

## Vials for needle cleaning system

## Safety Data Sheet

According to Annex II to REACH - Regulation 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:	40-500-053
Product name	Vials for needle cleaning system
INDEX number	601-022-00-9
EC number	215-535-7
CAS number	1330-20-7

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

Intended use	Not available
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## 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

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
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## 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:

Flammable liquid, category 3	H226	Flammable liquid and vapour.
Acute toxicity, category 4	H312	Harmful in contact with skin.
Acute toxicity, category 4	H332	Harmful if inhaled.
Aspiration hazard, category 1	H304	May be fatal if swallowed and enters airways.
Specific target organ toxicity - repeated exposure, category 2	H373	May cause damage to organs through prolonged or repeated exposure.
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.

Classification note according to Annex VI to the CLP Regulation: C

## 2.2. Label elements

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

Hazard pictograms:



## Vials for needle cleaning system

## SECTION 2. Hazards identification ... / &gt;&gt;

Signal words: Danger

Hazard statements:

**H226** Flammable liquid and vapour.  
**H312+H332** Harmful in contact with skin or if inhaled.  
**H304** May be fatal if swallowed and enters airways.  
**H373** May cause damage to organs through prolonged or repeated exposure.  
**H319** Causes serious eye irritation.  
**H315** Causes skin irritation.  
**H335** May cause respiratory irritation.

Precautionary statements:

**P210** Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
**P280** Wear protective gloves/ protective clothing / eye protection / face protection.  
**P301+P310** IF SWALLOWED: immediately call a POISON CENTER / doctor / . . .  
**P370+P378** In case of fire: use . . . to extinguish.  
**P303+P361+P353** IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  
**P331** Do NOT induce vomiting.

**Contains:** XYLENE (MIXTURE OF ISOMERS)

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## 2.3. Other hazards

The substance does not have persistence, bioaccumulation and toxicity (PBT) properties and is not very persistent and very bioaccumulative. (vPvB).

The substance does not have endocrine disrupting properties.

## SECTION 3. Composition/information on ingredients

## 3.1. Substances

Contains:

Identification	Conc. %	Classification (EC) 1272/2008 (CLP)
<b>XYLENE (MIXTURE OF ISOMERS)</b>		
CAS	1330-20-7 100	<b>Fam. Liq. 3 H226, Acute Tox. 4 H312, Acute Tox. 4 H332, Asp. Tox. 1 H304, STOT RE 2 H373, Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335, Classification note according to Annex VI to the CLP Regulation: C STA Dermal: 1100 mg/kg, STA Inhalation vapours: 11 mg/l</b>
EC	215-535-7	
INDEX	601-022-00-9	

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 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

**SKIN:** Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

**INHALATION:** Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

**INGESTION:** Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

Information not available

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

Information not available

**Vials for needle cleaning system****SECTION 5. Firefighting measures****5.1. Extinguishing media**

## SUITABLE EXTINGUISHING EQUIPMENT

Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.

## UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

**5.2. Special hazards arising from the substance or mixture**

## HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

**5.3. Advice for firefighters**

## GENERAL INFORMATION

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

## SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

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

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

Block the leakage if there is no hazard.

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

Send away individuals who are not suitably equipped. Use explosion-proof equipment. Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site.

**6.2. Environmental precautions**

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

**6.3. Methods and material for containment and cleaning up**

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

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

**6.4. Reference to other sections**

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

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

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. 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 cool and 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.

## Vials for needle cleaning system

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

#### 7.3. Specific end use(s)

Information not available

### 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	Ohutlike kemikaalide ja neid sisaldavate materjalide kasutamise töötervishoiu ja tööohutuse nõuded ning töökeskkonna keemiliste ohutegurite piinormid [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 Maddelerle 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) 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 2021

## Vials for needle cleaning system

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

#### XYLENE (MIXTURE OF ISOMERS)

##### Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>	ppm	
TLV	BGR	221	50	442	100	SKIN
TLV	CZE	200	45,4	400	90,8	SKIN
AGW	DEU	440	100	880	200	SKIN
MAK	DEU	440	100	880	200	SKIN
TLV	DNK	109	25			SKIN E
VLA	ESP	221	50	442	100	SKIN
TLV	EST	200	50	450	100	SKIN
VLEP	FRA	221	50	442	100	SKIN
HTP	FIN	220	50	440	100	SKIN
TLV	GRC	435	100	650	150	
AK	HUN	221		442		SKIN
GVI/KGVI	HRV	221	50	442	100	SKIN
VLEP	ITA	221	50	442	100	SKIN
RD	LTU	221	50	442	100	SKIN
RV	LVA	221	50	442	100	SKIN
TLV	NOR	108	25			SKIN
TGG	NLD	210		442		SKIN
VLE	PRT	221	50	442	100	SKIN
NDS/NDSch	POL	100		200		SKIN
TLV	ROU	221	50	442	100	SKIN
NGV/KGV	SWE	221	50	442	100	SKIN
NPEL	SVK	221	50	442	100	SKIN
ESD	TUR	221	50	442	100	SKIN
WEL	GBR	220	50	441	100	SKIN
OEL	EU	221	50	442	100	SKIN
TLV-ACGIH		434	100	651	150	

##### Predicted no-effect concentration - PNEC

Normal value in fresh water	0,32	mg/l
Normal value in marine water	0,32	mg/l
Normal value for fresh water sediment	12,46	mg/kg
Normal value for marine water sediment	12,46	mg/kg
Normal value for water, intermittent release	0,32	mg/l

##### Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers		Effects on workers					
	Acute	Acute	Chronic	Chronic	Acute	Acute	Chronic	Chronic
	local	systemic	local	systemic	local	systemic	local	systemic
Oral				12,5				
				mg/kg bw/d				
Inhalation				65,3	442			221
				mg/m <sup>3</sup>	mg/kg			mg/m <sup>3</sup>
Skin				125				212
				mg/kg bw/d				mg/kg bw/d

##### Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.  
VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

### 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.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

#### 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 Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

# Vials for needle cleaning system

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

Consider the appropriateness of providing antistatic clothing in the case of working environments in which there is a risk of explosion.

### EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

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	liquid	
Colour	colourless	
Odour	characteristic	
Melting point / freezing point	Not available	
Initial boiling point	139,6 °C	
Flammability	Not available	
Lower explosive limit	0,9 % (v/v)	
Upper explosive limit	7 % (v/v)	
Flash point	> 23 °C	
Auto-ignition temperature	Not available	
pH	Not available	
Kinematic viscosity	Not available	
Solubility	soluble in organic solvents	
Partition coefficient: n-octanol/water	Not available	
Vapour pressure	Not available	
Density and/or relative density	0,86	
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)	100,00 % - 864,00	g/litre
VOC (volatile carbon)	90,42 % - 781,24	g/litre

## SECTION 10. Stability and reactivity

### 10.1. Reactivity

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

### 10.2. Chemical stability

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

### 10.3. Possibility of hazardous reactions

The vapours may also form explosive mixtures with the air.

# Vials for needle cleaning system

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

Stable in normal conditions of use and storage. Reacts violently with: strong oxidants, strong acids, nitric acid, perchlorates. May form explosive mixtures with: air.

### 10.4. Conditions to avoid

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

### 10.5. Incompatible materials

Information not available

### 10.6. Hazardous decomposition products

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

## SECTION 11. Toxicological information

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

#### Metabolism, toxicokinetics, mechanism of action and other information

Information not available

#### Information on likely routes of exposure

WORKERS: inhalation; contact with the skin.

POPULATION: ingestion of contaminated food or water; inhalation of ambient air.

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

Toxic effect on the central nervous system (encephalopathy); irritating for the skin, conjunctiva, cornea and respiratory apparatus.

#### Interactive effects

Intake of alcohol interferes with the metabolism of the substance, inhibiting it. Ethanol consumption (0.8 g/kg) before a 4-hour exposure to xylene vapours (145 and 280 ppm) causes a 50% reduction in the excretion of methyl hippuric acid, whereas the concentration of xylenes in the blood increases approx. 1.5-2 times. At the same time there is an increase in the secondary side effects of the ethanol. The metabolism of the xylenes is increased by phenobarbital and 3-methyl-colantrene type enzyme inducers. Aspirin and xylenes mutually inhibit their conjugation with the glycine, which results in a decrease in urinary excretion of methyl hippuric acid. Other industrial products can interfere with the metabolism of xylenes.

#### ACUTE TOXICITY

##### XYLENE (MIXTURE OF ISOMERS)

LD50 (Dermal):

4350 mg/kg Rabbit

STA (Dermal):

1100 mg/kg estimate from table 3.1.2 of Annex I of the CLP

LD50 (Oral):

3523 mg/kg Rat

LC50 (Inhalation vapours):

26 mg/l/4h Rat

STA (Inhalation vapours):

11 mg/l estimate from table 3.1.2 of Annex I of the CLP

#### SKIN CORROSION / IRRITATION

Causes skin irritation

#### SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

#### RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

#### Respiratory sensitization

Information not available

#### Skin sensitization

Information not available



# Vials for needle cleaning system

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

### GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

### CARCINOGENICITY

Does not meet the classification criteria for this hazard class

Classified in Group 3 (not classifiable as a human carcinogen) by the International Agency for Research on Cancer (IARC). The US Environmental Protection Agency (EPA) affirms that "the data is inadequate for an assessment of the carcinogenic potential".

### REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

#### Adverse effects on sexual function and fertility

Information not available

#### Adverse effects on development of the offspring

Information not available

#### Effects on or via lactation

Information not available

### STOT - SINGLE EXPOSURE

May cause respiratory irritation

#### Target organs

Information not available

#### Route of exposure

Information not available

### STOT - REPEATED EXPOSURE

May cause damage to organs

#### Target organs

Information not available

#### Route of exposure

Information not available

### ASPIRATION HAZARD

Toxic for aspiration

### 11.2. Information on other hazards

Based on the available data, the substance is not 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



## Vials for needle cleaning system

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

## 12.2. Persistence and degradability

XYLENE (MIXTURE OF ISOMERS)  
Solubility in water 100 - 1000 mg/l  
Degradability: information not available

## 12.3. Bioaccumulative potential

XYLENE (MIXTURE OF ISOMERS)  
Partition coefficient: n-octanol/water 3,12  
BCF 25,9

## 12.4. Mobility in soil

XYLENE (MIXTURE OF ISOMERS)  
Partition coefficient: soil/water 2,73

## 12.5. Results of PBT and vPvB assessment

The substance does not have persistence, bioaccumulation and toxicity (PBT) properties and is not very persistent and very bioaccumulative. (vPvB).

## 12.6. Endocrine disrupting properties

Based on the available data, the substance is not 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.  
Waste transportation may be subject to ADR restrictions.  
CONTAMINATED PACKAGING  
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

## SECTION 14. Transport information

## 14.1. UN number or ID number

ADR / RID, IMDG, IATA: 1307

## 14.2. UN proper shipping name

ADR / RID: XYLENES  
IMDG: XYLENES  
IATA: XYLENES

## Vials for needle cleaning system

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

#### 14.3. Transport hazard class(es)

ADR / RID: Class: 3 Label: 3



IMDG: Class: 3 Label: 3



IATA: Class: 3 Label: 3



#### 14.4. Packing group

ADR / RID, IMDG, IATA: III

#### 14.5. Environmental hazards

ADR / RID: NO

IMDG: NO

IATA: NO

#### 14.6. Special precautions for user

ADR / RID:	HIN - Kemler: 30	Limited Quantities: 5 L	Tunnel restriction code: (D/E)
	Special provision: -		
IMDG:	EMS: F-E, S-D	Limited Quantities: 5 L	
IATA:	Cargo:	Maximum quantity: 220 L	Packaging instructions: 366
	Pass.:	Maximum quantity: 60 L	Packaging instructions: 355
	Special provision:	A3	

#### 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: P5c

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

<u>Product</u>	
Point	3 - 40
<u>Contained substance</u>	
Point	75

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

## Vials for needle cleaning system

## SECTION 15. Regulatory information ... / &gt;&gt;

## Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

## 15.2. Chemical safety assessment

Has not been performed / is not yet available a chemical safety assessment for the substance.

## SECTION 16. Other information

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

<b>Flam. Liq. 3</b>	Flammable liquid, category 3
<b>Acute Tox. 4</b>	Acute toxicity, category 4
<b>Asp. Tox. 1</b>	Aspiration hazard, category 1
<b>STOT RE 2</b>	Specific target organ toxicity - repeated exposure, category 2
<b>Eye Irrit. 2</b>	Eye irritation, category 2
<b>Skin Irrit. 2</b>	Skin irritation, category 2
<b>STOT SE 3</b>	Specific target organ toxicity - single exposure, category 3
<b>H226</b>	Flammable liquid and vapour.
<b>H312</b>	Harmful in contact with skin.
<b>H312+H332</b>	Harmful in contact with skin or if inhaled.
<b>H332</b>	Harmful if inhaled.
<b>H304</b>	May be fatal if swallowed and enters airways.
<b>H373</b>	May cause damage to organs through prolonged or repeated exposure.
<b>H319</b>	Causes serious eye irritation.
<b>H315</b>	Causes skin irritation.
<b>H335</b>	May cause respiratory irritation.

## 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

**Vials for needle cleaning system****SECTION 16. Other information ... / >>**

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)
21. Delegated Regulation (UE) 2021/849 (XVII 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:

08.