

635C1 - SuperSkin for PUR products

Material number 635C 1

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1. Product and company identification**Product identifier**

Trade name: 635C1 - SuperSkin for PUR products

Relevant identified uses of the substance or mixture and uses advised againstGeneral use: Coating agent for orthopedic procedures.
For commercial user only.**Details of the supplier of the safety data sheet**Company name: Otto Bock Health Care
Street/POB-No.: 3820 W. Great Lakes Drive
Postal Code, city: Salt Lake City, UT 84120
USAWWW: www.ottobockus.com

Telephone: +1 (801) 956-2400

Telefax: +1 (801) 956-2401

Dept. responsible for information:

Quality Department,
Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time),
Email: USRegulatory@ottobock.comAdditional information: Corporate headquarters:
Ottobock SE & Co. KGaA
Max-Näder-Straße 15
Duderstadt
Germany**Emergency phone number****CHEMTREC, Telephone: +1 (800) 424-9300****Transport:****CONSULTANK Lutz Harder GmbH (Contract QUALI003)****Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)****2. Hazards identification****Emergency overview**Appearance: Form: liquid
Color: transparent or RAL colors
Odor: characteristic

Classification: Flammable Liquid - Category 2; Eye Irritation - Category 2A; Carcinogenicity - Category 2; Specific Target Organ Toxicity (Single Exposure) - Category 3;

Hazard symbols:

Signal word: **Danger**

Hazard statements: Highly flammable liquid and vapor.
 Causes serious eye irritation.
 May cause respiratory irritation.
 Suspected of causing cancer.

Precautionary statements: Obtain special instructions before use.
 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 Use only outdoors or in a well-ventilated area.
 Wear protective gloves and eye protection.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 IF exposed or concerned: Get medical advice/attention.
 Store in a well-ventilated place. Keep container tightly closed.

Regulatory status

This material is considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200) and SIMDUT in Canada.

Hazards not otherwise classified

Higher doses may lead to a narcotic effect.
 see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Fluid, polyurethane based thermoplastic film with quickly volatile organic solvent additives (THF, alcohol) and colored with physiological innocuous pigments.

Relevant ingredients:

CAS No.	Designation	Content	Classification
CAS 109-99-9	Tetrahydrofuran	60 - 90 %	Flammable Liquid - Category 2. Eye Irritation - Category 2A. Carcinogenicity - Category 2. Specific Target Organ Toxicity (Single Exposure) - Category 3.

4. First aid measures

General information: If victim is at risk of losing consciousness, position and transport on their side.

In case of inhalation: Move victim to fresh air, put at rest and loosen restrictive clothing.
 In case of irregular breathing or respiratory arrest provide artificial respiration. Seek medical attention.

Following skin contact: Take off immediately all contaminated clothing.
 Thoroughly wash skin with soap and water. In case of skin irritation, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.

After swallowing: Do not induce vomiting. Rinse mouth with water. Have victim drink large quantities of water, with active charcoal if possible. Keep victim calm and seek medical attention immediately.

Most important symptoms/effects, acute and delayed

In case of inhalation:

Mucous membrane irritation, cough, shortage of breath, headache dizziness, nausea, unconsciousness.

Higher doses may lead to a narcotic effect.

In case of ingestion:

Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

After contact with skin: May cause irritations.

Tetrahydrofuran: Danger of cutaneous absorption.

Prolonged/repetitive skin contact may cause skin defatting or dermatitis.

Information to physician

Attention in case of vomiting and stomach pumping: danger of aspiration.

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

-5.8 °F (IP 170 Abel)

Auto-ignition temperature: No data available

Suitable extinguishing media:

Water spray jet, alcohol resistant foam, dry chemical powder, carbon dioxide, sand.

Extinguishing media which must not be used for safety reasons:

strong water jet

Specific hazards arising from the chemical

Highly flammable liquid and vapor.

On contact with air, potentially explosive mixtures may develop.

Vapor may travel great distances and cause fire and backflashes.

In case of fire may be liberated: Carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information:

Cool exposed containers with water spray.

6. Accidental release measures

Personal precautions:

Remove all sources of ignition.

Remove persons to safety.

Wear suitable protective clothing. Avoid contact with skin and eyes.

Do not breathe vapors. Provide adequate ventilation.

Environmental precautions:

Do not allow to enter drains, surface waters, basements or pits. Danger of explosion! If necessary notify appropriate authorities.

Methods for clean-up:

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents) and place in closed containers for disposal.

Additional information:

Use only spark proof tools. Beware of reignition.

Suppress gases/vapours/mists with water spray jet.

7. Handling and storage

Handling

Advices on safe handling: Handle and open container with care. Do not allow containers to stand open.
 Provide adequate ventilation, and local exhaust as needed.
 Extract vapors by suction at point of emission. Wear appropriate protective equipment.
 Avoid contact with skin and eyes. Do not breathe vapors.

Precautions against fire and explosion:
 Keep away from sources of ignition - No smoking. Keep away from heat.
 May form explosive peroxides. Avoid shock and friction.
 Take precautionary measures against static discharges. Do not weld.
 Vapors form potentially explosive mixtures with air, which are heavier than air. Air-Vapor mixture may travel great distances at floor level and lead to backflash when exposed to an ignition source.
 Use only explosion-protected equipment/instruments.

Specific use(s) Coating agent for orthopedic procedures.

Storage

Requirements for storerooms and containers:
 Keep container tightly closed in a cool, well-ventilated place.
 Keep container dry. Protect from heat and direct sunlight.
 Unsuitable materials: Various plastics, rubber, tin.
 Qualified materials: Refined steel, aluminium, polyethylene, Teflon, polyamide.

Hints on joint storage: Do not store together with combustible or self-igniting materials or any highly flammable solids.
 Keep away from food, drink and animal feedingstuffs.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
109-99-9	Tetrahydrofuran	USA: ACGIH: STEL	295 mg/m ³ ; 100 ppm
		USA: ACGIH: TWA	147 mg/m ³ ; 50 ppm
		USA: NIOSH: STEL	735 mg/m ³ ; 250 ppm
		USA: NIOSH: TWA	590 mg/m ³ ; 200 ppm
		USA: OSHA: TWA	590 mg/m ³ ; 200 ppm

Biological limit values:

CAS No.	Designation	Type	Limit value	Parameter	Sampling
109-99-9	Tetrahydrofuran	USA: ACGIH-BEI, urine	2 mg/L	Tetrahydrofuran	end of exposure or end of shift

Engineering controls

Provide good ventilation and/or an exhaust system in the work area.
 Processing temperature: room temperature.
 See also information in chapter 7, section storage.

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Personal protection equipment (PPE)

Eye/face protection	Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.
Skin protection	Protective work clothing, chemical resistant safety shoes. Protective gloves according to OSHA Standard - 29 CFR: 1910.138. Glove material: Neoprene, Nitrile rubber breakthrough time > 480 min. Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
Respiratory protection:	Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. Use filter type A (= against vapors of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2. In case of prolonged or repeated exposures: use self-contained breathing apparatus.
General hygiene considerations:	Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges. Avoid contact with skin and eyes. Do not breathe vapors. Take off immediately all contaminated clothing. When using do not eat, drink or smoke. Wash hands and face thoroughly after handling. Have eye wash bottle or eye rinse ready at work place.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Form: liquid Color: transparent or RAL colors
Odor:	characteristic
Odor threshold:	No data available
pH value:	No data available
Melting point/freezing point:	-162.4 °F
Initial boiling point and boiling range:	150.8 °F (ASTM D 97)
Flash point/flash point range:	-5.8 °F (IP 170 Abel)
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	LEL (Lower Explosion Limit): 1.50 Vol-% UEL (Upper Explosive Limit): 12.00 Vol-%
Vapor pressure:	at 68 °F: 173 hPa at 122 °F: (THF) 578.4 hPa
Vapor density:	No data available
Density:	at 68 °F: 0.9 g/mL
Water solubility:	at 68 °F: miscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	At normal air pressure, the product may be distilled without decomposition.
Viscosity, kinematic:	at 68 °F: 95 s (DIN 53211, 4mm Beche)
Ignition temperature:	413.6 °F (ASTM 2155)

10. Stability and reactivity

Reactivity:	Highly flammable liquid and vapor. May form explosive peroxides. Light-sensitive, sensitive to air.
Chemical stability:	Stabilized with 2,6-di-tert.-Butyl-4-methylphenol. Product is stable under normal storage conditions.
Possibility of hazardous reactions	In use, may form flammable/explosive vapor-air mixture.
Conditions to avoid:	Protect from heat and direct sunlight. Due to the high vapor pressure, bursting danger to containers/vessels when temperature increases. Avoid shock and friction.
Incompatible materials:	Oxygen, alcali hydroxide, hydrides, bromine, tin. Violent reaction with oxidizing agents. Attacks many plastics and rubbers.
Hazardous decomposition products:	Peroxide may form when product is exposed to light and air. Danger of explosion! In case of fire may be liberated: Carbon monoxide and carbon dioxide.
Thermal decomposition:	At normal air pressure, the product may be distilled without decomposition.

11. Toxicological information

Toxicological tests

Acute toxicity:	LD50 Rat, oral: (Tetrahydrofuran) 1650 mg/kg LC50 Rat, inhalative: (Tetrahydrofuran) 54 mg/l/4h
Toxicological effects:	Acute toxicity (oral): Lack of data. Acute toxicity (dermal): Lack of data. Acute toxicity (inhalative): Lack of data. Skin corrosion/irritation: Lack of data. Serious eye damage/irritation: Eye Irritation - Category 2A = Causes serious eye irritation. Sensitisation to the respiratory tract: Lack of data. Skin sensitisation: Lack of data. Germ cell mutagenicity/Genotoxicity: Lack of data. Carcinogenicity: Carcinogenicity - Category 2 = Suspected of causing cancer. Reproductive toxicity: Lack of data. Effects on or via lactation: Lack of data. Specific target organ toxicity (single exposure): Specific Target Organ Toxicity (Single Exposure) - Category 3 = May cause respiratory irritation. Organs affected: central nervous system. exposure route: inhalation. Specific target organ toxicity (repeated exposure): Lack of data. Aspiration hazard: Lack of data.
In case of inhalation:	irritant

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Other information: Tétrahydrofurane:
Causes depression of CNS.
Not known to cause sensitization.

Symptoms

In case of inhalation:
Mucous membrane irritation, cough, shortage of breath, headache dizziness, nausea, unconsciousness.
Higher doses may lead to a narcotic effect.
In case of ingestion:
Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.
After contact with skin: May cause irritations.
Tétrahydrofurane: Danger of cutaneous absorption.
Prolonged/repetitive skin contact may cause skin defatting or dermatitis.

12. Ecological information**Ecotoxicity**

Aquatic toxicity: Tétrahydrofurane:
Daphnia toxicity:
EC50 Daphnia magna: 382 mg/L/ 24 h.
Fish toxicity:
LC50 Pimephales promelas: 2160 mg/L/ 96 h.
LC50 Leuciscus idus: 2820 mg/L.

Effects in sewage plants: Technically correct releases of minimal concentrations to adapted biological sewage treatment facility, will not disturb the biodegradability of activated sludge.

Further details: Product may not be released into water without pre-treatment (biological sewage plant).

Mobility in soil

No data available

Persistence and degradability

Further details: Tétrahydrofurane:
Biodegradation: 39% / 28 d (closed bottle test).
Product is not readily biodegradable.

Additional ecological information

Volatile organic compounds (VOC):
54 % by weight = 486 g/L

General information: Do not allow to penetrate into soil, waterbodies or drains.

13. Disposal considerations**Product**

Recommendation: Incinerate as hazardous waste according to applicable local, state, and federal regulations.

Contaminated packaging

Recommendation: Dispose of waste according to applicable legislation.
 Non-contaminated packages may be recycled.

14. Transport information

USA: Department of Transportation (DOT)

Identification number: UN1993
 Proper shipping name: UN 1993, UN 1993, flammable liquids, n.o.s. (Tetrahydrofurane)
 Hazard class or Division: 3
 Packing Group: II
 Labels: 3
 Symbols: G
 Special provisions: IB2, T7, TP1, TP8, TP28
 Packaging – Exceptions: 150
 Packaging – Non-bulk: 202
 Packaging – Bulk: 242
 Quantity limitations – Passenger aircraft / rail: 5 L
 Quantity limitations – Cargo only: 60 L
 Vessel stowage – Location: B



Sea transport (IMDG)

UN number: UN 1993
 Proper shipping name: UN 1993, FLAMMABLE LIQUID, N.O.S. (Tetrahydrofurane)
 Class or division, Subsidiary risk: Class 3, Subrisk -
 Packing Group: II
 EmS: F-E, S-E
 Special provisions: 274
 Limited quantities: 1 L
 Excepted quantities: E2
 Contaminated packaging - Instructions: P001
 Contaminated packaging - Provisions: -
 IBC - Instructions: IBC02
 IBC - Provisions: -
 Tank instructions - IMO: -
 Tank instructions - UN: T7
 Tank instructions - Provisions: TP1, TP8, TP28
 Stowage and handling: Category B.
 Properties and observations: -
 Marine pollutant: no
 Segregation group: none

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Air transport (IATA)

UN/ID number: UN 1993
 Proper shipping name: UN 1993, FLAMMABLE LIQUID, N.O.S. (Tetrahydrofuran)
 Class or division, Subsidiary risk: Class 3
 Packing Group: II
 Hazard label: Flamm. liquid
 Excepted Quantity Code: E2
 Passenger and Cargo Aircraft: Ltd.Qty.: Pack.Instr. Y341 - Max. Net Qty/Pkg. 1 L
 Passenger and Cargo Aircraft: Pack.Instr. 353 - Max. Net Qty/Pkg. 5 L
 Cargo Aircraft only: Pack.Instr. 364 - Max. Net Qty/Pkg. 60 L
 Special provisions: A3
 Emergency Response Guide-Code (ERG): 3H

15. Regulatory information

National regulations - U.S. Federal Regulations

Tetrahydrofuran: TSCA Inventory: listed; EPA flags T
 TSCA HPVC: not listed
 Clean Air Act:
 SOCMI Chemical: yes
 Other Environmental Laws:
 CERCLA: RQ 1000 lbs.
 RCRA Hazardous Wastes: Code U213
 NIOSH Recommendations:
 Occupational Health Guideline: 0602

National regulations - U.S. State Regulations

Tetrahydrofuran: Delaware Air Quality Management List:
 DRQ: 1000 - RQ State: Federal Regulations Apply
 Idaho Air Pollutant List:
 Title 585 - AAC: 29.5 - EL: 39.3 - WEL: 590 - Title 586 -
 Massachusetts Haz. Substance codes: 2,4,5,6 F8
 Minnesota Haz. Substance:
 Codes: AO, Ratings: -, Status: Title III.
 New York List of Hazardous Substances:
 RQ -- Air: 1000 - RQ -- Land: 100 - Note: No Note Associated with this chemical.
 Pennsylvania Haz. Substance code: E
 Washington Air Contaminant:
 TWA: 200 ppm / 590 mg - STEL: 250 ppm / 735 mg

National regulations - Great Britain

Hazchem-Code: •3YE

16. Other information

Text for labeling: Contains 60 - 90 % Tetrahydrofuran. Safety data sheet available on request.

SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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Revision date: 3/22/2018

Version: 11

Language: en-US

Date of print: 5/24/2018

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Hazard rating systems:



NFPA Hazard Rating:

Health: 2 (Moderate)

Fire: 3 (Serious)

Reactivity: 1 (Slight)

HMIS Version III Rating:

Health: 2 (Moderate) - Chronic effects

Flammability: 3 (Serious)

Physical Hazard: 1 (Slight)

Personal Protection: X = Consult your supervisor

HEALTH	*	2
FLAMMABILITY		3
PHYSICAL HAZARD		1
		X

Reason of change:

Changes in section 1.3: Corporate headquarters

Date of first version:

1/20/1996

Department issuing data sheet

Contact person:

see section 1: Dept. responsible for information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.