



Material Safety Data Sheet
ISO/DIS 11014 / 29 CFR 1910.1200 / ANSI Z400.1

Printing date 01/07/2010

Reviewed on 01/07/2010

1 Identification of substance

- **Product details**
- **Trade name: IVOMEK Injection for Cattle**
- **Manufacturer/Supplier:**
 Merial Limited
 3239 Satellite Blvd.
 Duluth, Ga. 30096-4640
 1-888-MERIAL 1 (1-888-637-4251)
- **Emergency information:**
 Spill Information:
 CHEMTREC® 1-800-424-9300
 CHEMTREC® International 1+703-527-3887
 International calls 011+703-527-3887
 Reverse charges.

2 Composition/Data on components

- **Chemical characterization**

- **Components:**

	Non hazardous inert ingredients		59.0 %
5464-28-8	Glycerol Formal	Warning: 2.6/4	40.0%
70288-86-7	Ivermectin Comp. B1a Comp. B1b	T, N; R 20/21-25-50 Danger: 3.1.O/2, 3.1.D/3, 3.1.I/3 Warning: 4.1.A/1	1.0%

3 Hazards identification

- **Hazard description:** Not applicable.
- **Classification system:**
 The classification was made according to the latest editions of international substances lists, and from company and regulatory data.
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



- **GHS label elements**
Warning
 2.6/4 - Combustible liquid.
- **Prevention:**
 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

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Wear protective gloves/protective clothing/eye protection/face protection.

· **Response:**

In case of fire: Use for extinction: CO2, powder or water spray.

· **Storage:**

Store in a well-ventilated place. Keep cool.

· **Disposal:**

Dispose of contents/container in accordance with local/regional/national/international regulations.

4 First aid measures

· **General information:** *No special measures required.*

· **After inhalation:** *Not an expected route of entry.*

· **After skin contact:** *Immediately wash with water and soap and rinse thoroughly.*

· **After eye contact:**

Rinse opened eye for a minimum of 15 minutes under running water. Get medical attention immediately.

· **After swallowing:** *Immediately call a doctor.*

· **After self injection**

· **Information for doctor.**

Direct contact with the eye can cause irritation. Ivermectin is non-irritating to the skin in animal studies.

Overexposure to ivermectin may cause drowsiness, depressed motor activity, slowed breathing, dilation of the pupils, tremors, vomiting, anorexia and incoordination.

5 Fire fighting measures

· **Suitable extinguishing agents:** *Use water spray or all purpose dry chemical.*

· **Special hazards caused by the material, its products of combustion or resulting gases:**

If exposed to fire, toxic gases including CO and CO2 may be generated.

· **Protective equipment:**

Fire fighters should wear self-contained breathing apparatus and full protective equipment.

6 Accidental release measures

· **Person-related safety precautions:** *Not required.*

· **Measures for environmental protection:** *Do not allow product to reach sewage system or any water course.*

· **Measures for cleaning/collecting:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose of contaminated material as waste according to section 13.

· **Additional information:** *No dangerous substances are released.*

7 Handling and storage

· **Handling:**

· **Information for safe handling:**

Store in cool, dry place in tightly closed containers.

Handle with care. Avoid jolting and impact.

· **Information about protection against explosions and fires:** *No special measures required.*

· **Storage:**

· **Requirements to be met by storerooms and receptacles:** *Store only in the original container.*

· **Information about storage in one common storage facility:** *Not required.*

· **Further information about storage conditions:** *Store in a cool, dry, well ventilated place.*

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· **Recommended storage temperature:** < 30°C (86°F)

8 Exposure controls and personal protection

· **Components with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Do not eat, drink, smoke or inhale.

Do not store food in the working area.

· **Breathing equipment:** Not required for this formulation when used in accordance with directions.

· **Protection of hands:** Not required under normal conditions of use.

· **Eye protection:**



Safety goggles.

· **Body protection:** Use protective apron and/or outer garment.

9 Physical and chemical properties

· **General Information**

Form:	Liquid
Color:	Clear
Odor:	Practically odorless

· **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: 192°C (378°F)

· **Flash point:** 81°C (178°F)

· **Auto igniting:** Product is not self-igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Specific gravity:** Not determined.

· **Solubility in / Miscibility with**

Water: Not established

Organic solvents: 0.0 %

· **Solids content:** 1.0 %

10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided:** Stable, protect from light.

· **Dangerous reactions** No dangerous reactions known.

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· **Dangerous products of decomposition:** Carbon monoxide and carbon dioxide

11 Toxicological information

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

5464-28-8 Glycerol Formal

Oral	LD50	10200 mg/kg (rat)
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**70288-86-7 Ivermectin Comp. B1a
Comp. B1b**

Oral	LD Oral	>15 mg/kg (adult human)
	LD50	~80 mg/kg (dog) 25 mg/kg (mouse) 50 mg/kg (rat)
Dermal	LD50	>24 mg/kg (Rhesus monkey) 406 mg/kg (rabbit)
		>660 mg/kg (rat)
Inhalation	LC50/4h	>0.4 mg/kg (rat)
	LD Subcutaneous	>1.6 mg/kg (adult human)
	LD50 Intraperitoneal	55 mg/kg (rat)
	LD50 Subcutaneous	~10 mg/kg (juvenile dog)

· **Primary irritant effect:**

· **on the skin:** No irritating effect known.

· **on the eye:** No irritating effect known.

· **Sensitization:** No sensitizing effects known.

· **Other information (about experimental toxicology):**

Salient toxicologic effects of ivermectin observed at high doses in laboratory animals are transient acute neurotoxic effects, which are species-, strain-, and dose threshold-dependent, regardless of study duration. Primates uniquely present emesis as the first-sign of toxicosis, whereas dogs present mydriasis and rodents typically present tremor and ataxia. Primates are the least sensitive to ivermectin toxicosis with the relative order of species sensitivity from lowest to highest being human, non-human primate, dog, rat, rabbit and mouse.

· **Subacute to chronic toxicity:**

Ivermectin is clinically tested and shown to be well-tolerated in healthy subjects without signs of acute neurotoxicity through 2.0 mg/kg body weight (highest dose tested) when given orally as a single dose, and through 1.2 mg/kg bodyweight (highest dose tested) when given orally as a repeated dose (once every 2-3 days for 1 week). No reproductive or developmental toxicity resulted over background levels in pregnant women inadvertently administered orally-dosed ivermectin through approximately 0.33 mg/kg body weight as part of a community-based onchocerciasis treatment campaign. Based upon accidental human poisoning reports, a human male infant (16-months of age) tolerated an oral dose of approximately 7 to 9 mg/kg body weight presenting transient symptoms of toxicity, such as emesis, pallor, fever, tachycardia, somnolence, blood pressure fluctuation and mydriasis. An adult female (61-years of age) tolerated an oral dose of approximately 15 mg/kg body weight presenting transient coma, increased blood creatine kinase level, weakness, dizziness and agitation.

· **Additional toxicological information:**

The product is not subject to classification according to internally approved calculation methods for preparations.

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

No-effect levels in 2-week (daily dosed) toxicity studies in neonatal, juvenile and adult non-human primates support human no-effect levels for neurotoxicity. In the next more sensitive species, dog reproductive and developmental toxicity studies showed no abnormal observations through 0.60 mg/kg body weight (highest dose

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tested). In the next most sensitive species, rat, rabbit and mouse developmental toxicity was observed above or near maternal toxic doses, of which, the relevancy to human health is not known. Ivermectin is not a known carcinogen and tested negative in a series of in vitro and in vivo genotoxicity studies.

12 Ecological information

· **Ecotoxicological effects:**

· **Aquatic toxicity:**

70288-86-7 Ivermectin Comp. B1a
Comp. B1b

LC50 / 48 hrs 0.025 ppb (*Daphnia magna*)

LC50/96 hours .3 ug/l (*Rainbow Trout*)

· **Remark:** Components of this product are toxic to aquatic, avian and insect species.

· **General notes:**

Water hazard class 2 (Self-assessment): hazardous for water

Do not allow any volumes of product to reach ground water, water source or sewage system.

Danger to drinking water if even small quantities leak into the ground.

13 Disposal considerations

· **Product:**

· **Recommendation:**

Dispose by incineration or chemical waste landfill in accordance with local, state or federal regulations.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **DOT regulations:**

· **Hazard class:** Not Regulated

· **Land transport ADR/RID (cross-border):**

· **ADR/RID class:** 9 Miscellaneous dangerous substances and articles

· **UN-Number:** 3082

· **Packaging group:** III

· **Proper shipping name:** Environmentally hazardous substance, liquid, n.o.s. (ivermectin)

· **Maritime transport IMDG:**

· **IMDG Class:** 9

· **UN Number:** 3082

· **Packaging group:** III

· **Marine pollutant:** Yes

· **Proper shipping name:** Environmentally hazardous substance, liquid, n.o.s. (ivermectin)

· **Air transport ICAO-TI and IATA-DGR:**

· **ICAO/IATA Class:** 9

· **UN/ID Number:** 3082

· **Packing group:** III

· **Proper shipping name:** Environmentally hazardous substance, liquid, n.o.s. (ivermectin)

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· UN "Model Regulation": -

15 Regulations

· SARA

· **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**

None of the ingredients are listed.

· **CA Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenesis potential categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **MAK (German Maximum Workplace Concentration)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Product related hazard informations:**

Observe the general safety regulations when handling chemicals.

The product is not subject to identification regulations according to directives on hazardous materials.

· **Safety phrases:**

Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point

· **Water hazard class:** Water hazard class 2 (Self-assessment): hazardous for water.

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16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing MSDS:** MSDS Coordinator

· **Abbreviations and acronyms:**

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)

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

USA