

SAFETY DATA SHEETS

This SDS packet was issued with item:

078801117

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078353305 078353313 078412980 078413006 078435897 078438517 078470836 078470851 078470869 078800729

078800737 078801109



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:** ZIMECTERIN® GOLD Paste for Horses
- **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:**

70288-86-7	Ivermectin Comp. B1a Comp. B1b	T, N; R 20/21-25-50	1.55%
		Danger: 3.1.O/2, 3.1.D/3, 3.1.I/3	
		Warning: 4.1.A/1	

3 Hazards identification

- **Hazard description:** Not applicable.
- **Information pertaining to particular dangers for man and environment:**
The product does not have to be labeled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **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:**

May produce mild to moderate eye and skin irritation. No specific symptoms or effects of inhalation are known. This product may be harmful if swallowed in large amounts. No adverse effects were observed in target animal (horses) safety studies up to 10-times the recommended dose. Ingestion of large amounts may result in nausea, drowsiness, headache, tremors, and/or dizziness. Direct contact exposure to the skin or eyes may result in redness and/or pain.

· **After inhalation:** If lungs are irritated or breathing is difficult, move person to fresh air and contact a physician.

· **After skin contact:**

In case of contact, wash skin with plenty of water. Remove contaminated clothing and shoes and launder before reuse. If skin irritation develops and persists or recurs, contact a physician.

· **After eye contact:**

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

· **After swallowing:**

If person is conscious, induce vomiting as directed by a physician, preventing aspiration. Seek medical advice, and show label of material. Never give anything by mouth to an unconscious person.

· **After self injection**

· **Information for doctor.** In case of symptomatic effect provide treatment to maintain life functions.

5 Fire fighting measures

· **Suitable extinguishing agents:**

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **Protective equipment:** Self-contained breathing apparatus and full protective equipment.

6 Accidental release measures

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

· **Measures for environmental protection:** No special measures required.

· **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:** May produce oxides of carbon and nitrogen when heated to decomposition.

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.

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- **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 well ventilated location not to exceed 30°C.

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.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **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:** For normal working conditions, ensure adequate local exhaust ventilation.
- **Protection of hands:**
Wear protective clothing and butyl rubber or other impervious gloves when handling this material to prevent skin contact. Wash thoroughly after handling.
- **Eye protection:**
Wear chemical splash goggles when cleaning spilled material. Wear safety glasses with side shields for normal working conditions.
- **Body protection:** Impervious protective clothing

9 Physical and chemical properties

· General Information

Form:	Paste
Color:	Orange
Odor:	Amine-like

· Change in condition

Melting point/Melting range: Undetermined.
Boiling point/Boiling range: No Data

· **Flash point:** No Data

· **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 miscible or difficult to mix.

Organic solvents: 0.0 %

· **Solids content:** 6.0 %

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10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

Avoid exposure to heat, sparks, or flame.

· **Materials to be avoided:** May react with acids, strong oxidizers or reducers.

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

· **Dangerous products of decomposition:**

When heated to decomposition may produce oxides of carbon and nitrogen as well as uncharacterized decomposition products.

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		>24 mg/kg (Rhesus monkey)
	LD50	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	55 mg/kg (rat)
	LD50 Subcutaneous	~10 mg/kg (juvenile dog)

13463-67-7 Titanium Dioxide

Oral	LD50	>20000 mg/kg (rat)
Dermal	LD50	>10000 mg/kg (rabbit)
Inhalation	LC50/4 h	>6.82 mg/l (rat)

· **Primary irritant effect:**

· **on the skin:**

Prolonged dermal exposure may produce signs of slight skin irritation including redness and discomfort.

· **on the eye:** Material may produce transient eye irritation on contact.

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

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

CNS effects can occur if toxic amounts are swallowed (nausea, drowsiness, headache, tremors, and dizziness). This product is a veterinary medicine and should be regarded as harmful if swallowed or absorbed.

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.

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· **Subacute to chronic toxicity:**

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 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.

· **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.

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.

Praziquantel is used in human medicine and is clinically tested to be tolerated well at doses up to 50 mg/kg body weight.

12 Ecological information

· **Ecotoxological 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)

· **General notes:**

Water danger class 3 (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

13 Disposal considerations

· **Product:**

· **Recommendation:**

Disposal must be made according to official regulations.

Dispose of all waste product and containers in accordance with local, state, federal, and national regulations.

· **Uncleaned packagings:**

· **Recommendation:**

Disposal must be made according to official regulations.

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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)

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):**

13463-67-7 Titanium Dioxide

- **CA Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients are listed.

- **Carcinogenesis potential categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

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

None of the ingredients is listed.

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

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· **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.

· **Water hazard class:** Water danger class 3 (Self-assessment): extremely hazardous for water.

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.

· **Contact:** MSDS Coordinator, msds@merial.com

· **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

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