

635C3 - Priming coat for non-PUR products

Material number 635C 3

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1 Identification

Product identifier

Trade name: 635C3 - Priming coat for non-PUR products

Recommended use and restrictions on use

General use: Paint, 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

WWW: www.ottobock.ca

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.

Specific Target Organ Toxicity (Single Exposure) 3 May cause drowsiness or dizziness.

Information elements

Symbols:



Signal word:

Danger

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Hazard statements: Highly flammable liquid and vapour.
Causes serious eye irritation.
May cause drowsiness or dizziness.

Precautionary statements: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Keep container tightly closed.
Ground/bond container and receiving equipment.
Use explosion-proof equipment.
Use only non-sparking tools.
Take precautionary measures against static discharge.
Avoid breathing mist/vapours/spray.
Wash hands and face thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Wear protective gloves/protective clothing/eye protection.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/or shower.
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.
Call a POISON CENTER/doctor if you feel unwell.
If eye irritation persists: Get medical advice/attention.
In case of fire: Use ... to extinguish.

Store in a well-ventilated place. Keep container tightly closed.
Store in a well-ventilated place. Keep cool.
Store locked up.

Dispose of contents/container to hazardous or special waste collection point.

Other hazards known to the supplier with respect to the product

Potentially explosive mixtures may form if adequate ventilation is not provided.
Inhaling can lead to irritations of the respiratory tract and mucous membrane.
Special danger of slipping by leaking/spilling product.
Frequently or prolonged contact with skin may cause dermal irritation.

3 Composition/Information on ingredients

Mixture

Chemical name: Ethyl acetate solvent mixture

Hazardous ingredients:

CAS No.	Designation	Content	Classification
CAS 141-78-6	Ethyl acetate	60 - 80 %	Flammable Liquid 2. Eye Irritation 2A. Specific Target Organ Toxicity (Single Exposure) 3.
CAS 67-64-1	Acetone	10 - 25 %	Flammable Liquid 2. Eye Irritation 2A. Specific Target Organ Toxicity (Single Exposure) 3.

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

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4 First-aid measures

Description of necessary first-aid measures

General information:	If medical advice is needed, have product container or label at hand. First aider: Pay attention to self-protection! Take off contaminated clothing and wash it before reuse.
In case of inhalation:	Move victim to fresh air; if necessary, provide artificial respiration or oxygen. Do not allow victim to become chilled. Keep victim warm. Position and transport victim on their side. In case of respiratory distress, bring into semi-upright, seated position. Immediately get medical attention.
In case of swallowing:	Rinse mouth immediately and drink plenty of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical attention.
In case of skin contact:	Immediately clean with water and soap followed by thorough rinsing. In case of skin reactions, consult a physician.
In case of eye contact:	Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently consult an ophthalmologist.

Most important symptoms and effects, whether acute or delayed

Causes serious eye irritation.
May cause drowsiness or dizziness.
Repeated exposure may cause skin dryness or cracking.
Inhaling can lead to irritations of the respiratory tract and mucous membrane.

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

Treat symptomatically.

5 Fire-fighting measures

Suitable and unsuitable extinguishing media

Suitable extinguishing media:

Water spray jet, alcohol resistant foam, extinguishing powder, carbon dioxide

Unsuitable extinguishing media:

Full water jet

Specific hazards arising from the product

Highly flammable liquid and vapour.
Liquid evaporates very quickly. vapours form explosive mixtures with air. vapours are heavier than air and will travel at floor level. In case of heating: Danger of bursting container. In case of fire may be liberated: Carbon monoxide and carbon dioxide.

Special protective equipment and precautions for fire-fighters

Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.

Additional information:

Do not inhale explosion and combustion gases. Use fine water spray to cool endangered containers.
In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion. Do not allow fire water to penetrate into surface or ground water. Contaminated fire-fighting water must be collected separately.

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6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Eliminate all ignition sources if safe to do so.
Avoid contact with the substance. Wear appropriate protective equipment. Keep unprotected people away. Take off contaminated clothing and wash it before reuse. Avoid breathing mist/vapours/spray.

Environmental precautions:

Do not allow to enter into ground-water, surface water or drains. In case of release, notify competent authorities. Danger of explosion!

Methods and material for containment and cleaning up

Isolate leaked material using non-flammable absorption agent (e.g. sand, earth, vermiculit, diatomaceous earth) and collect it for disposal in appropriate containers in accordance with the local regulations (see section 13). Beware of reignition. Thoroughly clean surrounding area.

In case of greater quantities: Collect mechanically (use only explosion-proof equipment when pumping out). Never return spills in original containers for re-use.

Additional information:

Special danger of slipping by leaking/spilling product.

7 Handling and storage

Precautions for safe handling

Advices on safe handling: Do not allow containers to stand open. Store product in a quantity adequate for 1 work-shift only.
Provide adequate ventilation, and local exhaust as needed.
Concentrated vapours are heavier than air. Provide room air exhaust at ground level.
Avoid contact with skin and eyes. Avoid breathing mist/vapours/spray.
Use local exhaust in the field of the processing equipment.
Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse.
Do not eat, drink or smoke when using this product.
Have eye wash bottle or eye rinse ready at work place. When handling large quantities, supply emergency spray.

Precautions against fire and explosion:

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Take precautionary measures against static discharge.
Use only explosion-protected equipment/instruments. In partially filled containers explosive mixtures may form.

Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep container tightly closed in a cool, well-ventilated place. Keep away from sources of ignition and heat.
Attacks and dissolves many plastics.
Steel, stainless steel and aluminium are stable container materials.
Store locked up.
Storage stability: 2 years

Hints on joint storage: Keep away from food, drink and animal feedingstuffs.
Do not store together with: Strong reducing agents, strong oxidizing agents, halogenic hydrocarbons, alkali metals, ethanolamine, hydrogen peroxide.

8 Exposure controls/Personal protection

Control parameters

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
141-78-6	Ethyl acetate	Canada: Alberta, OEL 8 hour	1,440 mg/m ³ ; 400 ppm
		Canada: BC, OEL TWA	150 ppm
		Canada: Québec, VEMP	1,440 mg/m ³ ; 400 ppm
67-64-1	Acetone	Canada: Alberta, OEL 15 min	1,800 mg/m ³ ; 750 ppm
		Canada: Alberta, OEL 8 hour	1,200 mg/m ³ ; 500 ppm
		Canada: BC, OEL STEL	500 ppm
		Canada: BC, OEL TWA	250 ppm
		Canada: Québec, VECD	500 ppm
		Canada: Québec, VEMP	250 ppm

Biological limit values:

CAS No.	Designation	Type	Limit value	Parameter	Sampling
67-64-1	Acetone	USA: ACGIH-BEI, urine	25 mg/L	acetone	end of exposure or end of shift

Appropriate engineering controls

Provide good ventilation and/or an exhaust system in the work area.

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.
The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.

Hand protection: Protective gloves according to OSHA Standard - 29 CFR: 1910.138.
Glove material: butyl caoutchouc (butyl rubber) - Layer thickness: 0.7 mm
Breakthrough time >120 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: Flame retardant, antistatic and chemical resistant protective clothing.

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General hygiene considerations:

Do not allow containers to stand open. Store product in a quantity adequate for 1 work-shift only.
Avoid contact with skin and eyes. Avoid breathing mist/vapours/spray.
Take off contaminated clothing and wash it before reuse.
Do not eat, drink or smoke when using this product.
Have eye wash bottle or eye rinse ready at work place. When handling large quantities, supply emergency spray.

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	liquid
Colour:	white
Odour:	fruity
Odour threshold:	No data available
Melting point and freezing point:	-84 °C (Ethyl acetate)
Boiling point or initial boiling point and boiling range:	70 - 78 °C (Ethyl acetate)
Flammability:	Highly flammable liquid and vapour.
Lower and upper explosion limit or lower and upper flammability limit:	LEL (Lower Explosion Limit): 2.10 Vol-% (Ethyl acetate) UEL (Upper Explosive Limit): 11.50 Vol-% (Ethyl acetate)
Flash point/flash point range:	-4 °C (Ethyl acetate)
Evaporation rate:	4.3 g/s
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH:	at 20 °C: 7 (Ethyl acetate)
Kinematic viscosity:	at 20 °C: 200 mm ² /s (Ethyl acetate)
Dynamic viscosity:	at 20 °C: 0.44 mPa*s (Ethyl acetate)
Water solubility:	at 20 °C: 61 g/L (Ethyl acetate)
Partition coefficient — n-octanol/water:	at 25 °C: 0.68 log P(o/w) (Ethyl acetate) Based on the n-octanol/water partition coefficient accumulation in organisms is not expected.
Vapour pressure:	at 25 °C: 98.3 hPa (Ethyl acetate)
Density and/or relative density	at 20 °C: 1.19 g/mL (Ethyl acetate)
Vapour density:	No data available
Particle characteristics:	Not applicable

Additional information

Explosive properties:	Product is not explosive. vapours may form explosive mixtures with air.
Ignition temperature:	427 °C (Ethyl acetate)

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10 Stability and reactivity

Reactivity:	Highly flammable liquid and vapour. vapours may form explosive mixtures with air.
Chemical stability:	Stable under recommended storage conditions. Light-sensitive, sensitive to air.
Possibility of hazardous reactions:	Heating will lead to pressure increase: danger of bursting and explosion. Peroxide formation possible with air oxygen.
Conditions to avoid:	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge. Avoid high temperatures or direct sunlight.
Incompatible materials:	Strong reducing agents, strong oxidizing agents, halogenated hydrocarbons, alkali metals, ethanolamine, hydrogen peroxide
Hazardous decomposition products:	No hazardous decomposition products when regulations for storage and handling are observed.

11 Toxicological information

Information on the likely routes of exposure

No data available

Health hazard information

Acute toxicity (oral): Based on available data, the classification criteria are not met.
Acute toxicity (dermal): Based on available data, the classification criteria are not met.
Acute toxicity (inhalative): Based on available data, the classification criteria are not met.
Skin corrosion/irritation: Based on available data, the classification criteria are not met.
Repeated exposure may cause skin dryness or cracking.
Serious eye damage/irritation: Eye Irritation 2A = Causes serious eye irritation.
Sensitisation to the respiratory tract: Based on available data, the classification criteria are not met.
Skin sensitisation: Based on available data, the classification criteria are not met.
Germ cell mutagenicity/Genotoxicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.
Reproductive toxicity: Based on available data, the classification criteria are not met.
Effects on or via lactation: Lack of data.
Specific target organ toxicity (single exposure): Specific Target Organ Toxicity (Single Exposure) 3 = May cause drowsiness or dizziness.
Specific target organ toxicity (repeated exposure): Based on available data, the classification criteria are not met.
Aspiration hazard: Based on available data, the classification criteria are not met.

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Other information: Information about ethyl acetate (CAS 141-78-6):
LD50 Rabbit, oral: 4.934 mg/kg bw
LD50 Rabbit, dermal: > 20,000 mg/kg bw
LC0 Rat, inhalative, vapour: > 22.5 mg/L/6h
Information about acetone (CAS 67-64-1):
LD50 Rat, oral: 5,800 mg/kg bw
LD50 Rabbit, dermal: 7,400 mg/kg bw
LC50 Rat, inhalative: 76 mg/L/4h

Symptoms

In case of inhalation: Higher doses may lead to a narcotic effect.
After contact with skin: The product is skin resorptive.
After eye contact: Upon direct contact with eyes may cause burning, tearing, redness.

12 Ecological information

Ecotoxicity

Aquatic toxicity: Information about ethyl acetate (CAS 141-78-6):
Fish toxicity:
LC50 Pimephales promelas (fathead minnow): 230 mg/L/96h
NOEC: 6.9 mg/L/32d (QSAR)
Daphnia toxicity:
EC50 Daphnia Cucullata: 165 mg/L/48h
IC50 Artemia salina: 346 mg/L/24h
NOEC Daphnia magna (Big water flea): 2.4 mg/L/21d
Algae toxicity:
EC50 Desmodesmus subspicatus (green algae): 5,600 mg/L/72h
NOEC S. pannonicus: 1,000 mg/L/48h
Information about acetone (CAS 67-64-1):
Fish toxicity:
LC50 Oncorhynchus mykiss: 5,540 mg/L/96h
LC50 Alburnus alburnus (alburnum): 11,000 mg/L/96h
Daphnia toxicity:
LC50 Daphnia pulex (water flea): 8,800 mg/L/48h
LC50 Artemia salina: 2,100 mg/L/24h
NOEC Daphnia magna (Big water flea): 2,212 mg/L/28d
Algae toxicity:
NOEC Microcystis aeruginosa: 530 mg/L/8d
NOEC Prorocentrum minimum: 430 mg/L/96h

Persistence and degradability

Further details: Information about ethyl acetate (CAS 141-78-6): easily bio-degradable
Information about acetone (CAS 67-64-1): easily bio-degradable

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Bioaccumulative potential

Information about ethyl acetate (CAS 141-78-6): Bioconcentration factor (BCF) 30

Information about acetone (CAS 67-64-1): Bioconcentration factor (BCF) 3

Partition coefficient — n-octanol/water:

at 25 °C: 0.68 log P(o/w) (Ethyl acetate)

Based on the n-octanol/water partition coefficient accumulation in organisms is not expected.

Mobility in soil

No data available

Other adverse effects

General information: Do not allow to enter into ground-water, surface water or drains.

13 Disposal considerations

Waste treatment methods

Product

Recommendation: Dispose of waste according to applicable legislation.
Do not dispose of with household waste.
Do not empty into drains.

Package

Recommendation: Dispose of waste according to applicable legislation.
Handle contaminated packages in the same way as the substance itself.
Non-contaminated packages may be recycled.
Handle empty containers with care. Incineration may cause explosion.

14 Transport information

UN number

TDG: UN1993
IMDG, IATA-DGR: UN 1993

UN proper shipping name

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

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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

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. (ethyl acetate, acetone mixture)
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

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15 Regulatory information

National regulations - Canada

Ethyl acetate: DSL: listed

Acetone: DSL: listed

Further regulations, limitations and legal requirements

No data available

16 Other information

Text for labelling:	Contains: ethyl acetate acetone
Revision date:	17/12/2025
Date of first version:	22/2/1996
Reason of change:	General revision: Safety Data Sheet according to Hazardous Products Regulations (HPR) 2022
Classification procedure:	Physical hazards: on basis of test data Health hazards, environmental hazards: calculation method

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Abbreviations and acronyms:

AS/NZS: Australian Standards/New Zealand Standards
BCF: Bioconcentration Factor
CAS: Chemical Abstracts Service
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
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
IC50: Inhibition Concentration 50%
IMDG Code: International Maritime Dangerous Goods Code
IMO: International Maritime Organization
LC0: Lethal concentration 0%
LC50: Median lethal concentration
LD50: Lethal dose 50%
LEL: Lower Explosion Limit
log P(o/w): Partition coefficient: octanol/water
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
NOEC: No Observed Effect Concentration
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.