

Safety data sheet

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

Printing date: 26.05.2021
Revision date: 26.05.2021
Version number: 5 (replaces version 4)

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

Trade name: TMB-Complete

Other names: TMB-Complete 1, TMB-Complete 2, TMB-Complete 5

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 not classified as dangerous according to the Regulation (EC) No 1272/2008 (CLP).

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008: Void.

Hazard pictograms: Void.

Signal word: Void.

Hazard-determining components of labelling: Not apply.

Hazard statements: Void.

Precautionary statements: Void.

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.

(Continuation on page 2)

Safety data sheet

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

Printing date: 26.05.2021
Revision date: 26.05.2021
Version number: 5 (replaces version 4)

Trade name: TMB-Complete

(Continuation of page 1)

Dangerous components:		
CAS: 7722-84-1 EINECS: 231-765-0 Index number: 008-003-00-9 Reg.-No: 01-2119485845-22-XXXX	hydrogen peroxide Ox. Liq. 1, H271 Skin Corr. 1A, H314; Eye Dam. 1, H318 Acute Tox. 4, H302; Acute Tox. 4, H332; STOT SE 3, H335 Aquatic Chronic 3, H412 Specific concentration limits: Ox. Liq. 1; H271: C ≥ 70 % Ox. Liq. 2; H272: 50 % ≤ C < 70 % Skin Corr. 1A; H314: C ≥ 70 % Skin Corr. 1B; H314: 50 % ≤ C < 70 % Skin Irrit. 2; H315: 35 % ≤ C < 50 % Eye Dam. 1; H318: C ≥ 8 % Eye Irrit. 2; H319: 5 % ≤ C < 8 % STOT SE 3; C ≥ 35 % Aquatic Chronic 3; H412: C ≥ 63 % Note B	< 0.05%
Non dangerous components:		
CAS: 7732-18-5 EINECS: 231-791-2	water, distilled, conductivity or of similar purity	> 95.0%
CAS: 54827-17-7 EINECS: 259-364-6	3,3',5,5'-tetramethylbenzidine	< 0.06%

Notes:

Note B:

Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations.

In Part 3 entries with Note B have a general designation of the following type: 'nitric acid .. %'.

In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

SVHC:

The product does not contain substances classified as of the date of preparation of the safety data sheet as PBT or vPvB and stated in the Candidate list of substances producing very high concerns for Appendix XIV of Regulation (EC) No 1907/2006 (REACH).

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:

No special measures required.

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

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.

After eye contact:

Open the eye lids, possibly remove contact lenses, and rinse the affected eyes thoroughly with clean flowing water. Upon skin irritation or other problems, consult further procedure with an expert physician.

After swallowing:

Thoroughly rinse the mouth with water and do not cause vomiting. Put the affected person in warm and calm conditions. In case of appearance of symptoms or upon any problems, consult further procedure with a physician.

Provide a physician product safety data sheet.

4.2 Most important symptoms and effects, both acute and delayed

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

No further relevant information is available.

4.3 Indication of any immediate medical attention and special treatment needed

Show this safety data sheet to the physician or health professional.

(Continuation on page 3)

Safety data sheet

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

Printing date: 26.05.2021
Revision date: 26.05.2021
Version number: 5 (replaces version 4)

Trade name: TMB-Complete

(Continuation of page 2)

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.

5.2 Special hazards arising from the substance or mixture No special dangers are determined.

5.3 Advice for firefighters

Protective equipment:

No special measures required.

According to size of fire.

Additional information: No relevant information is available.

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.

Prevent the possibility of slipping on the spilled product.

Prevent entry of unauthorised persons.

For emergency responders: No relevant information available.

6.2 Environmental precautions 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.

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.

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.

Prevent contact of the product with the skin and eyes, use personal protective means.

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.

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.

Vessels already open must be reclosed carefully and stored in the upright position in order to prevent leakage of the contents.

Information about storage in one common storage facility: Keep away from food, drink and animal feedingstuffs.

Further information about storage conditions:

Store in a dry and well ventilated place.

Keep containers tightly sealed.

Protect from exposure to the light.

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

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

(Continuation on page 4)

Safety data sheet

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

Printing date: 26.05.2021
Revision date: 26.05.2021
Version number: 5 (replaces version 4)

Trade name: TMB-Complete

(Continuation of page 3)

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:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

DNELs:

7722-84-1 hydrogen peroxide

Inhalative	DNEL - Long term exposure, systemic effects	0.21 mg/m ³ (consumers) hydrogen peroxide, solution 1.4 mg/m ³ (workers) hydrogen peroxide, solution
	DNEL - Short term exposure, systemic effects	1.93 mg/m ³ (consumers) hydrogen peroxide, solution 3 mg/m ³ (workers) hydrogen peroxide, solution

PNECs:

7722-84-1 hydrogen peroxide

PNEC - Freshwater	0.0126 mg/l hydrogen peroxide, solution
PNEC - Marine water	0.0126 mg/l hydrogen peroxide, solution
PNEC - Sewage treatment plant	4.66 mg/l hydrogen peroxide, solution
PNEC - Sediment, freshwater	0.47 mg/kg hydrogen peroxide, solution
PNEC - Sediment, marine water	0.47 mg/kg hydrogen peroxide, solution
PNEC - Soil	0.0023 mg/kg hydrogen peroxide, solution

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.

Avoid contact with the eyes and skin.

Eye/face protection:



In case of danger of contact with eyes, use tightly adhering protective goggles (EN 166).

Body protection:



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

(Continuation on page 5)

Safety data sheet

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

Printing date: 26.05.2021
Revision date: 26.05.2021
Version number: 5 (replaces version 4)

Trade name: TMB-Complete

(Continuation of page 4)

Hand protection



Protective gloves (EN ISO 374-1).

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
Preventive skin protection by use of skin-protecting agents is recommended.

Material of gloves:

Not determined.

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.

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.

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:	Colourless to pale blue.
Odour:	Odourless.
Melting point/freezing point:	Not determined.
Boiling point or initial boiling point and boiling range:	~ 100 °C
Flammability:	Not applicable.
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Auto-ignition temperature:	Product is not selfigniting.
Decomposition temperature:	Not determined.
pH:	3.0 - 6.5
Viscosity	
Kinematic viscosity:	Not determined.
Dynamic viscosity:	Not determined.
Solubility	
water:	Unlimited miscible.
Partition coefficient n-octanol/water (log value):	Not determined.
Vapour pressure:	Not determined.
Density and/or relative density	
Density:	1.01 g/cm ³
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 applicable.
Explosive properties:	Product does not present an explosion hazard.
Solvent content	
VOC (2010/75/EC):	Not apply.
Oxidising properties:	Not determined.
Evaporation rate:	Not determined.

Information with regard to physical hazard classes

Explosives:	Void.
Flammable gases:	Void.
Aerosols:	Void.
Oxidising gases:	Void.

(Continuation on page 6)

Safety data sheet

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

Printing date: 26.05.2021
Revision date: 26.05.2021
Version number: 5 (replaces version 4)

Trade name: TMB-Complete

(Continuation of page 5)

Gases under pressure:	Void.
Flammable liquids:	Void.
Flammable solids:	Void.
Self-reactive substances and mixtures:	Void.
Pyrophoric liquids:	Void.
Pyrophoric solids:	Void.
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:	No relevant information available.

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 Upon regular manner of use and storage, no hazardous reactions are created.

10.4 Conditions to avoid

Permanent temperature above +8 °C.

Permanent access light.

10.5 Incompatible materials No substances and materials are specified.

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:

7722-84-1 hydrogen peroxide

Oral	LD50	> 1,026 mg/kg (rat)
Dermal	LD50	> 2,000 mg/kg (rabbit)
Inhalative	ATE	11 mg/l/4h (ATE)
	LC50/4 h	0.17 mg/l (rat) (OECD 403 - Acute Inhalation Toxicity) 50% concentration
	LC50/30 min	> 170 mg/m ³ (rat)

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

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

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

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.

Additional toxicological information: No relevant information is available.

Acute effects: No acute effects are known.

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.

Other information: No further information is available.

(Continuation on page 7)

Safety data sheet

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

Printing date: 26.05.2021
Revision date: 26.05.2021
Version number: 5 (replaces version 4)

Trade name: TMB-Complete

(Continuation of page 6)

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

No further relevant information available.

7722-84-1 hydrogen peroxide	
LC50/24 h	16.4 mg/l (fish) Pimephales promelas, 100% concentration
EC50/48 h	2.4 mg/l (invertebrates) Daphnia pulex, 100% concentration
EC50	466 mg/l (bacteria)
EC50/30 min	466 mg/l (bacteria) Activated sludge
NOEC/72 h	0.63 mg/l (algae) Reproduction, Skeletonema costatum
NOEC/21 d	0.63 mg/l (invertebrates) Daphnia magna
NOEC	0.63 mg/l (algae)

12.2 Persistence and degradability No further relevant information available.

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

12.3 Bioaccumulative potential Bioaccumulation is not expected.

12.4 Mobility in soil

7722-84-1 hydrogen peroxide	
Henry's constant H	0.00075 Pa*m ³ /mol

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: Generally not hazardous for water.

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.

Remove product residues according to the corresponding local directives as other waste.

E.g. put away at suitable waste dumps or remove in suitable waste incineration plants.

Waste disposal key:

The catalogue numbers with the asterisk (*) mark hazardous waste (N), numbers without the asterisk mark other waste (O).

The waste codes are recommendations based on the scheduled use of this product. Owing to the user's specific conditions for use and disposal, other waste codes may be allocated under certain circumstances. (2001/118/EC, 2001/119/EC, 2001/573/EC, 2014/955/EU).

European waste catalogue and hazardous properties of waste:	
18 02 06	chemicals other than those mentioned in 18 02 05
15 01 02	plastic packaging

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.

(Continuation on page 8)

Safety data sheet

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

Printing date: 26.05.2021
Revision date: 26.05.2021
Version number: 5 (replaces version 4)

Trade name: TMB-Complete

(Continuation of page 7)

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	Unless specified otherwise, general measures for safe transport must be followed.
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.

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.

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.

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.

(Continuation on page 9)

Safety data sheet

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

Printing date: 26.05.2021
Revision date: 26.05.2021
Version number: 5 (replaces version 4)

Trade name: TMB-Complete

(Continuation of page 8)

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 copyright. All copying, distribution or sales without the consent of the owner is forbidden.

Relevant phrases:

H271 May cause fire or explosion; strong oxidiser.

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

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.

Further information: This product must be stored, sold, and used in accordance with valid hygienic regulations.

Classification according to Regulation (EC) No 1272/2008:

Classification of the mixture according to the methods given in Annex I to Regulation (EC) No 1272/2008 (CLP): void.

Department issuing SDS:

Ing. Karel Královec, Studio2K

Phone: +420 777 145 808, E-mail: info@studio2k.cz, Websites: www.studio2k.cz / www.bezpecnostni-listy.eu

First issue of SDS: 20.07.2014

Date of previous version: 08.05.2018

Version number of previous version: 4

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: 810.011

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

Ox. Liq. 1: Oxidizing liquids – Category 1

Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

(Continuation on page 10)

Safety data sheet

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

Printing date: 26.05.2021

Revision date: 26.05.2021

Version number: 5 (replaces version 4)

Trade name: TMB-Complete

(Continuation of page 9)

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

© Studio2K & DR SoftWare ChemGes, 2021 (EU)
