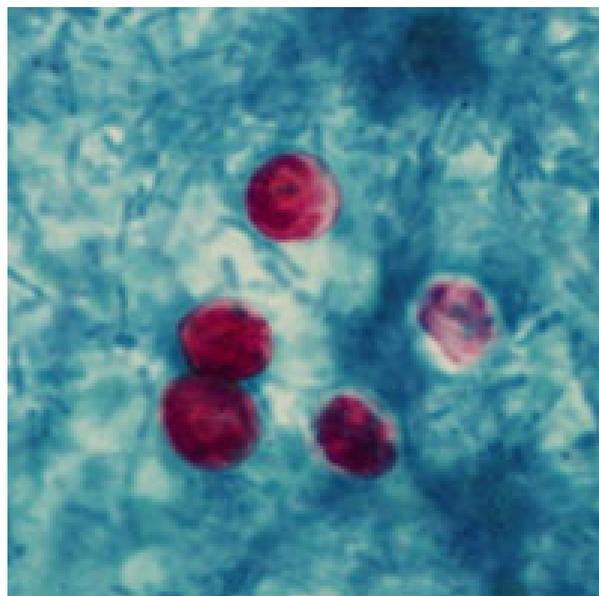


**ZIEHL - NEELSEN**  
*For Cryptosporidium*



*Cryptosporidium*

CODE	DESCRIPTION	TESTS NUMBER
04-110803	Ziehl Neelsen for Cryptosporidium	N.A.

**IVD** In Vitro Diagnostic – medical device

 Manufacturer: Bio-Optica Milano S.p.A.

Date of issue: 11/07/2018  
Rev. 02

Product for the preparation of cyto-histological samples for optical microscopy.  
To show *Cryptosporidium* sp. oocysts in faecal smears.

### PRINCIPLE

The method demonstrates acid-fast components present in the *Cryptosporidium* oocysts. It is characterized by use of a weaker decolorizing agent than the one used in traditional Ziehl-Neelsen stain.

### METHOD

- 1) Reagent A for 10 minutes
- 2) Wash in distilled water.
- 3) Reagent B for 10 – 15 seconds
- 4) Wash in distilled water
- 5) Reagent C for 30 seconds
- 6) Wash in distilled water
- 7) Dry the smear in the air



*The picture is for illustrative purposes only*

Date of issue: 11/07/2018

Rev. 02

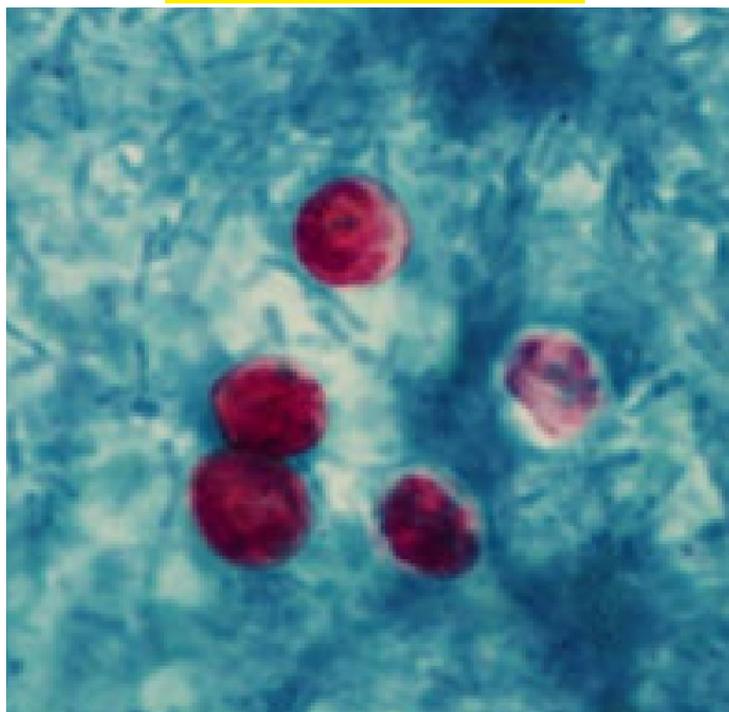
### Technical details

Method specifications	Procedure time	15 minutes	
	Complementary equipment	Not requested	
	Results	Cryptosporidium sp. oocysts (4 - 6 µm diameter):	Red
		Background:	Pale green
Components	A) Carbol fuchsin solution	500 ml	
	B) Decolorizing solution	2 x 500 ml	
	C) Malachite green solution	500 ml	
Storage	Storage	Store the preparation at room temperature. Keep the containers tightly closed.	
	Storage temperature	15-25°C	
	Stability	After the first opening, the product is usable until the expiry date, if correctly stored.	
	Validity	2 years	
Warning	Product classification	<p>The product must be used exclusively by specialized technical operators. The product is classified as hazardous.</p> <p>Read with attention the information written on the label (dangerous symbols, risks and safety phrases). Consult always the safety data sheet where the information about the risks of the preparation, precautionary measures during use, first aid and disposal are available.</p> <p>Do not use if primary packaging is damaged.</p>	
	Disposal	Hazardous preparation: observe all state and local environmental regulations regarding waste disposal.	

Date of issue: 11/07/2018

Rev. 02

**CYLIO - NILSENO**  
**for Cryptosporidium**



Cryptosporidium

<b>Kodas</b>	<b>Pavadinimas</b>	<b>Testų skaičius</b>
04-110803	Dažų rinkinys pirmuonių Cryptosporidium dažymui Cylio- Nilseno būdu	-

**IVD** In Vitro Diagnostic – medical device

 Manufacturer: Bio-Optica Milano S.p.A.

Date of issue: 11/07/2018  
Rev. 02

Bio-Optica Milano S.p.A. Via San Faustino 58 - 20134 Milano  
Phone +39 02.21.27.13.1 - Fax Italia +39 02.21.53.000 - Fax Export +39 02.21.54.155  
[www.bio-optica.it](http://www.bio-optica.it) – [info@bio-optica.it](mailto:info@bio-optica.it) – [claims@bio-optica.it](mailto:claims@bio-optica.it)

Produktas, skirtas paruošti citohistologinius mėginius optinei mikroskopijai.  
Norint parodyti *Cryptosporidium* sp. oocistas išmatose.

### PRINCIPAS

Metodas parodo, kad *Cryptosporidium* oocistose yra greitų-rūgščių turinčių komponentų. Jam būdingas silpnesnis blankintojas, nei naudojamas tradiciniame Cylio -Nilseno dažyme.

### METODAS

- 1) Reagentas A naudojamas 10 minučių.
- 2) Nuplauti destiliuotu vandeniu.
- 3) Reagentas B naudojamas 10-15 sekundžių.
- 4) Nuplauti destiliuotu vandeniu.
- 5) Reagentas C naudojamas 30 sekundžių.
- 6) Nuplauti destiliuotu vandeniu.
- 7) Tepinėlio džiovinimas.



Paveikslukas informacinio pobūdžio.

Date of issue: 11/07/2018

Rev. 02

**Techninės detalės**

Specifikacijos metodas	Procedūros laikas	15 min	
	Papildoma įranga	Nereikalinga	
	Rezultatai	Cryptosporidium sp. Oocistos (4-6 μm diametro):	Raudona sp.
		Fonas:	Blyškiai žalia
Sudėtis	a) Karbolio fuksinas	500 ml	
	b) Blankintojas	2x500 ml	
	c) Malachito žaliasis	500 ml	
Laikymas	Laikymas	Laikyti kambario temperatūroje, sandariai uždarytus.	
	Laikymo temperatūra	15-25 °C	
	Stabilumas	Po pirmo atidarymo, produktas naudojamas iki galiojimo datos pabaigos, jei laikoma teisingomis sąlygomis.	
	Tinkamumas	2 metai	
Įspėjimas	Produkto klasifikacija	<p>Produktą gali naudoti tik specializuoti operatoriai. Produktas klasifikuojamas kaip pavojingas. Atidžiai perskaitykite etiketėje užrašytą informaciją (pavojingi simboliai, rizika ir saugos frazės). Visada susipažinkite su saugos duomenų lapais, kuriuose pateikiama informacija apie riziką ir atsargumo priemonės reagento vartojimo metu. Taip pat pagalba bei šalinimą.</p> <p>Nenaudokite, jei pažeista pirminė pakuotė.</p>	
	Šalinimas	Pavojingas preparatas: šalinti pagal valstybinius ir regioninius įstatymus.	

Date of issue: 11/07/2018

Rev. 02

## Ziehl-Neelsen modified Reagent A

## Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

## 1.1. Product identifier

Code: 04-110803.A  
Product name: Ziehl-Neelsen modified Reagent A

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

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

## 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

info@bio-stain.it

Product distribution by: Bio-Optica Milano S.p.a.

## 1.4. Emergency telephone number

For urgent inquiries refer to: Please contact the nearest Toxicology and Antivenin Center

## SECTION 2. Hazards identification

## 2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Carcinogenicity, category 1B	H350	May cause cancer.
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.

## 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:

H350	May cause cancer.
H341	Suspected of causing genetic defects.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
	Restricted to professional users.

## Ziehl-Neelsen modified Reagent A

## SECTION 2. Hazards identification ... / &gt;&gt;

## Precautionary statements:

**P201** Obtain special instructions before use.  
**P280** Wear protective gloves/ protective clothing / eye protection / face protection.  
**P308+P313** IF exposed or concerned: Get medical advice / attention.

**Contains:** 4,4'-(4-iminocyclohexa-2,5-dienylidenemethylene)dianiline hydrochloride  
 PHENOL

## 2.3. Other hazards

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

## SECTION 3. Composition/information on ingredients

## 3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
<b>ETHANOL</b>		
CAS	64-17-5	$1 \leq x < 5$
EC	200-578-6	
INDEX	603-002-00-5	
<b>PHENOL</b>		
CAS	108-95-2	$1 \leq x < 3$
EC	203-632-7	
INDEX	604-001-00-2	
<b>4,4'-(4-iminocyclohexa-2,5-dienylidenemethylene)dianiline hydrochloride</b>		
CAS	569-61-9	$0,5 \leq x < 1$
EC	209-321-2	
INDEX	611-031-00-X	

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

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.

**Ziehl-Neelsen modified Reagent A****SECTION 5. Firefighting measures** ... / >>**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.

**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. Vapours may catch fire and an explosion may occur; vapour accumulation is therefore to be avoided by leaving windows and doors open and ensuring good cross ventilation. 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 well 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

## Ziehl-Neelsen modified Reagent A

## SECTION 8. Exposure controls/personal protection

## 8.1. Control parameters

Regulatory References:

DEU	Deutschland	TRGS 900 (Fassung 31.1.2018 ber.) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte
DNK	Danmark	Graensevaerdier per stoffer og materialer
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2017
FIN	Suomi	HTP-arvot 2012. Haitallisiksi tunnetut pitoisuudet - Sosiaali- ja terveystieteiden tutkimuskeskus julkaisu 2012:5
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
GBR	United Kingdom	EH40/2005 Workplace exposure limits
GRC	Ελλάδα	ΕΦΗΜΕΡΙΣ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ - ΤΕΥΧΟΣ ΠΡΩΤΟ Αρ. Φύλλου 19 - 9 Φεβρουαρίου 2012
HUN	Magyarország	50/2011. (XII. 22.) NGM rendelet a munkahelyek kémiai biztonságáról
NLD	Nederland	Databank of the social and Economic Council of Netherlands (SER) Values, AF 2011:18
NOR	Norge	Veiledning om Administrative normer for forurensning i arbeidsatmosfære
POL	Polska	ROZPORZĄDZENIE MINISTRA RODZIN Y, PRAC Y I POLITYKI SPOŁECZNEJ z dnia 12 czerwca 2018 r
ROU	România	Monitorul Oficial al României 44; 2012-01-19
SWE	Sverige	Occupational Exposure Limit Values, AF 2011:18
	TLV-ACGIH	ACGIH 2018

## ETHANOL

## Threshold Limit Value

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
AGW	DEU	960	500	1920	1000
MAK	DEU	960	500	1920	1000
TLV	DNK	1900	1000		
VLA	ESP			1910	1000
HTP	FIN	1900	1000	2500	1300
VLEP	FRA	1900	1000	9500	5000
WEL	GBR	1920	1000		
TLV	GRC	1900	1000		
AK	HUN	1900		7600	
OEL	NLD	260		1900	SKIN
TLV	NOR	950	500		
NDS	POL	1900			
TLV	ROU	1900	1000	9500	5000
MAK	SWE	1000	500	1900	1000
TLV-ACGIH				1884	1000

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.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

The product must be used inside a closed circuit, in a well-ventilated environment and with strong localised aspiration systems in place.

## 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 Directive 89/686/EEC 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.

## Ziehl-Neelsen modified Reagent A

### SECTION 8. Exposure controls/personal 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. 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.

### SECTION 9. Physical and chemical properties

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

Properties	Value	Information
Appearance	liquid	
Colour	dark red	
Odour	characteristic	
Odour threshold	Not available	
pH	Not available	
Melting point / freezing point	Not available	
Initial boiling point	Not available	
Boiling range	Not available	
Flash point	> 60 °C	
Evaporation Rate	Not available	
Flammability of solids and gases	Not available	
Lower inflammability limit	Not available	
Upper inflammability limit	Not available	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Vapour pressure	Not available	
Vapour density	Not available	
Relative density	Not available	
Solubility	soluble in water	
Partition coefficient: n-octanol/water	Not available	
Auto-ignition temperature	Not available	
Decomposition temperature	Not available	
Viscosity	Not available	
Explosive properties	Not available	
Oxidising properties	Not available	

#### 9.2. Other information

VOC (Directive 2010/75/EC) :	4,30 %
VOC (volatile carbon) :	2,27 %

### 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.

#### 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.

**Ziehl-Neelsen modified Reagent A****SECTION 10. Stability and reactivity** ... / >>**10.4. Conditions to avoid**

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

## ETHANOL

Avoid exposure to: sources of heat,naked flames.

**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 toxicological effects**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

LC50 (Inhalation) of the mixture:	> 5 mg/l
LD50 (Oral) of the mixture:	>2000 mg/kg
LD50 (Dermal) of the mixture:	>2000 mg/kg

4,4'-(4-iminocyclohexa-2,5-dienylidenemethylene)dianiline hydrochloride	
LD50 (Oral)	5000 mg/kg mause

ETHANOL	
LD50 (Oral)	> 5000 mg/kg Rat
LC50 (Inhalation)	120 mg/l/4h Pimephales promelas

PHENOL	
LD50 (Oral)	282 mg/kg Rat
LD50 (Dermal)	660 mg/kg Rat

SKIN CORROSION / IRRITATION

Causes skin irritation

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

**Ziehl-Neelsen modified Reagent A****SECTION 11. Toxicological information ... / >>**GERM CELL MUTAGENICITY

Suspected of causing genetic defects

CARCINOGENICITY

May cause cancer

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

**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

PHENOL  
Rapidly degradable

**12.3. Bioaccumulative potential**

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

PHENOL  
Partition coefficient: n-octanol/water 1,47

**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 greater than 0,1%.

**12.6. Other adverse effects**

Information not available



## Ziehl-Neelsen modified Reagent A

## SECTION 15. Regulatory information ... / &gt;&gt;

Substances subject to the Stockholm Convention:  
None

## Healthcare controls

Workers exposed to this health-dangerous chemical agent must undergo sanitary checks carried out in compliance with 2004/37/EC directive.

## 15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains.

## SECTION 16. Other information

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

<b>Flam. Liq. 2</b>	Flammable liquid, category 2
<b>Carc. 1B</b>	Carcinogenicity, category 1B
<b>Muta. 2</b>	Germ cell mutagenicity, category 2
<b>Acute Tox. 3</b>	Acute toxicity, category 3
<b>STOT RE 2</b>	Specific target organ toxicity - repeated exposure, category 2
<b>Skin Corr. 1B</b>	Skin corrosion, category 1B
<b>Eye Irrit. 2</b>	Eye irritation, category 2
<b>Skin Irrit. 2</b>	Skin irritation, category 2
<b>H225</b>	Highly flammable liquid and vapour.
<b>H350</b>	May cause cancer.
<b>H341</b>	Suspected of causing genetic defects.
<b>H301</b>	Toxic if swallowed.
<b>H311</b>	Toxic in contact with skin.
<b>H331</b>	Toxic if inhaled.
<b>H373</b>	May cause damage to organs through prolonged or repeated exposure.
<b>H314</b>	Causes severe skin burns and eye damage.
<b>H319</b>	Causes serious eye irritation.
<b>H315</b>	Causes skin irritation.

## LEGEND:

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

## GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament

**Ziehl-Neelsen modified Reagent A****SECTION 16. Other information ... / >>**

2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)

- 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.

**Changes to previous review:**

The following sections were modified:

01 / 02 / 03 / 08 / 09 / 10 / 11 / 12.

Changed TLVs in section 8.1 for following countries:

FIN,

## Ziehl-Neelsen modified Reagent B

## Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

## 1.1. Product identifier

Code: **04-110803.B**  
Product name **Ziehl-Neelsen modified Reagent B**

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

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

## 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

**info@bio-stain.it**

Product distribution by: **Bio-Optica Milano S.p.a.**

## 1.4. Emergency telephone number

For urgent inquiries refer to **Please contact the nearest Tossicology and Antivenin Center**

## SECTION 2. Hazards identification

## 2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Flammable liquid, category 2	H225	Highly flammable liquid and vapour.
Acute toxicity, category 3	H301	Toxic if swallowed.
Acute toxicity, category 3	H311	Toxic in contact with skin.
Acute toxicity, category 3	H331	Toxic if inhaled.
Specific target organ toxicity - single exposure, category 1	H370	Causes damage to organs.

## 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.  
**H301+H311+H331** Toxic if swallowed, in contact with skin or if inhaled.  
**H370** Causes damage to organs.

## Ziehl-Neelsen modified Reagent B

## SECTION 2. Hazards identification ... / &gt;&gt;

## 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.  
**P308+P311** IF exposed or concerned: call a POISON CENTER / doctor / . . .  
**P403+P233** Store in a well-ventilated place. Keep container tightly closed.

**Contains:** METHANOL

## 2.3. Other hazards

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

## SECTION 3. Composition/information on ingredients

## 3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
<b>METHANOL</b>		
CAS 67-56-1	80 ≤ x < 100	<b>Fam. Liq. 2 H225, Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H331, STOT SE 1 H370</b>
EC 200-659-6		
INDEX 603-001-00-X		
<b>HYDROCHLORIC ACID</b>		
CAS 7647-01-0	0 ≤ x < 0,5	<b>Met. Corr. 1 H290, Skin Corr. 1B H314, Eye Dam. 1 H318, STOT SE 3 H335, Classification note according to Annex VI to the CLP Regulation: B</b>
EC 231-595-7		
INDEX 017-002-01-X		

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. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated clothing before using it again.

**INHALATION:** Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.

**INGESTION:** Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

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

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

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

Information not available

## SECTION 5. Firefighting measures

## 5.1. Extinguishing media

## SUITABLE EXTINGUISHING EQUIPMENT

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

# Ziehl-Neelsen modified Reagent B

## SECTION 5. Firefighting measures ... / >>

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

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

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. 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.

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

Store only in the original container. Store in a ventilated and dry place, far away from sources of ignition. Keep containers well sealed. Keep the product in clearly labelled containers. Avoid overheating. Avoid violent blows. Keep containers away from any incompatible materials, see section 10 for details.

Store in a well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition.

### 7.3. Specific end use(s)

Information not available

## Ziehl-Neelsen modified Reagent B

### SECTION 8. Exposure controls/personal protection

#### 8.1. Control parameters

##### Regulatory References:

DEU	Deutschland	TRGS 900 (Fassung 31.1.2018 ber.) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte
DNK	Danmark	Graensevaerdier per stoffer og materialer
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2017
FIN	Suomi	HTP-arvot 2012. Haitallisiksi tunnetut pitoisuudet - Sosiaali- ja terveystieteiden tutkimuskeskus julkaisu 2012:5
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
GBR	United Kingdom	EH40/2005 Workplace exposure limits
GRC	Ελλάδα	ΕΦΗΜΕΡΙΣ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ - ΤΕΥΧΟΣ ΠΡΩΤΟ Αρ. Φύλλου 19 - 9 Φεβρουαρίου 2012
HUN	Magyarország	50/2011. (XII. 22.) NGM rendelet a munkahelyek kémiai biztonságáról
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
NLD	Nederland	Databank of the social and Economic Council of Netherlands (SER) Values, AF 2011:18
NOR	Norge	Veiledning om Administrative normer for forurensning i arbeidsatmosfære
POL	Polska	ROZPORZĄDZENIE MINISTRA RODZIN Y, PRAC Y I POLITYKI SPOŁECZNEJ z dnia 12 czerwca 2018 r
PRT	Portugal	Ministério da Economia e do Emprego Consolida as prescrições mínimas em matéria de protecção dos trabalhadores contra os riscos para a segurança e a saúde devido à exposição a agentes químicos no trabalho - Diário da Republica I 26; 2012-02-06
ROU	România	Monitorul Oficial al României 44; 2012-01-19
SWE	Sverige	Occupational Exposure Limit Values, AF 2011:18
EU	OEL EU	Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 91/322/EEC.
	TLV-ACGIH	ACGIH 2018

#### METHANOL

##### Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
AGW	DEU	270	200	1080	800	SKIN
MAK	DEU	270	200	1080	800	SKIN
TLV	DNK	260	200			
VLA	ESP	266	200			SKIN
HTP	FIN	270	200	330	250	SKIN
VLEP	FRA	260	200	1300	1000	SKIN
WEL	GBR	266	200	333	250	SKIN
TLV	GRC	260	200	325	250	
AK	HUN	260		1040		
VLEP	ITA	260	200			SKIN
OEL	NLD	133	100			SKIN
TLV	NOR	130	100			SKIN
NDS	POL	100		300		
VLE	PRT	260	200			SKIN
TLV	ROU	260	200		5	SKIN
MAK	SWE	250	200	350	250	SKIN
OEL	EU	260	200			SKIN
TLV-ACGIH		262	200	328	250	

#### HYDROCHLORIC ACID

##### Threshold Limit Value

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
VLA	ESP	7,6	5	15	10
VLEP	ITA	8	5	15	10
NDS	POL	5		10	
VLE	PRT	8	5	15	10
TLV	ROU	8	5	15	10
OEL	EU	8	5	15	10
TLV-ACGIH				2,9 (C)	2 (C)

##### Legend:

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

## Ziehl-Neelsen modified Reagent B

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

#### 8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

##### HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

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

##### SKIN PROTECTION

Wear category III professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC 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 166).

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

##### RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, wear a mask with a type AX filter, whose limit of use will be defined by the manufacturer (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.

### SECTION 9. Physical and chemical properties

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

Properties	Value	Information
Appearance	liquid	
Colour	colourless	
Odour	mild	
Odour threshold	Not available	
pH	Not available	
Melting point / freezing point	Not available	
Initial boiling point	64 °C	
Boiling range	Not available	
Flash point	< 23 °C	
Evaporation Rate	Not available	
Flammability of solids and gases	Not available	
Lower inflammability limit	Not available	
Upper inflammability limit	Not available	
Lower explosive limit	6 % (V/V)	
Upper explosive limit	36 % (V/V)	
Vapour pressure	Not available	
Vapour density	1,1	
Relative density	Not available	
Solubility	Not available	
Partition coefficient: n-octanol/water	Not available	
Auto-ignition temperature	Not available	
Decomposition temperature	Not available	
Viscosity	Not available	
Explosive properties	Not available	
Oxidising properties	Not available	

#### 9.2. Other information

VOC (Directive 2010/75/EC) : 99,00 % - 793,98 g/litre

**Ziehl-Neelsen modified Reagent B****SECTION 9. Physical and chemical properties** ... / >>

VOC (volatile carbon) : 37,08 %

**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**

The vapours may also form explosive mixtures with the air.

**HYDROCHLORIC ACID**

Risk of explosion on contact with: alkaline metals, aluminium powder, hydrogen cyanide, alcohol.

**10.4. Conditions to avoid**

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

**10.5. Incompatible materials****HYDROCHLORIC ACID**

Incompatible with: alkalis, organic substances, strong oxidants, metals.

**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.

**HYDROCHLORIC ACID**

In decomposition develops: hydrochloric acid fumes.

**SECTION 11. Toxicological information**

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

**11.1. Information on toxicological effects**Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure**METHANOL**

WORKERS: inhalation; contact with the skin.

POPULATION: ingestion of contaminated food or water; contact with the skin of products containing the substance.

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

The minimum lethal dose for humans by ingestion is considered to be in the range from 300 to 1000 mg/kg. Ingestion of 4-10 ml of the substance may cause permanent blindness in adult humans (IPCS).

Interactive effects

Information not available

ACUTE TOXICITY

LC50 (Inhalation) of the mixture:	3,00 mg/l
LD50 (Oral) of the mixture:	100,00 mg/kg
LD50 (Dermal) of the mixture:	300,00 mg/kg

**Ziehl-Neelsen modified Reagent B****SECTION 11. Toxicological information ... / >>**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

Causes damage to organs

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

**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**

## HYDROCHLORIC ACID

Solubility in water > 10000 mg/l

Degradability: information not available

## METHANOL

Solubility in water 1000 - 10000 mg/l

Rapidly degradable

**12.3. Bioaccumulative potential**

## METHANOL

Partition coefficient: n-octanol/water -0,77

BCF 0,2

**12.4. Mobility in soil**

Information not available

## Ziehl-Neelsen modified Reagent B

### SECTION 12. Ecological information ... / >>

#### 12.5. Results of PBT and vPvB assessment

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

#### 12.6. Other adverse effects

Information not available

### SECTION 13. Disposal considerations

#### 13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

Waste transportation may be subject to ADR restrictions.

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

ADR / RID, IMDG, IATA: 1230

#### 14.2. UN proper shipping name

ADR / RID: METHANOL SOLUTION  
 IMDG: METHANOL SOLUTION  
 IATA: METHANOL SOLUTION

#### 14.3. Transport hazard class(es)

ADR / RID: Class: 3 Label: 3 (6.1)



IMDG: Class: 3 Label: 3 (6.1)



IATA: Class: 3 Label: 3 (6.1)



#### 14.4. Packing group

ADR / RID, IMDG, IATA: II

#### 14.5. Environmental hazards

ADR / RID: NO  
 IMDG: NO  
 IATA: NO

#### 14.6. Special precautions for user

ADR / RID:	HIN - Kemler: 336	Limited Quantities: 1 L	Tunnel restriction code: (D/E)
	Special Provision: -		
IMDG:	EMS: F-E, S-D	Limited Quantities: 1 L	
IATA:	Cargo:	Maximum quantity: 60 L	Packaging instructions: 364
	Pass.:	Maximum quantity: 1 L	Packaging instructions: 352
	Special Instructions:	A113	

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

Information not relevant

## Ziehl-Neelsen modified Reagent B

## SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EC: P5c-H2

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

Product

Point 3 - 40

Contained substance

Point 69 METHANOL

Substances in Candidate List (Art. 59 REACH)

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

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

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

## 15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains.

## SECTION 16. Other information

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

<b>Flam. Liq. 2</b>	Flammable liquid, category 2
<b>Met. Corr. 1</b>	Substance or mixture corrosive to metals, category 1
<b>Acute Tox. 3</b>	Acute toxicity, category 3
<b>STOT SE 1</b>	Specific target organ toxicity - single exposure, category 1
<b>Skin Corr. 1B</b>	Skin corrosion, category 1B
<b>STOT SE 3</b>	Specific target organ toxicity - single exposure, category 3
<b>H225</b>	Highly flammable liquid and vapour.
<b>H290</b>	May be corrosive to metals.
<b>H301+H311+H331</b>	Toxic if swallowed, in contact with skin or if inhaled.
<b>H301</b>	Toxic if swallowed.
<b>H311</b>	Toxic in contact with skin.
<b>H331</b>	Toxic if inhaled.
<b>H370</b>	Causes damage to organs.
<b>H314</b>	Causes severe skin burns and eye damage.
<b>H335</b>	May cause respiratory irritation.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%

**Ziehl-Neelsen modified Reagent B****SECTION 16. Other information ... / >>**

- IMDG: International Maritime Code for dangerous goods- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

**GENERAL BIBLIOGRAPHY**

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)

- 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.

**Changes to previous review:**

The following sections were modified:

01.

## Ziehl-Neelsen modified Reagent C

## Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

## 1.1. Product identifier

Code:	04-110803.C
Product name	Ziehl-Neelsen modified Reagent C
EC number	219-441-7
CAS number	2437-29-8

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

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

## 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

info@bio-stain.it

Product distribution by:	Bio-Optica Milano S.p.a.
--------------------------	--------------------------

## 1.4. Emergency telephone number

For urgent inquiries refer to	Please contact the nearest Toxicology and Antivenin Center
-------------------------------	--

## SECTION 2. Hazards identification

## 2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Hazardous to the aquatic environment, chronic toxicity, category 3	H412	Harmful to aquatic life with long lasting effects.
--	------	--

## 2.2. Label elements

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

Hazard pictograms: --

Signal words: --

Hazard statements:

H412	Harmful to aquatic life with long lasting effects.
------	--

Precautionary statements:

P273	Avoid release to the environment.
------	-----------------------------------

Nr. EC:	219-441-7
---------	-----------

## 2.3. Other hazards

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

**Ziehl-Neelsen modified Reagent C****SECTION 3. Composition/information on ingredients****3.2. Mixtures**

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
<b>Malachite green oxalate</b>		
CAS	2437-29-8    0,25 ≤ x < 0,5	<b>Repr. 2 H361d, Acute Tox. 3 H301, Eye Dam. 1 H318, Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410 M=1</b>
EC INDEX	219-441-7	

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**

Not specifically necessary. Observance of good industrial hygiene is recommended.

**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**

Use breathing equipment if fumes or powders are released into the air. 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**

**Ziehl-Neelsen modified Reagent C****SECTION 6. Accidental release measures** ... / >>

Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water. 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.

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

Keep the product in clearly labelled containers. 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**

Information not available

**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 (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

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

**SKIN PROTECTION**

Wear category I professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC 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 B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

**ENVIRONMENTAL EXPOSURE CONTROLS**

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

**SECTION 9. Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Properties	Value	Information
Appearance	liquid	
Colour	green	
Odour	odourless	
Odour threshold	Not available	

**Ziehl-Neelsen modified Reagent C****SECTION 9. Physical and chemical properties** ... / >>

pH	Not available
Melting point / freezing point	Not available
Initial boiling point	Not available
Boiling range	Not available
Flash point	> 60 °C
Evaporation Rate	Not available
Flammability of solids and gases	Not available
Lower inflammability limit	Not available
Upper inflammability limit	Not available
Lower explosive limit	Not available
Upper explosive limit	Not available
Vapour pressure	Not available
Vapour density	Not available
Relative density	Not available
Solubility	soluble in water
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Explosive properties	Not available
Oxidising properties	Not available

**9.2. Other information**

VOC (Directive 2010/75/EC) :	0
VOC (volatile carbon) :	0

**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.

**10.4. Conditions to avoid**

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

**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 toxicological effects**

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

**Ziehl-Neelsen modified Reagent C****SECTION 11. Toxicological information ... / >>**

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

LC50 (Inhalation) of the mixture:	Not classified (no significant component)
LD50 (Oral) of the mixture:	>2000 mg/kg
LD50 (Dermal) of the mixture:	Not classified (no significant component)

Malachite green oxalate LD50 (Oral)	275 mg/kg
--	-----------

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

**SECTION 12. Ecological information**

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

**12.1. Toxicity**

Malachite green oxalate	
LC50 - for Fish	0,14 mg/l/96h Ictalurus punctatus
EC50 - for Crustacea	0,29 mg/l/48h Daphnia magna

**12.2. Persistence and degradability**

Information not available

**Ziehl-Neelsen modified Reagent C****SECTION 12. Ecological information** ... / >>**12.3. Bioaccumulative potential**

Information not available

**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 greater than 0,1%.

**12.6. Other adverse effects**

Information not available

**SECTION 13. Disposal considerations****13.1. Waste treatment methods**

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

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

**SECTION 14. Transport information**

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

**14.1. UN number**

Not applicable

**14.2. UN proper shipping name**

Not applicable

**14.3. Transport hazard class(es)**

Not applicable

**14.4. Packing group**

Not applicable

**14.5. Environmental hazards**

Not applicable

**14.6. Special precautions for user**

Not applicable

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

Information not relevant

**SECTION 15. Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EC: \_\_\_\_\_ None

## Ziehl-Neelsen modified Reagent C

## SECTION 15. Regulatory information ... / &gt;&gt;

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

Product	
Point	3

Substances in Candidate List (Art. 59 REACH)

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

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Information not available

## 15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains.

## SECTION 16. Other information

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

<b>Repr. 2</b>	Reproductive toxicity, category 2
<b>Acute Tox. 3</b>	Acute toxicity, category 3
<b>Eye Dam. 1</b>	Serious eye damage, category 1
<b>Aquatic Acute 1</b>	Hazardous to the aquatic environment, acute toxicity, category 1
<b>Aquatic Chronic 1</b>	Hazardous to the aquatic environment, chronic toxicity, category 1
<b>Aquatic Chronic 3</b>	Hazardous to the aquatic environment, chronic toxicity, category 3
<b>H361d</b>	Suspected of damaging the unborn child.
<b>H301</b>	Toxic if swallowed.
<b>H318</b>	Causes serious eye damage.
<b>H400</b>	Very toxic to aquatic life.
<b>H410</b>	Very toxic to aquatic life with long lasting effects.
<b>H412</b>	Harmful to aquatic life with long lasting effects.

## LEGEND:

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

**Ziehl-Neelsen modified Reagent C****SECTION 16. Other information ... / >>**

- TWA STEL: Short-term exposure limit- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

**GENERAL BIBLIOGRAPHY**

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)

- 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.

**Changes to previous review:**

The following sections were modified:

01 / 03 / 04 / 06 / 07 / 11 / 15.