

Klessidra 2.0 - solution A

Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

1.1. Product identifier

Code: 05-01V15PKF/A
Product name: Klessidra 2.0 - solution A

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

Intended use: In vitro medical-diagnostic disposable. Fixative for histology.

1.3. Details of the supplier of the safety data sheet

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

e-mail address of the competent person responsible for the Safety Data Sheet

info@bio-stain.it

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

1.4. Emergency telephone number

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

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

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

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

Hazard classification and indication:

Carcinogenicity, category 1B	H350	May cause cancer.
Germ cell mutagenicity, category 2	H341	Suspected of causing genetic defects.
Acute toxicity, category 4	H302	Harmful if swallowed.
Acute toxicity, category 4	H312	Harmful in contact with skin.
Eye irritation, category 2	H319	Causes serious eye irritation.
Skin irritation, category 2	H315	Causes skin irritation.
Specific target organ toxicity - single exposure, category 3	H335	May cause respiratory irritation.
Skin sensitization, category 1	H317	May cause an allergic skin reaction.

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:

Klessidra 2.0 - solution A

SECTION 2. Hazards identification ... / >>

H350	May cause cancer.
H341	Suspected of causing genetic defects.
H302+H312	Harmful if swallowed or in contact with skin.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.
EUH208	Contains: 2-metil-2H-isotiazol-3-one May produce an allergic reaction.

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.
P261	Avoid breathing dust / fume / gas / mist / vapours / spray.

Contains: FORMALDEHYDE
METHANOL

2.3. Other hazards

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

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
FORMALDEHYDE		
CAS	50-00-0 10 ≤ x < 13,5	Carc. 1B H350, Muta. 2 H341, Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H331, Skin Corr. 1B H314, Eye Dam. 1 H318, STOT SE 3 H335, Skin Sens. 1 H317, Classification note according to Annex VI to the CLP Regulation: B D
EC	200-001-8	
INDEX	605-001-00-5	
METHANOL		
CAS	67-56-1 0 ≤ x < 0,5	Flam. Liq. 2 H225, Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H331, STOT SE 1 H370
EC	200-659-6	
INDEX	603-001-00-X	
2-metil-2H-isotiazol-3-one		
CAS	55965-84-9 0 ≤ x < 0,5	Acute Tox. 4 H302, Acute Tox. 4 H332, Skin Corr. 1B H314, Eye Dam. 1 H318, Skin Sens. 1B H317, Aquatic Acute 1 H400 M=1, Aquatic Chronic 2 H411
EC		
INDEX	613-167-00-5	

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

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

Klessidra 2.0 - solution A**SECTION 4. First aid measures ... / >>**

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**

Block the leakage if there is no hazard.

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

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

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

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

6.4. Reference to other sections

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

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

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Vapours may catch fire and an explosion may occur; vapour accumulation is therefore to be avoided by leaving windows and doors open and ensuring good cross ventilation. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire.

Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. Vigorous stirring and flow through the tubes and equipment may cause the formation and accumulation of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during use. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities

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

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

FORMALDEHYDE

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
AGW	DEU	0,37	0,3	0,74 (C)	0,6 (C)	
TLV	DNK	0,4	0,3			
VLA	ESP			0,7	0,3	
HTP	FIN	0,37	0,3	1,2 (C)	1 (C)	
VLEP	FRA		0,5		1	
WEL	GBR	2,5	2	2,5	2	
TLV	GRC	2,5	2	2,5	2	
AK	HUN	0,6		0,6		
OEL	NLD	0,15		0,5		
TLV	NOR	0,6	0,5	1,2 (C)	1 (C)	
NDS	POL	0,5		1		
TLV	ROU	1,2	1	3	2	
MAK	SWE	0,37	0,3	0,74 (C)	0,6 (C)	SKIN
TLV-ACGIH			0,1		0,3 (C)	

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

METHANOL

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		
		mg/m ³	ppm	mg/m ³	ppm	
AGW	DEU	270	200	1080	800	SKIN
MAK	DEU	270	200	1080	800	SKIN
TLV	DNK	260	200			
VLA	ESP	266	200			SKIN
HTP	FIN	270	200	330	250	SKIN
VLEP	FRA	260	200	1300	1000	SKIN
WEL	GBR	266	200	333	250	SKIN
TLV	GRC	260	200	325	250	
AK	HUN	260		1040		
VLEP	ITA	260	200			SKIN
OEL	NLD	133	100			SKIN
TLV	NOR	130	100			SKIN
NDS	POL	100		300		
VLE	PRT	260	200			SKIN
TLV	ROU	260	200		5	SKIN
MAK	SWE	250	200	350	250	SKIN
OEL	EU	260	200			SKIN
TLV-ACGIH		262	200	328	250	

Legend:

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

8.2. Exposure controls

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

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

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

Provide an emergency shower with face and eye wash station.

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

HAND PROTECTION

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

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

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

SKIN PROTECTION

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

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

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, 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.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Not available	
Colour	Not available	

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

Odour	Not available
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	Not available
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Explosive properties	Not available
Oxidising properties	Not available

9.2. Other information

VOC (Directive 2010/75/EC) :	12,14 %
VOC (volatile carbon) :	4,84 %

SECTION 10. Stability and reactivity

10.1. Reactivity

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

FORMALDEHYDE

Decomposes under the effect of heat.

Aqueous solutions are stabilised with methanol but tend to polymerise over time. Solutions > 25% are also corrosive.

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.

FORMALDEHYDE

Risk of explosion on contact with: nitromethane,nitrogen dioxide,hydrogen peroxide,phenoles,performic acid,nitric acid.May polymerise on contact with: strong oxidising agents,alkalis.May react dangerously with: hydrochloric acid,magnesium carbonate,sodium hydroxide,perchloric acid,aniline.Forms explosive mixtures with: air.

10.4. Conditions to avoid

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

FORMALDEHYDE

Avoid exposure to: light,sources of heat,naked flames.

10.5. Incompatible materials

FORMALDEHYDE

Incompatible with: acids,alkalis,ammonia,tannin,strong oxidants,phenoles,copper salts,silver,iron.

10.6. Hazardous decomposition products

FORMALDEHYDE

May develop: carbon oxides.

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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 toxicological effectsMetabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

METHANOL

WORKERS: inhalation; contact with the skin.

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

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

METHANOL

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

Interactive effects

Information not available

ACUTE TOXICITY

LC50 (Inhalation) of the mixture:	> 20 mg/l
LD50 (Oral) of the mixture:	714,29 mg/kg
LD50 (Dermal) of the mixture:	1935,48 mg/kg

2-metil-2H-isotiazol-3-one

LD50 (Oral)	862 mg/kg
LD50 (Dermal)	2800 mg/kg

FORMALDEHYDE

LD50 (Oral)	100 mg/kg Rat
LD50 (Dermal)	270 mg/kg Rabbit
LC50 (Inhalation)	0,588 mg/l/4h Rat

SKIN CORROSION / IRRITATION

Causes skin irritation

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin
May produce an allergic reaction.
Contains:
2-metil-2H-isotiazol-3-one

GERM CELL MUTAGENICITY

Suspected of causing genetic defects

CARCINOGENICITY

May cause cancer

Klessidra 2.0 - solution A

SECTION 11. Toxicological information ... / >>REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

May cause respiratory irritation

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

No specific data are available for this product. Handle it according to good working practices. Avoid littering. Do not contaminate soil and waterways. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation. Please take all the proper measures to reduce harmful effects on aquifers.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

2-metil-2H-isotiazol-3-one
Degradability: information not available

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

FORMALDEHYDE
Solubility in water 55000 mg/l
Rapidly degradable

12.3. Bioaccumulative potential

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

FORMALDEHYDE
Partition coefficient: n-octanol/water 0,35
BCF < 1

12.4. Mobility in soil

FORMALDEHYDE
Partition coefficient: soil/water 1,202

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

Klessidra 2.0 - solution A

SECTION 15. Regulatory information ... / >>

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

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:

Flam. Liq. 2	Flammable liquid, category 2
Carc. 1B	Carcinogenicity, category 1B
Muta. 2	Germ cell mutagenicity, category 2
Acute Tox. 3	Acute toxicity, category 3
STOT SE 1	Specific target organ toxicity - single exposure, category 1
Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1B	Skin corrosion, category 1B
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Skin Sens. 1	Skin sensitization, category 1
Skin Sens. 1B	Skin sensitization, category 1B
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic toxicity, category 2
H225	Highly flammable liquid and vapour.
H350	May cause cancer.
H341	Suspected of causing genetic defects.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H370	Causes damage to organs.
H302	Harmful if swallowed.
H302+H312	Harmful if swallowed or in contact with skin.
H332	Harmful if inhaled.
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation

Klessidra 2.0 - solution A**SECTION 16. Other information ... / >>**

- 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 / 03 / 05 / 08 / 11 / 15.

Changed TLVs in section 8.1 for following countries:

DEU,

Klessidra 2.0 - solution B

Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

1.1. Product identifier

Code: 05-01V15PKF/B
Product name: Klessidra 2.0 - solution B

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

Intended use: In vitro medical-diagnostic disposable. Fixative for histology.

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 not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to (EU) Regulation 2015/830.

Hazard classification and indication: --

2.2. Label elements

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

Hazard pictograms: --

Signal words: --

Hazard statements:

EUH210 Safety data sheet available on request.
EUH208 Contains: 2-metil-2H-isotiazol-3-one
May produce an allergic reaction.

Precautionary statements: --

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%.

Klessidra 2.0 - solution B

SECTION 3. Composition/information on ingredients**3.2. Mixtures**

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
2-metil-2H-isotiazol-3-one		
CAS	55965-84-9 0 ≤ x < 0,5	Acute Tox. 4 H302, Acute Tox. 4 H332, Skin Corr. 1B H314, Eye Dam. 1 H318, Skin Sens. 1B H317, Aquatic Acute 1 H400 M=1, Aquatic Chronic 2 H411
EC		
INDEX	613-167-00-5	

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**

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

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

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

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

Information not available

SECTION 5. Firefighting measures**5.1. Extinguishing media**

SUITABLE EXTINGUISHING EQUIPMENT

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

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION

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

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

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

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

Use breathing equipment if fumes or powders are released into the air. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Klessidra 2.0 - solution B**SECTION 6. Accidental release measures** ... / >>

Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

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

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

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

Information not available

8.2. Exposure controls

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

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.

HAND PROTECTION

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

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

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

SKIN PROTECTION

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

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

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

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

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

ENVIRONMENTAL EXPOSURE CONTROLS

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

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

Properties	Value	Information
Appearance	Not available	
Colour	Not available	
Odour	Not available	

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

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	Not available
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Explosive properties	Not available
Oxidising properties	Not available

9.2. Other information

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

SECTION 10. Stability and reactivity**10.1. Reactivity**

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

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

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

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

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

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

11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

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SECTION 11. Toxicological information ... / >>

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)

2-metil-2H-isotiazol-3-one	
LD50 (Oral)	862 mg/kg
LD50 (Dermal)	2800 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

May produce an allergic reaction.

Contains:

2-metil-2H-isotiazol-3-one

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

No specific data are available for this product. Handle it according to good working practices. Avoid littering. Do not contaminate soil and waterways. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation. Please take all the proper measures to reduce harmful effects on aquifers.

12.1. Toxicity

Information not available

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SECTION 12. Ecological information ... / >>**12.2. Persistence and degradability**

2-metil-2H-isotiazol-3-one
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 greater than 0,1%.

12.6. Other adverse effects

Information not available

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

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

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

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

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

Information not relevant

Klessidra 2.0 - solution B**SECTION 15. Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
None

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:

Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1B	Skin corrosion, category 1B
Skin Sens. 1B	Skin sensitization, category 1B
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic toxicity, category 2
H302	Harmful if swallowed.
H332	Harmful if inhaled.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
EUH210	Safety data sheet available on request.

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

Klessidra 2.0 - solution B**SECTION 16. Other information ... / >>**

- 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

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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
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8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
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11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)

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

Note for users:

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

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

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

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

Changes to previous review:

The following sections were modified:

01 / 03 / 06.