

1. Product and company identification

Product identifier

Trade name: 635L12 - ORTHOCRYL Lacquer, clear

Relevant identified uses of the substance or mixture and uses advised against

General use: Paint for orthopedic procedures.
Only for industrial users.

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
USA

WWW: 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.com

Additional 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: colorless

Odor: type specific

Classification: Flammable Liquid - Category 2; Eye Irritation - Category 2A;
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.
 May cause drowsiness or dizziness.

Precautionary statements: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 Take precautionary measures against static discharge.
 Avoid breathing vapors.
 Use only outdoors or in a well-ventilated area.
 Wear protective gloves/protective clothing/eye protection/face protection.
 Store locked up.

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

Vapors may form explosive mixtures with air.
 see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Preparation with synthetic adhesive agent and solvent

Relevant ingredients:

CAS No.	Designation	Content	Classification
CAS 141-78-6	Ethyl acetate	25 - 50 %	Flammable Liquid - Category 2. Eye Irritation - Category 2A. Specific Target Organ Toxicity (Single Exposure) - Category 3.
CAS 108-10-1	4-Methylpentan-2-one	12.5 - 20 %	Flammable Liquid - Category 2. Acute Toxicity - inhalative - Category 4. Eye Irritation - Category 2A. Specific Target Organ Toxicity (Single Exposure) - Category 3.

4. First aid measures

General information: First aider: Pay attention to self-protection!

In case of inhalation: Move victim to fresh air, put at rest and loosen restrictive clothing. 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. If victim is at risk of losing consciousness, position and transport on their side.

Following skin contact: Thoroughly wash skin with soap and water. Follow up by applying skin cream. Do not use solvents or thinners. Immediately remove all contaminated clothing. 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. Subsequently consult an ophthalmologist.

After swallowing: If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting. Consult physician immediately. Keep victim resting calmly.

Most important symptoms/effects, acute and delayed

May cause respiratory irritation. May cause drowsiness or dizziness. 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. symptoms: Headache, dizziness, fatigue, muscle weakness, numbing effect and, in exceptional cases, unconsciousness. Causes serious eye irritation.

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

24.8 °F

Auto-ignition temperature: No data available

Suitable extinguishing media:

Water spray jet, alcohol resistant foam, dry chemical 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 form explosive mixtures with air. Exposure to fire produces thick, black smoke that is hazardous to health. In case of fire may be liberated: Nitrogen oxides, smoke, carbon dioxide, carbon monoxide.

Protective equipment and precautions for firefighters:

Wear self-contained breathing apparatus.

Additional information: Cool closed containers that are near the source of the fire.

Do not allow water used to extinguish fire to enter drains, ground or waterways.

6. Accidental release measures

Personal precautions: Eliminate all ignition sources if safe to do so.

Provide adequate ventilation.

Keep unprotected people away. Wear appropriate protective equipment.

Do not breathe vapors.

Environmental precautions:

Do not allow to enter soil, sewage, water bodies, lower level rooms or pits. If necessary notify appropriate authorities.

Methods for clean-up:

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Provide adequate ventilation. Clean using cleansing agents. Do not use solvents.

Beware of re-ignition. Thoroughly clean surrounding area.

Additional information:

Remove all sources of ignition.

Use only non-sparking tools.

7. Handling and storage

Handling

Advices on safe handling: Avoid formation of flammable and potentially explosive solvent vapors in the air.
 Anti-static clothing including shoes are recommended.
 Avoid contact with skin and eyes.
 Do not inhale vapor or fog.
 When using do not eat, drink or smoke.
 Wear appropriate protective equipment.

Precautions against fire and explosion:

Vapors are heavier than air and will travel at floor level.
 Vapors form explosive mixtures with air.
 Product may become electrostatically charged.
 Keep away from open flames and other sources of ignition.
 When decanting, use only grounded equipment and conduits.
 Use only spark proof tools.

Storage

Requirements for storerooms and containers:

Store in a well-ventilated and dry room at temperatures between 41 °F and 95 °F.
 Protect from heat and direct sunlight.
 Store carefully closed containers upright to prevent any leaks.

Hints on joint storage:

Keep away from strong acids and bases as well as oxidizing agents.

Further details:

Electrical equipment must be explosion protected according to standards. Floors must be electrically conductive.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
141-78-6	Ethyl acetate	USA: ACGIH: TWA	1440 mg/m ³ ; 400 ppm
		USA: NIOSH: TWA	1400 mg/m ³ ; 400 ppm
		USA: OSHA: TWA	1400 mg/m ³ ; 400 ppm
108-10-1	4-Methylpentan-2-one	USA: ACGIH: STEL	307 mg/m ³ ; 75 ppm
		USA: ACGIH: TWA	82 mg/m ³ ; 20 ppm
		USA: NIOSH: STEL	300 mg/m ³ ; 75 ppm
		USA: NIOSH: TWA	205 mg/m ³ ; 50 ppm
		USA: OSHA: TWA	410 mg/m ³ ; 100 ppm

Biological limit values:

CAS No.	Designation	Type	Limit value	Parameter	Sampling
108-10-1	4-Methylpentan-2-one	USA: ACGIH-BEI, urine	1 mg/L	MIBK	end of exposure or end of shift

Engineering controls

Use only explosion-protected equipment/instruments.
 Provide good ventilation and/or an exhaust system in the work area.
 See also information in chapter 7, section storage.

10. Stability and reactivity

Reactivity: Highly flammable liquid and vapor.

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions
Vapors may form explosive mixtures with air.

Conditions to avoid: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharge.
Keep away from heat.

Incompatible materials: Keep away from strong acids, strong bases and strong oxidizing agents to avoid exothermic reactions.

Hazardous decomposition products:
Exposure to heat may produce hazardous decomposition products.
Exposure to fire produces thick, black smoke that is hazardous to health.
In case of fire may be liberated: Nitrogen oxides, smoke, carbon dioxide, carbon monoxide.

Thermal decomposition: No data available

11. Toxicological information

Toxicological tests

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: 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) -
Category 3 = May cause respiratory irritation. May cause drowsiness or dizziness.
Specific target organ toxicity (repeated exposure): Lack of data.
Aspiration hazard: Lack of data.

Other information: 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.

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.

symptoms:

Headache, dizziness, fatigue, muscle weakness, numbing effect and, in exceptional cases, unconsciousness.

After contact with skin:

Prolonged or repeated contact with the product affects the skin's natural oils and induces drying up.

The product can be absorbed through skin.

After eye contact: Splashing may cause eye irritation and reversible damage.

12. Ecological information**Ecotoxicity**

Further details: The components in this formulation do not meet the criteria for classification as PBT or vPvB.

Mobility in soil

No data available

Persistence and degradability

Further details: No data available

Additional ecological information

Volatile organic compounds (VOC):

66 % by weight = 623 g/L (ASTM D 2369)

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

13. Disposal considerations**Product**

Recommendation: Incinerate 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: UN1263
 Proper shipping name: UN 1263, UN 1263, Paint
 Hazard class or Division: 3
 Packing Group: II
 Labels: 3
 Special provisions: 149, 367, B52, IB2, T4, TP1, TP8, TP28
 Packaging – Exceptions: 150
 Packaging – Non-bulk: 173
 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 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
 Contaminated packaging - Instructions: P001
 Contaminated packaging - 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 - U.S. Federal Regulations

Ethyl acetate:	TSCA Inventory: listed; EPA flags T TSCA HPVC: not listed Other Environmental Laws: CERCLA: RQ 5000 lbs. RCRA Hazardous Wastes: Code U112 NIOSH Recommendations: Occupational Health Guideline: 0260
4-Methylpentan-2-one:	TSCA Inventory: listed; EPA flags T TSCA HPVC: not listed Clean Air Act: Hazardous Air Pollutants: Code XOY SOCMI Chemical: yes Other Environmental Laws: CERCLA: RQ 5000 lbs. RCRA Hazardous Wastes: Code U161 RCRA Groundwater Monitoring: Methods 8015, 8240 / PQL 5, 50 SARA Title III Section 313, Toxic Release: Conc. 1.0% / Threshold Standard NIOSH Recommendations: Occupational Health Guideline: 0326*

National regulations - U.S. State Regulations

Ethyl acetate: Delaware Air Quality Management List:
 DRQ: 5000 - RQ State: Federal Regulations Apply
 Idaho Air Pollutant List:
 Title 585: AAC: 70 - EL: 93,3 - OEL: 1400 - Title 586: -
 Main Hazardous Air Pollutants:
 Me 2005: HAP - Hap Rpt: 20000
 Massachusetts Haz. Substance codes: 2,4,5,6 F8
 Minnesota Haz. Substance:
 Codes: AO - Ratings: 6.83 - Status: Title III.
 New York List of Hazardous Substances:
 RQ-Air: 5000 - RQ-Land: 1 - Note: No Note Associated with this chemical.
 Pennsylvania Haz. Substance code: E
 Washington Air Contaminant:
 TWA: 400 ppm - 1400 mg

4-Methylpentan-2-one: California Proposition 65 code: -
 Delaware Air Quality Management List:
 DRQ: 5000 - RQ State: Federal Regulations Apply
 Idaho Air Pollutant List:
 Title 585: -, Title 586: -
 Maine Hazardous Air Pollutants:
 Me 2005: HAP - Hap Rpt: 2000
 Massachusetts Haz. Substance codes: 2,4,5,6 F8 F9
 Minnesota Haz. Substance:
 Codes: -, Ratings: -, Status: -
 New Jersey RTK Hazardous Substance:
 DOT: 1245 - Sub No.: 1268 - TPQ: -
 New York List of Hazardous Substances:
 RQ-Air: 5000 - RQ-Land: 1 - Note: No Note Associated with this chemical.
 Pennsylvania Haz. Substance code: E
 Washington Air Contaminant:
 TWA: 50 ppm - 205 mg - STEL: 75 ppm - 300 mg
 California Proposition 65: cancer
 Rhode Island HSL: listed

National regulations - Great Britain

Hazchem-Code: •3YE

16. Other information

Text for labeling: Contains 25 - 50 % Ethyl acetate, 12.5 - 20 % 4-Methylpentan-2-one. Safety data sheet available on request.

Hazard rating systems:



NFPA Hazard Rating:
 Health: 1 (Slight)
 Fire: 3 (Serious)
 Reactivity: 0 (Minimal)

HMIS Version III Rating:
 Health: 1 (Slight)
 Flammability: 3 (Serious)
 Physical Hazard: 0 (Minimal)
 Personal Protection: X = Consult your supervisor

HEALTH	1
FLAMMABILITY	3
PHYSICAL HAZARD	0
	X



SAFETY DATA SHEET

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

Revision date: 3/22/2018

Version: 11

Language: en-US

Date of print: 5/24/2018

635L12 - ORTHOCRYL Lacquer, clear

Material number 635L12

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Literature: BGR 190
BGR 192
BGR 195

Reason of change: Changes in section 1.3: Corporate headquarters

Date of first version: 10/21/1994

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.