

640F18 - Donning spray for silicone liners and prosthetic gloves (silicone, PVC)

Material number 640F18

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1 Identification

Product identifier

Trade name: 640F18 - Donning spray for silicone liners and prosthetic gloves (silicone, PVC)

Recommended use and restrictions on use

General use: Pump spray: Solvent for orthopedic procedures

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

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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 3

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:

Warning

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

Precautionary statements: If medical advice is needed, have product container or label at hand.
Keep out of reach of children.

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/protective clothing/eye protection/face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

Other hazards known to the supplier with respect to the product

3 Composition/Information on ingredients

Mixture

Hazardous ingredients:

CAS No.	Designation	Content	Classification
CAS 67-63-0	Isopropyl alcohol	30 - 60 %	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.

4 First-aid measures

Description of necessary first-aid measures

In case of inhalation: Move victim to fresh air. Do not allow victim to become chilled. Keep victim warm.
If breathing becomes irregular or ceases, apply rescue breathing or artificial respiration immediately, where required supply oxygen. Seek medical attention.

In case of swallowing: Do not induce vomiting. Rinse mouth immediately and drink plenty of water. Immediately get medical attention.

In case of skin contact: Change contaminated clothing.
Thoroughly wash skin with soap and water.

In case of eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Consult an ophthalmologist.

Most important symptoms and effects, whether acute or delayed

May cause drowsiness or dizziness.
High concentrations of vapours irritate the eyes and mucous membranes.
After resorption: Headache, dizziness, inebriation, unconsciousness.
Prolonged/repetitive skin contact may cause skin defatting or dermatitis.

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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:

Carbon dioxide, extinguishing powder, water spray jet
In case of large fires water spray jet or alcohol resistant foam.

Unsuitable extinguishing media:

Strong water jet

Specific hazards arising from the product

Flammable. Liquid evaporates quickly.
vapours are heavier than air and will travel at floor level.
vapours may form explosive mixtures with air. Beware of reignition.
In case of fire may be liberated: Carbon monoxide and carbon dioxide.

Special protective equipment and precautions for fire-fighters

Wear self-contained breathing apparatus.

Additional information:

Use fine water spray to cool endangered containers.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Remove all sources of ignition. Remove persons not involved upwind.
Wear suitable protective clothing. Do not breathe vapours. Provide adequate ventilation.

Environmental precautions:

Do not allow to penetrate into soil, waterbodies or drains.
Risk of explosion if the liquid enters the sewage system.
If necessary, notify appropriate authorities.

Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder.
Store in special closed containers and dispose of according to ordinance.
Keep away from sources of ignition - No smoking.

7 Handling and storage

Precautions for safe handling

Advices on safe handling:

Provide adequate ventilation, and local exhaust as needed.
Wear appropriate protective equipment. Do not allow containers to stand open.
Store product in a quantity adequate for 1 work-shift only.
Do not spray in the eyes.

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Precautions against fire and explosion:

Take precautionary measures against static discharges.
Keep away from sources of ignition - No smoking.
Avoid sparks. Do not use any spark discharging tools/utensils.
Air combined with vapours may form potentially explosive mixtures that are heavier than air.

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 heat sources, sparks and open flames.
Protect from direct sunlight.

Hints on joint storage:

Do not store together with combustible or self-igniting materials or any highly flammable solids.

Avoid contact with strong oxidizing agents.

Further details:

Air combined with vapours may form potentially explosive mixtures that are heavier than air.

8 Exposure controls/Personal protection

Control parameters

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
67-63-0	Isopropyl alcohol	Canada: Alberta, OEL 15 min	984 mg/m ³ ; 400 ppm
		Canada: Alberta, OEL 8 hour	492 mg/m ³ ; 200 ppm
		Canada: BC, OEL STEL	400 ppm
		Canada: BC, OEL TWA	200 ppm
		Canada: Québec, VECD	400 ppm
		Canada: Québec, VEMP	200 ppm

Biological limit values:

CAS No.	Designation	Type	Limit value	Parameter	Sampling
67-63-0	Isopropyl alcohol	USA: ACGIH-BEI, urine	40 mg/L	Acetone in urine	end of shift at end of work week

Appropriate engineering controls

Provide good ventilation and/or an exhaust system in the work area.
Take precautionary measures against static discharges. Keep away from sources of ignition. Avoid sparks.

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Individual protection measures, such as personal protective equipment

Respiratory protection:	<p>When vapours form, use respiratory protection.</p> <p>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.</p> <p>When vapours form < 0.5%: Filter A2</p> <p>When vapours form > 0.5% - < 1%: Filter A3</p> <p>When vapours form > 1%: Respiratory protective device.</p>
Hand protection:	<p>protective gloves according to OSHA Standard - 29 CFR: 1910.138.</p> <p>Glove material:</p> <ul style="list-style-type: none"> - Butyl caoutchouc (butyl rubber), thickness $\geq 0,5$ mm, breakthrough time 8 h - Fluororubber (Viton), thickness $\geq 0,4$ mm, breakthrough time 8 h - Nitrile rubber, thickness $\geq 0,35$ mm, breakthrough time 8 h - Polychloroprene, thickness $\geq 0,5$ mm, breakthrough time 4 h <p>Observe glove manufacturer's instructions concerning penetrability and breakthrough time.</p>
Eye protection:	Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.
Body protection:	<p>Wear suitable protective clothing.</p> <p>If necessary: Flame retardant protective clothing.</p>
General hygiene considerations:	<p>When using do not eat, drink or smoke.</p> <p>Keep away from food and drinks.</p> <p>Do not spray in the eyes. Provide a conveniently located eye rinse station.</p>

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:	colourless, clear
Odour:	alcoholic
Odour threshold:	No data available
Melting point and freezing point:	No data available
Boiling point or initial boiling point and boiling range:	No data available
Flammability:	No data available
Lower and upper explosion limit or lower and upper flammability limit:	<p>LEL (Lower Explosion Limit): (Isopropyl alcohol) 2.00 Vol-%</p> <p>UEL (Upper Explosive Limit): (Isopropyl alcohol) 12.00 Vol-%</p>
Flash point/flash point range:	24 °C (DIN 51755)
Evaporation rate:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH:	No data available

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Water solubility:	at 20 °C: soluble
Partition coefficient — n-octanol/water:	(Isopropyl alcohol) -0.16 log P(o/w) Based on the n-octanol/water partition coefficient accumulation in organisms is not expected.
Vapour pressure:	at 20 °C: (Isopropyl alcohol) 44 hPa at 50 °C: (Isopropyl alcohol) 225 hPa
Density and/or relative density	at 20 °C: 0.908 g/mL
Vapour density:	No data available
Particle characteristics:	Not applicable

Additional information

Ignition temperature: 425 °C (DIN 51794)

10 Stability and reactivity

Reactivity:	Highly flammable liquid and vapour.
Chemical stability:	Product is stable under normal storage conditions.
Possibility of hazardous reactions:	Liquid evaporates quickly. vapours are heavier than air and will travel at floor level. vapours may form explosive mixtures with air. Beware of reignition.
Conditions to avoid:	Keep away from heat sources, sparks and open flames. Take precautionary measures against static discharges. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Incompatible materials:	Do not store together with combustible or self-igniting materials or any highly flammable solids.
Hazardous decomposition products:	In case of fire may be liberated: Carbon monoxide and carbon dioxide.

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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: Lack of data.

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 drowsiness or dizziness.

Specific target organ toxicity (repeated exposure): Lack of data.

Aspiration hazard: Lack of data.

Acute toxicity:

LD50 Rat, oral: 9,140 mg/kg

Symptoms

High concentrations of vapours irritate the eyes and mucous membranes.

After resorption: Headache, dizziness, inebriation, unconsciousness.

After contact with skin:

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

12 Ecological information

Ecotoxicity

Aquatic toxicity:

Isopropyl alcohol:

LC50 Leuciscus idus test: 8970 mg/l/48h

LC50 Goldfish: > 5000 mg/l/24h

EC50 Daphnia magna: 9740 mg/l/24h

Persistence and degradability

Further details:

Product is readily biodegradable.

Bioaccumulative potential

Partition coefficient — n-octanol/water:

(Isopropyl alcohol) -0.16 log P(o/w)

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

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Mobility in soil

No data available

Other adverse effects

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

13 Disposal considerations

Waste treatment methods

Product

Recommendation: Recycling or special waste incineration.

Package

Recommendation: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled. Cleaning agent (recommendation): water

14 Transport information

UN number

TDG: UN1993
IMDG, IATA-DGR: UN 1993

UN proper shipping name

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

Transport hazard class

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

Packing group

TDG, IMDG, IATA-DGR: III

Environmental hazards

Marine pollutant: no



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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: 5 L
Passenger carrying road or rail index: 60 L
Marine pollutant: P

Sea transport (IMDG)

EmS: F-E, S-E
Special Provisions: 223 274 955
Limited quantities: 5 L
Excepted quantities: E1
Package - Instructions: P001, LP01
Package - Provisions: -
IBC - Instructions: IBC03
IBC - Provisions: -
Tank instructions - IMO: -
Tank instructions - UN: T4
Tank instructions - Provisions: TP1, TP29
Stowage and handling: Category A.
Properties and observations: -
Marine pollutant: no
Segregation group: none

Air transport (IATA)

Proper shipping name: UN 1993, FLAMMABLE LIQUID, N.O.S. (Isopropyl alcohol, mixture)
Hazard label: Flamm. liquid
Excepted Quantity Code: E1
Passenger and Cargo Aircraft: Ltd.Qty.: Pack.Instr. Y344 - Max. Net Qty/Pkg. 10 L
Passenger and Cargo Aircraft: Pack.Instr. 355 - Max. Net Qty/Pkg. 60 L
Cargo Aircraft only: Pack.Instr. 366 - Max. Net Qty/Pkg. 220 L
Special Provisions: A3
Emergency Response Guide-Code (ERG): 3L

15 Regulatory information

National regulations - Canada

Isopropyl alcohol: DSL: listed

Further regulations, limitations and legal requirements

No data available

16 Other information

Text for labelling: Contains Isopropyl alcohol.



SAFETY DATA SHEET

according to Hazardous Products Regulations (HPR) 2022

640F18 - Donning spray for silicone liners and prosthetic gloves (silicone, PVC)

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Revision date: 17/12/2025
Version: 15.3
Replaces version: 15.2
Language: en-CA
Date of print: 1/6/2026

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Revision date: 17/12/2025
Date of first version: 23/4/2005
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)

Abbreviations and acronyms:

AS/NZS: Australian Standards/New Zealand Standards
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
IMDG Code: International Maritime Dangerous Goods Code
IMO: International Maritime Organization
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
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.