

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

RATMIX

Product type(s)

PT14: Rodenticides

Authorisation number: IT/2014/00222/AUT

R4BP asset number: IT-0006761-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	RATMIX
---------------	--------

1.2. Authorisation holder

Name and address of the authorisation holder	Name	CISA ADRIATICA Srl
	Address	VIALE DELLA LIBERTA' 4 65010 MOSCUFO (PE) Italy
Authorisation number	IT/2014/00222/AUT	
<i>R4BP asset number</i>	IT-0006761-0000	
Date of the authorisation	09/05/2019	
Expiry date of the authorisation	31/12/2026	

1.3. Manufacturer(s) of the product

Name of manufacturer	FERBI Srl
Address of manufacturer	Viale 1 Maggio 64023 Mosciano Sant Angelo Italy
Location of manufacturing sites	Viale 1 Maggio 64023 Mosciano Sant Angelo Italy

Name of manufacturer	LABIOFARMA Società Cooperativa
Address of manufacturer	Via Nettunense Km 23400 04011 Aprilia Italy
Location of manufacturing sites	Via Nettunense Km 23400 04011 Aprilia Italy

Name of manufacturer	INDIA INDUSTRIE CHIMICHE Spa
Address of manufacturer	Nona Strada 53/57 35100 Padova Italy
Location of manufacturing sites	Nona Strada 53/57 35100 Padova Italy

Name of manufacturer	INDUSTRIALCHIMICA srl
Address of manufacturer	Via Sorgaglia 25 35020 Arre Italy
Location of manufacturing sites	Via Sorgaglia 25 35020 Arre Italy

Name of manufacturer	VEBI ISTITUTO BIOCHIMICO Srl
Address of manufacturer	Via Desman 43 35010 S Eufemia di Borgoricco Italy
Location of manufacturing sites	Via Desman 43 35010 S Eufemia di Borgoricco Italy

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

Active substance	Brodifacoum
Name of manufacturer	DR TEZZA srl
Address of manufacturer	Via tre ponti 22 87050 Santa Maria de Zevio Italy
Location of manufacturing sites	Via tre ponti 22 87050 Santa Maria de Zevio Italy

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 (%)
Brodifacoum		active substance	56073-10-0	259-980-5	0,005

2.2. Type(s) of formulation

PA Paste

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	
Precautionary statements	P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P262: Do not get in eyes, on skin, or on clothing. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P301: IF SWALLOWED: P310: Immediately call a a POISON CENTER.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use in and around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Use in and around buildings
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: adults Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: adults
Field(s) of use	indoor use outdoor use
Application method(s)	Method: in bait boxes Detailed description: Baits shall be placed in bait boxes
Application rate(s) and frequency	Application rate: Rats: 60-100g of pasta bait per 100m ² of infested area; Mice: 40 g of pasta bait per 100m ² of infested area Dilution (%): 100 Number and timing of application: Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed
Category(ies) of users	industrial ; trained professional ; professional ; general public (non-professional)
Pack sizes and packaging material	Paper, cardboard, Sachet, 20g For non-professional use packs with 40-100-160-200-260-300-400-500g For professional use packs with 740g 1-2-3-5-10-20-25Kg

4.1.1. Use-specific instructions

RATMIX is applied via tamper resistant bait stations

Bait is deposited and fixed in the bait stations

The number of bait points employed is dependent on the treatment site the size and severity of the infestation the user and the user requirements and needs

Inspect and resupply the bait stations once a week as long as the bait is consumed

Remove all bait points after the end of treatment

The amount of bait per bait point and distances between bait points must be respected

Products have always to be used in accordance with the label

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development

4.1.4. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

The active ingredient in the form of bait may be palatable to humans and non-target species in sufficient quantity to produce toxic effects

Effects result from the inhibition of blood coagulation as Brodifacoum interacts with vitamine K1 inducing hemorrhages over the course of several days

If large quantity are ingested induce vomiting perform gastric lavage and monitor prothrombine activity

Note to doctor the product RATMIX contains an anticoagulant-rodenticide treatment with vitamin K1 could be needed for a long time

Emergency measures to protect the environment In case of accidental contamination avoid spreading in house drains rainy waters and environment

In case of a release had already occurred the competent authority has to be warned

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

Always read the label before use and follow the instruction provided

Keep out of reach of children

Keep away from food drink and animal feeding stuff

Avoid contact with skin

If swallowed seek medical advice immediately (show the label when possible)

Do not smoke eat or drink while handling this product

Baits must be secured in tamper resistant bait boxes to minimize the risk of consumption and poisoning to children companion animals and other non-target animals

Bait boxes must be placed in areas inaccessible to children companion animals and non-target animals

Bait boxes must always be clearly labelled "Do Not Touch" and warn of the contents

In public areas (such as business premises schools hospitals etc) it must be clearly signed that rodenticide control is in operation

Signage must provide information on the risks of interfering with the product and dead rodents

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

Store away from light

Keep container tightly closed in fresh and dry places

Keep out of the reach of children

Keep away from food drink and animal foodstuffs

Store in the original container

The product could be conserved 24 months since the manufacturing date

To be indicated on bait stations Keep out of the reach of children

Keep away from food drink and animal foodstuffs

4.2. Use description

Table 2. Use in open areas

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Use in open areas
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: adults Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: adults
Field(s) of use	outdoor use
Application method(s)	Method: in bait boxes Detailed description: Baits shall be placed in bait boxes
Application rate(s) and frequency	Application rate: Rats: 60-100g of pasta bait per 100m ² of infested area; Mice: 40 g of pasta bait per 100m ² of infested area Dilution (%): 100 Number and timing of application: Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed
Category(ies) of users	industrial ; trained professional ; professional ; general public (non-professional)
Pack sizes and packaging material	Paper, cardboard, Sachet, 20g For non-professional use packs with 40-100-160-200-260-300-400-500g For professional use packs with 740g 1-2-3-5-10-20-25Kg

4.2.1. Use-specific instructions

RATMIX is applied via tamper resistant bait stations

Bait is deposited and fixed in the bait stations

The number of bait points employed is dependent on the treatment site the size and severity of the infestation the user and the user requirements and needs

Inspect and resupply the bait stations once a week as long as the bait is consumed

Remove all bait points after the end of treatment

The amount of bait per bait point and distances between bait points must be respected

Products have always to be used in accordance with the label

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development

4.2.4. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

The active ingredient in the form of bait may be palatable to humans and non-target species in sufficient quantity to produce toxic effects

Effects result from the inhibition of blood coagulation as Brodifacoum interacts with vitamine K1 inducing hemorrhages over the course of several days

If large quantity are ingested induce vomiting perform gastric lavage and monitor prothrombine activity

Note to doctor the product RATMIX contains an anticoagulant-rodenticide treatment with vitamin K1 could be needed for a long time

Emergency measures to protect the environment In case of accidental contamination avoid spreading in house drains rainy waters and environment

In case of a release had already occurred the competent authority has to be warned

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

Always read the label before use and follow the instruction provided

Keep out of reach of children

Keep away from food drink and animal feeding stuff

Avoid contact with skin

If swallowed seek medical advice immediately (show the label when possible)

Do not smoke eat or drink while handling this product

Baits must be secured in tamper resistant bait boxes to minimize the risk of consumption and poisoning to children companion animals and other non-target animals

Bait boxes must be placed in areas inaccessible to children companion animals and non-target animals

Bait boxes must always be clearly labelled "Do Not Touch" and warn of the contents

In public areas (such as business premises schools hospitals etc) it must be clearly signed that rodenticide control is in operation

Signage must provide information on the risks of interfering with the product and dead rodents

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

Store away from light

Keep container tightly closed in fresh and dry places

Keep out of the reach of children

Keep away from food drink and animal foodstuffs

Store in the original container

The product could be conserved 24 months since the manufacturing date

To be indicated on bait stations

Keep out of the reach of children

Keep away from food drink and animal foodstuffs

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

RATMIX is applied via tamper resistant bait stations

Bait is deposited and fixed in the bait stations

The number of bait points employed is dependent on the treatment site the size and severity of the infestation the user and the user requirements and needs

Inspect and resupply the bait stations once a week as long as the bait is consumed

Remove all bait points after the end of treatment

The amount of bait per bait point and distances between bait points must be respected

Products have always to be used in accordance with the label

5.2. Risk mitigation measures

The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development

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

The active ingredient in the form of bait may be palatable to humans and non-target species in sufficient quantity to produce toxic effects

Effects result from the inhibition of blood coagulation as Brodifacoum interacts with vitamines K1 inducing hemorrhages over the course of several days

If large quantity are ingested induce vomiting perform gastric lavage and monitor prothrombine activity

Note to doctor the product RATMIX contains an anticoagulant-rodenticide treatment with vitamin K1 could be needed for a long time

Emergency measures to protect the environment In case of accidental contamination avoid spreading in house drains rainy waters and environment

In case of a release had already occurred the competent authority has to be warned

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

Always read the label before use and follow the instruction provided

Keep out of reach of children

Keep away from food drink and animal feeding stuff

Avoid contact with skin

If swallowed seek medical advice immediately (show the label when possible)

Do not smoke eat or drink while handling this product

Baits must be secured in tamper resistant bait boxes to minimize the risk of consumption and poisoning to children companion animals and other non-target animals

Bait boxes must be placed in areas inaccessible to children companion animals and non-target animals

Bait boxes must always be clearly labelled "Do Not Touch" and warn of the contents

In public areas (such as business premises schools hospitals etc) it must be clearly signed that rodenticide control is in operation

Signage must provide information on the risks of interfering with the product and dead rodents

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

Store away from light

Keep container tightly closed in fresh and dry places

Keep out of the reach of children

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

Keep away from food drink and animal foodstuffs
Store in the original container
The product could be conserved 24 months since the manufacturing date
To be indicated on bait stations
Keep out of the reach of children
Keep away from food drink and animal foodstuffs

6. OTHER INFORMATION