



SAFETY DATA SHEET

according to WHMIS 2015 and ANSI Z400.1-2010

617F3 - Parting Agent for ORTHOCRYL Resins

Material number 617F3

Revision date: 25/10/2023
Version: 8.2
Replaces version: 8.1
Language: en-CA,US
Date of print: 2/9/2025

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1. Product and company identification

Product identifier

Trade name: 617F3 - Parting Agent for ORTHOCRYL Resins

Recommended use and restrictions on use

General use: Varnish
For orthopedic procedures.
Reserved for industrial and professional use.

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: Form: liquid
Color: colorless
Odor: similar to solvents
Classification: This material is classified as not hazardous.

Regulatory status

This material is not considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200) and WHMIS in Canada.

Hazards not otherwise classified

vapors: Can damage your health.
see section 11: Toxicological information

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3. Composition / Information on ingredients

Chemical characterisation: Solution of polyvinyl alcohol in water and alcohol.

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 64-17-5	Ethanol	2.5 - 10 %	Flammable Liquid 2.
CAS 67-56-1	Methanol	< 2.5 %	Flammable Liquid 2. Acute Toxicity 3 (oral). Acute Toxicity 3 (dermal). Acute Toxicity 3 (inhalative). Specific Target Organ Toxicity (Single Exposure) 1.
CAS 78-93-3	Butanone	< 2.5 %	Flammable Liquid 2. Eye Irritation 2A. Specific Target Organ Toxicity (Single Exposure) 3.

4. First aid measures

General information:	Seek medical assistance when anyone has symptoms apparently due to inhalation, swallowing or contact with skin or eyes.
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.
Following skin contact:	Take off immediately all contaminated clothing. Thoroughly wash skin with soap and water. Do not use solvents or thinners.
After eye contact:	Remove contact lenses. Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.
After swallowing:	Do not induce vomiting. Keep victim calm. Consult physician.

Most important symptoms and effects, both acute and delayed

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.

Prolonged or repeated contact with the product affects the skin's natural oils and induces drying up. The product can be absorbed through skin.

Splashing may cause eye irritation and reversible damage.

Information to physician

Treat symptomatically.

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5. Fire fighting measures

Flash point/flash point range:

100 °C

Auto-ignition temperature: No data available

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

Exposure to fire produces thick, black smoke that is hazardous to health.

Special protective equipment and precautions for fire-fighters:

Wear self-contained breathing apparatus.

Additional information:

Use fine water spray to cool endangered containers.

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

6. Accidental release measures

Personal precautions:

Provide adequate ventilation. Do not breathe vapors.

Keep away from sources of ignition.

Wear appropriate protective equipment. Keep unprotected people away.

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:

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.

Do not clean with solvents.

Additional information:

Take precautionary measures against static discharge.

7. Handling and storage

Handling

Advices on safe handling:

Avoid formation of flammable and potentially explosive solvent vapors in the air. Avoid exceeding WEL threshold levels. Keep away from open flames and other sources of ignition.

Product may become electrostatically charged. When decanting, use only grounded equipment and conduits.

Use only spark proof tools. Avoid contact with skin and eyes. Do not inhale vapor or fog.

When using do not eat, drink or smoke.

Precautions against fire and explosion:

Keep away from sources of ignition - No smoking.

Vapors are heavier than air and will travel at floor level. Vapors form explosive mixtures with air.

Specific use(s)

Varnish

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Storage

Requirements for storerooms and containers:

Keep only in the original container in a cool, well-ventilated place.

Keep containers tightly closed and at a temperature between 15 °C and 30 °C.

Electrical equipment must be explosion protected according to standards. 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:

Protect from heat and direct sunlight.

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8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
64-17-5	Ethanol	Canada: OEL 8 hour	1,880 mg/m ³ ; 1,000 ppm
		Canada: OEL STEL	1,000 ppm
		Canada: VECD	1,000 ppm
		USA: ACGIH: STEL	1,000 ppm
		USA: IDLH: TWA	3,300 ppm [10% LEL]
		USA: NIOSH: TWA	1,900 mg/m ³ ; 1,000 ppm
		USA: OSHA: TWA	1,900 mg/m ³ ; 1,000 ppm
67-56-1	Methanol	Canada: OEL 15 min	328 mg/m ³ ; 250 ppm (may be absorbed through the skin)
		Canada: OEL 8 hour	262 mg/m ³ ; 200 ppm (may be absorbed through the skin)
		Canada: OEL STEL	250 ppm (may be absorbed through the skin)
		Canada: OEL TWA	200 ppm (may be absorbed through the skin)
		Canada: VECD	328 mg/m ³ ; 250 ppm (may be absorbed through the skin)
		Canada: VEMP	262 mg/m ³ ; 200 ppm (may be absorbed through the skin)
		USA: ACGIH: STEL	328 mg/m ³ ; 250 ppm (may be absorbed through the skin)
		USA: ACGIH: TWA	262 mg/m ³ ; 200 ppm (may be absorbed through the skin)
		USA: IDLH: TWA	6,000 ppm
		USA: NIOSH: STEL	325 mg/m ³ ; 250 ppm (may be absorbed through the skin)
		USA: NIOSH: TWA	260 mg/m ³ ; 200 ppm (may be absorbed through the skin)
		USA: OSHA: TWA	260 mg/m ³ ; 200 ppm
		Canada: OEL 15 min	885 mg/m ³ ; 300 ppm
		Canada: OEL 8 hour	590 mg/m ³ ; 200 ppm
78-93-3	Butanone	Canada: OEL STEL	100 ppm (may be absorbed through the skin)
		Canada: OEL TWA	50 ppm (may be absorbed through the skin)
		Canada: VECD	300 mg/m ³ ; 100 ppm
		Canada: VEMP	150 mg/m ³ ; 50 ppm
		USA: ACGIH: STEL	885 mg/m ³ ; 300 ppm
		USA: ACGIH: TWA	590 mg/m ³ ; 200 ppm
		USA: IDLH: TWA	3,000 ppm
		USA: NIOSH: STEL	885 mg/m ³ ; 300 ppm
		USA: NIOSH: TWA	590 mg/m ³ ; 200 ppm
		USA: OSHA: TWA	590 mg/m ³ ; 200 ppm

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Biological limit values:

CAS No.	Designation	Type	Limit value	Parameter	Sampling
67-56-1	Methanol	USA: ACGIH-BEI, urine	15 mg/L	Methanol	end of exposure or end of shift
78-93-3	Butanone	USA: ACGIH-BEI, urine	2 mg/L	MEK	end of exposure or end of shift

Engineering controls

Explosion protection required.

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: Anti-static clothing including shoes are recommended.
Protective gloves according to OSHA Standard - 29 CFR: 1910.138.
Glove material: Butyl caoutchouc (butyl rubber)-Layer thickness: 0,7 mm -
Breakthrough time: >240 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: Provide good ventilation and/or an exhaust system in the work area.
Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded.
OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2 Use filter type A (= against vapors of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.

General hygiene considerations:

Immediately remove all contaminated clothing. Wash hands before breaks and after work.

Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Form: liquid Color: colorless
Odor:	similar to solvents
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	n.a.
Initial boiling point and boiling range:	78 °C
Flash point/flash point range:	100 °C
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	LEL (Lower Explosion Limit): 3.50 Vol-% UEL (Upper Explosive Limit): 15.00 Vol-%
Vapor pressure:	at 20 °C: 60 hPa
Vapor density:	No data available
Density:	at 20 °C: 1.02 g/mL

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Water solubility:	at 20 °C: miscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	Hazardous decomposition byproducts may form with exposure to high temperatures.
Viscosity, kinematic:	at 20 °C: 45 - 55 s (DIN 53211)
Ignition temperature:	425 °C

10. Stability and reactivity

Reactivity:	refer to 10.3 Avoid formation of flammable and potentially explosive solvent vapors in the air.
Chemical stability:	Product is stable under normal storage conditions.
Possibility of hazardous reactions:	Vapors form explosive mixtures with air. Product may become electrostatically charged.
Conditions to avoid:	When decanting, use only grounded equipment and conduits. Use only spark proof tools. When using do not eat, drink or smoke.
Incompatible materials:	Strong acid or bases as well as oxidizing agents.
Hazardous decomposition products:	Nitrogen oxides, smoke, carbon dioxide, carbon monoxide.
Thermal decomposition:	Hazardous decomposition byproducts may form with exposure to high temperatures.

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

Symptoms

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.

Prolonged or repeated contact with the product affects the skin's natural oils and induces drying up. The product can be absorbed through skin.

Splashing may cause eye irritation and reversible damage.

12. Ecological information

Ecotoxicity

Further details: No data available

Mobility in soil

No data available

Persistence and degradability

Further details: No data available

Additional ecological information

Volatile organic compounds (VOC):

6.36 % by weight

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

13. Disposal considerations

Product

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

Package

Recommendation: Dispose of waste according to applicable legislation.

14. Transport information

UN number

ADR/RID, IMDG, IATA-DGR:

not applicable

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:

Not restricted



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Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:

not applicable

Packing group

ADR/RID, IMDG, IATA-DGR:

not applicable

Environmental hazards

Marine pollutant:

no

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

No data available

USA: Department of Transportation (DOT)

Proper shipping name:

Not restricted

Canada: Transportation of Dangerous Goods (TDG)

Shipping name:

Not restricted

Sea transport (IMDG)

Proper shipping name::

Not restricted

Marine pollutant:

no

Air transport (IATA)

Proper shipping name::

Not restricted

Further information

No dangerous good in sense of these transport regulations.

15. Regulatory information

National regulations - Canada

Ethanol:

DSL: listed

Methanol:

DSL: listed

Butanone:

DSL: listed

Polyvinyl alcohol:

DSL: listed

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National regulations - U.S. Federal Regulations

Ethanol:	<p>TSCA Inventory: listed</p> <p>NIOSH Recommendations: Occupational Health Guideline: 0262</p>
Methanol:	<p>TSCA Inventory: listed</p> <p>Clean Air Act: CAA Hazardous Air Pollutants: yes CAA SOCM Chemical: yes</p> <p>Other Environmental Laws: CERCLA: RQ 5000 lbs. RCRA Hazardous Wastes: Code U154 SARA Title III - Section 313, Toxic Release: Conc. 1.0% / Threshold Standard</p> <p>NIOSH Recommendations: Occupational Health Guideline: 0397</p>
Butanone:	<p>TSCA Inventory: listed</p> <p>Other Environmental Laws: CERCLA: RQ 5000 lbs. RCRA Hazardous Wastes: Code U159 RCRA Groundwater Monitoring: Methods 8015, 8240 / PQL 10, 100</p> <p>NIOSH Recommendations: Occupational Health Guideline: 0069*</p>
Polyvinyl alcohol:	<p>TSCA Inventory: listed</p> <p>Carcinogen Status: IARC Rating: Group 3 OSHA Carcinogen: not listed NTP Rating: not listed</p>

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National regulations - U.S. State Regulations

Ethanol:	<p>California Proposition 65 code: -</p> <p>Idaho Air Pollutant List: Title 585: AAC: 94 - EL: 125 - OEL: 1880 - Title 586: -</p> <p>Massachusetts Haz. Substance codes: 2,4,5,6 *T1*</p> <p>Minnesota Haz. Substance: Codes: AO - Ratings: 7.74</p> <p>Pennsylvania Haz. Substance code: -</p> <p>Washington Air Contaminant: TWA: 1000 ppm - 1900 mg</p>
Methanol:	<p>California Proposition 65: developmental</p> <p>Delaware Air Quality Management List: DRQ: 5000 - RQ State: Federal Regulations Apply</p> <p>Idaho Air Pollutant List: Title 585: AAC: 13 - EL: 17,3 - OEL: 260 - Title 586: -</p> <p>Main Hazardous Air Pollutants: Me 2005: HAP - Hap Rpt: 2000</p> <p>Massachusetts Haz. Substance codes: 2,4,5,6 F8 F9</p> <p>Minnesota Haz. Substance: Codes: ANO - Ratings: 7,5 - Status: Air Pollutant Title III. TRI.</p> <p>New Jersey RTK Hazardous Substance: DOT: 1230 - Sub No.: 1222 - TPQ: -</p> <p>New York List of Hazardous Substances: RQ-Air: 5000 - RQ-Land: 1 - Note: No Note Associated with this chemical.</p> <p>Pennsylvania Haz. Substance code: E</p> <p>Washington Air Contaminant: TWA: 200 ppm - 260 mg - STEL: 250 ppm - 325 mg Skin: Protective measures should be taken to prevent or reduce skin absorption.</p>
Butanone:	<p>Delaware Air Quality Management List: DRQ: 5000 - RQ State: Federal Regulations Apply</p> <p>Idaho Air Pollutant List: Title 585/Title 586: -</p> <p>Massachusetts Haz. Substance codes: 2,4,5,6 F8 F9</p> <p>Minnesota Haz. Substance: Codes: ANO - Ratings: 9.7 - Status: Air Pollutant Title III. TRI.</p> <p>New Jersey RTK Hazardous Substance: DOT: 1193 - Sub No.: 1258 - TPQ: -</p> <p>New York List of Hazardous Substances: RQ-Air: 5000 - RQ-Land: 1 - Note: No Note Associated with this chemical.</p> <p>Pennsylvania Haz. Substance code: E</p> <p>Washington Air Contaminant: TWA: 200 ppm - 590 mg - STEL: 300 ppm - 885 mg</p>

National regulations - EC member states

Further regulations, limitations and legal requirements:

Product:	Contents of 'Volatile Organic Compounds' (VOC): 6,36%
Butanone:	REGULATION (EC) 273/2004 (Drug precursors): Category 3
	REGULATION (EC) 111/2005 (Trade with drug precursors): Category 3

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16. Other information

Hazard rating systems:



NFPA Hazard Rating:

Health: 1 (Slight)

Fire: 1 (Slight)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 1 (Slight)

Flammability: 1 (Slight)

Physical Hazard: 0 (Minimal)

Personal Protection: X = Consult your supervisor

HEALTH	1
FLAMMABILITY	1
PHYSICAL HAZARD	0
	X

Abbreviations and acronyms:

Acute Toxicity: Acute toxicity
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
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
EC: European Community
EEC: European Economic Community
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
LEL: Lower Explosion Limit
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
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
STOT SE: Specific target organ toxicity - single exposure
TLV: Threshold Limit Value
TRGS: Technical Rules for Hazardous Substances
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit
WHMIS: Workplace Hazardous Materials Information System

Reason of change: Changes in section 8: Occupational exposure limit values

Date of first version: 6/10/1994

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.