SAFETY DATA SHEET

APITRAZ 500 mg / strips for beehives

Card No.: ES 290 Date of Revision: 12-06-13

Revision No.:

SECTION 1- IDENTIFICATION OF PRODUCT AND COMPANY

 Product name: 1.1. Product Category: 1.2. Formulation type: 1.3. Content: 	APITRAZ 500 mg / strips for beehives Formulated Strip for beehives 500 mg Amitraz / strip
2. Company Name	Laboratorios Calier, S.A. 26 Plá del Ramassá 08520 Les Franqueses del Vallés (Barcelona). SPAIN
	Tel.: +34 93 849 51 33

3. Emergency Telephone

Laboratorios Calier, S.A. Tel.: +34 93 849 51 33

SECTION 2 – COMPOSITION / INFORMATION ON COMPONENTS

Contains:

Amitraz 500 mg / strip

33089-61-1

CAS No:

SECTION 3- HAZARD IDENTIFICATION

Chemical hazard of the product due to its nature

Linked to Amitraz

The drug, due to its nature, is toxic by contact with the skin and mucosae. Amitraz dust and vapours are toxic by inhalation, but the presentation of the drug strongly reduces the risk. The product is also toxic by ingestion, if this should be considered. Amitraz is a sea pollutant.

First symptoms of intoxication: nauseas, vomiting, abdominal pain, diarrhoea, depression, tiredness, dyspnoea and arterial hypertension.

The copolymer phase is bio-chemically inert

Physical and chemical hazards of the product in combustion At high temperature, thermal decomposition releasing toxic and corrosive products At high temperature an explosion of the bags, with dispersion, is possible.

SECTION 4 – FIRST AID

- <u>Eve Contact</u>: wash with plenty of water for at least 15 minutes, leaving the eyelids slightly open. Consult an ophthalmologist.
- <u>Inhalation</u>: leave the patient resting in the open air. In case of inhalation of vapours released by thermal decomposition of the hot product, assisted respiration or oxygen therapy, if necessary.
 - In any case, consult a doctor.
- <u>Skin Contact</u>: wash with plenty of soapy water.
 Contact with the hot product: wash with plenty of cold water. In case of adherence, do not pull the product off. Treat the affected areas as in a thermal burn.
 - <u>Ingestion</u>: immediately consult a doctor. Do not give food or drinks. Do not attempt to induce vomiting. Carry out a gastric lavage with medical assistance. Refer to the toxicological information, Section 11.
- <u>Antidote</u>: There is no specific antidote. Treat according to symptoms.

SECTION 5 - PRECAUTIONS IN CASE OF FIRE

- <u>Extinguishing Agents</u>: use pressurized water or foam.
- <u>Incompatible extinguishing media</u>: none known.
- <u>Specific hazardous emanations</u>: carbon monoxide, carbon dioxide, acetic acid, nitrogen oxides, aldehydes, hydrocarbons and other unidentified organic substances.
- <u>Precautions to be taken by intervening people</u>: they should protect their faces. Firemen should wear butyl rubber boots, gloves, overalls and autonomous breathing devices. Water spray can be used to cool the metallic drums which are exposed to fire.
- <u>General measures in case of fire</u>: keep the liquids which have spilled during the fire; do not pour them into the sewage.
 - Empty drums may contain explosive vapours.

Other remarks: the fire produces toxic or irritant emanations. The personnel should be evacuated. Any contact of the product with the skin should be avoided and any spillage should be controlled.

SECTION 6 – MEASURES IN CASE OF SPILLAGE

Avoid its dispersion into natural waterways, pits and sewers. Do not pour into the environment.

SECTION 7 - HANDLING AND STORAGE

Keep at a temperature below 25°C.

SECTION 8 – EXPOSURE LIMITS AND PERSONAL PROTECTION

Handling of the packed drug

Do not smoke, eat nor drink. Wear gloves against to avoid cuts. Wash the hands after handling the drug. Have washbasins accessible. Eye protection: Wear certified safety goggles. Hand protection: Wear protective rubber or plastic gloves.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical state Colour Solubility Rectangular strips White Insoluble in water Soluble in carbon tetrachloride Soluble in dichloromethane

SECTION 10 – STABILITY AND REACTIVITY

Conditions to be respected: Protect from heat.

Stability: 12 months. Once the bag is opened, use immediately

Reactivity:

No incompatibilities known.

No dangerous polymerizations known.

No dangerous reactions known.

Hazardous products released by thermal decomposition: carbon monoxide, carbon dioxide, acetic acid, nitrogen oxides, aldehydes, hydrocarbons and other unidentified organic substances.

SECTION 11 – TOXICOLOGICAL INFORMATION

The polymeric phase is non-toxic. Only the active principle, AMITRAZ, is toxic.

Acute Toxicity:

Amitraz is, in mammals, a α_2 adrenoceptor agonist agent. Its effects can be inhibited by a α_2 antagonist agent, such as yohimbine.

This neurotoxic action requires ingestion and/or a very important skin and/or respiratory contact:

DL 50 oral acute toxicity in rats: 600 to 800 mg/kg.

DL 50 cutaneous acute toxicity in rats: > 1.800 mg/kg.

CL 50 acute toxicity by inhalation in rats: 65 mg/l of air during 8 hours.

Other acute effects: no information available.

These exposures and their toxicological consequences are inconceivable with the considered pharmaceutical form (strips with copolymer) except, during the manufacturing process, through the cutaneous and respiratory routes.

Chronic Toxicity:

Depression, weight loss, hepatomegaly, behaviour problems observed in experimental animals, depending on species and dosage.

These manifestations of chronic toxicity can not be theoretically excluded in people who are in permanent contact with the unpacked product (manufacturing personnel) and who do not take any precautions.

Carcinogenesis, teratogenesis, mutagenesis:

Amitraz is classed as C/D category by the EPA – USA: (weak carcinogenic potential for human beings). This classification is based on a study carried out with female mice subjected to doses higher than the tolerated doses. No carcinogenesis is known, under these conditions, for male mice. Carcinogenesis cases in humans are not known.

No teratogenesis appears in rats or in rabbits at the respective doses of 30 and 12 mg/kg./day.

Chromosomal mutagenesis is not known.

It does not affect fertility or descendents of male rats treated for 3 generations with doses above 20 mg/kg/day.

These carcinogenesis, teratogenesis and mutagenesis risks seem unlikely, even for people who are in permanent contact with the unpacked product (manufacturing personnel) and who do not take any precautions.

Caustic and irritant properties:

In its normal condition, the product only irritates the eyes; normally, the product does not cause any irritation.

The emanations released by a large quantity of product stored in small and poorly ventilated spaces could irritate the respiratory tract.

In case of combustion and/or thermal decomposition, the drug releases fumes and vapours which are violently irritant for the skin, eyes and respiratory tract.

SECTION 12 - ECOLOGICAL AND ECO-TOXICOLOGICAL INFORMATION

Amitraz has been classified as a marine pollutant. Due to its quick hydrolysis, it is unlikely that this toxicity can be manifested in natural aquatic systems. Amitraz is quickly degraded in the soil, under aerobic conditions.

The drug 'Apitraz 500 mg' /strip for beehives is not biodegradable.

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SECTION 13 - CONSIDERATIONS RELATED TO DISPOSAL

Exclusively by incineration at high temperature in a specialized and authorized environment.

SECTION 14 - INFORMATION RELATED TO TRANSPORT

SECTION 15 – REGULATORY INFORMATION

- Classification
- Hazard Symbol
- Indication
- R Sentences
- S Sentences

S2 Keep out of the reach of children

SECTION 16 – OTHER INFORMATION

It is advisable to receive basic training on safety and hygiene at work to handle the product correctly.

The information and recommendations given in this safety sheet are fruit of current knowledge. However, we decline any responsibility whatsoever derived from the information and recommendations given above.

Date: 12-06-13