

Safety Data Sheet

according to UK REACH Regulation

M-PRINT SurgicalGuide HT

Revision date: 27.07.2023

Product code: SGuideHT

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

1.1. Product identifier

M-PRINT SurgicalGuide HT

UFI: K1FQ-Y4MF-6MHD-MH3M

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 Luetjenburg (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:	Qualitaetssicherung (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
STOT SE 3; H335
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)
ethylene dimethacrylate
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)
Stabilisator

Signal word: Warning

Pictograms:



Hazard statements

H317	May cause an allergic skin reaction.
H335	May cause respiratory irritation.
H412	Harmful 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+P364

 If 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

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 %
	276-957-5			
	Skin Sens. 1, Aquatic Chronic 3; H317 H412			
97-90-5	ethylene dimethacrylate			5 - < 50 %
	202-617-2	607-114-00-5		
	Skin Sens. 1, STOT SE 3; H317 H335			
2082-81-7	1,4-butandiol dimethacrylate			5 - < 50 %
	218-218-1			
	Acute Tox. 4, STOT SE 3; H302 H336			
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			
52408-84-1	propoxylatedglycerol triacrylate			0.1 - < 1 %
	Eye Irrit. 2, Skin Sens. 1; H319 H317			
63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate			0.1 - < 1 %
	Acute Tox. 4, Skin Sens. 1A, Aquatic Chronic 2; H332 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		
97-90-5	202-617-2	ethylene dimethacrylate	5 - < 50 %
	oral: LD50 = 8700 mg/kg STOT SE 3; H335: >= 10 - 100		
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		
63225-53-6		2-[[[(butylamino)carbonyl]oxy]ethyl acrylate	0.1 - < 1 %
	inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); dermal: LD50 = > 2000 mg/kg; oral: LD50 = > 2000 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.

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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 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.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

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

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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.

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



Appropriate engineering controls

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

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:

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	Test method
Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	208 °C ASTM D 1120
Flammability:	not applicable not applicable
Flash point:	> 100 °C ASTM D 7094
Auto-ignition temperature:	290 °C
Decomposition temperature:	not determined
Solubility in other solvents	
not determined	
Partition coefficient n-octanol/water:	not determined
Vapour pressure:	0,01 hPa
(at 20 °C)	
Density:	1,097 g/cm ³ DIN 51757
Relative vapour density:	not determined

9.2. Other information**Information with regard to physical hazard classes**

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Evaporation rate:

not determined

Solid content:

not determined

Viscosity / dynamic:

650 mPa·s OECD 114

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**

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Acute toxicity

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
97-90-5	ethylene dimethacrylate				
	oral	LD50 mg/kg	8700	Rat	ECHA Dossier FDA (1959)
2082-81-7	1,4-butandiol dimethacrylate				
	oral	ATE mg/kg	500		0133
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)				
	oral	LD50 mg/kg	> 5000	Rat	REACH Dossier OECD 401
	dermal	LD50 mg/kg	> 2000	Rat	REACH Dossier OECD 402
63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate				
	oral	LD50 mg/kg	> 2000	Rat oral	Lieferant OECD 401
	dermal	LD50 mg/kg	> 2000	Rabbit oral	Lieferant OECD 402
	inhalation vapour	ATE	11 mg/l		
	inhalation dust/mist	ATE	1,5 mg/l		

11.2. Information on other hazards

Further information

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

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
2082-81-7	1,4-butandiol dimethacrylate					
	Acute fish toxicity	LC50 mg/l	12,4	96 h	n/n	REACH Dossier Quantitative structure-activity relationship (QSAR)
	Acute algae toxicity	ErC50 mg/l	9,79	72 h	Desmodesmus subspicatus	REACH Dossier OECD 201
63225-53-6	2-[[[butylamino]carbonyl]oxy]ethyl acrylate					
	Acute fish toxicity	LC50 mg/l	3348	96 h	Pimephales promelas (fathead minnow)	EpiSuite QSAR tool Quantitative structure-activity relationship (QSAR)
	Acute algae toxicity	ErC50 mg/l	0,294		Pseudokirchneriella subcapitata s.	EpiSuite QSAR tool Quantitative structure-activity relationship (QSAR)
	Acute crustacea toxicity	EC50 mg/l	7306	48 h	Daphnia magna (Big water flea)	EpiSuite QSAR tool Quantitative structure-activity relationship (QSAR)

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	ECHA	
	Not readily biodegradable (according to OECD criteria)				
97-90-5	ethylene dimethacrylate				
	OECD 301 F, GLP	69 %	28	ECHA Dossier	
	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
97-90-5	ethylene dimethacrylate	2,4
2082-81-7	1,4-butandiol dimethacrylate	3,1
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)	3,1
63225-53-6	2-[[[butylamino]carbonyl]oxy]ethyl acrylate	1.82

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CAS No	Chemical name	BCF	Species	Source
97-90-5	ethylene dimethacrylate	13,32	n.n.	EPIWIN Tool
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)	18 -55	Cyprinus carpio (Common Carp)	REACH Dossier
63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate	7,325	n/n	EpiSuite QSAR tool

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.

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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 dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

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):

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.

15.2. Chemical safety assessment

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

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,2,3,4,5,7,9,11,15,16.

Abbreviations and acronyms

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

CAS: Chemical Abstracts Service

DNEL: Derived No Effect Level

DMEL: Derived Minimal Effect Level

PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

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

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PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
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)
IMDG: International Maritime Code for Dangerous Goods
EmS: Emergency Schedules
MFA: Medical First Aid Guide
IATA: International Air Transport Association
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
Skin Sens. 1; H317	Calculation method
STOT SE 3; H335	Calculation method
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory 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.

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.)