

according to UK REACH Regulation

Xthetic® prime

Revision date: 29.03.2023

Product code: 1-342

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

1.1. Product identifier

Product group:

UFI:

Xthetic® prime

Liquid component 77N8-9EVG-2602-J0GG

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

Use of the substance/mixture

Manufacture of dental products.

1.3. Details of the supplier of the safety data sheet

Company name:	AcrylX GmbH
Street:	Industriestraße 7
Place:	D-61191 Rosbach v.d.H.
Telephone:	+49 (0) 6007 - 9382 300
e-mail:	info@acrylx.com
Contact person:	Oliver Wesner
e-mail:	info@acrylx.com
Internet:	www.acrylx.com

Telefax: +49 (0) 6007 - 9382 390

Telephone: 320

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Flam. Liq. 2; H225 Skin Irrit. 2; H315 Skin Sens. 1; H317 STOT SE 3; H335

Full text of hazard statements: see SECTION 16.

Danger

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

Methyl methacrylate 1,4-Butandiol dimethacrylate

Signal word:

Pictograms:



Hazard statements

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H335	May cause respiratory irritation.

Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No
	smoking.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing
	protection.



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Xthetic® prime Revision date: 29.03.2023 Product code: 1-342 Page 2 of 10 P302+P352 IF ON SKIN: Wash with plenty of Water and soap. P333+P313 If skin irritation or rash occurs: Get medical advice/attention. P362+P364 Take off contaminated clothing and wash it before reuse. P370+P378 In case of fire: Use Foam, Extinguishing powder, Carbon dioxide (CO2) to extinguish. P403+P235 Store in a well-ventilated place. Keep cool. P501 Dispose of contents/container to as hazardous waste - in accordance with local and national legislation - suitable, approved incinerator for combustible organic waste.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture based on methyl methacrylate.

Hazardous components

CAS No	Chemical name				
	EC No	EC No Index No REACH No			
	Classification (GB CLP Regulation)				
80-62-6	Methyl methacrylate				
	201-297-1		01-2119452498-28		
	Flam. Liq. 2, Skin Irrit. 2, Skin Sens. 1, STOT SE 3; H225 H315 H317 H335				
2082-81-7	I-7 1,4-Butandiol dimethacrylate				
	218-218-1		01-2119967415-30		
	Skin Sens. 1; H317				

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

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name				
	Specific Conc. Limits, M-factors and ATE					
80-62-6	201-297-1	1-297-1 Methyl methacrylate				
	inhalation: LC mg/kg	:50 = 29,8 mg/l (vapours); dermal: LD50 = >5000 mg/kg; oral: LD50 = >5000				
2082-81-7	218-218-1	1,4-Butandiol dimethacrylate	5 - < 10 %			
	dermal: LD50	= > 3000 mg/kg; oral: LD50 = > 10000 mg/kg				

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Remove contaminated, saturated clothing immediately. If skin irritation or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention.

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. In case of skin irritation, consult a physician.

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.



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After ingestion

Do NOT induce vomiting. Rinse mouth. Call a physician immediately.

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

Causes skin irritation. May cause respiratory irritation. May cause an allergic skin reaction.

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

Carbon dioxide (CO2), Foam, Extinguishing powder

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

Highly flammable liquid and vapour. Can polymerise exothermically if heated, exposed to air, sunlight or by addition or free radical initiators. Vapours can form explosive mixtures with air.

5.3. Advice for firefighters

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

Additional information

Use water spray jet to protect personnel and to cool endangered containers. 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

Remove all sources of ignition. 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

When using do not eat, drink, smoke, sniff. Use only in well-ventilated areas. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking. Flammable vapours can accumulate in head space of closed systems. Take precautionary measures against static discharges. Vapours can form explosive mixtures with air.



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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

Caution! Transport usually takes place at temperatures above the flash point.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed in a cool, well-ventilated place.

Protect from direct sunlight.

Hints on joint storage

Do not store together with: Material, oxygen-rich, Oxidising. Pyrophoric or self-heating substances.

Further information on storage conditions

Keep away from heat.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
80-62-6	Methyl methacrylate	50	208		TWA (8 h)	WEL
		100	416		STEL (15 min)	WEL

DNEL/DMEL values

CAS No	Substance		_				
DNEL type		Exposure route	Effect	Value			
80-62-6	Methyl methacrylate						
Worker DNEL,	long-term	inhalation		208 mg/m ³			
Worker DNEL,	long-term	dermal		17 mg/kg bw/day			

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

Wear suitable protective gloves. To protect against splashes: butyl; EN 374. To protect against immersion: butyl; 0.7 mm or thicker, EN 374. The suitability of gloves should be agreed with the manufacturer. Change gloves in the event of contamination or if the breakthrough time is exceeded. Resistance of the glove material: see information from the glove manufacturer.

Skin protection

Flame-retardant protective clothing. Wear anti-static footwear and clothing

Respiratory protection

Wear suitable respiratory protection if technical measures are inadequate or not available and exposure is to be expected that exceeds the DNEL (derived exposure level below which the substance does not cause any harm to human health). A suitable breathing mask with filter type A (EN141 or EN405) is recommended. A self-contained breathing apparatus may be necessary if particularly high vapor concentrations are formed.



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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

9.1. Information on basic physical and	a chemical properties	
Physical state:	Liquid	
Colour:	colourless	
Odour:	characteristic	
Melting point/freezing point:		-48 °C
Boiling point or initial boiling point ar	nd	100,5 °C
boiling range:		
Flammability:		not applicable
		not applicable
Lower explosion limits:		2,1 vol. %
Upper explosion limits:		12,5 vol. %
Flash point:		10 °C
Auto-ignition temperature:		421 °C
Decomposition temperature:		not determined
pH-Value:		not determined
Water solubility:		12,5 g/L
(at 20 °C)		-
Solubility in other solvents		
not determined		
Partition coefficient n-octanol/water:		1,38
Vapour pressure:		36 hPa
(at 20 °C)		
Density (at 15,5 °C):		0,949 g/cm ³
Relative vapour density:		3,5
(at 20 °C)		
9.2. Other information		
Information with regard to physica	I hazard classes	
Self-ignition temperature		
Solid:		not applicable
Gas:		not applicable
Oxidizing properties		
Not oxidising.		
Other safety characteristics		
Evaporation rate:		not determined
Solid content:		not determined
Viscosity / dynamic:		0,53 mPa∙s
(at 20 °C)		-,
. ,		

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable, Vapours can form explosive mixtures with air.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

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

10.4. Conditions to avoid

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. Can polymerise exothermically if heated, exposed to air, sunlight or by addition or free radical initiators. Protect from direct sunlight.



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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 hazard classes as defined in GB CLP Regulation

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix tested

	Dose	Species	Source
LD50, oral	7870 mg/kg	Rat	
LD50, dermal	> 5000 mg/kg	Rabbit	
LC50, inhalation (vapour) (4 h)	78 mg/l	Rat	

CAS No Chemical name

CAS NO										
	Exposure route	Dose		Species	Source	Method				
80-62-6	Methyl methacrylate	Methyl methacrylate								
	oral	LD50 mg/kg	>5000	Rat	OECD 401					
	dermal	LD50 mg/kg	>5000	Rabbit						
	inhalation vapour	LC50	29,8 mg/l	Rat						
2082-81-7	1,4-Butandiol dimethacry	/late								
	oral	LD50 mg/kg	> 10000	Rat						
	dermal	LD50 mg/kg	> 3000	Rabbit						

Irritation and corrosivity

Causes skin irritation.

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

Sensitising effects

May cause an allergic skin reaction. (Methyl methacrylate; 1,4-Butandiol dimethacrylate)

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

May cause respiratory irritation. (Methyl methacrylate)

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

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

Acute (short-term) fish toxicity



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CAS No	Chemical name							
	Aquatic toxicity	Dose		[h] [d]	Species	Source	Method	
80-62-6	Methyl methacrylate							
	Acute fish toxicity	LC50 mg/l	> 79	96 h	Oncorhynchus mykiss (Rainbow trout)	OECD 203		
	Acute algae toxicity	ErC50 mg/l	> 110	72 h	Selenastrum capricornutum	OECD 201		
	Acute crustacea toxicity	EC50	69 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202		
	Crustacea toxicity	NOEC	37 mg/l	21 d	Daphnia magna (Big water flea)	OECD 202		
2082-81-7	1,4-Butandiol dimethacryl	ate						
	Acute fish toxicity	LC50 mg/l	32,5	96 h	Oncorhynchus mykiss (Rainbow trout)			
	Acute crustacea toxicity	EC50 mg/l	7,51	48 h	Daphnia magna (Big water flea)	OECD 211		
	Crustacea toxicity	NOEC mg/l	7,51		Selenastrum capricornutum			

12.2. Persistence and degradability

Biodegradable.

12.3. Bioaccumulative potential

On the basis of existing data about the elimination/degradation and bioaccumulation potential longer term damage to the environment is unlikely.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
80-62-6	Methyl methacrylate	1,38
2082-81-7	1,4-Butandiol dimethacrylate	3,1

12.4. Mobility in soil

Mobility in soil: No adsoption in soil or sediment.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH. This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

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

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. 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.



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SECTION 14: Transport information

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Land transport (ADR/RID)		
14.1. UN number or ID number:	UN 1247	
14.2. UN proper shipping name:	METHYL METHACRYLATE MONOMER, STABILIZED	
14.3. Transport hazard class(es):	3	
14.4. Packing group:		
Hazard label:	3	
Classification code:	F1	
Limited quantity:	1 L	
Excepted quantity:	E2	
Transport category:	2	
Hazard No:	339	
Tunnel restriction code:	D/E	
Other applicable information (land trans SAPT: > 60 °C	port)	
Inland waterways transport (ADN)		
14.1. UN number or ID number:	UN 1247	
14.2. UN proper shipping name:	METHYL METHACRYLATE MONOMER, STABILIZED	
14.3. Transport hazard class(es):	3	
14.4. Packing group:	II	
Hazard label:	3	
Classification code:	F1	
Limited quantity:	1L	
Excepted quantity:	E2	
Other applicable information (inland wat SAPT: > 60 °C	terways transport)	
Marine transport (IMDG)		
14.1. UN number or ID number:	UN 1247	
14.2. UN proper shipping name:	METHYL METHACRYLATE MONOMER, STABILIZED	
14.3. Transport hazard class(es):	3	
14.4. Packing group:	II	
Hazard label:	3	
Special Provisions:	-	
Limited quantity:	1L	
Excepted quantity:	E2	
EmS:	F-E, S-D	
Other applicable information (marine transport) SAPT: > 60 °C		
Air transport (ICAO-TI/IATA-DGR)		
14.1. UN number or ID number:	UN 1247	
14.2. UN proper shipping name:	METHYL METHACRYLATE MONOMER, STABILIZED	
14.3. Transport hazard class(es):	3	
14.4. Packing group:	II	
Hazard label:	3	
Limited quantity Passenger:	1 L	
Passenger LQ:	Y-341	
Excepted quantity:	E2	
IATA-packing instructions - Passenger:	353	
IATA-max. quantity - Passenger:	5 L	
IATA-packing instructions - Cargo:	364	
IATA-max. quantity - Cargo:	60 L	



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Other applicable information (air transpo SAPT: > 60 °C	ort)		
14.5. Environmental hazards			
ENVIRONMENTALLY HAZARDOUS:	No		
 <u>14.6. Special precautions for user</u> Warning: Combustible liquids. <u>14.7. Maritime transport in bulk according t</u> not applicable 	o IMO instruments		
SECTION 15: Regulatory information			
15.1. Safety, health and environmental requ	lations/legislation specific for the substance or mixture		
EU regulatory information Restrictions on use (REACH, annex XVII) Entry 3, Entry 40			
2010/75/EU (VOC):	90 % (854,1 g/l)		
2004/42/EC (VOC):	90 % (854,1 g/l)		
Information according to 2012/18/EU (SEVESO III):	P5c FLAMMABLE LIQUIDS		
National regulatory information			
Employment restrictions:	Observe restrictions to employment for juveniles according to the 'juver work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.		
Water hazard class (D):	1 - slightly hazardous to water		
Skin resorption/Sensitization:	Causes allergic hypersensitivity reactions.		
15.2. Chemical safety assessment			
Chemical safety assessments for subs	stances in this mixture were not carried out.		

SECTION 16: Other information

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%

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

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data
Skin Irrit. 2; H315	Calculation method
Skin Sens. 1; H317	Calculation method
STOT SE 3; H335	Calculation method

Relevant H and EUH statements (number and full text)

Highly flammable liquid and vapour.

H225



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

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.

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