Tradename:

IMPRIMO® LC Splint comfort

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

1.1. Product identifier

Name of product: IMPRIMO® LC Splint comfort

UFI: V0M0-D5GV-RT3X-PX28

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

Use of the substance/mixture

Methacrylate based resin for DLP-systems with 385 nm light sources.

Uses advised against

Private households (= general public)

1.3. Details of the supplier of the safety data sheet

Distributor SCHEU-DENTAL GmbH Am Burgberg 20 58642 Iserlohn Tel.-Nr. +49 (0) 2374/ 9288-0 Fax-Nr. +49 (0) 2374/ 9288-90

Manufacturer

pro3dure medical GmbH Am Burgberg 13 D-58642 Iserlohn

1.4. Emergency telephone number:

pro3dure medical GmbH This number is serviced during office hours.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1/1A/1B, H317 Repr. 2, H361 Aquatic Chronic 2, H411

2.2. Label elements

Signal word: Warning Pictograms: GHS08 GHS09



Hazard statements

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H361d	Suspected of damaging the unborn child.
H411	Toxic to aquatic life with long lasting effects.



Email: <u>service@SCHEU-DENTAL.com</u> Internet: www.SCHEU-DENTAL.com

Telefon: +49 (0)2374 920050-10 Telefax: +49 (0)2374 920050-50 E-Mail (competent person) <u>info@pro3dure.com</u> Webseite: www.pro3dure.com

Telefon: +49 (0)2374 920050-10



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Precautionary statements

Trecautionary State	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+352	IF ON SKIN: Wash with plenty of water/soap.
P305+351+338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present
	and easy to do. Continue rinsing.
P308+313	IF exposed or concerned: Get medical advice/attention.
P332+313	If skin irritation occurs: Get medical advice/attention.
P333+313	If skin irritation or rash occurs: Get medical advice/attention.
P337+313	If eye irritation persists: Get medical advice/attention.
P362+364	Take off contaminated clothing and wash it before reuse.
P391	Collect spillage.
P405	Store locked up.
P501	Dispose of contents/container acc. to official regulations.

Special labelling of particular preparations:

none

2.3. Other hazards

No risks worthy of mention.

SECTION 3: Composition / information on ingredients

3.1. Substances

not applicable

3.2. Mixtures

Mixture with, among others, the following ingredients and other non-hazardous admixtures

Composition/information on ingredients

Substance:	CAS-No.:	REACH-No.:	Concentration:	Classifiction: EC 1272/2008 (CLP)	M, ATE, Note
aliphatic urethane methacrylate	-		40 - 60 %	Skin Irrit. 2, H315; Skin Sens. 1/1A/1B, H317; Eye Irrit. 2, H319;	-
2-phenoxyethyl methacrylate	10595-06-9		25 - 45 %	Skin Sens. 1/1A/1B, H317; Repr. 2, H361d; Aquatic Chronic 2, H411	ATE (dermal) = 2000 mg/kg ATE (oral) = 5000 mg/kg
Ethyl phenyl(2,4,6- trimethylbenzoyl) phosphinate	84434-11-7		01 - 04 %	Skin Sens. 1/1A/1B, H317; Aquatic Chronic 2, H411	ATE (dermal) = >2000 mg/kg ATE (oral) = >5000 mg/kg

Full text of H- and EUH-phrases: see Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General Information:	Remove contaminated, saturated clothing immediately. When in doubt or if symptoms are observed, get medical advice. When in doubt or if symptoms are observed, get medical advice.
In case of inhalation:	Provide fresh air. Seek medical attention if problems persist.
Following skin contact:	After contact with skin, wash immediately with plenty of water and soap. In case of skin
	irritation, consult a physician.
After eyes contact:	In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes
	holding eyelids apart and consult an ophthalmologist. Consult an ophthalmologist.
After ingestion:	Rinse mouth immediately and drink plenty of water. No administration in cases of
-	unconsciousness or cramps. Do NOT induce vomiting. Call a physician immediately.

4.2. Most important symptoms and effects, both acute and delayed Erythema (redness) Causes skin irritation.

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

First Aid, decontamination, treatment of symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Foam. Carbon dioxide (CO2). Nitrogen. ABC-powder. BC-powder.

Unsuitable extinguishing media

Water mist. Full water jet. Water spray jet.

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon dioxide (CO2). Carbon monoxide.

5.3. Advice for firefighters

General information

Move undamaged containers from immediate hazard area if it can be done safely. Use water spray to protect personnel and to cool endangered containers.

Special protective equipment for fire-fighters:

In case of fire: Wear self-contained breathing apparatus. Wear chemical resistant suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Remove persons to safety. Remove all sources of ignition. Provide adequate ventilation. Wear personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface or drains. Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Advice on safe handling

When using do not eat, drink, smoke, sniff. Use only in well-ventilated areas. All work processes must always be designed so that the following is as low as possible: Inhalation

Precautions against fire and explosion

Always close containers tightly after the removal of product. Use only in well-ventilated areas. Use only in well-ventilated areas.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed and store in a cool, well-ventilated place. Protect against: UV-radiation/sunlight.

Hints on joint storage

Do not store together with: Oxidizing agent. Organic peroxides. Keep away from food, drink and animal feeding stuffs.

7.3 Specific end use(s)

Observe instructions for use.



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SECTION 8: Exposure controls / personal protection

8.1. Control parameters

occupational exposure limit value

Substance	CAS-No.	Source	Occupational	Occupational	Limitation of	Remark:
			exposure	exposure	exposure	
			limit value:	limit value:	peaks:	
			[ppm]	[mg/m³]		

Substance with a common (EC) occupational exposure limit value

ſ	Substance	CAS-No.	Source	Occupational	Occupational	Limitation of	Remark:
				exposure	exposure	exposure	
				limit value:	limit value:	peaks:	
				[ppm]	[mg/m ³]		

DNEL/PNEC values

DNEL Value					
Substance: CAS-No.:		DNEL/DMEL			
Ethyl phenyl(2,4,6- trimethylbenzoyl)phosphinate	84434-11-7	worker inhalative long-term, systemic 4,93 mg/m ³ worker dermal long-term, systemic 1,4 mg/kg bw/day population inhalative long-term, systemic 0,87mg/m ³ population dermal long-term, systemic 0,5 mg/kg bw/day population oral long-term, systemic 0,5 mg/kg bw/day			

PNEC-Wert

Substance:	CAS-No.:	PNEC
2-phenoxyethyl methacrylate	10595-06-9	aquatic, freshwater 142 µg/l aquatic, marine water 1,42 µg/l sewage treatment plant 177 mg/l sediment, freshwater 655 µg/kg dw sediment, marine water 67 µg/l soil 125 µg/kg dw
Ethyl phenyl(2,4,6- trimethylbenzoyl)phosphinate	84434-11-7	aquatic, freshwater 1,01 µg/l aquatic, marine water 0,101 µg/l sediment, freshwater 240 µg/kg dw sediment, marine water 24 µg/l soil 47,5 µg/kg dw

Additional information

None.

8.2. Exposure controls

Occupational exposure controls.

Provide adequate ventilation as well as local exhaustion at critical locations. Technical measures and the application of suitable work processes have priority over personal protection equipment.

General protection and hygiene measures

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Apply skin care products after work. Wash contaminated clothing prior to re-use.

Personal protection equipment

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required. Respiratory protection necessary at: insufficient ventilation. Suitable respiratory protection apparatus: Protective respiration apparatus not using surrounding air (breathing apparatus) (DIN EN 133).

Hand protection

Tested protective gloves are to be worn: DIN-/EN-Norms: EN ISO 374 Suitable material: Butyl rubber.

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Eye/face protection

Eye glasses with side protection

Body protection: Lab coat

Environmental exposure controls.

See section 7. No additional measures necessary.

Consumer exposure controls

Refer to chapter 7. No further action is necessary.

Exposure Scenario

Skin contact. Inhalation.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

A	ppearanc	e

Аррсанинсс		
Physical state:	Liquid	
Colour:	Light blue	
Odour:	fruity	
Odour threshold:	-	

Safety relevant basis data

	Parameter	Value	Unit	Remark
Melting point/freezing point:				No data available
Initial boiling point and boiling range:				No data available
Flammability:				No data available
Lower flammability or explosive limits:				No data available
Upper flammability or explosive limits:				No data available
Decomposition temperature:				No data available
pH:				No data available
Kinematic viscosity:		400	mPa*s	23 °C, 10/s
Water solubility (g/l):				
Partition coefficient: n-octanol/water:				No data available
Vapour pressure:				No data available
Density:		1,1	g/ml	
Relative density:				No data available
Particle properties:				No data available

9.2. Other information

None.

SECTION 10: Stability and reactivity

10.1. Reactivity

Can polymerise exothermically if heated, exposed to air, sunlight or by addition or free readical intiators.

10.2. Chemical stability

The substance is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

Polymerization.

10.4. Conditions to avoid

Heat. UV-radiation/sunlight

10.5. Incompatible materials

Can polymerise exothermically if heated, exposed to air, sunlight or by addition or free readical intiators.





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10.6. Hazardous decomposition products

In case of fire may be liberated. Carbon dioxide. Carbon monoxide.

SECTION 11: Toxicological Information

11.1. Information on toxicological effects

There are no data available on the preparation/mixture itself.

M-factor: -

Acute toxicity (oral): > 2000 mg/kg Acute toxicity (dermal): > 2000 mg/kg Acute toxicity (inhalative): 2000 mg/kg

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate	84434-11-7	LD50 oral (rat) >5000 mg/kg
		LD50 dermal (rat) >=2000 mg/kg
2-phenoxyethyl methacrylate	10595-06-9	LD50 oral (rat) 5000 mg/kg
		LD50 dermal (rat) 2000 mg/kg
		NOAEL (rat) 200 mg/kg bw/Tag
		NOAEL STOT-RE (rat) 350 mg/kg/d

Skin corrosion/irritation:

Frequently or prolonged contact with skin may cause dermal irritation.

Serious eye damage/irritation:

Irritating to eyes.

Respiratory of skin sensitisation:

May cause sensitization especially in sensitive humans.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity: No information available.

Germ cell mutagenicity: No information available.

Reproductive toxicity:

Category 2 (EU): Materials that shout be regarded to be reproductive hazards (fetal development hazards).

STOT-single exposure:

No information available.

STOT-repeated exposure:

No information available.

Aspiration hazard:

May cause sensitisation especially in sensitive humans.

SECTION 12: Ecological Information

12.1. Toxicity

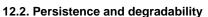
There are no data available on the preparation/mixture itself.

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Ethyl phenyl(2,4,6-trimethylbenzoyl)	84434-11-7	LC50 (fish, 96 h) 1,89 mg/l
phosphinate		EC50 (aquatic invertebrates, 48 h) 2,26 mg/l
		EC50 (algae, 72 h) 1,01 mg/l
		EC50 (microorganisms, 3 h) > 1g/l
2-phenoxyethyl methacrylate	10595-06-9	LC50 (Daphnia, 48 h) 1,21 mg/l
		EC50 Algae (Desmodesmus subspicatus) 72 h 4,44 mg/l
		- · · · · · · ·

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There are no data available on the mixture itself.

<u>12.3. Bioaccumulative potential</u> There are no data available on the mixture itself.

12.4. Mobility in soil

There are no data available on the mixture itself.

12.5. Results of PBT an vPvB assessment

There are no data available on the mixture itself.

12.6. Endocrine disruptive effect

There are no data available on the mixture itself.

12.7. Other adverse effects

There are no data available on the mixture itself.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Appropriate disposal / Product:

Dispose of waste according to applicable legislation. Waste disposal according to directive 2008/98/EC, covering waste and dangerous waste. Must not be disposed together with household garbage.

Appropriate disposal / Package

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

List of proposed waste codes/waste designations in accordance with EWC / AVV

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

SECTION 14: Transport Information

Alh

14.1 UN number UN No.: 3082

14.2 UN proper shipping name Landtransport (ADR/RID) UMWELTGEFÄHRDENDER STOFF, FLÜSSIG, N.A.G.

Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR) ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID N.O.S

14.3 Transport hazard class(es) Hazard label(s) / Label: 9 Classification Code: M6



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Ally,

14.4. Packing group Packing Group: III

14.5 Environmental hazards

ADR/RID / IMDG / ICAO_TI / IATA-DGR: Marine pollutant:

 14.6. Special precautions for user

 Land transport (ADR/RID)

 Transport category:
 3

 Special provisions:
 274, 335, 375, 601

 Tunnel restriction code:

 Limited quantity (LQ):
 5L

Sea transport (IMDG)EmS-No:F-A, S-FSpecial provisions:274 335 969Limited quantity (LQ):5L

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Remark -

SECTION 15: Regulatory Information

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

EU legislation

Information on Regulation (EC) No 166/2006 establishing a European Pollutant Release and Transfer Register:

No

X □

Yes

Х

Regulation (EC) No. 1005/2009 on substances that lead to the depletion of the ozone layer:

Regulation (EC) No. 648/2004 (Detergents regulation)

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

Regulation (EC) No. 649/2012 on the export and import of dangerous chemicals:

Use restriction according to REACH annex XVII, no.:

National regulatory information Observe in addition any national regulations!

Restrictions of occupation none

Other regulations, restrictions and prohibition regulations

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15.2. Chemical Safety Assessment

For this preparation a chemical safety assessment has been carried out. nein For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other Information

Relevant H- and EUH-phrases (number and full text) Hazard statements

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H361d Suspected of damaging the unborn child.

H411 Toxic to aquatic life with long lasting effects.

Training advice

Observe instructions for use.

Recommended restrictions of use:

Refer to chapter 1

Further information

The above information provided in this safety data sheet is correct to the best of our knowledge at the time of printing. The information is intended to provide guidance on the safe handling of the product specified in this safety data sheet during storage, processing, transport and disposal. The information is not transferable to other products. Insofar as the product is mixed, blended or processed with other materials or undergoes teatment, the information in this safety data sheet cannot be transferred to the new material thus produced, unless expressly stated otherwise.

Documentation of changes:

none

Key literature references and sources for data

Data arise from reference works and literature.

Abbreviations and acronyms

AC:	Artikelkategorie (Article Category)
ACGIH:	Rat für Arbeitsschutz und Gefahrstoffe, Amerika (American Conference of Government Industrial Hygienists)
ADN:	Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf Binnengewässern (Accord
	européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
ADR:	Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf der Straße (Accord européen
	relatif transport des merchandises dangereuses par route)
AGW:	Arbeitsplatzgrenzwert
AOX:	Adsorbierbare organisch gebundene Halogene (Adsorbable Organic halogen compounds
Bw:	Körpergewicht (Body weight)
CMR:	Stoffe klassifiziert als Krebserzeugend, Mutagen oder Reproduktionstoxisch (Carcinogenic, Mutagenic, toxic for
	Reproduction)
CSR:	Stoffsicherheitsbericht (Chemical Safety Report)
DIN:	Deutsches Institut für Normung / Deutsche Industrienorm
DNEL:	Grenzwert, unterhalb dessen der Stoff keine Wirkung ausübt (Derived No Effect Level)
DPD:	Zubereitungsrichtline / Richtline 1999-45-EC (Dangerous Preparations Directive)
DSD:	Stoffrichtlinie / Richtlinie 67-548-EC (Dangerous Substances Directive)
DU:	Nachgeschalteter Anwender (Downstream User)
EC50:	Wirksame Konzentration 50% (Effective Concentration 50%)
ECHA:	Europäische Chemikalienagentur
EN:	Europäische Norm
EWC/EWL:	Europäischer Abfallartenkatalog (European Waste Catalogue)
IATA:	Verband für den internationalen Lufttransport (International Air Transport Association)
IBC:	Großpackmittel (Intermediate Bulk Container)
ICAO:	Internationale Zivilluftfahrt-Organisation (International Civil Aviation Organization)
IMDG Code:	Gefahrgutvorschriften für den internationalen Seetransport (International Maritime Dangerous Goods Code)
IMO:	Internationale Seeschifffahrts-Organisation (International Maritime Organization)
ISO:	Internationale Normungsorganisation (International Standards Organisation)
LC50:	Lethale (Tödliche) Konzentration 50%
LD50:	Lethale (Tödliche) Dosis 50%
LEV:	Lokale Absaugung (Local exhaust ventilation)
MAK:	Maximale Arbeitsplatzkonzentration – DFG
	nicht anwendbar
n.a.:	



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OEL:	Arbeitsplatzgrenzwert (Occupational Exposure Limit)
PBT:	persistent, bioakkumlierbar, giftig (persistent, bioaccumulative, toxic)
PNEC:	Abgeschätzte Nicht-Effekt-Konzentration (Predicted No Effect Concentration
PPE/PSA:	Persönliche Schutzausrüstung (Personal Protective Equipment)
REACH:	Registrierung, Bewertung und Zulassung von Chemikalien (Registration, Evaluation and Authorization of Chemicals)
RID:	Gefahrgutvorschriften für den Transport mit der Eisenbahn (Règlement International concernant le transport de marchandises dangereuses par chemin de fer)
STEL:	Grenzwert für Kurzzeitexposition (Short-term Exposure Limit)
SVHC:	Stoff sehr hoher Besorgnis (Substance of Very High Concern)
TLV:	Arbeitsplatzgrenzwert (Threshold Limit Value)
VOC:	Flüchtige organische Kohlenwasserstoffe (Volatile Organic Compounds)
vPvB:	sehr persistent, sehr bioakkumulierbar (very persistent, very bioaccumulative)