



SAFETY DATA SHEET

Version Date: 13 June 2013
Supersedes: 28 January 2013

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: AFOXOLANER 2.27% CHEWABLE TABLETS

Trade Name(s): NEXGARD

The following information is intended to give general health and safety guidance on the manufacturing, storage and transport of the ingredient. Professional and non-professional users should consult label and package inserts for the proper use, storage and disposal of this ingredient. If label and package inserts are not available, use applicable handling and operating procedures.

Chemical Family: Mixture: Isoxazoline

Chemical Name: Mixture - Afoxolaner plus inert ingredients

Synonyms: NA

Formula: Mixture - NA

Product Use: Afoxolaner Soft Chewable is a mixture being developed for the treatment and prevention of ectoparasite infestations on dogs.

COMPANY ADDRESS Merial Limited
3239 Satellite Boulevard
Duluth, Georgia 30096-4640

EMERGENCY INFORMATION:

HEALTH INFORMATION 1-888-637-4251, option 3 (U.S.A. and Canada)

SPILL INFORMATION CHEMTREC® (In the U.S.A.): 1-800-424-9300
CHEMTREC® (International): 1-703-527-3887 (call collect)

2. HAZARDS IDENTIFICATION

Warning - Emergency Overview

The mixture is not anticipated to be harmful if swallowed. Very toxic to aquatic life. Do not eat, drink, or smoke while handling this material. Wash hands thoroughly after handling. Dispose of all waste mixture and containers in accordance with national, regional, state and local regulations.

Risk phrase(s):

R50 Very Toxic To Aquatic Organisms


Safety Phrase(s):

S2 Keep Out Of The Reach Of Children

S29 Do Not Empty Into Drains

S60 Avoid Release To The Environment

The following three boxes are relevant to GHS classification and are not labeling guides.

Environmental Hazard (GHS Classification)	Category	Pictogram	Signal Word	Hazard Statement
Acute Aquatic Hazard	1		Warning	Very toxic to aquatic life (H400)

POTENTIAL HEALTH EFFECTS

The following potential human health effects are the results of the exposure to the mixture or extrapolated from the individual ingredients of the mixture.

EYE:	The mixture is not anticipated to produce eye irritation.
SKIN:	The mixture is not anticipated to be harmful if in contact with skin. The mixture is not anticipated to produce skin irritation or sensitization.
INHALATION:	The mixture is not anticipated to produce vapors in a sufficient quantity that would be irritating to eyes, skin, nose and/or throat.
INGESTION:	The mixture is not anticipated to be harmful if swallowed.
CHRONIC EFFECTS:	The mixture is not anticipated to be carcinogenic, mutagenic, a reproductive toxin or a developmental toxin.
SIGNS AND SYMPTOMS OF EXPOSURE:	None known.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	None known.

POTENTIAL ENVIRONMENTAL EFFECTS	Some ingredients of this mixture are very toxic to aquatic life (computer modeling). Avoid release to the environment.
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No.	%W/W
Afoxolaner	1093861-60-9	2.27
Non-hazardous	-	97.73

4. FIRST AID MEASURES

EYE CONTACT: In case of contact or if eyes become irritated during administration, immediately flush eyes with plenty of water for at least 15 minutes. If ocular irritation persists, seek medical attention.

SKIN CONTACT:	In case of contact or if skin become irritated during administration, immediately wash skin with soap and water. Remove contaminated clothing and shoes and launder before reuse. If skin irritation develops and persists or recurs, seek medical attention.
INHALATION:	If lungs become irritated or breathing is difficult during administration, move to fresh air and seek medical attention.
INGESTION:	If swallowed, not anticipated to cause problems, however, if problems develop, seek immediate medical attention.

5. FIRE FIGHTING MEASURES

UNUSUAL FIRE AND EXPLOSION HAZARDS:	Prevent accumulation of vapors. When heated to decomposition, may produce oxides of carbon and nitrogen.
EXTINGUISHING MEDIA:	Carbon dioxide, dry chemical extinguishers, foam, water fog or spray. Large fires with "alcohol"-type foam extinguishers. Use extinguishing media appropriate for surrounding materials.
PROTECTION OF FIREFIGHTERS:	Fire fighters should wear approved/certified positive pressure self-contained breathing apparatus and full protective equipment.

6. ACCIDENTAL RELEASE MEASURES

For transportation-related and large spills call CHEMTREC at 1-800-424-9300. If outside the U.S.A., call CHEMTREC collect at 1-703-527-3887.

For small spills, use protective equipment as prescribed in Section 8. Sweep up and place in properly labeled containers. Dispose contaminated material in sealed container as waste according to Section 13.

PERSONAL PRECAUTIONS:	Evacuate unnecessary personnel and eliminate all sources of ignition. Follow protective measures provided under Personal Protection in Section 8.
ENVIRONMENTAL PRECAUTIONS:	Avoid release to the environment.
METHODS FOR CLEANING UP:	For small spills, sweep up and place in properly labeled containers.

7. HANDLING AND STORAGE

HANDLING:	Do not eat, drink, or smoke while using this ingredient. Keep container tightly closed when not in use. Provide for adequate ventilation. Avoid prolonged or repeated exposure. Do not get in eyes, on skin or clothing. Keep away from incompatible materials (see Section 10).
PROTECTION AGAINST EXPLOSION AND FIRES:	Not anticipated to burn or explode in fire conditions.
STORAGE:	Store in a well-ventilated place. Keep cool. Store locked up.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION (INDUSTRIAL)

ENGINEERING CONTROLS:	Use local exhaust ventilation appropriate for solid materials.
EYE / FACE PROTECTION:	Wear safety glasses with side shields for normal handling.
SKIN PROTECTION:	Wear butyl rubber, neoprene, vinyl or other chemical resistant impervious gloves.
RESPIRATORY PROTECTION:	For normal use, ensure adequate exhaust ventilation.
GENERAL HYGIENE CONSIDERATIONS:	Do not eat, drink, or smoke while using this ingredient. Wash hands thoroughly after use.
OTHER:	Provide emergency shower and eyewash facility in close proximity to use. Remove contaminated clothing and laundered before reuse or discard.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solid (a circular or rectangular-shaped chew ranging in size from 0.5 g to 6.0 g)
Color:	Mottled red to reddish brown
Odor:	No data
pH:	No data
Melting Point:	~111-150 °C (API)
Boiling Point:	No data
Flash Point:	No data
Flammability:	Non-flammable (API and ingredients)
Lower Explosive Limit:	No data
Upper Explosive Limit:	No data
Autoignition Temperature:	365-440 °C
Decomposition Temperature:	No data
Vapor Pressure:	7×10^{-16} (computer generated; API)
Vapor Density:	No data
Solubility in Water (mg/mL):	3.35×10^{-7} (API)
Specific gravity:	No data
Viscosity:	No data
Partition Coefficient (n-octanol/Water):	$\text{Log } K_{ow} = 5.15$ (API)
Partition Coefficient (n-octanol/Air):	$\text{Log } K_{oa} = 16.001$ (computer generated)
Soil Partition Coefficient:	$\text{Log } K_{oc} = 1.137 \times 10^4 - 4.577 \times 10^7$ (computer generated)

10. STABILITY AND REACTIVITY

STABILITY:	Stable under normal conditions.
CONDITIONS TO AVOID:	Unknown; DO NOT expose to heat, flames or extreme temperatures.

MATERIALS TO AVOID:	Unknown; DO NOT mix with other materials unless specifically instructed to do so under the guidance of a trained chemist.
HAZARDOUS DECOMPOSITION PRODUCTS:	When heated to decomposition may produce oxides of carbon and nitrogen as well as other uncharacterized decomposition products.
HAZARDOUS POLYMERIZATION:	Will not occur.

11. TOXICOLOGICAL INFORMATION

POTENTIAL EXPOSURE ROUTES:	This ingredient may be encountered through skin contact or ingestion. Due to mixture's physical properties and form, eye contact is not anticipated to be a relevant route of exposure.
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ACUTE ANIMAL TOXICITY DATA: *The following toxicity data are derived from the ingredients of the mixture, and are considered relevant to the final mixture.*

Parameter	Result	Comments
Oral LD₅₀ (mg/kg)	ATE = 6075	65% of the mixture consist of ingredients of unknown oral toxicity
Dermal LD₅₀ (mg/kg)	ATE = 9161	74% of the mixture consist of ingredients of unknown oral toxicity
Inhalation LC₅₀ (mg/L)	NE	Due to the low vapor pressure of ingredients, the mixture does not pose a respiratory hazard
Ocular Irritant	Non-irritating	Classification of mixture is based on the information/data of the ingredients
Dermal Irritant	Non-irritating	Classification of mixture is based on the information/data of the ingredients
Dermal Sensitizer	Non-sensitizing	Classification of mixture is based on the information/data of the ingredients

ATE – Acute Toxicity Estimate, NE = Not Established

CARCINOGENICITY:	None of the ingredients in the mixture are considered to be carcinogenic.
MUTAGENICITY:	None of the ingredients in the mixture are considered to be mutagenic.
REPRODUCTIVE EFFECTS:	None of the ingredients in the mixture are considered to be reproductive toxins.
TERATOGENICITY/ DEVELOPMENTAL EFFECTS:	None of the ingredients in the mixture are considered to be teratogenic or developmental toxins under normal use conditions.
SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE:	Not Established.

SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE:	Not Established.
INTERACTIONS WITH OTHER CHEMICALS WHICH ENHANCE TOXICITY:	Not Established.

12. ECOLOGICAL INFORMATION

TOXICITY:	Based upon computer modeling, Afoxolaner is considered toxic to highly toxic to aquatic organisms. The LC ₅₀ /EC ₅₀ ranged from 0.008 to 1.046 mg/L for freshwater and marine fish, invertebrates and plants. Based on computer modeling, the mixture is considered a Category 1 Acute Aquatic Hazard (GHS standards). However, due to limited quantities (i.e., packaging) the mixture is not considered an environmental hazard.
PERSISTENCE AND DEGRADABILITY:	Based upon computer modeling and physico-chemical characteristics of the ingredients in the mixture, the mixture is considered biodegradable in the environment.
BIOACCUMULATION 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.

13. DISPOSAL CONSIDERATIONS	Responsibility for proper waste disposal is with the owner of the waste.
	Dispose of all waste ingredient and containers in accordance with national, regional, state and local regulations.

14. TRANSPORT INFORMATION

Air Transport ICAO-TI and IATA-DGR:	ICAO/IATA Class:	Not Regulated
	UN/ID Number:	-
	Label:	-
	Packing Group:	-
	Proper Shipping Name:	-
Maritime Transport IMDG:	IMDG Class:	Not Regulated
	UN Number:	-
	Label:	-
	Packaging Group:	-
	EMS Number:	-
	Marine Pollutant:	-
	Proper Shipping Name:	-

Land Transport ADR/RID: (cross-border)	ADR/RID Class:	Not Regulated
	Danger Code (Kemler):	-
	UN Number:	-
	Packaging Group:	-
	Proper Shipping Name:	-
USDOT Regulations:	Hazard Class:	Not Regulated
	Identification Number:	-
	Packing Group:	-
	Proper Shipping Name:	-
	(technical name)	

15. REGULATORY INFORMATION

GHS Hazard Phrase:	H400	Very toxic to aquatic life
GHS Precautionary Phrases - Prevention:	P264	Wash hands thoroughly after handling.
	P270	Do not eat, drink or smoke when using this product.
GHS Precautionary Phrases - Response:	P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
	P330	Rinse mouth.
GHS Precautionary Phrases - Disposal:	P501	Dispose of contents/container to in accordance with local/regional/national/international regulation.

United States:

This ingredient is exempt from classification under Environmental Protection Agency (EPA) Superfund Amendments and Reauthorization Act (SARA), Hazardous Substances List or Toxic Substances Control Act (TSCA)

STATE RIGHT-TO-KNOW STATUS

Component	CA	NJ	PA	MA
Afoxolaner	Not listed	Not listed	Not Listed	Not listed

CA = California Proposition 65

NJ = New Jersey

PA = Pennsylvania

MA = Massachusetts

Canada:

CANADIAN WHMIS CLASS:

The ingredients of this mixture have been classified in accordance with the hazard criteria of the CPR.

16. OTHER INFORMATION

Information contain within this document was based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) (a.k.a. Purple Book).

KEY/LEGEND USED: ATE – Acute Toxicity Estimate
NE = Not Established
LD₅₀ = The median lethal dose where 50% mortality is noted
LC₅₀ = The median lethal concentration (in air or solution) where 50% mortality is noted
TWA = Time Weighted Average
OSHA PEL = Occupational Safety and Health Association Permissible Exposure Limits
ACGIH TLV = American Conference of Governmental Industrial Hygienists Threshold Limit Values

REVISION: Revised the product name and add the Trade name.

DISCLAIMER: The requirements or recommendations of any relevant site or working procedure, system or policy in force or arising from any risk assessment involving the substance or mixture should take precedence over any of the guidance contained in this safety data sheet where there is a difference in the information given.

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