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

Material Name: ALVERIN PLUS (Ivermectin/Clorsulon) Injection

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>ALVERIN PLUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms:</td>
<td>Ivermectin and Clorsulon Injection</td>
</tr>
<tr>
<td>Chemical Family:</td>
<td>Avermectin macrocyclic lactone, Benzenesulfonamide</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Veterinary product used as anti-worm agent (anthelmintic) endectocide</td>
</tr>
</tbody>
</table>

2. HAZARDS IDENTIFICATION

Appearance: Clear pale yellow to yellow liquid

Signal Word: DANGER

Statement of Hazard: Toxic if swallowed.
Toxic to aquatic life with long lasting effects.

Additional Hazard Information:
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus. May cause effects in cardiovascular 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.

EU Classification
EU Indication of danger: Toxic
Dangerous for the Environment

EU Risk Phrases:
R25 - Toxic if swallowed.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Australian Hazard Classification (NOHSC):
Hazardous Substance. Dangerous Goods.
2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>274-536-0</td>
<td>T+:R28</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.Cat.3;R63 N:R50/53</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Glycerol</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Clorsulon</td>
<td>60200-06-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>10</td>
</tr>
</tbody>
</table>

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

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

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

General Handling: Minimize generating airborne mists and vapors. Avoid breathing mist or aerosols. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Propylene glycol

<table>
<thead>
<tr>
<th>Country</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>150 ppm</td>
</tr>
<tr>
<td></td>
<td>474 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>150 ppm</td>
</tr>
<tr>
<td></td>
<td>470 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

Glycerol

<table>
<thead>
<tr>
<th>Country</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>20 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>50 mg/m³ inhalable fraction</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls:
Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls:
Refer to specific Member State legislation for requirements under Community environmental legislation.

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: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Physical State: Liquid
- Color: Pale yellow to yellow
- Molecular Formula: Mixture
- Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

- Chemical Stability: Stable under normal conditions of use.
- 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

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

- Acute Toxicity: (Species, Route, End Point, Dose)
  - Ivermectin
    - Rat Oral LD50 10 mg/kg
11. TOXICOLOGICAL INFORMATION

Clorsulon
Mouse Oral LD50 > 10,000 mg/kg

Propylene glycol
Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

Glycerol
Rat Oral LD 50 12600 mg/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.

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

Propylene glycol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Glycerol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

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

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

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

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

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
11. TOXICOLOGICAL INFORMATION

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

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

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

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

12. ECOLOGICAL INFORMATION

Environmental Overview:
The environmental characteristics of this mixture have not been fully evaluated. The following information is available for the individual ingredients. Releases to the environment should be avoided.

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 0.000057 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

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:
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

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.
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

15. REGULATORY INFORMATION

EU Symbol: T, N
EU Indication of danger: Toxic
Dangerous for the Environment

EU Risk Phrases:
R25 - Toxic if swallowed.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

EU Safety Phrases:
S 2 - Keep out of the reach of children.
S 7 - Keep container tightly closed.
S36/37 - Wear suitable protective clothing and gloves.
S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
DANGER
Toxic if swallowed.
Toxic to aquatic life with long lasting effects.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 1, Subdivision A
Class D, Division 2, Subdivision A

Ivermectin
Standard for the Uniform Scheduling for Drugs and Poisons:
Schedule 4
Schedule 5
Schedule 7
EU EINECS/ELINCS List
274-536-0

Propylene glycol
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>200-338-0</td>
</tr>
</tbody>
</table>

Glycerol

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>REACH - Annex V - Exemptions from the obligations of Register:</td>
<td>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</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>200-289-5</td>
</tr>
</tbody>
</table>

Clorsulon

| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 5 |

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R28 - Very toxic if swallowed.
R63 - Possible risk of harm to the unborn child.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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