SAFETY DATA SHEET

1. Identification

Product identifier **Oxymetazolin HCl**

Other means of identification

Material Number(s) 704153, 704213, 704242, 704243

CAS number 2315-02-8

Recommended use Pharmaceutical agent.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name Siegfried PharmaChemikalien Minden GmbH

Address Karlstrasse 15
32423 Minden
Germany

Telephone +49 571 391-0

E-mail she@siegfried.ch

Supplier

Company name Siegfried USA, LLC

Address 33 Industrial Park Road
Pennsville, NJ 08070, USA

Emergency telephone number 1.866.519.4752 (US, Canada, Mexico), Access Code: 334531

For the United States, Canada, Argentina, Brazil, Mexico, Puerto Rico, Peru (+)1 760 476 3962

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Acute toxicity, oral	Category 1
Acute toxicity, inhalation	Category 1
Serious eye damage/eye irritation	Category 1

Environmental hazards

Hazardous to the aquatic environment, acute hazard	Category 3
Hazardous to the aquatic environment, long-term hazard	Category 3

OSHA defined hazards Combustible dust

Label elements

Signal word Danger

Hazard statement May form combustible dust concentrations in air. Fatal if swallowed. Causes serious eye damage. Fatal if inhaled. Harmful to aquatic life with long lasting effects.

Precautionary statement

Prevention Prevent dust accumulation to minimize explosion hazard. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Ground/bond container and receiving equipment. Do not breathe dust. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves and eye/face protection. Wear respiratory protection.

Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. Specific treatment is urgent (see this label). Take off contaminated clothing and wash before reuse. In case of fire: Use appropriate media to extinguish.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Substances

Chemical name	Common name and synonyms	CAS number	%
OXYMETAZOLINE HYDROCHLORIDE		2315-02-8	100

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

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

4. First-aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Call a physician or poison control center immediately.
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 immediately.
Ingestion	Call a physician or poison control center immediately. Immediately rinse mouth and then drink 200-300 ml of water. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Dusts may irritate the respiratory tract, skin and eyes.
Indication of 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.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

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.
Specific hazards arising from the chemical	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 such as: Toxic gases/vapors. Carbon oxides. Hydrogen Chloride (HCl).
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Dust may form explosive mixture with air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

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 breathe dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS. Avoid contact with skin, eyes and clothing.

Methods and materials 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. Prevent product from entering drains. Stop the flow of material, if this is without risk.

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. For waste disposal, see section 13 of the SDS.

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.

7. Handling and storage

Precautions for safe handling

Minimize 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 breathe dust. Do not get this material in contact with eyes. Avoid contact with skin and clothing. Do not taste or swallow. 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.

Conditions for safe storage, including any incompatibilities

Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place. Protect from light. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Explosion-proof general and local exhaust ventilation. Good general ventilation 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. Provide eyewash station.

Individual protection measures, such as personal protective equipment

Eye/face protection

Chemical respirator with organic vapor cartridge, full facepiece, dust and mist filter.

Skin protection

Hand protection

Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.

Skin protection

Other

Wear suitable protective clothing. Use of an impervious apron is recommended.

Respiratory protection

If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations	When using, do not eat, drink or smoke. Keep away from food, drink and animal feeding stuffs. 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.

9. Physical and chemical properties

Appearance	
Physical state	Solid.
Form	Crystalline powder.
Color	White to pale yellow.
Odor	Faint. Specific.
Odor threshold	Not determined.
pH	4 - 6.5 (50 g/l)
Melting point/freezing point	> 572 °F (> 300 °C)
Initial boiling point and boiling range	Not applicable.
Flash point	Not applicable.
Evaporation rate	Negligible.
Flammability (solid, gas)	Not highly 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.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not applicable.
Relative density	Not applicable.
Solubility(ies)	
Solubility (water)	Soluble.
Partition coefficient (n-octanol/water)	0.97 (25 °C) (calculated)
Auto-ignition temperature	842 °F (450 °C) (VDI 2263 , sheet 1 , 2,6)
Decomposition temperature	No decomposition , if the regulations / notes for storage and handling are considered.
Viscosity	Not applicable.
Other information	
Dust explosion properties	
Kst	1 (Kst - value> 0 up to 200 bar m s - 1)
Dynamic viscosity	Not applicable.
Explosive properties	The product is not explosive, but a dust explosion by a dust / air mixture is possible.
Molecular formula	C16H24N2O.ClH
Molecular weight	296.84 g/mol
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Keep away from heat, sparks and open flame. Electrostatic discharge. Contact with incompatible materials. Minimize dust generation and accumulation.
Incompatible materials	None known.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation Fatal if inhaled.

Skin contact Dust or powder may irritate the skin.

Eye contact Causes serious eye damage.

Ingestion Fatal if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Dusts may irritate the respiratory tract, skin and eyes.

Information on toxicological effects

Acute toxicity Fatal if inhaled. Fatal if swallowed.

Product	Species	Test Results
OXYMETAZOLINE HYDROCHLORIDE (CAS 2315-02-8)		
Acute		
Inhalation		
Aerosolized dust		
	Rat	0.02 mg/l/4h
Oral		
	Rat	0.68 mg/kg Citation.

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin
Result: non-irritant (OECD Guideline 404)

Serious eye damage/eye irritation Causes serious eye damage.

Eye / Initial pain reaction score
Result: irreversible (HET - CAM test in vitro)

Respiratory or skin sensitization

Respiratory sensitization Due to partial or complete lack of data the classification is not possible.

Skin sensitization Due to partial or complete lack of data the classification is not possible.

Germ cell mutagenicity The substance was not mutagenic in bacteria.

Carcinogenicity Due to partial or complete lack of data the classification is not possible.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Reproductive toxicity Due to partial or complete lack of data the classification is not possible.

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 Due to partial or complete lack of data the classification is not possible.

Aspiration hazard Not relevant, due to the form of the product.

Chronic effects None known.

Further information None known.

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

Product		Species	Test Results
OXYMETAZOLINE HYDROCHLORIDE (CAS 2315-02-8)			
Aquatic			
Acute			
Algae	EC50	Desmodesmus subspicatus	24.2 mg/l, 72 h (growth rate) (OECD Guideline 201 , static)
Crustacea	EC50	Daphnia magna	21.1 mg/l, 48 h (OECD Guideline 202 , part 1 , static)
Fish	LC50	Brachydanio rerio	> 100 mg/l, 96 h (OECD Guideline 203 , static)
Other	EC20	Activated sludge	130 mg/l, 30 min (OECD Guideline 209 , aerobic)

Persistence and degradability Not readily biodegradable.

Bioaccumulative potential Due to the distribution coefficient n - octanol / water (log Pow) is not expected to accumulate in organisms.

Partition coefficient n-octanol / water (log Kow)
0.97, (25 °C) (calculated)

Mobility in soil Assessment transport between environmental compartments: A binding to the solid bottom phase is not expected.

Other adverse effects None known.

13. Disposal considerations

Disposal instructions 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products 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.

14. Transport information

DOT

UN number UN2811
UN proper shipping name Toxic solids, organic, n.o.s. (Oxymetazoline Hydrochloride)
Transport hazard class(es)
Class 6.1
Subsidiary risk -
Label(s) 6.1
Packing group I
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.
Special provisions IB7, T6, TP33
Packaging exceptions None
Packaging non bulk 211
Packaging bulk 242

IATA

UN number UN2811
UN proper shipping name Toxic solid, organic, n.o.s. (Oxymetazoline Hydrochloride)
Transport hazard class(es)
Class 6.1
Subsidiary risk -
Packing group I
Environmental hazards No.
ERG Code 6L

Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IMDG

UN number	UN2811
UN proper shipping name	TOXIC SOLID, ORGANIC, N.O.S. (Oxymetazoline Hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	I
Environmental hazards	
Marine pollutant	No.
EmS	F-A, S-A
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. This product is exempt from the TSCA Inventory. It is regulated by the FDA.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	Yes
Classified hazard categories	Combustible dust Acute toxicity (any route of exposure) Serious eye damage or eye irritation

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 25-July-2016

Revision date 26-March-2018

Version # 02

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

NFPA ratings

List of abbreviations

LD50: Lethal Dose, 50%.
LC50: Lethal Concentration, 50%.
TWA: Time weighted average.
STEL: Short term exposure limit.

Disclaimer

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