

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Insulin Porcine (with Metacresol) Formulation

Version 6.1 Revision Date: 05/09/2026 SDS Number: 11259180-00010 Date of last issue: 03/27/2026
Date of first issue: 08/11/2023

SECTION 1. IDENTIFICATION

Product name : Insulin Porcine (with Metacresol) Formulation
Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 37 McCarville Street
Charlottetown, PE C1E 2A7
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.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 the Hazardous Products Regulations

Not a hazardous substance or mixture.

GHS label elements

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS No./Unique ID	Concentration (% w/w)	Trade secret
m-Cresol	Phenol, 3-methyl-	108-39-4*	>= 0.1 - <= 1	TSC
Insulin (ox), 8A-l-threonine-10A-l-isoleucine-	No data available	12584-58-6*	>= 0.1 - <= 1	TSC

* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/27/2026
6.1	05/09/2026	11259180-00010	Date of first issue: 08/11/2023

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 ₂) 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).
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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Insulin Porcine (with Metacresol) Formulation

Version 6.1 Revision Date: 05/09/2026 SDS Number: 11259180-00010 Date of last issue: 03/27/2026
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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.
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	5 ppm 22 mg/m ³	CA AB OEL
		TWAEV (inhalable fraction and vapour)	20 mg/m ³	CA QC OEL
		TWA	10 mg/m ³	CA BC OEL
		TWA (Inhalable fraction and vapor)	20 mg/m ³	ACGIH
Insulin (ox), 8A-l-threonine-10A-l-isoleucine-	12584-58-6	TWA	3 µg/m ³ (OEB 4)	Internal

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according to the Hazardous Products Regulations



Insulin Porcine (with Metacresol) Formulation

Version 6.1 Revision Date: 05/09/2026 SDS Number: 11259180-00010 Date of last issue: 03/27/2026
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Engineering measures : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable. 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.

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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/27/2026
6.1	05/09/2026	11259180-00010	Date of first issue: 08/11/2023

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
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 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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/27/2026
6.1	05/09/2026	11259180-00010	Date of first issue: 08/11/2023

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.

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: > 2,000 mg/kg
Method: Calculation method

Components:

m-Cresol:

Acute oral toxicity : LD50 (Rat, male): 242 mg/kg
Method: OECD Test Guideline 401
Remarks: The test was conducted equivalent or similar to guideline

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

Acute dermal toxicity : LD50 (Rat): 1,100 mg/kg

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

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

Skin corrosion/irritation

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SAFETY DATA SHEET

according to the Hazardous Products Regulations



Insulin Porcine (with Metacresol) Formulation

Version 6.1 Revision Date: 05/09/2026 SDS Number: 11259180-00010 Date of last issue: 03/27/2026
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Components:

m-Cresol:

Species : Rabbit
Result : Corrosive after 4 hours or less 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 (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: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: The test was conducted according to guideline

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: The test was conducted equivalent or similar to guideline

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: positive
Remarks: The test was conducted according to guideline

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Insulin Porcine (with Metacresol) Formulation

Version 6.1 Revision Date: 05/09/2026 SDS Number: 11259180-00010 Date of last issue: 03/27/2026
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cytogenetic test, chromosomal analysis)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 475
Result: negative
Remarks: The test was conducted according to guideline

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.

Components:

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: Embryo-fetal development
Species: Rat

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Insulin Porcine (with Metacresol) Formulation

Version 6.1 Revision Date: 05/09/2026 SDS Number: 11259180-00010 Date of last issue: 03/27/2026
Date of first issue: 08/11/2023

Application Route: Ingestion
Result: negative

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

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.

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
Remarks : The test was conducted according to guideline

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

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Insulin Porcine (with Metacresol) Formulation

Version 6.1 Revision Date: 05/09/2026 SDS Number: 11259180-00010 Date of last issue: 03/27/2026
Date of first issue: 08/11/2023

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

m-Cresol:

Toxicity to fish : LC50 (Salvelinus fontinalis (Brook trout)): 7.6 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia sp. (Water flea)): > 99.5 mg/l
Exposure time: 48 h
Method: EPA OPP 72-2
Remarks: The test was conducted according to guideline

Toxicity to algae/aquatic plants : EC10 (Microcystis aeruginosa (blue-green algae)): > 13 mg/l
Exposure time: 8 d

ErC50 (Microcystis aeruginosa (blue-green algae)): > 13 mg/l
Exposure time: 8 d

Persistence and degradability

Components:

m-Cresol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 90 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
Remarks: The test was conducted according to guideline

Biodegradation Simulation Tests : Environmental Compartment: Soil
Value type: DT50
Value: 11.3 d
Temperature: 20 °C

Bioaccumulative potential

Components:

m-Cresol:

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/27/2026
6.1	05/09/2026	11259180-00010	Date of first issue: 08/11/2023

Bioaccumulation : Species: *Leuciscus idus melanotus* (Ide)
Bioconcentration factor (BCF): 17 - 20

Partition coefficient: n-octanol/water : log Pow: 1.96
Remarks: No test guideline followed

Mobility in soil

Components:

m-Cresol:

Distribution among environmental compartments : log Koc: 1.54
Method: OECD Test Guideline 106
Remarks: The test was conducted equivalent or similar to guideline

Other adverse effects

No data available

Endocrine disrupting properties

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 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

TDG

Not regulated as a dangerous good

Special precautions for user

Not applicable

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/27/2026
6.1	05/09/2026	11259180-00010	Date of first issue: 08/11/2023

SECTION 15. REGULATORY INFORMATION

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

AICS	:	not determined
CA. DSL	:	not determined
CN IECSC	:	not determined

Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWA EV	:	Time-weighted average exposure value

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 Standardization; 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 Organization for Standardization; KECl - 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/27/2026
6.1	05/09/2026	11259180-00010	Date of first issue: 08/11/2023

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, Authorization 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

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/>

Revision Date : 05/09/2026
Date format : mm/dd/yyyy

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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