



# Fiasp® (insulin aspart injection) 100U/ml

## Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision date: 06/29/2018

### SECTION 1: Identification

#### 1.1. Identification

Product source : Solution  
Product name : Fiasp® (insulin aspart injection)  
Other means of identification : Insulin aspart  
Injection: Insulin aspart 100 units/mL (U-100):  
-10 mL multiple-dose Fiasp® vial  
-3 mL single-patient-use Fiasp® FlexTouch® pen

#### 1.2. Recommended use

Recommended use : FIASP is a rapid-acting human insulin analog called insulin aspart indicated to improve glycemic control in adults with diabetes mellitus.

#### 1.3. Supplier

Novo Nordisk  
800 Scudders Mill Road  
Plainsboro, NJ 08536  
T 1-800-727-6500  
[NNIMedicalInformation@novonordisk.com](mailto:NNIMedicalInformation@novonordisk.com) - [www.novonordisk-us.com](http://www.novonordisk-us.com)

#### 1.4. Emergency telephone number

Emergency number : 1-800-727-6500

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

##### GHS-US classification

Not classified

#### 2.2. GHS Label elements, including precautionary statements

##### GHS-US labeling

No labeling applicable

#### 2.3. Other hazards which do not result in classification

No additional information available

#### 2.4. Unknown acute toxicity (GHS US)

Not applicable

### SECTION 3: Composition/Information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

| Name  | Product identifier   | %        | GHS-US classification   |
|---|----------------------|----------|---|
| Aqueous solution contains insulin aspart.<br>(Recombinant B28 Asp. Insulin) | (CAS No) 116094-23-6 | 95 - 100 | Not classified  |
| Metacresol  | (CAS No) 108-39-4    | < 1      | Acute Tox. 3 (Oral), H301<br>Acute Tox. 3 (Dermal), H311<br>Skin Corr. 1B, H314<br>Aquatic Acute 3, H402  |
| Phenol  | (CAS No) 108-95-2    | < 1      | Acute Tox. 3 (Oral), H301<br>Acute Tox. 3 (Dermal), H311<br>Acute Tox. 3 (Inhalation), H331<br>Skin Corr. 1B, H314<br>Muta. 2, H341<br>STOT RE 2, H373<br>Aquatic Acute 3, H402 |

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Full text of hazard classes and H-statements : see section 16

### SECTION 4: First-aid measures

#### 4.1. Description of first aid measures

- First-aid measures after inhalation : Not an anticipated route of entry. Remove person to fresh air and keep comfortable for breathing.
- 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 (acute and delayed)

- Symptoms/effects : Adverse reactions observed with FIASP include: hypoglycemia, allergic reactions, hypersensitivity, injection site reactions, lipodystrophy, and weight gain. Hypersensitivity reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur. Discontinue FIASP, monitor and treat if indicated.
- Symptoms/effects after inhalation : None under normal use.
- Symptoms/effects after skin contact : None anticipated under normal conditions and use. As with other insulin therapy, patients may experience rash, redness, inflammation, bruising or itching at the site of FIASP injection. These reactions usually resolve in a few days to a few weeks, but in some occasions, may require discontinuation of FIASP.
- Symptoms/effects after eye contact : None under normal conditions.
- Symptoms/effects after ingestion : None under normal conditions.
- Symptoms/effects upon intramuscular travenous administration : Allergic reactions may occur and include generalized rash, and in some cases anaphylactic shock with breathing difficulties, and hypotension. May result in severe hypoglycemia.

#### 4.3. Immediate medical attention and special treatment, if necessary

No additional information available.

### SECTION 5: Fire-fighting measures

Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

#### 5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

#### 5.2. Specific hazards arising from the chemical

- Reactivity : The product is non-reactive under normal conditions of use, storage and transport.

#### 5.3. Special protective equipment and precautions for fire-fighters

- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

### 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

Avoid release to the environment.

#### 6.3. Methods and material for containment and cleaning up

- For containment : To the extent possible cleaning is performed with normal cleaning agents. Avoid use of solvents.
- Methods for cleaning up : Take up liquid spill into absorbent material.
- Other information : Dispose of materials or solid residues at an authorized site.

#### 6.4. Reference to other sections

For further information refer to section 13.

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### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

- Additional hazards when processed : Smoking, storage of tobacco, consumption and storage of food or liquids are not allowed in the workrooms.
- Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.
- Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

#### 7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Do not freeze Fiasp® and do not use Fiasp® if it has been frozen.
- Storage conditions : Store in a well-ventilated place. Keep cool. Keep away from excessive heat or light. Keep the cap on the pen in order to protect from light. Keep unused vials and FIASP FlexTouch in the carton so they will stay clean and protected from light.
- Storage temperature : Unused Fiasp® vials should be stored between 2° to 8°C (36° to 46°F) in a refrigerator, but not in or near a freezing compartment.  
During use: Store vials at room temperature below 30°C (86°F) for no more than 28 days.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### Aqueous solution contains insulin aspart. (Recombinant B28 Asp. Insulin) (116094-23-6)

Not applicable

##### Metacresol (108-39-4)

|       |                                      |                      |
|-------|--------------------------------------|----------------------|
| ACGIH | ACGIH TWA (mg/m <sup>3</sup> )       | 22 mg/m <sup>3</sup> |
| ACGIH | ACGIH TWA (ppm)                      | 5 ppm                |
| OSHA  | OSHA PEL (TWA) (mg/m <sup>3</sup> )  | 22 mg/m <sup>3</sup> |
| OSHA  | OSHA PEL (TWA) (ppm)                 | 5 ppm                |
| OSHA  | Remark (OSHA)                        | Skin Irrt.           |
| NIOSH | NIOSH REL (TWA) (mg/m <sup>3</sup> ) | 10 mg/m <sup>3</sup> |
| NIOSH | NIOSH REL (TWA) (ppm)                | 2.3 ppm              |

##### Phenol (108-95-2)

|       |                                     |                               |
|-------|-------------------------------------|-------------------------------|
| ACGIH | ACGIH TWA (ppm)                     | 5 ppm                         |
| ACGIH | Remark (ACGIH)                      | URT irr; lung dam; CNS impair |
| OSHA  | OSHA PEL (TWA) (mg/m <sup>3</sup> ) | 19 mg/m <sup>3</sup>          |
| OSHA  | OSHA PEL (TWA) (ppm)                | 5 ppm                         |
| NIOSH | US IDLH (ppm)                       | 250 ppm                       |

#### 8.2. Appropriate engineering controls

- Appropriate engineering controls : Ensure good ventilation of the work station.
- Environmental exposure controls : Avoid release to the environment.

#### 8.3. Individual protection measures/Personal protective equipment

##### Personal protective equipment:

Use only CE marked protective equipment.

##### Hand protection:

Protective gloves

##### Eye protection:

Safety glasses

##### Skin and body protection:

Wear suitable protective clothing

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### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

|   |                       |
|---|-----------------------|
| Physical state                              | : Liquid              |
| Color                                       | : Clear and Colorless |
| Odor  | : Odorless.           |
| Odor threshold                              | : No data available   |
| pH  | : 7.1                 |
| Melting point                               | : Not applicable      |
| Freezing point                              | : No data available   |
| Boiling point                               | : No data available   |
| Flash point                                 | : No data available   |
| Relative evaporation rate (butyl acetate=1) | : No data available   |
| Flammability (solid, gas)                   | : Not applicable.     |
| Vapor pressure                              | : No data available   |
| Relative vapor density at 20 °C             | : No data available   |
| Relative density                            | : No data available   |
| Solubility                                  | : Soluble.            |
| Log Pow                                     | : No data available   |
| Auto-ignition temperature                   | : No data available   |
| Decomposition temperature                   | : No data available   |
| Viscosity, kinematic                        | : No data available   |
| Viscosity, dynamic                          | : No data available   |
| Explosion limits                            | : No data available   |
| Explosive properties                        | : No data available   |
| Oxidizing properties                        | : No data available   |

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use, storage and transport.

### 10.4. Conditions to avoid

Do not expose to any forms of heat (e.g. solar radiation). May lead to excess pressure. Do not use if frozen.

### 10.5. Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

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| <b>Metacresol (108-39-4)</b> |   |
|------------------------------|---|
| LD50 oral rat                | 242 mg/kg BIOFAX Industrial Bio-Test Laboratories, Inc., Data Sheets.Vol. 3-5/1969.   |
| LD50 dermal rabbit           | 2050 mg/kg BIOFAX Industrial Bio-Test Laboratories, Inc., Data Sheets. Vol. 3-5/1969, |
| ATE US (oral)                | 242.000 mg/kg body weight   |
| ATE US (dermal)              | 300.000 mg/kg body weight   |

| <b>Phenol (108-95-2)</b>  |   |
|---------------------------|---|
| LD50 oral rat             | 270 mg/kg Gigiena i Sanitariya. For English translation, see HYSAAV. Vol. 38(8), Pg. 6, 1973. |
| LD50 dermal rabbit        | 630 mg/kg Union Carbide Data Sheet. Vol. 1/6/1966.  |
| LC50 inhalation rat (ppm) | 81 ppm Nagoznyi 1976  |
| ATE US (oral)             | 270.000 mg/kg body weight   |
| ATE US (dermal)           | 630.000 mg/kg body weight   |
| ATE US (gases)            | 700.000 ppmV/4h   |
| ATE US (vapors)           | 3.000 mg/l/4h   |
| ATE US (dust, mist)       | 0.500 mg/l/4h   |

|                                   |                             |
|-----------------------------------|-----------------------------|
| Skin corrosion/irritation         | : Not classified<br>pH: 7.1 |
| Serious eye damage/irritation     | : Not classified<br>pH: 7.1 |
| Respiratory or skin sensitization | : Not classified            |
| Germ cell mutagenicity            | : Not classified            |
| Carcinogenicity                   | : Not classified            |

| <b>Phenol (108-95-2)</b> |                      |
|--------------------------|----------------------|
| IARC group               | 3 - Not classifiable |

|                        |                  |
|------------------------|------------------|
| Reproductive toxicity  | : Not classified |
| STOT-single exposure   | : Not classified |
| STOT-repeated exposure | : Not classified |

| <b>Phenol (108-95-2)</b> |                          |
|--------------------------|--------------------------|
| LOAEL (oral,rat,90 days) | 1.8 mg/kg bodyweight/day |

|  |  |
|--|--|
| Aspiration hazard  | : Not classified   |
| Potential Adverse human health effects and symptoms          | : Severe, life-threatening, generalized allergy, including anaphylaxis, generalized skin reactions, angioedema, bronchospasm, hypotension, and shock may occur with use of any insulin, including FIASP, and may be life threatening.Administration of insulin, including FIASP, has resulted in lipohypertrophy (enlargement or thickening of tissue) and lipodystrophy (depression in the skin).As with other insulin therapy, patients may experience rash, redness, inflammation, bruising or itching at the site of FIASP injection. These reactions usually resolve in a few days to a few weeks, but in some occasions, may require discontinuation of FIASP. Weight gain can occur with insulin therapy, including FIASP, and has been attributed to the anabolic effects of insulin and the decrease in glucosuria. Insulin, including FIASP, may cause sodium retention and edema, particularly if previous poor metabolic control is improved by intensified insulin therapy. |
| Symptoms/effects   | : Adverse reactions observed with FIASP include: hypoglycemia, allergic reactions, hypersensitivity, injection site reactions, lipodystrophy, and weight gain. Hypersensitivity reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur. Discontinue FIASP, monitor and treat if indicated.   |
| Symptoms/effects after inhalation                            | : None under normal use.   |
| Symptoms/effects after skin contact                          | : None anticipated under normal conditions and use. As with other insulin therapy, patients may experience rash, redness, inflammation, bruising or itching at the site of FIASP injection. These reactions usually resolve in a few days to a few weeks, but in some occasions, may require discontinuation of FIASP.   |
| Symptoms/effects after eye contact                           | : None under normal conditions.  |
| Symptoms/effects after ingestion                             | : None under normal conditions.  |
| Symptoms/effects upon intramuscular travenous administration | : Allergic reactions may occur and include generalized rash, and in some cases anaphylactic shock with breathing difficulties, and hypotension. May result in severe hypoglycemia.   |

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### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

| Metacresol (108-39-4)        |   |
|------------------------------|---|
| LC50 fish                    | 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)   |
| EC50 Daphnia                 | 18.8 mg/l Parkhurst, B.R., A.S. Bradshaw, J.L. Forte, and G.P. Wright 1979. An Evaluation of the Acute Toxicity to Aquatic Biota of a Coal Conversion Effluent and its Major Components. Bull. Environ.Contam.Toxicol. 23(3):349-356  |
| Phenol (108-95-2)            |   |
| LC50 fish                    | 20.5 mg/l Cairns, J.Jr., and A. Scheier 1959. The Relationship of Bluegill Sunfish Body Size to Tolerance for Some Common Chemicals. Proc.13th Ind.Waste Conf., Purdue Univ.Eng.Bull 96:243-252; Smith, S., V.J. Furay, P.J. Layiwola, and J.A. Menezes-Filho 1994. Ev  |
| EC50 Daphnia                 | 20 mg/l Kamshilov, M.M., and B.A. Flerov 1976. Experimental Research on Phenol intoxication of Aquatic Organisms and Destruction of Phenol in Model Communities. In: D.I.Mount, W.R.Swain, N.K.Ivanikiw (Eds.), Proc.1st and 2nd USA-USSR Symp.on Effects of Pollutants upon Aquatic Ecosystems, Duluth, MN :181-192 (U.S.NTIS PB-287-219) (Author Communication Used); Cowgill, U.M., and D.P. Milazzo 1991. The Sensitivity of Ceriodaphnia dubia and Daphnia magna to Seven Chemicals Utilizing the Three-Brood Test. Arch.Environ.Contam.Toxicol. 20(2):211-217 |
| EC50 Daphnia                 | 12.6 mg/l Holcombe, G.W., G.L. Phipps, A.H. Sulaiman, and A.D. Hoffman 1987. Simultaneous Multiple Species Testing: Acute Toxicity of 13 Chemicals to 12 Diverse Freshwater Amphibian, Fish, and Invertebrate Families. Arch.Environ.Contam.Toxicol. 16:697-710 (OECDG Data File)   |
| ErC50 (algae)                | 229 mg/l (72 hours) Tisler, T., and J. Zagorc-Koncan 1995. Relative Sensitivity of Some Selected Aquatic Organisms to Phenol. Bull.Environ.Contam.Toxicol. 54(5):717-723  |
| ErC50 (other aquatic plants) | 84.5 mg/l (96 hours) Thellen, C., C. Blaise, Y. Roy, and C. Hickey 1989. Round Robin Testing with the Selenastrum capricornutum Microplate Toxicity Assay. Hydrobiologia 188/189:259-268  |

#### 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

Effect on the global warming : No known effects from this product.  
GWPmix comment : No known effects from this product.

### SECTION 13: Disposal considerations

#### 13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

### SECTION 14: Transport information

#### Department of Transportation (DOT)

In accordance with DOT

Not applicable

#### TDG

Not applicable

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### Transport by sea

Not applicable

### Air transport

Not applicable

## SECTION 15: Regulatory information

### 15.1. US Federal regulations

|  |  |
|--|--|
| <b>Aqueous solution contains insulin aspart.<br/>(Recombinant B28 Asp. Insulin) (116094-23-6)</b>  |  |
| Not listed on the United States TSCA (Toxic Substances Control Act) inventory  |  |
| <b>Metacresol (108-39-4)</b>   |  |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory<br>Subject to reporting requirements of United States SARA Section 313 |  |
| CERCLA RQ  | 100 lb   |
| <b>Phenol (108-95-2)</b>   |  |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory<br>Subject to reporting requirements of United States SARA Section 313 |  |
| CERCLA RQ  | 1000 lb  |
| SARA Section 302 Threshold Planning Quantity (TPQ)   | 10000 lb 500lb if the substance is solid in powder form with particle size less than 100 microns, or is in solution or molten form |

### 15.2. International regulations

#### CANADA

|   |  |
|---|--|
| <b>Aqueous solution contains insulin aspart.<br/>(Recombinant B28 Asp. Insulin) (116094-23-6)</b> |  |
| Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)     |  |
| <b>Metacresol (108-39-4)</b>  |  |
| Listed on the Canadian DSL (Domestic Substances List)   |  |
| <b>Phenol (108-95-2)</b>  |  |
| Listed on the Canadian DSL (Domestic Substances List)   |  |

#### EU-Regulations

No additional information available

#### National regulations

No additional information available

### 15.3. US State regulations

|   |
|---|
| <b>Metacresol (108-39-4)</b>  |
| U.S. - Delaware - Pollutant Discharge Requirements - Reportable Quantities<br>U.S. - Idaho - Non-Carcinogenic Toxic Air Pollutants - Acceptable Ambient Concentrations<br>U.S. - New Jersey - Right to Know Hazardous Substance List<br>U.S. - New York - Reporting of Releases Part 597 - List of Hazardous Substances<br>U.S. - Pennsylvania - RTK (Right to Know) List |
| <b>Phenol (108-95-2)</b>  |
| U.S. - Delaware - Pollutant Discharge Requirements - Reportable Quantities<br>U.S. - Idaho - Non-Carcinogenic Toxic Air Pollutants - Acceptable Ambient Concentrations<br>U.S. - New Jersey - Right to Know Hazardous Substance List<br>U.S. - New York - Reporting of Releases Part 597 - List of Hazardous Substances<br>U.S. - Pennsylvania - RTK (Right to Know) List |

## SECTION 16: Other information

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Data sources : ChemADVISOR, Inc.[<https://www.chemadvisor.com>]. National Library of Medicine [<http://sis.nlm.nih.gov/enviro.html>]. Fiasp® (insulin aspart injection)[package insert]. Bagsvaerd, Denmark. Novo Nordisk A/S.2017

Full text of H-phrases:

|      |   |
|------|---|
| H301 | Toxic if swallowed  |
| H311 | Toxic in contact with skin  |
| H314 | Causes severe skin burns and eye damage                           |
| H331 | Toxic if inhaled  |
| H341 | Suspected of causing genetic defects                              |
| H373 | May cause damage to organs through prolonged or repeated exposure |
| H402 | Harmful to aquatic life   |

NFPA health hazard

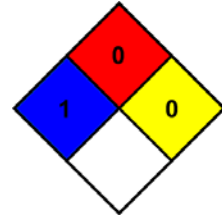
: 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.

NFPA fire hazard

: 0 - Materials that will not burn under typical dire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA reactivity

: 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health

: 1 Slight Hazard - Irritation or minor reversible injury possible

Flammability

: 0 Minimal Hazard - Materials that will not burn

Physical

: 0 Minimal Hazard - Materials that are normally stable, even under fire conditions, and will NOT react with water, polymerize, decompose, condense, or self-react. Non-Explosives.

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*