1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: ALVERIN PLUS (Ivermectin/Clorsulon) Injection
Trade Name: ALVERIN PLUS; LEVATUM
Synonyms: Ivermectin and Clorsulon Injection; Alverin; Levatum/Alverin Plus Solution; Levatum D; Levatum Plus; Levatum Super; Levatum/Alverin Plus 10/100 mg/ml
Chemical Family: Avermectin macrocyclic lactone, Benzenesulfonamide

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as anti-worm agent (anthelmintic) endectocide
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

2. HAZARDS IDENTIFICATION

Appearance: Clear pale yellow to yellow liquid

Classification of the Substance or Mixture

GHS - Classification
- Acute Oral Toxicity: Category 4
- Reproductive Toxicity: Category 2
- Acute aquatic toxicity: Category 1
- Chronic aquatic toxicity: Category 1

Label Elements

Signal Word: Warning
Hazard Statements:
- H302 - Harmful if swallowed
- H361 - Suspected of damaging fertility or the unborn child
- H410 - Very toxic to aquatic life with long lasting effects
Precautionary Statements:

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P273 - Avoid release to the environment
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P391 - Collect spillage
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

Short Term: May cause eye and skin irritation (based on components).
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus. May cause effects in cardiovascular system, nervous system, liver, heart, and skin through prolonged or repeated exposure.

Known Clinical Effects:
Cases of severe overdose may lead to swelling, allergic skin rash, headache, dizziness, weakness, nausea, vomiting, diarrhea, seizure, clumsy motion of limbs/trunk (ataxia), shortness of breath (dyspnea) abdominal discomfort.

Australian Hazard Classification (NOHSC):

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerol</td>
<td>56-81-5</td>
<td>200 - 289 - 5</td>
<td>Not Listed</td>
<td>&lt;50</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200 - 338 - 0</td>
<td>Not Listed</td>
<td>10</td>
</tr>
<tr>
<td>Clorsulon</td>
<td>60200-06-8</td>
<td>262-100-2</td>
<td>Repr. Cat 2 (H261)</td>
<td>10</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>274-536-0</td>
<td>Acute Tox.2 (H300)</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr. 2 (H361)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aq. Acute 1 (H400)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aq. Chronic 1 (H410)</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: ALVERIN PLUS (Ivermectin/Clorsulon) Injection
Revision date: 30-Jul-2015

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Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures
Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed
Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

**7. HANDLING AND STORAGE**

**Precautions for Safe Handling**
When handling, use appropriate personal protective equipment (see Section 8). Minimize generating airborne mists and vapors. Avoid breathing mist or aerosols. Avoid contact with eyes, skin and clothing. Avoid accidental injection. Wash thoroughly after handling. Releases to the environment should be avoided.

**Conditions for Safe Storage, Including any Incompatibilities**
- **Storage Conditions:** Store as directed by product packaging.
- **Specific end use(s):** No data available

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**Control Parameters**
Refer to available public information for specific member state Occupational Exposure Limits.

**Glycerol**
- **Australia TWA:** 10 mg/m³
- **Belgium OEL - TWA:** 10 mg/m³
- **Czech Republic OEL - TWA:** 10 mg/m³
- **Estonia OEL - TWA:** 10 mg/m³
- **Finland OEL - TWA:** 20 mg/m³
- **France OEL - TWA:** 10 mg/m³
- **Germany (DFG) - MAK:** 50 mg/m³
- **Greece OEL - TWA:** 10 mg/m³
- **Ireland OEL - TWAs:** 10 mg/m³
- **OSHA - Final PELS - TWAs:** 15 mg/m³
- **Poland OEL - TWA:** 10 mg/m³
- **Portugal OEL - TWA:** 10 mg/m³
- **Spain OEL - TWA:** 10 mg/m³
- **Switzerland OEL - TWAs:** 50 mg/m³

**Propylene glycol**
- **Australia TWA:** 150 ppm
- **Belgium OEL - TWA:** 474 mg/m³
- **Czech Republic OEL - TWA:** 10 mg/m³
- **Ireland OEL - TWAs:** 150 ppm
- **Latvia OEL - TWA:** 7 mg/m³
- **Lithuania OEL - TWA:** 7 mg/m³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

**Clorsulon**
- **Zoetis OEB:** OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ivermectin

Zoetis OEB

OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

Exposure Controls

Engineering Controls:
Engineering controls should be used as the primary means to control exposures. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:
Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:
Wear safety glasses or goggles if eye contact is possible.

Skin:
Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:
Whenever air contamination (mist or aerosol) is generated, respiratory protection is recommended as a precaution to minimize exposure. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Odor: No data available.
Color: Pale yellow to yellow
Odor Threshold: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
No data available
Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available
10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
   Oxidizing Properties: None
   Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
   Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
   Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.
Routes of exposure: eye contact, skin contact

Acute Toxicity: (Species, Route, End Point, Dose)

- **Clorsulon**
  - Mouse Oral LD50 > 10,000 mg/kg

- **Glycerol**
  - Rat Oral LD 50 12600 mg/kg

- **Ivermectin**
  - Rat Oral LD50 10 mg/kg

- **Propylene glycol**
  - Rat Oral LD 50 22,000 mg/kg
  - Mouse Oral LD 50 24,900mg/kg
  - Rabbit Dermal LD 50 20,800mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Ingestion Acute Toxicity
Harmful if swallowed.

Irritation / Sensitization: (Study Type, Species, Severity)

- **Glycerol**
  - Skin Irritation Rabbit Mild
  - Eye Irritation Rabbit Mild

- **Propylene glycol**
  - Skin Irritation Rabbit Mild
  - Eye Irritation Rabbit Mild

Irritation / Sensitization Comments: May cause eye irritation.
Skin Irritation / Sensitization: May cause skin irritation.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
11. TOXICOLOGICAL INFORMATION

Clorsulon
14 Week(s)  Dog  Oral 2 mg/kg/day  NOEL  Thyroid
13 Week(s)  Rat  Oral 20 mg/kg/day  LOAEL  Thyroid
1 Month(s)  Dog  Oral 10 mg/kg/day  LOAEL  Liver, Spleen, Bone Marrow
1 Month(s)  Rat  Oral 10 mg/kg/day  LOAEL  Bladder, Thyroid

Glycerol
28 Day(s)  Rat  Oral 16800 mg/kg  LOAEL  Endocrine system

Ivermectin
14 Week(s)  Dog  Oral 0.5 mg/kg/day  NOEL  Central nervous system, Gastrointestinal System

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Clorsulon
Embryo / Fetal Development  Mouse  Oral 10 mg/kg/day  NOEL  Fetotoxicity
Embryo / Fetal Development  Rabbit  Oral 10 mg/kg/day  NOEL  Fetotoxicity
Fertility and Embryonic Development  Rat  Oral 30 mg/kg/day  NOAEL  Fertility, Fetotoxicity

Glycerol
Reproductive & Fertility-Males  Rat  Oral 100 mg/kg  LOEL  Fertility

Ivermectin
Reproductive & Fertility  Rat  Oral 0.8 mg/kg/day  NOEL  Fetotoxicity
Embryo / Fetal Development  Mouse  Oral 0.2 mg/kg/day  NOEL  Maternal Toxicity, Teratogenic
Embryo / Fetal Development  Rat  Oral 5 mg/kg/day  NOEL  Maternal Toxicity, Teratogenic
Embryo / Fetal Development  Rabbit  Oral 1.5 mg/kg/day  NOEL  Fetotoxicity, Teratogenic

Reproductive & Development  may have the potential to produce effects on the developing fetus.
Toxicity Comments:

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Clorsulon
In Vitro Bacterial Mutagenicity (Ames)  Salmonella  Negative
In Vitro Unscheduled DNA Synthesis  Human  Negative
In Vitro Direct DNA Damage  Human  Negative
In Vivo Micronucleus  Mouse  Positive
In Vivo Chromosome Aberration  Mouse  Positive

Ivermectin
Bacterial Mutagenicity (Ames)  Salmonella  Negative
Mammalian Cell Mutagenicity  Mouse Lymphoma  Negative
Unscheduled DNA Synthesis  Human  Negative

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Product Level Toxicity Data
### 11. TOXICOLOGICAL INFORMATION

#### Acute Toxicity Estimate (ATE), oral

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Duration</th>
<th>End Point</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water Flea)</td>
<td>OECD</td>
<td>NOEC</td>
<td>21 Days</td>
<td>0.0003 ng/L</td>
</tr>
</tbody>
</table>

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. Releases to the environment should be avoided.

**Toxicity:**

**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Duration</th>
<th>Endpoint</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oncorhynchus mykiss</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shrimp</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daphnia Magna (Water Flea)</td>
<td>OECD</td>
<td>NOEC</td>
<td>21 Days</td>
<td>0.0003 ng/L</td>
</tr>
<tr>
<td>Daphnia magna (Water Flea)</td>
<td>OECD</td>
<td>LC50</td>
<td>48 Hours</td>
<td>0.007 mg/L</td>
</tr>
</tbody>
</table>

**Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)**

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Duration</th>
<th>Endpoint</th>
<th>Result</th>
<th>Adverse Endpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daphnia magna (Water Flea)</td>
<td>OECD</td>
<td>NOEC</td>
<td>21 Day(s)</td>
<td>0.0003 ng/L</td>
<td></td>
</tr>
</tbody>
</table>

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Should not be released into the environment. Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

As of January 1, 2015, materials offered for transport that are classified for transportation only as Marine Pollutants and which are packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 Liters or less for liquids or having a net mass per single or inner packaging of 5 kilograms or less for solids are NOT subject to ICAO/IATA, IMDG, or ADR transport regulations provided the general packaging requirements of those regulations are met. Refer to ICAO/IATA A197, IMDG 2.10.2.7, ADR SP 375.
UN number: UN 3082
UN proper shipping name: Environmentally hazardous substances, liquid, n.o.s. (Ivermectin)
Transport hazard class(es): 9
Packing group: III
Environmental Hazard(s): Marine Pollutant

Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

DOT / ANTT: Not regulated for transportation

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class: Class D, Division 2, Subdivision A
This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

Glycerol
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
REACH - Annex V - Exemptions from the obligations of Register:
EU EINECS/ELINCS List: 200-289-5

Propylene glycol
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 200-338-0
15. REGULATORY INFORMATION

Clorsulon
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Standard for the Uniform Scheduling for Drugs and Poisons:
  - Schedule 5
- EU EINECS/ELINCS List: 262-100-2

Ivermectin
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Standard for the Uniform Scheduling for Drugs and Poisons:
  - Schedule 4
  - Schedule 5
  - Schedule 7
- EU EINECS/ELINCS List: 274-536-0

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
- Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed
- Reproductive toxicity-Cat.2; H361 - Suspected of damaging fertility or the unborn child if inhaled
- Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
- Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

Data Sources:
The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision:
Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 11 - Toxicology Information. Updated Section 2 - Hazard Identification.
Updated Section 3 - Composition / Information on Ingredients.

Prepared by:
Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet