

635C2A - SuperSkin for none-PUR products

Material number 635C 2A

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1 Identification

Product identifier

Trade name: 635C2A - SuperSkin for none-PUR products

Recommended use and restrictions on use

General use: Coating agent for orthopedic procedures
For commercial user only.

Initial supplier identifier

Company name: Otto Bock HealthCare Canada Ltd.

Street/POB-No.: 5470 Harvester Road

Postal code, city: Burlington, ON L7L 5N5, CA
Canada

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Email: info.canada@ottobock.com

Telephone: (800) 665-3327

Telefax: (800) 463-3659

Department responsible for information:

Mark Agro, Telephone: (800) 665-3327 (9 am - 5 pm)

Additional information:

Corporate headquarters:
Ottobock SE & Co. KGaA
Max-Näder-Straße 15
Duderstadt
Germany

Emergency telephone number

COLLECT, Telephone: (613) 996-6666

Transport:

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)

2 Hazard identification

Classification

Flammable Liquid 2

Highly flammable liquid and vapour.

Eye Irritation 2A

Causes serious eye irritation.

Carcinogenicity 2

Suspected of causing cancer.

Specific Target Organ Toxicity (Single Exposure) 3 May cause respiratory irritation.

Information elements

Symbols:



Signal word:

Danger

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Hazard statements:

- Highly flammable liquid and vapour.
- 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.

Other hazards known to the supplier with respect to the product

Higher doses may lead to a narcotic effect.

3 Composition/Information on ingredients

Mixture

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

Hazardous ingredients:

CAS No.	Designation	Content	Classification
CAS 109-99-9	Tetrahydrofuran	70 - 90 %	Flammable Liquid 2. Eye Irritation 2A. Carcinogenicity 2. Specific Target Organ Toxicity (Single Exposure) 3.

The actual concentration or concentration range is withheld as a trade secret.

4 First-aid measures

Description of necessary 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.

In case of 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.

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

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In case of eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart.
Immediately get medical attention.

Most important symptoms and effects, whether acute or 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.

Indication of immediate medical attention and special treatment needed, if necessary

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

5 Fire-fighting measures

Suitable and unsuitable extinguishing media

Suitable extinguishing media:
Water spray jet, alcohol resistant foam, extinguishing powder, carbon dioxide, sand.
Unsuitable extinguishing media:
strong water jet

Specific hazards arising from the product

In case of fire carbon monoxide (CO) may be released. vapours may proceed on the ground over great distances and cause fire and backflashes.

Special protective equipment and precautions for fire-fighters

Wear a self-contained breathing apparatus and chemical protective clothing.
Additional information: Use fine water spray to cool endangered containers.
National regulations Germany:
Temperature Class (DIN 57165): T1-Explosion group: IIA

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Remove all sources of ignition.
Remove persons to safety.
Wear suitable protective clothing. Avoid contact with skin and eyes.
Do not breathe vapours. Provide adequate ventilation.

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

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Methods and material for containment and cleaning 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

Precautions for safe 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 vapours by suction at point of emission. Wear appropriate protective equipment.
Avoid contact with skin and eyes. Do not breathe vapours.

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.
vapours form potentially explosive mixtures with air, which are heavier than air. Air-vapour mixture may travel great distances at floor level and lead to backflash when exposed to an ignition source.
Use only explosion-protected equipment/instruments.

Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep container tightly closed in a cool, well-ventilated place.
Keep container dry. Protect from heat and direct sunlight.
Incompatible 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.

Further details: Processing temperature: room temperature.

Do not empty into drains.

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8 Exposure controls/Personal protection

Control parameters

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
109-99-9	Tetrahydrofuran	Canada: Alberta, OEL 15 min	295 mg/m ³ ; 100 ppm (may be absorbed through the skin)
		Canada: Alberta, OEL 8 hour	147 mg/m ³ ; 50 ppm (may be absorbed through the skin)
		Canada: BC, OEL STEL	100 ppm (may be absorbed through the skin)
		Canada: BC, OEL TWA	50 ppm (may be absorbed through the skin)
		Canada: Québec, VECD	100 ppm (may be absorbed through the skin)
		Canada: Québec, VEMP	50 ppm (may be absorbed through the skin)

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

Appropriate engineering controls

Provide good ventilation and/or an exhaust system in the work area.
Processing temperature: room temperature.
Handle in accordance with good industrial hygiene and safety practice.

Individual protection measures, such as personal protective equipment

Respiratory protection: Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. Use filter type A (= against vapours 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.

Hand protection: 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.

Eye protection: Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.

Body protection: Protective work clothing, chemical resistant safety shoes.

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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 vapours.
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.
Processing temperature: room temperature.

Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

9 Physical and chemical properties

Information on basic physical and chemical properties

Physical state at 20 °C and 101.3 kPa	Form: liquid
Colour:	transparent or RAL colours
Odour:	characteristic
Odour threshold:	No data available
Melting point and freezing point:	-108 °C
Boiling point or initial boiling point and boiling range:	66 °C (ASTM D 97)
Flammability:	No data available
Lower and upper explosion limit or lower and upper flammability limit:	LEL (Lower Explosion Limit): 1.50 Vol-% UEL (Upper Explosive Limit): 12.00 Vol-%
Flash point/flash point range:	-21 °C (IP 170 Abel)
Evaporation rate:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	At normal air pressure, the product may be distilled without decomposition.
pH:	No data available
Kinematic viscosity:	at 20 °C: 360 s (DIN 53211)
Water solubility:	at 20 °C: miscible
Partition coefficient — n-octanol/water:	No data available
Vapour pressure:	at 20 °C: 173 hPa at 50 °C: (THF) 578.4 hPa
Density and/or relative density	at 20 °C: 0.9 g/cm ³
Vapour density:	No data available
Particle characteristics:	Not applicable

Additional information

Ignition temperature:	212 °C (ASTM 2155)
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10 Stability and reactivity

Reactivity:	Highly flammable liquid and vapour. 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 vapour-air mixture.
Conditions to avoid:	Protect from heat and direct sunlight. Due to the high vapour pressure, bursting danger to containers/vessels when temperature increases. Avoid shock and friction.
Incompatible materials:	Oxygen, alkali 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.

11 Toxicological information

Information on the likely routes of exposure

No data available

Health hazard information

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 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 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) 3 = May cause respiratory irritation.
exposure route: inhalation.
Specific target organ toxicity (repeated exposure): Lack of data.
Aspiration hazard: Lack of data.

Acute toxicity: LD50 Rat, oral: (THF) 3,000 mg/kg
LC50 Rat, inhalative, 4h: 54 mg/l

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Other information: Tetrahydrofuran:
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.
Tetrahydrofuran: Danger of cutaneous absorption.
Prolonged/repetitive skin contact may cause skin defatting or dermatitis.

12 Ecological information

Ecotoxicity

Aquatic toxicity: Tetrahydrofuran:
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).

Persistence and degradability

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

Bioaccumulative potential

Partition coefficient — n-octanol/water:
No data available

Mobility in soil

No data available

Other adverse effects

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

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13 Disposal considerations

Waste treatment methods

Product

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

Package

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

14 Transport information

UN number

TDG: UN1993
IMDG, IATA-DGR: UN 1993

UN proper shipping name

TDG: UN 1993, Flammable liquid, n.o.s. (Tetrahydrofurane)
IMDG, IATA-DGR: UN 1993, FLAMMABLE LIQUID, N.O.S. (Tetrahydrofurane)

Transport hazard class

TDG: 3
IMDG: Class 3, Subrisk -
IATA-DGR: Class 3

Packing group

TDG, IMDG, IATA-DGR: II

Environmental hazards

Marine pollutant: no



Special precautions in connection with transport or conveyance either within or outside the premises

Canada: Transportation of Dangerous Goods (TDG)

Special Provisions: 16, 150
Explosive limit and limited quantity index: 1 L
Passenger carrying road or rail index: 5 L
Marine pollutant: P

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Sea transport (IMDG)

EmS: F-E, S-E
Special Provisions: 274
Limited quantities: 1 L
Excepted quantities: E2
Package - Instructions: P001
Package - 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

Air transport (IATA)

Proper shipping name: UN 1993, FLAMMABLE LIQUID, N.O.S. (Tetrahydrofuran)
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 - Canada

Tetrahydrofuran: DSL: listed

Further regulations, limitations and legal requirements

No data available

16 Other information

Text for labelling: Contains Tetrahydrofuran
Revision date: 17/12/2025
Date of first version: 11/12/1997
Reason of change: General revision: Safety Data Sheet according to Hazardous Products Regulations (HPR) 2022
General revision: Safety Data Sheet according to HCS 2024 (29 CFR 1910.1200)

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Abbreviations and acronyms:

AS/NZS: Australian Standards/New Zealand Standards
Carcinogenicity: Carcinogenicity
CAS: Chemical Abstracts Service
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
CNS: Central Nervous System
DMEL: Derived minimal effect level
DNEL: Derived no-effect level
DSL: Domestic Substances List
EC: European Community
EC50: Effective Concentration 50%
EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods
EN: European Standard
EQ: Excepted quantities
Eye Irritation: Eye irritation
Flammable Liquid: Flammable liquid
IATA: International Air Transport Association
IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IMDG Code: International Maritime Dangerous Goods Code
IMO: International Maritime Organization
LC50: Median lethal concentration
LEL: Lower Explosion Limit
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
MFSU: Manufacture, formulation, supply and use
OEL: Occupational Exposure Limit Value
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
STOT SE: Specific target organ toxicity - single exposure
TDG: Transportation of Dangerous Goods Regulation in Canada
TLV: Threshold Limit Value
TRGS: Technical Rules for Hazardous Substances
UN: United Nations
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit

Department issuing data sheet

Contact person: see section 1: Department 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.