

Papanicolaou Harris hematoxylin**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: **05-12011/L**
Product name: **Papanicolaou Harris hematoxylin**

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:

Serious eye damage, category 1	H318	Causes serious eye damage.
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:

H318	Causes serious eye damage.
H315	Causes skin irritation.

Precautionary statements:

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P280	Wear protective gloves / eye protection / face protection.

Papanicolaou Harris hematoxylin

SECTION 2. Hazards identification ... / >>

P310 Immediately call a POISON CENTER / doctor / . . .
P264 Wash hands thoroughly after handling.

Contains: ALUMINIUM SULFATE
ACETIC ACID

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)
ALUMINIUM SULFATE		
CAS	10043-01-3	5 ≤ x < 10 Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335
EC	233-135-0	
INDEX		
ACETIC ACID		
CAS	64-19-7	1 ≤ x < 5 Flam. Liq. 3 H226, Skin Corr. 1A H314, Eye Dam. 1 H318, Classification note according to Annex VI to the CLP Regulation: B
EC	200-580-7	
INDEX	607-002-00-6	

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

SECTION 4. First aid measures

4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 30-60 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.

INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor.

INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.

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

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

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

Information not available

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

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

Papanicolaou Harris hematoxylin

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

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

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

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

Block the leakage if there is no hazard.

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

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

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

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

6.4. Reference to other sections

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

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

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. 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. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. 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 tutkimuskeskus julkaisu 2012:5
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
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
PRT	Portugal	Ministério da Economia e do Emprego Consolida as prescrições mínimas em matéria de

Papanicolaou Harris hematoxylin

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

ROU	România	protecção dos trabalhadores contra os riscos para a segurança e a saúde devido à exposição a agentes químicos no trabalho - Diaro da Republica I 26; 2012-02-06
SWE	Sverige	Monitorul Oficial al României 44; 2012-01-19
EU	OEL EU	Occupational Exposure Limit Values, AF 2011:18
		Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 91/322/EEC.
	TLV-ACGIH	ACGIH 2018

ACETIC ACID

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
AGW	DEU	25	10	50	20
MAK	DEU	25	10	50	20
TLV	DNK	25	10		
VLA	ESP	25	10	37	15
HTP	FIN	13	5	25	10
VLEP	FRA			25	10
TLV	GRC	25	10	37	15
AK	HUN	25		25	
MAC	NLD		10		
TLV	NOR	25	10		
NDS	POL	25		50	
VLE	PRT	25	10		
TLV	ROU	25	10		
MAK	SWE	13	5	25	10
OEL	EU	25	10	50	20
TLV-ACGIH		25	10	37	15

Legend:

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

TLV of solvent mixture: 25 mg/m3

8.2. Exposure controls

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

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

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

Provide an emergency shower with face and eye wash station.

HAND PROTECTION

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

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

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

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear a hood visor or protective visor combined with airtight 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.

Papanicolaou Harris hematoxylin

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

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

9.2. Other information

VOC (Directive 2010/75/EC) :	4,00 %
VOC (volatile carbon) :	1,60 %

SECTION 10. Stability and reactivity

10.1. Reactivity

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

ALUMINIUM SULFATE
Decomposes at 770°C/1418°F.

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.

ALUMINIUM SULFATE
May react dangerously with: strong oxidising agents.

ACETIC ACID
Risk of explosion on contact with: chromium (VI) oxide, potassium permanganate, sodium peroxide, perchloric acid, phosphorus chloride, hydrogen peroxide. May react dangerously with: alcohols, bromine pentafluoride, chlorosulphuric acid, dichromate-sulphuric acid, ethane diamine, ethylene glycol, potassium hydroxide, strong bases, sodium hydroxide, strong oxidising agents, nitric acid, ammonium nitrate, potassium tert-butoxide, oleum. Forms explosive mixtures with: air.

10.4. Conditions to avoid

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

ACETIC ACID

Papanicolaou Harris hematoxylin

SECTION 10. Stability and reactivity ... / >>

Avoid exposure to: sources of heat,naked flames.

10.5. Incompatible materials

ACETIC ACID

Incompatible with: carbonates,hydroxides,phosphates,oxidising substances,bases.

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.

ALUMINIUM SULFATE

May develop: sulphur oxides,aluminium oxides.

SECTION 11. Toxicological information

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

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

11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

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

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

LC50 (Inhalation) of the mixture:	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)

ALUMINIUM SULFATE
LD50 (Oral)

1930 mg/kg Rat

ACETIC ACID
LD50 (Oral)
LD50 (Dermal)
LC50 (Inhalation)

3310 mg/kg Rat
1060 mg/kg Rabbit
11,4 mg/l/4h Rat

SKIN CORROSION / IRRITATION

Causes skin irritation

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye damage

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

Papanicolaou Harris hematoxylin**SECTION 11. Toxicological information ... / >>**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

12.2. Persistence and degradability

ALUMINIUM SULFATE

Solubility in water 1000 - 10000 mg/l
Degradability: information not available

ACETIC ACID

Solubility in water > 10000 mg/l
Rapidly degradable

12.3. Bioaccumulative potential

ACETIC ACID

Partition coefficient: n-octanol/water -0,17

12.4. Mobility in soil

ACETIC ACID

Partition coefficient: soil/water 1,153

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.

CONTAMINATED PACKAGING

Papanicolaou Harris hematoxylin

SECTION 16. Other information

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

Flam. Liq. 3	Flammable liquid, category 3
Skin Corr. 1A	Skin corrosion, category 1A
Eye Dam. 1	Serious eye damage, category 1
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
H226	Flammable liquid and vapour.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H315	Causes skin irritation.
H335	May cause respiratory irritation.

LEGEND:

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

Papanicolaou Harris hematoxylin**SECTION 16. Other information** ... / >>

- 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.