

Safety data sheet

Härter für Orthopur-Hartschaum Komp. B

Uniprox Safety data sheet in accordance to REACH 1907/2006/EC, Art. 31

Product: Härter für Orthopur Hartschaum Komp. B

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1. Substance/preparation and company identification

Trade name: Orthopur-Hartschaum Komp. B (MG104)

Application of the substance/ the preparation: Resin for orthopaedic technology

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2. Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008

Acute Tox. 4	H332	Harmful if inhaled.
Skin Irrit. 2	H315	Causes skin irritation.
Eye Irrit. 2	H319	Causes serious eye irritation.
Resp. Sens. 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sens. 1	H317	May cause an allergic skin reaction.
Carc. 2	H351	Suspected of causing cancer.
STOT SE 3	H335	May cause respiratory irritation.
STOT RE 2	H373	May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms



Signal Word Danger

Hazard-determining components of labelling:

diphenylmethanediisocyanate, isomers and homologues

Hazard statements

- H332 Harmful if inhaled.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317 May cause an allergic skin reaction.

- H351 Suspected of causing cancer.
H335 May cause respiratory irritation.
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P284 [In case of inadequate ventilation] wear respiratory protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information:

Contains isocyanates. May produce an allergic reaction.

2.3 Other hazards**Results of PBT and vPvB assessment**

PBT: Not applicable.

vPvB: Not applicable.

3. Composition/information on ingredients**3.2 Chemical characterisation: Mixtures**

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

CAS: 9016-87-9	diphenylmethanediisocyanate, isomers and homologues
Polymer	Resp. Sens. 1, H334; Carc. 2, H351; STOT RE 2, H373; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335
	>50–≤100%

Additional information: For the wording of the listed hazard phrases refer to section 16.

4. First aid measures**4.1 Description of first aid measures****General information:**

Immediately remove any clothing soiled by the product.
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

After skin contact: Immediately wash with water and soap and rinse thoroughly.

After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing: If symptoms persist consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5. Firefighting measures**5.1 Extinguishing media****Suitable extinguishing agents:**

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.

For safety reasons unsuitable extinguishing agents: Water with full jet

5.2 Special hazards arising from the substance or mixture

During heating or in case of fire poisonous gases are produced.

5.3 Advice for firefighters**Protective equipment:**

Mouth respiratory protective device.

Do not inhale explosion gases or combustion gases.

6. Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Mount respiratory protective device.

6.2 Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7. Handling and storage**7.1 Precautions for safe handling**

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Prevent formation of aerosols.

Information about fire - and explosion protection: Keep respiratory protective device available.

7.2 Conditions for safe storage, including any incompatibilities Storage:

Requirements to be met by storerooms and receptacles: No special requirements.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: Keep container tightly sealed.

7.3 Specific end use(s) No further relevant information available.

8. Exposure controls/personal protection

Additional information about design of technical facilities: No further data; see item 7.

8.1 Control parameters**Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls**Personal protective equipment:****General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Avoid contact with the eyes and skin.

Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or

longer exposure use self-contained respiratory protective device.

Protection of hands:

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and The degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

Tightly sealed goggles

9. Physical and chemical properties**9.1 Information on basic physical and chemical properties****General Information****Appearance:**

Form: Fluid

Colour: Dark brown

Odour: Characteristic

Odour threshold: Not determined.

pH-value: Not determined.

Change in condition

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: >100 °C

Flash point: >150 °C

Flammability (solid, gas): Not applicable.

Ignition temperature: >200 °C

Decomposition temperature: Not determined.

Auto-ignition temperature: Product is not selfigniting.

Explosive properties: Product does not present an explosion hazard.

Explosion limits:

Lower: Not determined.

Upper: Not determined.

Vapour pressure at 25 °C: 0 hPa

Density at 20 °C: ~1.23 g/cm³

see product data sheet

Relative density not determined

Vapour density Not determined.

Evaporation rate Not determined.

Solubility in / Miscibility with

water: Fully miscible.

Partition coefficient: n-octanol/water: Not determined.

Viscosity:

Dynamic at 20 °C: ~200 mPas

Kinematic:	see product data sheet
9.2 Other information	Not determined. No further relevant information available.

10. Stability and reactivity**10.1 Reactivity** No further relevant information available.**10.2 Chemical stability****Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions No dangerous reactions known.**10.4 Conditions to avoid** No further relevant information available.**10.5 Incompatible materials:** Ferrous metals, alloys and galvanized surfaces.**10.6 Hazardous decomposition products:** In the event of fire the following can be released:
CO_x, NO_x, SiO_x.

11. Toxicological information**11.1 Information on toxicological effects****Acute toxicity**

Harmful if inhaled.

LD / LC 50 values relevant for classification:**ATE (Acute Toxicity Estimates)**

Inhalative LC50/4 h 12.2 mg/l

9016-87-9 diphenylmethanediisocyanate, isomers and homologues

Oral LD50 >10,000 mg/kg (rat)

Dermal LD50 >9,400 mg/kg (rat)

Primary irritant effect:**Skin corrosion/irritation**

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**Germ cell mutagenicity** Based on available data, the classification criteria are not met.**Carcinogenicity**

Suspected of causing cancer.

Reproductive toxicity Based on available data, the classification criteria are not met.**STOT-single exposure**

May cause respiratory irritation.

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard Based on available data, the classification criteria are not met.

12. Ecological information**12.1 Toxicity****Aquatic toxicity:** No further relevant information available.**12.2 Persistence and degradability** No further relevant information available.**12.3 Bioaccumulative potential** No further relevant information available.**12.4 Mobility in soil** No further relevant information available.**Additional ecological information:****General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

13. Disposal considerations

13.1. Waste treatment methods

Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

European waste catalogue

HP4 Irritant - skin irritation and eye damage

HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

HP7 Carcinogenic

HP13 Sensitising

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

14. Transport information

14.1 UN-Number

ADR, IMDG, IATA not regulated

14.2 UN proper shipping name

ADR, IMDG, IATA not regulated

14.3 Transport hazard class(es)

ADR, IMDG, IATA

Class

not regulated

14.4 Packing group

ADR, IMDG, IATA

not regulated

14.5 Environmental hazards:

Not applicable.

14.6 Special precautions for user

Not applicable.

14.7 Transport in bulk according to Annex II of Marpol and the

IBC Code

Not applicable.

UN "Model Regulation":

not regulated

15. Regulatory information

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

Directive 2012/18/EU

Named dangerous substances - ANNEX I None of the ingredients is listed.

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

National regulations:

Other regulations, limitations and prohibitive regulations

Product does not contain any organic halogens.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16. Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases

- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H335 May cause respiratory irritation.
- H351 Suspected of causing cancer.
- H373 May cause damage to organs through prolonged or repeated exposure.

Further information

Take notice of the directions of use on the label.

Disclaimer

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