

Trade name: Paracetamol Crystal U / Armeeapotheke

Substance number: 066915

Version: 1 / CH

Date revised: 18.09.2023

Replaces Version: - / CH

Print date: 18.09.23

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

### **1.1. Product identifier**

Paracetamol Crystal U / Armeeapotheke

Item No. 06691525

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

#### **Use of the substance/preparation**

Active pharmaceutical substance

### **1.3. Details of the supplier of the safety data sheet**

#### **Address/Manufacturer**

Hänseler AG

Industriestrasse 35

9100 Herisau

Telephone no. 0041 (0)71 353 58 58

E-mail address of sdb@haenseler.ch

person responsible

for this SDS

### **1.4. Emergency telephone number**

Switzerland :145 / Abroad +41 (0)44 251 51 51

## **SECTION 2: Hazards identification**

### **2.1. Classification of the substance or mixture**

#### **Classification (Regulation (EC) No. 1272/2008)**

Classification (Regulation (EC) No. 1272/2008)

Acute Tox. 4 H302

The product is classified and labelled in accordance with Regulation (EC) No 1272/2008

For explanation of abbreviations see section 16.

### **2.2. Label elements**

#### **Labelling according to regulation (EC) No 1272/2008**

##### **Hazard pictograms**



##### **Signal word**

Warning

##### **Hazard statements**

H302 Harmful if swallowed.

##### **Precautionary statements**

P264.1	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P301+P312	IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
P330	Rinse mouth.
P501.3	Disposal in compliance with local and national regulations.

Trade name: Paracetamol Crystal U / Armeeapotheke

Substance number: 066915

Version: 1 / CH

Date revised: 18.09.2023

Replaces Version: - / CH

Print date: 18.09.23

**Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)**

contains paracetamol

**2.3. Other hazards**

The Substance does not meet PBT-criteria. This substance does not meet the vPvB-criteria. This substance does not have endocrine disrupting properties with respect to humans. This substance does not have endocrine disrupting properties with respect to non-target organisms.

**SECTION 3: Composition/information on ingredients****Chemical characterization**

substances

**Hazardous ingredients****paracetamol**

CAS No. 103-90-2

EINECS no. 203-157-5

Concentration  $\geq$  97 %Classification (Regulation (EC) No. 1272/2008)  
Acute Tox. 4 H302

ATE oral 1'944 mg/kg

**SECTION 4: First aid measures****4.1. Description of first aid measures****General information**

Poisonous symptoms can first be observed after several hours, therefore medical observation for at least 48 hours is necessary.

**After inhalation**

Ensure supply of fresh air. If necessary, give oxygen. Heat. In the event of symptoms take medical treatment. If the patient is likely to become unconscious, place and transport in stable sideways position.

**After skin contact**

Wash off immediately with soap and water and rinse well. Consult a doctor if skin irritation persists.

**After eye contact**

Separate eyelids, wash the eyes thoroughly with water (15 min.). Take medical treatment.

**After ingestion**

If swallowed, rinse mouth with water (only if the person is conscious). Take medical treatment.

**SECTION 5: Firefighting measures****5.1. Extinguishing media****Suitable extinguishing media**

Carbon dioxide, Dry powder, Water spray jet, Extinguish greater fire with water spray or alcohol-resistant foam.

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

In the event of fire the following can be released: Nitrogen oxides (NO<sub>x</sub>); Carbon monoxide (CO); Carbon dioxide (CO<sub>2</sub>)

**5.3. Advice for firefighters****Special protective equipment for fire-fighting**

Use self-contained breathing apparatus.

Trade name: Paracetamol Crystal U / Armeeapotheke

Substance number: 066915

Version: 1 / CH

Date revised: 18.09.2023

Replaces Version: - / CH

Print date: 18.09.23

**Other information**

Cool endangered containers with water spray jet. Fire residues and contaminated fire-fighting water must be disposed of in accordance with the local regulations.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep away unprotected persons. Keep people away and stay on the upwind side. Keep away sources of ignition. Use breathing apparatus if exposed to vapours/dust/aerosol. Ensure adequate ventilation. Avoid dust formation.

**6.2. Environmental precautions**

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

**6.3. Methods and material for containment and cleaning up**

Pick up mechanically. Avoid raising dust. Place in a suitable container. Ensure adequate ventilation. Clean up affected area. When picked up, treat material as prescribed under Section 13 "Disposal".

**6.4. Reference to other sections**

Information regarding Safe handling, see Section 7. Information regarding personal protective measures, see Section 8. Information regarding waste disposal, see Section 13.

**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Advice on safe handling**

Observe the usual precautions for handling chemicals. Use breathing apparatus when transferring large quantities without exhaust ventilation facilities. Provide good ventilation of working area (local exhaust ventilation if necessary). Avoid dust formation.

**Advice on protection against fire and explosion**

Keep away from sources of ignition - No smoking.

**7.2. Conditions for safe storage, including any incompatibilities****Recommended storage temperature**

Value	15	-	25	°C
-------	----	---	----	----

**Requirements for storage rooms and vessels**

Keep only in original packaging.

**Hints on storage assembly**

Do not store with oxidizing agents.

**Storage classes**

Storage class according to TRGS 510	13	Non- combustible solids
Storage category (Switzerland)	11/13	Other solid hazardous substances with classification/labelling hazardous

**Further information on storage conditions**

Keep container in a well-ventilated place. Keep container tightly closed.

**SECTION 8: Exposure controls/personal protection****8.2. Exposure controls****General protective and hygiene measures**

Observe the usual precautions for handling chemicals. Use barrier skin cream. Keep away from food-stuffs, beverages and feed-stocks. Wash hands before breaks and after work. Avoid contact with skin and eyes.

Trade name: Paracetamol Crystal U / Armeeapotheke

Substance number: 066915

Version: 1 / CH

Date revised: 18.09.2023

Replaces Version: - / CH

Print date: 18.09.23

**Respiratory protection**

Breathing apparatus in the event of high concentrations. Short term: filter apparatus, Filter P1; Short term: filter apparatus; At intensive and longer exposition use self-contained breathing apparatus. Dust mask

**Hand protection**

The glove material must be sufficient impermeable and resistant to the substance. Check the tightness before wear. Gloves should be well cleaned before being removed, then stored in a well ventilated location.

Appropriate Material	nitrile
Material thickness	0.11
Breakthrough time	480 min

Hand protection must comply with EN 374.

**Eye protection**

Safety glasses with side protection shield; Eye protection must comply with EN 166.

**Body protection**

Clothing as usual in the chemical industry.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

<b>Physical state</b>	solid
<b>Colour</b>	white
<b>Odour</b>	odourless
<b>Physical state</b>	Crystalline powder
<b>Melting point</b>	
Value	appr. 170 °C

<b>Boiling point or initial boiling point and boiling range</b>	
Value	> 250 °C
Pressure	980.1 hPa
Method	OECD 103
Source	Merck KGaA Safety Data Sheet

**Flammability**

Flammable.

**Upper and lower explosive limits**

Lower explosion limit	15	%(V)
Source	GESTIS-Stoffdatenbank	

**Flash point**

Value	°C
Remarks	Not applicable

**Ignition temperature**

Value	400 to 590	°C
-------	------------	----

**Decomposition temperature**

Value	250	°C
-------	-----	----

**pH value**

Value	5.5 to 6.5
Concentration/H <sub>2</sub> O	10 %
Temperature	20 °C

**Viscosity**

dynamic

Trade name: Paracetamol Crystal U / Armeeapotheke

Substance number: 066915

Version: 1 / CH

Date revised: 18.09.2023

Replaces Version: - / CH

Print date: 18.09.23

Remarks Not applicable

**kinematic**

Remarks Not applicable

**Solubility(ies)**

Ethanol

Remarks easily soluble

Acetone

Remarks easily soluble

Petroleum ether

Remarks insoluble

**Partition coefficient n-octanol/water (log value)**

pOW 0.51

**Vapour pressure**

Remarks Not applicable

**Density and/or relative density**Value 1.29 g/cm<sup>3</sup>

Temperature 20 °C

**Relative vapour density**

Remarks Not applicable

**9.2. Other information****Solubility in water**

Value 19 g/l

Temperature 28 °C

Source Merck KGaA Safety Data Sheet

**Minimum ignition energy**

Minimum ignition energy 4 to 5 MJ

**Auto-ignition temperature**

Value &gt; 550 °C

**Explosive properties**

evaluation no

**Oxidising properties**

evaluation Not oxidising

**SECTION 10: Stability and reactivity****10.1. Reactivity**

No dangerous reactions known.

**10.2. Chemical stability**

No decomposition if stored and applied as directed.

**10.3. Possibility of hazardous reactions**

No hazardous reactions known.

**10.4. Conditions to avoid**

No hazardous reactions known.

**10.5. Incompatible materials**

Strong oxidising agents

**10.6. Hazardous decomposition products**

In the event of fire the following can be released: Carbon monoxide and carbon dioxide, nitrous oxides

Trade name: Paracetamol Crystal U / Armeeapotheke

Substance number: 066915

Version: 1 / CH

Date revised: 18.09.2023

Replaces Version: - / CH

Print date: 18.09.23

(NOx)

**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute oral toxicity**

ATE	1'944	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)	

**Acute oral toxicity (Components)****paracetamol**

Species	rat	
LD50	1944	mg/kg

**Skin corrosion/irritation (Components)****paracetamol**

evaluation	Moderately irritating
Source	Primary Irritation Index: 0.3 Intact

**paracetamol**

Species	rabbit
evaluation	non-irritant
Method	OECD 404

**Serious eye damage/irritation (Components)****paracetamol**

evaluation	Moderately irritating
Source	Kay and Calandra Class: 4

**paracetamol**

Species	rabbit
evaluation	non-irritant

**Sensitization (Components)****paracetamol**

evaluation	non-sensitizing
------------	-----------------

**Mutagenicity (Components)****paracetamol**

evaluation	No mutagenicity in the Ames-test.
Method	OECD 471

**paracetamol**

Route of exposure	oral
Species	Human
evaluation	No experimental information on genotoxicity in vitro available.
Source	ECHA

**Reproduction toxicity (Components)****paracetamol**

evaluation	No negative effects
------------	---------------------

**Carcinogenicity (Components)****paracetamol**

evaluation	No negative effects
------------	---------------------

**Specific Target Organ Toxicity (STOT) (Components)****paracetamol**

Organs: Liver

Trade name: Paracetamol Crystal U / Armeeapotheke

Substance number: 066915

Version: 1 / CH

Date revised: 18.09.2023

Replaces Version: - / CH

Print date: 18.09.23

## 11.2 Information on other hazards

### Endocrine disrupting properties with respect to humans

This substance does not have endocrine disrupting properties with respect to humans.

### Other information

Warning - substance not yet fully tested.

Therapeutical substance.

After swallowing: feeling of sickness, vomiting, coma.

## SECTION 12: Ecological information

### 12.1. Toxicity

#### Fish toxicity (Components)

##### paracetamol

Species	Fathead minnow ( <i>Pimephales promelas</i> )		
EC50	814		mg/l
Duration of exposure	96	h	

##### paracetamol

Species	Oryzias latipes		
LC50	160		mg/l
Duration of exposure	96	h	
Method	OECD 203		

#### Daphnia toxicity (Components)

##### paracetamol

Species	Daphnia magna		
EC50	9.2		mg/l
Duration of exposure	48	h	
Method	static test		

#### Algae toxicity (Components)

##### paracetamol

Species	Scenedesmus subspicatus		
IC50	134		mg/l
Duration of exposure	72	h	

#### Bacteria toxicity (Components)

##### paracetamol

EC50	1000		mg/l
Duration of exposure	30	min	
Method	Microtox-Test		

### 12.2. Persistence and degradability

#### Biodegradability (Components)

##### paracetamol

Value	57	%
evaluation	not readily degradable	
Method	OECD 301F	

### 12.3. Bioaccumulative potential

#### Partition coefficient n-octanol/water (log value)

pOW	0.51
-----	------

### 12.4. Mobility in soil

Trade name: Paracetamol Crystal U / Armeeapotheke

Substance number: 066915

Version: 1 / CH

Date revised: 18.09.2023

Replaces Version: - / CH

Print date: 18.09.23

**General information**

No data available

**12.5. Results of PBT and vPvB assessment****General information**

No data available

**Results of PBT and vPvB assessment**

The Substance does not meet PBT-criteria.

This substance does not meet the vPvB-criteria.

**12.6 Endocrine disrupting properties****Endocrine disrupting properties with respect to the environment**

This substance does not have endocrine disrupting properties with respect to non-target organisms.

**12.7. Other adverse effects****General information / ecology**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Disposal recommendations for the product**

EWC waste code

No not dispose with rubbish.

EWC waste code

Should not be released into the sanitary sewer system.

Disposal in compliance with local and national regulations.

**Disposal recommendations for packaging**

Disposal in compliance with local and national regulations.

**SECTION 14: Transport information**

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
<b>14.1. UN number</b>	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Water Hazard Class (Germany)**

Water Hazard Class WGK 1

(Germany)

Remarks

Derivation of WGK according to Annex 1 No. 5.2 AwSV

**15.2. Chemical safety assessment**

For this substance a chemical safety assessment has not been carried out.

**SECTION 16: Other information**

Trade name: Paracetamol Crystal U / Armeepothke

Substance number: 066915

Version: 1 / CH

Date revised: 18.09.2023

Replaces Version: - / CH

Print date: 18.09.23

**Hazard statements listed in Chapter 3**

H302 Harmful if swallowed.

**CLP categories listed in Chapter 3**

Acute Tox. 4 Acute toxicity, Category 4

**Supplemental information**

Relevant changes compared with the previous version of the safety data sheet are marked with: \*\*\*  
This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.