

## Papanicolaou OG6

## 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: 05-12013/L  
Product name: Papanicolaou OG6

## 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:

Flammable liquid, category 2

H225

Highly flammable liquid and vapour.

## 2.2. Label elements

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

Hazard pictograms:



Signal words: Danger

Hazard statements:

H225 Highly flammable liquid and vapour.

Precautionary statements:

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

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**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 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      80 ≤ x < 100	<b>Flam. Liq. 2 H225</b>
EC	200-578-6	
INDEX	603-002-00-5	

The full wording of hazard (H) phrases is given in section 16 of the sheet.

**SECTION 4. First aid measures****4.1. Description of first aid measures**

No episodes of harm to the staff authorised to use the product have been reported. The following general measures should be adopted as necessary:

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

**INGESTION:** Get medical advice/attention. Induce vomiting only if indicated by the doctor. Do not give anything by mouth to an unconscious person.

**EYES and SKIN:** Wash with plenty of water. In the event of persistent irritation, get medical advice/attention.

**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****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).

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**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. 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

**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 ministeriön 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

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

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/m <sup>3</sup>	ppm	mg/m <sup>3</sup>	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.

#### 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.

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).

#### 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	orange	
Odour	characteristic	
Odour threshold	Not available	
pH	Not available	
Melting point / freezing point	Not available	
Initial boiling point	> 35 °C	

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

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	Not available
Upper explosive limit	Not available
Vapour pressure	Not available
Vapour density	Not available
Relative density	Not available
Solubility	soluble
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) :	85,00 %
VOC (volatile carbon) :	44,28 %

**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.

**ETHANOL**

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

**10.4. Conditions to avoid**

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

**ETHANOL**

Avoid exposure to: sources of heat,naked flames.

**10.5. Incompatible materials**

Information not available

**10.6. Hazardous decomposition products**

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

**SECTION 11. Toxicological information**

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

**11.1. Information on toxicological effects**

Metabolism, toxicokinetics, mechanism of action and other information

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### SECTION 11. Toxicological information ... / >>

Information not available

Information on likely routes of exposure

Information not available

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

Information not available

Interactive effects

Information not available

#### ACUTE TOXICITY

LC50 (Inhalation) of the mixture:	Not classified (no significant component)
LD50 (Oral) of the mixture:	Not classified (no significant component)
LD50 (Dermal) of the mixture:	Not classified (no significant component)

#### ETHANOL

LD50 (Oral)

LC50 (Inhalation)

> 5000 mg/kg Rat

120 mg/l/4h Pimephales promelas

#### 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

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

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

## 12.2. Persistence and degradability

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

## 12.3. Bioaccumulative potential

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

## 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. 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: 1170

## 14.2. UN proper shipping name

ADR / RID: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)  
IMDG: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)  
IATA: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

## 14.3. Transport hazard class(es)

ADR / RID: Class: 3 Label: 3



IMDG: Class: 3 Label: 3



IATA: Class: 3 Label: 3



## 14.4. Packing group

ADR / RID, IMDG, IATA: II

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### SECTION 14. Transport information ... / >>

#### 14.5. Environmental hazards

ADR / RID: NO  
IMDG: NO  
IATA: NO

#### 14.6. Special precautions for user

ADR / RID:	HIN - Kemler: 33	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: 5 L	Packaging instructions: 353
	Special Instructions:	A3, A58, A180	

#### 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: P5c

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

Product	
Point	3 - 40

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>Flam. Liq. 2</b>	Flammable liquid, category 2
<b>H225</b>	Highly flammable liquid and vapour.

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



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

- 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
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.