Summary of product characteristics for a biocidal product

Product name: Ratron Granulat 25 ppm

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

Authorisation number: DE-0019298-14

R4BP 3 asset reference number: DE-0019298-0000

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Administrative information

1.1. Trade names of the product

Ratron Granulat 25 ppm

BROMOL Fertigköder-Pellets 25

recozit Mäuse und Ratten Fraßköder

Ratron Mäuseköder

Ratron Granulat portionierte Power-Packs 25 ppm

1.2. Authorisation holder

Name and address of the authorisation holder

Name	frunol delicia GmbH
Address	Hansastrasse 74 B 59425 Unna Germany

Authorisation number

DE-0019298-14

R4BP 3 asset reference number

DE-0019298-0000

Date of the authorisation

10/08/2020

Expiry date of the authorisation

10/08/2025

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

frunol delicia GmbH

Address of the manufacturer

Hansastr. 74b 59425 Unna Germany

Location of manufacturing sites

Dübener Str. 145 04509 Delitzsch Germany

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

Active substance	11 - Brodifacoum
Name of the manufacturer	PelGar International Ltd.
Address of the manufacturer	Unit 13, Newman Lane, GU34 2QR Alton, Hampshire United Kingdom
Location of manufacturing sites	Praszka 54 28002 Kolin Czech Republic

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 (%)
Brodifacoum	3-[3-(4'-bromobiphenyl- 4-yl)-1,2,3,4-tetrahydro - 1-napthyl]-4- hydroxycoumarin	Active Substance	56073-10-0	259-980-5	0,0025

2.2. Type of formulation Ready-to-use granular bait

3. Hazard and precautionary statements

Hazard statements	
Precautionary statements	

4. Authorised use(s)

4.1 Use description

Use 1 - House mice and rats - trained prof - 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: Mus musculus Common name: House mouse Development stage: Juveniles

Scientific name: Mus musculus Common name: House mouse Development stage: Adults

Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Juveniles

Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Adults

Scientific name: Rattus rattus Common name: Black rat Development stage: Juveniles

Scientific name: Rattus rattus Common name: Black rat Development stage: Adults

Field(s) of use

Indoor

Application method(s)

Method: Bait application Detailed description: In hait boxes:

covered and protected baiting

Application rate(s) and frequencies

Application Rate: Mouse: 40 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2-4 meters. Rat: 40 - 200g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.

Dilution (%):

Number and timing of application:

Category(ies) of users

Trained professional

Pack sizes and packaging material

40 g sachets in 200-800 g folding box;

40 g sachets in 4 kg bucket;

200 g - 1 kg folding box;

0.5-10 kg bucket;

25 kg bag (Package with loose granular bait is restricted to separately packed bags with

a maximum of 10 kg per packed bag)

Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, bag (lined paper bag)

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.

4.1.2 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. 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
- 4) 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.
- 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.

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.

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 - House mice and rats - trained prof - 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: Juveniles

Scientific name: Mus musculus Common name: House mouse Development stage: Adults

Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Juveniles

Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Adults

Scientific name: Rattus rattus Common name: Black rat Development stage: Juveniles

Scientific name: Rattus rattus Common name: Black rat Development stage: Adults

Field(s) of use

Outdoor

Outdoor around buildings

Application method(s)

Method: Bait application Detailed description: In bait boxes;

covered and protected baiting

Application rate(s) and frequencies

Application Rate: Mouse: 40 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2-4 meters. Rat: 40 - 200g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.

Dilution (%):

Number and timing of application:

Category(ies) of users

Trained professional

Pack sizes and packaging material

40 g sachets in 200-800 g folding box;

40 g sachets in 4 kg bucket;

200 g - 1 kg folding box;

0.5-10 kg bucket;

25 kg bag (Package with loose granular bait is restricted to separately packed bags with a maximum of 10 kg per packed bag)

Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, bag (lined paper bag)

4.2.1 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.

4.2.2 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. Only in areas which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed.
- 4) 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.
- 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) Do not apply this product directly in the burrows.

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 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.

4.2.4 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	c to the use, the conditions of storage and shelf-life of the product itions of storage

4.3 Use description

Use 3 - Rats - trained prof -outdoor open areas and waste dumps

Product type

PT14 - Rodenticides (Pest control)

Where relevant, an exact description of the authorised use

Not relevant for rodenticides

Target organism(s) (including development stage)

Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Juveniles

Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Adults

Scientific name: Rattus rattus Common name: Black rat Development stage: Juveniles

Scientific name: Rattus rattus Common name: Black rat Development stage: Adults

Field(s) of use

Outdoor

Outdoor open areas and waste dumps

Application method(s)

Method: Bait application Detailed description:

In bait boxes;

covered and protected baiting

Application rate(s) and frequencies

Application Rate: 40 - 200g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters. Dilution (%):

Number and timing of application:

*

Category(ies) of users

Trained professional

Pack sizes and packaging material

40 g sachets in 200-800 g folding box;

40 g sachets in 4 kg bucket;

200 g - 1 kg folding box;

0.5-10 kg bucket;

 $25~{\rm kg}$ bag (Package with loose granular bait is restricted to separately packed bags with a maximum of 10 kg per packed bag)

Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: $GD2\ 350g/m^2$, buckets: PP, bag (lined paper bag)

4.3.1 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) 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.

4.3.2 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. Only in areas which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed.
- Outdoor 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.
- 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) 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 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.

4.3.4 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 - Rats - trained prof -sewers

Product type

PT14 - Rodenticides (Pest control)

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

Not relevant for rodenticides

Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Juveniles

Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Adults

Field(s) of use

Other

Sewers

Application method(s)

Method: Bait application Detailed description: In bait boxes;

covered and protected baiting

Application rate(s) and frequencies

Application Rate: 40 - 200g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters. Dilution (%):

Number and timing of application:

*

Category(ies) of users

Trained professional

Pack sizes and packaging material

40 g sachets in 200-800 g folding box;

40 g sachets in 4 kg bucket;

200 g - 1 kg folding box;

0.5-10 kg bucket;

25 kg bag (Package with loose granular bait is restricted to separately packed bags with a maximum of 10 kg per packed bag)

Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: $GD2\ 350g/m^2$, buckets: PP, bag (lined paper bag)

4.4.1 Use-specific instructions for use

- 1) Baits must be applied in a way so that they do not come into contact with water and are not washed away.
- 2) Bait points in sewer systems have to be visited for the first time after 14 days and subsequently every 2 to 3 weeks.
- 3) Remove and dispose all baits in accordance with local requirements at the end of the treatment period.

4.4.2 Use-specific risk mitigation measures

Do not use this product in pulsed baiting	treatments.
	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
See "Directions for use"	
4.4.4 Where specific to the uspackaging	se, the instructions for safe disposal of the product and its
See "Directions for use"	
4.4.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage
See "Directions for use"	
4.5 Use description	
Use 5 - Voles - trained profession	onal / professional - indoor / outdoor
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: Myodwes glareolus Common name: Bank vole Development stage: Juveniles
	Scientific name: Myodwes glareolus Common name: Bank vole Development stage: Adults
Field(s) of use	Indoor Outdoor
Application method(s)	Method: Bait application Detailed description: In bait boxes; covered and protected baiting

Application rate(s) and frequencies

Application Rate: 40 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2-4 meters Dilution (%): *

Number and timing of application:

*

Category(ies) of users

Trained professional

Pack sizes and packaging material

40 g sachets in 200-800 g folding box;

40 g sachets in 4 kg bucket;

200 g - 1 kg folding box;

0.5-10 kg bucket;

25 kg bag (Package with loose granular bait is restricted to separately packed bags with a maximum of 10 kg per packed bag)

Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, bag (lined paper bag)

4.5.1 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) Protect bait from the weathering (e.g. rain, snow, etc.). Place the baiting points in areas not liable to flooding.
- 3) Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.

4.5.2 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. 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.
- 4) 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
- 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) Do not apply this product directly in the burrows.

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

See "Directions for use"		

packaging	
See "Directions for use"	
4.5.5 Where specific to the use, the conditions of storage and shelf-life of the prod under normal conditions of storage	uct
See "Directions for use"	

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

- 5. General directions for use
- 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) 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 only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- 7) 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.).
- 8) Where possible, bait stations must be fixed to the ground or other structures.
- 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) 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).
- 12) 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.
- 13) Bait should be secured so that it cannot be dragged away from the bait station.
- 14) Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- 15) Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- 16) The following risk mitigation measure shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).:
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- 17) When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- 18) Replace consumed baits at each visit; the uptake of baits has to be documented.
- 19) 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.
- 20) 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.
- 21) 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.
- 22) Do not open the sachets containing the bait.
- 23) Place loose bait in the bait station using a dosage device. Specify the methods to minimise dust (suitable methods shall be moist or wet processes in accordance with the state of the art e.g. wet wiping or suction processes using suitable vacuum cleaners or dust removers).

5.2. Risk mitigation measures

- 1) 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".
- 2) Do not use in areas where resistance to the active substance can be suspected.
- 3) Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- 4) 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.
- 5) Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- 6) Undamaged bait stations and untouched baits may be reused.
- The success of the control measure has to be documented and proven.
- 8) The client has to be informed of possible preventive measures against re-infestation.
- 9) All relevant documents of the control measures have to be provided to the client as well as responsible authorities upon request.

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

- 1) First aid: Get medical advice/attention if you feel unwell.
- 2) 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.
- 3) Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- 4) In case of:
- Dermal exposure, wash skin with water and then with water and soap.
- · Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label [insert country specific information]. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information]
- 5) 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]"
- 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

- 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) Shelf life: 24 months

6. Other information

- 1) The product contains a bittering agent and a dye.
- 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) 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.

Due to technical deficits of the SPC editor I have to list the following points currently at this point of the SPC: H373 May cause damage to organs (blood).

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P314 Get medical advice/ attention if you feel unwell.

P501 Dispose of contents/ container to ...