according to Regulation (EC) No 1907/2006

artOpaque (Gum) PLUS

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

1.1. Product identifier

artOpaque (Gum) PLUS

Further trade names

- artOpaque O1
- artOpaque O2
- artOpaque O3
- artOpaque GUM

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

1.3. Details of the supplier of the safety data sheet

Company name:	Merz Dental GmbH		
Street:	Eetzweg 20		
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	+49-(0)551-19240 (Giftinformationszentrum-Nord)		

number:

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories: Skin corrosion/irritation: Skin Irrit. 2 Serious eye damage/eye irritation: Eye Irrit. 2 Respiratory or skin sensitisation: Skin Sens. 1 Hazard Statements: Causes skin irritation. Causes serious eye irritation. May cause an allergic skin reaction.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

1,4-butandiol dimethacrylate

TPO / Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide **nal word:** Warning

Signal word: Pictograms:



Hazard statements

H315	
H317	
H319	

Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation.

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Precautionary statem	ents	
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.	

If skin irritation or rash occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

P333+P313

P362+P364

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			
	EC No	Index No	REACH No	
	Classification according to Regulati	on (EC) No. 1272/2008 [CLP]		
2082-81-7	1,4-butandiol dimethacrylate			5 - < 50 %
	Skin Sens. 1B; H317	•		
63225-53 -6	Monofunctional aliphatic urethane a	acrylate		5 - < 50 %
	Skin Irrit. 2, Eye Irrit. 2; H315 H319			
10373-78-1	D,L-Campherchinon			1 - < 5 %
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3	; H315 H319 H335		
75980-60-8	TPO / Diphenyl(2,4,6-trimethylbenz		1 - < 5 %	
	278-355-8	015-203-00-X		
	Repr. 2, Skin Sens. 1, Aquatic Chro	onic 2; H361f H317 H411		

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

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 polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Rinse mouth immediately and drink plenty 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.

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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

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

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

No special measures are necessary.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Advice on storage compatibility

No special measures are necessary.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls



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Protective and hygiene measures

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.

Eye/face protection

Suitable eye protection: goggles.

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

Wear suitable 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:	ivory	
Odour:	characteristic	
pH-Value:		not determined
Changes in the physical state		
Melting point:		not determined
Initial boiling point and boiling range:		not determined
Flash point:		not determined
Flammability		
Solid:		not applicable
Gas:		not applicable
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Auto-ignition temperature		
Solid:		not applicable
Gas:		not applicable
Decomposition temperature:		not determined
Oxidizing properties		
Not oxidizing.		
Vapour pressure:		not determined
Density:		not determined
Water solubility:		insoluble
Solubility in other solvents not determined		
Partition coefficient:		not determined
Vapour density:		not determined
Evaporation rate:		not determined

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9.2. Other information

Solid content:

not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Revi

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

No known hazardous reactions.

10.4. Conditions to avoid

Heat

10.5. Incompatible materials

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
2082-81-7	1,4-butandiol dimethacryl	ate				
	oral	LD50 mg/kg	10066	Rat	REACH Dossier	OECD 401
	dermal	LD50 mg/kg	> 3000	Rabbit	REACH Dossier	not specified
63225- 53-6	Monofunctional aliphatic	urethane acryl	ate			
	oral	LD50 mg/kg	> 2000	Rat oral	Lieferant	OECD 401
	dermal	LD50 mg/kg	> 2000	Rabbit oral	Lieferant	OECD 402
10373-78-1	D,L-Campherchinon					
	oral	LD50 mg/kg	1500	Rat	EpiSuite QSAR tool	Quantitative structure-acivity relationship (QSAR)
75980-60-8	TPO / Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide					
	oral	LD50 mg/kg	> 5000	Rat	REACH Dossier	OECD 401
	dermal	LD50 mg/kg	> 2000	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

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12.1. Toxicity

The product is not: Ecotoxic.

CAS No	Chemical name	Chemical name							
	Aquatic toxicity	Dose		[h] [d]	Species	Source	Method		
2082-81-7	1,4-butandiol dimethacryl	ate							
	Acute fish toxicity	LC50 mg/l	5,861	96 h	Pimephales promelas (fathead minnow)	EpiSuite QSAR tool	Quantitative structure-acivity relationship (QSAR)		
63225- 53-6	Monofunctional aliphatic	urethane ac	rylate						
	Acute fish toxicity	LC50 mg/l	3348	96 h	Pimephales promelas (fathead minnow)	EpiSuite QSAR tool	Quantitative structure-acivity relationship (QSAR)		
	Acute algae toxicity	ErC50 mg/l	0,294		Pseudokirchneriella subcapitata s.	EpiSuite QSAR tool	Quantitative structure-acivity relationship (QSAR)		
	Acute crustacea toxicity	EC50 mg/l	7306	48 h	Daphnia magna (Big water flea)	EpiSuite QSAR tool	Quantitative structure-acivity relationship (QSAR)		
10373-78-1	D,L-Campherchinon								
	Acute fish toxicity	LC50 8 mg/l	1819,98	96 h	Pimephales promelas (fathead minnow)	EpiSuite QSAR tool	Quantitative structure-acivity relationship (QSAR)		
	Acute algae toxicity	ErC50 mg/l	425,108		Pseudokirchneriella subcapitata	EpiSuite QSAR tool	Quantitative structure-acivity relationship (QSAR)		
	Acute crustacea toxicity	EC50 mg/l	920,549	48 h	Daphnia magna (Big water flea)	EpiSuite QSAR tool	Quantitative structure-acivity relationship (QSAR)		

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name					
	Method	Value	d	Source		
	Evaluation					
2082-81-7	1,4-butandiol dimethacrylate					
	OECD 310 (Headspace Test)	76 - 92 %	28	REACH Dossier		
	Biodegradable.					
75980-60-8	TPO / Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide					
	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.

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Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
2082-81-7	1,4-butandiol dimethacrylate	3,1
63225-53-6	Monofunctional aliphatic urethane acrylate	1.82
10373-78-1	D,L-Campherchinon	1,52
75980-60-8	TPO / Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	3,1

BCF

CAS No	Chemical name	BCF	Species	Source
2082-81-7	1,4-butandiol dimethacrylate	59,21	n/n	EpiSuite QSAR tool
63225-53-6	Monofunctional aliphatic urethane acrylate	7,325	n/n	EpiSuite QSAR tool
10373-78-1	D,L-Campherchinon	4,76	n/n	EpiSuite QSAR tool
75980-60-8	TPO / Diphenyl(2,4,6-trimethylbenzoyl)phosph ine oxide	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 product has not been tested.

12.6. 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

Advice on disposal

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.

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)

Not restricted
Not restricted
Not restricted
Not restricted
Not restricted
Not restricted
Not restricted
Not restricted
Not restricted
Not restricted

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<u>14.3. Transport hazard class(es):</u>	Not restricted							
14.4. Packing group:	Not restricted							
Air transport (ICAO-TI/IATA-DGR)								
<u>14.1. UN number:</u>	Not restricted							
14.2. UN proper shipping name:	Not restricted							
14.3. Transport hazard class(es):	Not restricted							
14.4. Packing group:	Not restricted							
14.5. Environmental hazards								
ENVIRONMENTALLY HAZARDOUS:	no							
14.6. Special precautions for user No information available. 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code not applicable								
No information available.	x II of Marpol and the IBC Code							
No information available. <u>14.7. Transport in bulk according to Anne</u> not applicable SECTION 15: Regulatory information								
No information available. <u>14.7. Transport in bulk according to Anne</u> not applicable SECTION 15: Regulatory information	x II of Marpol and the IBC Code gulations/legislation specific for the substance or mixture	_						
No information available. 14.7. Transport in bulk according to Annel not applicable SECTION 15: Regulatory information 15.1. Safety, health and environmental reg								
No information available. 14.7. Transport in bulk according to Annel not applicable SECTION 15: Regulatory information 15.1. Safety, health and environmental reg EU regulatory information 2004/42/EC (VOC):	gulations/legislation specific for the substance or mixture							
No information available. 14.7. Transport in bulk according to Annernot applicable SECTION 15: Regulatory information 15.1. Safety, health and environmental regulatory information	gulations/legislation specific for the substance or mixture 10 % Observe restrictions to employment for juvenils according to the 'juvenile							
No information available. 14.7. Transport in bulk according to Annel not applicable SECTION 15: Regulatory information 15.1. Safety, health and environmental reg EU regulatory information 2004/42/EC (VOC): National regulatory information Employment restrictions: Water contaminating class (D):	gulations/legislation specific for the substance or mixture 10 % Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). 3 - highly water contaminating							
No information available. 14.7. Transport in bulk according to Annel not applicable SECTION 15: Regulatory information 15.1. Safety, health and environmental regulatory information 2004/42/EC (VOC): National regulatory information Employment restrictions:	gulations/legislation specific for the substance or mixture 10 % Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).							
No information available. 14.7. Transport in bulk according to Annel not applicable SECTION 15: Regulatory information 15.1. Safety, health and environmental reg EU regulatory information 2004/42/EC (VOC): National regulatory information Employment restrictions: Water contaminating class (D):	gulations/legislation specific for the substance or mixture 10 % Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). 3 - highly water contaminating							

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 2,6,7,9,10,16.

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

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H361f	Suspected of damaging fertility.
H411	Toxic to aquatic life with long lasting effects.

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Further Information

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

Data sources:

ECHA - https://echa.europa.eu/de/search-for-chemicals? ...

Quantitative structure-acivity relationship (QSAR) - Danish (Q)SAR Database, http://qsar.food.dtu.dk EPA Chemistry Dashboard - https://comptox.epa.gov/dashboard

Identified uses

No	Short title	LCS	SU	PC	PROC	ERC	AC	TF	Specification
	Werkstoff zur Herstellung zahntechnischer Laborprodukte	-	-	-	-	-	-	-	3
	LCS: Life cycle stages SU: Sectors of use								

PC: Product categories ERC: Environmental release categories TF: Technical functions SU: Sectors of use PROC: Process categories AC: Article categories

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