Safety Data Sheet

According to Annex II to REACH - Regulation 2020/878

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

1.1. Product identifier

Code: **DRAP087c**
Product name **EPOMALT FAST 50 COMP B**

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

Intended use **Two-component epoxy cementitious mortar**

1.3. Details of the supplier of the safety data sheet

Name **DRACO ITALIANA S.p.A.**
Full address **Via Monte Grappa, 11 D-E**
District and Country **20067 Tribiano (MI)**
Italia
Tel. +39 02.90632917
Fax +39 02.90631976

e-mail address of the competent person responsible for the Safety Data Sheet **info@draco-edilizia.it**

1.4. Emergency telephone number

For urgent inquiries refer to **Centro Antiveleni di Bergamo 800883300 (Azienda Ospedaliera Papa Giovanni XXII)**
Centro Antiveleni di Firenze 0557947819 (Az. Osp. "Careggi" U.O. Tossicologia Medica)
Centro Antiveleni di Foggia 80018345 (Az. Osp. Univ. Foggia)
Centro Antiveleni di Milano 0266101029 (Osp. Niguarda Ca' Granda)
Centro Antiveleni di Napoli 0817472870 (Az. Osp. "A. Cardarelli")
Centro Antiveleni di Pavia 038224444 (CAV Centro Nazionale di Informazione Tossicologica)
Centro Antiveleni di Roma 063054343 (CAV Policlinico "A. Gemelli")
Centro Antiveleni di Roma 0649978000 (CAV Policlinico "Umberto I")
Centro Antiveleni di Roma 06 68593726 (CAV "Osp. Pediatrico Bambino Gesù" Dip. Emergenza e Accettazione DEA)

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Serious eye damage, category 1	H318	Causes serious eye damage.
Hazardous to the aquatic environment, chronic toxicity, category 3	H412	Harmful to aquatic life with long lasting effects.

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

SECTION 2. Hazards identification ... / >>

Signal words: Danger

Hazard statements:

H318 Causes serious eye damage.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P280 Wear eye protection / face protection.
P310 Immediately call a POISON CENTER / doctor / . . .
P273 Avoid release to the environment.

Contains: Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration >= 0.1%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification		x = Conc. %	Classification 1272/2008 (CLP)
Quartz			
CAS	*14808-60-7*	30 ≤ x < 50	**Substance with a community workplace exposure limit.**
EC	*238-878-4*		
INDEX			
Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca			
CAS	*39423-51-3*	3 ≤ x < 9	**Acute Tox. 4 H302, Acute Tox. 4 H312, Eye Dam. 1 H318, Aquatic Chronic 2 H411**
EC	*500-105-6*		**LD50 Oral: 550 mg/kg, LD50 Dermal: >1000 mg/kg**
INDEX			
REACH Reg.	*01-2119556886-20-XXXX*		
2-ethylhexanoic acid			
CAS	*149-57-5*	1 ≤ x < 3	**Repr. 2 H361d**
EC	*205-743-6*		
INDEX	*607-230-00-6*		
Benzyldimethylamine			
CAS	*103-83-3*	0,5 ≤ x < 1	**Flam. Liq. 3 H226, Acute Tox. 3 H331, Acute Tox. 4 H302, Acute Tox. 4 H312, Skin Corr. 1B H314, Eye Dam. 1 H318, Aquatic Chronic 3 H412**
EC	*203-149-1*		**STA Oral: 500 mg/kg, STA Dermal: 1100 mg/kg, STA Inhalation vapours: 3 mg/l, STA Inhalation mists/powders: 0,501 mg/l, STA Inhalation gas: 700 ppm**
INDEX	*612-074-00-7*		
REACH Reg.	*01-2119529232-48-xxxx*		
C12-C16 Propoxylated ethoxylated alcohol			
CAS	*68213-24-1*	0 ≤ x < 0,5	**Aquatic Acute 1 H400 M=1**
EC			
INDEX			

The full wording of hazard (H) phrases is given in section 16 of the sheet.

Quartz
The substance Quarzo (CAS 14808-60-7), present as such or as part of a mineral filler, is not classified by the supplier as dangerous. However, the supplier declares a percentage of Alpha Quartz (crystalline silica) lower than 1%. The supplier then classifies the Alpha quartz (crystalline silica) as H372 (STOT RE 1). In order to allow a safe use of the mixture, useful information is reported for completeness both to check personal exposure (section 8) and toxicological information (section 11) regarding Quarzo alfa (crystalline silica).

SECTION 4. First aid measures

4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Wash contaminated clothing before using it again.
INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.
INGESTION: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
Do not breathe combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION
Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.
SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS
Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Block the leakage if there is no hazard.
Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.
Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory References:

FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
EU	OEL EU	Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC.
	TLV-ACGIH	ACGIH 2020

Quartz

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations	
		mg/m3	ppm	mg/m3	ppm		
VLEP	FRA	0,1				RESP	
WEL	GBR	0,1				RESP	
OEL	EU	0,1				INHAL	Quarzo alfa (Dir. 2017/2398)
TLV-ACGIH		3					Polveri tot. fraz. respirabile
TLV-ACGIH		10				INHAL	Polveri tot. fraz. inalabile
TLV-ACGIH		0,025				RESP	Quarzo alfa

Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca

Predicted no-effect concentration - PNEC

Normal value in marine water	0,00044	mg/l
Normal value for fresh water sediment	0,02	mg/kg
Normal value for marine water sediment	0,002	mg/kg
Normal value for water, intermittent release	0,044	mg/l
Normal value of STP microorganisms	10	mg/l
Normal value for the terrestrial compartment	0,002	mg/kg

Health - Derived no-effect level - DNEL / DMEL

	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation				3,8 mg/m3				14 mg/m3

SECTION 8. Exposure controls/personal protection ... / >>

Benzyldimethylamine								
Predicted no-effect concentration - PNEC								
Normal value in fresh water						0,005	mg/l	
Normal value in marine water						0	mg/l	
Normal value for fresh water sediment						0,071	mg/kg/d	
Normal value for marine water sediment						0,007	mg/kg/d	
Normal value of STP microorganisms						534	mg/l	
Normal value for the terrestrial compartment						0,011	mg/kg/d	
Health - Derived no-effect level - DNEL / DMEL								
	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral		0,5 mg/kg bw/d		0,25 mg/kg bw/d				
Inhalation		1,74 mg/m3		0,87 mg/m3		9,9 mg/m3		4,9 mg/m3
Skin		1 mg/kg bw/d		0,5 mg/kg bw/d		2,8 mg/kg bw/d		1,4 mg/kg bw/d

Legend:
(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.
VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

Quartz
Respect the legal exposure limits in the workplace for any type of airborne dust (eg total dust, respirable dust, respirable crystalline silica powder).
In Europe, the binding LEP (occupational exposure limit) for respirable crystalline silica dust has been set by Directive (EU) 2017/2398 to 0.1 mg / m3, measured as TWA (Time Weighted Average, time-weighted average concentration) over 8 hours.

Procedure di monitoraggio suggerite

Il monitoraggio della concentrazione di sostanze nella zona di inalazione dei lavoratori o nel luogo di lavoro generale può essere richiesto per confermare la conformità ai limiti di esposizione professionale e l'adeguatezza dei controlli dell'esposizione. Per alcune sostanze può essere appropriato anche il monitoraggio biologico.
I metodi di misurazione dell'esposizione validati devono essere applicati da una persona competente e i campioni devono essere analizzati da un laboratorio accreditato.
Si dovrebbe fare riferimento a standard di monitoraggio, come i seguenti:

Norma EN 689 (Esposizione nei luoghi di lavoro - Misurazione dell'esposizione per inalazione agli agenti chimici - Strategia per la verifica della conformità coi valori limite di esposizione occupazionale)
Norma EN 14042 (Atmosfere nell'ambiente di lavoro - Guida all'applicazione e all'utilizzo di procedimenti per la valutazione dell'esposizione ad agenti chimici e biologici)
Norma EN 482 (Atmosfere nell'ambiente di lavoro - Requisiti generali per la prestazione di procedure per la misurazione di agenti chimici)

Sarà inoltre richiesto il riferimento ai documenti di orientamento nazionali per i metodi per la determinazione delle sostanze pericolose.
Per reperire informazioni al tale riguardo si può consultare:
http://amcaw.ifa.dguv.de/WForm09.aspx

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.
When choosing personal protective equipment, ask your chemical substance supplier for advice.
Personal protective equipment must be CE marked, showing that it complies with applicable standards.
Provide an emergency shower with face and eye wash station.
HAND PROTECTION
Protect hands with category III work gloves (see standard EN 374).
The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.
The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.
SKIN PROTECTION
Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.
EYE PROTECTION
Wear airtight protective goggles (see standard EN 166).
RESPIRATORY PROTECTION

SECTION 8. Exposure controls/personal protection ... / >>

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required. Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.
If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS
The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.
Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

Quartz
In case of prolonged exposure to airborne dust concentrations, wear a respiratory protection device that meets the requirements of European or national legislation. The use of partial or complete facial masks with filters against particles of category 2 or 3 (FP2 - FP3) is recommended. See EN 143: 2000 - Respiratory protective devices. Particles filters

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties		Value		Information
Appearance		liquid		
Colour		white		
Odour		characteristic		
Odour threshold		Not available		
Melting point / freezing point		Not available		
Initial boiling point		Not available		
Flammability		Not available		
Lower explosive limit		Not available		
Upper explosive limit		Not available		
Flash point	>	60	°C	
Auto-ignition temperature		Not available		
Decomposition temperature		Not available		
pH		8		
Kinematic viscosity		Not available		
Solubility		partially soluble in water		
Partition coefficient: n-octanol/water		Not determined		
Vapour pressure		Not available		
Density and/or relative density		1.25 - 1.35	g/cm3	
Relative vapour density		Not available		

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

VOC (Directive 2010/75/EC)	3,00 %

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

SECTION 10. Stability and reactivity ... / >>

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

2-ethylhexanoic acid
Strong acids, strong bases, strong oxidizing agents.

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.
It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

11.1. Information on toxicological effects

Quartz
Notes on QUARTZ (fine fraction):

Prolonged and / or massive exposure to dust containing respirable crystalline silica can cause silicosis, a nodular fibrosis of the lungs due to the deposition in the alveoli of respirable particles of crystalline silica. Given that the European Union at the time of drafting this safety data sheet does not classify crystalline silica (alpha quartz) as a dangerous substance and that at the moment there are no requests for changes by Member States, the following is notified: Lo IARC (International Agency for Research on Cancer) has included crystalline silica as a human carcinogen since 1997, but stated that human carcinogenicity was not detected in all the industrial circumstances studied. Carcinogenicity may be dependent on the intrinsic characteristics of silica or external factors that can change its biological activity "(IARC Monographs on the evaluation of Caricinogenic Risk to Humans, volume 68 Silica, Silicates, Dust and Organic Fibers - Lyon, 15-22 Oct. 96) The IOM (Institute of Occupational Medicine), stated that "the data resulting from the completed epidemiological investigation are inadequate to determine whether crystalline silica is to be considered carcinogenic to men, it is also possible to note a predisposition to the development of lung cancer in silicotic subjects although it is not possible to determine a direct effect of silica in it "(Scientific Opinion on the Effects of Airborne Silica, A. Pilkington et al., Report TM / 96/08, Institute of Occupational Medicine, Edinburgh Jan, 99) . The S.C.O.E.L. (Scientific Committee on Occupational Exposure Limits) in 2002 stated that "the main effect in humans of silica dust is silicosis. There is sufficient information to conclude that the relative risk of cancer is increased in people with silicosis (and apparently not in workers without silicosis exposed to quartz dust in quarries or in the ceramic industry). On the other hand, preventing the onset of silicosis will also reduce the risk of cancer ... "On April 25, 2006 was signed a Voluntary Agreement between the social partners (Social Dialogue Agreement on Silica) at European level, on how to prevent from adopt, in the sectors concerned, to prevent the risks deriving from exposure to respirable crystalline free silica dusts. The agreement entered into force on 25 October 2006.

For crystalline free silica, Directive (EU) 2017/2398 sets a limit value for occupational exposure of 0.1 mg / m3 and includes work involving risks of exposure to carcinogens, including work involving exposure to crystalline silica dust breathable generated by a manufacturing process ". The problem of exposure to Silica Libera Cristallina (SLC) in the workplace is particularly significant, as this risk agent is present in numerous work activities. SLC is in fact extremely common in nature and used in a wide range of civil and industrial products. The International Agency for Research on Cancer has classified it as a certain carcinogen (group 1) as early as 1997, has reassessed its toxicity data in 2010 confirming its carcinogenicity (Volume 100, part C, IARC Monograph). Source: www.dors.it

Opinion of the Industrial Minerals Association (IMA), 2014:
Since 2010, in accordance with the CLP Regulation, since a harmonized classification for silica is not available, manufacturers of industrial minerals have jointly assessed that the GHS classification for quartz (fine fraction) and cristobalite (fine fraction) is STOT RE category 1 for silicosis risk. As a consequence of this classification, substances and mixtures containing crystalline silica (fine fraction), in the form of identified impurities, additive or single constituent, are classified as: STOT RE 1, if the concentration of quartz (fine fraction) or cristobalite (fine fraction) is 10% or more; STOT RE 2, if the concentration of quartz (fine fraction) or cristobalite (fine fraction) is between 1 and 10%; If quartz (fine fraction) or cristobalite (fine fraction) in mixtures and substances is less than 1%, no classification is required by law. The decision on the classification of products containing crystalline silica (fine fraction) takes into account the availability of these fine particles.
If a product exists in a form that prevents the fraction of fine particles from becoming airborne (for example in liquid form), this will be taken into account in the classification decision. Therefore, manufacturers of industrial minerals believe that when a mineral classified as STOT RE1 or STOT RE2 due to its fine fraction content of crystalline silica is incorporated into a mixture in liquid form, the fine fraction is no longer available and the classification it would not be justified. [IMA Europe © 2014, http://www.crystallinesilica.eu/content]

SECTION 11. Toxicological information ... / >>

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation - mists / powders) of the mixture:	> 5 mg/l
ATE (Inhalation - vapours) of the mixture:	> 20 mg/l
ATE (Inhalation - gas) of the mixture:	> 20000 mg/l
ATE (Oral) of the mixture:	>2000 mg/kg
ATE (Dermal) of the mixture:	>2000 mg/kg

Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca

LD50 (Oral):	550 mg/kg Rat. OECD 425
LD50 (Dermal):	> 1000 mg/kg Rat, OECD 402

Benzyldimethylamine

STA (Oral):	500 mg/kg estimate from table 3.1.2 of Annex I of the CLP (figure used for calculation of the acute toxicity estimate of the mixture)
STA (Dermal):	1100 mg/kg estimate from table 3.1.2 of Annex I of the CLP (figure used for calculation of the acute toxicity estimate of the mixture)
STA (Inhalation mists/powders):	0,501 mg/l estimate from table 3.1.2 of Annex I of the CLP (figure used for calculation of the acute toxicity estimate of the mixture)
STA (Inhalation vapours):	3 mg/l estimate from table 3.1.2 of Annex I of the CLP (figure used for calculation of the acute toxicity estimate of the mixture)
STA (Inhalation gas):	700 ppm estimate from table 3.1.2 of Annex I of the CLP (figure used for calculation of the acute toxicity estimate of the mixture)

C12-C16 Propoxylated ethoxylated alcohol

LD50 (Oral):	> 2000 mg/kg Rat, range 2000 - 5000 mg/kg

Quartz
Acute oral / dermal LD50 of quartz and cristobalite greater than 2000 mg / kg

Acute toxic inhalation
Lack of dose-specific acute toxicity data allowing categorical decisions on the classification of acute inhalation toxicity of 100% crystalline silica forms. Acute inhalation toxicity not expected based on study values according to OECD requirements, with substance containing 45% cristobalite and no lethality reported. No further testing is warranted in the interest of animal welfare.

2-ethylhexanoic acid
Repeated dose toxicity
Species: rat, male and female
NOAEL: 300 mg / kg
Method of application: ingestion
Exposure time: 2 160 h
Number of exhibitions: 7 d
Method: subchronic toxicity

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SECTION 11. Toxicological information ... / >>

Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca
Species: rabbit
Method: OECD 404
Result: slight skin irritation

2-ethylhexanoic acid
Species: rabbit
Evaluation: no skin irritation
Method: Guideline 404 for the OECD Test
Result: no skin irritation

Benzyldimethylamine
Specis: Rabbit
Exposure time: 4h
Method: OECD Test Guideline 404
Result: Causes burns

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye damage

Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca
Method: OECD 405
Result: irreversible effects on the eyes

2-ethylhexanoic acid
Species: rabbit
Evaluation: no eye irritation
Method: Guideline 405 for the OECD Test
Result: no eye irritation

Benzyldimethylamine
Specis: Rabbit
Assessment: Severe eye irritation
Result: Severe eye irritation

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca
Route of exposure: skin
Species: guinea pig
Result: does not cause skin sensitization

2-ethylhexanoic acid
Route of exposure: skin
Species: guinea pig
Method: Guideline 406 for the OECD Test
Result: no skin sensitization

Benzyldimethylamine
Test type: Maximization Test
Route of exposure: skin
Species: Guinea pig
Method: OECD Test Guideline 406
Result: Does not cause skin sensitization

C12-C16 Propoxylated ethoxylated alcohol
Species: Guinea pig
Result: negative
Method: Guideline 406 for the OECD Test

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

SECTION 11. Toxicological information ... / >>

Quartz
Quartz has genotoxic and mutagenic effects mainly due to inflammatory processes. Respirable quartz did not cause increases in HPRT mutations in epithelial cells of the lungs of rats in vitro.

Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca
Genotossicità in vitro
Attivazione metabolica: con o senza attivazione metabolica
Metodo: OECD 471
Risultato: negativo

Attivazione metabolica: attivazione metabolica
Metodo: OECD 482
Risultato: negativo

Attivazione metabolica: con o senza attivazione metabolica
Metodo: OECD 476
Risultato: negativo

Genotossicità in vivo
tipo di cellula: somatico
Modalità di applicazione: iniezione intraperitoneale
Dosi: 2,5 mg/kg
Metodo: OECD 474
Risultato: negativo

2-ethylhexanoic acid
Genotoxicity in vitro
Metabolic activation: with or without metabolic activation
Method: Guideline 471 for the OECD Test
Result: negative

Concentration: 5000 ug / plate
Metabolic activation: with or without metabolic activation
Method: OECD Test Guideline 476
Result: negative

Genotoxicity in vivo
Application method: Oral
Doses: 1600 mg / kg
Method: Guideline 474 for the OECD Test
Result: negative

Benzyldimethylamine
In vitro genotoxicity
Test type: Chromosomal aberration in vitro
Test system: Chinese hamster lung cells
Metabolic activation: with or without metabolic activation
Method: Chromosomal aberration in vitro
Result: Positive

Test type: Ames test
Test System: Salmonella typhimurium
Metabolic activation: with or without metabolic activation
Method: OECD Test Guideline 471
Result: Negative

Test type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster lung cells
Metabolic activation: with or without metabolic activation
Method: OECD Test Guideline 476
Result: Negative

Genotoxicity in vivo
Test type: In vivo micronucleus test
Species Essay: Mouse (male and female)
Cell type: Somatic
Method of application: oral
Exposure time: 24h

SECTION 11. Toxicological information ... / >>

Dose: 150 mg / kg
Result: Negative

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

Quartz
The risk of excess lung cancer is only proven for high occupational exposures to respirable crystalline silica. The risk of excess lung cancer is limited to patients with silicosis.

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Quartz
Silica is essential to normal body functions and is ingested orally with the consumption of foods containing silica in nature. A first mono-generational study on Wistar rats does not show the occurrence of adverse effects deriving from the long-term ingestion of silica-rich water.

2-ethylhexanoic acid
Effects on fertility
Species: Rat, male and female
Method of application: oral

Effects on fetal development
Species: rabbit, female
Application method: oral
General toxicity in mothers: no level of harmfulness observed: 25 mg / kg body weight
Method: EPA OTS 798.4900
Result: no teratogenic effect

Species: rat, female
Application method: oral
General toxicity in mothers: no level of harmfulness observed: 250 mg / kg body weight
Method: EPA OTS 798.4900
Result: teratogenic effects

Application method: oral
Teratogenicity: no level of harmfulness observed: 100 mg / kg body weight
Result: teraatogenic effects

Adverse effects on sexual function and fertility
Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca
Species: rat, male and female
Method of application: dermal
Method: OECD 421

Adverse effects on development of the offspring
Benzyldimethylamine
Test type: Prenatal
Species: Rat
Method of application: oral
Duration of the single treatment: 14d
Dose: 0,35,75,150 mg / kg bw / d
General toxicity in mothers: no harmful level observed: 75 mg / kg body weight
Developmental toxicity: level within which no effects were observed: 150 mg / kg body weight
Method: OECD Test Guideline 414
Result: No teratogenic effects

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

SECTION 11. Toxicological information ... / >>

Quartz
Prolonged or massive exposure to dust containing respirable crystalline silica can cause silicosis, a nodular pulmonary fibrosis caused by the deposition in the lungs of respirable fine particles of crystalline silica.
There is substantial evidence to support the fact that the increased risk of cancer would be limited to patients already suffering from silicosis. The protection of workers against silicosis must be guaranteed by respecting the limits of occupational exposure in accordance with the law and possibly adopting additional risk management measures.

Benzyldimethylamine
Species: Rat, male and female
NOAEL: 50 mg / kg
Method of application: oral (fattening)
Exposure time: 28d number of exposures 7d
Dose: 0,50,100,200 400 mg / kg bw / d
Method: Subacute toxicity

Species: Rat, male and female
NOAEL: about 150 mg / kg
Method of application: oral (fattening)
Exposure time: 28d number of exposures 7d / w
Dose: 0,6,30,150 mg / kg bw / d
Method: Subacute toxicity

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

2-ethylhexanoic acid
May be harmful in case of ingestion and penetration into the respiratory tract.

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

SECTION 12. Ecological information

This product is dangerous for the environment and the aquatic organisms. In the long term, it have negative effects on aquatic environment.

12.1. Toxicity

Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca
Toxicity to microorganisms
EC50 / 0,5h (activated sludge): 1000 mg / l (OECD 209, static test)

2-ethylhexanoic acid
Toxicity for microorganisms
EC50 (Pseudomonas putida): 112.7 mg / l
Exposure time: 17 h
Type of test: static test
Method: DIN 38412-8

Benzyldimethylamine
Toxicity to microorganisms
EC50 (Pseudomonas putida): 749.6 mg / L
Exposure time: 17h
Test type: static test
Monitoring by analysis: no
Substances to be tested: Fresh water
Method: DIN 38 412 Part 8

EC50 (Pseudomonas putida): 534 mg / L
Exposure time: 17h
Test type: static test
Monitoring by analysis: no
Substances to be tested: Fresh water
Method: DIN 38 412 Part 8

SECTION 12. Ecological information ... / >>

C12-C16 Propoxylated ethoxylated alcohol
Very toxic to aquatic organisms.

C12-C16 Propoxylated ethoxylated alcohol

LC50 - for Fish	> 0,1 mg/l/96h Oncorhynchus mykiss
EC50 - for Crustacea	> 1 mg/l/48h Daphnia magna

2-ethylhexanoic acid

LC50 - for Fish	180 mg/l/96h Oncorhynchus mykiss, static OECD 203
EC50 - for Crustacea	85,4 mg/l/48h Daphnia magna, prova statica DIN 38412
EC50 - for Algae / Aquatic Plants	49,3 mg/l/72h Desmodesmys subspicatus, static, DIN 38412
EC10 for Algae / Aquatic Plants	32 mg/l/72h Desmodesmus subspicatus, static, DIN 38412
Chronic NOEC for Crustacea	25 mg/l Daphnia magna, semistatic, OECD 211, 21 d

Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca

LC50 - for Fish	> 100 mg/l/96h Oncorhynchus mykiss, OECD 203, static test
EC50 - for Crustacea	13 mg/l/48h Daphnia magna, OECD 202, static test
EC50 - for Algae / Aquatic Plants	4,4 mg/l/72h Selenastrum capricomutum, OECD 201, static test

Benzyldimethylamine

LC50 - for Fish	37,8 mg/l/96h Pimephalies promelas (OECD 203)
EC50 - for Crustacea	> 100 mg/l/48h Daphnia magna (Direttiva 67/548/CEE, allegato V, C.2)
EC50 - for Algae / Aquatic Plants	1,34 mg/l/72h Desmodesmus subspicatus (Direttiva 67/548//CEE, Allegato V, C.3)
Chronic NOEC for Crustacea	0,789 mg/l/21d Daphnia magna (OED 211)

12.2. Persistence and degradability

Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca
Concentrazione: 100 mg/l
Risultato: non immediatamente biodegradabile
Biodegradazione: < 5%
Tempo di esposizione: 28 d
Metodo: OECD 301F

Stabilità nell'acqua
Tempo di dimezzamento per la degradazione (TD50) > 1 anno (25°C)
pH: 7,5
Metodo: OECD 111
Osservazioni: acqua dolce

2-ethylhexanoic acid
Inoculum: active mud
Concentration: 20 mh / l
Result: rapidly biodegradable
Biodegradation: 99%
Exposure time: 28 d
Method: 301E OECD Test Guideline

Benzyldimethylamine
Test type: aerobic
Inoculum: activated sludge
concentration: 100 mg / L
Result: Not readily biodegradable
Biodegradation: 0-2%
Exposure time: 28d
Method: OECD Test Guideline 301C

C12-C16 Propoxylated ethoxylated alcohol
Result: rapidly biodegradable.
Method: 301D OECD Test Guideline

C12-C16 Propoxylated ethoxylated alcohol
Rapidly degradable

SECTION 12. Ecological information ... / >>

2-ethylhexanoic acid
Rapidly degradable

Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca
Solubility in water 562 g/l

12.3. Bioaccumulative potential

2-ethylhexanoic acid
Partition coefficient: n-octanol/water 2,7 Log Kow 25°C, pH: 4,7, OECD 107
BCF 60

Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca
Partition coefficient: n-octanol/water -1,13 Log Kow 20-25°C, pH: 12,7

Benzyldimethylamine
Partition coefficient: n-octanol/water 1,98 pH13
BCF > 2,1 range 2,1-22, su Cyprinus carpio, 42 d

12.4. Mobility in soil

2-ethylhexanoic acid
Partition coefficient: soil/water 650

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

12.6. Other adverse effects

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

SECTION 14. Transport information ... / >>

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Information not relevant

SECTION 15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
Product
Point 3 - 40
Contained substance
Point 75

Regulation (EC) No. 2019/1148 - on the marketing and use of explosives precursors
Not applicable

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage ≥ than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:
None

Substances subject to the Rotterdam Convention:
None

Substances subject to the Stockholm Convention:
None

Healthcare controls
Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment

A chemical safety assessment has been performed for the following contained substances
Propilidinetrimetanolo, propossilato, prodotti della reazione con ammoniaca

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Liq. 3	Flammable liquid, category 3
Repr. 2	Reproductive toxicity, category 2
Acute Tox. 3	Acute toxicity, category 3
Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1B	Skin corrosion, category 1B
Eye Dam. 1	Serious eye damage, category 1
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic toxicity, category 2
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
H226	Flammable liquid and vapour.
H361d	Suspected of damaging the unborn child.
H331	Toxic if inhaled.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

LEGEND:
- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
4. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament

SECTION 16. Other information ... / >>

10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.
Provide appointed staff with adequate training on how to use chemical products.

CALCULATION METHODS FOR CLASSIFICATION
Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.
Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.
Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review:
The following sections were modified:
02 / 03 / 09 / 11 / 12 / 15 / 16.