

## Ziehl-Neelsen modified Reagent A

## Safety Data Sheet

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

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

## 1.1. Product identifier

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

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:

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.

## Ziehl-Neelsen modified Reagent A

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

Restricted to professional users.

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  $\geq$  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)
<b>ETHANOL</b>		
CAS 64-17-5	$1 \leq x < 5$	<b>Flam. Liq. 2 H225</b>
EC 200-578-6		
INDEX 603-002-00-5		
<b>PHENOL</b>		
CAS 108-95-2	$1 \leq x < 3$	<b>Muta. 2 H341, Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H331, STOT RE 2 H373, Skin Corr. 1B H314, Eye Dam. 1 H318 Skin Corr. 1B H314: <math>\geq</math> 3%, Skin Irrit. 2 H315: <math>\geq</math> 1% LD50 Oral: 282 , LD50 Dermal: 660 , STA Inhalation mists/powders: 0,501 mg/l</b>
EC 203-632-7		
INDEX 604-001-00-2		
<b>4,4'-(4-iminocyclohexa-2,5-dienylidenemethylene)dianiline hydrochloride</b>		
CAS 569-61-9	$0,5 \leq x < 1$	<b>Carc. 1B H350</b>
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

**Ziehl-Neelsen modified Reagent A****SECTION 5. Firefighting measures****5.1. Extinguishing media**

## SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

## UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

**5.2. Special hazards arising from the substance or mixture**

## HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products.

**5.3. Advice for firefighters**

## GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

## SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

**SECTION 6. Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

**6.2. Environmental precautions**

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

**6.3. Methods and material for containment and cleaning up**

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

**6.4. Reference to other sections**

Any information on personal protection and disposal is given in sections 8 and 13.

**SECTION 7. Handling and storage****7.1. Precautions for safe handling**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

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

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

**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 č. 41/2020 Sb. Nařízení vlády, kterým se mění nařízení vlády č. 361/2007 Sb., kterým se stanoví podmínky ochrany zdraví při práci, ve znění pozdějších předpisů
DEU	Deutschland	Technischen Regeln für Gefahrstoffe (TRGS 900) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte. MAK- und BAT-Werte-Liste 2020, Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 56
DNK	Danmark	Bekendtgørelse om grænseværdier for stoffer og materialer - BEK nr 1458 af 13/12/2019
ESP	España	Límites de exposición profesional para agentes químicos en España 2021
EST	Eesti	Ohtlike kemikaalide ja neid sisaldavate materjalide kasutamise töötavishoiu ja tööohutuse nõuded ning töökeskkonna keemiliste ohutegurite piirnormid [RT I, 17.10.2019, 1 - jõust. 17.01.2020]
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
FIN	Suomi	HTP-VÄRDEN 2020. Koncentrationer som befunnits skadliga. SOCIAL - OCH HÄLSOVÄRDSMINISTERIETS PUBLIKATIONER 2020:25
GRC	Ελλάδα	Π.Δ. 26/2020 (ΦΕΚ 50/Α' 6.3.2020) Εναρμόνιση της ελληνικής νομοθεσίας προς τις διατάξεις των οδηγιών 2017/2398/ΕΕ, 2019/130/ΕΕ και 2019/983/ΕΕ «για την τροποποίηση της οδηγίας 2004/37/ΕΚ "σχετικά με την προστασία των εργαζομένων από τους κινδύνους που συνδέονται με την έκθεση σε καρκινογόνους ή μεταλλαξιογόνους παράγοντες κατά την εργασία"»
HUN	Magyarország	Az innovációért és technológiáért felelős miniszter 5/2020. (II. 6.) ITM rendelete a kémiai kóroki tényezők hatásának kitett munkavállalók egészségének és biztonságának védelméről
HRV	Hrvatska	Pravilnik o izmjenama i dopunama Pravilnika o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)
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
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
GBR	United Kingdom TLV-ACGIH	EH40/2005 Workplace exposure limits (Fourth Edition 2020) ACGIH 2022

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

#### ETHANOL

##### Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>	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		3800		
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	
NGV/KGV	SWE	1000	500	1900 (C)	1000 (C)	
NPEL	SVK	960	500	1920	1000	
WEL	GBR	1920	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.

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

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

#### SKIN PROTECTION

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

#### EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

#### RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

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

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

#### ENVIRONMENTAL EXPOSURE CONTROLS

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

**Ziehl-Neelsen modified Reagent A****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	
Melting point / freezing point	not available	
Initial boiling point	not available	
Flammability	not available	
Lower explosive limit	not available	
Upper explosive limit	not available	
Flash point	> 60 °C	
Auto-ignition temperature	not available	
pH	not available	
Kinematic viscosity	not available	
Solubility	soluble in water	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	not available	
Density and/or relative density	not available	
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)	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.

**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

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**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 - mists / powders) of the mixture:	> 5 mg/l
ATE (Oral) of the mixture:	>2000 mg/kg
ATE (Dermal) of the mixture:	>2000 mg/kg

## ETHANOL

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

## PHENOL

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

## 4,4'-(4-aminocyclohexa-2,5-dienylidene)methyl)dianiline hydrochloride

LD50 (Oral):	5000 mg/kg mouse
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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

Respiratory sensitization

Information not available

Skin sensitization

Information not available

GERM CELL MUTAGENICITY

Suspected of causing genetic defects

CARCINOGENICITY

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

May cause cancer

**REPRODUCTIVE TOXICITY**

Does not meet the classification criteria for this hazard class

**Adverse effects on sexual function and fertility**

Information not available

**Adverse effects on development of the offspring**

Information not available

**Effects on or via lactation**

Information not available

**STOT - SINGLE EXPOSURE**

Does not meet the classification criteria for this hazard class

**Target organs**

Information not available

**Route of exposure**

Information not available

**STOT - REPEATED EXPOSURE**

Does not meet the classification criteria for this hazard class

**Target organs**

Information not available

**Route of exposure**

Information not available

**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



**Ziehl-Neelsen modified Reagent A****SECTION 12. Ecological information** ... / >>

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  $\geq$  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.

CONTAMINATED PACKAGING

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

**SECTION 14. Transport information**

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

**14.1. UN number or ID number**

not applicable

**14.2. UN proper shipping name**

not applicable

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

not applicable

**14.4. Packing group**

not applicable

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## SECTION 14. Transport information ... / &gt;&gt;

## 14.5. Environmental hazards

not applicable

## 14.6. Special precautions for user

not applicable

## 14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

## SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EU: None

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

Product

Point 3 - 40

Contained substance

Point 75

Point 72 4,4'-(4-iminocyclohexa-2,5-dienylidenemethylene)dianiline hydrochloride

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

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

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:

<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.

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### SECTION 16. Other information ... / >>

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

#### GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
  2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
  3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
  4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
  5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
  6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
  7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
  8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
  9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
  10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
  11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
  12. Regulation (EU) 2016/1179 (IX Atp. CLP)
  13. Regulation (EU) 2017/776 (X Atp. CLP)
  14. Regulation (EU) 2018/669 (XI Atp. CLP)
  15. Regulation (EU) 2019/521 (XII Atp. CLP)
  16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
  17. Regulation (EU) 2019/1148
  18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
  19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
  20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
  21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
- The Merck Index. - 10th Edition
  - Handling Chemical Safety
  - INRS - Fiche Toxicologique (toxicological sheet)
  - Patty - Industrial Hygiene and Toxicology
  - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
  - IFA GESTIS website

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

- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

**Note for users:**

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

**CALCULATION METHODS FOR CLASSIFICATION**

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

**Changes to previous review:**

The following sections were modified:

08.

## Ziehl-Neelsen modified Reagent B

## Safety Data Sheet

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

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

## 1.1. Product identifier

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.

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.
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

## Ziehl-Neelsen modified Reagent B

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

## Hazard statements:

<b>H225</b>	Highly flammable liquid and vapour.
<b>H301+H311+H331</b>	Toxic if swallowed, in contact with skin or if inhaled.
<b>H370</b>	Causes damage to organs.

## Precautionary statements:

<b>P210</b>	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
<b>P280</b>	Wear protective gloves/ protective clothing / eye protection / face protection.
<b>P308+P311</b>	IF exposed or concerned: call a POISON CENTER / doctor / . . .
<b>P403+P233</b>	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  $\geq$  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)
<b>METHANOL</b>		
<i>INDEX</i> 603-001-00-X	$80 \leq x < 100$	<b>Flam. Liq. 2 H225, Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H331, STOT SE 1 H370</b>
<i>EC</i> 200-659-6		<b>STOT SE 2 H371: <math>\geq</math> 3%</b>
<i>CAS</i> 67-56-1		<b>STA Oral: 100 mg/kg, STA Dermal: 300 mg/kg, STA Inhalation vapours: 3 mg/l</b>
<b>HYDROCHLORIC ACID</b>		
<i>INDEX</i> 017-002-01-X	$0 \leq x < 0,5$	<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>
<i>EC</i> 231-595-7		<b>Skin Corr. 1B H314: <math>\geq</math> 25%, Skin Irrit. 2 H315: <math>\geq</math> 10%, Eye Dam. 1 H318: <math>\geq</math> 25%, Eye Irrit. 2 H319: <math>\geq</math> 10%, STOT SE 3 H335: <math>\geq</math> 10%</b>
<i>CAS</i> 7647-01-0		

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

**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

**Ziehl-Neelsen modified Reagent B****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

## Ziehl-Neelsen modified Reagent B

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### SECTION 7. Handling and storage ... / >>

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 č. 41/2020 Sb. Nařízení vlády, kterým se mění nařízení vlády č. 361/2007 Sb., kterým se stanoví podmínky ochrany zdraví při práci, ve znění pozdějších předpisů
DEU	Deutschland	Technischen Regeln für Gefahrstoffe (TRGS 900) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte. MAK- und BAT-Werte-Liste 2020, Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 56
DNK	Danmark	Bekendtgørelse om grænseværdier for stoffer og materialer - BEK nr 1458 af 13/12/2019
ESP	España	Límites de exposición profesional para agentes químicos en España 2021
EST	Eesti	Ohtlike kemikaalide ja neid sisaldavate materjalide kasutamise töötavishoiu ja tööohutuse nõuded ning töökeskkonna keemiliste ohutegurite piinormid [RT I, 17.10.2019, 1 - jõust. 17.01.2020]
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
FIN	Suomi	HTP-VÄRDEN 2020. Koncentrationer som befunnits skadliga. SOCIAL - OCH HÄLSOVÄRDSMINISTERIETS PUBLIKATIONER 2020:25
GRC	Ελλάδα	Π.Δ. 26/2020 (ΦΕΚ 50/Α΄ 6.3.2020) Εναρμόνιση της ελληνικής νομοθεσίας προς τις διατάξεις των οδηγιών 2017/2398/ΕΕ, 2019/130/ΕΕ και 2019/983/ΕΕ «για την τροποποίηση της οδηγίας 2004/37/ΕΚ "σχετικά με την προστασία των εργαζομένων από τους κινδύνους που συνδέονται με την έκθεση σε καρκινογόνους ή μεταλλαξιογόνους παράγοντες κατά την εργασία"»
HUN	Magyarország	Az innovációért és technológiáért felelős miniszter 5/2020. (II. 6.) ITM rendelete a kémiai kóroki tényezők hatásának kitett munkavállalók egészségének és biztonságának védelmére
HRV	Hrvatska	Pravilnik o izmjenama i dopunama Pravilnika o zaštiti radnika od izloženosti opasnimkemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
LTU	Lietuva	Jsakymas dėl lietuvis 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
PRT	Portugal	Decreto-Lei n.º 1/2021 de 6 de janeiro, valores-limite de exposição profissional indicativos para os agentes químicos. Decreto-Lei n.º 35/2020 de 13 de julho, proteção dos trabalhadores contra os riscos ligados à exposição durante o trabalho a agentes cancerígenos ou mutagénicos
POL	Polska	Rozporządzenie ministra rozwoju, pracy i technologii z dnia 18 lutego 2021 r. Zmieniające rozporządzenie w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy
ROU	România	Hotărârea nr. 53/2021 pentru modificarea hotărârii guvernului nr. 1.218/2006, precum și pentru modificarea și completarea hotărârii guvernului nr. 1.093/2006
SWE	Sverige	Hygieniska gränsvärden, Arbetsmiljöverkets föreskrifter och allmänna råd om hygieniska gränsvärden (AFS 2018:1)
SVK	Slovensko	NARIADENIE VLÁDY Slovenskej republiky z 12. augusta 2020, ktorým sa mení a dopĺňa nariadenie vlády Slovenskej republiky č. 356/2006 Z. z. o ochrane zdravia zamestnancov pred rizikami súvisiacimi s expozíciou karcinogénnym a mutagénnym faktorom pri práci v znení neskorších predpisov
TUR	Türkiye	Kimyasal Maddelerin Çalışmalarda Sağlık ve Güvenlik Önlemleri Hakkında Yönetmelik 12.08.2013 / 28733
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
EU	OEL EU	Directive (EU) 2022/431; Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC.
	TLV-ACGIH	ACGIH 2022



## Ziehl-Neelsen modified Reagent B

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

#### HYDROCHLORIC ACID

Threshold Limit Value						
Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>	ppm	
TLV	BGR	8	5	15	10	
TLV	CZE	8	5,28	15	9,9	
AGW	DEU	3	2	6 (C)	4 (C)	
TLV	DNK			8 (C)	5 (C)	E
VLA	ESP	7,6	5	15	10	
TLV	EST	8	5	15	10	
VLEP	FRA			7,6	5	
AK	HUN	8		16		
GVI/KGVI	HRV	8	5	15	10	
VLEP	ITA	8	5	15	10	
RD	LTU	8	5	15	10	
RV	LVA	8	5	15	10	
TLV	NOR	7		5 (C)		
TGG	NLD	8		15		
VLE	PRT	8	5	15	10	
NDS/NDSch	POL	5		10		
TLV	ROU	8	5	15	10	
NGV/KGV	SWE	3	2	6	4	
NPEL	SVK	8	5	15	10	
ESD	TUR	8	5	15	10	
WEL	GBR	2	1	8	5	
OEL	EU	8	5	15	10	
TLV-ACGIH				2,9 (C)	2 (C)	

#### METHANOL

Threshold Limit Value						
Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>	ppm	
TLV	BGR	260	200			SKIN
TLV	CZE	250	187,75	1000	751	SKIN
AGW	DEU	270	200	1080	800	SKIN
MAK	DEU	130	100	260	200	SKIN
TLV	DNK	260	200			SKIN E
VLA	ESP	266	200			SKIN
TLV	EST	250	200	350	250	SKIN
VLEP	FRA	260	200	1300	1000	SKIN 11
HTP	FIN	270	200	330	250	SKIN
TLV	GRC	260	200	325	250	
AK	HUN	260				SKIN
GVI/KGVI	HRV	260	200			SKIN
VLEP	ITA	260	200			SKIN
RD	LTU	260	200			SKIN
RV	LVA	260	200			SKIN
TLV	NOR	130	100			SKIN
TGG	NLD	133				SKIN
VLE	PRT	260	200			SKIN
NDS/NDSch	POL	100		300		SKIN
TLV	ROU	260	200			SKIN
NGV/KGV	SWE	250	200	350 (C)	250 (C)	SKIN
NPEL	SVK	260	200			SKIN
ESD	TUR	260	200			SKIN
WEL	GBR	266	200	333	250	SKIN
OEL	EU	260	200			
TLV-ACGIH		262	200	328	250	SKIN

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.

## Ziehl-Neelsen modified Reagent B

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

Provide an emergency shower with face and eye wash station.

#### 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, 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 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 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	
Melting point / freezing point	not available	
Initial boiling point	64 °C	
Flammability	not available	
Lower explosive limit	6 % (v/v)	
Upper explosive limit	36 % (v/v)	
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	0,80	
Relative vapour density	1,1	
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)	99,00 % - 793,91	g/litre
VOC (volatile carbon)	37,08 % - 297,35	g/litre

**Ziehl-Neelsen modified Reagent B****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 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**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

ATE (Inhalation - vapours) of the mixture:	3,00 mg/l
ATE (Oral) of the mixture:	100,00 mg/kg
ATE (Dermal) of the mixture:	300,00 mg/kg

**METHANOL**

STA (Dermal): 300 mg/kg estimate from table 3.1.2 of Annex I of the CLP

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

STA (Oral):	(figure used for calculation of the acute toxicity estimate of the mixture) 100 mg/kg estimate from table 3.1.2 of Annex I of the CLP
LC50 (Inhalation vapours):	(figure used for calculation of the acute toxicity estimate of the mixture) > 87,6 mg/l/4h Rat
STA (Inhalation vapours):	3 mg/l estimate from table 3.1.2 of Annex I of the CLP (figure used for calculation of the acute toxicity estimate of the mixture)

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

**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****HYDROCHLORIC ACID**

Solubility in water > 10000 mg/l  
Degradability: information not available

**METHANOL**

Solubility in water 1000 - 10000 mg/l  
Rapidly degradable

## Ziehl-Neelsen modified Reagent B

## SECTION 12. Ecological information ... / &gt;&gt;

## 12.3. Bioaccumulative potential

METHANOL  
Partition coefficient: n-octanol/water -0,77  
BCF 0,2

## 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.

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: 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

## Ziehl-Neelsen modified Reagent B

## SECTION 14. Transport information ... / &gt;&gt;

## 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
	Passengers:	Maximum quantity: 1 L	Packaging instructions: 352
	Special provision:	A113	

## 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-H2

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
Point	69 METHANOL

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

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

## 15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

## SECTION 16. Other information

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

<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

## Ziehl-Neelsen modified Reagent B

## SECTION 16. Other information ... / &gt;&gt;

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

## GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)

- The Merck Index. - 10th Edition
- Handling Chemical Safety

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

- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

**Note for users:**

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

**CALCULATION METHODS FOR CLASSIFICATION**

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

**Changes to previous review:**

The following sections were modified:

01 / 03 / 08 / 09 / 11 / 15.



**Ziehl-Neelsen modified Reagent C****Safety Data Sheet**

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

**SECTION 1. Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

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

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

Intended use	<b>In vitro medical-diagnostic disposable. Reagent for microscopy.</b>
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**1.3. Details of the supplier of the safety data sheet**

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

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	<b>0845 46 47, Poison centres NHS Direct in England or Wales</b> <b>08454 24 24 24, Poison centres NHS 24 in Scotland</b>
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**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:

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

**2.2. Label elements**

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

Hazard pictograms: --

Signal words: --

Hazard statements:

<b>H412</b>	<b>Harmful to aquatic life with long lasting effects.</b>
-------------	---

Precautionary statements:

<b>P273</b>	<b>Avoid release to the environment.</b>
-------------	--

<b>Contains:</b>	<b>Verde malachite</b>
------------------	------------------------

Nr. EC: 219-441-7

**Ziehl-Neelsen modified Reagent C****SECTION 2. Hazards identification ... / >>****2.3. Other hazards**

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

The product does not contain substances with endocrine disrupting properties in concentration  $\geq$  0.1%.

**SECTION 3. Composition/information on ingredients****3.1. Substances**

Contains:

Identification	Conc. %	Classification (EC) 1272/2008 (CLP)
<b>Malachite green oxalate</b>		
CAS 2437-29-8	0,4	<b>Repr. 2 H361d, Acute Tox. 3 H301, Eye Dam. 1 H318, Aquatic Acute 1 H400</b>
EC INDEX 219-441-7		<b>M=1, Aquatic Chronic 1 H410 M=1</b>
		<b>LD50 Oral: 275</b>

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.

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

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.

The following should be considered when choosing work glove material (see standard EN 374): 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 Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

**EYE PROTECTION**

Wear airtight protective goggles (see standard EN 166).

**RESPIRATORY PROTECTION**

None required, unless indicated otherwise in the chemical risk assessment.

**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	
Melting point / freezing point	not available	
Initial boiling point	not available	

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

Flammability	not available
Lower explosive limit	not available
Upper explosive limit	not available
Flash point	> 60 °C
Auto-ignition temperature	not available
pH	not available
Kinematic viscosity	not available
Solubility	soluble in water
Partition coefficient: n-octanol/water	not available
Vapour pressure	not available
Density and/or relative density	not available
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

Information not available

**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 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

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

Information not available

ACUTE TOXICITY

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

Respiratory sensitization

Information not available

Skin sensitization

Information not available

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

Adverse effects on sexual function and fertility

Information not available

Adverse effects on development of the offspring

Information not available

Effects on or via lactation

Information not available

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

Target organs

Information not available

Route of exposure

Information not available

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

Does not meet the classification criteria for this hazard class

Target organs

Information not available

Route of exposure

Information not available

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**

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

EC50 - for Crustacea

0,14 mg/l/96h *Ictalurus punctatus*

0,29 mg/l/48h *Daphnia magna*

**12.2. Persistence and degradability**

Information not available

**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  $\geq$  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.

**CONTAMINATED PACKAGING**

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

## Ziehl-Neelsen modified Reagent C

**SECTION 14. Transport information**

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

**14.1. UN number or ID number**

not applicable

**14.2. UN proper shipping name**

not applicable

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

not applicable

**14.4. Packing group**

not applicable

**14.5. Environmental hazards**

not applicable

**14.6. Special precautions for user**

not applicable

**14.7. Maritime transport in bulk according to IMO instruments**

Information not relevant

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

Seveso Category - Directive 2012/18/EU:    None

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

<u>Product</u>	
<u>Point</u>	3

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

## Ziehl-Neelsen modified Reagent C

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

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:

<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
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
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- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

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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



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

12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

**Note for users:**

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

**CALCULATION METHODS FOR CLASSIFICATION**

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

**Changes to previous review:**

The following sections were modified:

01 / 02 / 03 / 08 / 09 / 11 / 12 / 13 / 15 / 16.