



SAFETY DATA SHEET

PRODUCT: NEXGARD

Issue Date: July 1st, 2013

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1 – Identification

GHS Product identifier:

NEXGARD

Recommended use of the chemical and restrictions on use:

The product is recommended for treatment and prevention of ectoparasite infestations on dogs. Veterinary use only.

Name:

Merial Saúde Animal Ltda.

Address:

Fazenda São Francisco, s/n

Paulínia / SP

CEP: 13140-970

Phone number:

(19) 3578 5304

Emergency phone number:

(19) 2127 9111

2 – Hazard identification

Classification of the mixture (*):

Hazard Classes

Category

Hazardous to the aquatic environment – Acute hazard

1

GHS label elements, including precautionary statements (*):

Pictograms:



Signal word:

Warning

Hazard statements:

H400: Very toxic to aquatic life

Precautionary statements:

Prevention:

P273: Avoid release to the environment.

Response:

P391: Collect spillage.

Disposal:

P501: Dispose of contents/container should be in accordance with local regulations.

(*) GHS 2011 (Globally harmonized system of classification and labeling of chemicals 2011).

Other hazards which do not result in classification:

It is not available.

3 – Composition/information on ingredients

MIXTURE

Hazardous ingredients:

Name	CAS number	Concentration
afoxolaner	1093861-60-9	2.27%



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Impurities which contribute to the classification of the substance:

It is not available.

4 – First-aid measures

Inhalation:

Take the victim to fresh air immediately. Give artificial respiration if victim is not breathing. Do not use mouth-to-mouth method, if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Seek immediate medical attention and take the product container or label with you.

Skin contact:

Take off contaminated clothes and shoes. Wash exposed skin with plenty of water and soap. For minor skin contact, avoid spreading material on unaffected skin. Get medical attention and take the product container or label with you.

Eye contact:

First check the victim for contact lenses and remove them if present. Wash exposed eyes with abundant water in room temperature for at least 15 minutes, lifting the eyelid while washing them. Seek medical attention and take the product container or label with you.

Ingestion:

Do not induce vomiting. Wash the mouth with plenty of water. In case of vomiting, keep the head below the level of the hips. If the individual is lying down, keep him/her in lateral position to avoid aspiration of the gastric content. Seek immediate medical attention and take the product container or label with you.

Most important symptoms/effects, acute and delayed:

The effects of the product in humans are still unknown. The product may cause nausea, vomiting and gastrointestinal irritation if ingested in large quantities. The adverse effects of human exposure to the product are not known.

Notes to an attending physician:

Symptomatic treatment. There is no specific antidote.

5 – Fire-fighting measures

Suitable extinguishing media:

Small fire: use dry chemical, carbon dioxide (CO₂), water fog or spray. Large fire: use water spray, "alcohol"-type foam extinguishers, water fog.

Specific hazards arising from the chemical:

Fire may produce irritating and/or toxic gases of nitrogen oxides, chlorides, fluorides, carbon monoxide and carbon dioxide.

Special protective actions for fire-fighters:

Move containers from fire area if you can do it without risk. Dike fire-control water for later disposal; do not scatter the material. Wear full protective clothing and positive pressure self-contained breathing apparatus. Structural firefighters' protective clothing provides limited protection in fire situations only; it is not effective in spill situations where direct contact with the substance is possible.

6 – Accidental release measures

Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Use personal protective equipment (PPE). Avoid contact of the product with the skin, eyes and mucous membranes. Do not handle broken packing unless wearing personal protective equipment. Keep out of low areas. Stay upwind.

For emergency responders:

Use suitable PPE. Keep unauthorized personnel away. As an immediate precautionary measure, isolate spill or leak area in all directions for at least 25 meters (75 feet).

Environmental precautions:

In case of spilling or leaking, contain the spill immediately. Do not allow spill to enter in sewers or watercourses. If product enters in the



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Methods and materials for containment and cleaning up:

watercourses, immediately interrupt the human or animal use and contact local environmental agency or the company emergency center, since the measures to be taken depend on a variety of factors such as the accident proportion, the watercourse characteristics and the amount of spilled product.

Use PPE. Isolate and signalize the area. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Stop leak if you can do it without risk.

Paved areas: collect the spilled material with a shovel, avoiding dust formation, and place it in specially marked, tightly closed containers. Spilled product cannot be used further and must be disposed of. Contact Merial Saúde Animal Ltda.

Soil: remove contaminated soil until achieving uncontaminated soil and conduct in accordance with the information above.

7 – Handling and storage

Precautions for safe handling:

Use PPE. Do not handle product without the recommended PPE or if they are damaged. Avoid the contact of the product with skin, eyes and mucous membranes. When opening the packaging, do it avoiding dust formation. Handle the product in a ventilated area away from sources of ignition or heat. Ensure good ventilation in work area.

The usual precautions for the handling of chemicals must be observed. Observe the expiration date. Do not reuse the empty package. Do not wash package in lakes, rivers and watercourses. Do not eat, drink or smoke while handling the product. Wash hands and exposed areas after handling the product, particularly before meals. After workday, remove protective clothing and shower.

Conditions for safe storage, including any incompatibilities:

Store the product in the original package, tightly closed, protected from sunlight. Store away from food, animal feed, beverage and incompatible materials. Lock the place, preventing the access of unauthorized people, mainly children. There must always be adequate packing available to cover and protect broken or cracked packages or to collect leaked products. Observe the disposals of the state and local legislation.

8 – Exposure controls/personal protection

Control parameters

Occupational exposure limit values:

Afoxolaner does not present occupational exposure limit values established by ACGIH (2013), OSHA and NIOSH.

Biological exposure indices:

Afoxolaner does not present biological exposure indices established by ACGIH (2013).

Appropriate engineering controls:

Provide local ventilation at workplace. Provide exhaust ventilation where processes require. Provide emergency shower and eye washer near workplace near the work area.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection:

Wear safety glasses for chemicals with side shields for normal handling.

Skin protection:

Wear butyl rubber, neoprene, vinyl or other chemical resistant impervious gloves and protective clothes.

Respiratory protection:

Provide exhaust ventilation and wear protective mask, where processes require.

Thermal hazards:

It is not available.



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9 – Physical and chemical properties

Appearance:	Mottled red to reddish brown solid (a circular or rectangular-shaped chew ranging in size from 0.5 g to 6.0 g).
Odour:	It is not available.
Odour threshold:	It is not available.
pH:	It is not available.
Melting point/freezing point:	~231.8 - 302°F (~111 - 150°C).
Initial boiling point and boiling range:	It is not applicable.
Flash point:	It is not applicable.
Evaporation Rate:	It is not applicable.
Flammability (solid, gas):	<u>Afoxolaner</u> : It is non-flammable.
Upper/lower flammability or explosive limits:	It is not available.
Vapour pressure:	<u>Afoxolaner</u> : 7×10^{-16} .
Relative vapour density:	It is not available.
Specific gravity:	It is not available.
Solubility in water:	<u>Afoxolaner</u> : $3.35 \times 10^{-7} \text{ kg/m}^3$ ($3.35 \times 10^{-7} \text{ mg/mL}$).
Partition coefficient: n-octanol/water:	<u>Afoxolaner</u> : Log K_{ow} : 5.15.
Auto-ignition temperature:	689 - 824°F (365 - 440°C).
Decomposition temperature:	It is not available.
Viscosity:	It is not applicable.

10 – Stability and reactivity

Reactivity:	None, when properly stored and used.
Chemical stability:	The product is stable when properly stored and used.
Possibility of hazardous reactions:	None, when properly stored and used.
Conditions to avoid:	Sources of ignition and heat and contact with incompatible materials.
Incompatible materials:	It is not available.
Hazardous decomposition products:	It is not available.

11 – Toxicological information

Acute toxicity:	LD ₅₀ oral: 6075 mg/kg b.w. (estimated). LD ₅₀ dermal: 9161 mg/kg b.w. (estimated).
Skin corrosion/irritation:	The ingredients are non-irritating to skin.
Serious eye damage/irritation:	The ingredients are non-irritating to eyes.
Respiratory or skin sensitization:	The ingredients do not cause skin sensitization.
Germ cell mutagenicity:	None of the ingredients in the mixture are considered to be mutagenic.
Carcinogenicity:	None of the ingredients in the mixture are considered to be carcinogenic.
Reproductive toxicity:	The ingredients in the mixture are considered to show neither reproductive toxicity nor teratogenicity or developmental effects.
Specific target organ toxicity - single exposure:	There are no data in the literature regarding specific target organ toxicity after single exposure.
Specific target organ toxicity - repeated exposure:	There are no data in the literature regarding specific target organ toxicity after repeated exposure.
Aspiration hazard:	There are no data in the literature regarding aspiration hazard of the ingredients of this product.



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12 – Ecological information

Ecotoxicity	<u>Afoxolaner (modelagem computacional):</u> LC ₅₀ /EC ₅₀ : 0.008 - 1.046 mg/L (freshwater and marine fish, invertebrates and plants).
Persistence and degradability:	Based on computer modeling and physical-chemical characteristics of the ingredients in the mixture, the mixture is considered biodegradable in the environment.
Bioaccumulative potential:	Based on the K _{OW} of the ingredients in the mixture, some of the ingredients have the potential for bioaccumulation. However, fugacity modeling and biodegradation testing suggest that the potential for bioaccumulation of those ingredients is low. Therefore, it is considered that the mixture will not accumulate in the environment.
Mobility in soil:	Based on the K _{OC} of the ingredients in the mixture and fugacity modeling, the mixture is not considered to have a high probability of mobility through the soil.
Other adverse effects:	It is not available.

13 – Disposal considerations

Disposal methods

Substance residues:	If this product becomes improper for use or in disuse, contact the company Merial Saúde Animal Ltda. for the devolution and final destination. Do not discard in sewers or watercourses. Disposal should be in accordance with local, state or national legislation.
Contaminated containers:	Do not use the empty package. The inadequate destination of the empty package and product waste in the environment causes soil, water and air contamination, harming fauna, flora and the population's health.

14 – Transport information

Land (Brazil) (*) Not regulated.

*ANTT - resolução nº 420 (12/02/2004) - item 1.1.1.2

Sea ()** Not regulated.

** IMDG Code 2012 - Special provision 335.

Air (*)** Not regulated.

*** DGR IATA 54th Edition, 2013 - Special provision A158.

15 – Regulatory information

This Safety Data Sheet (SDS) was prepared in accordance to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) – 4th ed. (2011).

16 – Other information

The data herein are based on current knowledge and experience. The purpose of this Safety Data Sheet is to describe the products in terms of their safety requirements. The data do not replace any guarantee regarding the products properties. It is the user's responsibility to ensure that his/her activities comply with Federal, State and Local laws.

Additional GHS Precautionary Phrases:

Prevention:	P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product.
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Response: P301 + P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P330: Rinse mouth.

Literature references: AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS (ACGIH). **Threshold Limit Values (TLVs[®]) and Biological Exposure Indices (BEIs[®])**. Cincinnati, OH, 2013.

BRASIL. Decreto nº 96.044, de 18 de maio de 1988. Aprova o Regulamento para o transporte Rodoviário de Produtos Perigosos e dá outras providências. **Diário Oficial [da] União**, Poder Executivo, Brasília, DF, 19 maio 1988.

BRASIL. Ministério dos Transportes. Resolução nº 420, de 12 de fevereiro de 2004. Aprova as instruções Complementares ao Regulamento do Transporte Terrestre de Produtos Perigosos. **Diário Oficial [da] União**, Poder Executivo, Brasília, DF, 31 maio 2004.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA). **Dangerous Goods Regulation**. 54th ed. Montreal, Canada, 2013.

INTERNATIONAL MARITIME ORGANIZATION. **International Maritime Dangerous Goods Code** (IMDG Code). London, England, 2012.

MERIAL LIMITED. **Safety Data Sheet**. Duluth, United States of America, 2013. Unpublished document.

Abbreviations:

b.w. - Body weight.

CAS - Chemical Abstract Service.

EC₅₀ - Concentration of test substance which results in a 50% reduction in biomass relative to the control.

LC₅₀ - Concentration resulting in death to 50% of experimental animals.

LD₅₀ - Administered dose resulting in death to 50% of experimental animals.

NIOSH - National Institute for Occupational Safety and Health.

OSHA - Occupational Safety and Health Administration.

PPE - Personal protective equipment.