1. Product and Company Identification

PRODUCT NAME: APIDRA® SoloStar® insulin glulisine injection 100 units/mL (U-100)
3 mL Prefilled Pen

Substance name: insulin glulisine (rDNA origin)

Supplier:
Sanofi-aventis U.S. LLC
A SANOFI COMPANY
55 Corporate Drive
Bridgewater, NJ 08807

24-Hour Transport Emergency, US (Chemtrec):	**(800) 424-9300**
24-Hour Transport Emergency, outside US (Chemtrec):	**(703) 527-3887**
US Customer Service	**(800) 207-8049**
24-Hour Emergency, sanofi-aventis US:	**(908) 981-5550**

Product use: Pharmaceutical product.

2. Hazards Identification

2.1 Classification in accordance with 29 CFR 1910.1200

Classification: not classified as a hazardous substance or mixture.

2.2 Label elements in accordance with 29 CFR 1910.1200

Labeling of the finished drug product is not required according to OSHA 29 CFR 1910.1200. The following information is provided for the drug substance, insulin glulisine:

Signal Word: none required.

Hazard Statement(s): none required.

Symbol(s): none required.

Precautionary Statement(s): none required.

- Prevention: none required.

- Response: none required.
- Storage: none required.
- Disposal: none required.

2.3 Hazards Not Otherwise Classified (HNOC)

Not classified.

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3. Composition/Information on Ingredients

Chemical Name:		**CAS #:**	**Percentage or concentration range**
3B-L-Lys-29B-L-Glu-insuline (human)	Insulin glulisine	207748-29-6	3.49 mg/mL (0.3%)
Phenol, m-methyl-	m-Cresol	108-39-4	3.15 mg/mL (0.3%)
1,3-Propanediol, 2-amino-2(hydroxymethyl)-	Tromethamine	77-86-1	6 mg/mL (0.6%)
Sodium chloride	Sodium chloride	7647-14-5	5 mg/mL (0.5%)
Sorbitan, monododeconoate, poly(oxy-1,2-ethanediyl)	Polysorbate 20	9005-64-5	0.01 mg/mL (0.001%)
Water	Water for injection	7732-18-5	Balance (>98%)

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4. First Aid Measures

4.1 First aid procedures

Eye contact: In case of contact with product, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention.

Skin contact: In case of contact with product, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Ingestion: If swallowed, call a poison center or physician immediately. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water.

Inhalation: If product is inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. Get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Presence of hypoglycemia (sweating, trembling, tachycardia, hunger, anxiety, dizziness, headache, clouding of vision, loss of fine motor skills, combativeness, seizures, mental confusion, and loss of consciousness).

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.

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5. Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media: All means: water, carbon dioxide, foam or dry chemical.

Unsuitable extinguishing media: Strong water jet.

5.2 Specific hazards arising from the chemical

Hazardous combustion products: Carbon monoxide, carbon dioxide, oxides of sulfur and nitrogen.

5.3 Special Protective Equipment and Precautions for Fire-fighters

In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.

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6. Accidental Release Measures

6.1 Personal precautions and Protective Equipment:

Eye protection, respiratory protective equipment, and suitable protective clothing should be worn (see Section 8).

6.2 Emergency Procedures:

Follow local workplace procedures. Prevent the product from entering the environment. Avoid discharges to sewers, drains, waterways, or onto the ground.

6.3 Methods for containment:

Absorb spilled liquid with a suitable inert material, place in suitable container for disposal and mop area.

6.4 Methods for clean-up:

Wash the floor with plenty of water, absorb or retain the cleaning water for disposal.

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7. Handling and Storage

7.1 Precautions for Safe Handling

Product should be used in a controlled work area. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Place a disposable absorbent pad under the product preparation area. Do not eat, smoke or drink while handling product. Wash thoroughly after handling.

7.2 Conditions for Safe Storage

Unopened Apidra vials and cartridge systems should be stored in a refrigerator, 36°F - 46°F (2°C - 8°C). Apidra should not be stored in the freezer and it should not be allowed to freeze. Discard if it has been frozen.

Opened vials, whether or not refrigerated, must be used within 28 days after the first use. They must be discarded if not used within 28 days. If refrigeration is not possible, the open vial can be kept unrefrigerated for up to 28 days away from direct heat and light, as long as the temperature is not greater than 86°F (30°C).

Consult the package insert for additional storage instructions.

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8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure limit, insulin glulisine: 0.2 mg/m^3, 8-hour TWA.

m-Cresol: OSHA PEL 5 ppm (skin), all isomers. ACGIH TLV: 5 ppm (skin), all isomers.

8.2 Appropriate Engineering Controls

Provide adequate ventilation. No other specific controls are needed under normal handling conditions.

8.3 Individual Protection Measures

Eye/face protection: Safety glasses or safety goggles should be worn if there is a potential for eye contact with the product.

Skin protection: Suitable protective gloves should be worn. Use of a protective or disposable gown or laboratory coat is recommended if there exists a potential for contact with the product.

Respiratory protection: None normally required for routine handling of the product. However, approved respiratory protection should be worn if there is a potential for exposure to the product. A respiratory protection program that meets OSHA 29 CFR 1910.134 and ANSI Z88.2 must be followed whenever workplace conditions warrant respirator usage.

General hygiene considerations: Wash hands before breaks and at the end of the work shift.

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9. Physical and Chemical Properties

Appearance: Clear, colorless liquid.
Odor: None
Odor threshold: Not applicable.
pH: Approximately 7.3
Melting point/ Freezing point: Not applicable.
Initial boiling point/boiling point range: Not applicable.
Flash point: Not available.
Evaporation rate: Not applicable.
Flammability: Not available.
Upper/lower flammability or explosive limits: No data available.
Vapor pressure: Not applicable.
Vapor density: Not applicable.
Relative density: 1.0051 g/cm^3 at 20^o C.
Solubility: Not available.
Partition coefficient: n-octanol/water: Not available.
Auto-ignition temperature: Not available.
Decomposition temperature: Not available.
Viscosity: Not available.

10. Stability and Reactivity

10.1 Reactivity

Not a reactive material under normal handling conditions.

10.2 Chemical Stability

Stable under normal handling conditions.

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to Avoid

Keep away from heat, sparks and flames.

10.5 Incompatible materials

Strong oxidizing and reducing agents.

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide, oxides of sulfur and nitrogen.

11. Toxicological Information

The following information is for the active ingredient insulin glulisine unless otherwise noted:

Information on likely routes of exposure: Not expected under normal handling conditions. Insulin is orally non-toxic as it can be broken down in the stomach. If absorbed through mucous membranes such as the respiratory tract or mouth, may exert a systemic hypoglycemic effect. Unintended spills or releases could result in exposure to eyes, skin and respiratory tract.

Symptoms related to the physical, chemical and toxicological characteristics: Presence of hypoglycemia (sweating, trembling, tachycardia, hunger, anxiety, dizziness, headache, clouding of vision, loss of fine motor skills, combativeness, seizures, mental confusion, and loss of consciousness).

Effects of short-term (acute) exposure: Hypoglycemia.

Effects of long-term (chronic) exposure: Hypoglycemia.

Acute toxicity (LD50):
Oral route, rat: > 2,000 mg/kg (OECD 423).

Skin corrosion/irritation: No data available.

Serious eye damage/irritation: No data available.

Sensitization: No data available.

Specific target organ toxicity – single exposure (STOT-SE): No data available.

Specific target organ toxicity – repeated exposure (STOT-RE): No data available.

Carcinogenicity: Standard 2-year carcinogenicity studies in animals have not been performed.

Not listed by NTP, not found to be a potential carcinogen by IARC or OSHA.

Reproductive toxicity and teratogenicity: Reproduction and teratology studies have been performed with insulin glulisine in rats and rabbits using regular human insulin as a comparator. Insulin glulisine was given to female rats throughout pregnancy at subcutaneous doses up to 10 Units/kg once daily (dose resulting in an exposure 2 times the average human dose, based on body surface area comparison) and did not have any remarkable toxic effects on embryo-fetal development. Insulin glulisine was given to female rabbits throughout pregnancy at subcutaneous doses up to 1.5 Units/kg/day (dose resulting in an exposure 0.5 times the average human dose, based on body surface area comparison). Adverse effects on embryo-fetal development were only seen at maternal toxic dose levels inducing hypoglycemia. The effects of insulin glulisine did not differ from those observed with subcutaneous regular human insulin at the same doses and were attributed to secondary effects of maternal hypoglycemia.

Mutagenicity: Insulin glulisine was not mutagenic in the following tests: Ames test, in vitro mammalian chromosome aberration test in V79 Chinese hamster cells, and in vivo mammalian erythrocyte micronucleus test in rats.

Aspiration hazard: Not determined.

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12. Ecological Information

The following information is for the active ingredient insulin glulisine unless otherwise noted:

12.1. Ecotoxicity

Fish toxicity (LC50): > 100 mg/l
Species: Danio rerio
Exposure duration: 96 h
Method: OECD 203

Chronic aquatic toxicity: not determined

Toxicity on invertebrates (EC50): > 100 mg/l
Species: Daphnia magna
Exposure duration: 48 h
Method: OECD 202

Toxicity on invertebrates (Chronic toxicity): not determined

Algae toxicity (EC50): > 100 mg/l
Species: Desmodesmus subspitacus
Exposure duration: 72 h
Endpoint : Biomass
Method: OECD 201

12.2. Persistence and degradability

Biological degradability: > 60%
Readily biodegradable.
Testing period: 28 d
Method of analysis: Theoretical oxygen demand
Method: OECD 301 F

12.3. Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Other adverse effects

No data available.

13. Disposal Considerations

13.1 Disposal of product waste

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. Apidra contains m-cresol, a RCRA characteristic waste (D024).

13.2 Disposal of packaging waste

Dispose of in a safe manner in accordance with federal, state and local environmental regulations. Empty packages, containers or liners may contain product residue.

14. Transport Information

14.1 Basic shipping information, finished product

U.S. DOT	Not a regulated material.
ICAO/IATA	Not a regulated material.
IMDG	Not a regulated material.

15. Regulatory Information

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4): m-cresol (RQ 100 lbs.).
Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): Not listed.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not listed.
SARA Title III:
Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): Not listed.
Section 313 Toxic Release Inventory (40 CFR 372): m-cresol.

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

Massachusetts Right-To-Know List: m-cresol.
New Jersey Right-To-Know List: m-cresol.
Pennsylvania Right-To-Know List: m-cresol.

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16. Other Information

Other Information: The information contained herein is based upon data considered true and accurate. Sanofi-aventis U.S. LLC. makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Abbreviations and Acronyms
CAS: Chemical Abstracts Service
DOT: U.S. Department of Transportation
EST: Eastern standard time (U.S.)
IATA: International Air Transport Association
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
OEL: Occupational Exposure Limit
PPE: Personal Protection Equipment
SDS: Safety Data Sheet
STEL: Short-term exposure limit
TWA: Time-weighted average
U.S.: United States

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Second version.