Safety data sheet in accordance with regulation (EC) No 1907/2006

Trade name: Promethazini hydrochloridum

Substance number: 067420

Version: 3 / CH Replaces Version: 2 / CH Date revised: 07.09.2020 Print date: 07.09.20

HANSELER

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

1.1. Product identifier

Promethazini hydrochloridum Item No. 06742000

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
Acute Tox. 4	H312
Acute Tox. 4	H332
Eye Dam. 1	H318
Skin Sens. 1	H317
Repr. 2	H361fd
Aquatic Chronic 2	H411

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



Signal word

Danger	
Hazard statements ***	
H318	Causes serious eye damage.
H317	May cause an allergic skin reaction.
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
H411	Toxic to aquatic life with long lasting effects.
H302+H312+H332	Harmful if swallowed, in contact with skin or if inhaled.

Trade name: Promethazini hy	drochloridum		
Substance number: 067420	Version: 3 / CH	Date revised: 07.09.2020	
	Replaces Version: 2 / CH	Print date: 07.09.2	
Precautionary staten	nents ***		
P201	Obtain special instructions before use.		
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.		
P280	Wear protective gloves/protective clothing/eye protection/face protection.		
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.		
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.		
P310	Immediately call a POISON CENTER or doctor.		
Hazardous compone	ent(s) to be indicated on label (Regulation (EC) No. 1272/2008)	
contains ***	promethazine hydrochloride		

%

Hazardous ingredients ***

promethazine	hydrochloride

58-33-3	
200-375-2	
>= 85	
tion (EC) No. 1272/2008)	
Acute Tox. 4	H302
Acute Tox. 4	H312
Acute Tox. 4	H332
Skin Sens. 1	H317
Eye Dam. 1	H318
Repr. 2	H361
Aquatic Chronic 2	H411
	58-33-3 200-375-2 >= 85 tion (EC) No. 1272/2008) Acute Tox. 4 Acute Tox. 4 Acute Tox. 4 Skin Sens. 1 Eye Dam. 1 Repr. 2

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Remove contaminated, soaked clothing immediately and dispose of safely.

After inhalation

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

After skin contact

Wash off immediately with soap and water and rinse well.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Seek medical advice immediately.

After ingestion

Rinse out mouth and give plenty of water to drink. Summon a doctor immediately.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water spray jet, Foam, Carbon dioxide, Dry chemical extinguisher

Non suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture



Trade name: Promethazini hydrochloridum

Substance number: 067420

Version: 3 / CH Replaces Version: 2 / CH Date revised: 07.09.2020

Print date: 07.09.20

In the event of fire the following can be released: Nitrogen oxides (NOx); Carbon monoxide (CO); Carbon dioxide (CO2)

5.3. Advice for firefighters

Special protective equipment for fire-fighting

Use self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures Ensure adequate ventilation. Avoid dust formation.

6.2. Environmental precautions

Do not allow to enter drains or waterways.

6.3. Methods and material for containment and cleaning up

Pick up mechanically. When picked up, treat material as prescribed under Section 13 "Disposal".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Provide good ventilation of working area (local exhaust ventilation if necessary). Isolate from sources of heat, sparks and open flame.

Advice on protection against fire and explosion

The product is combustible.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep only in original packaging.

Hints on storage assembly

Do not store together with foodstuffs. Do not store with oxidizing agents. Do not store with acids. Do not store with alkalies.

Storage classes

Storage class according to TRGS 510 13 Storage category (Switzerland) 8 Non- combustible solids Caustic and corrosive substances

Further information on storage conditions

Keep containers tightly closed in a dry, cool and well-ventilated place. Protect from light. Store in a dark place

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

General protective and hygiene measures

Keep away from food-stuffs, beverages and feed-stocks. Remove contaminated, soaked clothing immediately and dispose of safely. Avoid contact with skin and eyes. Wash hands before breaks and after work.

Respiratory protection

Short term: filter apparatus; At intensive and longer exposition use self-contained breathing apparatus.

Hand protection

Protective gloves Appropriate Material

The glove material must be sufficient impermeable and resistant to the

Synthetic rubber gloves Eye protection Tightly fitting safety glasses Body protection Clothing as usual in the chemical ind SECTION 9: Physical and chem 9.1. Information on basic physical Form Po Colour wh Odour chait PH value Value Temperature Melting point Value Initial boiling point and boiling ra Remarks not Flash point No Upper/lower flammability or explored	ed before bein dustry. nical prop and chemic wder	Version: he tightn ng remov	ess befo ed, then <u>S</u>	stored in a	Date revised: 07.09 Print date: 07	
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Upper/lower flammability or explo Remarks No						
Remarks No	t applicable					
vabour pressure	t applicable					
	topplicable					
	t applicable					
Density Remarks not	datarminad					
	determined					
Solubility in water Remarks sol	uble					
Ignition temperature	uble					
Value	390			°C		
Decomposition temperature	000			U		
	decompositio	on if used	d as pres	scribed		
Viscosity	decompeende					
dynamic						
	t applicable					
9.2. Other information						
Other information The product is not dangerous for ex	plosions.					
SECTION 10: Stability and read	ctivity					

10.6. Hazardous decomposition products

Safety data sheet in accordance wit	th regulation (EC) No 1907/2006		HÄNSELER SWISS PHARMA
Trade name: Promethazini hydrochlo	ridum		
Substance number: 067420	Version: 3 / CH		Date revised: 07.09.202
	Replaces Version: 2 / CH		Print date: 07.09.
Carbon monoxide and carbo	n dioxide, nitrous oxides (NOx)		
SECTION 11: Toxicologica	al information ***		
11.1. Information on toxicolog	gical effects		
Acute oral toxicity			
ATE	255	mg/kg	
Method	calculated value (Regulation (EC) No.	1272/2008)	
Acute oral toxicity (Compo	nents)		
promethazine hydrochloride			
Species LD50	mouse 255	mg/kg	
promethazine hydrochloride	200	iiig/itg	
Species	rat		
LD50	765	mg/kg	
Acute dermal toxicity			
ATE	1'100	mg/kg	
Method	calculated value (Regulation (EC) No.	1272/2008)	
Acute inhalational toxicity ATE	1.5	ma/l	
Administration/Form	Dust/Mist	mg/l	
Method	calculated value (Regulation (EC) No.	1272/2008)	
Skin corrosion/irritation			
Method	OECD 404		
Remarks	No effect of irritation known.		
Serious eye damage/irritati	· · · /		
promethazine hydrochloride evaluation		c	
Sensitization (Components	irritant - risk of serious damage to eye	5	
· ·)		
promethazine hydrochloride evaluation	May cause allergic skin reactions.		
Reproduction toxicity (Com			
promethazine hydrochloride evaluation	Suspected of damaging fertility or the	unborn child	
SECTION 12: Ecological in			
12.1. Toxicity			
Fish toxicity Remarks	Harmful to fishes.		
Daphnia toxicity (Compone			
	into j		
promethazine hydrochloride Species	Daphnia magna		
EC50	1.5	mg/l	
Duration of exposure	48 h		
12.2. Persistence and degrad	lability		
Biodegradability (Compone	ents)		
promethazine hydrochloride			

Safety data sheet in accordance w	vith regulation (EC) No 1907/2006	HANSELER C
Trade name: Promethazini hydrochl	loridum	
Substance number: 067420	Version: 3 / CH	Date revised: 07.09.2020
	Replaces Version: 2 / CH	Print date: 07.09.20
evaluation	Slightly biodegradable	
12.3. Bioaccumulative poter General information	ntial	
No data available		
12.4. Mobility in soil		
General information No data available		
12.5. Results of PBT and vP	vB assessment	
General information Toxic to aquatic life.		
12.6. Other adverse effects		
General information Do not allow undiluted prod system.	luct or large quantities of it to reach ground wa	ter, water bodies or sewage
General information / ecol	logy	
Do not allow undiluted prod system. Toxic for aquatic or	uct or large quantities of it to reach ground wa rganismes.	ter, water bodies or sewage
SECTION 13: Disposal co	onsiderations	
13.1. Waste treatment metho	ods	
Disposal recommendatior	ns for the product	
	n local and national regulations.	
Disposal recommendation Dispose of as unused produ		
SECTION 14: Transport i	nformation ***	
JEGHUN 14. Hallspull		

Page	7(8)
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Safety data sheet in accordance with regulation (EC) No 1907/2006

Trade name: Promethazini hydrochloridum

Substance number: 067420

Replaces Version: 2 / CH

Version: 3 / CH

Date revised: 07.09.2020

Print date: 07.09.20

Land transport ADR/RID Marine transport Air transport *** IMDG/GGVSee *** ICAO/IATA *** Tunnel restriction code -14.1. UN number 3077 3077 3077 14.2. UN proper shipping name ENVIRONMENTALLY ENVIRONMENTALLY ENVIRONMENTALLY HAZARDOUS SUBSTANCE. HAZARDOUS SUBSTANCE. HAZARDOUS SUBSTANCE. SOLID, N.O.S. (promethazine SOLID, N.O.S. (promethazine SOLID, N.O.S. (promethazine hydrochloride) hydrochloride) hydrochloride) 14.3. Transport hazard 9 9 9 class(es) Label 14.4. Packing group ш ш ш Limited Quantity 5 kg Transport category 3 14.5. Environmental hazards Marine Pollutant ENVIRONMENTALLY ENVIRONMENTALLY HAZARDOUS HAZARDOUS

SECTION 15: Regulatory information ***

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water Hazard Class (Germany) ***

	····· y ,
Water Hazard Class	WGK 3
(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

Hazard statements listed in Chapter 3

	•
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H361	Suspected of damaging fertility or the unborn child.



Safety data sheet in accordanc	e with regulation (EC) No 1907/2006	HANSELER
Trade name: Promethazini hydro	chloridum	
Substance number: 067420	Version: 3 / CH	Date revised: 07.09.2020
	Replaces Version: 2 / CH	Print date: 07.09.20
H411	Toxic to aquatic life with long lasting effects.	
CLP categories listed ir	n Chapter 3	
Acute Tox. 4 Aquatic Chronic 2 Eye Dam. 1 Repr. 2	Acute toxicity, Category 4 Hazardous to the aquatic environment, chro Serious eye damage, Category 1 Reproductive toxicity, Category 2	onic, Category 2

Skin sensitization, Category 1

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.

Skin Sens. 1

Supplemental information