

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 19.07.2016

Revision: 14.06.2016

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** JZP-110 150 mg Medium Yellow FC Tabs
- **Synonym** JZP-110 150 mg Medium Yellow FC Tabs - MT
- **Article number:** 299101, 299131, 299132, 299376, 299859, 299860
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** PC29 Pharmaceuticals
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Siegfried Ltd  
HHF070 Hal Far Industrial Estate  
Hal Far BBG 3000  
Malta
- **Informing department:**  
Tel: + 356 2227 7711  
Fax: + 356 2227 7701
- **1.4 Emergency telephone number:**  
TOX CENTER (Toxikologisches Informationszentrum Schweiz), Zürich, Tel. 145 (CH)  
(Tel. +41 44 251 51 51)

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

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- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
  - **Hazard pictograms** GHS07
  - **Signal word** Warning
  - **Hazard-determining components of labelling:**  
JZP-110 API
  - **Hazard statements**  
H302 Harmful if swallowed.
  - **Precautionary statements**  
P264 Wash thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.  
P330 Rinse mouth.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
  - **2.3 Other hazards**
  - **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Mixture of the substances listed below with harmless additions.

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**· Dangerous components:**

178429-65-7 JZP-110 API

 Acute Tox. 4, H302

50-100%

**· Additional information** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

**· 4.1 Description of first aid measures**
**· General information**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

**· After inhalation** Supply fresh air; consult doctor in case of symptoms.

**· After skin contact** The product is not skin irritating.

**· After eye contact** Rinse opened eye for several minutes under running water.

**· After swallowing** Instantly call for doctor.

**· 4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

**· 4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

### SECTION 5: Firefighting measures

**· 5.1 Extinguishing media**
**· Suitable extinguishing agents**

CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

**· 5.2 Special hazards arising from the substance or mixture**

No further relevant information available.

**· 5.3 Advice for firefighters**
**· Protective equipment:** Put on breathing apparatus.

### SECTION 6: Accidental release measures

**· 6.1 Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.

**· 6.2 Environmental precautions:**

Do not allow to enter drainage system, surface or ground water.

Keep dirty washing water for appropriate disposal.

**· 6.3 Methods and material for containment and cleaning up:**

Dispose of contaminated material as waste according to section 13.

**· 6.4 Reference to other sections**

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

### SECTION 7: Handling and storage

**· 7.1 Precautions for safe handling** No special measures required.

**· Information about protection against explosions and fires:** No special measures required.

**· 7.2 Conditions for safe storage, including any incompatibilities**
**· Storage**
**· Requirements to be met by storerooms and containers:** No special requirements.

**· Information about storage in one common storage facility:** Not required.

**· Further information about storage conditions:** Store in a cool place (15-25 °C).

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- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **8.1 Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the compilation were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**  
Keep away from foodstuffs, beverages and food.  
Wash hands during breaks and at the end of the work.
- **Breathing equipment:** Not required.
- **Protection of hands:**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Safety glasses recommended during refilling.

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Tablets
Colour:	Yellow
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/Melting range:	ca. 18 °C
Boiling point/Boiling range:	Not determined
- **Flash point:** Not applicable
- **Inflammability (solid, gaseous)** Not determined.
- **Ignition temperature:** Not determined.
- **Decomposition temperature:** Not determined.
- **Self-inflammability:** Product is not selfigniting.
- **Danger of explosion:** Product is not explosive.

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· <b>Critical values for explosion:</b>	
Lower:	Not determined.
Upper:	Not determined.
· <b>Vapour pressure:</b> Not applicable.	
· <b>Density</b> Not determined	
· <b>Relative density</b> Not determined.	
· <b>Vapour density</b> Not applicable.	
· <b>Evaporation rate</b> Not applicable.	
· <b>Solubility in / Miscibility with Water at 20 °C:</b> 460 g/l	
· <b>Partition coefficient (n-octanol/water):</b> Not determined.	
· <b>Viscosity:</b>	
dynamic:	Not applicable.
kinematic:	Not applicable.
· <b>Solvent content:</b>	
Organic solvents:	0.0 %
· <b>Solids content:</b> 100.0 %	
· <b>9.2 Other information</b> No further relevant information available.	

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**

· **Acute toxicity**  
Harmful if swallowed.

- **LD/LC50 values that are relevant for classification:**

#### ATE (Acute Toxicity Estimates)

Oral	LD50	1561 mg/kg (rat)
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#### 178429-65-7 JZP-110 API

Oral	LD50	>2000 mg/kg (mus) >1500 mg/kg (rat)
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- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.

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- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.  
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** No data available.
- **vPvB:** No data available.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

· <b>14.1 UN-Number</b>	
· <b>ADR,RID, ADN, IMDG, IATA</b>	Void
· <b>14.2 UN proper shipping name</b>	
· <b>ADR,RID, ADN, IMDG, IATA</b>	Void
· <b>14.3 Transport hazard class(es)</b>	
· <b>ADR,RID, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>14.4 Packing group</b>	
· <b>ADR,RID, IMDG, IATA</b>	Void
· <b>14.5 Environmental hazards:</b>	Not applicable.
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	Not dangerous according to the above specifications.

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· **UN "Model Regulation":** Void

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **National regulations**
- **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**  
H302 Harmful if swallowed.
- **Department issuing data specification sheet:** Safety and security
- **Abbreviations and acronyms:**  
 ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
 IMDG: International Maritime Code for Dangerous Goods  
 IATA: International Air Transport Association  
 GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
 EINECS: European Inventory of Existing Commercial Chemical Substances  
 ELINCS: European List of Notified Chemical Substances  
 CAS: Chemical Abstracts Service (division of the American Chemical Society)  
 LC50: Lethal concentration, 50 percent  
 LD50: Lethal dose, 50 percent  
 PBT: Persistent, Bioaccumulative and Toxic  
 vPvB: very Persistent and very Bioaccumulative  
 Acute Tox. 4: Acute toxicity – Category 4

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