# SAFETY DATA SHEET



## 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**

**Zoetis Belgium S.A.**
**Mercuriusstraat 20**
**1930 Zaventem**
**Belgium**

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

**Emergency telephone number:**
**International CHEMTREC (24 hours): +1-703-527-3887**

## 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):** Hazardous Substance. Non-Dangerous Goods.

**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

**Hazardous**

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

**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/m$^3$ |
| **Belgium OEL - TWA** | 10 mg/m$^3$ |
| **Czech Republic OEL - TWA** | 10 mg/m$^3$ |
| **Estonia OEL - TWA** | 10 mg/m$^3$ |
| **Finland OEL - TWA** | 20 mg/m$^3$ |
| **France OEL - TWA** | 10 mg/m$^3$ |
| **Germany (DFG) - MAK** | 50 mg/m$^3$ |
| **Greece OEL - TWA** | 10 mg/m$^3$ |
| **Ireland OEL - TWAs** | 10 mg/m$^3$ |
| **OSHA - Final PELS - TWAs:** | 15 mg/m$^3$ |
| **Poland OEL - TWA** | 10 mg/m$^3$ |
| **Portugal OEL - TWA** | 10 mg/m$^3$ |
| **Spain OEL - TWA** | 10 mg/m$^3$ |
| **Switzerland OEL -TWAs** | 50 mg/m$^3$ |

**Propylene glycol**

| | |
|---|---|
| **Australia TWA** | 150 ppm<br>474 mg/m$^3$<br>10 mg/m$^3$ |
| **Ireland OEL - TWAs** | 150 ppm<br>470 mg/m$^3$<br>10 mg/m$^3$ |
| **Latvia OEL - TWA** | 7 mg/m$^3$ |
| **Lithuania OEL - TWA** | 7 mg/m$^3$ |

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/m$^3$ to < 1000ug/m$^3$)

# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Ivermectin**

| | |
|---|---|
| **Zoetis OEB** | OEB 3 (control exposure to the range of 10ug/$m^3$ to < 100ug/$m^3$) |

**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 | **Color:** | Pale yellow to yellow |
| **Odor:** | No data available. | **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 |

**Flammablity:**

| | |
|---|---|
| **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 Oral2 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 Oral10 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 Toxicity Comments:** may have the potential to produce effects on the developing fetus.

**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** 1000 mg/kg

## 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)**

**Ivermectin**
*Oncorhynchus mykiss* (Rainbow Trout) LC50 48 Hours 0.000025 mg/L
Shrimp LC50 48 Hours 0.007 mg/L
*Daphnia Magna* (Water Flea) OECD NOEC 21 Days 0.0003 ng/L
*Daphnia magna* (Water Flea) OECD LC50 48 Hours 0.0000057 mg/L

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

**Ivermectin**
*Daphnia magna* (Water Flea) OECD 21 Day(s) NOEC 0.0003 ng/L

**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:** | Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern |
| **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<br>Schedule 5<br>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**