

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Name of the substance	Trospium chloride
Identification number	233-875-4 (EC number)
Registration number	-
Synonyms	None.
Material Number(s)	701551
Issue date	01-August-2016
Version number	02
Revision date	01-August-2016
Supersedes date	-

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

Identified uses	Pharmaceutical agent.
Uses advised against	None known.

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

Company name	Siegfried St. Vulbas SAS
Address	530 Allée de la Luye 01150 Saint Vulbas 01 France

Telephone + 33 9 71 16 91 00

Contact Information

Company name	Siegfried Evionnaz SA
Address	Route du Simplon 1,36 1902 Evionnaz Switzerland

Telephone +41 27 766 1200

e-mail she@siegfried.ch

1.4 Emergency telephone number For Chemical Emergency ONLY, call 3E at (+)1 760 476 3961. Access Code: 334531

General in EU 112 (Available 24 hours a day. SDS/Product information may not be available for the Emergency Service.)

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture**

The substance has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended**Health hazards**

Acute toxicity, oral	Category 4	H302 - Harmful if swallowed.
Serious eye damage/eye irritation	Category 2	H319 - Causes serious eye irritation.

Environmental hazards

Hazardous to the aquatic environment, long-term aquatic hazard	Category 3	H412 - Harmful to aquatic life with long lasting effects.
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Hazard summary Harmful if swallowed. Causes serious eye irritation. Dangerous for the environment if discharged into watercourses.

2.2. Label elements**Label according to Regulation (EC) No. 1272/2008 as amended**

Contains: Trospium chloride

Hazard pictograms



Signal word

Warning

Hazard statements

H302 Harmful if swallowed.
H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

Prevention

P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear eye protection/face protection.

Response

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.

Storage

Not available.

Disposal

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental label information None.

2.3. Other hazards May form combustible dust concentrations in air.

SECTION 3: Composition/information on ingredients

3.1. Substances

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Tropium chloride	100	10405-02-4 233-875-4	-	-	
Classification:	Acute Tox. 4;H302, Eye Irrit. 2;H319, Aquatic Chronic 3;H412				

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

SECTION 4: First aid measures

General information Remove contaminated clothing. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact Do not rub eyes. Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion Rinse mouth. Drink plenty of water. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Dusts may irritate the respiratory tract, skin and eyes.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed. Treatment: Treat according to symptoms (decontamination, vital functions), no known specific antidote.

SECTION 5: Firefighting measures

General fire hazards May form combustible dust concentrations in air.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂). Apply extinguishing media carefully to avoid creating airborne dust. Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
5.2. Special hazards arising from the substance or mixture	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. During fire, gases hazardous to health may be formed. Hydrogen chloride. Nitrogen Oxides (NOx).
5.3. Advice for firefighters	
Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	In case of fire and/or explosion do not breathe fumes. Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Use only non-sparking tools. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.
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6.3. Methods and material for containment and cleaning up	Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust using a vacuum cleaner equipped with HEPA filter. This product is miscible in water. Prevent product from entering drains. Stop the flow of material, if this is without risk.
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Large Spills: Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

6.4. Reference to other sections	For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling	Minimise dust generation and accumulation. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Explosion-proof general and local exhaust ventilation. Do not taste or swallow. Avoid contact with eyes. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.
7.2. Conditions for safe storage, including any incompatibilities	Keep containers tightly closed in a dry, cool and well-ventilated place.
7.3. Specific end use(s)	Pharmaceutical agent.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters	
Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no effect levels (DNELs)	Not available.

Predicted no effect concentrations (PNECs)

Not available.

8.2. Exposure controls

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits. Provide eyewash station.

Individual protection measures, such as personal protective equipment

General information

Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eyeface protection

Wear safety glasses with side shields (or goggles). (EN 166)

Skin protection

- Hand protection

Wear appropriate chemical resistant gloves such as Nitrile rubber; Butyl rubber. Chloroprene rubber.

- Other

Wear suitable protective clothing.

Respiratory protection

Breathing protection if dusts are formed. Particle filter with medium efficiency for solid and liquid particles (e.g. EN 143 or 149, Type P2 or FFP2).

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

Hygiene measures

Keep away from food and drink. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Environmental exposure controls

Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state

Solid.

Form

Crystalline.

Colour

White.

Odour

Almost odorless.

Odour threshold

Not determined.

pH

5.7 - 5.8 (1%(m))

Melting point/freezing point

265 °C (509 °F)

Initial boiling point and boiling range

Not applicable.

Flash point

Not applicable.

Evaporation rate

Negligible.

Flammability (solid, gas)

Not flammable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

For solids not relevant for classification and labelling.

Flammability limit - upper (%)

For solids not relevant for classification and labelling.

Explosive limit - lower (%)

Not determined.

Explosive limit - upper (%)

Not determined.

Vapour pressure

Not determined.

Vapour density

Not applicable.

Relative density

No data available.

Solubility(ies)

Soluble.

Partition coefficient (n-octanol/water)

4.98 (25 °C) (calculated)

Auto-ignition temperature

> 200 °C (> 392 °F)

Decomposition temperature

No decomposition if stored and handled as prescribed/indicated.

Viscosity	Not applicable.
Explosive properties	The product is not explosive, but a dust explosion by a dust / air mixture is possible.
Oxidising properties	Not oxidising.

9.2. Other information

Bulk density	400 kg/m ³ (20°C)
Density	Study does not need to be conducted.
Molecular formula	C25H30NO3.Cl

Flammability of Aerosol Products: not applicable, the product does not form flammable aerosols.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Keep away from heat, sparks and open flame. Minimise dust generation and accumulation.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	No hazardous decomposition products are known.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
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Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system.
Skin contact	Not irritating to skin.
Eye contact	Causes serious eye irritation.
Ingestion	Harmful if swallowed.

Symptoms	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Dusts may irritate the respiratory tract, skin and eyes.
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11.1. Information on toxicological effects

Acute toxicity	Harmful if swallowed.
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Product	Species	Test results
Tropium chloride (CAS 10405-02-4)		
Acute		
Oral		
LD50	Rat	1510 - 1730 mg/kg
Skin corrosion/irritation	Due to partial or complete lack of data the classification is not possible.	
	Skin corrosion/irritation rabbit: non-irritant (OECD Guideline 404)	
Serious eye damage/eye irritation	Causes serious eye irritation.	
	Serious eye damage/irritation rabbit: Irritant. (OECD Guideline 405).	
Respiratory sensitisation	Due to partial or complete lack of data the classification is not possible.	
Skin sensitisation	Due to partial or complete lack of data the classification is not possible.	
Germ cell mutagenicity	Mutagenicity tests revealed no genotoxic potential.	
Carcinogenicity	Results from a number of long-term carcinogenicity studies are available. Taking into account all of the information, there is no indication that the substance itself is carcinogenic.	
Reproductive toxicity	The results of animal studies gave no indication of a fertility impairing effect. No indications of a developmental toxic / teratogenic effect were seen in animal studies.	
Specific target organ toxicity - single exposure	Due to partial or complete lack of data the classification is not possible.	
Specific target organ toxicity - repeated exposure	Repeated oral uptake of the substance did not cause substance-related effects.	
Aspiration hazard	Not relevant, due to the form of the product.	
Mixture versus substance information	No information available.	
Other information	None known.	

SECTION 12: Ecological information

12.1. Toxicity Harmful to aquatic life with long lasting effects.

Product	Species		Test results
Tropium chloride (CAS 10405-02-4)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Daphnia magna	22.7 mg/l, 48 h (OECD Guideline 202, part 1, static)
Other	EC20	Activated sludge	123.4 mg/l, 180 min domestic (OECD Guideline 209, aquatic)
12.2. Persistence and degradability	Not readily biodegradable (by OECD criteria). Poorly biodegradable. Elimination information: < 10 % BOD of the ThOD (28 d) (OECD 301F; ISO 9408; 92/69/EEC, C.4-D) (aerobic, activated sludge, domestic).		
12.3. Bioaccumulative potential	Because of the n-octanol/water distribution coefficient (log Pow) accumulation in organisms is possible.		
Partition coefficient n-octanol/water (log Kow)			
4.98, (25 °C) (calculated)			
Bioconcentration factor (BCF)	Not available.		
12.4. Mobility in soil	Assessment transport between environmental compartments: Volatility: The substance will not evaporate into the atmosphere from the water surface. Adsorption in soil: Adsorption to solid soil phase is not expected.		
12.5. Results of PBT and vPvB assessment	Not a PBT or vPvB substance or mixture.		
12.6. Other adverse effects	None known.		
12.7. Additional information	The substance is not listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.		

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. - 14.6.: Not regulated as dangerous goods.

RID

14.1. - 14.6.: Not regulated as dangerous goods.

ADN

14.1. - 14.6.: Not regulated as dangerous goods.

IATA

14.1. - 14.6.: Not regulated as dangerous goods.

IMDG

14.1. - 14.6.: Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorisation, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Not listed.

Other regulations

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

LD50: Lethal Dose 50%.
EC50: Effective Concentration, 50%.
PBT: Persistent, bioaccumulative and toxic.
vPvB: Very Persistent and very Bioaccumulative.

References

Not available.

Information on evaluation method leading to the classification of mixture

Not applicable.

Full text of any H-statements not written out in full under Sections 2 to 15

H302 Harmful if swallowed.
H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.

Training information

Follow training instructions when handling this material.

Disclaimer

Siegfried St Vulbas-Evionnaz cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.