1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Ivermectin 0.6% Premix

Trade Name(s): IVERMIX PREMIX
IVOMEC 0.6%
IVOMEC 0.6% GYOGPREMIX A.U.V
IVOMEC 0.6% PREM. A.U.V.
IVOMEC 0.6% PREMIX
IVOMEC FOR SWINE
IVOMEC ORAAL POEDER 0,6%
IVOMEC POUDRE ORALE 0.6%
IVOMEC PRAMIX - PULVER FUR SCHWEINE
IVOMEC PRE-MISTURA PARA SUINOS (0.6%)
IVOMEC PREMIX
IVOMEC PREMIX - PULVER FUR SCHWEINE
IVOMEC PREMIX 0.6%
IVOMEC PREMIX 0.6% PARA CERDOS
IVOMEC PREMIX 0.6%, PREMELANGE MEDICAMENTEUX
IVOMEC PREMIX FOR PIGS
IVOMEC PREMIX FOR PIGS 0.6% W/W
IVOMEC PREMIX FOR SWINE
IVOMEC VET 0.6% PREMIX
IVOMEC VET 6MG/G PREMIX FOR MEDICATED FEED
IVOMEC 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
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.

<table>
<thead>
<tr>
<th>Health Hazard (GHS Classification)</th>
<th>Category</th>
<th>Pictogram</th>
<th>Signal Word</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Oral Toxicity</td>
<td>5</td>
<td>None</td>
<td>Warning</td>
<td>May be harmful if swallowed (H303)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Environmental Hazard (GHS Classification)</th>
<th>Category</th>
<th>Pictogram</th>
<th>Signal Word</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Aquatic Hazard</td>
<td>1</td>
<td>![Acute aquatic hazard pictogram]</td>
<td>Warning</td>
<td>Very toxic to aquatic life (H400)</td>
</tr>
<tr>
<td>Chronic Aquatic Hazard</td>
<td>2</td>
<td>![Chronic aquatic hazard pictogram]</td>
<td>-</td>
<td>Toxic to aquatic life with long lasting effects (H411)</td>
</tr>
</tbody>
</table>
POTENTIAL HEALTH EFFECTS

EYE: The mixture is not anticipated to produce eye irritation. However, because of the physical nature of the mixture (i.e., 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.e., 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS No.</th>
<th>Proportion % w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>0.6</td>
</tr>
<tr>
<td>Non-hazardous Substances</td>
<td></td>
<td>99.4</td>
</tr>
</tbody>
</table>

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.

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### 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.

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### 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.

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### 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.
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.

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9. **PHYSICAL AND CHEMICAL PROPERTIES**

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

**ACUTE ANIMAL TOXICITY DATA:** (The following toxicity data are derived from the ingredients of the mixture, and are considered relevant to the final mixture.)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Result</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD₅₀ (mg/kg)</td>
<td>ATE &gt;2000</td>
<td>Classification of mixture on the basis of information/data on ingredients and corresponding concentration</td>
</tr>
<tr>
<td></td>
<td>(Category 5)</td>
<td></td>
</tr>
<tr>
<td>Dermal LD₅₀ (mg/kg)</td>
<td>ATE &gt;5000</td>
<td>Classification of mixture on the basis of information/data on ingredients and corresponding concentration</td>
</tr>
<tr>
<td></td>
<td>(exceeds classification, none required)</td>
<td></td>
</tr>
<tr>
<td>Inhalation LC₅₀ (mg/L)</td>
<td>NE</td>
<td></td>
</tr>
<tr>
<td>Ocular Irritant</td>
<td>Non-irritating (GHS)</td>
<td>Classification of mixture on the basis of information/data on ingredients and corresponding concentration</td>
</tr>
<tr>
<td>Dermal Irritant</td>
<td>Non-irritating (GHS)</td>
<td>Classification of mixture on the basis of information/data on ingredients and corresponding concentration</td>
</tr>
<tr>
<td>Dermal Sensitizer</td>
<td>Non-sensitizing (GHS)</td>
<td>Classification of mixture on the basis of information/data on ingredients and corresponding concentration</td>
</tr>
</tbody>
</table>

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

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.

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.

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.

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.

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:

Acute Aquatic Toxicity: 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).

Chronic Aquatic Toxicity: 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).
### 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 needed 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: -
- Proper Shipping Name: -

**Land Transport ADR/RID:**
- ADR/RID Class: Not Regulated
- Danger Code (Kemler): -
- UN Number: -
- Packaging Group: -
- Proper Shipping 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

<table>
<thead>
<tr>
<th>Component</th>
<th>CA</th>
<th>NJ</th>
<th>PA</th>
<th>MA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>Not listed</td>
</tr>
<tr>
<td>CA = California Proposition 65</td>
<td>NJ = New Jersey</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PA = Pennsylvania</td>
<td>MA = Massachusetts</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
- LD50: The median lethal dose where 50% mortality is noted
- LC50: The median lethal concentration (in air or solution) where 50% mortality is noted
- EC50: 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.

To the best of our knowledge, the information provided in this safety data sheet is accurate at the date of publication and will be updated as and when appropriate. However, neither Merial nor any of its subsidiaries or parents assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards may be described herein, Merial cannot guarantee that these are the only hazards that exist.