

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

PROCLINIC COMPOSITE FLOW



Version: 4
Revision date: 14/01/2016

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Print date: 19/04/2017

SECTION 1: IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: PROCLINIC COMPOSITE FLOW

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

For dental use
Dental fillings

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company's identification:

Company: **MADESPA, S.A.**
Address: Calle Río Jarama, 120
City: Toledo
Province: Toledo
Telephone: 925241025
Fax: 925 241 028
E-mail: info@madespa.com
Web: www.madespa.com

Responsible for market placement:

Company: **Proclinic, S.A.**
Address: PASEO DE LA ZONA FRANCA, 111 TORRE AUDITORI, PLANTA 4ª
City: BARCELONA
Province: BARCELONA

1.4 Emergency telephone number: 925 241 025 (Only available during office hours; Monday-Friday; 07:00-15:00)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the mixture.

In accordance with Regulation (EU) No 1272/2008:

Eye Irrit. 2 : Causes serious eye irritation.
Skin Irrit. 2 : Causes skin irritation.
Skin Sens. 1 : May cause an allergic skin reaction.

2.2 Label elements.

Labelling in accordance with Regulation (EU) No 1272/2008:

Pictograms:



Signal Word:

Warning

H statements:

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

P statements:

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.

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P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 IF ON SKIN: Wash with plenty of water/...
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321 Specific treatment (see ... on this label).
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents/container to ...

Contains:

Bisphenol A glycidylmethacrylate

Although classified according to EC criteria, this product is exempt from labelling according to article 23 and Annex 1 (section 1.3.4.1) of regulation CE No. 1272/2008.

2.3 Other hazards.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Not Applicable.

3.2 Mixtures.

Substances posing a danger to health or the environment in accordance with the Regulation (EC) No. 1272/2008, assigned a Community exposure limit in the workplace, and classified as PBT/vPvB or included in the Candidate List:

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	specific concentration limit
CAS No: 1565-94-2 EC No: 216-367-7	Bisphenol A glycidylmethacrylate	10 - 25 %	Eye Irrit. 2, H319 - Skin Irrit. 2, H315 - Skin Sens. 1, H317	-
CAS No: 1309-37-1 EC No: 215-168-2 Registration No: 01- 2119457614-35-XXXX	[1] diiron trioxide	0 - 2.5 %	-	-

(*) The complete text of the H phrases is given in section 16 of this Safety Data Sheet.

[1] Substance with a Community workplace exposure limit (see section 8.1).

SECTION 4: FIRST AID MEASURES.

IRRITANT PREPARATION. Its repeated or prolonged contact with the skin or mucous membranes can cause irritant symptoms such as reddening of the skin, blisters, or dermatitis. Some of the symptoms may not be immediate. They can cause allergic reactions on the skin.

4.1 Description of first aid measures.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration. Do not administer anything orally. If unconscious, place them in a suitable position and seek medical assistance.

Eye contact.

If wearing contact lenses, remove them. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

Skin contact.

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Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. **NEVER** use solvents or thinners.

Ingestion.

If accidentally ingested, seek immediate medical attention. Keep calm. **NEVER** induce vomiting.

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

Irritant Product, repeated or prolonged contact with skin or mucous membranes can cause redness, blisters or dermatitis, inhalation of spray mist or particles in suspension may cause irritation of the respiratory tract, some symptoms may not be immediate. Can cause allergic reactions.

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

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

SECTION 5: FIREFIGHTING MEASURES.

The product does not present any particular risk in case of fire.

5.1 Extinguishing media.

Recommended extinguishing methods.

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray. Do not use a direct stream of water to extinguish.

5.2 Special hazards arising from the mixture.

Special risks.

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and gloves.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Prevent the contamination of drains, surface or subterranean waters, and the ground.

6.3 Methods and material for containment and cleaning up.

Pick up the spill with non-combustible absorbent materials (soil, sand, vermiculite, diatomite, etc.). Pour the product and the absorbent in an appropriate container. The contaminated area should be immediately cleaned with an appropriate decontaminator. Pour the decontaminator on the remains in an opened container and let it act various days until no further reaction is produced.

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

For personal protection, see section 8. Never use pressure to empty the containers. They are not pressure-resistant containers.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

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Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

Store according to local legislation. Observe indications on the label. Store the containers between 5 and 35° C, in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

Work exposure limit for:

Name	CAS No.	Country	Limit value	ppm	mg/m ³
diiron trioxide	1309-37-1	United Kingdom [1]	Eight hours		10 (total inhalable) 4 (respirable)
			Short term		

[1] According Limit Value (IOELV) list in 2nd Indicative Occupational Exposure adopted by Health and Safety Executive.

The product does NOT contain substances with Biological Limit Values.

Concentration levels DNEL/DMEL:

Name	DNEL/DMEL	Type	Value
diiron trioxide	DNEL (Workers)	Inhalation, Long-term, Local effects	10 (mg/m ³)
CAS No: 1309-37-1	DNEL (Workers)	Inhalation, Long-term, Systemic effects	10 (mg/m ³)
EC No: 215-168-2			

DNEL: Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.


DMEL: Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.

8.2 Exposure controls.

Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Concentration:	100 %		
Uses:	For dental use Dental fillings		
Breathing protection:			
If the recommended technical measures are observed, no individual protection equipment is necessary.			
Hand protection:			
PPE:	Work gloves.		
Characteristics:	«CE» marking, category I.		
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420		
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible.		
Observations:	Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.		
	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight.		
	Always use with clean, dry hands.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480
		Material thickness (mm):	0,35
Eye protection:			
PPE:	Face shield.		
Characteristics:	«CE» marking, category II. Face and eye protector against splashing liquid.		
CEN standards:	EN 165, EN 166, EN 167, EN 168		





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Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions. Make sure that mobile parts move smoothly.
Observations:	Face shields should offer a field of vision with a dimension in the central line of, at least, 150 mm vertically once attached to the frame.
Skin protection:	
PPE:	Protective clothing.
Characteristics:	«CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements.
CEN standards:	EN 340
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.
Observations:	The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use.
PPE:	Work footwear.
Characteristics:	«CE» marking, category II.
CEN standards:	EN ISO 13287, EN 20347
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Appearance: Highly viscous paste

Colour: White-creamy

Odour: Odourless

Odour threshold: N.A./N.A.

pH: N.A./N.A.

Melting point: N.A./N.A.

Boiling Point: N.A./N.A.

Flash point: 110 °C

Evaporation rate: N.A./N.A.

Inflammability (solid, gas): N.A./N.A.

Lower Explosive Limit: N.A./N.A.

Upper Explosive Limit: N.A./N.A.

Vapour pressure: N.A./N.A.

Vapour density: N.A./N.A.

Relative density: N.A./N.A.

Solubility: N.A./N.A.

Liposolubility: N.A./N.A.

Hydrosolubility: N.A./N.A.

Partition coefficient (n-octanol/water): N.A./N.A.

Auto-ignition temperature: N.A./N.A.

Decomposition temperature: N.A./N.A.

Viscosity: N.A./N.A.

Explosive properties: N.A./N.A.

Oxidizing properties: N.A./N.A.

N.A./N.A. = Not Available/Not Applicable due to the nature of the product

9.2 Other information.

Pour point: N.A./N.A.

Blink: N.A./N.A.

Kinematic viscosity: N.A./N.A.

N.A./N.A. = Not Available/Not Applicable due to the nature of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

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10.2 Chemical stability.

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

Protect from strong lights and heat sources

10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

Hazardous products of decomposition: Carbon oxides

SECTION 11: TOXICOLOGICAL INFORMATION.

IRRITANT PREPARATION. Splatters in the eyes can cause irritation.

IRRITANT PREPARATION. Its repeated or prolonged contact with the skin or mucous membranes can cause irritant symptoms such as reddening of the skin, blisters, or dermatitis. Some of the symptoms may not be immediate. They can cause allergic reactions on the skin.

11.1 Information on toxicological effects.

There are no tested data available on the product.

Repeated or prolonged contact with the product can cause the elimination of oil from the skin, giving rise to non-allergic contact dermatitis and absorption of the product through the skin.

Splatters in the eyes can cause irritation and reversible damage.

a) acute toxicity;

Not conclusive data for classification.

Oral LD50 for rats: >5000 mg/Kg

b) irritation;

Product classified:

Eye irritation, Category 2: Causes serious eye irritation.

Skin irritant, Category 2: Causes skin irritation.

c) corrosivity;

Not conclusive data for classification.

d) sensitisation;

Product classified:

Skin sensitizer, Category 1: May cause an allergic skin reaction.

e) repeated dose toxicity;

Not conclusive data for classification.

f) carcinogenicity;

Not conclusive data for classification.

g) mutagenicity;

Not conclusive data for classification.

h) toxicity for reproduction;

Not conclusive data for classification.

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SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

Name	Ecotoxicity			
	Type	Test	Kind	Value
diiron trioxide CAS No: 1309-37-1 EC No: 215-168-2	Fish	LC0	Danio rerio	>50000 mg/l (96 h)
	Aquatic invertebrates	EC50	Daphnia magna	>100 mg/l (48 h)
	Aquatic plants			

12.2 Persistence and degradability.

No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation of the substances present.

12.4 Mobility in soil.

No information is available about the mobility in soil.

The product must not be allowed to go into sewers or waterways.

Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Other adverse effects.

No information is available about other adverse effects for the environment.

SECTION 13 DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.

Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

14.1 UN number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR: Transportation is not dangerous.

IMDG: Transportation is not dangerous.

ICAO: Transportation is not dangerous.

14.3 Transport hazard class(es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

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14.5 Environmental hazards.

Transportation is not dangerous.

14.6 Special precautions for user.

Transportation is not dangerous.

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

Transportation is not dangerous.

SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

The product is not affected by Directive 2012/18/EU (SEVESO III).

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

Complete text of the H phrases that appear in section 3:

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

Classification codes:

Eye Irrit. 2 : Eye irritation, Category 2
Skin Irrit. 2 : Skin irritant, Category 2
Skin Sens. 1 : Skin sensitiser, Category 1

Sections changed compared with the previous version:

1,3,8,9,12,16

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

Abbreviations and acronyms used:

CEN:	European Committee for Standardization.
DMEL:	Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.
DNEL:	Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.
EC50:	Half maximal effective concentration.
PPE:	Personal protection equipment.
LC50:	Lethal concentration, 50%.
LD50:	Lethal dose, 50%.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>
<http://echa.europa.eu/>

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Regulation (EU) 2015/830.
Regulation (EC) No 1907/2006.
Regulation (EU) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.