ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Racumin Expert

Product type(s)

PT14: Rodenticides

Authorisation number: 1070-13

R4BP asset number: DK-0027208-0000

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1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Racumin Expert
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1.2. Authorisation holder

	Name	2022 ENVIRONMENTAL SCIENCE FR SAS
Name and address of the authorisation holder	Address	1, place Giovanni Da Verrazzano 69009 LYON France
Authorisation number		1070-13
R4BP asset number		DK-0027208-0000
Date of the authorisation		26/02/2019
Expiry date of the authorisation		31/12/2025

1.3. Manufacturer(s) of the product

Name of manufacturer	Bayer S.A.S.
Address of manufacturer	16 rue Jean-Marie Leclair CS90106 69266 Lyon Cedex 09 France
Location of manufacturing sites	INDUSTRIALCHIMICA Srl, Via Sorgaglia 40 35020 Arre (PD) Italy
	Kollant S.r.l., via C. Colombo 7/7 A I-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	Coumatetralyl
Name of manufacturer	Bayer S.A.S.
Address of manufacturer	16 rue Jean-Marie Leclair CS90106 69266 Lyon Cedex 09 France
Location of manufacturing sites	AlzChem Trostberg GmbH, CHEMIEPARK TROSTBERG, Dr. Albert Frank Str. 32 83308 Trostberg Germany

2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Coumatetralyl	Coumatetralyl	active substance	5836-29-3	227-424-0	0,0027

2.2. Type(s) of formulation

Bait (ready for use): Paste

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use 1: Rat control - Indoor - professional user

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: Adults and juveniles
Field(s) of use	indoor use
	Indoor Racumin Expert is designed for use in buildings (residential homes, factories, etc.) and on animal husbandry farms (pigs, poultry, cattle, etc.).
Application method(s)	Method: bait application
	Detailed description: - Ready to use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application Rate: 60g to 200g per tamper resistant bait station
	Dilution (%): -
	Number and timing of application: 60g to 200g per tamper resistant bait station If more than one bait
	station is needed, the minimum distance between bait stations should be of 5 meters.
	- High infestation: 200 g of bait per tamper resistant bait station Low infestation: 100 g of bait per tamper resistant bait station.
Category(ies) of users	professional
Pack sizes and packaging material	- Ready to use bait to be Primary bait packaging: tea bag/sachet 20g cellulose Bucket Up to 5kg (250 sachets): Inner LDPE plastic sachet in a plastic PP Bucket Box Up to 2,5kg (125 sachets) + Inner PE/PET plastic sachet in a cardboard box Bag 5 kg (250 sachets) + PE Plastic bag, with handle and reclosable zip

4.1.1. Use-specific instructions for use

- 1) The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- 2) 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 preferred places of rodent activity (travel paths, nesting sites, feedlots) in and around buildings have to be determined by e.g. displaying small amount of poison free baits such as oat flakes. Signs of gnawing and rodent faeces are also indications for rodent activity. Note that the poison free baits should be removed before the actual rodent control measure.
- 3) 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.

- 4) Prior to the use of biocidal products non-biocidal methods to control rodents should be considered. Especially for the control of mice, voles and occasionally appearing rats, traps should be considered. The use of biocidal products is the last method of choice and should always be reduced to a minimum.
- 5) If possible, bait should be secured so that it cannot be dragged away from the bait station.
- 6) Bait stations should be placed where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, etc.).
- 7) Prior to the rodent control measure all users of the premises and buildings and their surroundings, where baits are placed, have to be informed about the risks for humans, pets and wild animals. They also have to be informed about measures in the case of poisoning, bait spillage or the discovery of dead rodents (according to the product label).
- 8) The campaign has to be terminated if there is no further consumption of baits.
- 9) Remove the remaining bait or the bait stations at the end of the treatment period.
- 10) Undamaged bait stations can be reused.
- 11) To avoid a re-infestation after a successful control operation, the following measures should be taken:
 - a) Food and water sources (food, rubbish, etc.) should be removed or covered
- b) Elimination of debris and waste that might be used as hideouts. The vegetation cover in the immediate vicinity of buildings should be removed where necessary.
- c) Make all eventually existing entries in buildings (e.g. cleaving, loopholes, cat flaps, drainages) inaccessible to rodents as far as possible.
- 12) See chapter 5.1

4.1.2. Use-specific risk mitigation measures

- 1) Avoid any unnecessary contact with the product. Misuse may cause adverse effects on health.
- 2) Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- 3) The product information (i.e. label and/or leaflet) shall clearly show that:
- a) the product shall not be supplied to the general public (e.g. "for professionals only").
- b) the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
- c) 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").
- 4) 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.
- 5) Do not wash the bait stations with water between applications.
- 6) Search for and remove dead rodents during treatment, at least as often as baiting stations are inspected.
- 7) Dispose dead rodents in household waste or in a rendering plant. Avoid direct contact.
- 8) 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 points close to water drainage systems, ensure that bait contact with water is avoided. See chapter 5.3

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

Prevent skin contact when disposing remains of baits. See chapter 5.4

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

Keep away from food, drink and animal feeding stuffs. See chapter 5.5

4.2. Use description

Table 2. Use 2: Rat Control - Outdoor: around buildings- professional user

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development	_
stage)	Common name: brown rat
	Development stage: Adults and juveniles
Field(s) of use	outdoor use
	Outdoor around buildings within a maximum distance of 10 meter from the Buildings. The control of rats is however allowed also where an occurrence of rats farther than 10 meters acts as a source of rats in buildings (source control). Racumin Expert is designed for use around buildings (residential homes, factories etc.) and on animal husbandry farms (pigs, poultry, cattle, etc.).
Application method(s)	Method: bait application
	Detailed description: - Ready to use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application Rate: 60g to 200g per tamper resistant bait station
	Dilution (%): -
	Number and timing of application: 60g to 200g per tamper resistant bait station If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters. - High infestation: 200 g of bait per tamper resistant bait station. - Low infestation: 100 g of bait per tamper resistant bait station.
Category(ies) of users	professional
Pack sizes and packaging material	- Ready to use bait to be Primary bait packaging: tea bag/sachet 20g cellulose Bucket Up to 5kg (250 sachets): Inner LDPE plastic sachet in a plastic PP Bucket Box Up to 2,5kg (125 sachets) + Inner PE/PET plastic sachet in a cardboard box Bag 5 kg (250 sachets) + PE Plastic bag, with handle and reclosable zip

4.2.1. Use-specific instructions for use

- 1) Protect bait from the weathering (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- 2) The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- 3) Replace any in a bait station in which bait has been damaged by water or contaminated by dirt.
- 4) 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 preferred places of rodent activity (travel paths, nesting sites, feedlots) in and around buildings have to be determined by e.g. displaying small amount of poison free baits such as oat flakes. Signs of gnawing and rodent faeces are also indications for rodent activity. Note that the poison free baits should be removed before the actual rodent control measure.
- 5) 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.

- 6) Prior to the use of biocidal products non-biocidal methods to control rodents should be considered. Especially for the control of mice, voles and occasionally appearing rats, traps should be considered. The use of biocidal products is the last method of choice and should always be reduced to a minimum.
- 7) If possible, bait should be secured so that it cannot be dragged away from the bait station.
- 8) Bait stations should be placed where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, etc.).
- 9) Prior to the rodent control measure all users of the premises and buildings and their surroundings, where baits are placed, have to be informed about the risks for humans, pets and wild animals. They also have to be informed about measures in the case of poisoning, bait spillage or the discovery of dead rodents (according to the product label).
- 10) The campaign has to be terminated if there is no further consumption of baits.
- 11) Remove the remaining bait or the bait stations at the end of the treatment period.
- 12) Undamaged bait stations can be reused.
- 13) To avoid a re-infestation after a successful control operation, the following measures should be taken:
- a) Food and water sources (food, rubbish, etc.) should be removed or covered
- b) Elimination of debris and waste that might be used as hideouts. The vegetation cover in the immediate vicinity of buildings should be removed where necessary.
- c) Make all eventually existing entries in buildings (e.g. cleaving, loopholes, cat flaps, drainages) inaccessible to rodents as far as possible.
- 14) See chapter 5.1

4.2.2. Use-specific risk mitigation measures

- 1) Do not apply this product directly in the burrows.
- 2) Avoid any unnecessary contact with the product. Misuse may cause adverse effects on health.
- 3) Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- 4) The product information (i.e. label and/or leaflet) shall clearly show that:
- a) the product shall not be supplied to the general public (e.g. "for professionals only").
- b) the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
- c) 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").
- 5) 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.
- 6) Do not wash the bait stations with water between applications.
- 7) Search for and remove dead rodents during treatment, at least as often as baiting stations are inspected.
- 8) Dispose dead rodents in household waste or in a rendering plant. Avoid direct contact.
- 9) See chapter 5.2

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. See chapter 5.3

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

Prevent skin contact when disposing remains of baits. See chapter 5.4

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

Keep away from food, drink and animal feeding stuffs. See chapter 5.5

4.3. Use description

Table 3. Use 4: Rat control - Indoor- trained professional user

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development	Scientific name: Rattus norvegicus
stage)	Common name: brown rat Development stage: Adults and juveniles
Field(s) of use	indoor use
	Indoor Racumin Expert is designed for use in buildings (residential homes, factories, etc.) and on animal husbandry farms (pigs, poultry, cattle, etc.).
Application method(s)	Method: bait application
	Detailed description: - Ready to use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application Rate: - High infestation: 200 g of bait per baiting point Low infestation: 100 g of bait per baiting point.
	Dilution (%): -
	Number and timing of application:
	60g to 200g per bait station. If more than one bait station is
	needed, the minimum distance between bait stations should be of 5 meters.
	- High infestation: 200 g of bait per baiting point.
	- Low infestation: 100 g of bait per baiting point.
Category(ies) of users	trained professional
Pack sizes and packaging material	- Ready to use bait to be Primary bait packaging: tea bag/sachet 20g cellulose Bucket Up to 5kg (250 sachets): Inner LDPE plastic sachet in a plastic PP Bucket Box Up to 2,5kg (125 sachets) + Inner PE/PET plastic sachet in a cardboard box Bag 5 kg (250 sachets) + PE Plastic bag, with handle and reclosable zip

4.3.1. Use-specific instructions for use

- 1) Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning.
- 2) 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.
- 3) 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.
- 4) The aim of a baiting campaign is to eradicate the target rodents in the infested area/building.
- 5) 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.
- 6) 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.).
- 7) Bait stations have to be mechanically stable and tamper-resistant.

- 8) Bait stations have to be designed in a way which prevents the access from non-target organisms as far as possible.
- 9) 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:
- a) First measures to be taken in case of poisoning,
- b) Measures to be taken in case of spillage of the bait and the discovery of dead rodents,
- c) Name of the product and the active substance(s) incl. concentration
- d) Contact information of the person in charge of the rodent control,
- e) Telephone number of a poison information centre and the name of the antidote,
- f) Date of the beginning of the campaign, i.e. when the baits were deployed first.
- 10) Bait should be secured so that it cannot be dragged away from the bait station.
- 11) Replace consumed baits at each visit; the uptake of baits has to be documented.
- 12) See chapter 5.1

4.3.2. Use-specific risk mitigation measures

- 1) Search for and dispose dead rodents in the infested area at each visit to prevent secondary poisoning.
- 2) At the beginning of the campaign, visit the bait points at the latest after 5 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.
- 4) Take the following measures to avoid re-infestation after a successful control:
- a) 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.
- b) Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.
- c) As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.
- 5) Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- 6) Do not use the product in pulsed baiting treatments.
- 7) 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").
- 8) Do not use in areas where resistance to the active substance can be suspected.
- 9) 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.
- 10) Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- 11) Undamaged bait stations and untouched baits may be reused.
- 12) The success of the control measure has to be documented and proven.
- 13) The client has to be informed of possible preventive measures against re-infestation.
- 14) All relevant documents of the control measures have to be provided to the client as well as responsible authorities upon request.
- 15) See chapter 5.2

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. See chapter 5.3

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

See chapter 5.4

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

See chapter 5.5

4.4. Use description

Table 4. Use 5: Rat Control - Outdoor: around buildings - trained professional user

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: Adults and juveniles
Field(s) of use	outdoor use
	Outdoor around buildings within a maximum distance of 10 meter from the Buildings. The control of rats is however allowed also where an occurrence of rats farther than 10 meters acts as a source of rats in buildings (source control). Racumin Expert is designed to use around buildings (residential homes, factories, etc.) and on animal husbandry farms (pigs, poultry, cattle, etc.).
Application method(s)	Method: bait application
	Detailed description: - Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application Rate: - High infestation: 200 g of bait per baiting point Low infestation: 100 g of bait per baiting point.
	Dilution (%): -
	Number and timing of application: 60g to 200g per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters. - High infestation: 200 g of bait per baiting point. - Low infestation: 100 g of bait per baiting point.
Category(ies) of users	trained professional
Pack sizes and packaging material	- Ready to use bait to be Primary bait packaging: tea bag/sachet 20g cellulose Bucket Up to 5kg (250 sachets): Inner LDPE plastic sachet in a plastic PP Bucket Box Up to 2,5kg (125 sachets) + Inner PE/PET plastic sachet in a cardboard box Bag 5 kg (250 sachets) + PE Plastic bag, with handle and reclosable zip

4.4.1. Use-specific instructions for use

- 1) Protect bait from the weathering (e.g. rain, snow, etc.). Place the baiting points in areas not liable to flooding.
- 2) Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- 3) Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning.

- 4) 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.
- 5) 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.
- 6) The aim of a baiting campaign is to eradicate the target rodents in the infested area/building.
- 7) 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.
- 8) 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.).
- 9) Bait stations have to be mechanically stable and tamper-resistant.
- 10) Bait stations have to be designed in a way which prevents the access from non-target organisms as far as possible.
- 11) 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:
- a) First measures to be taken in case of poisoning,
- b) Measures to be taken in case of spillage of the bait and the discovery of dead rodents,
- c) Name of the product and the active substance(s) incl. concentration
- d) Contact information of the person in charge of the rodent control,
- e) Telephone number of a poison information centre and the name of the antidote,
- f) Date of the beginning of the campaign, i.e. when the baits were deployed first.
- 12) Bait should be secured so that it cannot be dragged away from the bait station.
- 13) Replace consumed baits at each visit; the uptake of baits has to be documented.

4.4.2. Use-specific risk mitigation measures

- 1) Search for and dispose dead rodents in the infested area at each visit to prevent secondary poisoning.
- 2) At the beginning of the campaign, visit the bait points at the latest after 5 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.
- 4) Take the following measures to avoid re-infestation after a successful control:
- a) 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.
- b) Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.
- c) As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.
- 5) Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- 6) Do not use this product in pulsed baiting treatments.
- 7) 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").
- 8) Do not use in areas where resistance to the active substance can be suspected.
- 9) 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.
- 10) Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- 11) Undamaged bait stations and untouched baits may be reused.
- 12) The success of the control measure has to be documented and proven.

- 13) The client has to be informed of possible preventive measures against re-infestation.
- 14) All relevant documents of the control measures have to be provided to the client as well as responsible authorities upon request.
- 15) See chapter 5.2

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 surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided. See chapter 5.3

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

See chapter 5.4

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

See chapter 5.5

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

- 1) Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- 2) 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.
- 3) Where possible, bait stations must be fixed to the ground or other structures.
- 4) Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened.
- 5) Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- 6) Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- 7) When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- 8) 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.
- 9) If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- 10) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- 11) 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.
- 12) 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.

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

- 1) 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.
- 2) Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- 3) In case of:
- a) Dermal exposure, wash skin with water and then with water and soap.
- b) Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
- c) 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]
- 4) Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name"; "active substance(s)" and "in case of incident, call a poison centre [insert national phone number]".
- 5) Hazardous to wildlife.

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

- 1) At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements.
- 2) Prevent skin contact when disposing remains of baits.

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¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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

- 1) Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
- 2) Store in places prevented from the access of children, birds, pets and farm animals.
- 3) Keep away from food, drink and animal feeding stuffs.
- 4) Shelf-life: 24 months

6. OTHER INFORMATION

- 1) 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.
- 2) Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
- 3) The product contains a bittering agent and a dye.

Bilag 1 Oplysninger til etiket og brugsanvisning for Racumin Expert, BPR-reg. nr. 1070-13

I. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen.

II. Det er udelukkende ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69. Etiket og mærkning skal være på dansk.

Nedenstående tekst i afsnit III er bidrag til overholdelsen af reglerne og således kun en del af de krav, som stilles til blandt andet etiketten.

III. Etiketten skal indeholde nedenstående oplysninger. Oplysninger i citationstegn skal angives ordret:

1) I hovedfeltet:

"Gnavermiddel

Må kun anvendes til bekæmpelse af brun rotte (*Rattus norvegicus*) i og omkring bygninger og kun i en afstand op til 10 meter. Bekæmpelse er dog også tilladt, hvor en forekomst af rotter længere væk end 10 meter fra bygninger fungerer som kilde til rotter i bygninger.

Må kun anvendes af personer, der er autoriserede af Miljøstyrelsen til at bekæmpe rotter med enten en R1- eller R2-autorisation."

2) I advarselsfeltet:

"FORSIGTIG

Vask huden grundigt efter brug.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes til bekæmpelse af brun rotte (Rattus norvegicus) i og omkring bygninger og kun i en afstand op til 10 meter. Bekæmpelse er dog også tilladt, hvor en forekomst af rotter længere væk end 10 meter fra bygninger fungerer som kilde til rotter i bygninger.

Må kun anvendes af personer, der er autoriserede af Miljøstyrelsen til at bekæmpe rotter med enten en R1- eller R2-autorisation.

Ved kildebekæmpelse skal betingelserne i Miljøstyrelsens vejledning om vurdering og godkendelse af kemiske bekæmpelsesmidler til rotter og mus være opfyldt.

Doseringen af det biocidholdige produkt skal afpasses bekæmpelsen af rotter på den pågældende lokalitet, dog må der højest anvendes 200 g pr. udlægningssted af hensyn til faren for forgiftning af mennesker, pattedyr og fugle.

Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte. Det biocidholdige produkt skal anbringes i aflåste foderstationer, så mennesker og dyr uden for målgruppen ikke kan komme i kontakt med giften.

Døde rotter skal eftersøges to gange ugentligt eller efter behov og bortskaffes som dagrenovation af hensyn til faren for sekundær forgiftning af rovfugle og rovdyr.

Produktet må ikke bruges mere end 35 dage uden en evaluering af angrebets status og effekten af behandlingen.

Giftrester og emballage skal afleveres til den kommunale affaldsordning for farligt affald efter endt bekæmpelse.

Foderstationer skal påføres en tekst, hvoraf det fremgår, at der foregår bekæmpelse af rotter i området, og hvorledes man forholder sig i tilfælde af forgiftning. Foderstationer skal være forsynet med kontaktinformation på dem, som udfører bekæmpelsen.

Må ikke benyttes til permanent bekæmpelse af rotter, såsom forebyggende brug i sikringsordninger.

Ved anbringelse af foderstationer tæt på overfladevand eller afløbssystemer skal det sikres, at det biocidholdige produkt ikke kommer i kontakt med vand.

Må ikke tømmes i kloakafløb.

Opbevares under lås og utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Emballagen må ikke genanvendes."

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder:

"Dette produkt indeholder et antikoagulerende stof.

Ved indtagelse kan der forekomme forsinkede symptomer, såsom næseblod og blødende tandkød.

I svære tilfælde kan der forekomme blå mærker og blod i afføring eller urin.

Modgift: K1-vitamin; må kun administreres af medicinsk/veterinært personale.

Hvis produktet:

- kommer på huden, vaskes huden med vand og sæbe.
- kommer i øjnene, skylles øjnene med øjenrensevæske eller vand; hold øjnene åbne i mindst 10 minutter.
- kommer i munden, skylles munden grundigt med vand.

Giv aldrig en bevidstløs person noget gennem munden.

Fremkald ikke opkastning.

Hvis produktet synkes, søges der straks lægehjælp. Vis produktets beholder eller etiketten til lægen.

Kontakt en dyrlæge, hvis produktet indtages af et kæledyr."

- 3) I deklarationsfeltet:
- a) Teksten "Gnavermiddel BPR-reg. nr. 18-660. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".
- b) Oplysning om præparattype: "pasta" for dette præparat.
- c) Indholdet af aktivstof i vægtprocent (% w/w) og g/kg.
- d) Udløbsdatoen skal anføres. Denne dato må højst være to år efter produktionsdatoen. Etikettens dato kan udformes som en henvisning til en produktionsdato andetsteds på emballagen.
- e) Batchnummer eller betegnelse skal anføres.
- f) Pakningsstørrelse i kg.
- g) Godkendelsesindehavers navn og adresse.
- 4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområdeog doseringer.

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning P501: "Rester og emballage bortskaffes som farligt affald." Følgende sætning skal anføres under sikkerhedssætning P501: "Ovenstående sætning er Miljøstyrelsens vejledning om affaldshåndtering af dette produkt. Følg altid kommunens affaldsregulativ og forhør dig hos kommunen, hvis du er i tvivl."