Safety Data Sheet

According to Annex II to REACH - Regulation 2020/878 and to Annex II to UK REACH

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

1.1. Product identifier

Product name **BIOTROL 158**

UFI : **4JE0-90R7-8004-KNCK**

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

Intended use **Odor control product**

Identified Uses	Industrial	Professional	Consumer
Additive for the elimination of bad smells	✓	✓	-

Uses Advised Against

Any use not included among those recommended

1.3. Details of the supplier of the safety data sheet

Name **N.C.R. BIOCHEMICAL S.p.A.**
Full address **Via dei Carpentieri, 8-Zona Industriale il Prato**
District and Country **40050 Castello d'Argile (BO)**
Italia
Tel. +39 051 6869611 Lun-Ven 8.30-13.00/14.00-16.30
Fax +39 051 6869617

e-mail address of the competent person responsible for the Safety Data Sheet **regulatory@ncr-biochemical.com**

1.4. Emergency telephone number

For urgent inquiries refer to **Italy:**
CAV Ospedale Niguarda Ca' Granda - Milano 02 66101029
CAV Azienda Ospedaliera Papa Giovanni XXII - Bergamo 800 883300
CAV Centro Nazionale di Informazione Tossicologica - Pavia 0382 24444
CAV Az. Osp. Careggi - Firenze 055 7947819
CAV Policlinico Gemelli - Roma 06 3054343
CAV Policlinico Umberto I - Roma 06 49978000
CAV Osp. Pediatrico Bambino Gesù - Roma 06 68593726
CAV Az. Osp. Cardarelli - Napoli 081 7472870
CAV Az. Osp. Univ. Foggia - Foggia 800183459

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 2020/878.
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:

Germ cell mutagenicity, category 2	H341	Suspected of causing genetic defects.
Serious eye damage, category 1	H318	Causes serious eye damage.
Skin sensitization, category 1	H317	May cause an allergic skin reaction.

SECTION 2. Hazards identification ... / >>

2.2. Label elements

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

Hazard pictograms:

Signal words: Danger

Hazard statements:

H341 Suspected of causing genetic defects.
H318 Causes serious eye damage.
H317 May cause an allergic skin reaction.

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 protective gloves/ protective clothing / eye protection / face protection.
P310 Immediately call a POISON CENTER/doctor.
P261 Avoid breathing dust, fume, gas, mist, vapours, spray.
P201 Obtain special instructions before use.

Contains: Glyoxal … %
Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
(S)-p-mentha-1,8-diene

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

3.1. Substances

Information not relevant

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-		
CAS *160875-66-1*	10 ≤ x < 15	**Acute Tox. 4 H302, Eye Dam. 1 H318**
EC		**LD50 Oral: >300 mg/kg**
INDEX		
REACH Reg. *Polymer*		
Glyoxal … %		
CAS *107-22-2*	3 ≤ x < 5	**Muta. 2 H341, Acute Tox. 4 H332, Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335, Skin Sens. 1 H317, Classification note according to Annex VI to the CLP Regulation: B**
EC *203-474-9*		**LC50 Inhalation mists/powders: 2,44 mg/l/4h**
INDEX *605-016-00-7*		
REACH Reg. *01-2119461733-37-XXXX*		

SECTION 3. Composition/information on ingredients ... / >>

Ethanediol

CAS	*107-21-1*	0,25 ≤ x < 0,5	**Acute Tox. 4 H302, STOT RE 2 H373**
EC	*203-473-3*		**STA Oral: 500 mg/kg**
INDEX	*603-027-00-1*		
REACH Reg.	*01-2119456816-28-XXXX*		

Isopentyl acetate

CAS	*123-92-2*	0,1 ≤ x < 0,25	**Flam. Liq. 3 H226, EUH066, Classification note according to Annex VI to the CLP Regulation: C**
EC	*204-662-3*		
INDEX	*607-130-00-2*		
REACH Reg.	*01-2119548408-32-XXXX*		

(S)-p-mentha-1,8-diene

CAS	*5989-54-8*	0,1 ≤ x < 0,25	**Flam. Liq. 3 H226, Asp. Tox. 1 H304, Skin Irrit. 2 H315, Skin Sens. 1 H317, Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410 M=1**
EC	*227-815-6*		
INDEX	*601-029-00-7*		

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 30-60 minutes, opening the eyelids fully. Get medical advice/attention.
SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.
INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor.
INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.

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.

SECTION 6. Accidental release measures ... / >>

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

Provide for a sufficient ventilation and air change in the warehouses or working places.
Keep the product into the original airtight closed containers, and at temperatures between 5 and 25°C. Protect against light.

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.

Provide for a sufficient ventilation and air change in the warehouses or working places.

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.

Keep the product into the original airtight closed containers, and at temperatures between 5 and 25°C. Protect against light.

7.3. Specific end use(s)

See the exposure scenarios attached to this safety datasheet.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory References:

BGR	България	НАРЕДБА № 13 ОТ 30 ДЕКЕМВРИ 2003 Г. ЗА ЗАЩИТА НА РАБОТЕЩИТЕ ОТ РИСКОВЕ, СВЪРЗАНИ С ЕКСПОЗИЦИЯ НА ХИМИЧНИ АГЕНТИ ПРИ РАБОТА (изм. ДВ. бр.5 от 17 Януари 2020г.)
CZE	Česká Republika	Nařízení vlády č. 41/2020 Sb. Nařízení vlády, kterým se mění nařízení vlády č. 361/2007 Sb., kterým se stanoví podmínky ochrany zdraví při práci, ve znění pozdějších předpisů
DEU	Deutschland	Technischen Regeln für Gefahrstoffe (TRGS 900) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte. MAK- und BAT-Werte-Liste 2020, Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 56
DNK	Danmark	Bekendtgørelse om grænseværdier for stoffer og materialer - BEK nr 1458 af 13/12/2019
ESP	España	Límites de exposición profesional para agentes químicos en España 2021
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
FIN	Suomi	HTP-VÄRDEN 2020. Koncentrationer som befunnits skadliga. SOCIAL - OCH HÄLSOVÅRDSMINISTERIETS PUBLIKATIONER 2020:25
GRC	Ελλάδα	Π.Δ. 26/2020 (ΦΕΚ 50/Α` 6.3.2020) Εναρμόνιση της ελληνικής νομοθεσίας προς τις διατάξεις των οδηγιών 2017/2398/ΕΕ, 2019/130/ΕΕ και 2019/983/ΕΕ «για την τροποποίηση της οδηγίας 2004/37/ΕΚ ''σχετικά με την προστασία των εργαζομένων από τους κινδύνους που συνδέονται με την έκθεση σε καρκινογόνους ή μεταλλαξιγόνους παράγοντες κατά την εργασία''»

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

HUN	Magyarország	Az innovációért és technológiáért felelős miniszter 5/2020. (II. 6.) ITM rendelete a kémiai kóroki tényezők hatásának kitett munkavállalók egészségének és biztonságának védelméről
HRV	Hrvatska	Pravilnik o izmjenama i dopunama Pravilnika o zaštiti radnika od izloženosti opasnimkemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
NOR	Norge	Forskrift om endring i forskrift om tiltaksverdier og grenseverdier for fysiske og kjemiske faktorer i arbeidsmiljøet samt smitterisikogrupper for biologiske faktorer (forskrift om tiltaks- og grenseverdier), 21. august 2018 nr. 1255
NLD	Nederland	Arbeidsomstandighedenregeling. Lijst van wettelijke grenswaarden op grond van de artikelen 4.3, eerste lid, en 4.16, eerste lid, van het Arbeidsomstandighedenbesluit
POL	Polska	Rozporządzenie ministra rozwoju, pracy i technologii z dnia 18 lutego 2021 r. Zmieniające rozporządzenie w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy
ROU	România	Hotărârea nr. 53/2021 pentru modificarea hotărârii guvernului nr. 1.218/2006, precum și pentru modificarea și completarea hotărârii guvernului nr. 1.093/2006
SWE	Sverige	Hygieniska gränsvärden, Arbetsmiljöverkets föreskrifter och allmänna råd om hygieniska gränsvärden (AFS 2018:1)
SVK	Slovensko	NARIADENIE VLÁDY Slovenskej republiky z 12. augusta 2020, ktorým sa mení a dopĺňa nariadenie vlády Slovenskej republiky č. 356/2006 Z. z. o ochrane zdravia zamestnancov pred rizikami súvisiacimi s expozíciou karcinogénnym a mutagénnym faktorom pri práci v znení neskorších predpisov
TUR	Türkiye	Kimyasal Maddelerle Çalışmalarda Sağlık ve Güvenlik Önlemleri Hakkında Yönetmelik 12.08.2013 / 28733
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 2021

Glyoxal ... %

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
TLV	DNK	0,5	0,2			
VLA	ESP	0,1				INHAL
HTP	FIN	0,02				
TLV-ACGIH		0,1				

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,319	mg/l
Normal value in marine water	0,0319	mg/l
Normal value for fresh water sediment	0,685	mg/kg
Normal value for marine water sediment	0,0685	mg/kg
Normal value for water, intermittent release	1,1	mg/l
Normal value of STP microorganisms	4,1	mg/l
Normal value for the terrestrial compartment	6,3	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								5,28 mg/m3
Skin								10,8 mg/kg

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

Ethanediol

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
TLV	BGR	52		104		SKIN
TLV	CZE	50		100		SKIN
AGW	DEU	26	10	52	20	SKIN
MAK	DEU	26	10	52	20	SKIN
TLV	DNK	26	10			SKIN
VLA	ESP	52	20	104	40	SKIN
VLEP	FRA	52	20	104	40	SKIN
HTP	FIN	50	20	100	40	SKIN
TLV	GRC	125	50	125	50	
AK	HUN	52		104		
GVI/KGVI	HRV	52	20	104	40	SKIN
VLEP	ITA	52	20	104	40	SKIN
TLV	NOR		25			SKIN
TGG	NLD	52		104		SKIN
NGV/KGV	SWE	25	10	50	20	SKIN
NPEL	SVK	52	20	104		SKIN
ESD	TUR	52	20	104	40	SKIN
WEL	GBR	52	20	104	40	
OEL	EU	52	20	104	40	SKIN
TLV-ACGIH				100 (C)		

Predicted no-effect concentration - PNEC

Normal value in fresh water	10	mg/l
Normal value in marine water	1	mg/l
Normal value for fresh water sediment	37	mg/kg
Normal value for marine water sediment	3,7	mg/kg
Normal value for water, intermittent release	10	mg/l
Normal value of STP microorganisms	199,5	mg/l
Normal value for the terrestrial compartment	1,53	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			VND	7 mg/m3			VND	35 mg/m3
Skin				53 mg/kg bw/d				106 mg/kg bw/d

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

(S)-p-mentha-1,8-diene

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
MAK	DEU	28	5	112	20	
HTP	FIN	140	25	280	50	

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,0054	mg/l
Normal value in marine water	0,00054	mg/l
Normal value for fresh water sediment	1,322	mg/kg/dw
Normal value for marine water sediment	132,2	mg/kg/dw
Normal value for water, intermittent release	0,0036	mg/l
Normal value of STP microorganisms	0,2	mg/l
Normal value for the food chain (secondary poisoning)	133	mg/kg
Normal value for the terrestrial compartment	262	mg/kg/dw
Normal value for the atmosphere	VND	

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				4,76 mg/kg bw/d				
Inhalation				8,33 mg/m3				33,3 mg/m3
Skin	0,111 mg/cm2				0,222 mg/cm2			

Isopentyl acetate

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
AGW	DEU	270	50	270	50	
MAK	DEU	270	50	270	50	
TLV	DNK	271	50	532	100	
VLA	ESP	270	50	540	100	
VLEP	FRA	270	50	540	100	
HTP	FIN	270	50	540	100	
AK	HUN	270		540		
VLEP	ITA	270	50	540	100	
TLV	NOR	260	50			
TGG	NLD			530		
NDS/NDSCh	POL	250		500		
TLV	ROU	270	50	540	100	
NGV/KGV	SWE	500	100	800	150	
WEL	GBR	270	50	541	100	
OEL	EU	270	50	540	100	

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.
When choosing risk management measures and operating conditions, consult the exposure scenarios attached.
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

SECTION 8. Exposure controls/personal 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.
ENVIRONMENTAL EXPOSURE CONTROLS
The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.
For information on controlling environmental exposure, see the exposure scenarios attached to this safety datasheet.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties		Value	Information
Appearance		liquid	
Colour		yellow	
Odour		fruity	
Odour threshold		Not determined	
Melting point / freezing point		-2 °C	Method:ITL 71
Initial boiling point	>	100 °C	
Flammability		not flammable	
Lower explosive limit		Not applicable	
Upper explosive limit		Not applicable	
Flash point	>	60 °C	Method:ASTM D93
Auto-ignition temperature		Not determined	
Decomposition temperature		Not determined	
pH		5,5 ± 0,5	Method:ITL 70 Temperature: 25 °C
Kinematic viscosity		3,33 mm2/s	Method:ITL 66 Remark:100 RPM; LCP Temperature: 23,8 °C
Dynamic viscosity		3,43 cPs	
Solubility		soluble in water	Method:ITL 73
Partition coefficient: n-octanol/water		Not determined	
Vapour pressure		Not determined	
Density and/or relative density		1,01 ÷ 1,05 g/ml	Method:ITL 15 B Temperature: 20 °C
Relative vapour density		Not determined	
Particle characteristics		Not applicable	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Evaporation rate	Not determined
Explosive properties	not applicable because it does not contain any explosives functional groups
Oxidising properties	not applicable because it does not contain any oxidizing functional groups

SECTION 10. Stability and reactivity

10.1. Reactivity

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

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
Stable in normal conditions of use and storage.

10.2. Chemical stability

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

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
Stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

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

Glyoxal ... %
It polymerises by contact with: amines, ammonia, water, akaline substances. It may react dangerously with nitric acid, sodium hydroxide, sulphuric acid, chlorosulohuric acid, ethyleneamine. It forms explosive mixtures with the air.

10.4. Conditions to avoid

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

Glyoxal ... %
Keep away from heat and direct light to avoid product polymerisation.

10.5. Incompatible materials

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
Avoid contact with: caustic substances,halogens,alkaline substances,acids,reactive chemicals.

10.6. Hazardous decomposition products

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
When heated to decomposition releases: irritating vapours,toxic substances.

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.

(S)-p-mentha-1,8-diene
Repeated oral dose toxicity:
NOAEL (rat): 600 - 3 300 mg/kg bw/day
NOAEL (mouse): 500 - 1 650 mg/kg bw/day
NOAEL (dog): 100 mg/kg bw/day
LOAEL (rat): 1 200 - 1 650 mg/kg bw/day
LOAEL (mouse): 3 300 mg/kg bw/day
Tests performed using read-across with analogous substances according to OECD Guideline 407, 408, 409 and GLP. Reliability: 2

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
Unless otherwise specified in the following paragraphs, for the involved substance toxicological data in the following list are considered not available: acute toxicity, skin corrosion/irritation, serious eye damage/irritation, respiratory or skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT - single exposure, STOT - repeated exposure, aspiration hazard.

Ethanediol
Unless otherwise specified in the following paragraphs, the toxicological data in the following list are for the substance concerned: acute toxicity, corrosion / skin irritation, serious eye / serious eye irritation, respiratory or skin sensitization, mutagenicity of germ cells , carcinogenicity, reproductive toxicity, target organ toxicity (STOT) - single exposure, target organ toxicity (STOT) - repeated exposure, danger in case of aspiration.

Metabolism, toxicokinetics, mechanism of action and other information

SECTION 11. Toxicological 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 (Oral) of the mixture: >2000 mg/kg
ATE (Dermal) of the mixture: Not classified (no significant component)

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
LD50 (Oral): > 300 mg/kg Rat, source CESIO

Glyoxal … %
LD50 (Dermal): > 2000 mg/kg Rat OECD 402 (LIMIT Test)
LD50 (Oral): 3300 mg/kg Rat, according to OECD Guideline 401, reliability 1
LC50 (Inhalation mists/powders): 2,44 mg/l/4h Rat, according to OECD Guideline 403, reliability 1

Ethanediol
LD50 (Dermal): > 3500 mg/kg Rat
LD50 (Oral): 7712 mg/kg Rat
LC50 (Inhalation vapours): > 2,5 mg/l Rat (6h on aereosol)

Ethanediol
Harmful if swallowed.

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
Based on available data, the classification criteria are not met.
Test carried out on rabbits, 4h, source: CESIO.

Glyoxal … %
Irritating in case of skin contact (OECD 405, rabbit).

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

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye damage

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
The substance is classified as irritating to the eyes.
Test carried out on rabbits, source: CESIO.

Glyoxal … %
Irritating in case of eye contact (OECD 404, rabbit).

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

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin

SECTION 11. Toxicological information ... / >>

Glyoxal … %
Skin sensitizing (OECD 406, Guinea pig Maximation test).

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

Respiratory sensitization

Information not available

Skin sensitization

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
Based on available data, the classification criteria are not met.

GERM CELL MUTAGENICITY

Suspected of causing genetic defects

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
Based on available data, the classification criteria are not met.

Glyoxal … %
The substance was mutagenic in various test microorganisms and cell cultures.

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

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
Based on available data, the classification criteria are not met.

Glyoxal … %
The available information does not provide any indication of a possible carcinogenic effect, nor effects to reproductive toxicity nor effects to developmental toxicity.

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

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
Based on available data, the classification criteria are not met.

Glyoxal … %
The available information does not provide any indication of a possible carcinogenic effect, nor effects to reproductive toxicity nor effects to developmental toxicity.

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

Adverse effects on sexual function and fertility

Information not available

Adverse effects on development of the offspring

Information not available

Effects on or via lactation

Information not available

STOT - SINGLE EXPOSURE

SECTION 11. Toxicological information ... / >>

Does not meet the classification criteria for this hazard class

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
Based on available data, the classification criteria are not met.

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

Target organs

Information not available

Route of exposure

Information not available

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
Based on available data, the classification criteria are not met.

Ethanediol
It may cause damage to organs in case of prolonged or repeated exposure.

Target organs

Information not available

Route of exposure

Information not available

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-
Based on available data, the classification criteria are not met.

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

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

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Glyoxal ... %
EC20 (0,5h)> 1000 mg / l Activated sludge OECD 209 static
LC50 (14d)> 398 mg / Kg Eisenia foetida OECD 207
NOEC (21d) 203 mg / kg Brassica napus OECD 20

(S)-p-mentha-1,8-diene

LC50 - for Fish	0,845 mg/l/96h Calculated (ECOSAR v1.00) according to REACH guidance models R.6, Reliability 2
EC50 - for Crustacea	0,36 mg/l/48h Daphnia magna, OECD Guideline 202, Reliability 1
EC50 - for Algae / Aquatic Plants	0,904 mg/l/96h Calculated (ECOSAR v1.00) according to REACH guidance models R.6, Reliability 2
Chronic NOEC for Crustacea	0,074 mg/l Daphnia magna, 48h, OECD Guideline 202, Reliability 1
Chronic NOEC for Algae / Aquatic Plants	0,514 mg/l 96h, calculated (ECOSAR v1.00) according to REACH guidance models R.6,

SECTION 12. Ecological information ... / >>

Reliability 2

Ethanediol

LC50 - for Fish	72860 mg/l/96h Pimepales Promelas (EPA 72-1, static)
EC50 - for Crustacea	> 100 mg/l/48h Daphnia Magna (EOCD 202, static)
EC50 - for Algae / Aquatic Plants	> 6500 mg/l/96h Selenastrum Capricornutum
Chronic NOEC for Fish	15380 mg/l Pimephales Promelas (7d)
Chronic NOEC for Crustacea	8590 mg/l Ceriodaphnia Sp. (7d)

Glyoxal ... %

LC50 - for Fish	464 mg/l/96h Leuciscus Idus DIN 38412 part 15, static
EC50 - for Crustacea	404 mg/l/48h Daphnia magna Directive 78/831/CEE, static
EC50 - for Algae / Aquatic Plants	> 100 mg/l/72h Scenedesmus subspicatus OECD 201 static
Chronic NOEC for Fish	112 mg/l/34d Pimephales promelas OPP 72-4 EPA, flux
Chronic NOEC for Crustacea	3,19 mg/l/21d Daphnia Magna OECD 211 semistatic

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-

LC50 - for Fish	> 10 mg/l/96h Carassius Auratus, source CESIO
EC50 - for Crustacea	> 10 mg/l/48h Daphnia magna, source CESIO
EC50 - for Algae / Aquatic Plants	> 10 mg/l/72h Scenedesmus subspicatus, data from similar products
Chronic NOEC for Fish	> 1 mg/l Bibliographic data

12.2. Persistence and degradability

(S)-p-mentha-1,8-diene

Rapidly degradable	85%, 28d, OECD Guideline 301 D

Glyoxal ... %

Rapidly degradable	90-100% COD (19d) OECD 301 A

Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-

Rapidly degradable	> 60%, 28d, OECD 301B, data from similar products

12.3. Bioaccumulative potential

(S)-p-mentha-1,8-diene

Partition coefficient: n-octanol/water	4,32 @ 37°C and pH 7,2

Ethanediol

Partition coefficient: n-octanol/water	-1,36 Calcolo Hansch-Leo 23°C

Glyoxal ... %

Partition coefficient: n-octanol/water	-1,15 OECD 107, 23°C pH 7
BCF	3,2 calculated

12.4. Mobility in soil

(S)-p-mentha-1,8-diene

Partition coefficient: soil/water	> 1120 QSAR according to Reach guidance on QSAR - R.6

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. Endocrine disrupting properties

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 or ID 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

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

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/EU: 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 (EU) 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 Regulation (EU) 649/2012:

SECTION 15. Regulatory information ... / >>

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.

German regulation on the classification of substances hazardous to water (AwSV, vom 18. April 2017)
WGK 1: Low hazard to waters

15.2. Chemical safety assessment

A chemical safety assessment has been performed for the following contained substances
Ethanediol

SECTION 16. Other information

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

Flam. Liq. 3	Flammable liquid, category 3
Muta. 2	Germ cell mutagenicity, category 2
Acute Tox. 4	Acute toxicity, category 4
Asp. Tox. 1	Aspiration hazard, category 1
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2
Eye Dam. 1	Serious eye damage, category 1
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 Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
H226	Flammable liquid and vapour.
H341	Suspected of causing genetic defects.
H302	Harmful if swallowed.
H332	Harmful if inhaled.
H304	May be fatal if swallowed and enters airways.
H373	May cause damage to organs through prolonged or repeated exposure.
H318	Causes serious eye damage.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

LEGEND:
- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 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: 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

SECTION 16. Other information ... / >>

- REACH: Regulation (EC) 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 (EC) 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
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 / 08 / 09 / 11 / 12 / 15 / 16.

Exposure Scenarios

Substance	Ethanediol
Scenario Title	SE_Glicole etilenico
Revision nr.	7
File	EN_SEGLICOLEETILENICO_7.pdf