

Trade name: Balsami tolutani sirupus

Substance number: 144051

Version: 1 / CH

Date revised: 18.01.2023

Replaces Version: - / CH

Print date: 18.01.23

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

### **1.1. Product identifier**

Balsami tolutani sirupus

Item No. 14405100

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

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

Active pharmaceutical substance, 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**

This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.

### **2.2. Label elements**

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

The product does not require a hazard warning label in accordance with Regulation (EC) No 1272/2008.

EUH208 Contains Gum benzoin, May produce an allergic reaction.

#### **Supplemental information**

EUH210 Safety data sheet available on request.

### **2.3. Other hazards**

No special hazards have to be mentioned.

The product contains no PBT substances. The product contains no vPvB substances. This product does not contain a substance that has endocrine disrupting properties with respect to human. The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

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

### **Chemical characterization**

Medicinal products

### **Hazardous ingredients**

#### **Gum benzoin**

CAS No. 9000-05-9

EINECS no. 232-523-7

Concentration &gt;= 0.1 &lt; 1 %

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Skin Irrit. 2	H315
Skin Sens. 1	H317
Eye Irrit. 2	H319
Aquatic Chronic 3	H412

**Further ingredients**

**Sucrose**

CAS No.	57-50-1				
EINECS no.	200-334-9				
Concentration		>=	50		%
Advice: [4]					

**water**

CAS No.	7732-18-5				
EINECS no.	231-791-2				
Concentration		>=	25	<	50 %
Advice: [4]					

**Glycerol**

CAS No.	56-81-5				
EINECS no.	200-289-5				
Concentration		>=	1	<	10 %
Advice: [4]					

**ethanol**

CAS No.	64-17-5				
EINECS no.	200-578-6				
Concentration		>=	1	<	10 %
Advice: [4]					

Classification (Regulation (EC) No. 1272/2008)  
Flam. Liq. 2 H225

**benzoic acid**

CAS No.	65-85-0				
EINECS no.	200-618-2				
Registration no.	01-2119455536-33				
Concentration		<	1		%
Advice: [4]					

Classification (Regulation (EC) No. 1272/2008)  
Skin Irrit. 2 H315  
Eye Dam. 1 H318  
STOT RE 1 H372

Lungs; Route of exposure:  
inhalative

**Cinnamaldehyde**

CAS No.	104-55-2				
EINECS no.	203-213-9				
Concentration		<	1		%
Advice: [4]					

Classification (Regulation (EC) No. 1272/2008)  
Acute Tox. 4 H312  
Skin Irrit. 2 H315  
Skin Sens. 1 H317  
Eye Irrit. 2 H319

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**Vanillin**

CAS No. 121-33-5

EINECS no. 204-465-2

Concentration &lt; 1 %

Advice: [4]

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

Eye Irrit. 2 H319

**Note**

[4] Voluntary information

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

In case of persistent symptoms consult doctor.

**After inhalation**

Ensure supply of fresh air. In the event of symptoms take medical treatment.

**After skin contact**

In case of contact with skin wash off with warm water. Consult a doctor if skin irritation persists.

**After eye contact**

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an oculist.

**After ingestion**

Rinse out mouth and give plenty of water to drink.

**Adhere to personal protective measures when giving first aid**

First aider: Pay attention to self-protection!

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

Until now no symptoms known so far.

**4.3. Indication of any immediate medical attention and special treatment needed****Hints for the physician / hazards**

In the case of swallowing with subsequent vomiting, aspiration of the lungs can occur which can lead to chemical pneumonia or asphyxiation.

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

Foam, Carbon dioxide, Dry powder, Water spray jet

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

In case of combustion use a suitable breathing apparatus.

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

Wear protective equipment

**6.2. Environmental precautions**

Do not allow to enter drains or waterways.

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

Pick up with absorbent material. Clean contaminated floors and objects thoroughly, observing environmental regulations.

**6.4. Reference to other sections**

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

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

Observe the usual precautions for handling chemicals.

**Advice on protection against fire and explosion**

No special measures required.

**7.2. Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

Store product in closed containers.

**Hints on storage assembly**

Do not store together with foodstuffs.

**Storage classes**

Storage class according to TRGS 510      12                      Non-combustible liquids

**Further information on storage conditions**

Keep container tightly closed and dry.

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****Exposure limit values****ethanol**

List	SUVA			
Type	MAK			
Value	960	mg/m <sup>3</sup>	500	ppm(V)
Short term exposure limit	1920	mg/m <sup>3</sup>	1000	ppm(V)
Pregnancy group: S;    Remarks: SSc; Formal; INRS NIOSH				

**Glycerol**

List	SUVA			
Type	MAK			
Value	50	mg/m <sup>3</sup>		
Short term exposure limit	100	mg/m <sup>3</sup>		
Pregnancy group: S;    Remarks: SSc; OAWKT AN				

**Other information**

Contains no substances with occupational exposure limit values.

**Derived No/Minimal Effect Levels (DNEL/DMEL)****benzoic acid**

Type of value	Derived No Effect Level (DNEL)
Reference group	Worker
Duration of exposure	Long term
Route of exposure	inhalative
Mode of action	Local effects

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Concentration	0.1	mg/m <sup>3</sup>
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Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	3	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	62.5	mg/kg/d

**ethanol**

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	1900	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	oral	
Mode of action	Systemic effects	
Concentration	434	mg/kg/d

**Predicted No Effect Concentration (PNEC)****benzoic acid**

Type of value	PNEC	
Type	Water	
Concentration	0.011	mg/l

Type of value	PNEC	
Type	Sewage treatment plant (STP)	
Concentration	100	mg/l
Source	Literature value	

**8.2. Exposure controls****General protective and hygiene measures**

Observe the usual precautions for handling chemicals.

**Respiratory protection**

Not necessary, but do not inhale vapours. If workplace limits are exceeded, a respiratory protection approved for this particular job must be worn.

**Hand protection**

Appropriate Material neoprene

**Eye protection**

Safety glasses

**Body protection**

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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>	liquid, clear
<b>Colour</b>	colourless
<b>Odour</b>	characteristic
<b>Physical state</b>	Liquid, opaque
<b>Colour</b>	yellowish
<b>Melting point</b>	
Remarks	not determined
<b>Freezing point</b>	
Remarks	not determined
<b>Boiling point or initial boiling point and boiling range</b>	
Remarks	not determined
<b>Flammability</b>	
not determined	
<b>Upper and lower explosive limits</b>	
Remarks	not determined
<b>Flash point</b>	
Value	°C
Remarks	Not applicable
<b>Ignition temperature</b>	
Remarks	not determined
<b>Decomposition temperature</b>	
Remarks	not determined
<b>pH value</b>	
Remarks	not determined
<b>Viscosity</b>	
Remarks	not determined
<b>Solubility(ies)</b>	
Remarks	not determined
<b>Partition coefficient n-octanol/water (log value)</b>	
Remarks	not determined
<b>Vapour pressure</b>	
Remarks	Not applicable
<b>Density and/or relative density</b>	
Value	1.27 to 1.31 g/ml
Remarks	Relative Density according specification
<b>Relative vapour density</b>	
Remarks	not determined
<b>9.2. Other information</b>	
<b>Odour threshold</b>	
Remarks	not determined
<b>Evaporation rate (ether = 1) :</b>	

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Remarks not determined

**Solubility in water**

Remarks not determined

**Explosive properties**

evaluation not determined

**Oxidising properties**

Remarks not determined

**Other information**

None known

**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**

None known

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

Remarks not determined

**Acute oral toxicity (Components)****benzoic acid**

Species	mouse		
LD50	2250		mg/kg
Method	OECD 401		

**ethanol**

Species	rat		
LD50	7060		mg/kg
Source	Toxicology and Applied Pharmacology. Vol. 16, Pg. 718, 1970.		

**ethanol**

Species	rat		
LD50	10470		mg/kg

**Glycerol**

Species	rat		
LD50	12600		mg/kg

**Glycerol**

Species	rat		
NOAEL	1310		mg/kg

**Glycerol**

Species	rat		
LD50	27200		mg/kg

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**Acute dermal toxicity**

Remarks not determined

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

Species	rabbit		
LD50	>	2000	mg/kg

**ethanol**

Species	rabbit		
LD50		15800	mg/kg

**Glycerol**

Species	guinea pig		
LD50		56750	mg/kg

**Acute inhalational toxicity**

Remarks not determined

**Acute inhalative toxicity (Components)****benzoic acid**

Species	rat		
LD50	>	12.2	mg/l
Duration of exposure		4	h
Method	Value taken from the literature		

**ethanol**

Species	rat		
LC50		30000	mg/m <sup>3</sup>
Duration of exposure		4	h
Administration/Form	Vapors		

**Glycerol**

Remarks No data available

**Skin corrosion/irritation**

Remarks not determined

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

Species	guinea pig		
evaluation	irritant		
Source	Literature value		

**ethanol**

evaluation	non-irritant		
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**Glycerol**

Species	rabbit		
Duration of exposure		24	h
evaluation	slightly irritant		

**Serious eye damage/irritation**

Remarks not determined

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

Species	rabbit		
evaluation	strongly irritant		
Source	Literature value		

**ethanol**

evaluation	irritant		
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**Glycerol**

Species rabbit  
 Duration of exposure 24 h  
 evaluation slightly irritant

**Sensitization**

Remarks not determined

**Sensitization (Components)****benzoic acid**

Species guinea pig  
 Remarks No sensitisation effect known.  
 Source Literature value

**Glycerol**

Remarks No data available.

**Subacute, subchronic, chronic toxicity**

Remarks not determined

**Subacute, subchronic, chronic toxicity (Components)****Glycerol**

Remarks No data available.

**Mutagenicity**

Remarks not determined

**Mutagenicity (Components)****benzoic acid**

evaluation No mutagenicity in the Ames-test.

**ethanol**

evaluation No mutagenicity in the Ames-test.

**Glycerol**

evaluation No experimental information on genotoxicity in vitro available.  
 Method OECD 471

**Glycerol**

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

**Reproductive toxicity**

Remarks not determined

**Reproduction toxicity (Components)****benzoic acid**

Remarks Indications of toxic effects are available from reproduction studies in animals.

**Glycerol**

Remarks Based on available data, the classification criteria are not met.

**Carcinogenicity**

Remarks not determined

**Carcinogenicity (Components)****benzoic acid**

evaluation No indications of carcinogenic effects are available from long-term trials.  
 Source Literature value

**Glycerol**

Remarks Based on available data, the classification criteria are not met.

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

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**benzoic acid**

Reference substance evaluation	benzoic acid May cause damage to organs. Route of exposure inhalative Organs: Lungs
Source	Literature value

**11.2 Information on other hazards****Endocrine disrupting properties with respect to humans**

The product does not contain a substance that has endocrine disrupting properties with respect to humans.

**Other information**

No toxicological data are available.

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

not determined

**Fish toxicity (Components)****benzoic acid**

Species	Bluegill ( <i>Lepomis macrochirus</i> )	
LC50	44.6	mg/l
Duration of exposure	96	h
Source	Literature value	

**benzoic acid**

Species	rainbow trout ( <i>Oncorhynchus mykiss</i> )	
NOEC	> 120	mg/l
Duration of exposure	28	d
Source	Literature value	

**Glycerol**

	Medi	68100	mg/l
	an		
Duration of exposure	96	h	

**Glycerol**

Species	rainbow trout ( <i>Oncorhynchus mykiss</i> )	
LC50	54	g/l
Duration of exposure	96	h

**Daphnia toxicity (Components)****benzoic acid**

Species	Daphnia magna	
EC50	> 100	
Duration of exposure	48	h
Source	Literature value	

**benzoic acid**

Species	Daphnia magna	
NOEC	>= 25	mg/l
Duration of exposure	21	d
Method	OECD 211	
Source	Literature value	

**Glycerol**

Species	Daphnia
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EC50	>	10		g/l
Duration of exposure		24	h	

**Algae toxicity (Components)****benzoic acid**

Species	Pseudokirchneriella subcapitata			
EC50	>	33.1		
Duration of exposure		72	h	
Method	OECD 201			
Source	Literature value			

**Bacteria toxicity (Components)****Glycerol**

Species	Pseudomonas putida			
EC5	>	10		g/l
Duration of exposure		16	h	

**12.2. Persistence and degradability****General information**

not determined

**Biodegradability (Components)****benzoic acid**

evaluation	Readily biodegradable		
Source	OECD		

**ethanol**

evaluation	Readily biodegradable		
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**Glycerol**

evaluation	Readily biodegradable		
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**Chemical oxygen demand (COD) (Components)****ethanol**

Value	0.93	to	1.67	mg/g
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**12.3. Bioaccumulative potential****General information**

not determined

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

Remarks	not determined
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**Octanol/water partition coefficient (log Pow) (Components)****Glycerol**

log Pow	-1.76
Source	GESTIS-Stoffdatenbank

**Bioconcentration factor (BCF) (Components)****ethanol**

BCF	0.66
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**12.4. Mobility in soil****General information**

not determined

**Mobility in soil (Components)****Glycerol**

Slightly mobile in soils

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

not determined

**Results of PBT and vPvB assessment**

The product contains no PBT substances  
The product contains no vPvB substances.

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

The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

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

not determined

**General information / ecology**

Do not discharge product unmonitored into the environment.

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

Disposal in compliance with local and national regulations.  
Allocation of a waste code number, according to the European Waste Catalogue (EWC), should be carried out in agreement with the regional waste disposal company.

**Disposal recommendations for packaging**

Packaging that cannot be cleaned should be disposed off as product waste.

**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 (Germany) WGK 1

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

**15.2. Chemical safety assessment**

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

**SECTION 16: Other information**

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**Hazard statements listed in Chapter 3**

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.

**CLP categories listed in Chapter 3**

Aquatic Chronic 3	Hazardous to the aquatic environment, chronic, Category 3
Eye Irrit. 2	Eye irritation, Category 2
Skin Irrit. 2	Skin irritation, Category 2
Skin Sens. 1	Skin sensitization, Category 1

**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.