

## 1. Product and company identification

### Product identifier

Trade name: 635L8 - Socket Lacquer, clear

### Recommended use and restrictions on use

General use: Varnish, 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

WWW: www.ottobock.ca

E-mail: 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 phone number

**COLLECT, Telephone: (613) 996-6666**

**Transport:**

**CONSULTANK Lutz Harder GmbH (Contract QUALI003)**

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

## 2. Hazards identification

### Emergency overview

Appearance: Physical state at 20 °C and 101.3 kPa: liquid

Color: colorless

Odor: Characteristic

Classification: Flammable Liquid 2. Skin Irritation 2. Eye Irritation 2A. Reproductive toxicity 2.  
Specific Target Organ Toxicity (Single Exposure) 3.  
Specific Target Organ Toxicity (Repeated Exposure) 2. Aquatic toxicity - acute 2.  
Aquatic toxicity - chronic 3.

Hazard symbols:



Signal word:

**Danger**

Hazard statements:

- Highly flammable liquid and vapor.
- Causes skin irritation.
- Causes serious eye irritation.
- May cause drowsiness or dizziness.
- Suspected of damaging the unborn child.
- May cause damage to organs through prolonged or repeated exposure.
- Toxic to aquatic life.
- Harmful to aquatic life with long lasting effects.

Precautionary statements:

- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Do not breathe vapors.
- Avoid release to the environment.
- Wear protective gloves/protective clothing/eye protection.
- Call a POISON CENTER/doctor if you feel unwell.
- In case of fire: Use dry powder, foam or water spray for extinction.
- Store in a well-ventilated place. Keep cool.

## Regulatory status

This material is considered hazardous by the WHMIS in Canada.

## Hazards not otherwise classified

Special danger of slipping by leaking/spilling product. Potentially explosive mixtures may form if adequate ventilation is not provided. Inhaling can lead to irritations of the respiratory tract and mucous membrane.  
see section 11: Toxicological information

## 3. Composition / Information on ingredients

Chemical characterisation: Preparation with synthetic adhesive agent and solvent

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 108-88-3	Toluene	35 - 50 %	Flammable Liquid 2. Skin Irritation 2. Reproductive toxicity 2. Specific Target Organ Toxicity (Single Exposure) 3. Specific Target Organ Toxicity (Repeated Exposure) 2. Aspiration Toxicity 1. Aquatic toxicity - acute 2. Aquatic toxicity - chronic 3.
CAS 141-78-6	Ethyl acetate	15 - 20 %	Flammable Liquid 2. Eye Irritation 2A. Specific Target Organ Toxicity (Single Exposure) 3.

## 4. 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 immediately all contaminated clothing and wash it before reuse.

In case of inhalation: Remove person to fresh air and keep comfortable for breathing. In case of irregular breathing or respiratory arrest provide artificial respiration. Seek medical attention if problems persist.

Following skin contact: Remove residues with soap and water. In case of skin reactions, consult a physician.

After 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.

After 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.

### Most important symptoms and effects, both acute and delayed

Causes skin irritation and serious eye irritation.  
May cause drowsiness or dizziness.  
May cause damage to organs through prolonged or repeated exposure.  
Inhaling can lead to irritations of the respiratory tract and mucous membrane.

### Information to physician

Treat symptomatically.

## 5. Fire fighting measures

Flash point/flash point range:

-4 °C (DIN 53213)

Auto-ignition temperature: Not self-igniting

Suitable extinguishing media:

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

Extinguishing media which must not be used for safety reasons:

Full water jet

### Specific hazards arising from the chemical

Highly flammable liquid and vapor. Vapors may proceed on the ground over great distances and cause fire and backflashes. In case of insufficient ventilation and/or when used, may form explosive/highly flammable vapor-air mixture.  
May form dangerous gases and vapors in case of fire. Furthermore, there may develop: 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. Fire residuals and contaminated extinguishing water must be disposed of in accordance with the regulations of the local authorities.

## 6. Accidental release measures

Personal precautions:

Avoid exposure. Do not breathe vapors. Do not get in eyes, on skin, or on clothing. If possible, eliminate leakage. Provide adequate ventilation. Wear appropriate protective equipment. Take off immediately all contaminated clothing and wash it before reuse. Keep unprotected people away. Cordon off downwind area at risk and warn inhabitants.

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 for clean-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

### Handling

Advices on safe handling: Obtain special instructions before use. Provide adequate ventilation, and local exhaust as needed. Do not breathe vapors. Do not get in eyes, on skin, or on clothing. Avoid contact during pregnancy/while nursing. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Wear appropriate protective equipment. Take off immediately all contaminated clothing and wash it before reuse. Work place should be equipped with a shower and an eye rinsing apparatus.

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.

### Storage

Requirements for storerooms and containers:

Keep container tightly closed and in a well-ventilated place. Keep container dry. Keep only in the original container.

Protect from direct sunlight. Store containers in upright position.

Storage temperature: 5 - 35 °C

Only approved packaging (e.g. in accordance with TDG) may be used.

Hints on joint storage: Keep away from food, drink and animal feedingstuffs.

Do not store together with: Strong acids, strong bases, strong oxidizing agents.

Further details: Only trained personnel may be allowed to enter storage area.

## 8. Exposure controls / personal protection

### Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
108-88-3	Toluene	Canada: OEL 8 hour	188 mg/m <sup>3</sup> ; 50 ppm
			(may be absorbed through the skin)
		Canada: OEL TWA	20 ppm
141-78-6	Ethyl acetate	Canada: VEMP	20 ppm
		Canada: OEL 8 hour	1,440 mg/m <sup>3</sup> ; 400 ppm
		Canada: OEL TWA	150 ppm
		Canada: VEMP	1,440 mg/m <sup>3</sup> ; 400 ppm

### Engineering controls

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

See also information in chapter 7, section storage.

### 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: Flame retardant, antistatic and chemical resistant protective clothing.  
Protective gloves according to OSHA Standard - 29 CFR: 1910.138.  
Glove material: Nitrile rubber - Layer thickness  $\geq 0.4$  mm  
Breakthrough time:  $> 480$  min  
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.  
Preventive skin protection (cremes) in accordance with manufacturer's recommendation.

Respiratory protection: Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. In case of inadequate ventilation wear respiratory protection.  
Recommendation: Use filter type A (= against vapors 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.

General hygiene considerations:

Obtain special instructions before use. Do not breathe vapors. Do not get in eyes, on skin, or on clothing.

Avoid contact during pregnancy/while nursing. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.

Take off immediately all contaminated clothing and wash it before reuse. Work place should be equipped with a shower and an eye rinsing apparatus.

### Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Appearance:	Physical state at 20 °C and 101.3 kPa: liquid Color: colorless
Odor:	Characteristic
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	-95 °C (toluene)
Initial boiling point and boiling range:	$> 76$ °C (ethyl acetate)
Flash point/flash point range:	-4 °C (DIN 53213)
Evaporation rate:	No data available
Flammability:	Highly flammable liquid and vapor.
Explosion limits:	LEL (Lower Explosion Limit): 1.00 Vol-% (toluene) UEL (Upper Explosive Limit): 11.50 Vol-% (ethyl acetate)
Vapor pressure:	at 20 °C: 60.23 hPa
Vapor density:	No data available
Density:	at 20 °C: 1 g/mL

Water solubility:	Practically insoluble
Partition coefficient: n-octanol/water:	at 20 °C: 2.73 log K(o/w) (toluene) Based on the n-octanol/water partition coefficient significant accumulation in organisms is not expected. at 25 °C: 0.68 log K(o/w) (ethyl acetate) Based on the n-octanol/water partition coefficient accumulation in organisms is not expected.
Auto-ignition temperature:	Not self-igniting
Thermal decomposition:	No data available
Viscosity, kinematic:	at 20 °C: < 400 mm <sup>2</sup> /s
Explosive properties:	Vapors may form explosive mixtures with air.
Ignition temperature:	426 °C
Solvent content:	70 %
Solid content:	30 %

## 10. Stability and reactivity

Reactivity:	Highly flammable liquid and vapor.
Chemical stability:	Product is stable under normal storage conditions.
Possibility of hazardous reactions:	Vapors may form explosive mixtures with air. Heating will lead to pressure increase: Danger of bursting and explosion.
Conditions to avoid:	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge. Protect from direct sunlight.
Incompatible materials:	Strong acids, strong bases, strong oxidizing agents
Hazardous decomposition products:	No hazardous decomposition products when regulations for storage and handling are observed.
Thermal decomposition:	No data available

## 11. Toxicological information

### Toxicological tests

**Toxicological effects:** The statements are derived from the properties of the single components. No toxicological data is available for the product as such.

Acute toxicity (oral): Based on available data, the classification criteria are not met.  
ATEmix (calculated) > 5,000 mg/kg

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.  
ATEmix (vapor, calculated) > 20 mg/kg

Skin corrosion/irritation: Skin Irritation 2 = Causes skin irritation.

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: Lack of data.

Carcinogenicity: Lack of data.

Reproductive toxicity: Reproductive toxicity 2 = Suspected of damaging the unborn child.

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): Specific Target Organ Toxicity (Repeated Exposure) 2 = May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard: Based on available data, the classification criteria are not met.

**Other information:** Information about Toluene (CAS 108-88-3):  
LD50 Rat, oral: 5,580 mg/kg (EU B.1)  
LD50 Rabbit, dermal: 12,267 mg/kg  
LC50 Rat, inhalative (vapor): 28.1 mg/L/4h (OECD 403)

Information about Ethyl acetate (CAS 141-78-6):  
LD50 Rabbit, oral: 4,934 mg/kg (OECD 401)  
LD50 Rabbit, dermal: > 20,000 mg/kg  
LC50 Rat, inhalative (vapor): > 22.5 mg/L/6h, no mortality occurred

### Symptoms

In case of inhalation:  
Inhalation of vapors exceeding the allowable WEL/TLV-levels may pose a health hazard as well as lead to irritation of mucous membranes and respiratory system, cause kidney and liver damage as well as adversely affect the central nervous system. Higher doses may lead to a narcotic effect.

After contact with skin:  
The product is skin resorptive. Repeated or prolonged contact with the preparation may cause removal of natural fat from the skin resulting in non-allergic contact dermatitis and/or absorption through skin.

After eye contact: Upon direct contact with eyes may cause burning, tearing, redness.

## 12. Ecological information

### Ecotoxicity

Aquatic toxicity: Toxic to aquatic life with long lasting effects.

Information about Toluene (CAS 108-88-3):

Fish toxicity:

LC50 *Oncorhynchus kisutch* (silver salmon): 5.5 mg/L/96h

NOEC *Oncorhynchus kisutch* (silver salmon): 1.39 mg/L/40d

Daphnia toxicity:

EC50 *Ceriodaphnia dubia* (water flea): 3.78 mg/L/48h (US EPA 600/4-91-003)

NOEC *Ceriodaphnia dubia* (water flea): 0.74 mg/L/7d (US EPA 600/4-91-003)

Algae toxicity:

EC50 *Chlamydomonas angulosa*: 134 mg/L/3h

NOEC *Skeletonema costatum*: 10 mg/L/72h (OECD 201)

Information about Ethyl acetate (CAS 141-78-6):

Fish toxicity:

LC50 *Pimephales promelas* (fathead minnow): 230 mg/L/96h (US EPA E03-05)

NOEC *Pimephales promelas* (fathead minnow): 6.9 mg/L/32d (data obtained by analogy conclusion, e.g. (Q)SAR)

Daphnia toxicity:

EC50 *Daphnia Cucullata*: 165 mg/L/48h (weight of evidence)

NOEC *Daphnia magna* (Big water flea): 2.4 mg/L/21d (OECD 211)

Algae toxicity:

ErC50 *Desmodesmus subspicatus* (green algae): 5,600 mg/L/48h (DIN 38412)

NOEC *Chlorella pyrenoidosa*: ≥ 1,000 mg/L/72h

Effects in sewage plants: Information about Toluene (CAS 108-88-3):

EC50 activated sludge: 84 mg/L/24h

### Mobility in soil

Information about Toluene (CAS 108-88-3):

log KOC: 2.31

### Persistence and degradability

Further details: Biodegradability:

Information about Toluene (CAS 108-88-3):

Oxygen consumption: 81%/5d, easily bio-degradable

Information about Ethyl acetate (CAS 141-78-6):

Oxygen consumption: 69%/20d, easily bio-degradable

### Additional ecological information

Volatile organic compounds (VOC):

662 g/L

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

## 13. Disposal considerations

### Product

Recommendation: Dispose of waste according to applicable legislation. Do not allow to enter drains.



### Package

Recommendation: Dispose of waste according to applicable legislation. Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

## 14. Transport information

### UN number

ADR/RID, IMDG, IATA-DGR:

UN 1263

### UN proper shipping name

ADR/RID, IMDG, IATA-DGR:

UN 1263, PAINT

### Transport hazard class(es)

ADR/RID:

Class 3, Code: F1

IMDG:

Class 3, Subrisk -

IATA-DGR:

Class 3



### Packing group

ADR/RID, IMDG, IATA-DGR:

II

### Environmental hazards

Marine pollutant:

no

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No transport as bulk according IBC - Code.

### Canada: Transportation of Dangerous Goods (TDG)

UN Number:

UN1263

Shipping name:

UN 1263, Paint

TDG class:

3

Packing group:

II

Special provisions:

59, 142

Explosive limit and limited quantity index:

5L

Passenger carrying road or rail index:

5L

### Sea transport (IMDG)

UN number:	UN 1263
Proper shipping name:	UN 1263, PAINT
Class or division, Subsidiary risk:	Class 3, Subrisk -
Packing Group:	II
EmS:	F-E, S-E
Special Provisions:	163 367
Limited quantities:	5 L
Excepted quantities:	E2
Package - Instructions:	P001
Package - Provisions:	PP1
IBC - Instructions:	IBC02
IBC - Provisions:	-
Tank instructions - IMO:	-
Tank instructions - UN:	T4
Tank instructions - Provisions:	TP1, TP8, TP28
Stowage and handling:	Category B.
Properties and observations:	Miscibility with water depends upon the composition.
Marine pollutant:	no
Segregation group:	none

### Air transport (IATA)

UN/ID number:	UN 1263
Proper shipping name:	UN 1263, PAINT
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 A72 A192
Emergency Response Guide-Code (ERG):	3L

## 15. Regulatory information

### National regulations - Canada

Toluene:	DSL: listed
Ethyl acetate:	DSL: listed

## 16. Other information

Text for labeling: Contains 35 - 50 % Toluene, 15 - 20 % Ethyl acetate.

Hazard rating systems:



**NFPA Hazard Rating:**

Health: 2 (Moderate)

Fire: 3 (Serious)

Reactivity: 0 (Minimal)

**HMIS Version III Rating:**

Health: 2 (Moderate) - Chronic effects

Flammability: 3 (Serious)

Physical Hazard: 0 (Minimal)

Personal Protection: X = Consult your supervisor

HEALTH	*	2
FLAMMABILITY		3
PHYSICAL HAZARD		0
		X

Classification procedure:

Physical hazards: on basis of test data

Health hazards, environmental hazards: calculation method

Abbreviations and acronyms:

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways  
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road  
 Aquatic toxicity - acute: Hazardous to the aquatic environment - acute  
 Aquatic toxicity - chronic: Hazardous to the aquatic environment - chronic  
 AS/NZS: Australian Standards/New Zealand Standards  
 Aspiration Toxicity: Aspiration toxicity  
 ATEmix: Acute Toxicity Estimate of mixture  
 BCF: Bioconcentration Factor  
 CAS: Chemical Abstracts Service  
 CFR: Code of Federal Regulations  
 CLP: Classification, Labelling and Packaging  
 DIN: German Institute for Standardization  
 DMEL: Derived minimal effect level  
 DNEL: Derived no-effect level  
 DOT: Department of Transportation's Safety Regulations (USA)  
 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  
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships  
 NOEC: No Observed Effect Concentration  
 OECD: Organisation for Economic Co-operation and Development  
 OEL: Occupational Exposure Limit Value  
 OSHA: Occupational Safety and Health Administration  
 PBT: Persistent, bioaccumulative and toxic  
 PNEC: Predicted no-effect concentration  
 QSAR: Quantitative Structure-Activity Relationship  
 Reproductive toxicity: Reproductive toxicity  
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail  
 Skin Irritation: Skin irritation  
 STOT RE: Specific target organ toxicity - repeated exposure  
 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  
 WHMIS: Workplace Hazardous Materials Information System

Reason of change: Changes in section 2: Classification, labelling  
Changes in section 3: Composition/information on ingredients  
Changes in section 9: Physical and chemical properties  
General revision

Date of first version: 21/10/1994

**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.