



# Material Safety Data Sheet

Code No. Section 1 :	<b>Name of the Product</b> <b>Chemical Identification</b> Code No. : <b>TCL1035</b> Name of the Product : <b>Recombinant Human Insulin Solution, 10mg/ml</b> Produced : Central Drug House Pvt. Ltd. Address : 7/28 Vardaan House, Darya Ganj, New Delhi (INDIA) Tel. No. : 00 91 11 49404040	<b>Recombinant Human Insulin Solution, 10mg/ml</b> <b>TCL1035</b>
Section 2	<b>Hazards Identification</b>	
	<p><b>2.1 Classification of the substance or mixture</b> <b>CLP Classification-Regulation (EC) No. 1272/2008[EU-GHS/CLP]</b> Not a hazardous substance or mixture according to Regulation (EC) No.1272/2008</p> <p><b>2.2 Label elements</b> <b>Labeling according to Regulation (EC) No.1272/2008</b> The product does not need to be labelled in accordance with EC directives or respective national laws.</p> <p><b>2.3 Other Hazards</b> None</p>	
Section 3	<b>Composition/Information On Ingredients</b>	
	No components need to be disclosed according to the applicable regulations.	
Section 4	<b>First - Aid Measures</b>	
	<p><b>4.1 Description of first aid measures</b> <b>General advice</b> Show this safety data sheet to the doctor in attendance. <b>If inhaled</b> If breathed in, move person into fresh air. Consult a physician. <b>In case of skin contact</b> Wash off with soap and plenty of water. If skin irritation occurs, get medical advice/attention. <b>In case of eye contact</b> Rinse out with plenty of water with the eyelid held wide open. If eye irritation persists, get medical advice/attention. <b>If swallowed</b> Rinse mouth with water. Consult a physician if feeling unwell.</p> <p><b>4.2 Most important symptoms and effects, both acute and delayed</b> The most important known symptoms and effects are described in the labeling (see section 2.2) and/or in section 11.</p> <p><b>4.3 Indication of immediate medical attention and special treatment needed</b> No data available</p>	
Section 5	<b>Fire Fighting Measures</b>	
	<p><b>5.1 Extinguishing media</b> <b>Suitable extinguishing media</b> Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. <b>Unsuitable extinguishing media</b></p> <p><b>5.2 Special hazards arising from the substance or mixture</b> Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides</p> <p><b>5.3 Precautions for fire-fighters</b> No data available</p>	



	<b>5.4 Further information</b> Wear self-contained breathing apparatus for firefighting if necessary.
Section 6	<b>Accidental Release Measures</b>
	<b>6.1 Personal precautions, protective equipment and emergency procedures</b> Use personnel protective equipment. Wear disposable gloves, dust mask and eye protection. Avoid dust formation. For personal protection see section 8. <b>6.2 Environmental precautions</b> Prevent further leakage or spillage if safe to do so. No special environmental precautions required. <b>6.3 Methods and materials for containment and cleaning up</b> Keep in suitable, closed containers for disposal. <b>6.4 Reference to other sections</b> For disposal see Section 13.
Section 7	<b>Handling and Storage</b>
	<b>7.1 Precautions for safe handling</b> Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2. <b>7.2 Conditions for safe storage, including any incompatibilities</b> Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. <b>Recommended Storage Temperature :</b> On receipt store between 2 to 8 °C <b>7.3 Specific end uses</b> Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.
Section 8	<b>Exposure Controls / Personal Protection</b>
	<b>8.1 Control parameters</b> Components with workplace control parameters <b>8.2 Exposure controls</b> <b>Appropriate engineering controls</b> Handle in accordance to general industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the products. <b>Personal protective equipment</b> <b>Hygiene measures</b> Avoid contact with skin, eyes and clothing. Immediately change contaminated clothing. <b>Eye/face protection</b> Safety glasses with side-shields conforming to EN 166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU). <b>Skin protection</b> The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. <b>Body protection</b> Impervious clothing The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.



	<p><b>Respiratory protection</b> For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).</p> <p><b>Environment exposure controls</b> Do not let product enter drains.</p>																																								
Section 9	<b>Physical and Chemical Properties</b>																																								
	<p><b>9.1 Information on basic physical and chemical properties</b></p> <table> <tr><td>Appearance</td><td>Colorless clear solution</td></tr> <tr><td>Odour</td><td>No data available</td></tr> <tr><td>Odour Threshold</td><td>No data available</td></tr> <tr><td>pH</td><td>No data available</td></tr> <tr><td>Melting/freezing point</td><td>No data available</td></tr> <tr><td>Initial boiling point and boiling range</td><td>No data available</td></tr> <tr><td>Flash point</td><td>No data available</td></tr> <tr><td>Upper/lower flammability or explosive limits</td><td>No data available</td></tr> <tr><td>Evaporation rate</td><td>No data available</td></tr> <tr><td>Flammability (Solid, gas)</td><td>No data available</td></tr> <tr><td>Vapour pressure</td><td>No data available</td></tr> <tr><td>Relative density</td><td>No data available</td></tr> <tr><td>Partition coefficient: n-octanol/water</td><td>No data available</td></tr> <tr><td>Autoignition Temperature</td><td>No data available</td></tr> <tr><td>Decomposition Temperature</td><td>No data available</td></tr> <tr><td>Viscosity</td><td>No data available</td></tr> <tr><td>Explosive properties</td><td>No data available</td></tr> <tr><td>Oxidizing properties</td><td>No data available</td></tr> <tr><td>Vapour density</td><td>No data available</td></tr> <tr><td>Thermal decomposition</td><td>No data available</td></tr> </table> <p><b>9.2 Other safety information</b> No data available</p>	Appearance	Colorless clear solution	Odour	No data available	Odour Threshold	No data available	pH	No data available	Melting/freezing point	No data available	Initial boiling point and boiling range	No data available	Flash point	No data available	Upper/lower flammability or explosive limits	No data available	Evaporation rate	No data available	Flammability (Solid, gas)	No data available	Vapour pressure	No data available	Relative density	No data available	Partition coefficient: n-octanol/water	No data available	Autoignition Temperature	No data available	Decomposition Temperature	No data available	Viscosity	No data available	Explosive properties	No data available	Oxidizing properties	No data available	Vapour density	No data available	Thermal decomposition	No data available
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Section 10	<b>Stability and Reactivity</b>																																								
	<p><b>10.1 Reactivity</b> No data available</p> <p><b>10.2 Chemical stability</b> Stable under recommended storage conditions.</p> <p><b>10.3 Possibility of hazardous reactions</b> No data available</p> <p><b>10.4 Conditions to avoid</b> No data available</p> <p><b>10.5 Incompatible materials</b> No data available</p> <p><b>10.6 Hazardous decomposition products</b> None under normal use conditions. Other decomposition products. No data available. In event of fire – refer section 5</p>																																								



Section 11	<b>Toxicological Information</b>
	<p><b>11.1 Information on toxicological effects</b></p> <p><b>Acute toxicity</b> No data available</p> <p><b>Skin corrosion/irritation</b> No data available</p> <p><b>Serious eye damage/eye irritation</b> No data available</p> <p><b>Respiratory or skin sensitisation</b> No data available</p> <p><b>Germ cell mutagenicity</b> No data available</p> <p><b>Carcinogenicity</b> IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.</p> <p><b>Reproductive toxicity</b> No data available</p> <p><b>Specific target organ toxicity- single exposure</b> No data available</p> <p><b>Specific target organ toxicity - repeated exposure</b> No data available</p> <p><b>Aspiration hazard</b> No data available</p>
Section 12	<b>Ecological Information</b>
	<p><b>12.1 Toxicity</b> No data available</p> <p><b>12.2 Persistence and degradability</b> No data available</p> <p><b>12.3 Bioaccumulative potential</b> No data available</p> <p><b>12.4 Mobility in soil</b> No data available</p> <p><b>12.5 PBT and vPvB assessment</b> PBT and vPVB assessment not available Chemical safety assessment is not required</p> <p><b>12.6 Other adverse effects</b> No data available</p>
Section 13	<b>Disposal Considerations</b>
	<p><b>13.1 Waste treatments methods</b></p> <p><b>Product</b> Offer surplus and non-recyclable solutions to a licenced disposal company. Dispose off waste in accordance with all applicable Federal, state and local laws.</p> <p><b>13.2 Contaminated packaging</b> Dispose in accordance with all applicable federal, state, and local environmental regulations.</p>



## Material Safety Data Sheet

Section 14	<b>Transport Information</b>
	<p><b>14.1 UN-No</b> ADNR : ADR : IATA_C : IATA_P : IMDG : RID :</p> <p><b>14.2 UN proper shipping name</b> ADNR : Not dangerous goods ADR : Not dangerous goods IATA_C : Not dangerous goods IATA_P : Not dangerous goods IMDG : Not dangerous goods RID : Not dangerous goods</p> <p><b>14.3 Transport hazard class(es)</b> ADNR : - ADR : - IATA_C : - IATA_P : - IMDG : - RID : -</p> <p><b>14.4 Packaging group</b> ADNR : - ADR : - IATA_C : - IATA_P : - IMDG : - RID : -</p> <p><b>14.5 Environmental hazards</b></p> <p><b>14.6 Special precautions for use</b> No data available</p>
Section 15	<b>Regulatory Information</b>
	<p>This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.</p> <p><b>15.1 Safety health and environment regulations/legislation specific for the substance or mixture</b> No data available</p> <p><b>15.2 Chemical Safety Assessment</b> No data available</p>
Section 16	<b>Other Information</b>
	<p><b>Further Information</b></p> <p>The information contained in this data sheet represents the best information currently available to us. However, no warranty is made with respect to its completeness and we assume no liability resulting from its use. The information is offered solely for user's obligation to investigate and determine the suitability of the information for their particular purpose.</p>