SAFETY DATA SHEET

Ivomec®, solution 1%

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	10/28/2019	000000049279	Date of first issue: 10/28/2019

SECTION 1. IDENTIFICATION

Product name	:	Ivomec®, solution 1%
Synonyms	:	Ivomec® solution for injection, Ivomec® Classic solution for injection, Ivomec® Gold solution for injection, Ivomec Swine with API: Ivermectin

Manufacturer or supplier's details

Company name of supplier	:	Boehringer Ing. Pharma GmbH & Co.KG
Address	:	Binger Straße 173 Ingelheim 55216
Telephone	:	+498007790900
Prepared by	:	EHS-Services@Boehringer-Ingelheim.com
Emergency telephone number	:	Int. Emergency Telephone number: +1 703-527-3887 Chemtrec 24-hours

Recommended use of the chemical and restrictions on use

Recommended use	:	Pharmaceutical
Restrictions on use	:	Safety Data Sheet only for the professional user.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Flammable liquids	:	Category 4
Acute toxicity (Oral)	:	Category 4
Eye irritation	:	Category 2A

GHS label elements

Hazard pictograms :

Signal word	:	Warning
Hazard statements	:	H227 Combustible liquid. H302 Harmful if swallowed. H319 Causes serious eye irritation.
Precautionary statements	:	**Prevention:**

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.

Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

The pharmacological effect of the medicament has to be considered (see package leaflet).

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : organic

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
1,3-Dioxolane-4-methanol	5464-28-8	>= 30 - < 50
Ivermectin	70288-86-7	>= 1 - < 5

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
First Aid responders should pay attention to self-protection and use the recommended protective clothing
Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.

If inhaled : Move to fresh air.

In case of skin contact : Wash off immediately with plenty of water.

In case of eye contact	:	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing.
If swallowed	:	Rinse mouth. Drink plenty of water.
Most important symptoms and effects, both acute and delayed	:	No information available. Harmful if swallowed. Causes serious eye irritation.
Notes to physician	:	Observe the summary of product characteristics of proprietary medicinal products Symptomatic treatment (decontamination, vital functions).

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water Dry chemical Foam Carbon dioxide (CO2)
Specific hazards during firefighting	:	In case of fire and/or explosion do not breathe fumes. Can be released in case of fire: Carbon oxides Product itself is non-combustible; fire extinguishing method of surrounding areas must be considered.
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Wear personal protective equipment. Ensure adequate ventilation. High risk of slipping due to leakage/spillage of product.
Environmental precautions	:	Do not flush into surface water or sanitary sewer system.
Methods and materials for containment and cleaning up	:	Pick up and transfer to properly labelled containers.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	No special protective measures against fire required. The product is not flammable.

Advice on safe handling	:	Provide sufficient air exchange and/or exhaust in work rooms.
Conditions for safe storage	:	No special storage conditions required.
Materials to avoid	:	Keep away from food, drink and animal feedingstuffs. Observe joint storage prohibition.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters
Contains no substances with occupational exposure limit values.

Engineering measures : Local exhaust
Emergency sprinkling nozzle

Personal protective equipment
Respiratory protection : Use NIOSH approved respiratory protection.

Hand protection

Material	:	Nitrile rubber
Break through time	:	480 min
Glove thickness	:	0.43 mm
Directive	:	Protective gloves against chemicals and micro-organisms
Protective index	:	Class 6

Eye protection	:	Wear as appropriate: Safety glasses with side-shields
Skin and body protection	:	Laboratory: laboratory coat; factory: disposable Overall.
Protective measures	:	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.
Hygiene measures	:	General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	No data available
Odour	:	almost odourless
Odour Threshold	:	No data available

pH	:	No data available
Melting point/range	:	Not applicable
Boiling point/boiling range	:	378 °F / 192 °C
Flash point	:	178 °F / 81 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Bulk density	:	Not applicable
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Explosive properties	:	Not tested
Oxidizing properties	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	No decomposition if stored and applied as directed.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.

Conditions to avoid	:	Extremes of temperature and direct sunlight.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 317.46 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 162.22 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:

1,3-Dioxolane-4-methanol:

Acute oral toxicity	:	LD50 (Rat): 10,200 mg/kg
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available

Ivermectin:

Acute oral toxicity	:	LD50 (Rat): = 10 mg/kg LD50 (Mouse): = 25 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): 5.11 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit, male and female): = 406 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

1,3-Dioxolane-4-methanol:

Remarks	:	No data available

Ivermectin:

Species	:	Rabbit
Result	:	No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

1,3-Dioxolane-4-methanol:

Result	:	Eye irritation

Ivermectin:

Species	:	Rabbit
Result	:	Slightly irritating.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

1,3-Dioxolane-4-methanol:

Remarks	:	No data available

Ivermectin:

Remarks	:	No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

1,3-Dioxolane-4-methanol:

Genotoxicity in vitro	:	Remarks: No data available
Genotoxicity in vivo	:	Remarks: No data available

Ivermectin:

Genotoxicity in vitro	:	Test Type: Ames-test Test system: Salmonella typhimurium Result: negative Test Type: Mouse lymphoma assay Result: negative Test Type: Unscheduled DNA synthesis Test system: fibroblast cell line

Result: negative

Genotoxicity in vivo : Remarks: No data available

Carcinogenicity

Not classified based on available information.

Components:

1,3-Dioxolane-4-methanol:

Remarks : No data available

Ivermectin:

Remarks : Did not show carcinogenic effects in animal experiments.

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

1,3-Dioxolane-4-methanol:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

Ivermectin:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

Components:

1,3-Dioxolane-4-methanol:

Remarks : No data available

Ivermectin:

Remarks : No data available

STOT - repeated exposure

Not classified based on available information.

Components:

1,3-Dioxolane-4-methanol:

Remarks : No data available

Ivermectin:

Assessment : The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 2.

Aspiration toxicity

Not classified based on available information.

Components:

1,3-Dioxolane-4-methanol:

No data available

Ivermectin:

No data available

Further information

Components:

Ivermectin:

Remarks : No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

1,3-Dioxolane-4-methanol:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chron- : Remarks: No data available

ic toxicity)

Toxicity to microorganisms : Remarks: No data available

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Ivermectin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0053 mg/l
Exposure time: 96 h

Toxicity to algae : Remarks: No data available

M-Factor (Acute aquatic toxicity) : 100

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC50 (Hyalella azteca (Amphipod)): 0.0017 mg/l
Exposure time: 10 d

NOEC (Hyalella azteca (Amphipod)): 0.00021 mg/l
Exposure time: 10 d

M-Factor (Chronic aquatic toxicity) : 100

Toxicity to microorganisms : Remarks: No data available

Persistence and degradability

Components:

1,3-Dioxolane-4-methanol:

Biodegradability : Result: No data available

Ivermectin:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

1,3-Dioxolane-4-methanol:

Bioaccumulation : Remarks: No data available

Ivermectin:

Bioaccumulation : Remarks: An appreciable bioaccumulation potential is to be expected (log P(o/w) > 3).

Partition coefficient: n-octanol/water : log Pow: 3.22 (68 °F / 20 °C)

Mobility in soil

Components:

1,3-Dioxolane-4-methanol:
Distribution among environmental compartments : Remarks: No data available

Ivermectin:
Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Product:
Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:

1,3-Dioxolane-4-methanol:
Additional ecological information : No data available

Ivermectin:
Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Ivermectin)
Class	:	9
Packing group	:	III
Labels	:	Class 9 - Miscellaneous dangerous substances and articles
Packing instruction (cargo aircraft)	:	964
Packing instruction (passenger aircraft)	:	964
Environmentally hazardous	:	yes

IMDG-Code

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

49 CFR

UN/ID/NA number	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Ivermectin)
Class	:	9
Packing group	:	III
Labels	:	Class 9 - Miscellaneous dangerous substances and articles
ERG Code	:	171
Marine pollutant	:	yes

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)

SARA 311/312 Hazards : Flammable (gases, aerosols, liquids, or solids)
Acute toxicity (any route of exposure)
Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

1,3-Dioxolane-4-methanol	5464-28-8
Ivermectin	70288-86-7

Maine Chemicals of High Concern

This product does not contain any chemicals that are listed as Maine Chemicals of High Concern.

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

The components of this product are reported in the following inventories:

REACH : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

1,3-Dioxolane-4-methanol

AICS : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Substance(s) not listed on TSCA inventory

TSCA list

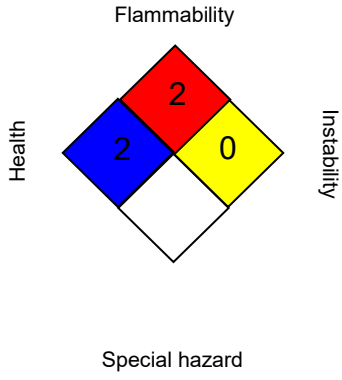
No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

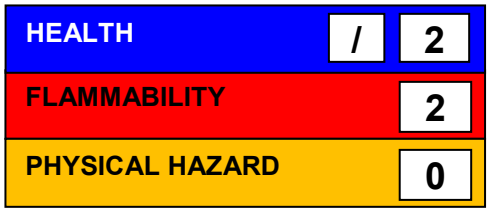
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification

System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Vertical lines in the left hand margin indicate an amendment from the previous version.

Sources of key data used to compile the Safety Data Sheet	:	The specifications are based on own tests and/or literature data.
Revision Date	:	10/28/2019

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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