according to Regulation (EC) No. 1907/2006 (REACH)

## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62 date of compilation: 11.10.2021 Version: 1.0 en

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

#### **Product identifier** 1.1

Identification of the substance Papanicolaou solution 2b Orange II solution

for microscopy

Article number AE62

Registration number (REACH) not relevant (mixture)

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

Relevant identified uses: Laboratory chemical

Laboratory and analytical use

Uses advised against: Do not use for products which come into contact

with foodstuffs. Do not use for private purposes

(household).

#### 1.3 Details of the supplier of the safety data sheet

Carl Roth GmbH + Co KG Schoemperlenstr, 3-5 D-76185 Karlsruhe Germany

**Telephone:**+49 (0) 721 - 56 06 0 Telefax: +49 (0) 721 - 56 06 149 e-mail: sicherheit@carlroth.de Website: www.carlroth.de

Competent person responsible for the safety data :Department Health, Safety and Environment

sheet:

e-mail (competent person): sicherheit@carlroth.de

#### 1.4 **Emergency telephone number**

## **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

## Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
2.6	Flammable liquid	2	Flam. Liq. 2	H225
3.10	Acute toxicity (oral)	3	Acute Tox. 3	H301
3.1D	Acute toxicity (dermal)	3	Acute Tox. 3	H311
3.1I	Acute toxicity (inhal.)	3	Acute Tox. 3	H331
3.8	Specific target organ toxicity - single exposure	1	STOT SE 1	H370

For full text of abbreviations: see SECTION 16

## The most important adverse physicochemical, human health and environmental effects

Immediate effects can be expected after short-term exposure. The product is combustible and can be ignited by potential ignition sources.

Page 1 / 19 Malta (en)

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

#### 2.2 Label elements

## Labelling according to Regulation (EC) No 1272/2008 (CLP)

Signal word Danger

## **Pictograms**

GHS02, GHS06, GHS08







## **Hazard statements**

H225 Highly flammable liquid and vapour

H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled

H370 Causes damage to organs (eye)

## **Precautionary statements**

## **Precautionary statements - prevention**

P210 Keep away from heat. No smoking

P270 Do not eat, drink or smoke when using this product

P280 Wear protective gloves/eye protection

## **Precautionary statements - response**

P302+P352 IF ON SKIN: Wash with plenty of water

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing

P308+P311 IF exposed or concerned: Call a POISON CENTER/doctor

Hazardous ingredients for labelling: Methanol

## Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

#### Symbol(s)







H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled.

H370 Causes damage to organs (eye).

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/eye protection. P302+P352 IF ON SKIN: Wash with plenty of water.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P308+P311 IF exposed or concerned: Call a POISON CENTER/doctor.

contains: Methanol

## 2.3 Other hazards

## Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Malta (en) Page 2 / 19

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

# **SECTION 3: Composition/information on ingredients**

#### 3.1 **Substances**

not relevant (mixture)

#### 3.2 **Mixtures**

## **Description of the mixture**

Name of sub- stance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Methanol	CAS No 67-56-1 EC No 200-659-6 Index No 603-001-00-X REACH Reg. No 01-2119433307- 44-xxxx	75 - < 100	Flam. Liq. 2 / H225 Acute Tox. 3 / H301 Acute Tox. 3 / H311 Acute Tox. 3 / H331 STOT SE 1 / H370		GHS-HC IOELV

#### Notes

GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/

2008/EC, Annex VI)
Substance with a community indicative occupational exposure limit value

Name of sub- stance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Methanol	CAS No 67-56-1 EC No 200-659-6 Index No 603-001-00-X	STOT SE 1; H370: C ≥ 10 % STOT SE 2; H371: 3 % ≤ C < 10 %	-	100 <sup>mg</sup> / <sub>kg</sub> 300 <sup>mg</sup> / <sub>kg</sub> 3 <sup>mg</sup> / <sub>I</sub> /4h	oral dermal inhalation: va- pour

For full text of abbreviations: see SECTION 16

## **SECTION 4: First aid measures**

#### 4.1 **Description of first aid measures**



## **General notes**

Take off immediately all contaminated clothing. Self-protection of the first aider.

## Following inhalation

Call a physician immediately. If breathing is irregular or stopped, administer artificial respiration.

## **Following skin contact**

After contact with skin, wash immediately with plenty of water.

## Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

Malta (en) Page 3 / 19

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

## Following ingestion

Rinse mouth immediately and drink plenty of water. Call a physician immediately.

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

Vertigo, Headache, Gastrointestinal complaints, Vomiting, Nausea, Spasms, Dyspnoea, Unconsciousness, Risk of blindness

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

none

# **SECTION 5: Firefighting measures**

## 5.1 Extinguishing media



## Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings water spray, alcohol resistant foam, dry extinguishing powder, BC-powder, carbon dioxide (CO<sub>2</sub>)

## Unsuitable extinguishing media

water jet

## 5.2 Special hazards arising from the substance or mixture

Combustible. In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture. Solvent vapours are heavier than air and may spread along floors. Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures.

## **Hazardous combustion products**

In case of fire may be liberated: Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

#### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus. Wear full chemical protective clothing.

## **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures



## For non-emergency personnel

Do not breathe vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protective equipment as required. Provide adequate ventilation. Avoidance of ignition sources.

## 6.2 Environmental precautions

Keep away from drains, surface and ground water. Danger of explosion.

## 6.3 Methods and material for containment and cleaning up

## Advice on how to contain a spill

Covering of drains.

Malta (en) Page 4 / 19

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

## Advice on how to clean up a spill

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

## Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

# **SECTION 7: Handling and storage**

## 7.1 Precautions for safe handling

Provision of sufficient ventilation. Use extractor hood (laboratory). Handle and open container with care. Clear contaminated areas thoroughly.

## Measures to prevent fire as well as aerosol and dust generation



Keep away from sources of ignition - No smoking.

Take precautionary measures against static discharge. Due to danger of explosion, prevent leakage

of vapours into cellars, flues and ditches.

## Advice on general occupational hygiene

When using do not eat or drink. Thorough skin-cleansing after handling the product. When using do not smoke.

## 7.2 Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep container tightly closed.

## **Incompatible substances or mixtures**

Observe hints for combined storage.

## Consideration of other advice:

Store locked up. Ground/bond container and receiving equipment.

#### **Ventilation requirements**

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted. Use local and general ventilation.

## Specific designs for storage rooms or vessels

Recommended storage temperature: 15 - 25 °C

## 7.3 Specific end use(s)

No information available.

Malta (en) Page 5 / 19

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

# **SECTION 8: Exposure controls/personal protection**

## **Control parameters**

## **National limit values**

## **Occupational exposure limit values (Workplace Exposure Limits)**

Cou ntr y	Name of agent	CAS No	Identi- fier	TW A [pp m]	TWA [mg/ m³]	STE L [pp m]	STEL [mg/ m³]	Ceil ing- C [pp m]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
EU	methanol	67-56-1	IOELV	200	260						2006/15/ EC
MT	methanol	67-56-1	OELV	200	260						CAP. 424

Notation

Ceiling-C STEL

Ceiling value is a limit value above which exposure should not occur Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)
Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified) **TWA** 

# Relevant DNELs of components of the mixture

Name of sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time
Methanol	67-56-1	DNEL	130 mg/m <sup>3</sup>	human, inhalat- ory	worker (industry)	chronic - systemic effects
Methanol	67-56-1	DNEL	130 mg/m <sup>3</sup>	human, inhalat- ory	worker (industry)	acute - systemic effects
Methanol	67-56-1	DNEL	130 mg/m <sup>3</sup>	human, inhalat- ory	worker (industry)	chronic - local ef- fects
Methanol	67-56-1	DNEL	130 mg/m <sup>3</sup>	human, inhalat- ory	worker (industry)	acute - local ef- fects
Methanol	67-56-1	DNEL	20 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Methanol	67-56-1	DNEL	20 mg/kg bw/day	human, dermal	worker (industry)	acute - systemic effects

## Relevant PNECs of components of the mixture

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Methanol	67-56-1	PNEC	20,8 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	freshwater	short-term (single instance)
Methanol	67-56-1	PNEC	2,08 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	marine water	short-term (single instance)
Methanol	67-56-1	PNEC	100 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Methanol	67-56-1	PNEC	77 <sup>mg</sup> / <sub>kg</sub>	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Methanol	67-56-1	PNEC	7,7 <sup>mg</sup> / <sub>kg</sub>	aquatic organ- isms	marine sediment	short-term (single instance)

Malta (en) Page 6 / 19

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

Relevant PNECs	Relevant PNECs of components of the mixture									
Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time				
Methanol	67-56-1	PNEC	100 <sup>mg</sup> / <sub>kg</sub>	terrestrial organ- isms	soil	short-term (single instance)				

#### 8.2 Exposure controls

## Individual protection measures (personal protective equipment)

## **Eye/face protection**





Use safety goggle with side protection.

## Skin protection





## hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

#### type of material

Butyl caoutchouc (butyl rubber)

#### material thickness

0.7mm

## • breakthrough times of the glove material

>480 minutes (permeation: level 6)

## other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

Flame-retardant protective clothing.

## **Respiratory protection**





Respiratory protection necessary at: Aerosol or mist formation. Type: A (against organic gases and vapours with a boiling point of > 65 °C , colour code: Brown).

Malta (en) Page 7 / 19

according to Regulation (EC) No. 1907/2006 (REACH)

# ROTH

## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

## **Environmental exposure controls**

Keep away from drains, surface and ground water.

## **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

Physical state liquid

Colour clear - orange
Odour like: - methanol
Melting point/freezing point not determined

Boiling point or initial boiling point and boiling

range

>65 °C

Flammability flammable liquid in accordance with GHS criteria

Lower and upper explosion limit 5,5 vol% (LEL) - 44 vol% (UEL)

data apply to the main component

Flash point 12 °C

Auto-ignition temperature 455 °C (data apply to the main component)

Decomposition temperature not relevant pH (value) 5 – 7 (20 °C)

Kinematic viscosity not determined

Solubility(ies)

Water solubility miscible in any proportion

Partition coefficient

Partition coefficient n-octanol/water (log value): this information is not available

Vapour pressure 128 hPa at 20 °C

data apply to the main component

Density  $\sim 0.8 \, \mathrm{g}/\mathrm{cm}^3$  at 20 °C

Relative vapour density information on this property is not available

Particle characteristics not relevant (liquid)

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard

classes:

Malta (en) Page 8 / 19

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

Flammable liquids

Sustained combustibility yes, sustained combustion was observed

Other safety characteristics:

Miscibility completely miscible with water

Temperature class (EU, acc. to ATEX)

Maximum permissible surface temperature on

the equipment: 450°C

# **SECTION 10: Stability and reactivity**

## 10.1 Reactivity

The mixture contains reactive substance(s). Risk of ignition. Vapours may form explosive mixtures with air.

#### If heated

Risk of ignition.

## 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

## 10.3 Possibility of hazardous reactions

**Violent reaction with:** Reducing agents, Chloroform, Alkaline earth metal, Alkali metals, Perchlorates, Chlorates, Nitric acid, Hydrogen peroxide, strong oxidiser, Sulphuric acid, => Explosive properties

## 10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

## 10.5 Incompatible materials

aluminium, plastic and rubber

## 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

# **SECTION 11: Toxicological information**

## 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Test data are not available for the complete mixture.

#### **Classification procedure**

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

## Classification according to GHS (1272/2008/EC, CLP)

## **Acute toxicity**

Toxic if swallowed. Toxic in contact with skin. Toxic if inhaled.

Malta (en) Page 9 / 19

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

## Acute toxicity estimate (ATE) of components of the mixture

Name of substance	CAS No	Exposure route	ATE
Methanol	67-56-1	oral	100 <sup>mg</sup> / <sub>kg</sub>
Methanol	67-56-1	dermal	300 <sup>mg</sup> / <sub>kg</sub>
Methanol	67-56-1	inhalation: vapour	3 <sup>mg</sup> / <sub>l</sub> /4h

## Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Methanol	67-56-1	inhalation: va- pour	LC50	131 <sup>mg</sup> / <sub>l</sub> /4h	rat
Methanol	67-56-1	oral	LD50	5.628 <sup>mg</sup> / <sub>kg</sub>	rat
Methanol	67-56-1	oral	LDLo	143 <sup>mg</sup> / <sub>kg</sub>	human
Methanol	67-56-1	dermal	LD50	15.800 <sup>mg</sup> / <sub>kg</sub>	rabbit

## Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

## Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

## Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

## **Germ cell mutagenicity**

Shall not be classified as germ cell mutagenic.

## Carcinogenicity

Shall not be classified as carcinogenic.

## **Reproductive toxicity**

Shall not be classified as a reproductive toxicant.

## Specific target organ toxicity - single exposure

Causes damage to organs (eye).

Hazard category	Target organ	Exposure route
1	eye	if exposed

## Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

## **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

## Symptoms related to the physical, chemical and toxicological characteristics

## If swallowed

gastrointestinal complaints, vomiting, nausea, risk of blindness after swallowing the product

Malta (en) Page 10 / 19

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

#### • If in eyes

Data are not available.

#### If inhaled

vertigo, headache

#### • If on skin

has degreasing effect on the skin, risk of absorption via the skin

#### Other information

Other adverse effects: Agitation, Impairment of vision, Blood pressure drop, Poisoning effect on central nervous system can cause convulsions, laboured breathing and loss of consciousness, Symptoms can occur only after several hours

## 11.2 Endocrine disrupting properties

None of the ingredients are listed.

#### 11.3 Information on other hazards

There is no additional information.

## **SECTION 12: Ecological information**

## 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute) of components of the mixture									
Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time				
Methanol	67-56-1	LC50	15.400 <sup>mg</sup> / <sub>l</sub>	fish	96 h				
Methanol	67-56-1	ErC50	22.000 <sup>mg</sup> / <sub>l</sub>	algae	96 h				

## **Biodegradation**

Data are not available.

## 12.2 Process of degradability

Process of degradability							
Process	Degradation rate	Time					
biotic/abiotic	99 %	30 d					

#### Degradability of components of the mixture Name of **CAS No Process** Degrada-**Time** Method Source substance tion rate Methanol 67-56-1 biotic/abiotic 99 % 30 d Methanol 67-56-1 oxygen deple-69 % 5 d **ECHA** tion

## 12.3 Bioaccumulative potential

Data are not available.

Malta (en) Page 11 / 19

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Methanol	67-56-1		-0,77	

## 12.4 Mobility in soil

Data are not available.

## 12.5 Results of PBT and vPvB assessment

Data are not available.

#### 12.6 Endocrine disrupting properties

None of the ingredients are listed.

#### 12.7 Other adverse effects

Data are not available.

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains.

## Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used.

## 13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. Waste catalogue ordinance (Germany).

#### 13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions.

# **SECTION 14: Transport information**

## 14.1 UN number or ID number

ADR/RID/ADN	UN 1230
IMDG-Code	UN 1230
ICAO-TI	UN 1230

## 14.2 UN proper shipping name

ADR/RID/ADN	METHANOL
IMDG-Code	METHANOL
ICAO-TI	Methanol

Malta (en) Page 12 / 19

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

14.3	<b>Transport</b>	hazard	class(	es)	)

 ADR/RID/ADN
 3 (6.1)

 IMDG-Code
 3 (6.1)

 ICAO-TI
 3 (6.1)

## 14.4 Packing group

ADR/RID/ADN II
IMDG-Code II
ICAO-TI II

## **14.5 Environmental hazards** non-environmentally hazardous acc. to the dan-

gerous goods regulations

## 14.6 Special precautions for user

Provisions for dangerous goods (ADR) should be complied within the premises.

## 14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

## 14.8 Information for each of the UN Model Regulations

# Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information

Proper shipping name METHANOL

Particulars in the transport document UN1230, METHANOL, 3 (6.1), II, (D/E)

Classification code FT1

Danger label(s) 3+6.1





Special provisions (SP) 279, 802(ADN)

Excepted quantities (EQ) E2
Limited quantities (LQ) 1 L
Transport category (TC) 2
Tunnel restriction code (TRC) D/E
Hazard identification No 336

## International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name METHANOL

Particulars in the shipper's declaration UN1230, METHANOL, 3 (6.1), II, 12°C c.c.

Marine pollutant -

Danger label(s) 3+6.1





Special provisions (SP) 279

Malta (en) Page 13 / 19

according to Regulation (EC) No. 1907/2006 (REACH)

## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

Excepted quantities (EQ) E2 Limited quantities (LQ) 1 L

**EmS** F-E, S-D

Stowage category

## International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Proper shipping name Methanol

Particulars in the shipper's declaration UN1230, Methanol, 3 (6.1), II

Danger label(s) 3+6.1



Special provisions (SP) A113 Excepted quantities (EQ) E2 Limited quantities (LQ) 1 L

## **SECTION 15: Regulatory information**

# Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

## Dangerous substances with restrictions (REACH, Annex XVII)

Name of substance	Name acc. to inventory	CAS No	Restriction	No
Papanicolaou solution 2b Orange II solution	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
Methanol	methanol	67-56-1	R69	69
Methanol	flammable / pyrophoric		R40	40

#### Legend

1. Shall not be used in:

ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,

- tricks and jokes,

- games for one or more participants, or any article intended to be used as such, even with ornamental aspects, 2. Articles not complying with paragraph 1 shall not be placed on the market.

3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume,

can be used as fuel in decorative oil lamps for supply to the general public, and

- present an aspiration hazard and are labelled with H304
- 4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation
- 5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following require-
- (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil
- or even sucking the wick of lamps may lead to life-threatening lung damage";

  (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage';

  (c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black
- opaque containers not exceeding 1 litre by 1 December 2010.';

Page 14 / 19 Malta (en)

according to Regulation (EC) No. 1907/2006 (REACH)

## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

#### Legend

R40 1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:

- metallic glitter intended mainly for decoration,

- artificial snow and frost,
- 'whoopee' cushions,
- silly string aerosols,
- imitation excrement,
- horns for parties,
  decorative flakes and foams,
- artificial cobwebs,
- stink bombs.
- 2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with: 'For professional users only'.
- 3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (2).
- 4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.
- Shall not be placed on the market to the general public after 9 May 2019 in windscreen washing or defrosting fluids, in a concentration equal to or greater than 0,6 % by weight. R69

## List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

None of the ingredients are listed.

#### **Seveso Directive**

2012/18/EU (Seveso III)				
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements		
22	methanol	500 5.000		

#### **Deco-Paint Directive**

VOC content	93 % , 782,9 <sup>g</sup> / <sub>l</sub>

## **Industrial Emissions Directive (IED)**

VOC content	93 %
VOC content	793,6 <sup>g</sup> / <sub>l</sub>
VOC content Water content was discounted	782,9 <sup>g</sup> / <sub>l</sub>

## Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

## Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

none of the ingredients are listed

Page 15 / 19 Malta (en)

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

## **Water Framework Directive (WFD)**

## **List of pollutants (WFD)**

Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Methanol	Substances and preparations, or the breakdown products of such, which have been proved to pos- sess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine- related functions in or via the aquatic environment		A)	

Legend

A) Indicative list of the main pollutants

## Regulation on the marketing and use of explosives precursors

none of the ingredients are listed

## **Regulation on drug precursors**

none of the ingredients are listed

## Regulation on substances that deplete the ozone layer (ODS)

none of the ingredients are listed

## Regulation concerning the export and import of hazardous chemicals (PIC)

none of the ingredients are listed

## Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

#### Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

#### **National inventories**

Country	Inventory	Status
AU	AICS	all ingredients are listed
CA	DSL	not all ingredients are listed
CN	IECSC	all ingredients are listed
EU	ECSI	not all ingredients are listed
EU	REACH Reg.	all ingredients are listed
JP	CSCL-ENCS	not all ingredients are listed
JP	ISHA-ENCS	not all ingredients are listed
KR	KECI	not all ingredients are listed
MX	INSQ	not all ingredients are listed
NZ	NZIoC	all ingredients are listed
PH	PICCS	not all ingredients are listed
TR	CICR	not all ingredients are listed

Malta (en) Page 16 / 19

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

Country	Inventory	Status
TW	TCSI	all ingredients are listed
US	TSCA	not all ingredients are listed

Legend

AICS Australian Inventory of Chemical Substances
CICR Chemical Inventory and Control Regulation
CSCL-ENCS List of Existing and New Chemical Substances (CSCL-ENCS)
DSL Domestic Substances List (DSL)
ECSI EC Substance Inventory (EINECS, ELINCS, NLP)
IECSC Inventory of Existing Chemical Substances Produced or Imported in China INSQ
INSTANCES Inventory of Chemical Substances
INSTANCES Inventory of Existing and New Chemical Substances (ISMA ENCS)

Taiwan Chemical Substance Inventory

TCSI TSCA **Toxic Substance Control Act** 

## 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

# **SECTION 16: Other information**

## Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2006/15/EC	Commission Directive establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de naviga- tion intérieures (European Agreement concerning the International Carriage of Dangerous Goods by In- land Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ADR/RID/ADN	Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
CAP. 424	Occupational Health and Safety Authority Act (CAP. 424)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances

Malta (en) Page 17 / 19

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

Abbr.	Descriptions of used abbreviations
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
Flam. Liq.	Flammable liquid
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
IOELV	Indicative occupational exposure limit value
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
LEL	Lower explosion limit (LEL)
log KOW	n-Octanol/water
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
STEL	Short-term exposure limit
STOT SE	Specific target organ toxicity - single exposure
SVHC	Substance of Very High Concern
TWA	Time-weighted average
UEL	Upper explosion limit (UEL)
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

## Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Malta (en) Page 18 / 19

according to Regulation (EC) No. 1907/2006 (REACH)



## Papanicolaou solution 2b Orange II solution for microscopy

article number: AE62

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

## **Classification procedure**

Physical and chemical properties. The classification is based on tested mixture. Health hazards. Environmental hazards. The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

## List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H370	Causes damage to organs (eye).

## **Disclaimer**

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

Malta (en) Page 19 / 19