

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 117**
UFI : **Y5F0-U0K0-D00M-61F1**

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.
Eye irritation, category 2	H319	Causes serious eye irritation.
Skin irritation, category 2	H315	Causes skin irritation.
Specific target organ toxicity - single exposure, category 3	H335	May cause respiratory irritation.
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: Warning

Hazard statements:

H341	Suspected of causing genetic defects.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.

Precautionary statements:

P280	Wear protective gloves/ protective clothing / eye protection / face protection.
P261	Avoid breathing dust, fume, gas, mist, vapours, spray.
P201	Obtain special instructions before use.
P312	Call a POISON CENTRE/doctor if you feel unwell.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

Contains: Glyoxal ... %

2.3. Other hazards

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

The product does not contain substances with endocrine disrupting properties in concentration \geq 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)
Glyoxal ... %		
CAS 107-22-2	$25 \leq x < 50$	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 LC50 Inhalation mists/powders: 2,44 mg/l/4h
EC 203-474-9		
INDEX 605-016-00-7		
REACH Reg. 01-2119461733-37-XXXX		
Ethanediol		
CAS 107-21-1	$1 \leq x < 3$	Acute Tox. 4 H302, STOT RE 2 H373 STA Oral: 500 mg/kg
EC 203-473-3		
INDEX 603-027-00-1		
REACH Reg. 01-2119456816-28-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.

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.

Storage class TRGS 510 (Germany): 12

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 HÄLSOVÄRDSMINISTERIETS 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 μεταλλαξιογόνους παράγοντες κατά την εργασία"»
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 opasnim kemikalijama 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
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 karcinogénym a mutagénym 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

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

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

Route of exposure	Effects on consumers				Effects on workers			
	Acute	Acute	Chronic	Chronic	Acute	Acute	Chronic	Chronic
	local	systemic	local	systemic	local	systemic	local	systemic
Inhalation								5,28 mg/m3
Skin								10,8 mg/kg

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

Route of exposure	Effects on consumers				Effects on workers			
	Acute	Acute	Chronic	Chronic	Acute	Acute	Chronic	Chronic
	local	systemic	local	systemic	local	systemic	local	systemic
Inhalation			VND	7 mg/m3			VND	35 mg/m3
Skin				53 mg/kg bw/d				106 mg/kg bw/d

Legend:

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

(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

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	from colourless to slightly coloured	
Odour	characteristic	
Melting point / freezing point	< -15 °C	
Initial boiling point	103,6 °C	
Flammability	not flammable	
Lower explosive limit	Not applicable	
Upper explosive limit	Not applicable	
Flash point	> 60 °C	
Auto-ignition temperature	Not applicable	
pH	2,5 ÷ 3,5	
Kinematic viscosity	6,6 mm ² /s	Temperature: 20 °C
Dynamic viscosity	8,38 mPa/s	Temperature: 20 °C
Solubility	soluble in water	
Partition coefficient: n-octanol/water	Not available	
Vapour pressure	20,2 (20 °C)	
Density and/or relative density	1,27	Temperature: 20 °C
Relative vapour density	Not available	
Particle characteristics	Not applicable	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

SECTION 9. Physical and chemical properties ... / >>

9.2.2. Other safety characteristics

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.

10.2. Chemical stability

The product is 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, alkaline substances. It may react dangerously with nitric acid, sodium hydroxide, sulphuric acid, chlorosulphuric 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

Information not available

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 hazard classes as defined in Regulation (EC) No 1272/2008

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

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

SECTION 11. Toxicological information ... / >>

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)

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
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)
LC50 (Inhalation vapours): > 2,5 mg/l Rat (6h on aereosol)

Ethanediol
Harmful if swallowed.

SKIN CORROSION / IRRITATION

Causes skin irritation

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 irritation

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

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

Information not available

GERM CELL MUTAGENICITY

Suspected of causing genetic defects

SECTION 11. Toxicological information ... / >>

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

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

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

May cause respiratory irritation

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

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

SECTION 11. Toxicological information ... / >>

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

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

Ethanediol

LC50 - for Fish

EC50 - for Crustacea

EC50 - for Algae / Aquatic Plants

Chronic NOEC for Fish

Chronic NOEC for Crustacea

72860 mg/l/96h Pimepales Promelas (EPA 72-1, static)

> 100 mg/l/48h Daphnia Magna (EOCD 202, static)

> 6500 mg/l/96h Selenastrum Capricornutum

15380 mg/l Pimepales Promelas (7d)

8590 mg/l Ceriodaphnia Sp. (7d)

Glyoxal ... %

LC50 - for Fish

EC50 - for Crustacea

EC50 - for Algae / Aquatic Plants

Chronic NOEC for Fish

Chronic NOEC for Crustacea

464 mg/l/96h Leuciscus Idus DIN 38412 part 15, static

404 mg/l/48h Daphnia magna Directive 78/831/CEE, static

> 100 mg/l/72h Scenedesmus subspicatus OECD 201 static

112 mg/l/34d Pimepales promelas OPP 72-4 EPA, flux

3,19 mg/l/21d Daphnia Magna OECD 211 semistatic

12.2. Persistence and degradability

Glyoxal ... %

Rapidly degradable

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

12.3. Bioaccumulative potential

Ethanediol

Partition coefficient: n-octanol/water

-1,36 Calcolo Hansch-Leo 23°C

Glyoxal ... %

Partition coefficient: n-octanol/water

BCF

-1,15 OECD 107, 23°C pH 7

3,2 calculated

12.4. Mobility in soil

Information not available

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 \geq 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.

SECTION 15. Regulatory information ... / >>

None

Substances subject to exportation reporting pursuant to Regulation (EU) 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.

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:

Muta. 2	Germ cell mutagenicity, category 2
Acute Tox. 4	Acute toxicity, category 4
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2
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
H341	Suspected of causing genetic defects.
H302	Harmful if swallowed.
H332	Harmful if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.

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
- 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

SECTION 16. Other information ... / >>

- 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 / 09 / 11 / 12 / 15 / 16.

Exposure Scenarios

Substance	Ethanediol
Scenario Title	SE_Glicole etilenico
Revision nr.	7
File	EN_SEGGLICOLEETILENICO_7.pdf