



clara

3D printing resin for additive manufacturing of bite splints

Safety Data Sheet

Created on: 26.11.2021

Valid from: 29.11.2021

1. Description of the substance or mixture and the company

1.1. Product identifier: Additive plastic

1.2 Application: Methacrylate-based resin 3D printing systems with 385 nm or 405 nm light sources for additive manufacturing of bite splints

1.2 Manufacturer: dentona AG
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UK: 0844 892 0111 (UK only, Monday to Friday, 08.00-18.00)

2. Potential hazards

2.1 Classification of substance or mixture according to Regulation (EC) No. 1272/2008:

Skin irrit.	Cat. 2	H315
Skin sens	Cat. 1	H317
Eye irrit.	Cat. 2	H319
STOT SE	Cat. 3	H335
Aquatic Acute	Cat. 1	H400
Aquatic chronic	Cat. 1	H410

2.2. Identifying elements according to Regulation (EC) No. 1272/2008:

Symbols and signal word of product



Signal word: hazard

Hazard warnings:

H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H333	May cause respiratory irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

Safety Tips:

P261	Avoid breathing dust/fume/gas/mist/vapors/spray
P264	Wash contaminated skin thoroughly after handling.
P270	Do not eat, drink or smoke when using.
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.
P312	Call a POISON CENTER / doctor if you feel unwell.
P321	Specific treatment (see medical advice on this label)
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove any existing contact lenses if possible. Continue rinsing.
P332+P313	If skin irritation occurs: Get medical advice / assistance.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P337+P313	If skin irritation or rash occurs: Get medical advice / attention.
P391	Collect spillage.
P403+P233	Keep in a well-ventilated place. Leave container tightly closed.
P405	Store locked up.
P501	Dispose of contents / container in accordance with local regulations.

2.3 Other hazards:

3. Composition / information on ingredients

3.1 Substances

This product is a mixture

3.2 Mixtures

Composition / information on ingredients

Reagent	Percentage	EC No.: CAS No. REACH Registration No.	Classification according to Regulation (EC) No. 1272/2008	Hazard class and category
Urethane Acrylate	< 40	Company Secret	Not rated	
Methacrylic acid, monoester with propane-1,2-diol	< 8	Company Secret	H317 H319	Skin Sens 1 Eye Irrit 2
Isobornyl acrylate	< 25	Company Secret	H315 H319 H317 H335 H400 H410	Skin Irrit. 2 Eye Irrit.. 2 Skin Sens. 1B STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1
Polyethylene glycol 200 Dimethacrylate	< 30	Company Secret	Not rated	
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	< 2	Company Secret	H317 H361 H411	Skin Sens 1B Rep 2 Aquatic Chronic. 2

4. First aid measures

4.1 Description of first aid measures

General information: Immediately remove stained and soaked clothing. In all cases of doubt of if symptoms are present, seek medical advice.

If consciousness is lost, place in the recovery position and seek medical advice.

After inhalation: Ensure that there is fresh air. If the product irritates the respiratory tract: Consult a doctor.

After contact with skin: Wash out and rinse with plenty of soap and water.

After contact with eyes: In the event of contact with the eyes, remove contact lenses and immediately rinse with running water for 10-15 minutes while keeping the eyes open, and see an eye specialist.

After swallowing: Never administer something orally to an unconscious person or someone who is experiencing cramps. Consult a doctor immediately. Prevent vomiting.

4.2 The most significant acute and delayed occurring symptoms and impact

Skin contact: May cause an allergic skin reaction.

4.3 Information about emergency medical aid or special treatment

Note for the physician: Treat symptomatically

5. Fire-fighting procedures

5.1. Solvents

Suitable solvents: Water spray, foam, dry fire extinguisher or carbon dioxide.

Unsuitable solvents: Do not use a water jet as an extinguishing agent, as this will cause the fire to spread.

5.2. Particular hazards arising from substance or mixture

Hazardous decomposition products: Thermal decomposition or combustion products may contain the following substances: Carbon oxides.

5.3. Information for fire-fighting:

Safety precautions during fire-fighting: No actions should be taken without appropriate training or which are associated with personal risk.

Particular protective equipment for fire-fighters: Wear self-contained breathing apparatuses (SCBA) and suitable protective clothing.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: At work, wear suitable protective clothing, including gloves, safety goggles / face guard, respiratory protection, boots, or other clothing or an apron as appropriate.

Suitable respiratory protection in the event of inadequate ventilation.

6.2. Environmental protection measures

Environmental protection measures to prevent discharge into the environment.

6.3. Methods and material for retention and cleaning

Methods for cleaning: No smoking, sparks, flames or other ignition sources near spillages. Bind leaked material with sand or another inert absorbent. Collect it and fill a suitable disposal bin, then seal securely. Containers with collected spilled material must have the correct hazard labeling. Spillages must be collected and disposed of in accordance with the information in Section 13.

6.4. Reference to other sections

Reference to other sections: For information on personal protective equipment, see Section 8. Section 13 contains information about waste disposal.

7. Handling and storage

7.1. Safety precautions for safe handling

Safety precautions during use: Avoid contact with the eyes and skin. Wash contaminated skin thoroughly after handling. The hands and all contaminated parts of the body must be washed with soap and water before leaving the factory premises. Keep away from heat, sparks and open flame. Mechanical suction is required if dust is discharged during handling. Open and handle containers with care. At work, wear suitable safety equipment in the event of longer exposure and / or high concentrations of vapors, spray or mist.

General work hygiene measures

When using the product, do not eat, drink or smoke.

7.2. Conditions for safe storage, taking cases of incompatibility into account

Safety precautions for storage

Store in a cool and dry place in a tightly sealed original container.

Store at temperatures between 5°C and 30°C. Keep away from frost and direct sunlight. Keep away from hot surfaces, sparks, open flames and other types of ignition sources. Do not smoke.

7.3. Specific end uses

Intended end use(s)

The intended uses of this product are described in Section 1.2.

8. Limitation and monitoring of exposure/personal protective equipment

8.1 Parameters to be monitored:

No maximum allowable concentration(s) is/are known for the ingredient(s).

8.2 Limitation and monitoring of exposure

Protective equipment



Suitable technical controller:

Adequate room ventilation and local aspiration must be ensured. The maximum allowable concentration of the product or ingredients must be observed.

Eye/face protection:

Eye protection corresponding to a recognized standard should be worn if a risk assessment shows that eye contact is possible. The following personal protective clothing should be worn: Chemical safety goggles. Wear close-fitting chemical safety goggles or face protection.

Hand protection:

Wear protective gloves. In accordance with the data specified by the protective glove manufacturers, it is required while using them to check whether the gloves maintain their repellent properties and to change them as soon as damage is detected. In the case of exposure up to 8 hours, protective gloves made of the following material must be worn: Nitrile rubber.

Other skin and personal protection:

Avoid contact with the skin. Wear suitable clothing to prevent possible skin contact.

Hygiene measures:

Wash contaminated skin thoroughly after handling. Before removing the clothing, wash contaminated clothing and skin immediately with plenty of water. Immediately remove all contaminated garments and wash before wearing them again. Contaminated work clothing should not be allowed out of the workplace. When using the product, do not eat, drink or smoke.

Respiratory protection:

If ventilation is inadequate, suitable respiratory protection must be worn. Wear a protective mask with full face protection and the following filter cartridge: Filter against organic vapors. Highly effective particle filters.

9. Physical and chemical properties

9.1 Information about the fundamental physical and chemical properties

	Value	Unit
Appearance	Liquid	
Odor	Ester	
Color	Clear transparent	
Melting point	Not determined	
Initial boiling point and boiling range	Not determined	
Flash point	> 120	°C
Inflammability (solid, gaseous)	Not determined	
Upper/lower inflammability or explosion limits	Not determined	
Vapor pressure	Not determined	
Relative density	1.1	g/cm ³
Solubility	Insoluble in water	
Soluble in most organic solvents		
Viscosity	Approx. 700-1200	Pa s
pH	Not determined	

9.2 Other information

10. Stability and reactivity

10.1 Reactivity

Reactivity: No information is available

10.2 Chemical stability

Stability: Stable at normal room temperatures

10.3 Possible hazardous reactions

Possible hazardous reactions May polymerize

10.4 Conditions to be avoided

Incompatible conditions: Reaction with light, risk of polymerization. Keep away from heat, flames and other ignition sources. Do not expose to high temperatures or direct sunlight. Avoid contact with strong oxidizers

10.5 Incompatible materials

Incompatible materials Keep away from radical-forming initiators, peroxides, strongly alkaline substances and reactive metals to prevent exothermic polymerization reactions.

10.6 Hazardous decomposition products

Hazardous decomposition products: Carbon oxides

11. Toxicological information

11.1 Information about toxicological effects

Methacrylic acid, monoester with propane-1,2-diol (at 100%)	
Acute toxicity – oral LD ₅₀	>2000 mg/kg, oral, rat
Acute toxicity – dermal LD ₅₀	>5000 mg/kg, dermal, rabbit
Acute toxicity – inhalative LC ₅₀	No information available
Caustic/irritant effect on the skin	Not irritating
Severe eye damage/irritation	Moderately irritating
Respiratory tract sensitization	No information available
Skin sensitization	Sensitizing
Germ cell mutagenicity	Gene mutation: negative Chromosomal aberration: negative
Carcinogenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	Screening: NOAEL 1000 mg / kg body weight / day, oral, rat F1 Developmental toxicity: NOAEL 1000 mg / kg body weight / day, oral, rat NOAEL 0.5 mg / l, inhalation, rat
Specific target organ toxicity (repeated exposure)	STOT - repeated exposure NOAEL 300 mg/kg KG/day, oral, rat
Isobornyl acrylate (at 100%)	
Acute toxicity – oral LD ₅₀	4350 mg/kg, oral, rat
Acute toxicity – dermal LD ₅₀	>3000 mg/kg, dermal, rat
Acute toxicity – inhalative LC ₅₀	No information is available.
Caustic/irritant effect on the skin	weakly irritating
Severe eye damage/irritation	weakly irritating
Respiratory tract sensitization	No information available
Skin sensitization	Sensitizing. Local lymph node test (LLNA) - mouse
Germ cell mutagenicity / genotoxicity - in vitro	Gene mutation: Negative.
Carcinogenicity	No information is available.
Reproductive toxicity - fertility	Screening: - NOAEL 1000 mg/kg/d, oral, rat F1
Reproductive toxicity - Development	Embryotoxicity: - NOAEL: 500 mg/kg KG/day, oral, rat

Specific target organ toxicity (repeated exposure)	NOAEL 10 mg / kg bw / day, oral, rat NOAEL 0.075 mg / l inhalation, rat
Polyethylene glycol 200 Dimethacrylate (at 100%)	
Acute toxicity – oral LD ₅₀	No information is available.
Estimated acute oral toxicity	No information is available.
Acute toxicity – dermal LD ₅₀	No information is available.
Acute toxicity – inhalative LC ₅₀	No information is available.
Caustic/irritant effect on the skin	No information is available.
Severe eye damage/irritation	No information is available.
Respiratory tract sensitization	No information is available.
Skin sensitization	No information is available.
Germ cell mutagenicity / genotoxicity - in vitro	No information is available.
Carcinogenicity	No information is available.
Reproductive toxicity - fertility	No information is available.
Reproductive toxicity - Development	No information is available.
Specific target organ toxicity (repeated exposure)	No information is available.
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (at 100%)	
Acute toxicity – oral LD ₅₀	>5000 mg/kg rat
Acute toxicity – dermal LD ₅₀	<2000 mg/kg rat
Acute toxicity – inhalative LC ₅₀	No information is available.
Caustic/irritant effect on the skin	0.5 g / 24h dermal, rabbit, not irritating
Severe eye damage/irritation	0.056 g / 5d eye, rabbit, not irritating
Respiratory tract sensitization	OECD Test 429 local lymph node test, dermal, mouse sensitizing
Skin sensitization	-
Germ cell mutagenicity / genotoxicity - in vitro	negativ
Carcinogenicity	No evidence of carcinogenicity in animal experiments
The table below shows ingredients that are above the limit value considered relevant and are listed as toxic to reproduction:	
Reproductive toxicity	OECD Test No. 414: Study to examine the prenatal developmental toxicity, rat Developmental toxicity: NOAL 150 mg / kg body weight / day OECD Test No. 421: Screening Test for Reproductive / Developmental Toxicity, Rat Reproductive toxicity: NOAL 60 mg / kg body weight / day OECD Test No. 421: Screening Test for Reproductive / Developmental Toxicity, Rat Developmental toxicity: NOAL 200 mg / kg body weight / day OECD Test No. 421: Screening Test for Reproductive / Developmental Toxicity, Rat Parental: NOAL 200 mg / kg body weight / day
European Union	Repr. 2
Reproductive toxicity - Development	Based on the available data, the criteria for classification are not met.
Specific target organ toxicity (repeated exposure)	OECD Test 408: 90 day tox study with repeated oral administration to rodents - oral, rat NOAL 100mg / kg body weight / day
Germ cell mutagenicity / genotoxicity - in vitro	negative
Carcinogenicity	No evidence of a carcinogenic effect
Reproductive toxicity - fertility	No evidence of reprotoxic properties.
Reproductive toxicity - Development	NOAEL 1000 mg/kg KG/Tag, oral, rat
Specific target organ toxicity (repeated exposure)	Silicosis or other product-specific properties of the respiratory tract were not observed when handling the product

12 Environment-related information

12.1 Toxicity

Methacrylic acid, monoester with propane-1,2-diol (at 100%)	
Acute toxicity - fish	LC ₅₀ , 48 hours: 493 mg / l, <i>Leuciscus idus</i> (golden orfe)
Acute toxicity - invertebrate aquatic animals	EC ₅₀ , 48 hours: > 143 mg / l, <i>Daphnia magna</i>
Acute toxicity - aquatic plants	NOEC, 72 hours: > 97.2 mg / l, <i>Pseudokirchneriella subcapitata</i>
Acute toxicity - microorganisms	NOEC, 21 days: 45.2 mg / l, <i>Daphnia magna</i>
Isobornyl acrylate (at 100%)	
Acute toxicity - fish	LC ₅₀ , 96 hours: 3.2mg / L mg / l, fish
Acute toxicity - invertebrate aquatic animals	EC ₅₀ , 48 hours: 13mg / L mg / l, <i>Daphnia magna</i>
Acute toxicity - aquatic plants	NOEC, 96 hours: 0.31 mg / l, <i>Pseudokirchneriella subcapitata</i>
Acute toxicity - microorganisms	EC ₅₀ , 3 hours: 100 mg / l, activated sludge
2.2' ethylenedioxydiethyl dimethacrylate (at 100%)	
Acute toxicity - fish	Not available
Acute toxicity - invertebrate aquatic animals	Not available
Acute toxicity - aquatic plants	Not available
Acute toxicity - microorganisms	Not available
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (at 100%)	
Acute toxicity - fish	LC ₅₀ , 48 hours: 6.53 mg/l, <i>Oryzias latipes</i>
Acute toxicity - invertebrate aquatic animals	EC ₅₀ , 48 hours: 3,53 mg/l, <i>Daphnia magna</i>
Acute toxicity - aquatic plants	EC ₅₀ , 72 hours: > 2,01 mg/l, <i>Pseudokirchneriella subcapitata</i> EC ₁₀ , 72 hours: > 1,56 mg/l, <i>Pseudokirchneriella subcapitata</i>
Acute toxicity - microorganisms	No information is available.

12.2. Persistence and degradability

The product is not easily biodegradable.

12.3. Bioaccumulation potential

Methacrylic acid, monoester with propane-1,2-diol (at 100%)	
Distribution coefficient	BFC: 3.2, calculation method
Isobornyl acrylate (at 100%)	
Distribution coefficient	log Kow: 4.52
Polyethylene glycol 200 Dimethacrylate (at 100%)	
Distribution coefficient	Not determined
Bioaccumulation potential	No bioaccumulation data are available.
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (at 100%)	
Distribution coefficient	Log Pow: 3,1
Bioconcentration Factor (BFC)	18-72

12.4 Mobility on the ground

Methacrylic acid, monoester with propane-1,2-diol (at 100%)	
Adsorption / desorption coefficient	Not determined
Isobornyl acrylate (at 100%)	
Adsorption / desorption coefficient	Not determined

Polyethylene glycol 200 Dimethacrylate (at 100%)	
Mobility	No information is available.
Adsorption / desorption coefficient	No information available
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (at 100%)	
Henry constant	0 Pa m ³ /mol @ 25°C
Absorption coefficient	Log K _{oc} = 784.8

12.5 Results of PBT and vPvB assessment

Methacrylic acid, monoester with propane-1,2-diol (at 100%)	
According to the currently valid EU classification criteria, this substance is not classified as PBT or vPvB..	
Isobornyl acrylate (at 100%)	
According to the currently valid EU classification criteria, this substance is not classified as PBT or vPvB.	
Polyethylene glycol 200 Dimethacrylate (at 100%)	
No information available	
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (at 100%)	
According to the criteria of the REACH regulation, no PBT or vPvB substance.	

13. Disposal instructions

13.1 Procedure for waste disposal

Proper disposal/product

Disposal in accordance with regulatory requirements.

Proper disposal/packaging

May be disposed of in accordance with local regulatory requirements.

Ecology - waste materials

Avoid discharge into the environment

14. Transport information

14.1 UN No.

none

14.2 Proper UN shipping name

none

14.3 Transport hazard classes

No dangerous goods pursuant to transportation regulations.

14.4 Packaging group

none

14.5 Environmental hazards

none

14.6 Special precautions for transport

none

14.7 Bulk transport in accordance with Annex II of the MARPOL Convention 73/79 pursuant to IBC Code

No

15. Legal regulations

15.1. Regulations on safety, health and environmental protection/specific laws for the substance or mixture

EU regulations

Information about Regulation (EC) No. 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register:

irrelevant

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer:

irrelevant

Regulation (EC) No. 648/2004 on detergents:

irrelevant

Regulation (EC) No. 850/2004 [POP regulation]:

irrelevant

Regulation (EU) No. 649/2012 concerning the import and export of hazardous chemicals:

irrelevant

Restriction on use in accordance with REACH Annex XVII No.:

irrelevant

National regulations

National regulations must also be observed.

Instructions on employment restriction:

No information is available.

Major Accidents Ordinance

Not subject to the German Major Accidents Ordinance.

Solvent Ordinance (31st Federal Immission Protection Ordinance [BlmSchV]):

irrelevant

Storage class

10-13 Other flammable and non-flammable substances.

Water hazard class (WHC)

1 slightly hazardous to water (WHC 1)

Technical Instructions on Air Quality Control (TA-Luft)

Not subject to the Technical Instructions on Air Quality Control.

Other regulations, restrictions and prohibition ordinances

None

15.2. Chemical safety assessment

A chemical safety assessment was carried out for this preparation.

Chemical safety assessments were not carried out for substances in this mixture.

16. Other information**Text of H and P phrases (number and full text)**

H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H333	May cause respiratory irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
P261	Avoid breathing dust/fume/gas/mist/vapors/spray
P264	Wash contaminated skin thoroughly after handling.
P270	Do not eat, drink or smoke when using.
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.
P312	Call a POISON CENTER / doctor if you feel unwell.
P321	Specific treatment (see medical advice on this label)
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove any existing contact lenses if possible. Continue rinsing.
P332+P313	If skin irritation occurs: Get medical advice / assistance.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P337+P313	If skin irritation or rash occurs: Get medical advice / attention.
P391	Collect spillage.
P403+P233	Keep in a well-ventilated place. Leave container tightly closed.
P405	Store locked up.
P501	Dispose of contents / container in accordance with local regulations.

Training tips

None

Recommended restriction(s) on use:

No special measures are required.

Data sources:

REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No. 1907/2006.

Further information:

REJECTION OF LIABILITY We have obtained the information in this data sheet from sources that we consider reliable. The accuracy of expressed or implied information cannot be guaranteed. The conditions or methods for handling, storage, use or disposal of the product are beyond our control and possibly also our knowledge. For these and other reasons, we accept no responsibility and expressly reject liability for any losses, damage or costs that may arise from handling, storage, use or disposal of the product or that may be associated therewith in any way. This Safety Data Sheet was created for this product and may only be used for this product. If the product is used as a component of another product, the information indicated in the data sheet may not apply.

This information is based on our current knowledge and should only describe the product with regard to health, safety and environmental conditions. It must therefore not be construed as a guarantee for any specific property of the product.