

Safety Data Sheet

according to UK REACH Regulation

Monomer: Promolux/Promolux HI

Revision date: 20.09.2022

Product code: D251_M

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

1.1. Product identifier

Monomer: Promolux/Promolux HI

Further trade names

- Promolux Monomer Liquid
- Promolux High Impact Monomer
- Promolux High Impact Liquid

UFI: 1W2M-KR71-XG80-Y4F4

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

+49-(0)551-19240 (Giftinformationszentrum-Nord)

number:

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.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

methyl methacrylate
1,4-butanediol dimethacrylate, Tetramethylene dimethacrylate

Signal word: Danger

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.

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Precautionary statements

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves and eye/face protection.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P403+P235	Store in a well-ventilated place. Keep cool.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Acrylate

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
80-62-6	methyl methacrylate			50 - < 100 %
	201-297-1	607-035-00-6	01-2119452498-28	
	Flam. Liq. 2, Skin Irrit. 2, Skin Sens. 1, STOT SE 3; H225 H315 H317 H335			
2082-81-7	1,4-butandiol dimethacrylate, Tetramethylene dimethacrylate			1 - < 5 %
	218-218-1			
	Skin Sens. 1B; H317			

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		
80-62-6	201-297-1	methyl methacrylate	50 - < 100 %
	inhalation: LC50 = 29,8 mg/l (vapours); dermal: LD50 = > 5000 mg/kg; oral: LD50 = 7872 mg/kg		
2082-81-7	218-218-1	1,4-butandiol dimethacrylate, Tetramethylene dimethacrylate	1 - < 5 %
	dermal: LD50 = > 3000 mg/kg; oral: LD50 = 10066 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. 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. In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

After ingestion

Observe risk of aspiration if vomiting occurs. Rinse mouth immediately and drink 1 glass of water.



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

Headache, Dizziness, Causes skin and eye irritation. Skin sensitisation.

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

Treat symptomatically. When in doubt or if symptoms are observed, get medical advice.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Carbon dioxide (CO₂), Foam, Extinguishing powder. Carbon dioxide (CO₂). Foam. Extinguishing powder.
Water spray jet

Unsuitable extinguishing media

Water.

5.2. Special hazards arising from the substance or mixture

Highly flammable. Vapours can form explosive mixtures with air. May be released in case of fire: carbon dioxide, organic products of decomposition.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit. Use water spray jet to protect personnel and to cool endangered containers.

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. Vapours are heavier than air and will spread at floor level.
Use non-sparking tools.
Do not allow to enter into surface water or drains.

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. Avoid contact with skin, eyes and clothes. Wear protective gloves/protective clothing and eye/face protection.

6.2. Environmental precautions

Do not allow uncontrolled discharge of product into the environment. Explosion risk.
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

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Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray. Keep container tightly closed. Ensure adequate ventilation of the storage area.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges. Vapours can form explosive mixtures with air. Keep away from sources of ignition - No smoking.

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

Further information on handling

Put lids on containers immediately after use. Always close containers tightly after the removal of product. Keep cool. Protect from sunlight.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations. Keep in a cool, well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Store in a cool dry place. Protect from sunlight. Proceed with caution when dealing with emptied containers. In case of ignition, explosions are possible.

Hints on joint storage

Do not store together with: Oxidizing agent. Pyrophoric or self-heating substances.

7.3. Specific end use(s)

Material for the manufacture of dental medical devices.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	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	Exposure route	Effect	Value
80-62-6	methyl methacrylate			
Worker DNEL, long-term		inhalation	local	210 mg/m ³
Worker DNEL, long-term		dermal	systemic	13,67 mg/kg bw/day

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PNEC values

CAS No	Substance	
Environmental compartment		Value
80-62-6	methyl methacrylate	
Freshwater		< 0,94 mg/l
Marine water		< 0,94 mg/l
Soil		-----
Air		-----

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.

For exposure monitoring, the following may be used: direct-reading Photo Ionisation Detector Dosimeters (e.g. ToxiRAE made by Ansyc), short-term measuring tubes for methyl acrylate (e.g. made by Dräger) or pumps with adsorption tubes, and subsequent GC analysis by an accredited institute.

Measuring method: - OSHA 94 - NIOSH 2537 - DIN EN 482 - DIN EN 689

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. Protective gloves made from butyl rubber (impermeable up to 60 min with material thickness of >0.5mm; EN 374), nitrile (impermeable up to 10 min with material thickness of >0.33mm); natural latex (impermeable up to 10 min with material thickness of >1mm). Since abnormal conditions often arise in practice, these details can only be an orientation guide when choosing suitable chemical protective gloves. In particular, these details do not replace any suitability tests carried out by the end-consumer.

General information:

Protective gloves should be changed regularly, particularly after intensive contact with the product. A suitable type of glove must be selected for each work place.

Protect skin by using skin protective cream.

Skin protection

Wear safety working clothes (lab coat) and closed shoes. .

Wear anti-static footwear and clothing

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Respiratory protection necessary at: high concentrations (air limit values) (Methyl methacrylate)

In case of fire: Wear self-contained breathing apparatus.

Thermal hazards

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

Environmental exposure controls

Do not allow to enter into surface water or drains.

Do not allow to enter into soil/subsoil.

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SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state:	Liquid	
Colour:	colourless	
Odour:	characteristic	
		Test method
Melting point/freezing point:	not applicable	
Boiling point or initial boiling point and boiling range:	100 °C	calculated.
Flammability:	not applicable	
	not applicable	
Lower explosion limits:	2,1 vol. %	
Upper explosion limits:	12,5 vol. %	
Flash point:	10 °C	calculated.
Auto-ignition temperature:	430 °C	calculated.
Water solubility:	ca. 16 g/L	
Solubility in other solvents		
not determined		
Partition coefficient n-octanol/water:	not determined	
Vapour pressure:	37 hPa	calculated.
(at 20 °C)		
Density:	0,94 g/cm ³	calculated.
Relative vapour density:	not determined	

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

The product is not: Explosive.

Sustaining combustion:

No data available

Oxidizing properties

Not oxidising.

Other safety characteristics**Viscosity / dynamic:**

ca. 0,6 mPa·s

SECTION 10: Stability and reactivity**10.1. Reactivity**

Highly flammable.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

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

> 125mL:

With strong oxidants, e.g. peroxides - strong exothermic reactions, heat generation and risk of ignition or emergence of flammable gases or vapours.

10.4. Conditions to avoid

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. Vapours can form explosive mixtures with air. UV-radiation/sunlight.

10.5. Incompatible materials

Free radical initiators

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Reducing agent

Tertiary amines

Heavy metals

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.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
80-62-6	methyl methacrylate				
	oral	LD50 7872 mg/kg	Rat	RTECS	
	dermal	LD50 > 5000 mg/kg	Rabbit	REACH Dossier	OECD 402
	inhalation (4 h) vapour	LC50 29,8 mg/l	Rat	REACH Dossier	standard acute metho
2082-81-7	1,4-butandiol dimethacrylate, Tetramethylene dimethacrylate				
	oral	LD50 10066 mg/kg	Rat	REACH Dossier	OECD 401
	dermal	LD50 > 3000 mg/kg	Rabbit	REACH Dossier	not specified

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, Tetramethylene 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.

SECTION 12: Ecological information**12.1. Toxicity**

Conclusive data but not sufficient for classification

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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	191 mg/l	96 h	Lepomis macrochirus (Bluegill)	Merck
	Acute algae toxicity	ErC50	> 110	72 h	Pseudokirchneriella subcapitata	REACH Dossier
	Acute crustacea toxicity	EC50	69 mg/l	48 h	Daphnia magna (Big water flea)	REACH Dossier
2082-81-7	1,4-butandiol dimethacrylate, Tetramethylene dimethacrylate					
	Acute fish toxicity	LC50	5,861	96 h	Pimephales promelas (fathead minnow)	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			
80-62-6	methyl methacrylate			
	OECD 301C/ ISO 9408/ EEC 92/69/V, C.4-F	94 %	14	Publication
	Readily biodegradable (according to OECD criteria).			
	EPA, title 40 Code of Federal Regulations Part 160	> 99 %	2	40 CFR 160
	Readily biodegradable (according to OECD criteria).			
2082-81-7	1,4-butandiol dimethacrylate, Tetramethylene dimethacrylate			
	OECD 310 (Headspace Test)	76 - 92 %	28	REACH Dossier
	Biodegradable.			

12.3. Bioaccumulative potential

The product has not been tested.

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, Tetramethylene dimethacrylate	3,1

BCF

CAS No	Chemical name	BCF	Species	Source
80-62-6	methyl methacrylate	2,97 - 3,5	Pisces	SDB HIT-ICE, B
2082-81-7	1,4-butandiol dimethacrylate, Tetramethylene dimethacrylate	59,21	n/n	EpiSuite QSAR tool

12.4. Mobility in soil

The product has not been tested. On the basis of existing data about the elimination/degradation and bioaccumulation potential longer term damage to the environment cannot be ruled out. If product enters soil, it will be mobile and may contaminate groundwater.

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.

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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

160508 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded organic chemicals consisting of or containing hazardous substances; hazardous waste

List of Wastes Code - used product

160508 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded organic chemicals consisting of or containing hazardous substances; hazardous waste

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself. Contaminated packages must be completely emptied and can be re-used following proper cleaning. Non-contaminated packages may be recycled. Packing which cannot be properly cleaned must be disposed of.

SECTION 14: Transport information

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:

II

Hazard label:

3



Classification code:

F1

Special Provisions:

386

Limited quantity:

1 L

Excepted quantity:

E2

Transport category:

2

Hazard No:

339

Tunnel restriction code:

D/E

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



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Classification code: F1
Special Provisions: 386
Limited quantity: 1 L
Excepted quantity: E2

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: 386
Limited quantity: 1 L
Excepted quantity: E2
EmS: F-E, S-D

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



Special Provisions: A209
Limited quantity Passenger: 1 L
Passenger LQ: Y341
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

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No
Danger releasing substance: METHYL METHACRYLATE MONOMER, STABILIZED

14.6. Special precautions for user

Warning: Combustible liquid. See section 14.2.

14.7. Maritime transport in bulk according to IMO instruments

Cristobalite (filler, CAS no. 14464-46-1) is firmly bound in the matrix and does not contribute to labeling (no hazardous dust release)

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 40

Information according to 2012/18/EU (SEVESO III): P5c FLAMMABLE LIQUIDS

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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):	1 - slightly hazardous to water
Skin resorption/Sensitization:	Causes allergic hypersensitivity reactions.

Additional information

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). According to directive 94/33/EC, juveniles are only allowed to handle this product as long as all effects of dangerous substances are prevented. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

:
:

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s): 1,2,3,4,5,6,7,8,9,10,12,13,14,15,16.

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
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
MFAG: 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: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

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Key literature references and sources for data

ECHA - REACH Dossier

TOXNET - Hazardous Substances Data Bank (HSDAB) & ChemIDplus

Environmental Protection Agency (EPA) - Chemistry Dashboard

OECD SIDS

Danish QSAR Database

Crit Rev Toxicol. 2011 Mar; 41(3): 230–268: Methyl methacrylate and respiratory sensitization: A Critical review

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)

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

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.)