

BIO-OPTICA MILANO SPA

B-Alcohol 95 for B-PRO 450

Revision nr.6
Dated 06/12/2024
Printed on 06/12/2024
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EN

Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878

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

1.1. Product identifier

Code: **450005**
Product name **B-Alcohol 95 for B-PRO 450**

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

Intended use **In vitro medical-diagnostic disposable.Reagent for microscopy.**

Identified Uses	Industrial	Professional	Consumer
In vitro diagnostic reagent	-	✓	-

1.3. Details of the supplier of the safety data sheet

Name **BIO-OPTICA MILANO SPA**
Full address **via San Faustino, 58**
District and Country **20134 Milano (MI) Italia**
Tel. **0039 02 2127131**
Fax **0039 02 2153000**

e-mail address of the competent person responsible for the Safety Data Sheet

sds@bio-optica.it

Supplier: **Bio-Optica Milano S.p.a.**

1.4. Emergency telephone number

For urgent inquiries refer to **0845 46 47, Poison centres NHS Direct in England or Wales
08454 24 24 24, Poison centres NHS 24 in Scotland**

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:

Flammable liquid, category 2 H225 Highly flammable liquid and vapour.

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:
H225 Highly flammable liquid and vapour.

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Precautionary statements:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective gloves/ protective clothing / eye protection / face protection.
P370+P378 In case of fire: use . . . to extinguish.
P233 Keep container tightly closed.

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

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
ETHANOL		
INDEX 603-002-00-5	$83,6 \leq x < 87,4$	Flam. Liq. 2 H225
EC 200-578-6		
CAS 64-17-5		
PROPAN-2-OL		
INDEX 603-117-00-0	$7,6 \leq x < 11,4$	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336
EC 200-661-7		
CAS 67-63-0		

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

No effects requiring implementation of special first aid measures are expected. The following information represents practical indications of correct behaviour in the event of contact with a chemical product, even if not hazardous.

In case of doubt or in the presence of symptoms contact a doctor and show him this document.

In case of more severe symptoms, ask for immediate medical aid.

EYES: Wash immediately and thoroughly with running water. Get medical advice if you feel symptoms.

SKIN: Wash with plenty of water. Get medical advice if you feel symptoms.

INGESTION: Do not induce vomiting unless explicitly authorised by a doctor. Do not give anything by mouth to an unconscious person. Get medical advice.

INHALATION: Remove to open air. Get medical advice if you feel symptoms.

Rescuer protection

It is good practice for rescuers lending support to a person who has been exposed to a chemical substance or to a mixture to wear personal protective equipment. The nature of such protection depends on the hazard level of the substance or mixture, on the type of exposure and on the extent of the contamination. In the absence of other more specific indications, use of disposable gloves in the event of possible contact with body fluids is recommended. For the type of PPE suitable for the characteristics of the substance or mixture, see section 8.

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

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

DELAYED EFFECTS: Based on the information currently available, there are no known cases of delayed effects following exposure to this product.

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

If symptoms occur, whether acute or delayed, consult a doctor.

Means to have available in the workplace for specific and immediate treatment

Running water for skin and eye wash.

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SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.

UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Excess pressure may form in containers exposed to fire at a risk of explosion. 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.

Send away individuals who are not suitably equipped. Use explosion-proof equipment. Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site.

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

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. Vigorous stirring and flow through the tubes and equipment may cause the formation and accumulation of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during 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 the containers sealed, in a well ventilated place, away from direct sunlight. Store in a cool and well

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ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. 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:

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 ze dne 10. května 2021, kterým se mění nařízení vlády č. 361/2007 Sb., kterým se stanoví podmínky ochrany zdraví při práci
DEU	Deutschland	Forschungsgemeinschaft MAK- und BAT-Werte-Liste 2022 Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe Mitteilung 58
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 2023
EST	Eesti	Ohtlike kemikaalide ja neid sisaldavate materjalide kasutamise töötavishoiu ja tööohutuse nõuded ning töökeskkonna keemiliste ohutegurite piirnormid [RT I, 21.12.2022, 14]
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France Décret n° 2021-1849 du 28 décembre 2021
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)
LTU	Lietuva	Jsakymas dėl lietuvos higienos normos hn 23:2011 „cheminių medžiagų profesinio poveikio ribiniai dydžiai. Matavimo ir poveikio vertinimo bendrieji reikalavimai“ patvirtinimo
LVA	Latvija	Grozījumi Ministru kabineta 2007. gada 15. maija noteikumos Nr. 325 "Darba aizsardzības prasības saskarē ar ķīmiskajām vielām darba vietās" (prot. Nr. 32 18. §; prot. Nr. 1 22. §)
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
RUS	Россия	ПОСТАНОВЛЕНИЕ от 13 февраля 2018 г. N 25 ОБ УТВЕРЖДЕНИИ ГИГИЕНИЧЕСКИХ НОРМАТИВОВ ГН 2.2.5.3532-18 "ПРЕДЕЛЬНО ДОПУСТИМЫЕ КОНЦЕНТРАЦИИ (ПДК) ВРЕДНЫХ ВЕЩЕСТВ В ВОЗДУХЕ РАБОЧЕЙ ЗОНЫ"
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; 20.10.2023 / 32345.
GBR	United Kingdom TLV-ACGIH	EH40/2005 Workplace exposure limits (Fourth Edition 2020) ACGIH 2023

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ETHANOL

Threshold Limit Value						Remarks / Observations
Type	Country	TWA/8h		STEL/15min		
		mg/m ³	ppm	mg/m ³	ppm	
TLV	BGR	1000				
TLV	CZE	1000	522	3000	1566	
AGW	DEU	380	200	1520	800	
MAK	DEU	380	200	1520	800	
TLV	DNK	1900	1000			
VLA	ESP			1910	1000	
TLV	EST	1000	500	1900	1000	
VLEP	FRA	1900	1000	9500	5000	
HTP	FIN	1900	1000	2500	1300	
TLV	GRC	1900	1000			
AK	HUN	1900	1000	3800	2000	
GVI/KGVI	HRV	1900	1000			
RD	LTU	1000	500	1900	1000	
RV	LVA	1000				
TLV	NOR	950	500			
TGG	NLD	260		1900		SKIN
NDS/NDSch	POL	1900				
TLV	ROU	1900	1000	9500	5000	
ПДК	RUS	1000		2000		n
NGV/KGV	SWE	1000	500	1900 (C)	1000 (C)	
NPEL	SVK	960	500	1920	1000	
ESD	TUR	1900	1000			
WEL	GBR	1920	1000			
TLV-ACGIH				1884	1000	

PROPAN-2-OL

Threshold Limit Value						Remarks / Observations
Type	Country	TWA/8h		STEL/15min		
		mg/m ³	ppm	mg/m ³	ppm	
TLV	BGR	980		1225		
TLV	CZE	500	200	1000	400	
AGW	DEU	500	200	1000	400	
MAK	DEU	500	200	1000	400	
TLV	DNK	490	200			
VLA	ESP	500	200	1000	400	
TLV	EST	350	150	600	250	
VLEP	FRA			980	400	
HTP	FIN	500	200	620	250	
TLV	GRC	980	400	1225	500	
AK	HUN	500	200	1000	400	SKIN
GVI/KGVI	HRV	999	400	1250	500	
RD	LTU	350	150	600	250	
RV	LVA	350		600		
TLV	NOR	245	100			
TGG	NLD	650				
NDS/NDSch	POL	900		1200		SKIN
TLV	ROU	200	81	500	203	
ПДК	RUS	10		50		n
NGV/KGV	SWE	350	150	600 (C)	250 (C)	
NPEL	SVK	500	200	1000	400	
ESD	TUR	980	400			
WEL	GBR	999	400	1250	500	
TLV-ACGIH		492	200	983	400	

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

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.

HAND PROTECTION

Protect hands with category III work gloves.

The following should be considered when choosing work glove material (see standard EN 374): compatibility, degradation, permeability

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time.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

Consider the appropriateness of providing antistatic clothing in the case of working environments in which there is a risk of explosion.

EYE PROTECTION

Wear airtight protective goggles (see standard EN ISO 16321).

RESPIRATORY PROTECTION

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. Use a mask with a type AX filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387).

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.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	liquid	
Colour	colourless	
Odour	characteristic of solvent	
Melting point / freezing point	not available	
Initial boiling point	> 35 °C	
Flammability	not available	
Lower explosive limit	not available	
Upper explosive limit	not available	
Flash point	< 23 °C	
Auto-ignition temperature	not available	
Decomposition temperature	not available	
pH	not available	
Kinematic viscosity	not available	
Solubility	not available	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	not available	
Density and/or relative density	0,79	
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

9.2.2. Other safety characteristics

VOC (Directive 2010/75/EU)	95,00 %	-	748,32	g/litre
VOC (volatile carbon)	50,23 %	-	395,68	g/litre

SECTION 10. Stability and reactivity

10.1. Reactivity

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

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10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

The vapours may also form explosive mixtures with the air.

ETHANOL

Risk of explosion on contact with: alkaline metals,alkaline oxides,calcium hypochlorite,sulphur monofluoride,acetic anhydride,acids,concentrated hydrogen peroxide,perchlorates,perchloric acid,perchloronitrile,mercury nitrate,nitric acid,silver,silver nitrate,ammonia,silver oxide,ammonia,strong oxidising agents,nitrogen dioxide.May react dangerously with: bromoacetylene,chlorine acetylene,bromine trifluoride,chromium trioxide,chromyl chloride,fluorine,potassium tert-butoxide,lithium hydride,phosphorus trioxide,black platinum,zirconium (IV) chloride,zirconium (IV) iodide.Forms explosive mixtures with: air.

10.4. Conditions to avoid

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

ETHANOL

Avoid exposure to: sources of heat,naked flames.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

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

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

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

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)
ATE (Oral) of the mixture:	Not classified (no significant component)
ATE (Dermal) of the mixture:	Not classified (no significant component)

ETHANOL

LD50 (Oral):	> 5000 mg/kg Rat
LC50 (Inhalation vapours):	117 mg/l/4h Rat

PROPAN-2-OL

LD50 (Dermal):	12800 mg/kg Rat
LD50 (Oral):	4710 mg/kg Rat
LC50 (Inhalation vapours):	72,6 mg/l/4h Rat

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SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

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

Information not available

12.2. Persistence and degradability

ETHANOL
Solubility in water 1000 - 10000 mg/l
Rapidly degradable

PROPAN-2-OL
Rapidly degradable

12.3. Bioaccumulative potential

ETHANOL
Partition coefficient: n-octanol/water -0,35

PROPAN-2-OL
Partition coefficient: n-octanol/water 0,05

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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.

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.

Waste transportation may be subject to ADR restrictions.

The management of waste arising from the use or dispersal of this product must be organised in accordance with occupational safety regulations. See section 8 for possible need for PPE.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

14.1. UN number or ID number

ADR / RID, IMDG, IATA: UN 1987

14.2. UN proper shipping name

ADR / RID: ALCOHOLS, N.O.S. (ETHANOL; PROPAN-2-OL)

IMDG: ALCOHOLS, N.O.S. (ETHANOL; PROPAN-2-OL)

IATA: ALCOHOLS, N.O.S. (ETHANOL; PROPAN-2-OL)

14.3. Transport hazard class(es)

ADR / RID: Class: 3 Label: 3

IMDG: Class: 3 Label: 3

IATA: Class: 3 Label: 3



14.4. Packing group

ADR / RID, IMDG, IATA: II

14.5. Environmental hazards

ADR / RID: NO

IMDG: not marine pollutant

IATA: NO

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14.6. Special precautions for user

ADR / RID:	HIN - Kemler: 33 Special provision: 274, 601, 640D	Limited Quantities: 1 lt	Tunnel restriction code: (D/E)
IMDG:	EMS: F-E, S-D	Limited Quantities: 1 lt	
IATA:	Cargo: Passengers: Special provision:	Maximum quantity: 60 L Maximum quantity: 5 L A3, A180	Packaging instructions: 364 Packaging instructions: 353

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: P5c

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

<u>Product</u>	
Point	3 - 40
<u>Contained substance</u>	
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 \geq than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
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
Information not available

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:

Flam. Liq. 2	Flammable liquid, category 2
Eye Irrit. 2	Eye irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

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)

BIO-OPTICA MILANO SPA

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EN

SECTION 16. Other information ... / >>

- 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
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PMT: Persistent, mobile and toxic
- 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
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very persistent and very bioaccumulative
- vPvM: Very persistent and very mobile
- 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)
22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
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26. Delegated Regulation (UE) 2024/197 (XXI 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

B-Alcohol 95 for B-PRO 450**SECTION 16. Other information ... / >>**

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:

03 / 04 / 08 / 09 / 11 / 13 / 14 / 15.