### **ANNEX**

### SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

### **BLACK PEARL GRAIN**

**Product type(s)** 

PT14: Rodenticides

**Authorisation number:** FR-2018-0012 1-1

**R4BP asset number:** FR-0019764-0001

### 1. ADMINISTRATIVE INFORMATION

### 1.1. Trade name(s) of the product

Trade name(s)	BLACK PEARL GRAIN
	LE FOUDROYANT SOURIS GRAIN
	FLASH GRAIN
	GRAIN AF
	MAGIK GRAIN
	RONGI GRAINS FOUDROYANT

### 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		FR-2018-0012 1-1
R4BP asset number		FR-0019764-0001
Date of the authorisation		19/03/2013
Expiry date of the authorisation		31/12/2024

## **1.3.** 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

## **1.4.** 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, N232 MIDS, TARAPUR 401 506 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- Trichloroethylider a-D- glucofuranose		15879-93-3	240-016-7	4

## 2.2. Type(s) of formulation

RB Bait (ready for use)

### 3. HAZARD AND PRECAUTIONARY STATEMENTS

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 {0::contents container} to {1::}.

# 4. AUTHORISED USE(S)

# 4.1. Use description

 Table 1. Product for trained professionnal users

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development	Scientific name: Mus musculus
stage)	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: For use in tamper-resistant bait boxes or covered bait stations
Application rate(s) and frequency	Application rate: High infestation: (10-25) g of bait per baiting point. Low infestation: (10-25) g of bait per baiting point.
	Dilution (%): 0
	Number and timing of application:
	High infestation: (10-25) g of bait per baiting point. If more than
	one bait station is needed, the minimum distance between bait stations should be of 3 meters.
	Low infestation: (10-25) g of bait per baiting point. If more than
	one bait station is needed, the minimum distance between bait stations should be of 5 meters.
	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.
	Time required for the appearance of the biocidal effect: between 1 and 3 days after ingestion of the bait.
Category(ies) of users	trained professional
Pack sizes and packaging material	Individual sachets in polyethylene or polyethylene/paper
	The products are supplied in:
	- Individual sachet in paper (10 or 25g)
	Sachets in paper are supplied in:
	- Bucket (PP): 1Kg, 2.5Kg, 5Kg
	- Cardboard box: 1Kg, 2.5Kg, 5kg, 6kg, 7kg, 8kg, 9kg, 10kg, 15kg, 20kg.
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	Sales to trained professionals will be done in a package that does
	not allow the purchase of less than 5 kg of product.

### **4.1.1.** Use-specific instructions

- 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.

#### 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. Product for professionnal and non professional users

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development	
stage)	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: For use in tamper-resistant bait boxes.
Application rate(s) and frequency	Application rate: High infestation: (10-25) g of bait per baiting point. Low infestation: (10-25) g of bait per baiting point.

	Dilution (%): 0  Number and timing of application: High infestation: (10-25) g of bait per baiting point. If more than one bait station is needed, the minimum distance between bait stations should be of 3 meters.  Low infestation: (10-25) g of bait per baiting point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.  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. Time required for the appearance of the biocidal effect: between 1 and 3 days after ingestion of the bait.
Category(ies) of users	professional; general public (non-professional)
Pack sizes and packaging material	The product is supplied in: - individual sachet in paper: 10 or 25 g  Sachets in paper or PE/paper are supplied in: - Carton (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g) - doypacks (200 or 500g) - Can /Tin, Metal + PP bag (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g) - Can /Tin, Metal (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g) - Can /Tin, Metal (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g) - Bucket PP (500g) - PE or PP bag (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g) - Carton Box of (1 to 10) pre-filled bait stations (PP or PS) containing 1 x 10g or 2x 10g sachets - Sales to the general public and to professionals will be carried out in a package that does not allow the purchase of a quantity greater than 1.5 kg of product.

### **4.2.1.** Use-specific instructions

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### 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

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<sup>1</sup>

#### **5.1.** Instructions for use

- Do not open the sachets containing the bait
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- 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.
- 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.
- Gloves are recommended.

Users shall properly label bait stations with following informations:

• Do not open bait stations.

#### **5.2.** Risk mitigation measures

- 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.

# 5.3. 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.

- Bait stations must be labelled with the following information:
- 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.

#### 5.4. 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.

<sup>&</sup>lt;sup>1</sup>Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

- 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.

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

Keep out of the reach of children.

- Keep away from food and drink, including animal feed.
- Keep only in the original container.
- The product will keep for 2 years from the date of manufacture.

Information to be reported on bait stations, for people other than the user:

- Keep out of the reach of children.
- Keep away from food and drink, including animal feed.

#### 6. OTHER INFORMATION

- The sachets and the label must bear the following statement: "Do not open the sachets".
- 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.
- •The label of the product shall indicate that it contains silicone dioxide (nano)