

SAFETY DATA SHEET

1. Identification

Product identifier	Insulin Lispro RS
Other means of identification	
Item Code	
Synonyms	28B-L-lysine-29B-L-proline human insulin analog
Recommended use	Specified Quality test and assay use only.
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	No Symbol
Signal word	Not available
Hazard statement	Not available
Precautionary statement	
Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.
Hazard(s) not otherwise classified (HNOC)	Not classified
Supplemental information	Not applicable.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Insulin, Lispro Crystals	Insulin (human), 28B- L- lysine-29B-L-proline-human insulin analog	133107-64-9	100%

Composition comments

This product are non-hazardous and/or are present at concentrations below reportable levels.

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Safety Data Sheet	Catalog Number: : Insulin Lispro HIL-02
Issue date : 14.09.2018	Amendment: 00 Page No.: 1/6

4. First-aid measures

Inhalation	Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists. Take off contaminated clothing and wash before reuse.
Eye contact	Immediately flush eye(s) with plenty of water. Get medical attention.
Ingestion	Consult a physician.
Most important symptoms/effects, acute and delayed	None known.

5. Fire-fighting measures

Suitable extinguishing media	Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	None known.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
General fire hazards	This product is an aqueous mixture which will not burn.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Avoid inhalation of mists or aerosols.
Methods and materials for containment and cleaning up	Prevent runoff from entering drains, sewers, or streams. Use absorbent/adsorbent material to solidify liquids. Clean up promptly by sweeping or vacuum.
Environmental precautions	Avoid release to the environment.

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. See Section 8 of the SDS for Personal Protective Equipment.
Conditions for safe storage, including any incompatibilities	Keep refrigerated.

8. Exposure controls/personal protection

Occupational exposure limits

Components	Type	Value	Form
Insulin, Lispro Crystals (CAS 133107-64-9)	STEG (15min)	600 ug/m3	Respirable
	TWA (12hrs)	120 ug/m3	Respirable
Biological limit values	No biological exposure limits noted for the ingredient(s).		
Appropriate engineering controls	Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.		
Individual protection measures, such as personal protective equipment			
Eye/face protection	Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/faceshield.		
Skin protection	Chemical resistant gloves.		
Hand protection	Chemical-resistant gloves and impermeable body covering to minimize skin contact.		
Other Respiratory protection	If the applicable occupational exposure level (OEL) is anticipated to be exceeded, wear an approved respirator with sufficient protection factor to control exposure below the OEL.		

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Safety Data Sheet	Catalog Number: : Insulin Lispro HIL-02	
Issue date : 14.09.2018	Amendment: 00	Page No.: 2/6

Thermal hazards Not available.

General hygiene considerations Engineering controls should be used as the primary means to control workplace exposures. Follow good workplace hygiene practices such as washing hands after handling this material.

9. Physical and chemical properties

Appearance

Physical state	solid
Form	Lyophilized solid
Color	White, off white
Odor	Odorless
Odor threshold	No data available.
pH	7 - 7.8
Melting point/freezing point	No data available.
Initial boiling point and boiling range	> 212 °F (> 100 °C)
Flash point	No data available.
Evaporation rate	No data available.
Flammability (solid, gas)	Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	No data available.
Flammability limit - upper (%)	No data available.
Explosive limit - lower (%)	No data available.
Explosive limit - upper (%)	No data available.

Vapor pressure	No data available.
Vapor density	No data available.
Relative density	No data available.

Solubility(ies)	
Solubility (water)	Soluble (water)

Partition coefficient (n-octanol/water)	No data available.
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Auto-ignition temperature	No data available.
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Decomposition temperature	No data available.
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Viscosity	No data available.
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Other information

Density	No data available.
Explosive properties	Not explosive
Oxidizing properties	The substance or mixture is not classified as oxidizing.
Percent volatile	No data available.
Specific gravity	1.004 - 1.008
VOC (Weight %)	No data available.

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Safety Data Sheet	Catalog Number: : Insulin Lispro HIL-02
Issue date : 14.09.2018	Amendment: 00 Page No.: 3/6

10. Stability and reactivity

Reactivity

Chemical stability

Not water reactive.

Possibility of hazardous reactions

Material is stable under normal conditions.
Hazardous polymerization does not occur.

Conditions to avoid

Incompatible materials

None under normal conditions.

Hazardous decomposition products

Strong oxidizing agents.

No hazardous decomposition products are known.

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Safety Data Sheet

Catalog Number: : Insulin Lispro HIL-02

Issue date : 14.09.2018

Amendment: 00

Page No.: 4/6

11. Toxicological information

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Insulin, Lispro Crystals (CAS 133107-64-9)		
<u>Acute</u>		
Other	Dog	2 units/kg, Subcutaneous 0.1 units/kg, Intravenous
	Rat	10 units/kg, Intravenous 10 units/kg, Subcutaneous

Skin corrosion/irritation Due to lack of data the classification is not possible.

Serious eye damage/eye irritation Due to lack of data the classification is not possible.

Respiratory or skin sensitization

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Rhesus monkeys, extremely weak immunogenic potential. (Insulin, Lispro Crystals)
Due to inconclusive data the classification is not possible.

Germ cell mutagenicity Results in genetic toxicity assays (in vitro): Negative (Insulin, Lispro Crystals) Due to inconclusive data the classification criteria are not met.

Carcinogenicity One-year subcutaneous injection studies demonstrated no evidence of carcinogenicity in rats. (Insulin, Lispro Crystals)
Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

Reproductive toxicity Mixed results reported in animal studies. Effects were attributed to hypoglycemia. Insulin itself is not considered a reproduction hazard. (Insulin, Lispro Crystals)
Based on available data, the classification criteria are not met.

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Animal studies have reported the following effects: Decreased blood sugar levels. (Subcutaneous) (Insulin, Lispro Crystals)
Based on available data, the classification criteria are not met.

Aspiration hazard No aspiration toxicity classification

12. Ecological information

Ecotoxicity No data available.
No data is available on the degradability of this product.

Persistence and degradability No data available for this product

Bioaccumulative potential No data available.

Mobility in soil Not available

Other adverse effects

13. Disposal considerations

Disposal instructions: Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

DOT Not regulated as dangerous goods

IATA Not regulated as dangerous goods

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Issue date : 14.09.2018	Amendment: 00 Page No.: 5/6

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

16. Other information

Disclaimer

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE

ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

Reference: Lilly Safety Data Sheet

Read product leaflet of catalogue no. HIL-02 before use.

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Issue date : 14.09.2018		Amendment: 00	Page No.: 6/6