Tradename:

IMPRIMO® LC Splint



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

1.1. Product identifier

Name of product: IMPRIMO® LC Splint

UFI: SNNX-K48T-FT31-NXDW

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.-No. +49 (0) 2374/ 9288-0 Fax-No. +49 (0) 2374/ 9288-90

Manufacturer

pro3dure medical GmbH Am Burgberg 13 D-58642 Iserlohn

Email: service@SCHEU-DENTAL.com

Internet: www.SCHEU-DENTAL.com

Telephone: +49 (0)2374 920050-10 Telefax: +49 (0)2374 920050-50

E-Mail (fachkundige Person) info@pro3dure.com

Webseite: www.pro3dure.com

1.4. Emergency telephone number: +49 (2374) 920050-10

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 [CLP]

Skin Irrit. 2, H315 Eye Irrit. 2, H319

Skin Sens. 1/1A/1B, H317

STOT SE 3, H335

2.2. Label elements

Signal word: Warning Pictograms: GHS07



Hazard statements

H315	Causes skin irritation		
H317	May cause an allergic skin reaction.		
H319	Causes serious eye irritation		
H335	May cause respiratory irritation.		

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Precautionary statements

Frecautionary Statem	icito
P261	Avoid breathing dust/fume/gas/mist/vapours/spray
P264	Wash thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+352	IF ON SKIN: Wash with plenty of water/soap.
P304+340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+351+338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present
	and easy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor if you feel unwell.
P321	Specific treatment (see label).
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.
P403+233	Store in a well-ventilated place. Keep container tightly closed.
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)	
Esterification products of 4,4'- isopropylidenediphenol, ethoxylated and 2- methylprop-2-enoic acid	41637-38-1		80 - 100	Skin Irrit. 2, H315; Skin Sens. 1/1A/1B, H317; Eye Irrit. 2, H319; STOT SE 3, H335	ATE (dermal) = 2000 ATE (oral) = 2000 ATE (inhalativ) = Kein Wert ermittelbar
Diphenyl(2,4,6 trimethylbenzoyl)phosphin oxid	75980-60-8		< 03	Repr. 2, H361; Skin Sens. 1/1A/1B, H317; Aquatic Chronic 2, H411	ATE (dermal) = 2000 ATE (oral) = 5000 ATE (inhalativ) = 2000

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General Information: In case of accident or unwellness, seek medical advice immediately. Take off immediately

all contaminated clothing.

In case of inhalation: Provide fresh air. Seek medical attention if problems persist. 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 rinse immediately with plenty of flowing water for 10 to 15

minutes holding eyelids apart. Consult an ophthalmologist.

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After ingestion: Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Seek medical

attention if problems persist.

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

May cause sensitization by skin contact.

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

ABC-powder. Alcohol resistant foam. BC-powder. Carbon dioxide (CO2). Sand.

Unsuitable extinguishing media

Water spray jet. Excess water. Full water 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 jet 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

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

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.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

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

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Hints on joint storage

Do not store together with: Oxidizing agent. Keep away from food, drink and animal feedingstuffs.

7.3 Specific end use(s)

Observe instructions for use.

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

occupational exposure limit value

occupationa	occupational exposure infilt value						
Substance	CAS-No.	Source	Occupational	Occupational	Limitation of	Remark:	
			exposure	exposure	exposure		
			limit value:	limit value:	peaks:		
			[maga]	[ma/m³]	•		

Substance with a common (EC) occupational exposure limit value

Substance	CAS-No.		Sour	ce	Occupational	Occupational	Limitation of	Remark:
					exposure	exposure	exposure	
					limit value:	limit value:	peaks:	
					[maga]	[ma/m³]		

DNEL/PNEC values

DNEL value

Substance:	CAS-No.:	DNEL/DMEL		
Esterification products of 4,4'- isopropylidenediphenol, ethoxylated and 2-methylprop- 2-enoic acid	41637-38-1	worker inhalative short-term, systemic 3,52 mg/m³ worker dermal short-term, systemic 2 mg/m3/24h population inhalative short-term, systemic 870 µg/m³ population dermal short-term, systemic 1 mg/m3/24h population short-term, systemic 500 µg/m3/24h		
Diphenyl(2,4,6- trimethylbenzoyl)phosphine 75980-6 oxide		worker inhalative long-term, systemic 0,822 mg/m³ worker dermal long-term, systemic 0,233 mg/kg bw/day population inhalative long-term, systemic 0,145 mg/m³ population dermal long-term, systemic 0,0833 mg/kg bw/day population oral long-term, systemic 0,0833 mg/kg bw/day		

PNEC-Wert

Substance:	CAS-No.:	PNEC
Diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide	75980-60-8	aquatic, freshwater 1,4 µg/l aquatic, marine water 0,14 µg/l sediment, freshwater 115 µg/kg dw sediment, marine water 11,5 µg/kg dw soil 22,2 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

Only wear fitting, comfortable and clean protective clothing.

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Respiratory protection

With correct an 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.

Eye/face protection

Eye glasses with side protection

Body protection:

For the protection against direct skin contact, body protective clothing is essential (in addition to the usual working clothes). Only wear fitting, comfortable and clean protective clothing. Barrier creams are not substitutes for body protection.

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

Appearance

Physical state:	Liquid			
Colour:	See product labeling			
Odour:	fruity			
Odour threshold:	No data available			

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:		500	mPa*s	20 °C
Water solubility (g/l):				
Partition coefficient: n-octanol/water:				No data available
Vapour pressure:				No data available
Density:		1,1	g/cm³	20 °C
Relative density:				No data available
Particle properties:				No data available

9.2. Other information

None

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

With proper storge and handling the product is stable.

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10.3. Possibility of hazardous reactions

Polymerization.

10.4. Conditions to avoid

Heat. Frost. UV-radiation/sunlight.

10.5. Incompatible materials

Can polymerise exothermically if heated, exposed to air, sunlight or by addition or free radical initiators.

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): -

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	LC50 inhalation (Rat) 2000 mg/ kg bw
		LD50 oral (rat) 5000 mg/kg bw
		LD50 dermal (rat) > 2000 mg/kg bw
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated	41637-38-1	LD50 oral (rat) 2000 mg/kg
and 2-methylprop-2-enoic acid		LD50 dermal (rat) 2000 mg/kg

Skin corrosion/irritation:

Frequently or prolonged contact with skin may cause dermal irritation.

Serious eye damage/irritation:

Irritant.

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:

No information available.

STOT-single exposure:

No information available.

STOT-repeated exposure:

No information available.

Aspiration hazard:

The inhalation of dust/mist or aerosols causes irritation of the respiratory tract.

SECTION 12: Ecological Information

12.1. Toxicity

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

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Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	EC50 (Daphnia, 48 h) 3,53 mg/l
		EC50 (algae, 72 h) > 2,01 mg/l
Esterification products of 4,4'-isopropylidenediphenol,	41637-38-1	LC50 oral (fish, 96h) 100 mg/l
ethoxylated		LC50 (crustaceans, 48 h) 6 mg/l
and 2-methylprop-2-enoic acid		EC50 (algae, 72 h) 100 mg/l

12.2. Persistence and degradability

There are no data available on the mixture itself.

12.3. Bioaccumulative potential

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

Land transport (ADR/RID)

14.1. UN number:	
14.2. UN proper shipping name:	
14.3. Transport hazard class(es):	
14.4. Packing group:	
Hazard label:	No hazardous material according to transport regulations.
Classification code:	
Special Provisions:	
Limited quantity:	
Transport category:	
Hazard No:	
Tunnel restriction code:	
Other applicable information (land transport)	

Inland waterways transport (ADN)

14.1. UN number:	
14.2. UN proper shipping name:	
14.3. Transport hazard class(es):	
14.4. Packing group:	No hazardous material according to transport regulations.
Hazard label:	

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Classification code:
Spezial Provisions:
Limited quantity:
Other applicable information
(inland waterways transport)

Marine transport (IMDG)

14.1. UN number:	
14.2. UN proper shipping name:	
14.3. Transport hazard class(es):	
14.4. Packaging group:	No hazardous material according to transport regulations.
Hazard label:	
Special Provisions::	
Limited quantity:	
EmS:	
Other applicable information (marine transport):	

Air transport (ICAO)

14.1. UN number:	
14.2. UN proper shipping name:	
14.3. Transport hazard class(es):	
14.4. Packaging group:	No hazardous material according to transport regulations.
Hazard label:	
Special Provisions:	
Limited quantity Passenger:	
IATA-packing instructions - Passenger:	
IATA-max. quantity - Passenger:	
IATA-packing instructions - Cargo:	
IATA-max. quantitiy - Cargo:	
Other applicable information (air transport)	
Passenger-LQ:	

14.5. Environmental hazards

ADR/RID / IMDG / ICAO-TI / IATA-DGR: no

Marine pollutant: no

14.6. Special precautions for user

Land transport (ADR/RID)

Transport category: Special provisions: Tunnel restriction code: Limited quantity (LQ): -

Sea transport (IMDG)

EmS-No: -

Special provisions: -Limited quantity (LQ): -

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

Remark none

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:

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

-

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

-

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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

-

15.2. Chemical Safety Assessment

For this preparation a chemical safety assessment has been carried out. -

Chemical safety assessments for substances in this mixture hat 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.

H335 May cause respiratory irritation.

Training advice

Observe instructions for use.

Recommended restrictions of use:

Refer to chapter 1

Further information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

Key literature references and sources for data

Data arise from reference works and literature.

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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

n.a.: nicht anwendbar

n.b.: nicht bestimmt

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 bioaccumulativ