

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

ALPHAMAYER PASTA

Product type(s)

PT14: Rodenticides

Authorisation number: IT/2014/00233/MRA

R4BP asset number: IT-0006710-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	ALPHAMAYER PASTA
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	LODI S.A.S.
	Address	Parc d'Activités des Quatre Routes 35390 Grand Fougeray France
Authorisation number	IT/2014/00233/MRA	
<i>R4BP asset number</i>	IT-0006710-0000	
Date of the authorisation	19/03/2013	
Expiry date of the authorisation	30/06/2026	

1.3. Manufacturer(s) of the product

Name of manufacturer	LODI SAS
Address of manufacturer	Parc d'Activités des Quatre Routes 35390 Grand-Fougeray France
Location of manufacturing sites	Parc d'Activités des Quatre Routes 35390 Grand-Fougeray France

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

Active substance	alphachloralose
Name of manufacturer	LODI SAS
Address of manufacturer	Parc d'Activités des Quatre Routes 35390 Grand-Fougeray France
Location of manufacturing sites	HIKAL Ltd. T-21. MIDC Industrial Area Taloja Raigad district 410208 Maharashtra India

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 (%)
alphachloralose	(R)-1,2-O-(2,2,2-Trichloroethylidene)- α-D-glucofuranose	active substance	15879-93-3	240-016-7	4

2.2. Type(s) of formulation

PA Paste

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P273: Avoid release to the environment. P391: Collect spillage. P501: Dispose of container to in accordance to the national regulation.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Non-professionals

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	The product is authorised for indoor use against house mouse by the general public/non-professionals in tamper-resistant bait stations only.
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: adults Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles
Field(s) of use	indoor use Bait stations could be used inside domestic, industrial and commercial buildings including farm buildings in infested areas (along walls, windows...). Aim of use: Stored product protection, food protection, health protection and material protection (ie. historical buildings, technical objects).
Application method(s)	Method: bait application Detailed description: Bait stations could be used inside domestic, industrial and commercial buildings including farm buildings in infested areas (along walls, windows...). The application rate or the number of sachets per bait station must be adapted to the effective rate. The number of bait stations is function of the area of treatment and infestation rate. Distances between bait stations must be respected. Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed.
Application rate(s) and frequency	Application rate: Application rates : Indoor use: - Mice, high infestation: from 5g to 20g of product / bait station. Distance between bait stations: 3 meters. - Mice, low infestation: from 5g to 20g of product / bait station. Distance between bait stations: 5 meters. Dilution (%): 0 Number and timing of application: Use in case of infestation.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Baitbox, Plastic: PP or PS , 5g Baitbox, Plastic: PP or PS , 10g Baitbox, Plastic: PP or PS , 20g Box, Paper, cardboard: 80g, 100g, 120g, 150g, 160g, 200g, 240g, 250g, 300g, 320g, 350g, 400g, 500g

The product is supplied in: - individual packets in paper

4.1.1. Use-specific instructions

Bait stations could be used inside domestic, industrial and commercial buildings including farm buildings in infested areas (along walls, windows...). The application rate or the number of sachets per bait station must be adapted to the effective rate. The number of bait stations is function of the area of treatment and infestation rate. Distances between bait stations must be respected. Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

- Keep out of reach of children. - Keep away from food, drink and animal foodstuffs - When using do not eat, drink or smoke - Do not lay on surfaces or materials which could be in contact with food to prevent contamination of food or animal foodstuffs. - Prevent access to children, pets and wild animals. - Place the bait stations in sites sheltered from flooding. - Keep only in the original container. - Bait stations should only contain rodenticides. - Wearing gloves is recommended. - Do not open the sachet - Do not damage the cartridge, even when empty - Wash hands after use. - Remove all bait stations after the treatment. - The treatment must be used alternately with other kinds of active substances in order to avoid resistances and crossresistances occurrence to anticoagulants. - Adopt measures of integrated pest management like chemical and physical methods and hygiene practices. - Check the efficacy of the product on site: if necessary, the reasons for reduced efficacy have to be investigated for possible evidence of resistance. - Do not use the product in an area where resistance is suspected or established. - The users should 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

If exposed, contact immediately a poisoning control centre or a doctor and describe the situation (give information on the label and assess the exposition rate): · If inhaled: breathe fresh air and keep at rest. · If a contact occurs with skin: Remove contaminated clothes and wash skin with soap and rinse copiously with water. Do not use solvents or thinners. · If a contact occurs with eyes: Wash copiously under a trickle of water (tepid if possible) for several minutes, keeping eyelids open under the trickle of water. · If swallowed, seek medical advice immediately and show this container or label. Do not induce vomiting. Whatever the quantity of the product ingested, do not eat and do not drink. Install the victim in the recovery position and protect him against injury from sudden movements or convulsion. Monitor breathing. Follow the doctor's advice. In case of emergency, contact a anti poison centre. Note to doctor: the product contains a depressant and convulsant of the nervous system. The bronchial congestion is fast. The treatment is symptomatic, there is no specific antidote.

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

- Do not clean the bait stations between two applications.- This material and its container must be disposed of in a safe way. - Do not dispose the product in environment or pipings. - Dispose of the bait stations in waste reception centres or appropriate collect points. - The packaging must not be re-used or recycled. - Unconsumed baits, unused baits and ejected baits outside bait stations must be collected and disposed in waste reception centres or in appropriate collect points.

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

The product can be conserved and used until 2 years after its date of manufacturing.

4.2. Use description

Table 2. Trained Professionals

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	The product is authorised for indoor use against house mouse by trained professionals in tamper-resistant bait stations only.
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: adults Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles
Field(s) of use	indoor use Stored product protection, food protection, health protection and material protection (ie. historical buildings, technical objects).
Application method(s)	Method: bait application Detailed description: Bait stations could be used inside domestic, industrial and commercial buildings including farm buildings in infested areas (along walls, windows...). The application rate or the number of sachets per bait station must be adapted to the effective rate. The number of bait stations is function of the area of treatment and infestation rate. Distances between bait stations must be respected. Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed.
Application rate(s) and frequency	Application rate: Dose: Application rates : Indoor use: - Mice, high infestation: from 5g to 20g of product / bait station. Distance between bait stations: 3 meters. - Mice, low infestation: from 5g to 20g of product / bait station. Distance between bait stations: 5 meters. Dilution (%): 0 Number and timing of application: In case of infestation.
Category(ies) of users	trained professional
Pack sizes and packaging material	Baitbox, Plastic: PP or PS , 5g Baitbox, Plastic: PP or PS , 10g Baitbox, Plastic: PP or PS , 20g Box, Paper, cardboard : 80g, 100g, 120g, 150g, 160g, 200g, 240g, 250g, 300g, 320g, 350g, 400g, 500g, 1Kg, 2.5Kg, 5Kg

	<p>Cartridge, Plastic: PP , 50g Cartridge, Plastic: PP , 100g Cartridge, Plastic: PP , 310g</p> <p>Bucket, Plastic: PP: 80g, 100g, 120g, 150g, 160g, 200g, 240g, 250g, 300g, 320g, 350g, 400g, 500g, 1Kg, 2.5Kg, 5Kg</p> <p>The product is supplied in: - individual packets in paper. - cartridge.</p>
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4.2.1. Use-specific instructions

Bait stations could be used inside domestic, industrial and commercial buildings including farm buildings in infested areas (along walls, windows...). The application rate or the number of sachets per bait station must be adapted to the effective rate. The number of bait stations is function of the area of treatment and infestation rate. Distances between bait stations must be respected. Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

- Keep out of reach of children. - Keep away from food, drink and animal foodstuffs - When using do not eat, drink or smoke - Do not lay on surfaces or materials which could be in contact with food to prevent contamination of food or animal foodstuffs. - Prevent access to children, pets and wild animals. - Place the bait stations in sites sheltered from flooding. - Keep only in the original container. - Bait stations should only contain rodenticides. - Wearing gloves is recommended. - Do not open the sachet - Do not damage the cartridge, even when empty - Wash hands after use. - Remove all bait stations after the treatment.

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

If exposed, contact immediately a poisoning control centre or a doctor and describe the situation (give information on the label and assess the exposition rate): · If inhaled: breathe fresh air and keep at rest. · If a contact occurs with skin: Remove contaminated clothes and wash skin with soap and rinse copiously with water. Do not use solvents or thinners. · If a contact occurs with eyes: Wash copiously under a trickle of water (tepid if possible) for several minutes, keeping eyelids open under the trickle of water. · If swallowed, seek medical advice immediately and show this container or label. Do not induce vomiting. Whatever the quantity of the product ingested, do not eat and do not drink. Install the victim in the recovery position and protect him against injury from sudden movements or convulsion. Monitor breathing. Follow the doctor's advice. In case of emergency, contact a anti poison centre. Note to doctor: the product contains a depressant and convulsant of the nervous system. The bronchial congestion is fast. The treatment is symptomatic, there is no specific antidote.

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

- Do not clean the bait stations between two applications.- This material and its container must be disposed of in a safe way. - Do not dispose the product in environment or pipings. - Dispose of the bait stations in waste reception centres or appropriate collect points. - The packaging must not be re-used or recycled. - Unconsumed baits, unused baits and ejected baits outside bait stations must be collected and disposed in waste reception centres or in appropriate collect points.

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

The product can be conserved and used until 2 years after its date of manufacturing.

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Bait stations could be used inside domestic, industrial and commercial buildings including farm buildings in infested areas (along walls, windows...). The application rate or the number of sachets per bait station must be adapted to the effective rate. The number of bait stations is function of the area of treatment and infestation rate. Distances between bait stations must be respected. Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed.

5.2. Risk mitigation measures

The product label and the sachet label have to mention “Do not open the sachet”. Cartridges have to mention “Do not damage the cartridge, even when empty” Authorisation holder should assure the availability of opaque and secured bait stations. Boxes in which the bait is inaccessible to children and non-target organisms, are considered as secure bait stations. Furthermore, a device must be provided to prevent opening by children. These devices must be designed to keep baits inaccessible to the general public and non-target animals. - Keep out of reach of children. - Keep away from food, drink and animal foodstuffs - When using do not eat, drink or smoke - Do not lay on surfaces or materials which could be in contact with food to prevent contamination of food or animal foodstuffs. - Prevent access to children, pets and wild animals. - Place the bait stations in sites sheltered from flooding. - Keep only in the original container. - Bait stations should only contain rodenticides. - Wearing gloves is recommended. - Do not open the sachet - Do not damage the cartridge, even when empty - Wash hands after use. - Remove all bait stations after the treatment. - The treatment must be used alternately with other kinds of active substances in order to avoid resistances and crossresistances occurrence to anticoagulants. - Adopt measures of integrated pest management like chemical and physical methods and hygiene practices. - Check the efficacy of the product on site: if necessary, the reasons for reduced efficacy have to be investigated for possible evidence of resistance. - Do not use the product in an area where resistance is suspected or established. - The users should 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

If exposed, contact immediately a poisoning control centre or a doctor and describe the situation (give information on the label and assess the exposition rate): · If inhaled: breathe fresh air and keep at rest. · If a contact occurs with skin: Remove contaminated clothes and wash skin with soap and rinse copiously with water. Do not use solvents or thinners. · If a contact occurs with eyes: Wash copiously under a trickle of water (tepid if possible) for several minutes, keeping eyelids open under the trickle of water. · If swallowed, seek medical advice immediately and show this container or label. Do not induce vomiting. Whatever the quantity of the product ingested, do not eat and do not drink. Install the victim in the recovery position and protect him against injury from sudden movements or convulsion. Monitor breathing. Follow the doctor's advice. In case of emergency, contact a anti poison centre. Note to doctor: the product contains a depressant and convulsant of the nervous system. The bronchial congestion is fast. The treatment is symptomatic, there is no specific antidote.

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

- Do not clean the bait stations between two applications.- This material and its container must be disposed of in a safe way. - Do not dispose the product in environment or pipings. - Dispose of the bait stations in waste reception centres or appropriate collect points. - The packaging must not be re-used or recycled. - Unconsumed baits, unused baits and ejected baits outside bait stations must be collected and disposed in waste reception centres or in appropriate collect points.

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

The product can be conserved and used until 2 years after its date of manufacturing.

6. OTHER INFORMATION

Bilag 1

Oplysninger til etiket og brugsanvisning for Black Pearl Pasta BPR-reg. nr. 669-5

I. Etiketten skal udformes i overensstemmelse med artikel 69 i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP Forordningen [1].

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

Nedstående 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 (PT14)

Må kun anvendes til indendørs bekæmpelse af husmus (*Mus musculus*).”

2) I advarselsfeltet:

”FORSIGTIG

Vær opmærksom på, at Arbejdstilsynet har regler for arbejde med bekæmpelsesmidler. Læs nærmere i det eventuelt lovpligtige sikkerhedsdatablad samt i Arbejdstilsynets informationsmateriale om bekæmpelsesmidler. Vask huden efter arbejdet.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes til indendørs bekæmpelse af husmus (*Mus musculus*).

Doseringen af det biocidholdige produkt skal afpasses bekæmpelsen af mus på den pågældende lokalitet, dog må der højst anvendes 20 g. pr. 3 meter af hensyn til faren for forgiftning af mennesker, pattedyr og fugle.

Produktet skal anbringes i forsvarligt lukkede lokkemiddelkasser, som ikke kan udsættes for manipulation og så mennesker og dyr ikke kan komme i kontakt med giften.

Emballagen med alphachloralose må ikke åbnes.

Giftrester og døde mus bortskaffes i overensstemmelse med kommunale anvisninger for bortskaffelse af affald.

Foderstationer skal påføres en tekst, hvoraf det fremgår, at der foregår musebekæmpelse i området, og hvorledes man forholder sig i tilfælde af forgiftning.

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Evt. oplysninger om førstehjælp.

3) I deklarationsfeltet:

a) Teksten ”Gnavermiddel BPR-reg. nr. 669-5. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)”.

b) Oplysning om præparattype: ”Foderpasta” for dette præparat.

c) Indholdet af aktivstof i vægtprocent 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, anvendelsesområde og doseringer.

Brugsanvisningen skal rettes til eftereffektivitetsvurderingen vedlagt godkendelsesbrevet af 26. november 2013.

Følgende retningslinjer gælder i forhold til bortskaffelse:

Der skal mærkes med sikkerhedssætning P501: ”Indholdet/holderen bortskaffes i overensstemmelse med kommunale regler for affaldshåndtering.”

Derudover skal mærkningen ske efter følgende retningslinjer:

Rester og tom emballage bortskaffes i henhold til de kommunale affaldsregulativer.

5) Foderstationer med produktet skal påføres en tekst med tydelig oplysning om, at der foregår musebekæmpelse i området, og hvorledes man skal forholde sig i tilfælde af forgiftning.

[1] Europa-Parlamentets og Rådets forordning (EF) Nr. 1272/2008 af 16. december 2008

om klassificering, mærkning og emballering af stoffer og blandinger og om ændring og ophævelse af direktiv 67/548/EØF og 1999/45/EF og om ændring af forordning (EF) nr. 1907/2006