



SAFETY DATA SHEET

Version Date: 29 July 2014
Supersedes: 30 July 2000

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Ivermectin 0.6% Premix

Trade Name(s): IVERMIX PREMIX
IVOMEK 0.6%
IVOMEK 0.6% GYOGYPREMIX A.U.V
IVOMEK 0.6% PREM. A.U.V.
IVOMEK 0.6% PREMIX
IVOMEK FOR SWINE
IVOMEK ORAAL POEDER 0,6%
IVOMEK POWDRE ORALE 0.6%
IVOMEK PRAMIX - PULVER FUR SCHWEINE
IVOMEK PRE-MISTURA PARA SUINOS (0.6%)
IVOMEK PREMIX
IVOMEK PREMIX - PULVER FUR SCHWEINE
IVOMEK PREMIX 0.6%
IVOMEK PREMIX 0.6% PARA CERDOS
IVOMEK PREMIX 0.6%, PREMELANGE MEDICAMENTEUX
IVOMEK PREMIX FOR PIGS
IVOMEK PREMIX FOR PIGS 0.6% W/W
IVOMEK PREMIX FOR SWINE
IVOMEK VET 0.6% PREMIX
IVOMEK VET 6MG/G PREMIX FOR MEDICATED FEED
IVOMEK VET., MSD, PREMIX 0.6% IVERMECTIN
VALANEQ 0.6% W/W
ZIMECTERIN (IVERMECTIN) EZ 0.6%

The following information is intended to give general health and safety guidance on the manufacturing, storage and transport of the ingredients. Professional and non-professional users should consult label and package inserts for the proper use, storage and disposal of the ingredients.

Chemical Family: Mixture: Macrocyclic lactone plus inert ingredients
Chemical Name: Mixture: Ivermectin plus inert ingredients
Synonyms: NA
Formula: Mixture
Product Use: Ivermectin 0.6% Premix is used in veterinary medicine for the treatment and control of gastro-intestinal roundworms, lungworms, lice and mange in adult and growing pigs.

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 – “Warning”**

Toxic to aquatic life with long lasting effects. Do not eat, drink, or smoke when handling this mixture. Wash hands thoroughly after handling. Dispose of all waste mixture and containers in accordance with national, regional, state and local regulations.

Risk phrase(s):



- R52 Very Toxic To Aquatic Organisms (acute effects)
R53 May Cause Long-Term Adverse Effects In The Aquatic Environment

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 information is relevant to GHS classification and is not labeling guidance.

Health Hazard (GHS Classification)	Category	Pictogram	Signal Word	Hazard Statement
Acute Oral Toxicity	5	None	Warning	May be harmful if swallowed (H303)

Environmental Hazard (GHS Classification)	Category	Pictogram	Signal Word	Hazard Statement
Acute Aquatic Hazard	1		Warning	Very toxic to aquatic life (H400)
Chronic Aquatic Hazard	2		-	Toxic to aquatic life with long lasting effects (H411)

POTENTIAL HEALTH EFFECTS

EYE:	The mixture is not anticipated to produce eye irritation. However, because of the physical nature of the mixture (<i>i.e.</i> , powder) direct exposure to the eyes may result in mechanical trauma.
SKIN:	The mixture is not anticipated to produce skin irritation or sensitization. However, because of the physical nature of the mixture (<i>i.e.</i> , powder) direct exposure to the skin may result in mechanical trauma.
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 may 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:	At higher exposures in humans and animals vomiting, tachycardia, blood pressure fluctuation, CNS effects (somnolence, ataxia) and visual disturbances (mydriasis) have been observed. At lower exposures signs and symptoms include: allergic reactions; joint or muscle pain; fever; painful and tender glands in neck, armpits, or groin; pruritus or skin rash; tachycardia; facial or peripheral edema; headache; diarrhea; and dizziness. People with known hypersensitivity (allergy) to macrocyclic lactone should avoid contact with ivermectin.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	None known.

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

Ingredients	CAS No.	Proportion % w/w
Ivermectin	70288-86-7	0.6
Non-hazardous Substances		99.4

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. Remove contact lenses, if present and easy to do. Continue rinsing. If ocular irritation persists, seek medical attention.
SKIN CONTACT:	In case of contact or if skin become irritated during administration, immediately wash skin with plenty of soap and water. Remove

contaminated clothing and shoes and launder or clean before reuse. If skin irritation develops and persists or recurs, seek medical attention.

INHALATION: Do not breathe dust/fume/gas/mist/vapor/spray. If lungs become irritated or breathing is difficult during administration, move to fresh air and seek medical attention.

INGESTION: If swallowed, rinse mouth and seek medical attention.

5. FIRE FIGHTING MEASURES

UNUSUAL FIRE AND EXPLOSION HAZARDS: Prevent accumulation of dust material.

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: No special requirements are needed for single units or packages. For larger amounts, self-contained breathing apparatus and full protective equipment and clothing are recommended to minimize contact with respiratory tract, skin and eyes.

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. Clean affected area with soap and water. Dispose of materials according to the applicable international, national, regional, state, or local regulations.

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: No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

STORAGE: Store in a well-ventilated place. Keep cool.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION (INDUSTRIAL)

No exposure limits have been set for Ivermectin.

ENGINEERING CONTROLS: Use local exhaust ventilation.

EYE / FACE PROTECTION: Wear chemical splash goggles when cleaning spilled mixture or if the potential for eye contact exists, wear safety glasses with side shields for normal handling.

SKIN PROTECTION: Wear butyl rubber, neoprene, vinyl or other chemical resistant impervious gloves. Persons known to be allergic to latex rubber should select a non-latex glove. Gloves should be changed regularly, and removed immediately after known contamination.

RESPIRATORY PROTECTION: Wear approved/certified respirator when cleaning up spills. For normal use, ensure adequate exhaust ventilation.

GENERAL HYGIENE CONSIDERATIONS: Do not eat, drink, or smoke while using this mixture. Wash hands thoroughly after use. Wear protective clothing.

OTHER: Provide emergency shower and eyewash facility in close proximity to use. Remove/take off immediately all contaminated clothing and laundered or clean before reuse. Contaminated work clothing should not be allowed out of the workplace.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solid
Color:	Brown
Odor:	No data
pH:	No data
Solubility in Water:	No data
Specific gravity at 20°C (68°F):	No data
Viscosity:	No data
Melting/Freezing Point:	No data
Boiling Point:	No data
Flash Point:	No data
Flammability:	No data
Lower Explosive Limit:	No data
Upper Explosive Limit:	No data
Autoignition Temperature:	No data
Decomposition Temperature:	No data
Vapor Pressure:	No data
Vapor Density:	No data
Partition Coefficient (n-octanol/Water):	Log K_{ow} -5.56 – 4.48 (ingredients) (computer generated)
Partition Coefficient (n-octanol/Air):	Log K_{oa} 5.358 – 29.748 (ingredients) (computer generated)
Soil Partition Coefficient:	Log K_{oc} -3.657 – 1.88 (ingredients) (computer generated)

10. STABILITY AND REACTIVITY

STABILITY:	Stable under normal conditions.
CONDITIONS TO AVOID:	Avoid exposure to heat, sparks, or flame.
MATERIALS TO AVOID:	Avoid strong oxidizing agents
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:	The final mixture may be encountered through dermal contact or ingestion.
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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 >2000 (Category 5)	Classification of mixture on the basis of information/data on ingredients and corresponding concentration
Dermal LD₅₀ (mg/kg)	ATE >5000 (exceeds classification, none required)	Classification of mixture on the basis of information/data on ingredients and corresponding concentration
Inhalation LC₅₀ (mg/L)	NE	
Ocular Irritant	Non-irritating (GHS)	Classification of mixture on the basis of information/data on ingredients and corresponding concentration
Dermal Irritant	Non-irritating (GHS)	Classification of mixture on the basis of information/data on ingredients and corresponding concentration
Dermal Sensitizer	Non-sensitizing (GHS)	Classification of mixture on the basis of information/data on ingredients and corresponding concentration

ATE – Acute Toxicity Estimate, NE = Not Established, GHS = Globally Harmonized System of Classification and Labeling of Chemicals

CARCINOGENICITY:	<p>IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.</p> <p>ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.</p> <p>NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.</p> <p>OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.</p>
MUTAGENICITY:	No component of this product present at levels greater than or equal to 0.1%, is identified as a known or anticipated mutagenic toxin.
REPRODUCTIVE EFFECTS:	No component of this product present at levels greater than or equal to 0.1%, is identified as a known or anticipated reproductive toxins.
TERATOGENICITY/ DEVELOPMENTAL EFFECTS:	No component of this product present at levels greater than or equal to 0.1%, is identified as a known or anticipated teratogenic or developmental toxins.
SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE:	None known
SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE:	None known
INTERACTIONS WITH OTHER CHEMICALS WHICH ENHANCE TOXICITY:	None known

12. ECOLOGICAL INFORMATION

The following toxicity data are derived from the ingredients of the mixture, and are considered relevant to the mixture.

TOXICITY:	<p><u>Acute Aquatic Toxicity:</u> LC₅₀/EC₅₀ for ivermectin is less than 1 mg/L for freshwater and marine fish and invertebrates, and between 1 mg/L and 10 mg/L for plants. Based on test results for the most sensitive species (freshwater and marine invertebrates) and mathematical modeling, the mixture is considered a Category 1 Acute Aquatic Hazard (GHS standards).</p> <p><u>Chronic Aquatic Toxicity:</u> NOEC for ivermectin is less than 0.01 mg/L for freshwater and marine invertebrates. Based on test results for the most sensitive species (freshwater and marine invertebrates) and mathematical modeling, the mixture is considered a Category 1 Chronic Aquatic Hazard (GHS standards).</p>
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PERSISTENCE AND DEGRADABILITY:	Based upon biodegradation testing, computer modeling and physico-chemical characteristics of the ingredients in the mixture, the mixture is considered readily 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 bioconcentrate 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 mixture and containers in accordance with international, national, regional, state and local regulations.

SPECIAL PRECAUTIONS:	As the active ingredient is highly toxic to aquatic organisms, great care is need to ensure that the product does not reach a drain, waterway or unpaved soil.
PREFERRED METHOD OF DISPOSAL:	For the disposal of the clean-up materials from a significant spill or leak, negotiate with the EPA responsible for the jurisdiction. Incineration may be permitted by local authority; otherwise secure landfill should be used, if approved by local authority.

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:	-
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:	H303	May be harmful if swallowed
	H400	Very toxic to aquatic life
	H411	Toxic to aquatic life with long lasting effects
GHS Precautionary Phrases - Prevention:	P264	Wash hands thoroughly after handling.
GHS Precautionary Phrases - Response:	P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
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
Ivermectin	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.

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
	LD ₅₀ : The median lethal dose where 50% mortality is noted
	LC ₅₀ : The median lethal concentration (in air or solution) where 50% mortality is noted
	EC ₅₀ : The median effective concentration where 50% of the population is effected
	NOEC: No-observed-effect-concentration

GHS: Globally Harmonized System of Classification and Labelling of Chemicals
IARC: International Agency for Research on Cancer
NTP: National Toxicology Program
Kow: Octanol-Water Partition Coefficient
Koc: Soil Organic Carbon-Water Partitioning Coefficient
Koa: Octanol-Air Partition Coefficient
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
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

REVISION: New format; GHS classification.

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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