

## Safety Data Sheet

according to UK REACH Regulation

### CreaPRINT Splint Flex

Revision date: 10.06.2022

Product code: CreaSplintFlex

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

### 1.1. Product identifier

CreaPRINT Splint Flex

UFI: H5AP-DJ6A-AJHE-9FPX

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

#### Use of the substance/mixture

Material for the manufacture of dental medical devices.

### 1.3. Details of the supplier of the safety data sheet

Company name:	Merz Dental GmbH	
Street:	Kieferweg 1	
Place:	D-24321 Lütjenburg (GERMANY)	
Telephone:	+49-(0)4381-403-0	Telefax: +49-(0)4381-403-100
e-mail:	info@merz-dental.de	
Contact person:	Dipl. Chem Dr. Thomas Panther	Telephone: +49-(0)4381-403-448
e-mail:	Thomas.Panther@merz-dental.de	
Internet:	www.merz-dental.de	
Responsible Department:	Qualitätssicherung (Quality Assurance)	

**1.4. Emergency telephone number:** +49-(0)551-19240 (Giftinformationszentrum-Nord)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### GB CLP Regulation

Acute Tox. 4; H332  
Skin Sens. 1; H317  
Aquatic Chronic 2; H411

Full text of hazard statements: see SECTION 16.

### 2.2. Label elements

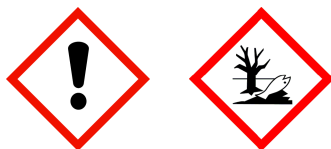
#### GB CLP Regulation

##### Hazard components for labelling

2-[[[butylamino)carbonyl]oxy]ethyl acrylate  
Diuurethane dimethacrylate, Mix of isomers (UDMA)  
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)  
Stabilisator

**Signal word:** Warning

**Pictograms:**



#### Hazard statements

H317	May cause an allergic skin reaction.
H332	Harmful if inhaled.
H411	Toxic to aquatic life with long lasting effects.

#### Precautionary statements

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.

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P333+P313  
P362+P364If skin irritation or rash occurs: Get medical advice/attention.  
Take off contaminated clothing and wash it before reuse.**2.3. Other hazards**

No information available.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Chemical characterization**

Light-curing (meth-)acrylate mixture

**Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate			5 - < 50 %
	Skin Irrit. 2, Eye Irrit. 2; H315 H319			
72869-86-4	Diurethane dimethacrylate, Mix of isomers (UDMA)			5 - < 50 %
	Skin Sens. 1, Aquatic Chronic 3; H317 H412			
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)			1 - < 5 %
	278-355-8	015-203-00-X		
	Repr. 2, Skin Sens. 1, Aquatic Chronic 2; H361f H317 H411			
	Stabilisator			0.1 - < 1 %
	Eye Irrit. 2, Skin Sens. 1, Aquatic Chronic 2; H319 H317 H411			
131-57-7	Oxybenzone			0.1 - < 1 %
	Aquatic Acute 1, Aquatic Chronic 2; H400 H411			

Full text of H and EUH statements: see section 16.

**Specific Conc. Limits, M-factors and ATE**

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
63225-53-6		2-[[[(butylamino)carbonyl]oxy]ethyl acrylate	5 - < 50 %
	dermal: LD50 = > 2000 mg/kg; oral: LD50 = > 2000 mg/kg		
75980-60-8	278-355-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)	1 - < 5 %
	dermal: LD50 = > 2000 mg/kg; oral: LD50 = > 5000 mg/kg		
131-57-7		Oxybenzone	0.1 - < 1 %
	oral: LD50 = 12800 mg/kg		

**SECTION 4: First aid measures****4.1. Description of first aid measures****After inhalation**

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

**After contact with skin**

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse.

**After contact with eyes**

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.



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#### After ingestion

Rinse mouth immediately and drink 1 glass of water.

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

No information available.

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

Treat symptomatically.

### SECTION 5: Firefighting measures

#### **5.1. Extinguishing media**

##### **Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

#### **5.3. Advice for firefighters**

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

#### **Additional information**

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately.

Do not allow entering drains or surface water.

### SECTION 6: Accidental release measures

#### **6.1. Personal precautions, protective equipment and emergency procedures**

##### **General advice**

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

#### **6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

#### **6.3. Methods and material for containment and cleaning up**

##### **For cleaning up**

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

##### **Other information**

Absorb with liquid-binding material (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**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

##### **Advice on protection against fire and explosion**

No special fire protection measures are necessary.

##### **Advice on general occupational hygiene**

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

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#### Further information on handling

Sensitivity to light (photosensitive).

#### 7.2. Conditions for safe storage, including any incompatibilities

##### Requirements for storage rooms and vessels

Sensitivity to light (photosensitive). Keep container tightly closed. Heat (> 30 °C) or UV light should be avoided in order to prevent a spontaneous and explosive polymerisation and also to prevent the accompanying generation of heat. none UV-radiation/sunlight. Can polymerise exothermically if heated, exposed to air, sunlight or by addition of free radical initiators. Avoid high temperatures or direct sunlight.

##### Hints on joint storage

No special measures are necessary.

#### 7.3. Specific end use(s)

Material for the manufacture of dental medical devices.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

#### 8.2. Exposure controls



#### Individual protection measures, such as personal protective equipment

##### Eye/face protection

Wear eye/face protection.

##### Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

##### Skin protection

Use of protective clothing.

##### Respiratory protection

In case of inadequate ventilation wear respiratory protection.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	colourless
Odour:	characteristic

#### Test method

##### Changes in the physical state

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	215 - 235 °C EEC A.2
Flash point:	> 95 °C ASTM D 7094

##### Flammability

Solid/liquid: not applicable



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Gas: not applicable

#### Explosive properties

The product is not: Explosive.

Auto-ignition temperature: 410 °C

Decomposition temperature: not determined

Viscosity / dynamic: 700 mPa·s DIN 3219

#### Solubility in other solvents

not determined

Partition coefficient n-octanol/water: not determined

Vapour pressure:  
(at 20 °C) 0,000232 hPaDensity: 1,1 g/cm<sup>3</sup>

Bulk density: ISO 1183 (A)

Relative vapour density: not determined

#### 9.2. Other information

##### Information with regard to physical hazard classes

Sustaining combustion: Not sustaining combustion

Oxidizing properties

The product is not: oxidising.

##### Other safety characteristics

Solid content: not determined

Evaporation rate: not determined

##### Further Information

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

#### 10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

#### 10.3. Possibility of hazardous reactions

In the presence of radical formers (e.g. peroxides, persulfates), reducing or oxidising substances and/or heavy metal ions and other polymerisation initiators as well as polymethyl methacrylates (polymer powder), polymerisation takes place under heat generation.

#### 10.4. Conditions to avoid

UV-radiation/sunlight.

#### 10.5. Incompatible materials

No information available.

#### 10.6. Hazardous decomposition products

No known hazardous decomposition products.

### SECTION 11: Toxicological information

#### 11.1. Information on hazard classes as defined in GB CLP Regulation

##### ATEmix calculated

ATE (inhalation dust/mist) 3,061 mg/l

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#### Acute toxicity

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate				
	oral	LD50 > 2000 mg/kg	Rat oral	Lieferant	OECD 401
	dermal	LD50 > 2000 mg/kg	Rabbit oral	Lieferant	OECD 402
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)				
	oral	LD50 > 5000 mg/kg	Rat	REACH Dossier	OECD 401
	dermal	LD50 > 2000 mg/kg	Rat	REACH Dossier	OECD 402
131-57-7	Oxybenzone				
	oral	LD50 12800 mg/kg	Rat	ECHA Dossier	OECD 401

#### Additional information on tests

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

### SECTION 12: Ecological information

#### 12.1. Toxicity

Toxic to aquatic life with long lasting effects.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate					
	Acute fish toxicity	LC50 3348 mg/l	96 h	Pimephales promelas (fathead minnow)	EpiSuite QSAR tool	Quantitative structure-activity relationship (QSAR)
	Acute algae toxicity	ErC50 0,294 mg/l		Pseudokirchneriella subcapitata s.	EpiSuite QSAR tool	Quantitative structure-activity relationship (QSAR)
	Acute crustacea toxicity	EC50 7306 mg/l	48 h	Daphnia magna (Big water flea)	EpiSuite QSAR tool	Quantitative structure-activity relationship (QSAR)
72869-86-4	Diurethane dimethacrylate, Mix of isomers (UDMA)					
	Acute fish toxicity	LC50 10,1 mg/l	96 h	Danio rerio (zebrafish)	Merck	OECD 203
131-57-7	Oxybenzone					
	Acute algae toxicity	ErC50 0,47 mg/l	72 h		ECHA Dossier	

#### 12.2. Persistence and degradability

The product has not been tested.

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CAS No	Chemical name	Method	Value	d	Source
		Evaluation			
72869-86-4	Diurethane dimethacrylate, Mix of isomers (UDMA)				
	OECD 301 B		22%	28	Merck
	Not readily biodegradable (according to OECD criteria)				
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)				
	OECD 301B/ ISO 9439/ EEC 92/69V, C.4-C		0 - 10 %	28	REACH Dossier
	Not readily biodegradable (according to OECD criteria)				

**12.3. Bioaccumulative potential**

The product has not been tested.

**Partition coefficient n-octanol/water**

CAS No	Chemical name	Log Pow
63225-53-6	2-[[[butylamino]carbonyl]oxy]ethyl acrylate	1.82
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)	3,1

**BCF**

CAS No	Chemical name	BCF	Species	Source
63225-53-6	2-[[[butylamino]carbonyl]oxy]ethyl acrylate	7,325	n/n	EpiSuite QSAR tool
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)	18 -55	Cyprinus carpio (Common Carp)	REACH Dossier
131-57-7	Oxybenzone	36 -158		

**12.4. Mobility in soil**

The product has not been tested.

**12.5. Results of PBT and vPvB assessment**

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

The product has not been tested.

**12.6. Endocrine disrupting properties**

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

**12.7. Other adverse effects**

No information available.

**Further information**

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

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Disposal recommendations**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

**List of Wastes Code - residues/unused products**

070208 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; other still bottoms and reaction residues; hazardous waste

**List of Wastes Code - used product**

070208 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; other still bottoms and reaction residues; hazardous waste



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#### Contaminated packaging

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

### SECTION 14: Transport information

#### Land transport (ADR/RID)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

#### Inland waterways transport (ADN)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

#### Marine transport (IMDG)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

#### Air transport (ICAO-TI/IATA-DGR)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

#### 14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

#### 14.6. Special precautions for user

No information available.

#### 14.7. Maritime transport in bulk according to IMO instruments

not applicable

### SECTION 15: Regulatory information

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

##### EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Information according to 2012/18/EU (SEVESO III): E2 Hazardous to the Aquatic Environment

##### National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 3 - highly hazardous to water

Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

#### 15.2. Chemical safety assessment

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

### SECTION 16: Other information





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#### Changes

This data sheet contains changes from the previous version in section(s): 1,4,7,9,11.

#### Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service  
LC50: Lethal concentration, 50%  
LD50: Lethal dose, 50%  
CLP: Classification, labelling and Packaging  
REACH: Registration, Evaluation and Authorization of Chemicals  
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals  
UN: United Nations  
DNEL: Derived No Effect Level  
DMEL: Derived Minimal Effect Level  
PNEC: Predicted No Effect Concentration  
ATE: Acute toxicity estimate  
LL50: Lethal loading, 50%  
EL50: Effect loading, 50%  
EC50: Effective Concentration 50%  
ErC50: Effective Concentration 50%, growth rate  
NOEC: No Observed Effect Concentration  
BCF: Bio-concentration factor  
PBT: persistent, bioaccumulative, toxic  
vPvB: very persistent, very bioaccumulative  
RID: Regulations concerning the international carriage of dangerous goods by rail  
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)  
EmS: Emergency Schedules  
MFAG: Medical First Aid Guide  
ICAO: International Civil Aviation Organization  
MARPOL: International Convention for the Prevention of Marine Pollution from Ships  
IBC: Intermediate Bulk Container  
VOC: Volatile Organic Compounds  
SVHC: Substance of Very High Concern  
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>  
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

#### Key literature references and sources for data

supplier (manufacturer/importer/downstream user/distributor)  
ECHA

#### Classification for mixtures and used evaluation method according to GB CLP Regulation

Classification	Classification procedure
Acute Tox. 4; H332	Calculation method
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 2; H411	Calculation method

#### Relevant H and EUH statements (number and full text)

H315 Causes skin irritation.

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H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H361f	Suspected of damaging fertility.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

**Further Information**

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

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*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*