

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31, Annex II
according to Regulation (EU) No 2020/878

Printing date: 25.05.2021
Revision date: 25.05.2021
Version number: 4 (replaces version 3)

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name: Reagent PYRstrip

Other names: REAGENT

UFI: Not apply.

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

No use descriptors (LCS, SU, PC, PROC, ERC, AC, TF categories) of the substance or mixture are available.

Application of the substance / the mixture: Preparation for in vitro diagnostic use.

Uses advised against: Any other than the above mentioned.

1.3 Details of the supplier of the safety data sheet**Supplier:**

TestLine Clinical Diagnostics s.r.o.

Production of diagnostic sets for human, veterinary, inorganic and organic laboratories.

Business Address: Křižíkova 68, 612 00 Brno, Czech Republic

Company Identification Number: 479 13 240

Phone/Fax: +420 541 243 390

E-mail: pospisiljar@testlinecd.com / Website: www.testlinecd.com

Further information obtainable from:

Ing. Karel Královec, Studio2K

Phone: +420 777 145 808, E-mail: bl@studio2k.cz, Website: www.bezpecnostni-listy.eu

1.4 Emergency telephone number

Phone: +420 224 919 293 or +420 224 915 402; E-mail: tis@vfn.cz

Toxicology Information Centre in Prague (TIS), Na Bojišti 1, 120 00 Prague 2, Czech Republic

Permanent medical information service for cases of acute poisoning of humans and animals.

National helpdesks contact details - <https://echa.europa.eu/support/helpdesks>.

Links to Poison Centers and Clinical Toxicologists all over the World: <https://www.eapcct.org/index.php?page=links>.

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture**

The product is an in vitro diagnostic medical device in accordance with Directive 98/79/EC of the European Parliament and of the Council, is in the finished state and intended for the final user.

It therefore does not apply to its Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) according to Article 1, par. 5d).

They need not be classified, labelled or packaged in accordance with this Regulation.

Classification according to Regulation (EC) No 1272/2008

The product is classified as dangerous in the terms of the Regulation (EC) No 1272/2008 (CLP).

Eye Irrit. 2 H319 Causes serious eye irritation.

Repr. 1B H360FD May damage fertility. May damage the unborn child.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008: The product is classified and labelled according to the CLP regulation.

Hazard pictograms:

GHS07

GHS08

Signal word: Danger

Hazard-determining components of labelling:

2-methoxyethanol

Hazard statements:

H319 Causes serious eye irritation.

H360FD May damage fertility. May damage the unborn child.

Precautionary statements:

P201 Obtain special instructions before use.

P280 Wear eye protection/face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container to hazardous or special waste collection point.

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Additional information:

Restricted to professional users.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT:

The mixture does not contain substances classified at the date of preparation of the safety data sheet as PBT according to Regulation (EC) No 1907/2006 (REACH) in a concentration equal to or greater than 0.1 % by weight.

vPvB:

The mixture does not contain substances classified at the date of preparation of the safety data sheet as vPvB according to Regulation (EC) No 1907/2006 (REACH) in a concentration equal to or greater than 0.1 % by weight.

Determination of endocrine-disrupting properties

The mixture does not contain substances that have been identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:		
CAS: 109-86-4 EINECS: 203-713-7 Index number: 603-011-00-4	2-methoxyethanol Flam. Liq. 3, H226 Repr. 1B, H360FD Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332	6.2%
CAS: 151-21-3 EINECS: 205-788-1 Reg.-No: 01-2119489461-32-XXXX	sodium dodecyl sulphate Flam. Sol. 2, H228 Eye Dam. 1, H318 Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; STOT SE 3, H335 Aquatic Chronic 3, H412 Specific concentration limits: Eye Dam. 1; H318: C ≥ 20 % Eye Irrit. 2; H319: 10 % ≤ C < 20 %	3.7%
CAS: 6153-56-6 EC number: 612-167-2 Reg.-No: 01-2119534576-33-XXXX	oxalic acid, dihydrate Eye Dam. 1, H318 Acute Tox. 4, H302; Acute Tox. 4, H312	1.3%
CAS: 6203-18-5 EINECS: 228-267-0	4-dimethylaminocinnamaldehyde Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	0.06%
Non dangerous components:		
CAS: 7732-18-5 EINECS: 231-791-2	water, distilled, conductivity or of similar purity	88.74%
SVHC:		
109-86-4	2-methoxyethanol	

Regulation (EC) No 648/2004 on detergents / Labelling for contents: Not apply.

Additional information:

The substances named in this section are given with their actual, appropriate classification!

For substances that are listed in appendix VI, table 3 of the Regulation (EC) No 1272/2008 (CLP Regulation) this means that all notes that may be given here for the named classification have been taken into account.

For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

In case of doubt, appearance of symptoms or upon any problems, seek medical help and present this safety data sheet or the product label.

Never pour anything into the mouth of an unconscious person!

Personal protection for the First Aider.

Immediately remove any clothing soiled by the product.

After inhalation:

Remove person from danger area.

Take care of fresh air supply and seek medical assistance upon subsequent or lasting problems.

After skin contact:

Wash the affected skin with water and soap and rinse thoroughly. Upon skin irritation or other problems, consult further procedure with an expert physician.

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After eye contact:

Open the eye lids, possibly remove contact lenses, and rinse the affected eyes thoroughly with clean flowing water for a period of several minutes. Seek medical assistance immediately.

After swallowing:

Thoroughly rinse the mouth with water, have the affected person drink plenty of water and do not induce vomiting. Seek medical assistance immediately.

Information for doctor: Symptomatic treatment.

4.2 Most important symptoms and effects, both acute and delayed

Possible toxicological effects resulting from the classification are stated in Section 11.

Upon skin contact:

Skin irritation.

Upon eye contact:

Eye irritation.

There is a certain health risk upon ingestion.

4.3 Indication of any immediate medical attention and special treatment needed

In case of ingestion or affecting of eyes, seek medical help immediately.

For special medical advice, contact the Toxicology Information Centre.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

No extinguishing substances are determined, the mixture is not flammable. Use fire extinguishing methods suitable to surrounding conditions.

For safety reasons unsuitable extinguishing agents: No extinguishing substances are determined, the mixture is not flammable.

5.2 Special hazards arising from the substance or mixture

No danger is known.

5.3 Advice for firefighters

Protective equipment:

No special measures required.

According to size of fire.

Additional information:

Cool with water the products in enclosed packaging, which is near the fire. If possible, remove the products in un-damaged packaging from the danger area. Store the contaminated extinguishing water separately and do not let it into the sewerage. Remove the extinguishing water or used extinguishing materials together with the remnants of the fire according to the corresponding regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:

Ensure adequate ventilation.

Use personal protective equipment.

Avoid contact with eyes and skin.

Avoid inhalation of vapors.

Prevent entry of unauthorized and unprotected persons.

For emergency responders: No relevant information available.

6.2 Environmental precautions

No special measures required.

Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust) and place into suitable and marked vessels.

Possibly wipe the leaked product with a paper towel and place it into a waste vessel.

Thoroughly wash the affected spot and the tools used with a suitable detergent, it is possible to use a larger quantity of water.

Protect health against exposure of contained substances from the atmosphere, see the limit values of exposure, which are stated in Section 8.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Before use, it is necessary to familiarize oneself with the contents of Sections 2, 6, 8, and 11 of the safety data sheet.

Use personal protective equipment.

Avoid contact with eyes and skin.

Avoid inhalation of vapors.

Use working methods according to operating instructions.

General hygiene measures for the handling of chemicals are applicable.

Before a pause and after ending the work, wash the hands and take off the polluted working clothes. Keep these clothes separately.

Remove contaminated clothing and protective equipment before entering areas in which food is consumed.

Do not eat, drink, smoke, or snuff during use.

Women at the fertile age must be warned against possible hazards.

Pregnant women should avoid contact with the product and should not work with it.

Information about fire - and explosion protection:

No special measures required.

Respect general regulations on fire prevention.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and receptacles:

Secure impermeable floors against the liquids.

Store only in unopened original receptacles.

Information about storage in one common storage facility:

Keep away from food, drink and animal feedingstuffs.

Do not store together with strong oxidizing agents, strong acids and strong bases.

Further information about storage conditions:

Store in a dry and well ventilated place.

Keep containers tightly sealed.

Protect from direct sunlight and warming.

Store under lock and key and with access restricted to technical experts or their assistants only.

Recommended storage temperature: +2 °C to +8 °C.

7.3 Specific end use(s)

The product is intended only for professional use.

Specific use is stated in the manual for use on the product packaging label or in the product documentation.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

109-86-4 2-methoxyethanol

IOELV	Long-term value: 1 ppm
	Skin

144-62-7 oxalic acid

IOELV	Long-term value: 1 mg/m ³
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Regulatory information:

IOELV: COMMISSION DIRECTIVE (EU) 2019/1831

Legend: IOELV = indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC.

DNELs:

151-21-3 sodium dodecyl sulphate

Oral	DNEL - Long term exposure, systemic effects	24 mg/kg/d (consumers)
Dermal	DNEL - Long term exposure, systemic effects	2,440 mg/kg/d (consumers) 4,060 mg/kg/d (workers)
Inhalative	DNEL - Long term exposure, systemic effects	85 mg/m ³ (consumers) 285 mg/m ³ (workers)

6153-56-6 oxalic acid, dihydrate

Oral	DNEL - Long term exposure, systemic effects	1.14 mg/kg/d (consumers)
Dermal	DNEL - Long term exposure, systemic effects	1.14 mg/kg/d (consumers) 2.29 mg/kg/d (workers)
	DNEL - Short term exposure, systemic effects	0.35 mg/cm ² (consumers) 0.69 mg/cm ² (workers)

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Inhalative	DNEL - Long term exposure, systemic effects	4.03 mg/m ³ (workers)
PNECs:		
151-21-3 sodium dodecyl sulphate		
PNEC - Freshwater		0.137 mg/l
PNEC - Marine water		0.0137 mg/l
PNEC - Sewage treatment plant		1,084 mg/l
PNEC - Sediment, freshwater		4.82 mg/kg
PNEC - Sediment, marine water		0.482 mg/kg
PNEC - Soil		0.882 mg/kg
PNEC - Water (sporadic release)		0.055 mg/l
6153-56-6 oxalic acid, dihydrate		
PNEC - Freshwater		0.1622 mg/l
PNEC - Marine water		0.016 mg/l
PNEC - Intermittent release		1.622 mg/l
PNEC - Sewage treatment plant		1,550 mg/l

Ingredients with biological limit values:

The product does not contain any relevant quantities of materials with biological limit values.

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Appropriate engineering controls:

Ensure good ventilation. This can be achieved by local suction or general air extraction. If this is insufficient to maintain the concentration under WEL or IOEL values, suitable breathing protection should be worn. Applies only if maximum permissible exposure values are listed here.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Do not eat, drink, smoke or sniff while working.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Avoid contact with the eyes and skin.

Do not inhale gases/fumes/aerosols.

Eye/face protection:



Tightly sealed goggles (EN 166).

Body protection:



As needed, use the working protective clothes with long sleeves, possibly overalls, and protective working footwear.

Hand protection



Protective gloves (EN ISO 374-1).

Preventive skin protection by use of skin-protecting agents is recommended.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Material of gloves:

Butyl rubber, BR (EN ISO 374-1).

Fluorocarbon rubber, Viton (EN ISO 374-1).

Use for example:

For example protective surgical gloves.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

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Penetration time of glove material:

Not determined.

No tests have been performed, glove resistance must be tested before use.

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Respiratory protection:

Unnecessary during regular use.



In case of insufficient ventilation and exceeding of permitted exposure limits use a suitable breathing mask with a filter (EN 14387).

Recommended filter device for short term use: Organic vapour filter (EN 14387+A1).

Thermal hazards: Not applicable.

Environmental exposure controls: Adhere to usual measures for environmental protection, see Section 6.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state:	Fluid.
Colour:	Light yellow.
Odour:	Odourless.
Melting point/freezing point:	Not determined.
Boiling point or initial boiling point and boiling range:	Not determined.
Flammability:	Not applicable.
Lower and upper explosion limit	
Lower:	2.5 Vol % (*)
Upper:	14.0 Vol % (*)
Flash point:	Not applicable.
Auto-ignition temperature:	Product is not selfigniting.
Decomposition temperature:	Not determined.
pH:	Not determined.
Viscosity	
Kinematic viscosity:	Not determined.
Dynamic viscosity:	Not determined.
Solubility	
water:	Miscible.
Partition coefficient n-octanol/water (log value):	-0.77 log POW (*)
Vapour pressure at 20 °C:	11.0 mbar (*)
Density and/or relative density	
Density:	Not determined.
Relative density:	Not determined.
Vapour density:	Not determined.
Relative gas density:	Not determined.

9.2 Other information

Important information on protection of health and environment, and on safety.

Ignition temperature:	Not determined.
Explosive properties:	Product does not present an explosion hazard.
Solvent content	
VOC (2010/75/EC):	Not apply.
Oxidising properties:	No.
Evaporation rate:	Not determined.

Information with regard to physical hazard classes

Explosives:	Void.
Flammable gases:	Void.
Aerosols:	Void.
Oxidising gases:	Void.
Gases under pressure:	Void.
Flammable liquids:	Void.
Flammable solids:	Void.
Self-reactive substances and mixtures:	Void.
Pyrophoric liquids:	Void.
Pyrophoric solids:	Void.

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Self-heating substances and mixtures:	Void.
Substances and mixtures, which emit flammable gases in contact with water:	Void.
Oxidising liquids:	Void.
Oxidising solids:	Void.
Organic peroxides:	Void.
Corrosive to metals:	Void.
Desensitised explosives:	Void.
Additional information:	(*) Value for 2-methoxyethanol.

SECTION 10: Stability and reactivity

10.1 Reactivity Upon adhering to the determined regulations of storage and use, no reactivity is expected (see Section 7).

10.2 Chemical stability Upon adhering to the determined regulations of storage and use, the product is stable (see Section 7).

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid

Prevent contact with incompatible materials.

Protect against strong heating.

10.5 Incompatible materials Inorganic acids, peroxides, strong oxidizing agents, alkali metals.

10.6 Hazardous decomposition products No decomposition when used as directed.

SECTION 11: Toxicological information

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

Acute toxicity: Based on available data, the classification criteria are not met.

Relevant toxicological values for classification:

ATE (Acute Toxicity Estimates)

Oral	LD50	> 6,329 - 18,809 mg/kg
Dermal	ATE	16,596 mg/kg
Inhalative	ATE	33 mg/l/4h

109-86-4 2-methoxyethanol

Oral	LD50	2,370 mg/kg (mouse) the EU classification does not agree
Dermal	LD50	1,280 mg/kg (rabbit)
Inhalative	ATE	11 mg/l/4h (ATE)

151-21-3 sodium dodecyl sulphate

Oral	LD50	> 300 - 2,000 mg/kg (rat)
Dermal	LD50	> 2,000 mg/kg (rat)
Inhalative	ATE	1.5 mg/l/4h (ATE)
	LC50/1 h	3,900 mg/m ³ (rat)

6153-56-6 oxalic acid, dihydrate

Oral	LD50	375 mg/kg (rat) (IUCLID) Anhydrous substance
Dermal	ATE	1,100 mg/kg (ATE)

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation:

Causes serious eye irritation.

Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity:

May damage fertility. May damage the unborn child.

STOT-single exposure: Based on available data, the classification criteria are not met.

STOT-repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Other information: No further information is available.

Additional toxicological information:

Possible risk of impaired fertility.

Women at the fertile age must be warned against possible hazards.

Pregnant women should avoid contact with the product and should not work with it.

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Acute effects: Serious eye irritation, Eye Irrit. category 2.

Sensitisation: Based on available data, the classification criteria are not met.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction): No CMR effects are known.

11.2 Information on other hazards

Endocrine disrupting properties:

None of the ingredients is listed.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

Based on available data, the classification criteria are not met.

109-86-4 2-methoxyethanol

LC50/96 h	15.52 mg/l (fish)
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151-21-3 sodium dodecyl sulphate

LC50/96 h	10 - 100 mg/l (fish)
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EC50/48 h	1 - 10 mg/l (daphnia)
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NOEC/96 h	19.6 mg/l (fish) Oncorhynchus mykiss
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6153-56-6 oxalic acid, dihydrate

LC50/48 h	160 mg/l (fish) (IUCLID)
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Anhydrous substance - Leuciscus idus

EC50/48 h	162.2 mg/l (daphnia) (OECD 202 - Daphnia sp. Acute Immobilisation Test)
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Anhydrous substance

6203-18-5 4-dimethylaminocinnamaldehyde

LC50/96 h	5.9 mg/l (fish)
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Pimephales promelas

12.2 Persistence and degradability

6153-56-6 oxalic acid, dihydrate

Biodegradability, aerobic	89 %/20 d
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the substance is readily biodegradable

Behaviour in waste water treatment plants: No relevant information is available.

12.3 Bioaccumulative potential

109-86-4 2-methoxyethanol

log Pow	-0.77
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bioaccumulation is not expected

151-21-3 sodium dodecyl sulphate

log Pow	1.6
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significant bioaccumulation is not expected

6153-56-6 oxalic acid, dihydrate

log Pow	-1.7 (OECD 107 - Partition Coefficient (n-octanol/water))
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at +23 °C, bioaccumulation is not expected

12.4 Mobility in soil No further relevant information available.

12.5 Results of PBT and vPvB assessment

The product does not contain substances classified as PBT or vPvB and included in the list of substances subject to authorization (Annex XIV of EP and R Regulation No 1907/2006, as amended).

PBT: No relevant information is available.

vPvB: No relevant information is available.

12.6 Endocrine disrupting properties The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

Additional ecological information

AOX-indication: No relevant information is available.

General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation:

Must not be disposed together with household waste. Do not allow product to reach sewage system.
Hand over to hazardous waste disposers.
E.g. put away at suitable waste dumps or remove in suitable waste incineration plants.

European waste catalogue and hazardous properties of waste:	
18 02 05*	chemicals consisting of or containing hazardous substances
15 01 10*	packaging containing residues of or contaminated by hazardous substances
15 01 02	plastic packaging
HP10	Toxic for reproduction

Uncleaned packaging

Recommendation:

Dispose of packaging according to regulations on the disposal of packagings.
Non contaminated packagings may be reused.
Non contaminated packagings may be recycled.
Dispose of packaging that cannot be cleaned in the same manner as the mixture.
Empty container completely. Dispose of hazardous waste pursuant to corresponding local directives in adequate equipment. Put other waste away according to the material type into collection vessels for sorted waste.

Regulations:

Commission Decision No 2014/955/EU of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council.
Commission Regulation (EU) No 1357/2014, replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives.
Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, as amended.

SECTION 14: Transport information

14.1 UN number or ID number ADR, ADN, IMDG, IATA	Void.
14.2 UN proper shipping name ADR, ADN, IMDG, IATA	Void.
14.3 Transport hazard class(es) ADR, ADN, IMDG, IATA Class:	Void.
14.4 Packing group ADR, IMDG, IATA	Void.
14.5 Environmental hazards Marine pollutant:	No.
14.6 Special precautions for user	Persons employed in transporting dangerous goods must be trained. All persons involved in transporting must observe safety regulations. Precautions must be taken to prevent damage.
14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
Transport/Additional information:	Non-dangerous material according to Transport Regulations.
UN "Model Regulation":	Void.

SECTION 15: Regulatory information

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

Named dangerous substances - ANNEX I: None of the ingredients is listed.

REGULATION (EC) No 1907/2006 ANNEX XVII: Conditions of restriction for the group No 3, 30.

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II:
None of the ingredients is listed.

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REGULATION (EU) 2019/1148:

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Information about limitation of use: Employment restrictions concerning women of child-bearing age must be observed.

Other regulations, limitations and prohibitive regulations:

Substances of very high concern (SVHC) according to REACH, Article 57:

109-86-4	2-methoxyethanol
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Legal regulations of the European Community:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended.

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, as amended.

COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC, as amended.

COMMISSION REGULATION (EU) 2016/918 of 19 May 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

COMMISSION REGULATION (EU) 2019/521 of 27 March 2019 amending, for the purposes of its adaptation to technical and scientific progress Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

15.2 Chemical safety assessment A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Warning:

The safety data sheet contains data needed for securing safety and health protection during work and environmental protection. The stated data correspond to the current state of knowledge and experience and is in accordance with valid legal regulations. It cannot be deemed as a guarantee of the properties, suitability, and usefulness of the product for specific application and therefore no contractual legal relationships are hereby created.

The safety data sheet is the property of the physical or legal entity stated in Section 1 and is protected by copy-right. All copying, distribution or sales without the consent of the owner is forbidden.

Relevant phrases:

H226 Flammable liquid and vapour.
H228 Flammable solid.
H302 Harmful if swallowed.
H312 Harmful in contact with skin.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
H360FD May damage fertility. May damage the unborn child.
H412 Harmful to aquatic life with long lasting effects.

Training hints:

Pursuant to article No 35 of the European Parliament and Council Regulation (ES) No 1907/2006, the employer must allow employees or their representatives access to information from the safety data sheet of the substance or preparation, which the employees use or to the effects of which they may be exposed during their work.

Physical entities performed individual activities within the scope of handling of this hazardous product are trained and regularly, at least once a year, retrained.

Product information sources: safety data sheet, product or technical information, safety instructions, and other expert documents for the product, issued by the supplier.

Recommended restriction of use:

The product is to be used only for the purpose, for which it is designed. It is up to the user's responsibility to adhere to the product usage conditions and to respect the safety instructions for health and environmental protection.

The product is designed only for professional purposes. It must not be used in households. The product can only be handled by a person older than 18 years, who is sufficiently informed about the work procedures, hazardous properties of the product, and also about the necessary safety measures.

(Continuation on page 11)

Safety data sheet**according to Regulation (EC) No 1907/2006, Article 31, Annex II
according to Regulation (EU) No 2020/878**Printing date: 25.05.2021
Revision date: 25.05.2021
Version number: 4 (replaces version 3)**Trade name: Reagent PYRstrip**

(Continuation of page 10)

Further information: This product must be stored, sold, and used in accordance with valid hygienic regulations.**Classification according to Regulation (EC) No 1272/2008:**

Serious eye damage/eye irritation	Calculation method
Reproductive toxicity	

Department issuing SDS:

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First issue of SDS: 20.03.2014**Date of previous version:** 02.05.2018**Version number of previous version:** 3**Reasons for alterations:**

Revision of the safety data sheet due to adaptation to the requirements of Commission Regulation (EU) 2020/878 of 18 June 2020 with effect from 1 January 2021.

Revised sections: 1, 2, 3, 4, 6, 7, 8, 9, 11, 12, 13, 15, 16.**Internal code formula:** 810.005**Documents used to prepare SDS:**

The original documents provided by the supplier or manufacturer related to the product (mixture), eventually to individual substances contained.

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids – Category 3

Flam. Sol. 2: Flammable solids – Category 2

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Repr. 1B: Reproductive toxicity – Category 1B

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

Sources:

The safety data sheet was prepared in accordance with the European Parliament and Council Regulation (EC) No 1272/2008 (CLP) and according to the requirements of the European Parliament and Council Regulation (EC) No 1907/2006 about the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency - head IV, article 31, appendix II (instructions for safety data sheet compiling), as amended by the Commission Regulation (EU) No 2020/878 of 18 June 2020.

The missing ecotoxicology and toxicology data was obtained from the ESIS (European chemical Substances Information System), specifically from the IUCLID (International Uniform Chemical Information Database). As needed, data from further available chemical databases was used.

*** Data compared to the previous version altered.**

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