MATERIAL SAFETY DATA SHEET

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1. PRODUCT IDENTIFICATION

Product Name(s): **Lantus SoloStar®**

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**

2. HAZARDS IDENTIFICATION

Emergency Overview No hazards expected. This is a disposable insulin pen with a glass cartridge that contains 3 mL of Lantus.

Eye No data for determination of unusual hazard to the eyes is available at this time.

Skin Contact No adverse dermal effects are known.

Skin Absorption Not expected.

Ingestion Not intended for oral use but expected to be non-toxic by ingestion.

Inhalation Not an expected route of exposure.

Chronic Effects/ Carcinogenicity None known.

Medical Conditions Aggravated by Exposure Hypersensitivity to insulin.

3. COMPOSITION / INFORMATION ON INGREDIENTS

CAS#	CHEMICAL IDENTITY
160337-95-1	Insulin glargine
7732-18-5	Water for Injection
108-39-4	m-Cresol
7646-85-7	Zinc chloride
56-81-5	Glycerol
1310-73-2	Sodium hydroxide (for pH adjustment only)
7647-01-0	Hydrochloric acid (for pH adjustment only)

None of the components are listed as carcinogens by IARC, NTP or OSHA.

4. FIRST AID MEASURES

Eyes Flush with water for 15 minutes. If irritation develops, seek medical attention.

Skin Wash with soap and water. If irritation develops, seek medical attention.

Ingestion If accidentally swallowed, seek medical attention and show the physician the package insert.

Inhalation Not an expected route of exposure, but if exposure should occur, risk of hypoglycemia exists. Seek medical attention if symptoms appear.

Note to Physician Symptoms 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).

5. FIRE FIGHTING MEASURES

General Hazards Only potential fire hazard would involve packaging material.

Fire Fighting Extinguishing Media In case of fire use waterspray, foam or dry chemical.

Fire Fighting Instructions In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire.

Hazardous Combustion Products Packaging material fires may produce carbon monoxide and other gaseous asphyxiants plus airborne particulate matter, soot and smoke.

6. ACCIDENTAL RELEASE MEASURES

Large Spill Contain spill. Absorb on suitable medium and deposit in container for disposal. Mop area with soap and water.

Small Spill Absorb on paper towels. Deposit in suitable container for disposal. Broken glass requires additional caution.

7. HANDLING AND STORAGE

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

The opened (in-use) SoloStar® should NOT be refrigerated but should be kept at room temperature (below 86°F [30°C]) away from direct heat and light. The opened (in-use) SoloStar® kept at room temperature must be discarded after 28 days.

Consult the package insert for additional storage instructions.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eye Protection Clean-up, manufacturing and packaging operations may require safety glasses or goggles if there is a potential for splashing.

Skin Protection Nitrile gloves or gloves of equal or greater protection are recommended for spill clean-up, manufacturing and packaging operations.

Respiratory Protection None normally required.

Engineering Controls Clean-up, manufacturing and packaging operations should be required so as to offer no significant exposure to the ingredients.

Exposure Limits Insulin glargine: sanofi-aventis OEB 2, 8-hour OEL-TWA = 200 mcg/m3.
m-Cresol: OSHA PEL 5 ppm (skin), all isomers. ACGIH TLV 5 ppm (skin), all isomers.

9. PHYSICAL AND CHEMICAL PROPERTIES

Lantus solution:

Color:	Clear
Physical State:	Liquid
pH:	4.4 at 1 g/L, 20^{O} C
Odor:	None
Density:	1.0051 g/cm3 at 20^{O} C

10. STABILITY AND REACTIVITY

Incompatibility No known incompatibilities.

Hazardous Decomposition Products No known hazardous decomposition products.

Hazardous Polymerization Hazardous polymerization has not been reported to occur under normal temperatures and pressures.

11. TOXICOLOGICAL INFORMATION

Information below is for Insulin Glargine:

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.

Carcinogenic Effects: In mice and rats, standard two-year carcinogenicity studies with insulin glargine were performed at doses up to 0.455 mg/kg, which is for the rat approximately 10 times and for the mouse approximately 5 times the recommended human subcutaneous starting dose of 10 IU (0.008 mg/kg/day), based on mg/m^2. The findings in female mice were not conclusive due to excessive mortality in all dose groups during the study. Histiocytomas were found at injection sites in male rats (statistically significant) and male mice (not statistically significant) in acid vehicle containing groups. These tumors were not found in female animals, in saline control, or insulin comparator groups using a different vehicle. The relevance of these findings to humans is unknown.

Genotoxicity: Insulin glargine was not mutagenic in tests for detection of gene mutations in bacteria and mammalian cells (Ames- and HGPRT-test) and in tests for detection of chromosomal aberrations (cytogenetics in vitro in V79 cells and in vivo in Chinese hamsters).
In a combined fertility and prenatal and postnatal study in male and female rats at subcutaneous doses up to 0.36 mg/kg/day, which is approximately 7 times the recommended human subcutaneous starting dose of 10 IU (0.008 mg/kg/day), based on mg/m^2, maternal toxicity due to dose-dependent hypoglycemia, including some deaths, was observed. Consequently, a reduction of the rearing rate occurred in the high-dose group only. Similar effects were observed with NPH human insulin.

Teratogenic Effects: Pregnancy Category C. Subcutaneous reproduction and teratology studies have been performed with insulin glargine and regular human insulin in rats and Himalayan rabbits. The drug was given to female rats before mating, during mating, and throughout pregnancy at doses up to 0.36 mg/kg/day, which is approximately 7 times the recommended human subcutaneous starting dose of 10 IU (0.008 mg/kg/day), based on mg/m^2. In rabbits, doses of 0.072 mg/kg/day, which is approximately 2 times the recommended human subcutaneous starting dose of 10 IU (0.008 mg/kg/day), based on mg/m^2, were administered during organogenesis. The effects of insulin glargine did not generally differ from those observed with regular human insulin in rats or rabbits. However, in rabbits, five fetuses from two litters of the high-dose group exhibited dilation of the cerebral ventricles. Fertility and early embryonic development appeared normal.

12. ECOLOGICAL INFORMATION

Ecological Information No information for determination of unusual environmental fate or toxicity is available at this time.

13. DISPOSAL CONSIDERATIONS

Disposal Information This material and its container must be disposed of in a safe way.

Waste Disposal Methods Wastes must be disposed of in accordance with federal, state and local environmental regulations. The finished product would not be regulated under 40 CFR 261 for disposal under normal use and handling conditions. This product contains m-cresol and may be regulated under 40 CFR 261.24 when disposed of in bulk quantities.

14. TRANSPORT INFORMATION

DOT/IATA Not a regulated material.

15. REGULATORY INFORMATION

TSCA Inventory Status: This product is a pharmaceutical agent and as such is regulated by the United States Food and Drug Administration (FDA).

Individual components:

TSCA Inventory: m-Cresol; Glycerin
CERCLA: m-Cresol (RQ 1000 lb)
Zinc chloride (RQ 1000 lb)
Sodium hydroxide (RQ 1000 lb)
Hydrochloric acid (RQ 5000 lb)
SARA Section 313: m-Cresol; Hydrochloric acid (de minimis concentration 1.0%)

16. OTHER INFORMATION

Other Information The information contained herein is based upon data considered true and accurate. Sanofi-aventis US 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.