

# OTTO CHEMIE PVT LTD

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ISO 9001: 2015

## MATERIAL SAFETY DATA SHEET

### 1 Product identifiers

Product name : Insulin, from porcine pancreas powder,  $\geq 27$  USP units/mg

Product Code : I 3789

CAS-No. : 12584-58-6

### SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

2.2 Label elements

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

2.3 Other hazards – none

### SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms : Insulin

Formula : C<sub>256</sub>H<sub>381</sub>N<sub>65</sub>O<sub>76</sub>S<sub>6</sub>

Molecular weight : 5.777,54 g/mol

CAS-No. : 12584-58-6

EC-No. : 235-703-3

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

### SECTION 4: First aid measures

4.1 Description of first-aid measures

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

In case of skin contact

Wash off with soap and plenty of water.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

No data available

### SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides

Nitrogen oxides (NO<sub>x</sub>)

Sulfur oxides

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

### SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing vapors, mist or gas.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Advice on protection against fire and explosion

Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures

General industrial hygiene practice.

For precautions see section 2.2.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Storage stability

Recommended storage temperature

-20 °C

Storage class

Storage class (TRGS 510): 13: Non Combustible Solids

### 7.3 Specific end use(s)

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

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

Ingredients with workplace control parameters

### 8.2 Exposure controls

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

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 of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail

sales@kcl.de, test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the EC approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Do not let product enter drains.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

a) Physical state	powder
b) Color	white
c) Odor	No data available
d) Melting point/freezing point	No data available
e) Initial boiling point and boiling range	No data available
f) Flammability (solid,gas)	No data available
g) Upper/lower flammability or explosive limits	No data available
h) Flash point	No data available
i) Autoignition temperature	No data available
j) Decomposition temperature	No data available
k) pH	No data available
l) Viscosity	Viscosity, kinematic: No data available Viscosity, dynamic: No data available
m) Water solubility	No data available
n) Partition coefficient: n-octanol/water	No data available
o) Vapor pressure	No data available
p) Density	No data available
Relative density	No data available
q) Relative vapor density	No data available
r) Particle characteristics	No data available
s) Explosive properties	No data available
t) Oxidizing properties	No data available
9.2 Other safety information	No data available

## SECTION 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

Strong oxidizing agents

### 10.6 Hazardous decomposition products

In the event of fire: see section 5

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

Oral: No data available

Inhalation: No data available

Dermal: No data available

LD50 Intraperitoneal - Rat - > 2.000 mg/kg

#### Skin corrosion/irritation

No data available

#### Serious eye damage/eye irritation

No data available

#### Respiratory or skin sensitization

No data available

#### Germ cell mutagenicity

Test Type: Human

Test system: fibroblast

Remarks: Unscheduled DNA synthesis

Test Type: Rat

Test system: Liver

Remarks: Unscheduled DNA synthesis

Carcinogenicity  
No data available  
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  
11.2 Additional Information  
RTECS: NM8895000  
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

**SECTION 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 Results of PBT and vPvB assessment  
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted  
12.6 Endocrine disrupting properties  
No data available  
12.7 Other adverse effects  
No data available

**SECTION 13: Disposal considerations**

13.1 Waste treatment methods  
Product  
Offer surplus and non-recyclable solutions to a licensed disposal company.  
Contaminated packaging  
Dispose of as unused product.

**SECTION 14: Transport information**

14.1 UN number  
ADR/RID: - IMDG: - IATA: -  
14.2 UN proper shipping name  
ADR/RID: Not dangerous goods  
IMDG: Not dangerous goods  
IATA: Not dangerous goods  
14.3 Transport hazard class(es)  
ADR/RID: - IMDG: - IATA: -  
14.4 Packaging group  
ADR/RID: - IMDG: - IATA: -  
14.5 Environmental hazards  
ADR/RID: no IMDG Marine pollutant: no IATA: no  
14.6 Special precautions for user  
Further information  
Not classified as dangerous in the meaning of transport regulations.

**SECTION 15: Regulatory information**

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture  
This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.  
International Chemical Weapons Convention :  
(CWC) Schedules of Toxic Chemicals and Precursors  
Restrictions on the marketing and use of certain :  
dangerous substances  
Regulation (EC) No 649/2012 of the European :  
Parliament and the Council concerning the export and import of dangerous chemicals

Candidate List of Substances of Very High Concern for Authorisation :

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

#### **Section 16: Other Information**

This safety data sheet should be used in conjunction with technical sheets. It does not replace them. The information given is based on our knowledge of this product, at the time of publication. It is given in good faith. The attention of the user is drawn to the possible risks incurred by using the product for any other purpose other than that for which it was intended. This does not in any way excuse the user from knowing and applying all the regulations governing his activity. It is the sole responsibility of the user to take all precautions required in handling the product. The aim of the mandatory regulations mentioned is to help the user to fulfill his obligations regarding the use of hazardous products.

