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

1.1. Product identifier

Product form : Solution
Product name : NovoLog®
Formula : C₂₀H₂₆N₄O₁₇P₂S₉
Other means of identification : NovoLog® 10 ml vial
NovoLog® FlexPen
NovoLog® PenFill® cartridge

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 800-727-8500
www.novonordisk-us.com

1.4. Emergency telephone number

Emergency number : 800-727-8500

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 fume, mist, spray, vapors
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

Inactive ingredients include: disodium hydrogen phosphate dihydrate, glycerin, hydrochloric acid, metacresol, phenol, sodium chloride and zinc.

2.4. Unknown acute toxicity (GHS-US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

Full text of H-phrases: see section 16

3.2. Mixture

11/19/2014 EN (English)
**NovoLog®**  
Safety Data Sheet  
according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqueous solution contains insulin aspart.</td>
<td>(CAS No) 116094-23-8</td>
<td>100</td>
<td>Not classified</td>
</tr>
<tr>
<td>(Recombinant B28 Asp. Insulin)</td>
<td></td>
<td></td>
<td>Acute Tox. 3 (Oral), H301</td>
</tr>
<tr>
<td>Metacresol</td>
<td>(CAS No) 108-39-4</td>
<td>≤0.17</td>
<td>Acute Tox. 3 (Dermal), H311</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Corr. 1B, H314</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 3, H402</td>
</tr>
<tr>
<td>Phenol</td>
<td>(CAS No) 108-95-2</td>
<td>≤0.14</td>
<td>Acute Tox. 3 (Oral), H301</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 3 (Dermal), H311</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 3 (Inhalation), H331</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Corr. 1B, H314</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mut. 2, H341</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT RE 2, H373</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 3, H402</td>
</tr>
</tbody>
</table>

**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: When swallowed, seek medical attention if symptoms persist and show the physician the package insert. Do NOT induce vomiting. Not expected to be active orally (hypoglycemia).

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

Symptoms/injuries after inhalation: Not investigated. Inhalation of sprit 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 : NovoLog® must be kept in tightly closed original packings in a well ventilated place. 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></th>
</tr>
</thead>
<tbody>
<tr>
<td>USA ACGIH</td>
<td>ACGIH TWA (ppm)</td>
</tr>
<tr>
<td>USA ACGIH</td>
<td>Remark (ACGIH)</td>
</tr>
<tr>
<td>USA OSHA</td>
<td>OSHA PEL (TWA) (mg/m³)</td>
</tr>
<tr>
<td>USA OSHA</td>
<td>OSHA PEL (TWA) (ppm)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Metacresol (108-39-4)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>USA ACGIH</td>
<td>ACGIH TWA (mg/m³)</td>
</tr>
<tr>
<td>USA ACGIH</td>
<td>ACGIH TWA (ppm)</td>
</tr>
<tr>
<td>USA OSHA</td>
<td>OSHA PEL (TWA) (mg/m³)</td>
</tr>
<tr>
<td>USA OSHA</td>
<td>OSHA PEL (TWA) (ppm)</td>
</tr>
<tr>
<td>USA OSHA</td>
<td>Remark (US OSHA)</td>
</tr>
</tbody>
</table>

8.2. Exposure controls
Appropriate engineering controls : Work must be done with effective mechanical ventilation (e.g. local extractor fan). 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, nitril rubber or similar protection are recommended for waste clear-up and manufacturing operations.
Respiratory protection : Not normally required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Physical state : Liquid
Appearance : Colorless, clear liquid with a smell of cresol/phenol (preservative).
Molecular mass : 58.258 g/mol
Color : Colorless, clear.
Odor : Cresol/ Phenol.
Odor threshold : No data available
NovoLog®
Safety Data Sheet
according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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<tbody>
<tr>
<td>pH</td>
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</tr>
<tr>
<td>pH solution</td>
<td>7.2-7.6 (at 20 °C)</td>
</tr>
<tr>
<td>Relative evaporation rate (butylacetate=1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>100 °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density at 20 °C</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>1.005 g/ml (at 25 °C)</td>
</tr>
<tr>
<td>Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Log Pow</td>
<td>No data available</td>
</tr>
<tr>
<td>Log Kow</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive limits</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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

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®

Additional information: Hypersensitivity to the active substance or to any of the excipients. NovoLog® contains metacresol, which may cause allergic reactions.

Phenol (108-95-2)

<table>
<thead>
<tr>
<th>Toxicity Test</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 oral rat</td>
<td>270 mg/kg Gigi, 38(8), Pg. 6, 1973.</td>
</tr>
<tr>
<td>LD50 dermal rabbit</td>
<td>630 mg/kg Union Carbide Data Sheet. Vol. 1/6/1966.</td>
</tr>
<tr>
<td>LC50 inhalation rat (ppm)</td>
<td>81 ppm Nagosny 1976</td>
</tr>
<tr>
<td>ATE CLP (oral)</td>
<td>100,000 mg/kg body weight</td>
</tr>
<tr>
<td>ATE CLP (dermal)</td>
<td>300,000 mg/kg body weight</td>
</tr>
<tr>
<td>ATE CLP (gases)</td>
<td>700,000 ppm/l/4h</td>
</tr>
<tr>
<td>ATE CLP (vapors)</td>
<td>3,000 mg/l/4h</td>
</tr>
<tr>
<td>ATE CLP (dust, mist)</td>
<td>0.500 mg/l/4h</td>
</tr>
</tbody>
</table>

11/19/2014           EN (English)
Metacresol (108-39-4)

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin corrosion/irritation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Respiratory or skin sensitisation</td>
<td>May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

(Based on available data, the classification criteria are not met)

NovoLog®

Additional information

Standard 2-year carcinogenicity studies in animals have not been performed to evaluate the carcinogenic potential of NovoLog. At a dose of 200 U/kg/day, NovoLog increased the incidence of mammary gland tumors in females when compared to untreated controls. The incidence of mammary tumors for NovoLog 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

Reproductive toxicity

Pregnancy Category B

Specific target organ toxicity (single exposure)

Not classified

Specific target organ toxicity (repeated exposure)

Not classified

Phenol (108-95-2)

LOAEL (oral, rat, 90 days)

1.8 mg/kg bodyweight/day

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)

LC50 fish

20.5 mg/l


EC50 Daphnia


EC50 Daphnia

12.6 mg/l


EC50 (algae)

229 mg/l (72 hours)


11/19/2014 5/7 EN (English)
## Phenol (108-95-2)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fish</td>
<td>15.9 (8.9 - 55.9) mg/l Wellens, H. 1982. Comparison of the Sensitivity of Brachydanio rerio and Leuciscus idus by Testing the Fish Toxicity of Chemicals and Wastewaters. Z.Wasser-Abwasser-Forsch. 51(2):49-52 (GER) (ENG ABS)</td>
</tr>
</tbody>
</table>

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

**Phenol (108-95-2)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Log Pow</td>
<td>1.5</td>
</tr>
</tbody>
</table>

### 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

**Metacresol (108-39-4)**

- 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): 100 lb

**Aqueous solution contains insulin aspart. (Recombinant B28 Asp. Insulin) (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]
Not classified

Classification according to Directive 67/548/EEC (DSD) or 1999/45/EC (DPD)

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

Metacresol (108-39-4)
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

SECTION 16: Other information

Data sources:

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 sensitization 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 therefore be construed as guaranteeing any specific property of the product.