

KLESSIDRA 160 10% Neutral buffered formalin**Safety Data Sheet**

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

SECTION 1. Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**Code: **05-01V250PK**
Product name: **KLESSIDRA 160 10% Neutral buffered formalin****1.2. Relevant identified uses of the substance or mixture and uses advised against**Intended use: **In vitro medical-diagnostic disposable. Reagent for microscopy.**

Identified Uses	Industrial	Professional	Consumer
In vitro diagnostic reagent	-	✓	-
Uses Advised Against			
This product is not intended for consumer use			

1.3. Details of the supplier of the safety data sheetName: **BIO-OPTICA MILANO SPA**
Full address: **via San Faustino, 58**
District and Country: **20134 Milano (MI)**
Tel.: **0039 02 2127131**
Fax: **0039 02 2153000**e-mail address of the competent person responsible for the Safety Data Sheet: **sds@bio-optica.it**Supplier: **Bio-Optica Milano S.p.a.****1.4. Emergency telephone number**For urgent inquiries refer to: **0845 46 47, Poison centres NHS Direct in England or Wales**
08454 24 24 24, Poison centres NHS 24 in Scotland**SECTION 2. Hazards identification****2.1. Classification of the substance or mixture**

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.

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

Hazard classification and indication:

Carcinogenicity, category 1B	H350	May cause cancer.
Germ cell mutagenicity, category 2	H341	Suspected of causing genetic defects.
Acute toxicity, category 4	H332	Harmful if inhaled.
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**

KLESSIDRA 160 10% Neutral buffered formalin

SECTION 2. Hazards identification ... / >>

Hazard statements:

H350	May cause cancer.
H341	Suspected of causing genetic defects.
H332	Harmful if inhaled.
H317	May cause an allergic skin 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

2.3. Other hazards

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

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

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
FORMALDEHYDE		
INDEX 605-001-00-5	$2,94 \leq x < 5$	Carc. 1B H350, Muta. 2 H341, Acute Tox. 2 H330, Acute Tox. 3 H301, Acute Tox. 3 H311, 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		Skin Corr. 1B H314: $\geq 25\%$, Skin Irrit. 2 H315: $\geq 5\%$, Skin Sens. 1 H317: $\geq 0,2\%$, Eye Dam. 1 H318: $\geq 25\%$, Eye Irrit. 2 H319: $\geq 5\%$, STOT SE 3 H335: $\geq 5\%$
CAS 50-00-0		LD50 Oral: 100 mg/kg, LD50 Dermal: 270 mg/kg, LC50 Inhalation vapours: 0,588 mg/l/4h
METHANOL		
INDEX 603-001-00-X	$0 \leq x < 0,5$	Flam. Liq. 2 H225, Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H331, STOT SE 1 H370
EC 200-659-6		STOT SE 2 H371: $\geq 3\%$
CAS 67-56-1		STA Oral: 100 mg/kg, STA Dermal: 300 mg/kg, STA Inhalation vapours: 3 mg/l

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.

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SECTION 4. First aid measures ... / >>

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

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

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. Specific end use(s)

Information not available

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SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory references:

BGR	България	НАРЕДБА № 13 ОТ 30 ДЕКЕМВРИ 2003 Г. ЗА ЗАЩИТА НА РАБОТЕЩИТЕ ОТ РИСКОВЕ, СВЪРЗАНИ С ЕКСПОЗИЦИЯ НА ХИМИЧНИ АГЕНТИ ПРИ РАБОТА (изм. ДВ. бр.5 от 17 Януари 2020г.)
CZE	Česká Republika	Nařízení vlády č. 41/2020 Sb. Nařízení vlády, kterým se mění nařízení vlády č. 361/2007 Sb., kterým se stanoví podmínky ochrany zdraví při práci, ve znění pozdějších předpisů
DEU	Deutschland	Technischen Regeln für Gefahrstoffe (TRGS 900) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte. MAK- und BAT-Werte-Liste 2020, Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 56
DNK	Danmark	Bekendtgørelse om grænseværdier for stoffer og materialer - BEK nr 1458 af 13/12/2019
ESP	España	Límites de exposición profesional para agentes químicos en España 2021
EST	Eesti	Ohtlike kemikaalide ja neid sisaldavate materjalide kasutamise töötavishoiu ja tööohutuse nõuded ning töökeskkonna keemiliste ohutegurite piirnormid [RT I, 17.10.2019, 1 - jõust. 17.01.2020]
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
FIN	Suomi	HTP-VÄRDEN 2020. Koncentrationer som befunnits skadliga. SOCIAL - OCH HÄLSOVÄRDSMINISTERIETS PUBLIKATIONER 2020:25
GRC	Ελλάδα	Π.Δ. 26/2020 (ΦΕΚ 50/Α` 6.3.2020) Εναρμόνιση της ελληνικής νομοθεσίας προς τις διατάξεις των οδηγιών 2017/2398/ΕΕ, 2019/130/ΕΕ και 2019/983/ΕΕ «για την τροποποίηση της οδηγίας 2004/37/ΕΚ "σχετικά με την προστασία των εργαζομένων από τους κινδύνους που συνδέονται με την έκθεση σε καρκινογόνους ή μεταλλαξιογόνους παράγοντες κατά την εργασία"»
HUN	Magyarország	Az innovációért és technológiáért felelős miniszter 5/2020. (II. 6.) ITM rendelete a kémiai kóroki tényezők hatásának kitett munkavállalók egészségének és biztonságának védelméről
HRV	Hrvatska	Pravilnik o izmjenama i dopunama Pravilnika o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
LTU	Lietuva	Jsakymas dėl lietuvis higienos normos hn 23:2011 „cheminių medžiagų profesinio poveikio ribiniai dydžiai. Matavimo ir poveikio vertinimo bendrieji reikalavimai“ patvirtinimo
LVA	Latvija	Grozījumi Ministru kabineta 2007. gada 15. maija noteikumos Nr. 325 "Darba aizsardzības prasības saskarē ar ķīmiskajām vielām darba vietās" (prot. Nr. 32 18. §; prot. Nr. 1 22. §)
NOR	Norge	Forskrift om endring i forskrift om tiltaksverdier og grenseverdier for fysiske og kjemiske faktorer i arbeidsmiljøet samt smitterisikogrupper for biologiske faktorer (forskrift om tiltaks- og grenseverdier), 21. august 2018 nr. 1255
NLD	Nederland	Arbeidsomstandighedenregeling. Lijst van wettelijke grenswaarden op grond van de artikelen 4.3, eerste lid, en 4.16, eerste lid, van het Arbeidsomstandighedenbesluit
PRT	Portugal	Decreto-Lei n.º 1/2021 de 6 de janeiro, valores-limite de exposição profissional indicativos para os agentes químicos. Decreto-Lei n.º 35/2020 de 13 de julho, proteção dos trabalhadores contra os riscos ligados à exposição durante o trabalho a agentes cancerígenos ou mutagénicos
POL	Polska	Rozporządzenie ministra rozwoju, pracy i technologii z dnia 18 lutego 2021 r. Zmieniające rozporządzenie w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy
ROU	România	Hotărârea nr. 53/2021 pentru modificarea hotărârii guvernului nr. 1.218/2006, precum și pentru modificarea și completarea hotărârii guvernului nr. 1.093/2006
SWE	Sverige	Hygieniska gränsvärden, Arbetsmiljöverkets föreskrifter och allmänna råd om hygieniska gränsvärden (AFS 2018:1)
SVK	Slovensko	NARIADENIE VLÁDY Slovenskej republiky z 12. augusta 2020, ktorým sa mení a dopĺňa nariadenie vlády Slovenskej republiky č. 356/2006 Z. z. o ochrane zdravia zamestnancov pred rizikami súvisiacimi s expozíciou karcinogénnym a mutagénnym faktorom pri práci v znení neskorších predpisov
TUR	Türkiye	Kimyasal Maddelerin Çalışmalarda Sağlık ve Güvenlik Önlemleri Hakkında Yönetmelik 12.08.2013 / 28733
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
EU	OEL EU	Directive (EU) 2022/431; Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC.
	TLV-ACGIH	ACGIH 2022

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

METHANOL

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

FORMALDEHYDE

Threshold Limit Value						
Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m ³	ppm	mg/m ³	ppm	
TLV	BGR	1		2		
TLV	CZE	0,5	0,4005	1	0,801	
AGW	DEU	0,37	0,3	0,74	0,6	
TLV	DNK			0,4 (C)	0,3 (C)	
VLA	ESP	0,37	0,3	0,74	0,6	
TLV	EST	0,6	0,5	1,2 (C)	1 (C)	
VLEP	FRA	0,37	0,3	0,74	0,6	
HTP	FIN	0,37	0,3	0,74	0,6	
TLV	GRC	0,37	0,3	0,74	0,6	
AK	HUN	0,6		0,6		SKIN
GVI/KGVI	HRV	0,37	0,3	0,74	0,6	
VLEP	ITA	0,37	0,3	0,74	0,6	
RD	LTU	0,37	0,3	0,74	0,6	
RV	LVA	0,5				
TLV	NOR	0,6	0,5	1,2 (C)	1 (C)	
TGG	NLD	0,15		0,5		
VLE	PRT	0,37	0,3	0,74	0,6	
NDS/NDSch	POL	0,37		0,74		SKIN
TLV	ROU	0,37	0,3	0,74	0,6	
NGV/KGV	SWE	0,37	0,3	0,74	0,6	SKIN
NPEL	SVK	0,37	0,3	0,74	0,6	
WEL	GBR	2,5	2	2,5	2	
OEL	EU	0,37	0,3	0,74	0,6	
TLV-ACGIH			0,1		0,3	

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.

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

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

Provide an emergency shower with face and eye wash station.

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

HAND PROTECTION

Protect hands with category III work gloves.

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

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

SKIN PROTECTION

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

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

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

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

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

ENVIRONMENTAL EXPOSURE CONTROLS

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

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	liquid	
Colour	colourless	
Odour	pungent	
Melting point / freezing point	not available	
Initial boiling point	100 °C	
Flammability	not available	
Lower explosive limit	not available	
Upper explosive limit	not available	
Flash point	> 60 °C	
Auto-ignition temperature	not available	
Decomposition temperature	not available	
pH	7,2	
Kinematic viscosity	not available	
Solubility	soluble	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	not available	
Density and/or relative density	1,032 kg/l	
Relative vapour density	not available	
Particle characteristics	not applicable	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

VOC (Directive 2010/75/EU)	3,94 % - 40,65	g/litre
VOC (volatile carbon)	1,57 % - 16,22	g/litre

KLESSIDRA 160 10% Neutral buffered formalin**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.

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**

When heated to decomposition releases: methanol, carbon monoxide.

SECTION 11. Toxicological information

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

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

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure**METHANOL**

WORKERS: inhalation; contact with the skin.

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

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

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

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation - vapours) of the mixture: 11,76 mg/l

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SECTION 11. Toxicological information ... / >>

ATE (Oral) of the mixture: >2000 mg/kg
 ATE (Dermal) of the mixture: >2000 mg/kg

METHANOL
 LC50 (Inhalation vapours): > 87,6 mg/l/4h Rat

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

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

Sensitising for the skin

GERM CELL MUTAGENICITY

Suspected of causing genetic defects

CARCINOGENICITY

May cause cancer

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

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

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

KLESSIDRA 160 10% Neutral buffered formalin**SECTION 12. Ecological information** ... / >>

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 \geq than 0,1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

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

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

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

SECTION 14. Transport information

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

14.1. UN number or ID number

not applicable

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

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SECTION 14. Transport information ... / >>

14.4. Packing group

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EU: None

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

Product

Point 3 - 40

Contained substance

Point 28-72-75 FORMALDEHYDE

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

not applicable

Substances in Candidate List (Art. 59 REACH)

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

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Workers exposed to this health-dangerous chemical agent must undergo sanitary checks carried out in compliance with 2004/37/EC directive.

15.2. Chemical safety assessment

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

SECTION 16. Other information

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

Flam. Liq. 2	Flammable liquid, category 2
Carc. 1B	Carcinogenicity, category 1B
Muta. 2	Germ cell mutagenicity, category 2
Acute Tox. 2	Acute toxicity, 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

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SECTION 16. Other information ... / >>

STOT SE 3	Specific target organ toxicity - single exposure, category 3
Skin Sens. 1	Skin sensitization, category 1
H225	Highly flammable liquid and vapour.
H350	May cause cancer.
H341	Suspected of causing genetic defects.
H330	Fatal if inhaled.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H370	Causes damage to organs.
H332	Harmful if inhaled.
H314	Causes severe skin burns and eye damage.
H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.

LEGEND:

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

GENERAL BIBLIOGRAPHY

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

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21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)

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

Note for users:

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

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

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

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

CALCULATION METHODS FOR CLASSIFICATION

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

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

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

Changes to previous review:

The following sections were modified:

01.