### Revision nr. 1 Meccanocar Italia S.r.l. Dated 12/02/2020 First compilation Printed on 12/02/2020 CHEMICAL ANCHOR IN VIAL Page n. 1/22

# Safety Data Sheet According to Annex II to REACH - Regulation 2015/830

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

1.1. Product identifier

155 00 01330-10X85VFP Code: 155 00 01340-12X105VFP 155 00 01350-16X120VFP

Product name **CHEMICAL ANCHOR IN VIAL** 

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

Intended use Percussion vial chemical anchor

1.3. Details of the supplier of the safety data sheet

Meccanocar Italia S.r.l. Name Full address Via San Francesco, 22 District and Country 56033 Capannoli (PI)

Italy

Tel. +39 0587 609433 Fax +39 0587 607145

e-mail address of the competent person

responsible for the Safety Data Sheet moreno.meini@meccanocar.it

1.4. Emergency telephone number

For urgent inquiries refer to National Poisons Information Service: +44 121 507 4123

# **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:

Skin sensitization, category 1 H317 May cause an allergic skin reaction.

### 2.2. Label elements

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

Hazard pictograms:

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Signal words: Warning

Hazard statements:

**H317** May cause an allergic skin reaction.

Precautionary statements:

**P280** Wear protective gloves/ protective clothing / eye protection / face protection.

P362+P364 Take off contaminated clothing and wash it before reuse.

P272 Contaminated work clothing should not be allowed out of the workplace.

P302+P352 IF ON SKIN: wash with plenty of water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue

rinsing.

P333+P313 If skin irritation or rash occurs: Get medical advice / attention.

Contains: BENZOILE PEROXIDE

METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

ETHYLENE DIMETHACRYLATE

## 2.3. Other hazards

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

# **SECTION 3. Composition/information on ingredients**

### 3.2. Mixtures

Contains:

Identification x = Conc. % Classification 1272/2008 (CLP)

METHACRYLIC ACID,

MONOESTER WITH PROPANE-1, 2-

DIOL

CAS 27813-02-1  $8 \le x < 9$  Eye Irrit. 2 H319, Skin Sens. 1 H317

EC 248-666-3

INDEX -

Reg. no. 01-2119490226-37-XXXX **ETHYLENE DIMETHACRYLATE** 

CAS 97-90-5 8 ≤ x < 9 STOT SE 3 H335, Skin Sens. 1 H317

EC 202-617-2

INDEX 607-114-00-5

Reg. no. 01-2119965172-38-XXXX

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# **CHEMICAL ANCHOR IN VIAL**

CAS 94-36-0  $2 \le x < 2,5$ 

Self-react. B H241, Eye Irrit. 2 H319, Skin Sens. 1 H317, Aquatic Chronic 1

H410 M=1

EC 202-327-6

INDEX -

Reg. no. 01-2119511472-50-XXXX

N-METHYL-2-PYRROLIDONE

CAS 872-50-4  $0.5 \le x < 0.6$ 

Repr. 1B H360D, Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335

EC 212-828-1

INDEX 606-021-00-7

Reg. no. 01-2119472430-46-XXXX

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

### **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. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless 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.

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### 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

Ensure that there is an adequate earthing system for the equipment and personnel. Avoid contact with eyes and skin. Do not breathe powders, vapours or mists. Do not eat, drink or smoke during use. Wash hands after use. Avoid leakage of the product into the environment.

### 7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store in a ventilated and dry place, far away from sources of ignition. Keep containers well sealed. Keep the product in clearly labelled containers. Avoid overheating. Avoid violent blows. 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:

**ESP** España LÍMITES DE EXPOSICIÓN PROFESIONAL PARA AGENTES QUÍMICOS EN ESPAÑA 2019 (INSST) **GBR** United Kingdom EH40/2005 Workplace exposure limits (Third edition, published 2018) DIRETTIVA (UE) 2017/164 DELLA COMMISSIONE del 31 gennaio 2017 ΙΤΔ Italia Fastsatt av Arbeids- og sosialdepartementet 21. august 2018 med hjemmel i lov 17. juni 2005 nr. 62 om NOR Norge arbeidsmiljø, arbeidstid, stillingsvern mv. (arbeidsmiljøloven) § 1-3, § 1-4 og § 4-5 PRT Portugal Ministério da Economia e do Emprego Consolida as prescrições mínimas em matéria de protecção dos

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trabalhadores contra os riscos para a segurança e a saúde devido à exposição a agentes químicos no trabalho - Diário da República, 1.ª série - N.º 111 - 11 de junho de 2018
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 91/322/EEC.

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Predicted no-effect concentration - PNEC			
Normal value in fresh water	0,139	mg/l	
Normal value in marine water	0,014	mg/l	
Normal value for fresh water sediment	1,6	mg/kg	
Normal value for marine water sediment	0,16	mg/kg	
Normal value of STP microorganisms	57	mg/l	
Normal value for the terrestrial compartment	0,239	mg/kg	

Health - Derived no-effect level - DNEL / DMEL								
	Effects on				Effects on			
	consumers				workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral				0,83 mg/kg bw/d				
Inhalation				1,45 mg/m3				2,45 mg/m3
Skin				0,83 mg/kg bw/d				1,3 mg/kg bw/d

# METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Predicted no-effect concentration - PNEC			
Normal value in fresh water	0,904	mg/l	
Normal value in marine water	0,904	mg/l	
Normal value for fresh water sediment	6,28	mg/kg	
Normal value for marine water sediment	6,28	mg/kg	
Normal value of STP microorganisms	10	mg/l	
Normal value for the terrestrial compartment	0,727	mg/kg	

	Effects on				Effects on			
	consumers				workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic	Acute local	Acute	Chronic local	Chronic
				systemic		systemic		systemic
Oral				2,5 mg/kg				
				bw/d				
Inhalation				8,8 mg/m3				14,7 mg/m3
Skin				2,5 mg/kg				4,2 mg/kg
				bw/d				bw/d

# **N-METHYL-2-PYRROLIDONE**

Туре	Country	TWA/8h	TWA/8h STEL/15min		Remarks / Observations		
		mg/m3	ppm	mg/m3	ppm		
VLA	ESP	40	10	80	20	SKIN	
WEL	GBR	40	10	80	20	SKIN	
VLEP	ITA	40	10	80	20	SKIN	
TLV	NOR	20	5	80	20	SKIN	
VLE	PRT	40	10	80	20	SKIN	
OEL	EU	40	10	80	20	SKIN	

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	LAI	$\Delta N$	L.HUR	IN VIA	

Predicted no-effect concentration - PNEC			
Normal value in fresh water	0,25	mg/l	
Normal value in marine water	0,025	mg/l	
Normal value for fresh water sediment	1,09	mg/kg	
Normal value for marine water sediment	0,109	mg/kg	
Normal value of STP microorganisms	10	mg/l	
Normal value for the terrestrial compartment	0,07	mg/kg	

Health - Derived no-ef	fect level - DNEL / Effects on consumers	OMEL			Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral				0,85 mg/kg bw/d				
Inhalation			4,5 mg/m3	3,6 mg/m3			40 mg/m3	14,4 mg/m3
Skin				2,4 mg/kg bw/d				4,8 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.

### 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 II 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

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.

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### 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.

### ETHYLENE DIMETHACRYLATE

Glove material: nitrile rubber

EN 374

Suitable as a spray protection. Glove material: butyl rubber Breakthrough time: 60 min Glove thickness: 0.3 mm

METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Nitrile rubber gloves

Additional information: suitable as splash protection. Material: butyl rubber gloves (minimum thickness 0.3 mm)

Breakthrough time: 480 min

Guideline: EN 374

### BENZOILE PEROXIDE

Hand protection: gloves (nitrile rubber, neoprene) tested EN374.

### N-METHYL-2-PYRROLIDONE

Chemical resistant protective gloves (EN 374)

Suitable materials also with prolonged direct contact (Recommended: protection index 6, corresponding to> 480 minutes of permeation time according to EN 374):

butyl rubber (butyl) - coating thickness 0.7 mm

Suitable materials for short-term contact (recommended: at least protection index 2, corresponding to> 30 minutes of breakthrough time according to EN 374)

nitrile rubber (NBR) - coating thickness of 0.4 mm

chloroprene rubber (CR) - coating thickness 0.5 mm

Additional note: specifications are based on tests, literature data and information from glove manufacturers or derive from similar substances by analogy. Due to many conditions (eg temperature), it should be considered that the practical use of a chemical protective glove in practice can be much shorter than the breakthrough time determined through testing.

The manufacturer's instructions for use must be observed due to the wide variety of types.

# **SECTION 9. Physical and chemical properties**

### 9.1. Information on basic physical and chemical properties

Appearance liquid Colour yellowish Odour similar to ester Odour threshold Not available Not available Melting point / freezing point Not available Initial boiling point 240 °C Boiling range Not available 110 °C Flash point

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Evaporation rate Not available Flammability (solid, gas) Not available Lower inflammability limit Not available Upper inflammability limit Not available Lower explosive limit Not available Upper explosive limit Not available Vapour pressure Not available Vapour density Not available Relative density Not available

Solubility immiscible with water

Partition coefficient: n-octanol/water Not available
Auto-ignition temperature Not available
Decomposition temperature Not available
Viscosity Not available
Explosive properties Not explosive
Oxidising properties Not available

### 9.2. Other information

Information not available

# **SECTION 10. Stability and reactivity**

# 10.1. Reactivity

N-METHYL-2-PYRROLIDONE

Decomposes at temperatures above 300°C/572°F.Dissolves various plastic materials.

When exposed to the air it oxidates slowly to develop hydroperoxides. Completely mixable with water with a neutral or slightly basic reaction. It does not attack common materials.

### 10.2. Chemical stability

N-METHYL-2-PYRROLIDONE

Is stable up to 315°C/599°F.

# 10.3. Possibility of hazardous reactions

The product may react violently with water.

### ETHYLENE DIMETHACRYLATE

Heat-evolving polymerization can occur in the presence of radical-forming substances (eg peroxides), reducing substances and / or heavy metal ions.

METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

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Heat-evolving polymerization can occur in the presence of radical-forming substances (eg peroxides), reducing substances and / or heavy metal ions.

### BENZOILE PEROXIDE

Decomposition temperature: starts at 105 °C. Dangerous decomposition, risk of explosion.

### N-METHYL-2-PYRROLIDONE

May react dangerously with: strong oxidants, strong acids.

Exothermic reaction. Reacts with strong acids and alkalis.

### 10.4. Conditions to avoid

Avoid overheating. Prevent moisture or water from penetrating inside the containers.

### ETHYLENE DIMETHACRYLATE

The product is normally supplied in a stabilized form. If the permitted storage period and / or storage temperature are exceeded, the product may polymerize with the evolution of heat.

### METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

The product is normally supplied in a stabilized form. If the permitted storage period and / or storage temperature are exceeded, the product may polymerize with the evolution of heat.

# BENZOILE PEROXIDE

Temperatures above 30 ° C. Keep away from heat and other causes of fire (risk of exothermic decomposition). Protect from light. Protect from frost. Explosion hazard due to shock, friction, fire or other sources of ignition.

### N-METHYL-2-PYRROLIDONE

Avoid all sources of ignition: heat, sparks, open flames.

### 10.5. Incompatible materials

### ETHYLENE DIMETHACRYLATE

Peroxides, amines, sulfur compounds, heavy metal ions, alkalis, reducing agents and oxidizing agents. Mineral acids. Free radical initiators.

# METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Peroxides, amines, sulfur compounds, heavy metal ions, alkalis, reducing agents and oxidizing agents. Free radical initiators. Mineral acid.

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### BENZOILE PEROXIDE

Strong oxidizing agents, powerful reducers, acids, bases, sulfur compounds, heavy metal compounds, heavy metals, rust, ash, powders.

### N-METHYL-2-PYRROLIDONE

Incompatible with: sulphur,carbon disulphide,oxidising substances,aluminium,metals.Incompatible materials: natural rubbers,plastic materials.

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# 10.6. Hazardous decomposition products

### BENZOILE PEROXIDE

Through thermal decomposition, the formation of very reactive free radicals.

Thermal decomposition for flammable and toxic products: carbon dioxide (CO2), benzoic acid, benzene, phenyl benzoate, diphenyl.

### N-METHYL-2-PYRROLIDONE

May develop: nitric oxide, carbon oxides.

Toxic gases / vapors.

# **SECTION 11. Toxicological information**

### 11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

N-METHYL-2-PYRROLIDONE

WORKERS: inhalation; contact with the skin.

POPULATION: ingestion of contaminated food or water; inhalation of envoronmental air.

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

### N-METHYL-2-PYRROLIDONE

There are no reported cases of acute or chronic intoxication or sensitisation. On volunteers, repeated skin applications caused modest and transient erythema. Oral and inhalation trials on mice and rats revealed no teratogenic effects at non embryotoxic doses. Not mutagenic in the Ames test.

Interactive effects

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### N-METHYL-2-PYRROLIDONE

The substance enhances the skin permeability of many other substances.

### **ACUTE TOXICITY**

LC50 (Inhalation) of the mixture:

Not classified (no significant component)

LD50 (Oral) of the mixture:

Not classified (no significant component)

LD50 (Dermal) of the mixture:

Not classified (no significant component)

### ETHYLENE DIMETHACRYLATE

Method: "Appraisal of the safety of chemicals in foods, drugs and cosmetics, FDA"

Reliability: 1

Species: Rat (Wistar: male / female)

Route of exposure: Oral

Results: LD50 = 8300 mL / kg bw

Method: OECD 402

Reliability: 1

Species: Rat (Wistar; male / female) Route of exposure: Dermal Results: LD50> 2000 mg / kg bw

METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Method: OECD 401

Reliability: 1

Species: Rat (Crj: CD (SD); male / female)

Route of exposure: Oral

Results: LD50> = 2000 mg / kg bw

Method: Not indicated Reliability: 2

Species: Rabbit (male)
Route of exposure: Dermal
Results: LD50> 5000 mg / kg bw

# BENZOILE PEROXIDE

Method: OECD 401

Reliability: 1

Species: Mouse (ICR; male / female)

Route of exposure: Oral Results: Not classified

Method: Equivalent or similar to OECD 403

Reliability: 2

Species: Rat (albino Spartan; male) Route of exposure: Inhalation (dust)

Results: Not classified

# N-METHYL-2-PYRROLIDONE

Method: Equivalent or similar to OECD 401

Reliability: 2

Species: Rat (Sprague-Dawley; male / female)

Route of exposure: Oral

Results: LD50 = 4150 mg / kg bw

Method: OECD 403

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# **CHEMICAL ANCHOR IN VIAL**

Reliability: 1

Species: Rat (Wistar; male / female) Route of exposure: Inhalation (aerosol)

Results: LC50> 5.1 mg / L air

Method: Equivalent or similar to OECD 402

Reliability: 2

Species: Rat (Sprague-Dawley; male / female)

Route of exposure: Dermal Results: LD50> 5000 mg / kg bw

### SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Method: Appraisal of the safety of Chemicals in foods, drugs and cosmetics by staff of the Division of Pharmacology, FDA acc. to Draize

Reliability: 2

Species: Rabbit (New Zealand White)

Route of exposure: Dermal Results: Not irritating

### BENZOILE PEROXIDE

Method: Equivalent or similar to OECD 404

Reliability: 2

Species: Rabbit (New Zealand, Albino)

Route of exposure: Dermal Results: Not irritating

# N-METHYL-2-PYRROLIDONE

Method: Equivalent or similar to OECD 404

Reliability: 2

Species: Rabbit (albino)
Route of exposure: Dermal
Results: Not irritating

### SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

# ETHYLENE DIMETHACRYLATE

Method: according to Appraisal of the Safety of Chemicals in foods, drugs and cosmetics, FAD Draize (1959)

Reliability: 2

Species: Rabbit (New Zealand White)

Route of exposure: Ocular Results: Not irritating

### METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Method: Appraisal of the safety of Chemicals in foods, drugs and cosmetics by staff of the Division of Pharmacology, FDA acc. to Draize

Reliability: 2

Species: Rabbit (New Zealand White)

Route of exposure: Ocular

Results: Category 2B (slightly irritating to eyes)

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# CHEMICAL ANCHOR IN VIAL

Method: US FDA, 21 CFR, Part 191, Hazardous substances test for eye irritants

Reliability: 2

Species: Rabbit (New Zealand White)

Route of exposure: Ocular Results: Slightly irritating

### N-METHYL-2-PYRROLIDONE

Method: Equivalent or similar to OECD 405

Reliability: 2

Species: Rabbit (New Zealand White) Route of exposure: Ocular Results: Category 2 (eye irritant)

### RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin

### ETHYLENE DIMETHACRYLATE

Method: OECD 406 Reliability: 2

Species: Mouse (CBA; female)
Route of exposure: Dermal

Results: Category 1B (indication of skin sensitizing potential)

### METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Method: Equivalent or similar to OECD 429

Reliability: 2

Species: Mouse (CBA / Ca; female) Route of exposure: Dermal Results: Not sensitizing

# BENZOILE PEROXIDE

Method: Equivalent or similar to OECD 429

Reliability: 1

Species: Mouse (CBA / Ca, CBA / JHsd; female)

Route of exposure: Dermal

Results: Category 1 (skin sensitization)

### N-METHYL-2-PYRROLIDONE

Method: OECD 429

Reliability: 2

Species: Mouse (CBA; female) Route of exposure: Dermal Results: Not irritating

# GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

### ETHYLENE DIMETHACRYLATE

Method: OECD 473 in vitro test

Reliability: 1

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Human species

Results: Positive with and without metabolic activation

Method: OECD 474-test in vivo

Reliability: 1

Species: Mouse (CD-1; male / female)

Route of exposure: Oral Results: Negative

METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Method: OECD 476 in vitro test

Reliability: 1 Species: Chinese hamster

Results: Negative with and without metabolic activation

Method: OECD 474-test in vivo

Reliability: 1

Species: Mouse (NMRI; male / female)

Route of exposure: Oral Results: Negative

### BENZOILE PEROXIDE

Method: OECD 476 in vitro test

Reliability: 1

Species: Mouse lymphoma cells

Results: Negative

Method: OECD 474-test in vivo

Reliability: 1

Species: Mouse (ICR; male) Route of exposure: Oral Results: Negative

# N-METHYL-2-PYRROLIDONE

Method: OECD 476 in vitro test

Reliability: 1

Species: Chinese hamster

Results: Negative with and without metabolic activation

Method: OECD 474-test in vivo

Reliability: 1

Species: Mouse (NMRI; male / female)

Route of exposure: Oral Results: Negative

# CARCINOGENICITY

Does not meet the classification criteria for this hazard class

# ETHYLENE DIMETHACRYLATE

Method: Equivalent or similar to OECD 451

Reliability: 1

Species: Rat (Fischer 344; male / female)

Route of exposure: Inhalation Results: NOAEC> = 2.05 mg / L air

METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Method: Equivalent or similar to OECD 451

Reliability: 1

Species: Rat (Fischer 344; male / female)

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# CHEMICAL ANCHOR IN VIAL

Route of exposure: Inhalation

Results: Negative

### N-METHYL-2-PYRROLIDONE

Method: EPA OTS 798.3300

Reliability: 1

Species: Rat (Sprague-Dawley; male / female)

Route of exposure: Oral

Results: Negative, NOAEL = 5000 ppm

### REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

### BENZOILE PEROXIDE

Method: OECD 422

Reliability: 1

Species: Rat (Sprague-Dawley; male / female)

Route of exposure: Oral

Results: NOAEL (fertility) = 500 mg / kg

Method: OECD 414

Reliability: 1

Species: Rat (Sprague-Dawley) Route of exposure: Oral

Results: Negative, NOAEL (development) = 300 mg / kg bw / day

Adverse effects on sexual function and fertility

ETHYLENE DIMETHACRYLATE

Method: Equivalent or similar to OECD Combined Repeated Dose and Reproductive / Developmental Toxicity Screening Test (Precursor Protocol of GL

422) Reliability: 1

Species: Rat (Crj: CD (SD); male / female)

Route of exposure: Oral

Results: Negative, NOAEL (fertility)> = 1000 mg / kg bw / day

METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Method: OECD 416

Reliability: 1

Species: Rat (Wistar; male / female)

Route of exposure: Oral

Results: Negative, NOAEL (fertility) = 400 mg / kg bw / day

# N-METHYL-2-PYRROLIDONE

Method: OECD 416

Reliability: 1

Species: Rat (Wistar; male / female)

Route of exposure: Oral

Results: Negative, NOAEL (fertility) = 160 mg / kg bw / day

Adverse effects on development of the offspring

ETHYLENE DIMETHACRYLATE

Method: OECD 414

Reliability: 1

Species: Rat (Sprague-Dawley) Route of exposure: Oral

Results: Negative, NOAEL (development) = 100 mg / kg bw / day

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# **CHEMICAL ANCHOR IN VIAL**

METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Method: Equivalent or similar to OECD 414

Reliability: 1

Species: Rat (Crl: CDBR) Route of exposure: Inhalation

Results: NOAEC (development) = 8.44 mg / L air

N-METHYL-2-PYRROLIDONE

Method: Equivalent or similar to OECD 414

Reliability: 1

Species: Rabbit (New Zealand White)

Route of exposure: Oral

Results: Negative, NOAEL (development) = 55 mg / kg bw / day

### STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

### ETHYLENE DIMETHACRYLATE

Based on available data and through expert judgment, the substance is classified in the target organ toxicity class for single exposure.

METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Based on available data and through expert judgment, the substance is not classified in the target organ toxicity class for single exposure.

### BENZOILE PEROXIDE

Based on available data and through expert judgment, the substance is not classified in the target organ toxicity class for single exposure.

N-METHYL-2-PYRROLIDONE

Based on available data and through expert judgment, the substance is classified in the target organ toxicity class for single exposure.

Target organ

ETHYLENE DIMETHACRYLATE

Respiratory tract

N-METHYL-2-PYRROLIDONE

Nose

### STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ETHYLENE DIMETHACRYLATE

Method: OECD 422

Reliability: 1

Species: Rat (Crj: CD (SD); male / female)

Route of exposure: Oral

Results: Negative, NOAEL = 100 mg / kg bw / day

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# CHEMICAL ANCHOR IN VIAL

Method: OECD 413 Reliability: 1

Species: Rat (Sprague-Dawley; male / female)

Route of exposure: Inhalation Results: NOAEC = 100 ppm Method: Not indicated

Reliability: 2

Species: Mouse (C3H / HeNHsd; male)

Route of exposure: Dermal

Results: NOAEL = 100 mg / kg bw / day

### METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Method: Not indicated

Reliability: 2

Species: Rat (Wistar) Route of exposure: Dermal Results: Not indicated

# BENZOILE PEROXIDE

Method: OECD 451 Reliability: 1

Species: Mouse (B6C3F1; male / female)

Route of exposure: Dermal

Results: NOAEL> 833 mg / kg bw / day

### N-METHYL-2-PYRROLIDONE

Method: OECD 408 Reliability: 1

Species: Rat (Crl: CD BR; male / female)

Route of exposure: Oral Results: NOAEL = 3000 ppm

Method: OECD 413 Reliability: 1

Species: Rat (Wistar; male / female) Route of exposure: Inhalation (aerosol) Results: NOAEC = 0.5 mg / L air Method: Equivalent or similar to OECD 410

Reliability: 2 Species: Rabbit (albino; male) Route of exposure: Oral

Results: NOAEL = 826 mg / kg bw / day

# ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

# **SECTION 12. Ecological information**

# 12.1. Toxicity

METHACRYLIC ACID. MONOESTER WITH

PROPANE-1, 2-DIOL

LC50 - for Fish 493 mg/l/96h EC50 - for Crustacea 143 mg/l/48h EC50 - for Algae / Aquatic Plants 97,2 mg/l/72h EC10 for Algae / Aquatic Plants 97,2 mg/l/72h

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# **CHEMICAL ANCHOR IN VIAL**

Chronic NOEC for Algae / Aquatic Plants

97,2 mg/l

ETHYLENE DIMETHACRYLATE

LC50 - for Fish 15,95 mg/l/96h
EC50 - for Crustacea 44,9 mg/l/48h
EC50 - for Algae / Aquatic Plants 17,3 mg/l/72h
EC10 for Algae / Aquatic Plants 6,93 mg/l/72h
Chronic NOEC for Algae / Aquatic Plants 6,93 mg/l

### 12.2. Persistence and degradability

ETHYLENE DIMETHACRYLATE

Easily degradable in water, 69% in 28 days.

METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Rapidly degradable in water, 81% in 28 days.

BENZOILE PEROXIDE

Rapidly degradable in water, 68% in 28 days.

N-METHYL-2-PYRROLIDONE

Easily degradable in water, 73% in 28 days.

N-METHYL-2-PYRROLIDONE

Solubility in water 1000 - 10000 mg/l

Rapidly degradable

### 12.3. Bioaccumulative potential

N-METHYL-2-PYRROLIDONE

Partition coefficient: n-octanol/water -0,46

12.4. Mobility in soil

N-METHYL-2-PYRROLIDONE

Partition coefficient: soil/water 1,32

# 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 greater than 0,1%.

## 12.6. 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.

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### ETHYLENE DIMETHACRYLATE

Waste is dangerous. It must be disposed of according to the following regulations consultation with the competent local authorities and the disposal company in a suitable and authorized structure.

# METHACRYLIC ACID, MONOESTER WITH PROPANE-1, 2-DIOL

Waste is dangerous. It must be disposed of in compliance with the regulations after consulting the competent local authorities and the disposal company in a suitable and authorized facility. Strictly controlled conditions during the disposal or treatment of air, waste water and waste. Do not add waste water to a biological waste water treatment plant. Bring waste water containing AOX for professional disposal. The key number for the waste must be determined according to the European waste type list (decision on the EU waste type list 2000/532 / EC) in collaboration with the disposal company / producer / authority Official.

# BENZOILE PEROXIDE

Do not throw waste into the sewers. Discard the product by incineration after dilution in a suitable flammable solvent (in accordance with local and national regulations). The amount of active oxygen must be less than 1%.

The product is not dangerous under	<ul> <li>current provisions of the Cod</li> </ul>	de of International Carriage	of Dangerous Goods by	<sup>,</sup> Road (ADR) and by Rai	il (RID), of
the International Maritime Dangerou	s Goods Code (IMDG), and of	f the International Air Transp	oort Association (IATA) re	egulations.	

N-METHYL-2-PYRROLIDONE Incinerate in an appropriate incineration plant, observing the regulations of the local authorities. It is not possible to specify a waste code compliant with the European waste catalog (EWC), due to the dependence on use. The waste code in accordance with the European waste catalog (EWC) must be specified in collaboration with the agency / producer / dispose authorities.
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
14.3. Transport hazard class(es)
Not applicable
14.4. Packing group
Not applicable
14.5. Environmental hazards

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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 not been performed for the preparation/for the substances indicated in section 3.

# **SECTION 16. Other information**

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

Self-react. B Self-reactive substance or mixture, category B

Repr. 1B Reproductive toxicity, category 1B

Eye Irrit. 2 Eye irritation, category 2
Skin Irrit. 2 Skin irritation, category 2

STOT SE 3 Specific target organ toxicity - single exposure, category 3

Skin Sens. 1 Skin sensitization, category 1

Aquatic Chronic 1 Hazardous to the aquatic environment, chronic toxicity, category 1

H241 Heating may cause a fire or explosion.

H360D May damage the unborn child.H319 Causes serious eye irritation.

H315 Causes skin irritation.

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

**H410** Very toxic to aquatic life with long lasting effects.

EUH014 Reacts violently with water.

### LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- 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

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- 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 STEL: Short-term exposure limit
- TWA: Time-weighted average 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) 790/2009 (I Atp. CLP) of the European Parliament
- 4. Regulation (EU) 2015/830 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 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) 2018/1480 (XIII Atp. CLP)
- 16. Regulation (EU) 2019/521 (XII 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.

Product's classification is based on the calculation methods set out in Annex I of the CLP Regulation, unless otherwise indicated in sections 11 and 12. The data for evaluation of chemical-physical properties are reported in section 9.