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# Safety data sheet(SDS)

According to Regulation (EC) No.1907/2006

Revision: 00000

Date of Revision: 23.10.2017

# 1 Identification of the substances/ mixture and of the company/ undertaking

1.1 Product Identifiers

Product Number TCL035

Product Name Recombinant Human Insulin Solution, 10mg/ml

1.2 Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant identified uses Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Produced by HiMedia Laboratories Private Limited

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1.4 Emergency Tel. No.

Emergency Tel. No. Please contact the regional HiMedia representation in your country

# 2 Hazards Identification

## 2.1 Classification of the substance or mixture

CLP Classification-Regulation (EC) No. 1272/2008[EU-GHS/CLP]

Not a hazardous substance or mixture according to Regulation (EC) No.1272/2008

## 2.2 Label elements

Labeling according to Regulation (EC) No.1272/2008

The product does not need to be labelled in accordance with EC directives or respective national laws.

## 2.3 Other Hazards

None

## 3 Composition/Information On Ingredients

No components need to be disclosed according to the applicable regulations.

## 4 First Aid Measures

## 4.1 Description of first aid measures

## General advice

Show this safety data sheet to the doctor in attendance.

## If inhaled

If breathed in, move person into fresh air. Consult a physician.

## In case of skin contact

Wash off with soap and plenty of water. If skin irritation occurs, get medical advice/attention.

# In case of eye contact

Rinse out with plenty of water with the eyelid held wide open. If eye irritation persists, get medical advice/attention.

## If swallowed

Rinse mouth with water. Consult a physician if feeling unwell.

## 4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labeling (see section 2.2) and/or in section 11.

## 4.3 Indication of immediate medical attention and special treatment needed

No data available

## 5 Fire Fighting Measures

# 5.1 Extinguishing media

# Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

## Unsuitable extinguishing media

# 5.2 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides (NOx),, Sulphur oxides

## **5.3** Precautions for fire-fighters

No data available.

#### 5.4 Further information

Wear self-contained breathing apparatus for firefighting if necessary.

# 6 Accidental Release Measures

## 6.1 Personal precautions, protective equipment and emergency procedures

Use personnel protective equipment. Wear disposable gloves, dust mask and eye protection. Avoid dust formation. For personal protection see section 8.

## 6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. No special environmental precautions required.

## 6.3 Methods and materials for containment and cleaning up

Keep in suitable, closed containers for disposal.

## 6.4 Reference to other sections

For disposal see Section 13.

## 7 Handling and Storage

# 7.1 Precautions for safe handling

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.

# 7.2 Conditions for safe storage, including any incompatibilities

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.

Recommended Storage Temperature: On receipt store between 2-8°C

# 7.3 Specific end uses

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

# 8 Exposure Controls/Personal Protection

## 8.1 Control parameters

Components with workplace control parameters

# 8.2 Exposure controls

## Appropriate engineering controls

Handle in accordance to general industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the products.

## Personal protective equipment

# Hygiene measure

Avoid contact with skin, eyes and clothing. Immediately change contaminated clothing.

## Eye/face protection

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).

## Skin protection

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.

## **Body protection**

Impervious clothing The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

## Respiratory protection

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).

## **Environment exposure controls**

Do not let product enter drains.

# 9 Physical and chemical properties

# 9.1 Information on basic physical and chemical properties

Colorless, clear solution **Appearance** Odour No data available **Odour Threshold** No data available рН 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 No data available Flammability (Solid, gas) Vapour pressure No data available Relative density No data available Partition coefficient: n-octanol/water No data available

Autoignition Temperature

Decomposition Temperature

Viscosity

No data available

# 9.2 Other safety information

No data available

# 10 Stability and Reactivity

# 10.1 Reactivity

No data available

#### 10.2 Chemical stability

Stable under recommended storage conditions.

## 10.3 Possibility of hazardous reactions

No data available

#### 10.4 Conditions to avoid

No data available

# 10.5 Incompatible materials

No data available

## 10.6 Hazardous decomposition products

None under normal use conditions. Other decomposition products. No data available. In event of fire - refer section 5

# 11 Toxicological Information

# 11.1 Information on toxicological effects

# Acute toxicity

No data available

# Skin corrosion/irritation

No data available

# Serious eye damage/eye irritation

No data available

## Respiratory or skin sensitisation

No data available

## Germ cell mutagenicity

No data available

# **Carcinogenicity**

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.

# Reproductive toxicity

No data available

# Specific target organ toxicity- single exposure

No data available

## Specific target organ toxicity - repeated exposure

No data available

## **Aspiration hazard**

No data available

# 12 Ecological Information

## 12.1 Toxicity

No data available

# 12.2 Persistence and degradability

No data available

## 12.3 Bioaccumulative potential

No data available

## 12.4 Mobility in soil

No data available

## 12.5 PBT and vPvB assessment

PBT and vPVB assessment not available Chemical safety assessment is not required

## 12.6 Other adverse effects

No data available

## 13 Disposal Considerations

## 13.1 Waste treatments methods

#### **Product**

Offer surplus and non-recyclable solutions to a licenced disposal company. Dispose off waste in accordance with all applicable Federal, state and local laws.

## 13.2 Contaminated packaging

Dispose in accordance with all applicable federal, state, and local environmental regulations.

## 14 Transport Information

## 14.1 UN-No

ADNR : ADR : IATA\_C : IATA\_P : IMDG : RID :

## 14.2 UN proper shipping name

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

# 14.3 Transport hazard class(es)

ADNR: -ADR: -IATA\_C: -IATA\_P: -IMDG: -RID: -

# 14.4 Packaging group

ADNR : ADR : IATA\_C : IATA\_P : IMDG : RID :

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#### 14.5 Environmental hazards

## 14.6 Special precautions for use

No data available

## 15 Regulatory Information

This safety datasheet complies with the requirements of Regulation(EC) No. 1907/2006.

# 15.1 Safety health and environment regulations/legislation specific for the substance or mixture

No data available

## 15.2 Chemical Safety Assessment

No data available

## 16 Other information

#### **Further Information**

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