ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT FAMILY

ALPHACHLORALOSE PASTA

Product type(s)

PT14: Rodenticides

Authorisation number FR-2018-0006

R4BP asset number FR-0018427-0000

Part I. FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name ALPHACHLORALOSE PASTA

1.2. Product type(s)

1.3. Authorisation holder

	Name	LODI S.A.S.
Name and address of the authorisation holder	Address	Parc d'Activités des Quatre Routes 35390 Grand Fougeray France
Authorisation number		FR-2018-0006
R4BP asset number		FR-0018427-0000
Date of the authorisation		19/03/2013
Expiry date of the authorisation		31/12/2024

1.4. Manufacturer(s) of the product

Name of manufacturer	LODI S.A.S.
Address of manufacturer	PARC D'ACTIVITES DES QUATRE ROUTES 35390 GRAND FOUGERAY France
Location of manufacturing sites	LODI S.A.S. site 1 PARC D'ACTIVITES DES QUATRE ROUTES 35390 GRAND FOUGERAY France

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

Active substance	Alphachloralose
Name of manufacturer	LODI S.A.S.
Address of manufacturer	PARC D'ACTIVITES DES QUATRE ROUTES 35390 GRAND FOUGERAY France
Location of manufacturing sites	LODI S.A.S. site 1 HIKAL LTD. T-21. MIDC INDUSTRIAL AREA TALOJA RAIGAD DISTRICT 410 208 MAHARASHTRA India LODI S.A.S. site 2 SUNTTON CO. LTD JINGYI ROAD. XINYI TANGDIAN CHEMICAL ZONE 221415 JIANGSU China LODI S.A.S. site 3 SAREX Plot n°N129, N130, N131, N132 & N232, MIDC, Tarapur 401 506 Maharashtra India

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Alphachloralose	(R)-1,2-O-(2.2,2- Trichloroethylider a-D- glucofuranose		15879-93-3	240-016-7	4 - 4 % (w/w)

2.2. Type(s) of formulation

Formulation type(s)	RB Bait (ready for use)
31 (7)	

$\label{eq:partII.} \textbf{SECOND INFORMATION LEVEL - META SPC}(S)$

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	Meta SPC: meta SPC
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1.2. Suffix to the authorisation number

Number	1-1
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1.3. Product type(s)

Product type(s)	PT14: Rodenticides
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2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Alphachloralose	(R)-1,2-O-(2.2,2- Trichloroethylider a-D- glucofuranose		15879-93-3	240-016-7	4 - 4 % (w/w)

2.2. Type(s) of formulation of the meta SPC 1

Formulation type(s)	RB Bait (ready for use)
31 (7)	

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P273: Avoid release to the environment.
	P391: Collect spillage.
	P501: Dispose of contents/container to

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1. Professional users – indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	-
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
Field(s) of use	indoor use
	This product is to be used inside private, public and agricultural buildings against house mouses in tamper-resistant bait boxes or covered bait stations.
Application method(s)	Method: bait application
	Detailed description: Ready to use bait to be used in tamper resistant stations
Application rate(s) and frequency	Application rate: High infestation: from 10g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 3 meters. Low infestation: from 10g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 5 meters.
	Dilution (%): 0
	Number and timing of application: High infestation: from 10g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 3 meters.
	Low infestation: from 10g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 5 meters.
	Biocidal effect appears about 24 hours after ingestion of the baits.
Category(ies) of users	professional
Pack sizes and packaging material	The product is packaged in: - cartridge PP (50, 100, 150, 270 or 310g), - metal cartridge (50g, 100g, 150g, 170g, 200g), - individual paper sachets of 5, 10 or 20g. Paper sachets are package in: - PP bucket (1, 2.5 or 5kg),
	- Carboard with internal bag in PP or PE: 1kg, 2.5kg, 5kg, 6kg, 7kg, 8kg, 9kg, 10kg, 15kg, 20kg.

4.1.1. Use-specific instructions

- Adapt number of sachet at the efficacy application rate and respect distance between bait station.

- The number of bait station depend of the treatment area, geographical context and level of infestation.
- The bait stations should be visited only few 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.
- Alternate products with active substances with different modes of action to avoid the appearance of resistance phenomena.
- Adopt integrated management methods such as a combination of chemical, physical control and hygiene measures.
- Check the effectiveness of the product on site: if necessary, the causes of the decrease in effectiveness must be sought in order to
- ensure the absence of resistance.
- Do not use the product in areas where resistance cases are suspected or established.
- Notify the authorisation holder in the event of treatment ineffectiveness or signs that may be interpreted as the development of
- resistance.
- Do not damage the cartridge, even when it is empty

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

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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

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

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

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4.2. Use description

Table 2. Professionals (non specialised) and non professional users - indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	-
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
Field(s) of use	Development stage: adults indoor use This product is to be used inside private, public and agricultural buildings against house mouses in tamper-resistant bait boxes or covered bait stations.

Application method(s)	Method: bait application
	Detailed description: Ready to use bait to be used in tamper resistant stations
Application rate(s) and frequency	Application rate: High infestation: from 10g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 3 meters. Low infestation: from 10g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 5 meters.
	Dilution (%): 0
	Number and timing of application: High infestation: from 10g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 3 meters.
	Low infestation: from 10g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 5 meters.
	Biocidal effect appears about 24 hours after ingestion of the baits.
Category(ies) of users	professional; general public (non-professional)
Pack sizes and packaging material	Bait in sachets: Bait in 5g, 10g or 20g paper sachets supplied in the following outer packs: - Cardboard box case with inner PE or PP lining: 40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g - Doypack (coextruded polystyrene): 200g or 500g - Metal can: 40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g - Metal can + PP bag: 40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 320g, 360g, 400g, 440g, 480g, 520g, 560g, 1kg, 1.5kg - Bucket (PP): 40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g - PE or PP bag (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g) Bait in 10 g or 20 g paper sachets supplied prefilled in the following outer packs: .
	Carton Box of (1 to 10) pre-filled bait stations (PP or PS) containing 1 or 2 x 10g sachet Bait supplied prefilled in the following outer packs: Carton Box of (1 to 10) pre-filled bait stations (PP or PS) containing 10g or 20 of product (without a sachet)
	Bait in cartridge: - Cartridge (PP): 50g or 100g

Use-specific instructions

- Adapt number of sachet at the efficacy application rate and respect distance between bait station.
 The number of bait station depend of the treatment area, geographical context and level of infestation.
 The bait stations should be visited only few 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.

- 4.2.2. Use-specific risk mitigation measures
- **4.2.3.** Use-specific risk mitigation measures

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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

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

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

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5. GENERAL DIRECTIONS FOR USE OF THE META SPC 1

5.1. Instructions for use

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5.2. Risk mitigation measures

5.3. Risk mitigation measures

- Do not open the sachets containing the bait
- Do no open bait boxes
- When using the product do not eat, drink or smoke.
- Wash hands and directly exposed skin after using the product.
- Keep out of the reach of children.
- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals. bait boxes or bait stations should not be used to contain anything other than rodenticides.
- Gloves are recommended. Keep only in the original container.
- Remove the remaining bait or the bait stations at the end of the treatment period.
- Do not place bait stations near water drainage systems where they can come into contact with water.
- Indicate on the packaging, via well visible pictogram, the risk for humans and non target organisms. Indicate on the packaging the necessity to use bait box to apply rodenticides.

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

• In case of exposure, immediately contact a poison control center, a samu or a doctor and in all cases describe the situation

(provide the information on the label, assess the exposure dose).

- In case of:
- Inhalation, breathe fresh air and rest.
- Dermal exposure, remove contaminated clothes, wash skin with water and soap. Do not use solvents or thinners
- Eye exposure, rinse eyes with water, keep eyes lids open during several minutes under the stream of water.
- Oral exposure, seek medical advice immediately and show the container or label. Do not induce vomiting. Regardless of the

amount of product ingested, do not eat or drink. Place the victim in a lying position in a safe position and protect him from injury in the event of sudden movement and convulsion. Monitor his breathing. Follow the doctor's advice. In case of acute distress, contact 15 (or 112).

- Indication for the doctor:

This product contains a rodenticide nervous system depressant and convulsant. Bronchial congestion is precocious. Treatment is

symptomatic, there is no specific antidote.

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

Do not dispose of this product and its container without taking all precautions for use.

- Do not discharge the product into the environment or the pipes.
- Drop used bait stations or boxes at a recycling center or other appropriate collection center.
- The packaging must not be reused or recycled.
- Bait that is not consumed, unused and trained outside of bait stations or bait boxes and dead rodents must be collected and

deposited in a recycling center or any other appropriate collection center.

• Do not clean the bait boxes or bait stations between 2 applications.

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

Shelf-life: 2 years

6. OTHER INFORMATION

- The sachets and the label must bear the following statement: "Do not open the sachets"
- For professionnal uses, cartridge must beat the following statement : "Do not damage the cartridge, even when empty"
- Baiting points are are tamper resistant bait stations and other bait stations
- Are consider as tamper resistant bait stations boxes whose bait is made inaccessible to children and non-target organisms. In addition, a closing device must be provided to prevent it from being opened by children.
- The holder of the marketing authorization must ensure the availability of secure opaque bait boxes.
- Are considered as other bait stations devices ensuring the same level of protection regarding humans and the environment as bait boxes, fixed so as not to be entrained, thus avoiding direct contact of the bait with the environment. These devices must be designed to keep the baits inaccessible to the general public and to non-target animals, and protect them from the weather.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

$\textbf{7.1.} \quad \textbf{Trade name}(s), \textbf{ authorisation number and specific composition of each individual product}$

Trade name(s)	BLACK PEARL PASTA	Market area: FR
	ALPHA PASTA 4%	Market area: FR
	RACAN PASTE AF	Market area: FR
	PASTE AF	Market area: FR
	LE FOUDROYA SOURIS PATE NOIRE	Market area: FR NT
	MAGIK PASTE	Market area: FR
	FLASH PASTE	Market area: FR
Authorisation number		FR-0018427-0001 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Alphachloralose	(R)-1,2-O-(2.2,2- Trichloroethylider a-D- glucofuranose		15879-93-3	240-016-7	4

$\textbf{7.2.} \quad \textbf{Trade name}(s), \textbf{ authorisation number and specific composition of each individual product}$

Trade name(s)	LE	Market area: FR
	FOUDROY	ANT
	SOURIS	
	PATE	
	ROUGE	
	ALPHA P	Market area: FR
Authorisation number		FR-0018427-0002 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Alphachloralose	(R)-1,2-O-(2.2,2- Trichloroethylider a-D- glucofuranose		15879-93-3	240-016-7	4