Hazard Statement Under the EC Regulations REACH and CLP

We, **TestLine Clinical Diagnostics s.r.o.** (manufacturer),

Křižíkova 188/68, 612 00 Brno, Czech Republic,

hereby declare that the products listed below contain components that include chemical substances classified as hazardous under Regulation (EC) No 1272/2008 (CLP). Safety Data Sheets (SDS) for the components of the products listed below that contain chemical substances classified as hazardous are prepared in accordance with the requirements of Regulation (EC) No 1907/2006, Article 31, Annex II, as amended by Regulation (EU) 2020/878, and are available below or on the manufacturer's website.

Products containing chemical substances classified as hazardous:

Cat. number	Product name	Product components containing chemical substances classified as hazardous:
AIGAMA48	Microblot-Array Autoimmune gastroenteritis panel IgA	Positive Control (ProClin 300), Universal Solution (ProClin 300), Substrate solution (maleic acid)
AIGGMA48	Microblot-Array Autoimmune gastroenteritis panel IgG	Positive Control (ProClin 300), Universal Solution (ProClin 300), Substrate solution (maleic acid)

All remaining components of the listed products have been assessed concerning their hazardous properties and potential content of hazardous chemical substances, and based on the outcome of this assessment, these components are not classified as hazardous.

For more information, please visit our website at https://www.testlinecd.com or contact us at regulatory@testlinecd.com.

Revision Date: 18.11.2026

Safety data sheet

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

Printing date: 30.04.2025
Revision date: 30.04.2025
Version number: 1

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

1.1 Product identifier

Trade name: **Solution containing ProClin 300 <0.1%**
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: Laboratory reagent for professional 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 188/68, 612 00 Brno, Czech Republic
Company Identification Number: 479 13 240, VAT ID: CZ47913240
Phone/Fax: +420 549 121 256
E-mail: pozgayova@testlinecd.com
Website: www.testlinecd.com

Further information obtainable from:
Ing. Karel Královec, Studio2K, Czech Republic
Phone: +420 777 145 808, Email: bl@studio2k.cz, Website: www.bezpecnostni-listy.eu

1.4 Emergency telephone number

European Chemicals Agency. 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

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).

Skin Sens. 1 H317 May cause an allergic skin reaction.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

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

Signal word: Warning

Hazard-determining components of labelling:
Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)
Hazard statements:
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.
Precautionary statements:
P261 Avoid breathing mist/vapours/spray.
P280 Wear protective gloves.
P302+P352 IF ON SKIN: Wash with plenty of water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

Additional information:
Restricted to professional users.

Classification system: The product is intended for professional use only and this corresponds to its labeling on the packaging.

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.

(Continuation on page 2)

(Continuation of page 1)

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: 55965-84-9 EC: 611-341-5 INDEX: 613-167-00-5	Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1) Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330 Skin Corr. 1C, H314; Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=100); Aquatic Chronic 1, H410 (M=100) Skin Sens. 1A, H317 EUH071 Specific concentration limits: Skin Corr. 1C; H314: C ≥ 0.6 % Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 % Eye Dam. 1; H318: C ≥ 0.6 % Eye Irrit. 2; H319: 0.06 % ≤ C < 0.6 % Skin Sens. 1A; H317: C ≥ 0.0015 % Note B	< 0.005%

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:
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 plenty of water. 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.
Information for doctor: Symptomatic treatment.

(Continuation on page 3)

(Continuation of page 2)

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 unsuitable extinguishing materials are known.

5.2 Special hazards arising from the substance or mixture
No special dangers are determined.
Hazardous combustion products: Dangerous decomposition is not anticipated.

5.3 Advice for firefighters
Protective equipment:
No special measures required.
According to size of fire.
Corresponding protective insulation breathing apparatus and overpressure counter-chemical protective clothing.
Additional information: No relevant information is available.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Respect the instructions set forth in Sections 7 and 8 of the safety data sheet.
For non-emergency personnel:
In case of spillage or accidental release, wear personal protective equipment as specified in section 8 to prevent contamination.
Leave the danger zone if possible, use existing emergency plans if necessary.
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: See section 8 for suitable protective equipment and material specification.

6.2 Environmental precautions
The product is classified as dangerous for the environment.
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 section 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
In addition to the information provided in this section, important information is also provided in Sections 6 and 8.
Information about fire - and explosion protection:
No special measures required.
Respect general regulations on fire prevention.
Handling:
Before use, it is necessary to familiarize oneself with the contents of Sections 2, 6, 8, and 11 of the safety data sheet.
Ensure good ventilation.
Prevent formation of aerosols.
Use personal protective equipment.
Avoid contact with eyes and skin.

(Continuation on page 4)

(Continuation of page 3)

Use working methods according to operating instructions.
Observe directions on label and instructions for use.
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.

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: Store away from foodstuffs.
Further information about storage conditions:
Store in a well ventilated place.
Store in a dry and cool place.
Keep containers tightly sealed.
Protect from exposure to the light.
Protect from frost.
Protect containers from physical damage.
Store under lock and key and with access restricted to technical experts or their assistants only.
Keep out of reach of children.
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:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

DNELs:		
55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)		
Oral	DNEL - Long term exposure, systemic effects	0.09 mg/kg/d (consumers)
	DNEL - Short term exposure, systemic effects	0.11 mg/kg/d (consumers)
Inhalative	DNEL - Long term exposure, local effects	0.02 mg/m3 (consumers)
		0.02 mg/m3 (workers)
	DNEL - Short term exposure, local effects	0.04 mg/m3 (consumers)
		0.04 mg/m3 (workers)

PNECs:	
55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)	
PNEC - Freshwater	0.00339 mg/l
PNEC - Marine water	0.00339 mg/l
PNEC - Sewage treatment plant	0.23 mg/l
PNEC - Sediment, freshwater	0.027 mg/kg
PNEC - Sediment, marine water	0.027 mg/kg
PNEC - Soil	0.01 mg/kg
PNEC - Water (sporadic release)	0.00339 mg/l

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

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.
Immediately remove all soiled and contaminated clothing.

(Continuation on page 5)

(Continuation of page 4)

Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.

Eye/face protection:
Not required during regular use.



Alternatively, use closed safety glasses (EN 166).

Body protection:



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

When handling laboratory scale quantities, a lab coat is recommended.

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.
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Preventive skin protection by use of skin-protecting agents is recommended.
Material of gloves:
Nitrile rubber gloves (EN ISO 374-1).
Recommended thickness of the material: ≥ 0.11 mm.
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.
Glove material selection was performed based on the glove producers' data and information on substances contained in the product.
Penetration time of glove material:
≥ 480 minutes (EN 16523-1).
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 forming of vapours or aerosol, use a suitable breathing mask with a filter (EN 14387+A1).

Observe wearing time limitations for respiratory protection equipment.
Recommended filter device for short term use: Filter ABEK (EN 14387+A1), code colors: brown, gray, yellow, green stripe.

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:	Liquid.
Colour:	Not determined.
Odour:	Not determined.
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:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Auto-ignition temperature:	Not applicable.
Decomposition temperature:	Not determined.

(Continuation on page 6)

(Continuation of page 5)

pH:	Not determined.
Viscosity	
Kinematic viscosity:	Not determined.
Dynamic viscosity:	Not determined.
Solubility	
water:	Not determined.
Partition coefficient n-octanol/water (log value):	Not determined.
Vapour pressure:	Not determined.
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:	Not determined.
Evaporation rate:	Not determined.
Relative 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 No dangerous reactions known.
10.4 Conditions to avoid
Prevent contact with incompatible materials.
Protect against high temperatures.
Protect against frost.
10.5 Incompatible materials
Strong oxidizing and reducing agents.
Amines.
Mercaptans.
10.6 Hazardous decomposition products No hazardous decomposition products are known.

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.

(Continuation on page 7)

(Continuation of page 6)

Relevant toxicological values for classification:		
55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)		
Oral	LD50	53 mg/kg (rat)
Dermal	LD50	87 mg/kg (rabbit)
Inhalative	LC50/4 h	0.33 mg/l (rat)

Primary irritant effect

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: May cause an allergic skin reaction.

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.

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 other relevant information available on adverse effects on health.

SECTION 12: Ecological information

12.1 Toxicity
Aquatic toxicity:
Hazardous to the aquatic environment - Aquatic Chronic 3.

55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)	
LC50/96 h	0.19 mg/l (fish) Oncorhynchus mykiss
EC50/48 h	0.16 mg/l (daphnia) Daphnia magna
EC50/72 h	> 0.037 mg/l (algae) Pseudokerchneriella subcapitata
EC50/16 h	5.7 mg/l (bacteria) Pseudomonas putida

12.2 Persistence and degradability
Ingredients are not expected to be resistant to biodegradation.

55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)	
Biodegradability in water	< 50 %/10 d the substance is not readily biodegradable

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

12.3 Bioaccumulative potential	
55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)	
log Pow	0.401 measured value, bioaccumulation is not expected

Bioconcentration factor (BCF):	
55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)	
BCF	3.6 calculated value

(Continuation on page 8)

(Continuation of page 7)

12.4 Mobility in soil	
55965-84-9 Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)	
log Koc	28 estimated value

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 No information available on other adverse effects on the environment.
Remark: Harmful to fish.

Additional ecological information

AOX-indication: No relevant information is available.

General notes:
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Harmful to aquatic organisms.

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 in the adequate equipment as hazardous 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 01 06*	chemicals consisting of or containing hazardous substances
15 01 10*	packaging containing residues of or contaminated by hazardous substances
15 01 02	plastic packaging
HP14	Ecotoxic

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.
Hand over possible empty packaging to an authorised organisation, which is entitled to their disposal.
Recommended cleansing agents: Water, if necessary together with cleansing agents.

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.

(Continuation on page 9)

(Continuation of page 8)

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

Directive 2004/42/EC of the European Parliament and the Council: Does not apply.
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.

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.

Regulation (EC) No 273/2004 on drug precursors:
None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug 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) 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:
2016/918 (8. ATP from 1.2.2018), 2016/1179 (9. ATP from 1.3.2018), 2017/776 (10. ATP from 1.12.2018), 2018/669 (11. ATP from 1.12.2019), 2019/521 (12. ATP from 17.10.2020), 2018/1480 (13. ATP from 1.5.2020).
COMMISSION DELEGATED REGULATION (EU) 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:
2020/217 (14. ATP from 1.10.2021), 2020/1182 (15. ATP from 1.3.2022), 2021/643 (16. ATP from 10.5.2021), 2021/849 (17. ATP from 17.12.2022), 2022/692 (18. ATP from 1.12.2023), 2023/1434 (19. ATP from 1.8.2023).

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

(Continuation on page 10)

(Continuation of page 9)

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.
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:
H301 Toxic if swallowed.
H310 Fatal in contact with skin.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H330 Fatal if inhaled.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
EUH071 Corrosive to the respiratory tract.

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 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.
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.

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

Classification according to Regulation (EC) No 1272/2008:	
Skin sensitisation Hazardous to the aquatic environment - long-term (chronic) aquatic hazard	Calculation method

Department issuing SDS:
Ing. Karel Královec, Studio2K, Czech Republic
Phone: +420 777 145 808, Email: info@studio2k.cz, Website: www.studio2k.cz / www.bezpecnostni-listy.eu

First issue of SDS: 30.04.2025
Internal code formula: 810.019

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. 3: Acute toxicity – Category 3
Acute Tox. 2: Acute toxicity – Category 2
Skin Corr. 1C: Skin corrosion/irritation – Category 1C

(Continuation on page 11)

(Continuation of page 10)

Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1A: Skin sensitisation – Category 1A
Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

Information on data sources used in compiling the safety data sheet:
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.

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End of safety data sheet!

Safety data sheet

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

Printing date: 16.08.2026
Revision date: 16.08.2026
Version number: 1

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

1.1 Product identifier

Trade name: **Substrate solution MBA**
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 188/68, 612 00 Brno, Czech Republic
Company Identification Number: 479 13 240, VAT ID: CZ47913240
Phone/Fax: +420 549 121 256
E-mail: pozgayova@testlinecd.com
Website: www.testlinecd.com

Further information obtainable from:
Ing. Karel Královec, Studio2K, Czech Republic
Phone: +420 777 145 808, Email: bl@studio2k.cz, Website: www.bezpecnostni-listy.eu

1.4 Emergency telephone number

European Chemicals Agency (ECHA). National helpdesks contact details: https://echa.europa.eu/support/helpdesks
Link to the European Association of Poison Centres and Clinical Toxicologists (EAPCCT): https://eapcct.org/poison-centres/
List of European Poison Centers: https://eapcct.org/tabella/

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The product is an in vitro diagnostic medical device in accordance with Regulation (EU) 2017/746 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).

Skin Sens. 1 H317 May cause an allergic skin reaction.

Additional information: The full text of the classification and labelling elements mentioned is given in Section 16.

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

Signal word: Warning

Hazard-determining components of labelling:
Maleic acid
Hazard statements:
H317 May cause an allergic skin reaction.
Precautionary statements:
P261 Avoid breathing mist/vapours/spray.
P280 Wear protective gloves.
P302+P352 IF ON SKIN: Wash with plenty of water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents/container to hazardous or special waste collection point.

Additional information:
Restricted to professional users.

Classification system: The product is intended for professional use only and this corresponds to its labeling on the packaging.

(Continuation on page 2)

(Continuation of page 1)

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: 124-68-5 EINECS: 204-709-8 INDEX: 603-070-00-6 REACH: 01-2119475788-16-XXXX	2-Amino-2-methyl-1propanol Skin Irrit. 2, H315; Eye Irrit. 2, H319 Aquatic Chronic 3, H412	≤ 1%
CAS: 110-16-7 EINECS: 203-742-5 INDEX: 607-095-00-3	Maleic acid Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335 Specific concentration limit: Skin Sens. 1; H317: C ≥ 0.1 %	≤ 0.4%

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:
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 plenty of water. Upon skin irritation or other problems, consult further procedure with an expert physician.
After eye contact:
Open the eyelids, possibly remove the contact lenses, and thoroughly rinse the affected eyes with clean flowing water for about 15 minutes. Upon persisting eye irritation or other troubles, consult further procedure with an ophthalmologist.
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.
Provide a physician product safety data sheet.
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.
In case of prolonged inhalation:
Respiratory tract irritation.
After skin contact:
Allergic reaction possible.
In case of eye contact:

(Continuation on page 3)

(Continuation of page 2)

Mild eye irritation.
Upon ingestion:
May cause adverse effects.

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:
Water spray, carbon dioxide (CO_2), extinguishing powder, extinguishing foam. Use fire extinguishing methods suitable to surrounding conditions.
For safety reasons unsuitable extinguishing agents: Water with full jet.

5.2 Special hazards arising from the substance or mixture
Formation of irritating, toxic and harmful fumes of burning is possible in case of fire.
In case of fire, the following may be released:
Carbon monoxide (CO) a carbon dioxide (CO_2).
Nitrogen oxides (NO_x).
Sulphur oxides (SO_x).
Inhalation of hazardous decomposition products of burning may result in damaged health.

5.3 Advice for firefighters
Protective equipment:
Do not inhale explosion gases or combustion gases.
According to size of fire.
Corresponding protective insulation breathing apparatus and overpressure counter-chemical protective clothing.
Additional information: No relevant information is available.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Respect the instructions set forth in Sections 7 and 8 of the safety data sheet.
For non-emergency personnel:
In case of spillage or accidental release, wear personal protective equipment as specified in section 8 to prevent contamination.
Leave the danger zone if possible, use existing emergency plans if necessary.
Ensure adequate ventilation.
Use personal protective equipment.
Avoid contact with eyes and skin.
Prevent the possibility of slipping on the spilled product.
Prevent the entry of unauthorised persons, ban smoking.
For emergency responders: No relevant information available.

6.2 Environmental precautions
Do not allow to enter sewers/surface or ground water.
The product is not classified as dangerous for the environment.

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 section 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
In addition to the information provided in this section, important information is also provided in Sections 6 and 8.
Information about fire - and explosion protection:
No special measures required.
Respect general regulations on fire prevention.
Handling:
Before use, it is necessary to familiarize oneself with the contents of Sections 2, 6, 8, and 11 of the safety data sheet.
Ensure good ventilation.
Prevent formation of aerosols.

(Continuation on page 4)

(Continuation of page 3)

Use personal protective equipment.
Avoid contact with eyes and skin.
Use working methods according to operating instructions.
Observe directions on label and instructions for use.
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.

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:
Store away from foodstuffs.
Do not store together with incompatible materials, see subsection 10.5.
Further information about storage conditions:
Store in a well ventilated place.
Store in a dry and cool place.
Keep containers tightly sealed.
Protect from exposure to the light.
Protect from frost.
Protect containers from physical damage.
Store under lock and key and with access restricted to technical experts or their assistants only.
Keep out of reach of children.
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:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

DNELs:		
124-68-5 2-Amino-2-methyl-1propanol		
Dermal	DNEL - Long term exposure, systemic effects	7.3 mg/kg/d (workers)
Inhalative	DNEL - Long term exposure, systemic effects	6.5 mg/m3 (workers)

PNECs:	
124-68-5 2-Amino-2-methyl-1propanol	
PNEC - Freshwater	0.188 mg/l
PNEC - Marine water	0.0188 mg/l
PNEC - Intermittent release	1.88 mg/l
PNEC - Sewage treatment plant	10 mg/l
PNEC - Sediment, freshwater	0.00071 mg/kg
PNEC - Sediment, marine water	0.000071 mg/kg
PNEC - Soil	0.03 mg/kg

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.
Immediately remove all soiled and contaminated clothing.

(Continuation on page 5)

(Continuation of page 4)

Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.

Eye/face protection:
Not required during regular use.



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.

When handling laboratory scale quantities, a lab coat is recommended.

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.
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
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.
Recommended filter device for short term use: Not determined.

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:	Liquid.
Colour:	Clear, light yellow.
Odour:	Weak, characteristic
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:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Auto-ignition temperature:	Not applicable.
Decomposition temperature:	Not determined.
pH:	9.5 - 9.8 (+/- 0,5)
Viscosity	
Kinematic viscosity:	Not determined.
Dynamic viscosity:	Not determined.
Solubility	
water:	Not determined.
Partition coefficient n-octanol/water (log value):	Not determined.
Vapour pressure:	Not determined.

(Continuation on page 6)

(Continuation of page 5)

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:	Not determined.
Evaporation rate:	Not determined.
Relative 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 Hazardous polymerization will not occur.
10.4 Conditions to avoid
Prevent contact with incompatible materials.
Protect against extreme temperature and direct sunlight.
Protect against frost.
Contact with metals or metal surfaces may cause purple color formation.
10.5 Incompatible materials Strong acids, strong alkalis, strong oxidizing agents.
10.6 Hazardous decomposition products
No decomposition when used as directed.
At high temperatures, hazardous decomposition products may be created (see Subsection 5.2).

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:		
124-68-5 2-Amino-2-methyl-1propanol		
Oral	LD50	2,900 mg/kg (rat)
Dermal	LD50	> 2,000 mg/kg (rabbit)
110-16-7 Maleic acid		
Oral	LD50	708 mg/kg (rat)
Dermal	LD50	1,560 mg/kg (rabbit)
Inhalative	LC50	> 720 mg/m3 (rat)

Primary irritant effect

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

(Continuation on page 7)

(Continuation of page 6)

Serious eye damage/irritation: Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation: May cause an allergic skin reaction.

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.

Other information: No further information is available.

Additional toxicological information: No relevant information is available.

Acute effects: No acute effects are known.

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 other relevant information available on adverse effects on health.

SECTION 12: Ecological information

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

124-68-5 2-Amino-2-methyl-1propanol	
LC50/96 h	190 mg/l (fish) Lepomis macrochirus
EC50/48 h	193 mg/l (daphnia) Daphnia magna
110-16-7 Maleic acid	
LC50/96 h	5 mg/l (fish) Pimephales promelas
EC50/48 h	250 - 400 mg/l (daphnia) Daphnia magna

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
No relevant information available.

110-16-7 Maleic acid	
log Pow	-0.79 - 0.32 bioaccumulation is not expected

Bioconcentration factor (BCF):
No relevant information is available.

124-68-5 2-Amino-2-methyl-1propanol	
BCF	< 1 (fish)
110-16-7 Maleic acid	
BCF	10 (fish)

12.4 Mobility in soil No 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 C 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 No information available on other adverse effects on the environment.

(Continuation on page 8)

(Continuation of page 7)

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 in the adequate equipment as hazardous 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 01 06*	chemicals consisting of or containing hazardous substances
15 01 10*	packaging containing residues of or contaminated by hazardous substances
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.
Hand over possible empty packaging to an authorised organisation, which is entitled to their disposal.

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

Directive 2004/42/EC of the European Parliament and the Council: Does not apply.
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.

(Continuation on page 9)

(Continuation of page 8)

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.

Regulation (EC) No 273/2004 on drug precursors:
None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug 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) 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:
2016/918 (8. ATP from 1.2.2018), 2016/1179 (9. ATP from 1.3.2018), 2017/776 (10. ATP from 1.12.2018), 2018/669 (11. ATP from 1.12.2019), 2019/521 (12. ATP from 17.10.2020), 2018/1480 (13. ATP from 1.5.2020).
COMMISSION DELEGATED REGULATION (EU) 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:
2020/217 (14. ATP from 1.10.2021), 2020/1182 (15. ATP from 1.3.2022), 2021/643 (16. ATP from 10.5.2021), 2021/849 (17. ATP from 17.12.2022), 2022/692 (18. ATP from 1.12.2023), 2023/1434 (19. ATP from 1.8.2023), 2023/1435 (20. ATP from 1.2.2025), 2024/197 (21. ATP from 1.9.2025), 2024/2564 (22. ATP from 1.5.2026).

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 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.
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:
H302 Harmful if swallowed.
H312 Harmful in contact with skin.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
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 ex-pert documents for the product, issued by the supplier.

(Continuation on page 10)

(Continuation of page 9)

Recommended restriction of use:
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.
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.

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

Classification according to Regulation (EC) No 1272/2008:	
Skin sensitisation	Calculation method

Department issuing SDS:
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First issue of SDS: 16.08.2026
Internal code formula: 810.022

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
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – 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

Information on data sources used in compiling the safety data sheet:
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.

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End of safety data sheet!