NovoLog® Mix 70/30
Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Product name : NovoLog® Mix 70/30
Formula : C_{26}H_{38}N_{2}O_{7}S_{6}
Other means of identification : NovoLog® Mix 70/30 10 ml vial, NovoLog® Mix 70/30 FlexPen®

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Drug Product

1.3. Details of the supplier of the safety data sheet

Novo Nordisk
800 Scudders Mill Road
Plainsboro, NJ 08536
T 800-727-6500
www.novonordisk-us.com

1.4. Emergency telephone number

Emergency number : 800-727-6500

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification
Skin Sens. 1 H317

2.2. Label elements

GHS-US labelling
Hazard pictograms (GHS-US):

Signal word (GHS-US) : Warning
Hazard statements (GHS-US) : H317 - May cause an allergic skin reaction
Precautionary statements (GHS-US) : P261 - Avoid breathing mist
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear appropriate PPE
P302+P352 - IF ON SKIN. Wash with plenty of soap and water
P321 - Specific treatment (see Section 4 on this label)
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
P362+P364 - Take off contaminated clothing and wash it before reuse
P501 - Dispose of contents/container to comply with local/regional/national/international regulations

2.3. Other hazards

Other hazards not contributing to the classification : Inactive ingredients include: disodium hydrogen phosphate dihydrate, glycerin, metacresol, phenol, protamine sulfate, sodium chloride, hydrochloric acid, and or sodium hydroxide, and zinc.

2.4. Unknown acute toxicity (GHS-US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable
Full text of H-phrases: see section 16

3.2. Mixture
SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general: Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

First-aid measures after inhalation: Not an anticipated route of entry. If inhaled, remove person to fresh air.

First-aid measures after skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash contaminated clothing before reuse.

First-aid measures after eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

First-aid measures after ingestion: Rinse mouth. Drink plenty of water. Seek medical advice in case of persistent discomfort.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation: Not investigated. Inhalation of mist containing protein may cause sensitization.

Symptoms/injuries after skin contact: May cause irritation by the active substance or any of the excipients.

Symptoms/injuries after eye contact: May cause irritation. Avoid contact with the eyes.

Symptoms/injuries after ingestion: Not expected to be active orally. Absorption is not expected. Ingestion is not known to cause health effects.

Symptoms/injuries upon inadvertent injection: Local Allergic Reaction. As with any insulin therapy, injection site reactions may occur and include pain, redness, itching, hives, swelling, bruising and inflammation. Systemic Reactions - Severe, life-threatening, generalized allergy, including anaphylaxis, may occur with any insulin product. May cause hypoglycemia.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Any. Use media appropriate for surrounding fire.

5.2. Special hazards arising from the substance or mixture

Fire hazard: Not flammable.

Reactivity: Not reactive under normal use and conditions.

5.3. Advice for firefighters

Protection during firefighting: Positive pressure self-contained breathing apparatus (SCBA) and structural firefighters' protective clothing will provide adequate protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures: Seek fresh air.

6.1.1. For non-emergency personnel

Emergency procedures: Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment: Equip cleanup crew with proper protection.

6.2. Environmental precautions

Under normal use, this product is not expected to impact the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment: Do not touch or walk through spilled material.

Methods for cleaning up: Absorb with non-combustible material and transfer to containers.
SECTION 7: Handling and storage

7.1. Precautions for safe handling
Precautions for safe handling: Do not get in eyes, on skin, or on clothing. Use personal protective equipment as required.
Hygiene measures: Do not eat, drink or smoke when using this product. Practice good housekeeping. Wash thoroughly after handling. Change contaminated clothing. Do not reuse until laundered.

7.2. Conditions for safe storage, including any incompatibilities
Storage conditions: Must be kept in tightly original packings and store according to product instruction and to prevent degradation. Store protected from light.
Storage temperature: Before opening: Store in a refrigerator (2°C - 8°C). Do not freeze. During use or when carried as a spare: Store below 30°C. Do not refrigerate. Do not freeze.

7.3. Specific end use(s)
Drug product.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

<table>
<thead>
<tr>
<th>Phenol (108-95-2)</th>
<th>ACGIH TWA (ppm)</th>
<th>USA OSHA OSHA PEL (TWA) (mg/m³)</th>
<th>USA OSHA OSHA PEL (TWA) (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA ACGIH</td>
<td>Remark (ACGIH)</td>
<td>URT irr; lung dam; CNS impair</td>
<td></td>
</tr>
<tr>
<td>USA OSHA</td>
<td>19 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA OSHA</td>
<td>5 ppm</td>
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</tr>
</tbody>
</table>

8.2. Exposure controls
Appropriate engineering controls: Work must be done with effective mechanical ventilation. There must be access to running water and eye wash.
Personal protective equipment: Avoid all unnecessary exposure.
Hand protection: Polyvinylchloride (PVC) / Nitrile rubber gloves.
Eye protection: Eye protection such as chemical splash goggles and/or face shield must be worn when possibility exists for eye contact due to splashing or spraying liquid. Contact lenses should not be worn.
Skin and body protection: PVC gloves, nitrile rubber or similar protection are recommended for waste clear-up and manufacturing operations.
Respiratory protection: Respiratory protection is not required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Physical state: Liquid
Appearance: Uniform, white suspension with a smell of cresol/phenol (preservative).
Molecular mass: 6825.8 Dalton
Color: Uniform white suspension
Odor: Cresol/ Phenol.
Odour threshold: No data available
pH: No data available
pH solution: 7.4 (at 20 °C)
Relative evaporation rate (butylacetate=1): No data available
Melting point: No data available
Freezing point: No data available
Boiling point: 100 °C
Flash point: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Flammability (solid, gas): No data available
Vapour pressure: No data available
Relative vapour density at 20 °C: No data available
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Relative density : 1.005 g/ml (at 25 °C)
Solubility : No data available
Log Pow : No data available
Log Kow : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : No data available

SECTION 10: Stability and reactivity

10.1. Reactivity
Not reactive under normal use and conditions.

10.2. Chemical stability
Product is stable.

10.3. Possibility of hazardous reactions
Hazardous polymerization will not occur.

10.4. Conditions to avoid
None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials
Drugs added to the insulin may cause degradation of the insulin, e.g. if the drugs contain thiols or sulphites. Light or heat.

10.6. Hazardous decomposition products
No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

NovoLog® Mix 70/30
Additional information : Hypersensitivity to the active substance or to any of the excipients.

Phenol (108-95-2)
LD50 oral rat : 270 mg/kg Gignera i Sanitariya. For English translation, see HYSAV. Vol. 38(8), Pg. 6, 1973.
LC50 inhalation rat (ppm) : 81 ppm Nagoznyi 1976
ATE CLP (oral) : 100.000 mg/kg body weight
ATE CLP (dermal) : 300.000 mg/kg body weight
ATE CLP (gases) : 700.000 ppm/Vl/4h
ATE CLP (vapors) : 3.000 mg/l/4h
ATE CLP (dust, mist) : 0.500 mg/l/4h

Skin corrosion/irritation : Causes skin irritation.
Serious eye damage/irritation : Causes serious eye irritation.
Respiratory or skin sensitisation : May cause an allergic skin reaction.
Germ cell mutagenicity : Suspected of causing genetic defects.
Carcinogenicity : Not classified
(Based on available data, the classification criteria are not met)

NovoLog® Mix 70/30
Additional information : Standard 2-year carcinogenicity studies in animals have not been performed to evaluate the carcinogenic potential of NovoLog Mix. At a dose of 200 U/kg/day, NovoLog Mix increased the incidence of mammary gland tumors in females when compared to untreated controls. The incidence of mammary tumors for NovoLog Mix was not significantly different than for regular human insulin. The relevance of these findings to humans is not known.

Phenol (108-95-2)
IARC group : 3 - Not classifiable

11/26/2014
EN (English)
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Reproductive toxicity: Not classified
(In fertility studies in male and female rats, NovoLog® Mix at subcutaneous doses up to 200 U/kg/day (approximately 32 times the human subcutaneous dose, based on U/body surface area) had no direct adverse effects on male and female fertility, or on general reproductive performance of animals.)

Specific target organ toxicity (single exposure): Not classified

Specific target organ toxicity (repeated exposure): Not classified

Aspiration hazard: Not classified

Symptoms/injuries after inhalation: Not investigated. Inhalation of mist containing protein may cause sensitization.

Symptoms/injuries after skin contact: May cause irritation by the active substance or any of the excipients.

Symptoms/injuries after eye contact: May cause irritation. Avoid contact with the eyes.

Symptoms/injuries after ingestion: Not expected to be active orally. Absorption is not expected. Ingestion is not known to cause health effects.

Symptoms/injuries upon inadvertent injection: Local Allergic Reaction: As with any insulin therapy, injection site reactions may occur and include pain, redness, itching, hives, swelling, bruising and inflammation. Systemic Reactions - Severe, life-threatening, generalized allergy, including anaphylaxis, may occur with any insulin product. May cause hypoglycemia.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general: Avoid discharge to drain or surface water.

Phenol (108-95-2)


12.2. Persistence and degradability
No additional information available

12.3. Bioaccumulative potential
Phenol (108-95-2)

| Log Pow | 1.5

12.4. Mobility in soil
No additional information available

12.5. Other adverse effects
No additional information available
SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations: The product is not hazardous waste. Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with DOT
Not regulated for transport

Additional Information

Other information: No supplementary information available.

ADR
Transport document description:

Transport by sea
No additional information available

Air transport
No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

Phenol (108-95-2)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Listed on United States SARA Section 313

RQ (Reportable quantity, section 304 of EPA’s List of Lists): 1000 lb

Aqueous suspension contains insulin aspart 70 (Recombinant B28 Asp. Insulin), Biphasic Aspart 30 (116094-23-6)
Not listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA
No additional information available

EU-Regulations
No additional information available

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]
Not classified

15.2. National regulations

No additional information available

15.3. US State regulations

Phenol (108-95-2)
U.S. - Idaho - Non-Carcinogenic Toxic Air Pollutants - Acceptable Ambient Concentrations
U.S. - Maine - Air Pollutants - Hazardous Air Pollutants
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - New York - Reporting of Releases Part 597 - List of Hazardous Substances
U.S. - Pennsylvania - RTK (Right to Know) List
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SECTION 16: Other information


Training advice: No special training is necessary but a thorough knowledge of this safety data sheet is assumed.

Full text of H-phrases: see section 16:

<table>
<thead>
<tr>
<th>Skin Sens. 1</th>
<th>Skin sensitzation Category 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction</td>
</tr>
</tbody>
</table>

NFPA health hazard: 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.
NFPA fire hazard: 0 - Materials that will not burn.
NFPA reactivity: 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.

SDS US (GHS HazCom 2012)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.