

## Insulin Porcine (with Metacresol) Formulation

Version 2.0      Revision Date: 20.09.2023      SDS Number: 11259179-00003      Date of last issue: 14.09.2023  
 Date of first issue: 11.08.2023

### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : 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 a hazardous substance or mixture.

#### 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	Flammable liquids, Category 4 Acute toxicity (Oral), Category 3 Acute toxicity (Der- mal), Category 3 Skin corrosion, Category 1B Serious eye damage, Category 1 Short-term (acute) aquatic hazard,	>= 0,1 -< 0,25

## Insulin Porcine (with Metacresol) Formulation

Version 2.0      Revision Date: 20.09.2023      SDS Number: 11259179-00003      Date of last issue: 14.09.2023  
 Date of first issue: 11.08.2023

		Category 2 Long-term (chronic) aquatic hazard, Category 3	
Insulin (ox), 8A-l-threonine- 10A-l-isoleucine-	12584-58-6		>= 0,1 -< 1

### SECTION 4. FIRST AID MEASURES

- If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.
- In case of skin contact : Wash with water and soap as a precaution.  
Get medical attention if symptoms occur.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : None known.
- Protection of first-aiders : No special precautions are necessary for first aid responders.
- Notes to physician : Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : No hazardous combustion products are known
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

## Insulin Porcine (with Metacresol) Formulation

Version 2.0      Revision Date: 20.09.2023      SDS Number: 11259179-00003      Date of last issue: 14.09.2023  
 Date of first issue: 11.08.2023

- Environmental precautions : Avoid release to the environment.  
 Prevent further leakage or spillage if safe to do so.  
 Prevent spreading over a wide area (e.g., by containment or oil barriers).  
 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	Control parameters / Permissible	Basis
------------	---------	------------------------	----------------------------------	-------

## Insulin Porcine (with Metacresol) Formulation

Version 2.0      Revision Date: 20.09.2023      SDS Number: 11259179-00003      Date of last issue: 14.09.2023  
 Date of first issue: 11.08.2023

		exposure)	concentration	
m-Cresol	108-39-4	TWA (Inhalable fraction and vapor)	20 mg/m <sup>3</sup>	ACGIH
Insulin (ox), 8A-I-threonine- 10A-I-isoleucine-	12584-58-6	TWA	3 µg/m <sup>3</sup> (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

Appearance : 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

**Insulin Porcine (with Metacresol) Formulation**

Version 2.0      Revision Date: 20.09.2023      SDS Number: 11259179-00003      Date of last issue: 14.09.2023  
Date of first issue: 11.08.2023

---

Flash point	:	No data available
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 <sup>3</sup>
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 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	:	No hazardous decomposition products are known.

## Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.09.2023
2.0	20.09.2023	11259179-00003	Date of first issue: 11.08.2023

products

### 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	Revision Date:	SDS Number:	Date of last issue: 14.09.2023
2.0	20.09.2023	11259179-00003	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.

## Insulin Porcine (with Metacresol) Formulation

Version 2.0      Revision Date: 20.09.2023      SDS Number: 11259179-00003      Date of last issue: 14.09.2023  
 Date of first issue: 11.08.2023

### Carcinogenicity

Not classified based on available information.

#### 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



**Insulin Porcine (with Metacresol) Formulation**

Version 2.0      Revision Date: 20.09.2023      SDS Number: 11259179-00003      Date of last issue: 14.09.2023  
Date of first issue: 11.08.2023

---

development were detected.

**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 2.0      Revision Date: 20.09.2023      SDS Number: 11259179-00003      Date of last issue: 14.09.2023  
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

**Insulin Porcine (with Metacresol) Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.09.2023
2.0	20.09.2023	11259179-00003	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 : 20.09.2023  
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/>

---

**Insulin Porcine (with Metacresol) Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.09.2023
2.0	20.09.2023	11259179-00003	Date of first issue: 11.08.2023

---

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

**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; TECl - 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.

BR / Z8