and replace eaten bait. If a bait point is completely consumed, replace with the maximum amount of bait at that bait point. This will ensure optimum control in the shortest time is achieved. Inspect baits regularly (at least weekly) in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Continue placing bait every 7 days until consumption ceases. Note that if an insufficient amount of bait is used at any time of the treatment, this may lead to sub-optimal results.

Remove the remaining product at the end of the treatment period.

Follow any additional instructions provided by the relevant code of best practice.

4.1.2 Use-specific risk mitigation measures

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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

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

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4.2 Use description

Use 2 - Use # 2 – Rats – professionals – indoor

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: Rattus rattus Common name: Black or roof rat Development stage: Adults and juveniles Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Adults and juveniles
Field(s) of use	Indoor
Application method(s)	Bait application - Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequencies	Rats: 100 - 140 g (5 - 7 units) of bait up to 10 metres apart. - - The number of bait points used depends on the pest pressure at the site where the product is to be used:

	Rats: 100 - 140 g (5 - 7 units) of bait up to 10 meters apart.
Category(ies) of users	Professional
Pack sizes and packaging material	Up to 10 kg in PP or HDPE or PET or PE or LDPE buckets with lids and re-closable pots. Up to 10 kg in PP or HPDE or PET or PE or LDPE lined re-closable container such as a pot, tin or cardboard carton, also lacquered tins. Pre-filled PP or PE or LDPE bait boxes overpacked in up to 10 kg in PP, PET or PE re-closable container or re-cloasable cardboard carton.

4.2.1 Use-specific instructions for use

Bait may only have to be placed for 7 days to achieve control provided that sufficient bait for the size of the infestation is placed on day 1 of the treatment. Inspect baits 1-2 days after the first placement and replace eaten bait. If a bait point is completely consumed, replace with the maximum amount of bait at that bait point. This will ensure optimum control in the shortest time is achieved. Inspect baits regularly (at least weekly) in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Continue placing bait every 7 days until consumption ceases. Note that if an insufficient amount of bait is used at any time of the treatment, this may lead to sub-optimal results.

Remove the remaining product at the end of the treatment period.

Follow any additional instructions provided by the relevant code of best practice.

4.2.2 Use-specific risk mitigation measures

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 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

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

4.3 Use description

Use 3 - Use #3 - House mice and rats - professionals - outdoor around buildings

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: House mouse Development stage: Adults and juveniles Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: Adults and juveniles Scientific name: <i>Rattus norvegicus</i> Common name: Brown rat Development stage: Adults and juveniles
Field(s) of use	Outdoor Outdoor around buildings.
Application method(s)	Bait application - Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequencies	Mice: 20 - 40 g (1 or 2 units) of bait every 1 - 2 metres. Rats: 100 - 140 g (5 - 7 units) of bait up to 10 metres apart. - - The number of bait points used depends on the pest pressure at the site where the product is to be used: Mice: 20 - 40 g (1 or 2 units) of bait every 1 - 2 meters. Rats: 100 - 140 g (5 - 7 units) of bait up to 10 meters apart.
Category(ies) of users	Professional
Pack sizes and packaging material	Up to 10 kg in PP or HDPE or PET or PE or LDPE buckets with lids and re-closable pots. Up to 10 kg in PP or HDPE or PET or PE or LDPE lined re-closable container such as a pot, tin or cardboard carton, also lacquered tins. Pre-filled PP or PE or LDPE bait boxes overpacked in up to 10 kg in PP, PET or PE re-closable container or re-closable cardboard carton.

4.3.1 Use-specific instructions for use

Bait may only have to be placed for 7 days to achieve control provided that sufficient bait for the size of the infestation is placed on day 1 of the treatment. Inspect baits 1-2 days after the first placement and replace eaten bait. If a bait point is completely consumed,

replace with the maximum amount of bait at that bait point. This will ensure optimum control in the shortest time is achieved. Inspect baits regularly (at least weekly) in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Continue placing bait every 7 days until consumption ceases. Note that if an insufficient amount of bait is used at any time of the treatment, this may lead to sub-optimal results.

Remove the remaining product 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 and bait in a bait station in which bait has been damaged by water or contaminated by dirt.

Follow any additional instructions provided by the relevant code of best practice.

4.3.2 Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

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 stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or 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

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

4.4 Use description

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

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: House mouse Development stage: Adults and juveniles Scientific name: <i>Rattus rattus</i> Common name: Black or roof rat Development stage: Adults and juveniles

	<p>Scientific name: <i>Rattus norvegicus</i> Common name: Brown rat Development stage: Adults and juveniles</p>
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.
Application rate(s) and frequencies	<p>Mice: 20 - 40 g (1 or 2 units) of bait every 1 - 2 metres. Rats: 100 - 140 g (5 - 7 units) of bait up to 10 metres apart. - - The number of bait points used depends on the pest pressure at the site where the product is to be used: Mice: 20 - 40 g (1 or 2 units) of bait every 1 - 2 meters. Rats: 100 - 140 g (5 - 7 units) of bait up to 10 meters apart.</p> <p>Permanent baiting: Mice: 20 - 40 g (1 or 2 units) per baiting point. Rats: 100 - 140 g (5 - 7 units) per baiting point.</p>
Category(ies) of users	Trained professional
Pack sizes and packaging material	<p>Up to 10 kg in PP or HDPE or PET or PE or LDPE buckets with lids and re-closable pots. Up to 10 kg in PP or HDPE or PE or PET or LDPE lined reclosable container such as a pot, tin or cardboard carton, also lacquered tins. Pre-filled PP or PE or LDPE bait boxes overpacked in up to 10 kg in PP, PET or PE re-closable container or re-closable cardboard carton.</p>

4.4.1 Use-specific instructions for use

Bait may only have to be placed for 7 days to achieve control provided that sufficient bait for the size of the infestation is placed on day 1 of the treatment. Inspect baits 1-2 days after the first placement and replace eaten bait. If a bait point is completely consumed, replace with the maximum amount of bait at that bait point. This will ensure optimum control in the shortest time is achieved. Inspect baits regularly (at least weekly) in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Continue placing bait every 7 days until consumption ceases. Note that if an insufficient amount of bait is used at any time of the treatment, this may lead to sub-optimal results.

Remove the remaining product at the end of the treatment period.

Permanent baiting: where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.

Follow any additional instructions provided by the relevant code of best practice.

4.4.2 Use-specific risk mitigation measures

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].

Consider preventative control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven 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.

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 points close to 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

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

4.5 Use description

Use 5 - Use #5 - House mice and rats - trained professionals - outdoor around buildings

Product type

PT14 - Rodenticides (Pest control)

Where relevant, an exact description of the authorised use

Not relevant for rodenticides.

Target organism(s) (including development stage)

Scientific name: *Mus musculus*
Common name: House mouse
Development stage: Adults and juveniles

Scientific name: *Rattus rattus*
Common name: Black or roof rat
Development stage: Adults and juveniles

Scientific name: *Rattus norvegicus*

	Common name: Brown rat Development stage: Adults and juveniles
Field(s) of use	Outdoor 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.
Application rate(s) and frequencies	Mice: 20 - 40 g (1 or 2 units) of bait every 1 - 2 metres. Rats: 100 - 140 g (5 - 7 units) of bait up to 10 metres apart. - - The number of bait points used depends on the pest pressure at the site where the product is to be used: Mice: 20 - 40 g (1 or 2 units) of bait every 1 - 2 meters. Rats: 100 - 140 g (5 - 7 units) of bait up to 10 meters apart. Permanent baiting: Mice: 20 - 40 g (1 or 2 units) per baiting point. Rats: 100 - 140 g (5 - 7 units) per baiting point.
Category(ies) of users	Trained professional
Pack sizes and packaging material	Up to 10 kg in PP or HDPE or PET or PE or LDPE buckets with lids and re-closable pots. Up to 10 kg in PP or HDPE or PET or PE or LDPE lined re-closable container such as a pot, tin or cardboard carton, also lacquered tins. Pre-filled PP or PE or LDPE bait boxes overpacked in up to 10 kg in PP or PET or PE re-closable container or re-closable cardboard carton.

4.5.1 Use-specific instructions for use

Bait may only have to be placed for 7 days to achieve control provided that sufficient bait for the size of the infestation is placed on day 1 of the treatment. Inspect baits 1-2 days after the first placement and replace eaten bait. If a bait point is completely consumed, replace with the maximum amount of bait at that bait point. This will ensure optimum control in the shortest time is achieved. Inspect baits regularly (at least weekly) in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Continue placing bait every 7 days until consumption ceases. Note that if an insufficient amount of bait is used at any time of the treatment, this may lead to sub-optimal results.

Protect the 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.

For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

Remove the remaining product at the end of the treatment period.

Permanent baiting: where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.

Follow any additional instructions provided by the relevant code of best practice.

4.5.2 Use-specific risk mitigation measures

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].

Consider preventative control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

Do not apply this product directly in the burrows.

Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven 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.

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

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

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

5. General directions for use

5.1. Instructions for use

Professionals and trained professionals

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- Use the higher bait point density and the maximum number of bait units wherever rats or mice have been seen. Be aware of under-baiting – follow the label recommendations for the quantity of bait per bait-point and the frequency of bait-points.
- Use the lower density of bait points in light infestations.
- 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.
- Try to establish a barrier of bait points between living and feeding areas.
- 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.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 for the information to be shown on the label).
- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- 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 points to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, consider the use of a rodenticide with a different mode of action. Also consider the use of traps as an alternative control measure.

Professionals only

- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- 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.).
- Remove the remaining bait or the bait stations at the end of the treatment period.

Trained professionals only

- Use the lower density of bait points in light infestations or in permanent baiting by trained professionals.
- 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.).

5.2. Risk mitigation measures

Professionals and trained professionals

- 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].

Professionals only

- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). [Where relevant, specify if more frequent or daily inspection is required].
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- The product information (i.e. label and/or leaflet) shall clearly show that:
 - o the product shall not be supplied to the general public (e.g. "for professionals only").
 - o the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
 - o 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.

Trained professionals only

- 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").
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment [unless authorised for permanent baiting treatments].
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.

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

- Cholecalciferol causes hypercalcaemia. Treat symptomatically. Treatment would include a low calcium diet, a high salt and fluid intake and avoidance of exposure to sunlight. Monitoring serum calcium levels may aid treatment. Cortisone has been used successfully in some cases.
 - First Aid
 - o Inhalation: Keep patient calm, remove to fresh air.
 - o Skin contact: Wash thoroughly with soap and water.
 - o Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If present, remove any contact lenses after the first 5 minutes and continue rinsing eye. Seek medical attention if irritation develops and persists.
 - o Ingestion: Rinse mouth and then drink plenty of water. If swallowed, seek medical advice immediately and show the product's container or label. Contact a veterinary surgeon in case of ingestion by a pet.
 - Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.
- Keep the container or label available.
- Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre [insert national phone number]"
 - Hazardous to wildlife.

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 [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

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 away from food stuffs and animal feeding stuffs and products which may have an odour.
- Store in places prevented from the access of children, birds, pets and farm animals.
- Shelf life: 3 years.

6. Other information

- Rodent death will occur 2-5 days after ingestion of a lethal amount of 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.