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DEGAPLAST® laminating resin C

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

DEGAPLAST® laminating resin C

preparation

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

Recommended use(s): laminating resin for orthopedic technology

Non-recommended use(s): None known.

1.3. Details of the supplier of the safety data sheet

Schein Orthopädie Service KG Hildegardstr. 5 42897 Remscheid Germany +49 2191 910-0 E-Mail: remscheid@schein.de

1.4. Emergency telephone number

+49 6151 18 43 42 (international) Interpreting service available

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

This mixture is classified as hazardous according to GHS

GHS-Classification As per UN-GHS

Flammable liquids	Hazard category 2	H225
Caustic burning / irritation of skin	Hazard category 2 A	H315
Skin Sensitisation	Hazard category 1 B	H317
Specific Target Organ Toxicity - Single exposure	Hazard category 3	H335
Hazardous to the aquatic environment - AcuteHazard	Hazard category 3	H402

2.2. Label elements As per UN-GHS

GHS-Labelling

Signal word	
GHS pictogram	



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hazard statement	Highly flammable liquid and vapour. (H225) Causes skin irritation. (H315) May cause an allergic skin reaction. (H317) May cause respiratory irritation. (H335) Harmful to aquatic life. (H402)	
Safety notice (general)	Wear protective gloves/protective clothing/eye protection. (P280)	
Precautionary Statement (Prevention)	Avoid release to the environment. (P273)	
Precautionary Statement (Response)	 Call a POISON CENTER/doctor if you feel unwell. (P312) IF INHALED: Remove person to fresh air and keep comfortable for breathing. (P304 + P340) IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. (P303 + P361 + P353) 	
Precautionary Statement (Disposal)	Dispose of contents/container in accordance with local regulation. (P501)	
Hazardous component(s) for labelling	contains methyl methacrylate	

2.3. Other hazards

electrostatic charge

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

3.2. Mixtures

Hazardous Ingredients As per UN-GHS

'Component	CAS-No.	Content	Hazard dass / Hazard category / Hazard statement
triethyleneglycol dimethacrylate	109-16-0	1.0 - 5.0 %	Aquatic Acute 3 ; H402
methyl methacrylate	80-62-6	40.0 - 70.0 %	Flam. Liq. 2 ; H225 Skin Irrit. 2 ; H315 Skin Sens. 1 ; H317 STOT SE 3 (inhalation); H335 Aquatic Acute 3 ; H402
N,N-bis-(2-hydroxypropyl)-p- toluidine	38668-48-3	0.1 - 1.0 %	Acute Tox. 2 (oral); H300 Eye Irrit. 2A ; H319 Aquatic Chronic 3 ; H412

4. FIRST AID MEASURES

4.1. Description of first aid measures

General advice

Medical treatment is necessary if symptoms occur which are obviously caused by skin or eye contact with the product or by inhalation of its vapours. Take off all contaminated clothing immediately.

Inhalation

Move subject to fresh air and keep him calm. See a physician.

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Skin contact	Wash off immediately with soap and water. If skin irritation occurs consult a physician.
Eye contact	Flush eyes thoroughly with a large amount of water and consult a physician.
Ingestion	Do not induce vomiting. Consult a physician immediately.

4.2. Most important symptoms and effects, both acute and delayed

Skin Sensitisation, Skin irritation, Excessive or prolonged exposure can cause the following:, Headache, confusion

4.3. Indication of any immediate medical attention and special treatment needed

no

5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media foam, dry chemical, carbon dioxide

Extinguishing media which must not water be used for safety reasons

5.2. Special hazards arising from the substance or mixture

May be released in case of fire: carbon monoxide, carbon dioxide, organic products of decomposition.

5.3. Advice for firefighters

Wear self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Assure sufficient ventilation. Keep away sources of ignition. Use personal protective clothing. Use breathing apparatus if exposed to vapours/dust/mist/aerosol.

6.2. Environmental precautions

Prevent product from getting into drains/surface water/groundwater.

6.3. Methods and material for containment and cleaning up

Larger quantities: Remove mechanically (by pumping). Use explosion-proof equipment! Smaller quantities and/or residues: Contain with absorbent material (e.g. sand, diatomaceous earth, acid absorbent, universal absorbent or sawdust). Dispose of in accordance with regulations.

6.4. Reference to other sections

For personal protection see section 8.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling advice	Ensure there is good room ventilation. Keep container tightly closed.
Advice on protection against fire and explosion	Keep away from sources of ignition No smoking. Take precautionary measures against static discharges. In the event of fire, cool the endangered containers with water. When heated above the flash point and/or during spraying (atomizing), ignitible mixtures may form in air. Use only explosion-proof equipment.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage areas and	Keep only in the original container at a temperature not exceeding 25 °C. Protect
containers	from the action of light. Fill the container by approximately 90 % only as oxygen
	(air) is required for stabilisation. With large storage containers make sure the
	oxygen (air) supply is sufficient to ensure stability.

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7.3. Specific end use(s)

no

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

see section 8.2.

8.2. Exposure controls

For monitoring procedures refer for instance to "Empfohlene Analysenverfahren für Arbeitsplatzmessungen", Schriftenreihe der Bundesanstalt für Arbeitsschutz and "NIOSH Manual of Analytical Methods", National Institute for Occupational Safety and Health

Protective measures	Do not breathe vapours. Avoid contact with eyes and skin.
Hygiene measures	Store work clothing separately. Take off all contaminated clothing immediately. Follow the usual good standards of occupational hygiene. Clean skin thoroughly after work; apply skin cream.
Respiratory protection	Breathing apparatus in case of high concentrations
Hand protection	butyl rubber gloves (0.7 mm), Break through time ca. 60 min (EN 374) In practice, due to variable exposure conditions, this information can only be an aid to orientation for the selection of a suitable chemical protection glove. In particular, this information does not substitute suitability tests by the end user.
General information	Gloves should be replaced regularly, especially after extended contact with the product. For each work-place a suitable glove type has to be selected.
Eye protection	tightly fitting goggles
Skin and body protection	On handling of larger quantities: face mask, chemical-resistant boots and apron

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Form Colour Odour	liquid colourless ester-like
Freezing Temperature	notavailable
Boiling Temperature	100.5 °C(methyl methacrylate)
Flash point	10 °C (methyl methacrylate)
Ignition temperature	430 °C (methyl methacrylate)
Lower explosion limit	2.1 %(V) (methyl methacrylate)
Upper explosion limit	12.5 %(V) (methyl methacrylate)
Vapour pressure	38.7 hPa (20 °C) (methyl methacrylate)
Density	ca. 1 g/cm3 (20 °C)
Relative vapour density (related to air)	> 1 (20 °C)
Solubility in water	ca. 16 g/l (methyl methacrylate)
рН	not applicable
Viscosity (dynamic)	ca. 400 mPa⋅s
9.2. Other information	

none

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10. STABILITY AND REACTIVITY

10.1. Reactivity

see section 10.2.

10.2. Chemical stability

No decomposition if used as directed.

10.3. Possibility of hazardous reactions

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

10.4. Conditions to avoid

Heat and ignition sources, aging, contamination, oxygen free atmosphere.

10.5. Incompatible materials

Peroxides, amines, sulfur compounds, heavy metal ions, alkalis, reducing agents and oxidizing agents.

10.6. Hazardous decomposition products

None when used as directed.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

LD50 rat, OECD 401, Related to substance: methyl methacrylate LD50 rat, Related to substance: N,N-bis-(2-hydroxypropyl)-p- toluidine	> 5,000 mg/kg 25 - 200 mg/kg
LC50 rat, Related to substance: methyl methacrylate, Low toxicity by inhalation	29.8 mg/l
LD50 rabbit, Related to substance: methyl methacrylate, Practically non-toxic in contact with skin	> 5,000 mg/kg
Contact with skin may cause irritations.Related to substance: product	
Contact with the eyes may cause irritation.Related to substance: product	
In sensitization tests on guinea pigs with and without adjuvant, both positive and negative results were found. In humans various types of allergic reactions have been observed (symptoms: headache, eye irritations, skin affections). Related to substance: methyl methacrylate	
not applicable	
Positive as well as negative results in <i>in vitro</i> mutagenicity/ genotoxicity tests. No experimental indication of genotoxicity <i>in vivo</i> available. In summary not mutagenic according to internationally accepted criteria. Related to substance: methyl methacrylate	
Non-carcinogenic in inhalation and feeding studies carried out on radogs.	ts, mice and
Related to substance: methyl methacrylate	
No indications of toxic effects were observed in reproduction studies	in animals.
	LD50 rat, Related to substance: N,N-bis-(2-hydroxypropyl)-p- toluidine LC50 rat, Related to substance: methyl methacrylate, Low toxicity by inhalation LD50 rabbit, Related to substance: methyl methacrylate, Practically non-toxic in contact with skin Contact with skin may cause irritations.Related to substance: product Contact with the eyes may cause irritation.Related to substance: product In sensitization tests on guinea pigs with and without adjuvant, both positive and negative results were found. In humans various types of allergic reactions have been observed (symptoms: headache, eye irritations, skin affections). Related to substance: methyl methacrylate not applicable Positive as well as negative results in <i>in vitro</i> mutagenicity/ genotoxi No experimental indication of genotoxicity <i>in vivo</i> available. In summary not mutagenic according to internationally accepted crit Related to substance: methyl methacrylate Non-carcinogenic in inhalation and feeding studies carried out on ra dogs. Related to substance: methyl methacrylate

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	Related to substance: methyl methacrylate	
Human health hazard assessment	CMR: no	
Genotoxicity in vitro	salmonella typhimurium +/-not mutagenic (Ames-test) mouse lymphoma L 5178 Y TK+/- cells +/-mutagenic	
Toxicity on Repeated Administration	rat, inhalation, 2 Years Findings: Damage to mucous membranes in the nose at 400 ppm Related to substance: methyl methacrylate rat, in drinking water, 2 Years Findings: no toxic effects Related to substance: methyl methacrylate	
General information	Avoid contact with the skin and eyes and inhalation of the product vap	ours.
12. ECOLOGICAL INFORMATION		
12.1. Toxicity		
Aquatoxicity, fish	LC50 Oncorhynchus mykiss, rainbow trout, OECD 203, flow through, GLP, 96 h Related to substance: methyl methacrylate	> 79 mg/l
Aquatoxicity, in vertebrates	EC50 Daphnia magna, OECD 202, flow through, 48 h	69 mg/l
	Related to substance: methyl methacrylate NOEC Daphnia magna, OECD 202 part 2, flow through, 21 d Related to substance: methyl methacrylate	37 mg/l
Aquatoxicity, algae / aquatic plants	EC3 Scenedesmus quadricauda, DIN 38412 section 9, 8 d Related to substance: methyl methacrylate	37 mg/l
Toxicity in microorganisms	EC0 Pseudomonas putida Related to substance: methyl methacrylate	100 mg/l
12.2. Persistence and degradability	,	
Biodegradability	readily biodegradable, OECD 301 C, 14 d Related to substance: methyl methacrylate	94 %
12.3. Bioaccumulative potential		
Bioaccumulation	no specific test data available no evidence for hazardous properties (structure-activity-relationships) (analogy)	
12.4. Mobility in soil		
Mobility	no specific test data available	
12.5. Results of PBT and vPvB asse	essment	
PBT and vPvB assessment	PBT: no vPvB: no	
12.6. Other adverse effects		
General Information	Prevent substance from entering soil, natural bodies of water and sew	ersystems.

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13. DISPOSAL CONSIDERATIONS

13.1. Waste	treatment methods
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Product	Waste is hazardous. It must be disposed of in accordance with the regulations after consultation of the competent local authorities and the disposal company in a suitable and licensed facility.
Uncleaned packaging	Contaminated packaging should ideally be emptied; it can then be recycled after having been decontaminated. Packaging that cannot be cleaned should be disposed of professionally. Uncontaminated packaging may be taken for recycling.
14. TRANSPORT INFORMATION	

14.1. UN number

see section 14.2.

14.2. UN proper shipping name

Land transport ADR/GGVSEB	
UN 1866 RESIN SOLUTION, 3, II, (D/E)	
Hazard no. 33	6

Land transport RID/GGVSEB UN 1866 RESIN SOLUTION, 3, II Hazard no. 33

Inland waterway transport ADN/GGVSEB (Germany)

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UN 1866 RESIN SOLUTION, 3, II

Shipment by sea IMDG/GGVSee	
UN number	1866
Class	3
FmS	F-E. S-E
Marine pollutant	No
Packaging group	
Proper Shipping Name	" RESIN SOLUTION
Proper Shipping Name	RESIN SOLUTION
Air transport ICAO/IATA	
UN number	1866
Class	3
Packaging group	II.
Proper Shipping Name	RESIN SOLUTION
	REGIN GOLD HOR
Remarks	
	0
ADR	Special provision 640

ADR	Special provision 640D
RID	Special provision 640D
ADNR	Special provision 640D

14.3. Transport hazard class(es)

see section 14.2.

14.4. Packing group

see section 14.2.

14.5. Environmental hazards

if not mentioned in Point 14.2 then it does not apply

14.6. Special precautions for user

see section 14.2.

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

for transportapproval see regulatory information 14.8. Transport/Additional information If Component Degaplast laminating resin C and Component Degaplast hardening powder are delivered together UN-number 3269 (polyester resin kit) is applicable! **15. REGULATORY INFORMATION**

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Classification as per Directive 67/548/EC or Directive 1999/45/EC

Labelling in accordance with directive 1999/45/EC	requires labelling		
Hazardous component(s) for labelling	contains	methyl methacrylate	
hazard symbol(s)	F Xi	Highly flammable Irritant	
R-phrase(s)	11 37/38 43	Highly flammable. Irritating to respiratory system and skin. May cause sensitisation by skin contact.	

National legislation

Occupational restrictions

Note for juveniles. Note for pregnant woman and nursing mothers (EC Directive

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	92/85/EEC).		
Status of Registration	REACH (EU) TSCA (USA) DSL (CDN) ECL (KOR) PICCS (RP) IECSC (CN) ECS (Taiwan)	preregistered, registered or exempted listed or exempted	
16. OTHER INFORMATION			
Other information		Ily supplied in a stabilized form. If the permissible storage temperature is exceeded, the product may polymerize to be a stabilized to be a stabilized for the product may polymer may polymerized to be a stabilized for the product may polymer may	
Relevant H phrases from chapter 3	triethyleneglycol dimethacrylate H402 Hamful to aquatic life. methyl methacrylate H225 Highly flammable liquid and vapour. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H335 May cause respiratory irritation. H402 Hamful to aquatic life. N,N-bis-(2-hydroxypropyl)-p-toluidine H300 Fatal if swallowed. H319 Causes serious eye irritation. H412 Hamful to aquatic life with long lasting effects.		
References		publications ecotoxicological studies oxicological studies of other manufacturers	

Places marked by **||** have been amended from the last version.

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