in accordance with regulation (EC) 1907/2006

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

#### 1.1. Product identifier

# DEGAPLAST® Siegelharz (Gebinde < 30 L)

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

Tel.:+49 2191 910-0 Fax: +49 2191 910-100 remscheid@schein.de

www.schein.de

## 1.4. Emergency telephone number

+49 6151 18 43 42

# 2. HAZARDS IDENTIFICATION

#### 2.1. Classification of the substance or mixture

This mixture is classified as hazardous according to CLP/GHS

# Regulation (EC) No 1272/2008

Flammable liquids	Hazard category 2	H225
Caustic burning / irritation of skin	Hazard category 2	H315
Skin Sensitisation	Hazard category 1 B	H317
Specific Target Organ Toxicity -	Hazard category 3	H335

Single exposure

# Classification according to EU Directives 67/548/EEC or 1999/45/EC

Highly flammable.

Irritating to respiratory system and skin. May cause sensitisation by skin contact.

# 2.2. Label elements

# Regulation (EC) No 1272/2008

Signal word Danger

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GHS pictogram





hazard statement Highly flammable liquid and vapour. (H225)

Causes skin irritation. (H315)

May cause an allergic skin reaction. (H317) May cause respiratory irritation. (H335)

Safety notice (general) Wear protective gloves/protective clothing/eye protection. (P280)

Precautionary Statement (Response) IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin

with water/shower. (P303 + P361 + P353)

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

(P304 + P340)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. (P305 + P351 + P338) Call a POISON CENTER or doctor/ physician if you feel unwell. (P312)

Precautionary Statement (Disposal) Dispose of contents/container in accordance with local regulation. (P501)

Further Information Nota D

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.

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# 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1. Substances

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#### 3.2. Mixtures

## Regulation (EC) No 1272/2008

'Component	EINECS-No. REACH-No. CAS-No.	Content	Hazard cass / Hazard category / Hazard statement
methyl methacrylate	201-297-1 01-2119452498-28 80-62-6	60.0 - 100.0 %	Flam. Liq. 2; H225 Skin Irrit. 2; H315 Skin Sens. 1B; H317 STOT SE 3; H335
N,N-bis-(2-hydroxypropyl)-p- toluidine	254-075-1 01-2119980937-17 38668-48-3	0.1 - 1.0 %	Acute Tox. 2 (oral); H300 Eye Irrit. 2; H319 Aquatic Chronic 3; H412
tris (nonylphenyl) phosphite	247-759-6 - 26523-78-4	0.1 - 1.0 %	Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410

# Hazardous Ingredients as per Directive 67/548/EC or Directive 1999/45/EC

,				
Component	CAS Number	Hazard sym	bol(s) / R-phrase(s)	Content
methyl methacrylate	80-62-6	F,Xi	11-37/38-43	60.0 - 100.0 %
N,N-bis-(2-hydroxypropyl)-p-toluidine	38668-48-3	T	25-52/53-R36	0.1 - 1.0 %
tris (nonylphenyl) phosphite	26523-78-4	Xi, N	43-50/53	0.1 - 1.0 %

# 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.

Skin contact Wash off immediately with soap and water. If skin irritation occurs consult a

physician.

Eye contact Keeping the eyelids apart flush thoroughly with water immediately. If irritation

persists, contact a physician.

Ingestion Do not induce vomiting. Call a physician immediately.

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

Skin Sensitisation, Causes skin and eye 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

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Suitable extinguishing media foam, dry chemical, carbon dioxide

Extinguishing media which must not

be used for safety reasons

high volume water jet

# 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 Provide good room ventilation even at ground level (vapours are heavier than air).

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. Vapours are heavier than air and can form an explosive mixture with air. Use only explosion-proof equipment.

# 7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage areas and

containers

Keep only in the original container at a temperature not exceeding 25 °C. Protect 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.

## 7.3. Specific end use(s)

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no

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1. Control parameters

Components or products of decomposition according to point 10, with limit values related to the place of work which require monitoring

methyl methacrylate 80-62-6

 WEL (long-term) 2011
 208 mg/m3
 50 ppm

 WEL (short-term) 2011
 416 mg/m3
 100 ppm

 Indicative occupational exposure limit value
 50 ppm

2009/161/EC 2009

Indicative occupational exposure limit value 100 ppm

2009/161/EC (15 minutes) 2009

8.2. Exposure controls

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. After work-time and during work intervals the affected skin areas must be thoroughly cleaned.

Respiratory protection Breathing apparatus in case of high concentrations, short term: filter appliance,

filter A

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 liquid
Colour colourless
Odour ester-like

Freezing Temperature not available

Boiling Temperature ca.100 °C (1,013 hPa)

Flash point 10 °C (methyl methacrylate)

Ignition temperature 430 °C (methyl methacrylate)

Lower explosion limit 2.1 %(V) at 10,5°C(methyl methacrylate)

Upper explosion limit 12.5 %(V) (methyl methacrylate)

Vapour pressure ca. 40 hPa (20 °C)
Density ca. 1 g/cm3 (20 °C)

Relative vapour density (related to

air)

> 1 (20 °C)

Solubility in water ca. 16 g/l (20 °C)
Fat solubility not available
pH not applicable

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25 - 200

mg/kg

n-Octanol/water partition coefficient not available

Viscosity (dynamic) ca. 500 mPa·s

9.2. Other information

none

## 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

Acute Oral Toxicity LD50 rat, OECD 401, Related to substance: methyl methacrylate > 5,000 mg/kg

LD50 rat, Related to substance: N,N-bis-(2-hydroxypropyl)-p-

toluidine

Acute Inhalational Toxicity LC50 rat, Related to substance: methyl methacrylate, Low toxicity 29.8 mg/l

by inhalation

Acute Dermal Toxicity LD50 rabbit, Related to substance: methyl methacrylate, > 5,000 mg/kg

Practically non-toxic in contact with skin

Caustic burning / irritation of skin Contact with skin may cause irritations. Related to substance:

product

Serious eye damage/eye irritation Contact with the eyes may cause irritation. Related to substance:

product

Respiratory/skin sensitization 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

Aspiration hazard not applicable

Mutagenicity assessment Positive as well as negative results in *in vitro* mutagenicity/ genotoxicity tests.

No experimental indication of genotoxicity in vivo available.

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37 mg/l

94 %

In summary not mutagenic according to internationally accepted criteria.

Related to substance: methyl methacrylate

Carcinogenicity Non-carcinogenic in inhalation and feeding studies carried out on rats, mice and

dogs.

Related to substance: methyl methacrylate

Reprotoxicity / teratogenicity No indications of toxic effects were observed in reproduction studies in animals.

Related to substance: methyl methacrylate

Human health hazard assessment CMR: no

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 vapours.

## 12. ECOLOGICAL INFORMATION

## 12.1. Toxicity

Aquatoxicity, fish LC50 Oncorhynchus mykiss, rainbow trout, OECD 203, flow > 79 mg/l

through, GLP, 96 h

Related to substance: methyl methacrylate

Aquatoxicity, invertebrates 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 37 mg/l

Related to substance: methyl methacrylate

Related to substance: methyl methacrylate

Toxicity in microorganisms EC0 Pseudomonas putida 100 mg/l

Related to substance: methyl methacrylate

12.2. Persistence and degradability

Biodegradability readily biodegradable, OECD 301 C, 14 d

Related to substance: methyl methacrylate

## 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 assessment

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 sewer systems.

in accordance with regulation (EC) 1907/2006

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# 13. DISPOSAL CONSIDERATIONS

#### 13.1. Waste treatment methods

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.

Code of waste EWC 07 02 08

waste from the manufacture, formulation, supply and use (MFSU) of plastics, synthetic rubber and man-made fibres - other still bottoms and reaction residues

Always check the given waste codes according to the actual conditions of

manufacturing, formulation or use in your facilities.

## 14. TRANSPORT INFORMATION

#### 14.1. UN number

see section 14.2.

## 14.2. UN proper shipping name

Transport on land ADR/GGVSEB UN 1866 RESIN SOLUTION, 3, III, (E)

Transport on land RID/GGVSEB UN 1866 RESIN SOLUTION, 3, III

Inland waterway transport ADN/GGVSEB (Germany)

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# UN 1866 RESIN SOLUTION, 3, III

Shipment by sea IMDG/GGVSee

UN number 1866
Class 3
EmS F-E, S-E
Marine pollutant No
Packaging group III

Proper Shipping Name RESIN SOLUTION

Air transport ICAO/IATA

UN number 1866 Class 3 Packaging group III

Proper Shipping Name RESIN SOLUTION

Remarks

ADR
ADNR
Classification according to 2.2.3.1.4 ADR
Classification according to 2.2.3.1.4 ADN
RID
Classification according to 2.2.3.1.4 RID

IMDG Transport in accordance with 2.3.2.2 of the IMDG-Code (Receptables <= 30L

capacity).

IATA\_C

According to classification criteria 3.3.3.1 IATA-DGR
The capacity of the packaging used does not exceed 30 L

IATA\_P

According to classification criteria 3.3.3.1 IATA-DGR
The capacity of the packaging used does not exceed 30 L

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

#### 15. REGULATORY INFORMATION

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

# National legislation

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

92/85/EEC).

Chemical safety assessment No chemical safety assessment was carried out for this product.

Status of Registration

REACH (EU) preregistered, registered or exempted

TSCA (USA) listed or exempted DSL (CDN) listed or exempted ECL (KOR) listed or exempted

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PICCS (RP)	listed or exempted
IECSC (CN)	listed or exempted
ECS (Taiwan)	listed or exempted

## **16. OTHER INFORMATION**

Other information The product is normally supplied in a stabilized form. If the permissible storage

period and/or storage temperature is exceeded, the product may polymerize with

heat evolution.

Relevant H phrases from chapter 3 methyl methacrylate

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H335 May cause respiratory irritation.

N,N-bis-(2-hydroxypropyl)-p-toluidine H300 Fatal if swallowed.

H319 Causes serious eye irritation.

H412 Harmful to aquatic life with long lasting effects.

R-phrases of relevance from chapter

3

11 Highly flammable.25 Toxic if swallowed.

37/38 Irritating to respiratory system and skin.
43 May cause sensitisation by skin contact.

50/53 Very toxic to aquatic organisms, may cause long-term adverse

effects in the aquatic environment.

52/53 Hamful to aquatic organisms, may cause long-term adverse effects

in the aquatic environment.

R36 Irritating to eyes.

References relevant manuals and publications

own examinations

own toxicological and ecotoxicological studies

toxicological and ecotoxicological studies of other manufacturers

SIAR OECD-SIDS RTK public files

Places marked by have been amended from the last version.

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