

Insulin Porcine (with Metacresol) Formulation

Version 2.1 Revision Date: 28.09.2024 SDS Number: 11259179-00004 Date of last issue: 20.09.2023
Date of first issue: 11.08.2023

SECTION 1. IDENTIFICATION

Product identifier : Insulin Porcine (with Metacresol) Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification in accordance with ABNT NBR 14725 Standard**

Not classified as hazardous in accordance with ABNT NBR 14725

GHS label elements in accordance with ABNT NBR 14725 Standard

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
m-Cresol	108-39-4	Flam. Liq., 4 Acute Tox. (Oral), 3 Acute Tox. (Dermal), 3 Skin Corr., 1B Eye Dam., 1 Aquatic Acute, 2 Aquatic Chronic, 3	$\geq 0,1$ - $< 0,25$
Insulin (ox), 8A-I-threonine-10A-I-isoleucine-	12584-58-6		$\geq 0,1$ - < 1

Insulin Porcine (with Metacresol) Formulation

Version 2.1 Revision Date: 28.09.2024 SDS Number: 11259179-00004 Date of last issue: 20.09.2023
Date of first issue: 11.08.2023

Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly labeled containers.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
m-Cresol	108-39-4	TWA	20 mg/m ³	ACGIH

Insulin Porcine (with Metacresol) Formulation

Version 2.1 Revision Date: 28.09.2024 SDS Number: 11259179-00004 Date of last issue: 20.09.2023
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		(Inhalable fraction and vapor)		
Insulin (ox), 8A-I-threonine-10A-I-isoleucine-	12584-58-6	TWA	3 µg/m ³ (OEB 4)	Internal

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : suspension

Color : white to off-white

Odor : No data available

Odor Threshold : No data available

pH : 6,9 - 7,8

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Insulin Porcine (with Metacresol) Formulation

Version 2.1 Revision Date: 28.09.2024 SDS Number: 11259179-00004 Date of last issue: 20.09.2023
Date of first issue: 11.08.2023

Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1,003 g/cm ³
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

Insulin Porcine (with Metacresol) Formulation

Version 2.1 Revision Date: 28.09.2024 SDS Number: 11259179-00004 Date of last issue: 20.09.2023
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SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

Components:**m-Cresol:**

Acute oral toxicity : LD50 (Rat): 121 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

Acute dermal toxicity : LD50 (Rabbit): 301 mg/kg
Remarks: Based on data from similar materials

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Acute toxicity (other routes of administration) : LD50 (Rat): > 36 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**m-Cresol:**

Species : Rabbit
Result : Corrosive after 3 minutes to 1 hour of exposure

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:**m-Cresol:**

Species : Rabbit
Result : Irreversible effects on the eye

Insulin Porcine (with Metacresol) Formulation

Version 2.1 Revision Date: 28.09.2024 SDS Number: 11259179-00004 Date of last issue: 20.09.2023
Date of first issue: 11.08.2023

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Remarks : No data available

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:**m-Cresol:**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: positive

Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow
cytogenetic test, chromosomal analysis)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 475
Result: negative

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Test system: Salmonella typhimurium
Method: OECD Test Guideline 471
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster lung cells
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Cell type: Bone marrow
Method: OECD Test Guideline 475
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ
cell mutagen.

Carcinogenicity

Not classified based on available information.

Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.09.2023
2.1	28.09.2024	11259179-00004	Date of first issue: 11.08.2023

Components:

m-Cresol:

Species : Mouse, males
 Application Route : Ingestion
 Exposure time : 105 weeks
 Result : equivocal
 Remarks : Based on data from similar materials

Species : Mouse, female
 Application Route : Ingestion
 Exposure time : 106 - 107 weeks
 Result : positive
 Remarks : Based on data from similar materials

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Species : Rat
 Application Route : Subcutaneous
 Exposure time : 2 Years
 LOAEL : 180 µg/kg

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

Reproductive toxicity

Not classified based on available information.

Components:

m-Cresol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: negative

Effects on fetal development : Test Type: Prenatal development toxicity study (teratogenicity)
 Species: Rat
 Application Route: Ingestion
 Result: negative

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Effects on fertility : Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: Intraperitoneal
 Fertility: NOAEL Mating/Fertility: 360 µg/kg
 Symptoms: No effects on fertility.
 Result: No effects on fertility and early embryonic development were detected.

Insulin Porcine (with Metacresol) Formulation

Version 2.1 Revision Date: 28.09.2024 SDS Number: 11259179-00004 Date of last issue: 20.09.2023
Date of first issue: 11.08.2023

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:****m-Cresol:**

Species : Rat
NOAEL : 150 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks
Method : OECD Test Guideline 408

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Species : Rat
: 5,8 mg/kg
Application Route : Inhalation
Exposure time : 6 Months
Symptoms : Hypoglycemia

Species : Monkey
: 0,64 mg/kg
Application Route : Inhalation
Exposure time : 6 Months
Symptoms : Hypoglycemia

Species : Rat
NOAEL : 0,085 mg/kg
Application Route : Subcutaneous
Exposure time : 1 Months

Species : Dog
NOAEL : 0,07 mg/kg
Application Route : Subcutaneous
Exposure time : 1 Months

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:**

Inhalation : Symptoms: Hypoglycemia, Fatigue, Drowsiness, Sweating, Headache, Nausea, Palpitation, tingling, numbness, altered mental status, Breathing difficulties

Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.09.2023
2.1	28.09.2024	11259179-00004	Date of first issue: 11.08.2023

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

m-Cresol:

- | | | |
|--|---|--|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 8,6 mg/l
Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia pulex (Water flea)): > 99,5 mg/l
Exposure time: 48 h |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 1,35 mg/l
Exposure time: 32 d
Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 1 mg/l
Exposure time: 21 d
Remarks: Based on data from similar materials |

Persistence and degradability

Components:

m-Cresol:

- | | | |
|------------------|---|---|
| Biodegradability | : | Result: Readily biodegradable.
Biodegradation: 90 %
Exposure time: 28 d
Method: OECD Test Guideline 301D |
|------------------|---|---|

Bioaccumulative potential

Components:

m-Cresol:

- | | | |
|--|---|---|
| Bioaccumulation | : | Species: Leuciscus idus (Golden orfe)
Bioconcentration factor (BCF): 17 - 20 |
| Partition coefficient: n-octanol/water | : | log Pow: 1,96 |

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- | | | |
|------------------------|---|---|
| Waste from residues | : | Do not dispose of waste into sewer.
Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste |

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Version	Revision Date:	SDS Number:	Date of last issue: 20.09.2023
2.1	28.09.2024	11259179-00004	Date of first issue: 11.08.2023

handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation**ANTT**

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 28.09.2024
Date format : dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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Version	Revision Date:	SDS Number:	Date of last issue: 20.09.2023
2.1	28.09.2024	11259179-00004	Date of first issue: 11.08.2023

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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