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: 4 (replaces version 3)

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

1.1 Product identifier

Trade name: Ammonium oxalate solution
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:
EUH210 Safety data sheet available on request.
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.

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Dangerous components:		
CAS: 6009-70-7 EINECS: 238-135-4 Index number: 607-007-00-3	ammonium oxalate monohydrate Acute Tox. 4, H302; Acute Tox. 4, H312	1.0%

Non dangerous components:		
CAS: 7732-18-5 EINECS: 231-791-2	water, distilled, conductivity or of similar purity	99.0%

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. Seek medical assistance immediately.

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
In case of ingestion 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.

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.

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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 handing 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.
Store under lock and key and with access restricted to technical experts or their assistants only.
Recommended storage temperature: Store at temperatures below +25 °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:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

DNELs: No values available.

PNECs: No values available.

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 worm. 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.

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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.

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.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information	
Physical state:	Fluid.
Colour:	Colourless.
Odour:	Odourless.
Melting point/freezing point:	cca 0 °C
Boiling point or initial boiling point and boiling range:	cca 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:	Not determined.
Viscosity	
Kinematic viscosity:	Not determined.
Dynamic viscosity:	Not determined.
Solubility	
water:	Miscible.
Partition coefficient n-octanol/water (log value):	Not determined.
Vapour pressure:	Not determined.
Density and/or relative density	
Density at 20 °C:	cca 1.0 g/cm³
Vapour density:	Not determined.

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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.
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 No conditions are known.
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:		
ATE (Acute Toxicity Estimates)		
Oral	LD50	50,000 mg/kg
Dermal	ATE	110,000 mg/kg

6009-70-7 ammonium oxalate monohydrate		
Oral	LD50	500 mg/kg (ATE)
Dermal	ATE	1,100 mg/kg (ATE)

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.

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Acute effects: No acute effects are known.

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

CMR effects (carcinogenity, 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.

* SECTION 12: Ecological information

12.1 Toxicity
Aquatic toxicity: Based on available data, the classification criteria are not met.

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 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: 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.

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.

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Trade name: Ammonium oxalate solution

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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.

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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.

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SECTION 16: Other information

Warning:
The safety data sheet contains data needed for securing safety and health protection during work and environ-mental protection. The stated data correspond to the current state of knowledge and experience and is in accord-ance 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.

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Relevant phrases:
H302 Harmful if swallowed.
H312 Harmful in contact with skin.

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 ex-pert 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 ad-here 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:
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First issue of SDS: 20.04.2014
Date of previous version: 07.05.2018
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, 4, 6, 7, 8, 9, 11, 12, 13, 15, 16.
Internal code formula: 810.009

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
Acute Tox. 4: Acute toxicity – Category 4

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.**