

Otto Bock® SAFETY DATA SHEET 617H21 - ORTHOCRYL Sealing Resin Material number 617H21

Date of print: 4/5/2006
Revision date: 6/18/2005
Date of first version: 9/4/1998

Page: 1 of 7

1. Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

Commercial Product name: 617H21 - ORTHOCRYL Sealing Resin

Use of the substance / preparation

Lamination Resin For orthopaedic procedures

information on manufacturer / supplier

Company's title: Otto Bock Health Care
Street/POB-No.: 2 Carlson Parkway North
Suite 100
State/city/postal code: USA Plymouth, MN 55447
World Wide Web: www.ottobockus.com
Email: shelly.stockman@ottobockus.com
Telephone: +1-763-553-9464
Telefax: +1-763-519-6153

Dept. responsible for information:

MSDS Department 9 am - 5 pm

Telephone: +1-763-553-9464

Number for emergency calls:

CHEMTREK

Telephone: +1-800-424-9300

2. Composition/information on ingredients

Chemical characterization (preparation)

Solution of acrylic polymers in methylmethacrylate, containing softener.

Dangerous constituents:

CAS-No.	EINECS/ELINCS	Chemical name	Content	Symbol(s)	R-phrases
80-62-6	201-297-1	Methyl methacrylate	60-100 %	F, Xi	11, 37/38, 43
38668-48-3	254-075-1	N,N-bis-(2-hydroxypropyl)-p-toluidine	0.1-1 %	T	25, 52/53
123-81-9	204-653-4	Ethylen-di(S-thioacetate)	0.1-1 %	Xn, N	22, 51/53

Customs tariff number: 3906 10 00

3. Hazard identification

Classification



F



Xi

Highly flammable Irritant

R 11

Highly flammable.

R 37/38

Irritating to respiratory system and skin.

R 43

May cause sensitization by skin contact.

Critical hazard to man and environment:

High concentrations of vapor or inhalation for an extended period may lead to paralysis of the central nervous system. Pulmonary edema is possible.



SAFETY DATA SHEET

617H21 - ORTHOCRYL Sealing Resin

Material number 617H21

Date of print: 4/5/2006
Revision date: 6/18/2005
Date of first version: 9/4/1998

Page:

2 of 7

4. First aid measures

- general information:** Take off immediately all contaminated clothing
Always seek medical assistance if symptoms develop that are possibly due to exposure through skin or eye contact or through inhalation of fumes.
- after inhalation:** Move victim to fresh air, loosen restrictive clothing and calm the victim. If breathing becomes irregular or ceases, apply mouth-to-mouth breathing or artificial ventilation immediately, where required administer oxygen. Seek medical attention.
- after skin contact:** After contact with skin, wash immediately with soap and plenty of water.
Seek medical attention if irritation persists.
- 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:** Do not induce vomiting. Seek medical attention immediately.
- Information to physician:** Monitor breathing.
Treat symptomatically.
If spray contacts eyes, immediately and thoroughly flush eyes with water; profitable is the application of isotonic eye rinse.
On irritation of the respiratory system use an aerosol dispenser and treat with 5 doses of dexamethasone aerosol (e.g. Auxiloson, Thomae) every 10 minutes until symptoms cease.
Estimated lethal dose: 30g

5. Fire fighting measures

- Suitable extinguishing media:** Foam, extinguishing powder, carbon dioxide
- Extinguishing agent unsuitable on safety grounds:** Water
- Particular protective equipment:** Wear a self-contained breathing apparatus and chemical resistant suit.
- Additional information:** Cool endangered containers with water spray and, as soon as possible, remove from danger zone.

6. Accidental release measures

- Personal precautions:** Provide adequate ventilation.
Wear suitable protective clothing.
Keep away from sources of ignition.
When vapors form, use respiratory protection.
- Environmental precautions:** Do not allow to enter ground water, sewage or drains.
- Methods for cleaning up / spillage removal:**
In case of greater quantities: Collect mechanically (use only explosion-proof equipment when pumping out).
Smaller amounts:
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.

7. Handling and storage

Handling

- Information for safe handling:**
Keep container tightly closed.
Provide adequate ventilation.



SAFETY DATA SHEET

617H21 - ORTHOCRYL Sealing Resin

Material number 617H21

Date of print: 4/5/2006
Revision date: 6/18/2005
Date of first version: 9/4/1998

Page: 3 of 7

Precautions against fire and explosion:

Keep away from sources of ignition. No smoking.
Take precautionary measures against static discharges.
In case of fire, cool endangered containers with water.
Flammable mixtures may form in the air when product is heated above the flash point and/or during spraying.
Only use explosion-proof equipment.

Storage

Requirements for storerooms and containers:

Keep only in the original container at temperature not exceeding 25 °C.
Protect from light.
Because oxygen (air) is necessary to stabilize product, fill container only to 90% of capacity.
Provide adequate oxygen (air) circulation for large containers to ensure product stability.

Information about storage in one common storage facility:

Do not store together with organic peroxides, ammonia or persulphates.

8. Exposure controls / personal protection

Critical values of exposure

CAS-No.	Chemical name	type	Value
80-62-6	Methyl methacrylate	TWA (= German AGW)	50 ml/m ³
		TWA (= German AGW)	210 mg/m ³
		OSHA/NIOSH/ACGIH-TWA	100 ppm
		OSHA/NIOSH/ACGIH-TWA	410 mg/m ³

Additional information:

National regulations Germany - Methyl methacrylate:
Limitation of exposure peaks - category I (Local irritants): Peak level 2 x MAK - Maximum duration per shift: 5 min., momentary value - Maximum frequency per shift: 8.
Pregnancy risk group C:
There is no reason to fear a risk of damage to the embryo or foetus when TLV values are observed.

limitation and monitoring of exposure

Do not inhale vapors.
Avoid contact with skin and eyes.
See also Information in chapter 7, section storage.

Limitation and monitoring of exposure at workplace.

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment.
For short exposures or in case of accident: Filter apparatus type A (= against vapors of organic substances).

Hand protection:

Protective gloves according to EN 374.
Glove material: butyl rubber - Breakthrough time ca. 300 min
The glove manufacturer's instructions must be observed concerning the penetrability and the wearing-out time.

eye protection:

Tightly sealed safety glasses according to EN 166.

Body protection:

When handling larger quantities: face protection, rubber boots and rubber apron.

General protection and hygiene measures:

Store work clothing separately.
Take off immediately all contaminated clothing
During handling chemical products the normal precautionary measures should be followed.

9. Physical and chemical properties

Appearance

Form: liquid
Colour: liquid
Odour: ester like

Safety relevant data

Important data concerning health- and environmental protection and safety thereto

Boiling temperature / boiling range: 100,5 (1013 hPa)
Flash point: 10 °C (DIN 51755 (MMA))
Ignition temperature: 430 °C (DIN 51794 (MMA))
Explosion limits: LEL (Lower Explosive Limit): 2.1 Vol% (Methylmethacrylat)
UEL (Upper Explosive Limit): 12.5 Vol% (Methylmethacrylat)
Vapour pressure: at 20 °C: 47 hPa
at 50 °C: 159 hPa
Density: at 20 °C: approx. 1 g/ml
Solubility in water: at 20 °C: (MMA) 16 g/l
viscosity, dynamic: at 20 °C: approx. 500 mPa.s

Additional information

Relative vapor density at 20°C = 68°F (air=1): >1

10. Stability and reactivity

Materials to avoid: Watch for exothermic reactions with peroxides. Polymerization with heat production may occur when material contacts reducing agents and heavy metals.
Hazardous decomposition products: In case of fire may form: Carbon monoxide and carbon dioxide
Polymerization: Polymerization with heat production may occur when material contacts reducing agents, peroxides and heavy metals.
Additional information: stable
Product is normally delivered in a stable state. However, if shelf life and/or recommended storage temperature are exceeded, product may polymerize.

11. Toxicological information

Toxicological Tests:

Acute toxicity: LD50 rat, oral: Methyl methacrylate >= 5000 mg/kg
LD50 rabbit, dermal: Methyl methacrylate >= 5000 mg/kg
LC50 rat, inhalant: Methyl methacrylate 29.8 mg/l
after inhalation: irritant
after skin contact: irritant
May cause sensitization by skin contact.



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617H21 - ORTHOCRYL Sealing Resin

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Page:

5 of 7

general remarks

Sensitization: Sensitivity testing among guinea pigs with and without adjuvants afforded both positive and negative results.

Varying incidences of allergic reactions have been observed in humans. (Symptoms: Headache, eye irritations, skin problems)

Mutagenicity: not a mutagen (Dose 10000 µg/plate (Salmonella typhimurium, Ames-Test) mouse, Lymphoma L 5178 Y TK+/-cells: mutagen

CHO-cells: Slight increase of the SCE (SCE-test)

No increase of the number of micronucleides under the following test conditions:

OECD 474: 4520 mg/kg/Dose 1 - 1130 mg/kg/Dose 4

CD-1 mouse, male, 6h/d, 5d: not a mutagen (Dominant lethal Test)

The product is not a carcinogen, genetic altering or reproductive hazard in laboratory animals. (Teratogenicity:

rat, inhalant: 2028 ppm, 6 - 15 d)

Chronic toxicity:

rat, inhalant 250 - 1000 ppm (6h/d, 5d/w) exceeding 2a). Symptoms: Damage of the mucous membranes in nose, throat and lungs. Degeneration of the olfactory epithelia.

mouse, inhalant 500 - 1000 ppm (6h/d, 5d/w) exceeding 2a). Symptoms: Damage of the mucous membranes in nose, throat and lungs. Degeneration of the olfactory epithelia.

The following information pertains to the component N,N-Bis-(2-hydroxypropyl)-p-toluidine:
LD50 rat, oral: 172 mg/kg

12. Ecological information

details of elimination

Further details: Product is easily biodegradable. (OECD 301 C, 14d: 94%)

Ecotoxicological effects

Aquatic toxicity: The following information pertains to the component Methyl methacrylate:

Algae toxicity:

EC3 Scenedesmus quadricauda: 37mg/l, 8d (DIN 38412 T.9)

Bacterial toxicity:

EC0 Pseudomonas putida: 100 mg/l

Daphnia toxicity:

EC50 Daphnia magna: 69mg/l, 48h (OECD 202/ISO 6341/EEC 84/449/V, C2)

Fish toxicity:

LC50 Oncorhynchus mykiss >79 mg/l/96h (OECD 203/ISO 7346/EEC 84/449/V, C1)

NOEC Oncorhynchus mykiss >40 mg/l/96h (OECD 203/ISO 7346/EEC 84/449/V, C1)

Additional ecological information

general information: Do not allow to enter ground soil, sewage or drains.

13. Disposal considerations

Product

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

Contaminated packaging

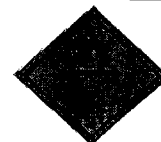
Recommendation: Dispose of waste according to applicable local, state, and federal regulations. Handle contaminated packaging in the same way as the substance itself.
Cleaned containers may be recycled.

14. Transport information

Overland transport

Warning board:
Description of goods:

ADR/RID: Kemmler-number 33, Substance number 1866
UN 1866, Resins in solution
flammable (with a point of ignition below 23 °C and viscous
according to 2.2.3.1.4)
(Vapor pressure: 50°C ≤110 kPa)



ADR/RID	Class 3, Code: F1
Packaging group	III
Label	3
Special provisions	640 H
Limited quantities	LQ7
Contaminated packaging: Instructions	P001 - IBC02 - LP01 - R001
Contaminated packaging: Special provisions	PP1
Special provisions for packing together	MP19
Portable Tanks: Instructions	T2
Portable Tanks: Special provisions	TP1
Tank coding	LGBF

Transport by sea

UN number:	1866
Proper shipping name:	Resin solution flammable
IMDG:	Class 3
Packing Group:	III
EmS number:	F-E, S-E
Special provisions	223 - 944 - 955
Limited quantities	5 I
Contaminated packaging: Instructions	P001 - LP01
Contaminated packaging: Provisions	PP1
IBC: Instructions	IBC03
IBC: Provisions	-
Tank instructions: IMO	T1
Tank instructions: UN	T2
Tank instructions Provisions	TP1
Stowage and segregation	Category A.
Properties and observations	Miscibility with water depends upon the composition.

Air transport

UN/ID number:	1866
Proper shipping name:	Resin solution flammable
ICAO/IATA:	Class 3
Hazard	Flamm. liquid
Packing Group:	III
Passenger Ltd.Qty.:	Y309 - Maximum quantity: 10 L
Passenger:	309 - Maximum quantity: 60 L
Cargo:	310 - Maximum quantity: 220 L
ERG	3L

15. Regulatory information

Classification

Code letter and hazard symbol:

	F	Highly flammable
	Xi	Irritant
R phrase(s):	R 11	Highly flammable.
	R 37/38	Irritating to respiratory system and skin.
	R 43	May cause sensitization by skin contact.
S phrase(s):	S (2)	Keep out of reach of children.
	S 16	Keep away from sources of ignition. No smoking.
	S 24	Avoid contact with skin.
	S 37	Wear suitable gloves.

National regulations

National regulations USA



NFPA Hazard Rating:

- Health = 1 (Slight)
- Fire = 3 (Serious)
- Reactivity = 2 (Moderate)

16. Other information

Further remarks

R phrase(s):	R 11 = Highly flammable.
	R 22 = Harmful if swallowed.
	R 25 = Toxic if swallowed.
	R 37/38 = Irritating to respiratory system and skin.
	R 43 = May cause sensitization by skin contact.
	R 51/53 = Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.
	R 52/53 = Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Reason of change:	Changes in section 14: ADR/RID2003 + ADNR 640G --> 640H, IMDG 2004 General revision

Group that issues data sheet

Contact person: see chapter 1, department responsible for information.

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.