Revision date: 12/08/2022 Revision: 0.0 Supersedes date: 12/08/2022

SAFETY DATA SHEET

Powerresins Surgical Guide Resin

According to Regulation (EC) No 1907/2006, Annex II, as amended. Commission Regulation (EU) No 2015/830 of 28 May 2015.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name Powerresins Surgical Guide Resin

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

Identified uses Industrial use.

Uses advised against No specific uses advised against are identified.

1.3. Details of the supplier of the safety data sheet

Supplier 3BFAB TEKNOLOJÍ A.Ş.

Ihlamurkuyu Mah. Çanakkale Cad. Eren Plaza No: 5 Kat: 4 PK: 34771 Ümraniye / İstanbul / TURKEY

Tel: +90 216 612 00 94 www.3bfab.com

Contact person Gülgün Satıcı

1.4. Emergency telephone number

Emergency telephone PROMARKET: +90 216 612 00 94

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Not Classified

Health hazards Skin Sens. 1 - H317 Repr. 2 - H361f

Environmental hazards Aquatic Chronic 2 - H411

2.2. Label elements

Hazard pictograms





Signal word Warning

Hazard statements H317 May cause an allergic skin reaction.

H361f Suspected of damaging fertility.

H412 Harmful to aquatic life with long lasting effects

Precautionary statements P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P333+P313 If skin irritation or rash occurs: Get medical advice/ attention. P501 Dispose of contents/ container in accordance with national regulations.

Contains 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate,

diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

2.3. Other hazards

This product does not contain any substances classified as PBT or vPvB.

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

40-60%

CAS number: 72869-86-4

Classification

Skin Sens. 1B - H317 Aquatic Chronic 2 - H411

Esterification products of 4,4'-isopropylidenediphenol, ethoxylated

25-40%

and 2-methylprop-2-enoic acid

Classification

Aquatic Chronic 4 - H413

CAS number: 41637-38-1

diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

1-5%

Classification

Skin Sens. 1 - H317 Repr. 2 - H361f Aquatic Chronic 2 - H411

1-isopropyl-2,2-dimethyltrimethylene diisobutyrate

1-5%

CAS number: 6846-50-0 EC number: 229-934-9

Classification

Aquatic Chronic 3 - H412

The full text for all hazard statements is displayed in Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Get medical attention immediately. Show this Safety Data Sheet to the medical personnel.

Inhalation

Remove affected person from source of contamination. Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Maintain an open airway. Loosen tight clothing such as collar, tie or belt. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Place unconscious person on their side in the recovery position and ensure breathing can take place.

Ingestion

Rinse mouth thoroughly with water. Remove any dentures. Give a few small glasses of water or milk to drink. Stop if the affected person feels sick as vomiting may be dangerous. Do not induce vomiting unless under the direction of medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Never give anything by mouth to an unconscious person. Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Place unconscious person on their side in the recovery position and ensure breathing can take place. Maintain an open airway. Loosen tight clothing such as collar, tie or belt.

Skin contact

It is important to remove the substance from the skin immediately. In the event of any sensitisation symptoms developing, ensure further exposure is avoided. Remove contamination with soap and water or recognised skin cleansing agent. Get medical attention if symptoms are severe or persist after washing.

According to Regulation (EC) No 1907/2006, Annex II, as amended. Commission Regulation (EU) No 2015/830 of 28 May 2015.

Eye contact Rinse immediately with plenty of water. Remove any contact lenses and open eyelids wide apart.

Continue to rinse for at least 10 minutes.

Protection of first aiders First aid personnel should wear appropriate protective equipment during any rescue. Wash contaminated

clothing thoroughly with water before removing it from the affected person, or wear gloves.

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

General information See Section 11 for additional information on health hazards. The severity of the symptoms described will

vary dependent on the concentration and the length of exposure.

Inhalation Prolonged inhalation of high concentrations may damage respiratory system.

Ingestion May cause sensitisation or allergic reactions in sensitive individuals. Gastrointestinal symptoms, including

upset stomach. Fumes from the stomach contents may be inhaled, resulting in the same symptoms as

inhalation.

Skin contact May cause skin sensitisation or allergic reactions in sensitive individuals. Prolonged contact may cause

dryness of the skin.

Eye contact May cause temporary eye irritation.

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

Notes for the doctor

Treat symptomatically. May cause sensitisation or allergic reactions in sensitive individuals.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media The product is not flammable. Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water

fog. Use fire-extinguishing media suitable for the surrounding fire.

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards Containers can burst violently or explode when heated, due to excessive pressure build-up.

Hazardous combustion products Thermal decomposition or combustion products may include the following substances: Harmful gases or

vapours.

5.3. Advice for firefighters

Protective actions during firefighting

Avoid breathing fire gases or vapours. Evacuate area. Keep upwind to avoid inhalation of gases, vapours, fumes and smoke. Ventilate closed spaces before entering them. Cool containers exposed to heat with water spray and remove them from the fire area if it can be done without risk. Cool containers exposed to flames with water until well after the fire is out. If a leak or spill has not ignited, use water spray to disperse vapours and protect men stopping the leak. Avoid discharge to the aquatic environment. Control run-off water by containing and keeping it out of sewers and watercourses. If risk of water pollution occurs, notify appropriate authorities.

Special protective equipment for firefighters

Personal precautions

Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing. Firefighter's clothing conforming to European standard EN469 (including helmets, protective boots and gloves) will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

o. . . . ordonar production, protocare equipment and emergency process

No action shall be taken without appropriate training or involving any personal risk. Keep unnecessary and unprotected personnel away from the spillage. Wear protective clothing as described in Section 8 of this safety data sheet. Follow precautions for safe handling described in this safety data sheet. Wash thoroughly after dealing with a spillage. Ensure procedures and training for emergency decontamination and disposal are in place. Do not touch or walk into spilled material. Avoid contact with skin and eyes.

According to Regulation (EC) No 1907/2006, Annex II, as amended. Commission Regulation (EU) No 2015/830 of 28 May 2015.

6.2. Environmental precautions

Environmental precautions

Avoid discharge into drains or watercourses or onto the ground. Avoid discharge to the aquatic environment. Large Spillages: Inform the relevant authorities if environmental pollution occurs (sewers, waterways, soil or air).

6.3. Methods and material for containment and cleaning up

Methods for cleaning up

Wear protective clothing as described in Section 8 of this safety data sheet. Approach the spillage from upwind.

Small Spillages: If the product is soluble in water, dilute the spillage with water and mop it up. Alternatively, or if it is not water-soluble, absorb the spillage with an inert, dry material and place it in a suitable waste disposal container.

Large Spillages: If leakage cannot be stopped, evacuate area. Flush spilled material into an effluent treatment plant, or proceed as follows. Contain and absorb spillage with sand, earth or other non-combustible material. Place waste in labelled, sealed containers. Clean contaminated objects and areas thoroughly, observing environmental regulations. The contaminated absorbent may pose the same hazard as the spilled material. Flush contaminated area with plenty of water. Wash thoroughly after dealing with a spillage. Dangerous for the environment. Do not empty into drains. Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

6.4. Reference to other sections

Reference to other sections

For personal protection, see Section 8. See Section 11 for additional information on health hazards. See Section 12 for additional information on ecological hazards. For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions

Read and follow manufacturer's recommendations. Wear protective clothing as described in Section 8 of this safety data sheet. Keep away from food, drink and animal feeding stuffs. Handle all packages and containers carefully to minimise spills. Keep container tightly sealed when not in use. Avoid the formation of mists. Suspected of damaging fertility. Avoid discharge to the aquatic environment. Do not handle until all safety precautions have been read and understood. Do not handle broken packages without protective equipment. Do not reuse empty containers.

Advice on general occupational hygiene

Wash promptly if skin becomes contaminated. Take off contaminated clothing. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Wash at the end of each work shift and before eating, smoking and using the toilet. Change work clothing daily before leaving workplace.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions

Store away from incompatible materials (see Section 10). Store in accordance with local regulations. Keep only in the original container. Keep container tightly closed, in a cool, well ventilated place. Keep containers upright. Protect containers from damage. Bund storage facilities to prevent soil and water pollution in the event of spillage. The storage area floor should be leak-tight, jointless and not absorbent.

7.3. Specific end use(s)

Specific end use(s)

The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure controls/Personal protection

8.1. Control parameters

Occupational exposure limits

No exposure limits known for ingredient(s).

8.2. Exposure controls

Protective equipment







According to Regulation (EC) No 1907/2006, Annex II, as amended. Commission Regulation (EU) No 2015/830 of 28 May 2015.

Appropriate engineering controls

Provide adequate ventilation. Personal, workplace environment or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Use process enclosures, local exhaust ventilation or other engineering controls as the primary means to minimise worker exposure. Personal protective equipment should only be used if worker exposure cannot be controlled adequately by the engineering control measures. Ensure control measures are regularly inspected and maintained. Ensure operatives are trained to minimise exposure

Eye/face protection

Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. Personal protective equipment for eye and face protection should comply with European Standard EN166. Unless the assessment indicates a higher degree of protection is required, the following protection should be worn: Tight-fitting safety glasses.

Hand protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible. The most suitable glove should be chosen in consultation with the glove supplier/manufacturer, who can provide information about the breakthrough time of the glove material. To protect hands from chemicals, gloves should comply with European Standard EN374. Considering the data specified by the glove manufacturer, check during use that the gloves are retaining their protective properties and change them as soon as any deterioration is detected. Frequent changes are recommended.

For exposure up to 4 hours, wear gloves made of the following material: Butyl rubber. Nitrile rubber.

Other skin and body protection

Appropriate footwear and additional protective clothing complying with an approved standard should be worn if a risk assessment indicates skin contamination is possible.

Hygiene measures

Provide eyewash station and safety shower. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Clean equipment and the work area every day. Good personal hygiene procedures should be implemented. Wash at the end of each work shift and before eating, smoking and using the toilet. When using do not eat, drink or smoke. Preventive industrial medical examinations should be carried out. Warn cleaning personnel of any hazardous properties of the product.

Respiratory protection

Respiratory protection complying with an approved standard should be worn if a risk assessment indicates inhalation of contaminants is possible. Ensure all respiratory protective equipment is suitable for its intended use and is 'CE'-marked. Check that the respirator fits tightly and the filter is changed regularly. Gas and combination filter cartridges should comply with European Standard EN14387. Full face mask respirators with replaceable filter cartridges should comply with European Standard EN136. Half mask and quarter mask respirators with replaceable filter cartridges should comply with European Standard EN140.

Environmental exposure controls

Keep container tightly sealed when not in use. Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels. Store in a demarcated bunded area to prevent release to drains and/or watercourses.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance Liquid.

Colour Transparent.

Odour Odourless.

Odour thresholdNo information available.pHNo information available.Melting pointNo information available.Initial boiling point and rangeNo information available.

Flash point No information available.

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Evaporation rate No information available. Flammability (solid, gas) No information available. Upper/lower flammability or No information available.

explosive limits

Vapour pressure No information available. Vapour density No information available. Solubility(ies) No information available. Auto-ignition temperature Product is not selfigniting.

Decomposition Temperature 300°C

500-600 mPa.s Viscosity

Explosive properties No information available. No information available. Oxidising properties

9.2. Other information

Other information No information required.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity There are no known reactivity hazards associated with this product.

10.2. Chemical stability

Stability Stable at normal ambient temperatures and when used as recommended. Stable under the prescribed

storage conditions.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No potentially hazardous reactions known.

10.4. Conditions to avoid

Avoid excessive heat for prolonged periods of time. Containers can burst violently or explode when Conditions to avoid

heated, due to excessive pressure build-up.

10.5. Incompatible materials

Materials to avoid No specific material or group of materials is likely to react with the product to produce a hazardous

situation.

10.6. Hazardous decomposition products

Hazardous decomposition

Does not decompose when used and stored as recommended. Thermal decomposition or combustion

products may include the following substances: Harmful gases or vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - oral

products

Notes (oral LD50) Based on available data the classification criteria are not met.

Acute toxicity - dermal

Based on available data the classification criteria are not met. Notes (dermal LD50)

Acute toxicity - inhalation

Notes (inhalation LC50) Based on available data the classification criteria are not met.

Skin corrosion/irritation

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According to Regulation (EC) No 1907/2006, Annex II, as amended. Commission Regulation (EU) No 2015/830 of 28 May 2015.

Skin corrosion/irritation Based on available data the classification criteria are not met.

Serious eye damage/irritation

Serious eye damage/irritation Based on available data the classification criteria are not met.

Respiratory sensitisation

Respiratory sensitisation Based on available data the classification criteria are not met.

Skin sensitisation

Skin sensitisation May cause skin sensitisation or allergic reactions in sensitive individuals.

Germ cell mutagenicity

Genotoxicity - in vitroBased on available data the classification criteria are not met.

Carcinogenicity

Carcinogenicity Based on available data the classification criteria are not met.

IARC carcinogenicityNone of the ingredients are listed or exempt.

Reproductive toxicity

Reproductive toxicity - fertility Suspected of damaging fertility.

Reproductive toxicity -

development

Based on available data the classification criteria are not met.

Specific target organ toxicity - single exposure

STOT - single exposure Not classified as a specific target organ toxicant after a single exposure.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure Not classified as a specific target organ toxicant after repeated exposure.

Aspiration hazard

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

General information May damage fertility. The severity of the symptoms described will vary dependent on the concentration

and the length of exposure.

Inhalation Prolonged inhalation of high concentrations may damage respiratory system.

Ingestion May cause sensitisation or allergic reactions in sensitive individuals. Gastrointestinal symptoms, including

upset stomach. Fumes from the stomach contents may be inhaled, resulting in the same symptoms as

inhalation.

Skin contact May cause skin sensitisation or allergic reactions in sensitive individuals. Prolonged contact may cause

dryness of the skin.

Eye contact May cause temporary eye irritation.

Route of exposure Ingestion Inhalation Skin and/or eye contact

Target organs No specific target organs known.

Medical considerations Skin disorders and allergies.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity Toxic to aquatic life with long lasting effects.

No specific test data are available.

12.2. Persistence and degradability

Persistence and degradability The degradability of the product is not known.

According to Regulation (EC) No 1907/2006, Annex II, as amended. Commission Regulation (EU) No 2015/830 of 28 May 2015.

12.3. Bioaccumulative potential

Bioaccumulative potential No data available on bioaccumulation.

12.4. Mobility in soil

Mobility The product contains volatile substances which may spread in the atmosphere.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB

This product does not contain any substances classified as PBT or vPvB.

assessment

12.6. Other adverse effects

Other adverse effects None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

General information Reuse or recycle products wherever possible. This material and its container must be disposed of in a

safe way. When handling waste, the safety precautions applying to handling of the product should be considered. Care should be taken when handling emptied containers that have not been thoroughly cleaned or rinsed out. Empty containers or liners may retain some product residues and hence be

potentially hazardous.

Disposal methodsDo not empty into drains. Dispose of surplus products and those that cannot be recycled via a licensed

waste disposal contractor. Waste, residues, empty containers, discarded work clothes and contaminated

cleaning materials should be collected in designated containers, labelled with their contents.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

According to Regulation (EC) No 1907/2006, Annex II, as amended. Commission Regulation (EU) No 2015/830 of 28 May 2015.

Marine transport (IMDG)

14.1. UN number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

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

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

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

National regulations

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According to Regulation (EC) No 1907/2006, Annex II, as amended. Commission Regulation (EU) No 2015/830 of 28 May 2015.

EU legislation Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006

concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as

amended).

Commission Regulation (EU) No 2015/830 of 28 May 2015.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on

classification, labelling and packaging of substances and mixtures (as amended).

Seveso Directive - Control of major accident hazards

E2 Lower-tier 200 tonnes Upper-tier 500 tonnes.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

in the safety data sheet

Abbreviations and acronyms used ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland

Waterways

RID: European Agreement concerning the International Carriage of Dangerous Goods by Rail.

IATA: International Air Transport Association.

ICAO: Technical Instructions for the Safe Transport of Dangerous Goods by Air.

IMDG: International Maritime Dangerous Goods.

CAS: Chemical Abstracts Service. ATE: Acute Toxicity Estimate.

LC₅o: Lethal Concentration to 50 % of a test population.

LD₅o: Lethal Dose to 50% of a test population (Median Lethal Dose).

EC50: 50% of maximal Effective Concentration. PBT: Persistent, Bioaccumulative and Toxic substance. vPvB: Very Persistent and Very Bioaccumulative.

Classification abbreviations and

acronyms

Repr. = Reproductive toxicity Skin Sens. = Skin sensitisation

Aquatic Chronic = Hazardous to the aquatic environment (chronic)

Key literature references and sources for data

This SDS is prepared based on the information received from the product owner.

Source: European Chemicals Agency, http://echa.europa.eu/

Classification procedures according to Regulation (EC)

1272/2008

Skin Sens. 1 - H317: Repr. 2 - H361f: : Calculation method. Aquatic Chronic 2 - H411: : Calculation

method.

Training advice

Read and follow manufacturer's recommendations. Only trained personnel should use this material.

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11270

Hazard statements in full

H317 May cause an allergic skin reaction. H361f Suspected of damaging fertility.

H411 Toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects. H413 May cause long lasting harmful effects to aquatic life.

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.