

Trade name: Acid fumaricum/Sigma-Aldrich GmbH

Substance number: 060212

Version: 3 / CH

Date revised: 28.10.2020

Replaces Version: 2 / CH

Print date: 28.10.20

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

### **1.1. Product identifier**

Acid fumaricum/Sigma-Aldrich GmbH

Item No. 06021200

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

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

Manufacture of pharmaceutical products

### **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)

Eye Irrit. 2 H319

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**

H319 Causes serious eye irritation.

##### **Precautionary statements \*\*\***

P264.1 Wash hands thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

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### **SECTION 3: Composition/information on ingredients \*\*\***

#### **Hazardous ingredients \*\*\***

##### **fumaric acid**

CAS No. 110-17-8

EINECS no. 203-743-0

Concentration &gt;= 50 %

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

Eye Irrit. 2 H319

### **SECTION 4: First aid measures**

#### **4.1. Description of first aid measures**

##### **After inhalation**

Ensure supply of fresh air.

##### **After skin contact**

After contact with skin, wash immediately with plenty of water. Remove contaminated, soaked clothing immediately and dispose of safely.

##### **After eye contact**

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

##### **After ingestion**

Drink water in small gulps. Never give anything by mouth to an unconscious person. Take medical treatment.

### **SECTION 5: Firefighting measures**

#### **5.1. Extinguishing media**

##### **Suitable extinguishing media**

Water, Carbon dioxide, Foam, Dry powder

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

The product is combustible. Forms explosive mixture with air are possible. In case of combustion evolution of dangerous gases possible.

#### **5.3. Advice for firefighters**

##### **Special protective equipment for fire-fighting**

Use self-contained breathing apparatus. Wear full protective suit.

##### **Other information**

Do not discharge into surface waters/groundwater. Do not inhale explosions- and combustion gases.

### **SECTION 6: Accidental release measures**

#### **6.1. Personal precautions, protective equipment and emergency procedures**

Avoid contact with eyes and skin. Use personal protective clothing. Do not inhale dust. Ensure supply of fresh air.

#### **6.2. Environmental precautions**

Do not empty into drains.

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

To pick up dry. When picked up, treat material as prescribed under Section 13 "Disposal". Clean up

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affected area. Avoid raising dust.

## **SECTION 7: Handling and storage**

### **7.1. Precautions for safe handling**

#### **Advice on safe handling**

Avoid contact with skin, eyes and clothing. Danger of dust explosion

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

#### **Recommended storage temperature**

Value	15	25	°C
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#### **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 tightly closed. Store in a dry place

## **SECTION 8: Exposure controls/personal protection**

### **8.2. Exposure controls**

#### **General protective and hygiene measures**

Observe the usual precautions for handling chemicals. Remove contaminated, soaked clothing immediately and dispose of safely. Preventative skin protection. Wash hands and face after work.

#### **Respiratory protection**

Breathing apparatus in the event of aerosol. Particle filter P2

#### **Hand protection**

Appropriate Material	nitrile rubber - NBR
Material thickness	0.11 mm
Breakthrough time	> 480 min

#### **Eye protection**

Safety glasses

#### **Body protection**

Protective clothing

## **SECTION 9: Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

<b>Form</b>	solid
<b>Colour</b>	white
<b>Odour</b>	odourless

#### **pH value**

Value	2.1
Concentration/H <sub>2</sub> O	4.9 g/l
Temperature	20 °C

#### **Melting point**

Value	287	°C
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#### **Initial boiling point and boiling range**

Value	290	°C
Pressure	1.013	hPa

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**Flash point**

Value	273	°C
Method	DIN 51758	

**Vapour pressure**

Value	<	0.001	hPa
Temperature		20	°C

**Density**

Value	1.64	g/cm <sup>3</sup>
Temperature	20	°C

**Solubility in water**

Value	4.9	g/l
Temperature	20	°C

**Partition coefficient: n-octanol/water**

log Pow	0.33
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**Decomposition temperature**

Value	>	350	°C
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**SECTION 10: Stability and reactivity****10.1. Reactivity**

Danger of dust explosion, Formation of explosive gas/air mixtures.

**10.2. Chemical stability**

No decomposition if stored and applied as directed.

**10.3. Possibility of hazardous reactions**

Possible incompatibility with materials listed under section 10.5.

**10.4. Conditions to avoid**

To avoid thermal decomposition, do not overheat.

**10.5. Incompatible materials**

Oxidising agents, Bases, Reducing agents, amines

**10.6. Hazardous decomposition products****Other information**

Formation of explosive gas/air mixtures. Danger of dust explosion

**SECTION 11: Toxicological information \*\*\*****11.1. Information on toxicological effects****Acute oral toxicity (Components)****fumaric acid**

Species	rat	
LD50	9300	mg/kg
Method	OECD 401	

**Acute dermal toxicity (Components)****fumaric acid**

Species	rabbit	
LD50	20000	mg/kg
Method	OECD 402	

**Acute inhalative toxicity (Components)**

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**fumaric acid**

Species	rat		
LC50	>	1306	mg/l
Duration of exposure	4	h	
Administration/Form	Dust/Mist		
Method	OECD 403		
Remarks	Irritating to respiratory system.		

**Skin corrosion/irritation (Components)****fumaric acid**

Species	rabbit
evaluation	non-irritant
Method	OECD 404

**Serious eye damage/irritation (Components)****fumaric acid**

Species	rabbit
evaluation	irritant - risk of serious damage to eyes
Method	OECD 405

**Sensitization (Components)****fumaric acid**

Species	guinea pig
evaluation	non-sensitizing
Method	OECD 406

**Mutagenicity (Components)****fumaric acid**

Species	Salmonella typhimurium
evaluation	No mutagenicity in the Ames-test.
Method	Ames test

**fumaric acid**

Species	hamster
evaluation	No experimental information on genotoxicity in vitro available.
Method	OECD 473

**fumaric acid**

Species	mouse
evaluation	No experimental information on genotoxicity in vitro available.
Method	OECD 476

**Reproduction toxicity (Components)****fumaric acid**

evaluation	No negative effects
Source	IUCLID

**Carcinogenicity (Components)****fumaric acid**

evaluation	No negative effects
Source	IUCLID

**Other information**

Warning - substance not yet fully tested.  
Observe the usual precautions for handling chemicals.

**SECTION 12: Ecological information \*\*\*****12.1. Toxicity**

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**Fish toxicity (Components)****fumaric acid**

Species	zebra fish (Brachydanio rerio)		
LC50	> 100		mg/l
Duration of exposure	96	h	
Method	OECD 203		

**Daphnia toxicity (Components)****fumaric acid**

Species	Daphnia magna		
EC50	> 100		mg/l
Duration of exposure	48	h	
Method	OECD 202		

**Algae toxicity (Components)****fumaric acid**

Species	Pseudokirchneriella subcapitata		
IC50	> 100		mg/l
Duration of exposure	72	h	
Method	OECD 201		

**fumaric acid**

Species	Pseudokirchneriella subcapitata		
NOEC	> 100		mg/l
Duration of exposure	72	h	
Method	OECD 201		

**Bacteria toxicity (Components)****fumaric acid**

Species	activated sludge		
	> 300		mg/l
Duration of exposure	3	h	
Method	OECD 209		

**12.2. Persistence and degradability****Biodegradability (Components)****fumaric acid**

Value	67.5		%
Duration of test evaluation	28	d	
Method	Readily biodegradable		
	OECD 301 B		

**12.3. Bioaccumulative potential****Partition coefficient: n-octanol/water**

log Pow	0.33
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**12.4. Mobility in soil****General information**

No data available

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

No data available

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

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Do not allow it to reach soil, ground water, water bodies or sewage system.

## **SECTION 13: Disposal considerations**

### **13.1. Waste treatment methods**

#### **Disposal recommendations for the product**

Disposal in compliance with local and national regulations.

#### **Disposal recommendations for packaging**

Dispose of as unused product.

## **SECTION 14: Transport information**

	<b>Land transport ADR/RID</b>	<b>Marine transport IMDG/GGVSee</b>	<b>Air transport ICAO/IATA</b>
<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 (Germany) WGK 1

Remarks Derivation of WGK according to Annex 1 No. 5.2 AwSV

#### **Other regulations, restrictions and prohibition regulations**

Observe employment restrictions for young people.

### **15.2. Chemical safety assessment**

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

## **SECTION 16: Other information**

#### **Hazard statements listed in Chapter 3**

H319 Causes serious eye irritation.

#### **CLP categories listed in Chapter 3**

Eye Irrit. 2 Eye irritation, Category 2

#### **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.