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

1.1. Product identifier

CreaPRINT Splint

Product group:	Endprodukt
UFI:	WWJU-W0C7-2TMC-H0DN

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

Skin Sens. 1; H317
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

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

Signal word: Warning

Pictograms:

Hazard statements

H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements

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

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

Special labelling of certain mixtures

EUH204 Contains isocyanates. May produce an allergic reaction.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Findings: Damage to mucous membranes in the nose at 400 ppm

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
72869-86-4	Diurethane dimethacrylate, Mix of isomers (UDMA)			50 - < 100 %
	Skin Sens. 1, Aquatic Chronic 3; H317 H412			
63225-53-6	2-[[(butylamino)carbonyl]oxy]ethyl acrylate			5 - < 50 %
	Skin Irrit. 2, Eye Irrit. 2; H315 H319			
2082-81-7	1,4-Butandiol dimethacrylate			5 - < 50 %
	218-218-1			
	Acute Tox. 4, STOT SE 3; H302 H336			
	urethane acrylate inpolyether polyol tetraacrylate			1 - < 5 %
	Skin Irrit. 2, Eye Irrit. 2, Aquatic Chronic 2; H315 H319 H411			
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			1 - < 5 %
	Eye Irrit. 2, Skin Sens. 1, Aquatic Chronic 2; H319 H317 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		
2082-81-7	218-218-1	1,4-Butandiol dimethacrylate	5 - < 50 %
	oral: ATE = 500 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		

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

IF ON SKIN: Wash with plenty of soap and water. 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.

After ingestion

Rinse mouth immediately and drink 1 glass of 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

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

No special measures are necessary.

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.

Further information on handling

Sensitivity to light (photosentive).

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Sensitivity to light (photosentive). 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 or free radical initiators. Avoid high temperatures or direct sunlight.

Hints on joint storage

No special measures are necessary.

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:	243-265 °C	EEC A.2
Flash point:	155 °C	ASTM D 7094
Flammability		
Solid/liquid:	not applicable	
Gas:	not applicable	

Explosive properties

The product is not: Explosive.

Self-ignition temperature

Solid:	not applicable	
Gas:	not applicable	
Decomposition temperature:	not determined	
Viscosity / dynamic:	850 mPa·s	DIN 3219

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:	not determined	
Vapour pressure: (at 20 °C)	0,001 hPa	
Density:	1,099 g/cm³	EEC A.3

9.2. Other information

Information with regard to physical hazard classes

Oxidizing properties

Not oxidising.

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

IIn 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

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
2082-81-7	1,4-Butandiol dimethacrylate				
	oral	ATE 500 mg/kg			0133
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

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

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] | [d]	Species	Source	Method
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
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)
2082-81-7	1,4-Butandiol dimethacrylate					
	Acute fish toxicity	LC50 12,4 mg/l	96 h	n/n	REACH Dossier	Quantitative structure-activity relationship (QSAR)
	Acute algae toxicity	ErC50 9,79 mg/l	72 h	Desmodesmus subspicatus	REACH Dossier	OECD 201
	urethane acrylate inpolyether polyol tetraacrylate					
	Acute fish toxicity	LC50 1,76 mg/l	96 h		Rahn	
	Acute algae toxicity	ErC50 76,3 mg/l	72 h		Rahn	
	Acute crustacea toxicity	EC50 90,94 mg/l	48 h		Rahn	

12.2. Persistence and degradability

The product has not been tested.

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)			
2082-81-7	1,4-Butandiol dimethacrylate			
	OECD 310; Headspace Test and CO2	24 %	28	REACH Dossier
	Biodegradable.			
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)			
	OECD 301B/ ISO 9439/ EEC 92/69/V, 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
2082-81-7	1,4-Butandiol dimethacrylate	3,1
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

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

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)

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

Inland waterways transport (ADN)

14.1. UN number or ID number: No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name: No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.
14.4. Packing group: No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

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

Air transport (ICAO-TI/IATA-DGR)

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

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

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.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,2,4,5,6,9,15,16.

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

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
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H361f	Suspected of damaging fertility.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH204	Contains isocyanates. May produce an allergic reaction.

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.

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