

BioVendor – Laboratorní medicína a.s. Karásek 1767/1, 621 00 Brno, Czech Republic +420 549 124 185

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SAFETY INFORMATION

Product name: HUMAN Galectin-3 ELISA

Catalogue number: RAF015R

Characteristics: The human Galectin-3 ELISA is an enzyme-linked immunosorbent assay for the

quantitative detection of human Galectin-3.

Intended use: For professional use only. Users should have a thorough understanding of the IFU

prior to their use of this kit.

Manufacturer: BioVendor – Laboratorní medicína a.s.

Registered office: Karásek 1767/1, 621 00 Brno, Czech Republic

Company ID: 63471507

Kit Components	Contents hazardous substance
Microwell Plate coated	No
HRP Conjugate	No
Galectin-3 Standard	No
Sample Diluent	No
Assay Buffer Concentrate 20x	ProClin 300 < 0.0025 %
Wash Buffer Concentrate 20x	No
Substrate Solution	No
Stop Solution	Phosphoric acid < 10 %
Adhesive Films	No

Safety Data Sheets in accordance with the current (EC/EU) Regulations as amended are attached.

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SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: ProClin 300 < 0.0025 %

Other names:

Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) in

a concentration of 0.0015 - < 0.0025 %

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: Preservative agent for laboratory chemicals.

Uses advised against: Any other than the above mentioned.

1.3 Details of the supplier of the safety data sheet

BioVendor - Laboratorní medicína a.s.

Karásek 1767/1 621 00 Brno Czech Republic

Identification number: 63471507

Tel: +420 549 124 185 E-mail: <u>info@biovendor.com</u> Website: <u>www.biovendor.com</u>

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.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

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Hazard pictograms:



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.

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: Void.

Labelling of packages where the contents do not exceed 125 ml

Hazard pictograms:



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.

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.

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.

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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

3.1 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:		
CAS: 55965-84-9 EC: 611-341-5	Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3one (3:1)	0.0015 ≤
INDEX: 613-167-00-5	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	0.0025 %
	EUH071 Specific concentration limits: Skin Corr. 1C; H314: $C \ge 0.6$ % Skin Irrit. 2; H315: 0.06 % $\le C < 0.6$ % Eye Dam. 1; H318: $C \ge 0.6$ % Eye Irrit. 2; H319: 0.06 % $\le C < 0.6$ % Skin Sens. 1A; H317: $C \ge 0.0015$ % Note B	

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!

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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.

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.

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5.4 Further 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:

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 not 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 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

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.

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.

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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 isothiazol-3	Reaction mass of 5-chloro-2-methyl-2H-isothiazo	ol-3-one and 2-methyl-2H-
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, systemic 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

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Ingredients with biological limit values:

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

8.2 Exposure controls

8.2.1 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.

8.2.2 Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

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

Keep away from foodstuffs, beverages and feed.

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

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

a) Eye/face protection:



Not required during regular use.

Alternatively, use closed safety glasses (EN 166).

b) Skin protection



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.

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.

c) Respiratory protection:

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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).

d) Thermal hazards: Not applicable.

8.2.3 Environmental exposure controls:

Adhere to usual measures for environmental protection, see Section 6.

PHYSICAL AND CHEMICAL PROPERTIES **SECTION 9**

9.1 Information on basic physical and chemical properties

General Information

Physical state: Fluid.

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

Not determined. Lower: Not determined. Upper: Flash point: Not applicable. Ignition temperature: Not applicable. Decomposition temperature: Not determined. Not determined. pH:

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.

Auto-ignition temperature: Product is not selfigniting.

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. Not determined. Relative evaporation rate:

Information with regard to physical hazard classes

Explosives: Void. Flammable gases: Void. Aerosols: Void. Oxidising gases: Void. Gases under pressure: Void. Flammable liquids: Void.

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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

Substances and mixtures, which emit flammable gases in contact with water:

Oxidising liquids:

Oxidising solids:

Organic peroxides:

Corrosive to metals:

Desensitised explosives:

Void.

Void.

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.

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)

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.

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

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

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

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

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

Additional toxicological information: No relevant information is available.

Acute effects: No acute effects are known.

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

CMR effects (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.

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 R isothiazol-3-	eaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-one (3:1)
log Pow	0.401 measured value, bioaccumulation is not expected

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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

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

Additional ecological information

AOX-indication: No relevant information is available.

General notes:

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

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

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.

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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

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

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 Packaging 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 to Transport Regulations

UN "Model Regulation": Void

SECTION 15 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.

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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:

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:

H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
L1240	Causas sariaus ava damasa

Causes serious eye damage. H318 H330 Fatal if inhaled.

Very toxic to aquatic life. H400

Very toxic to aquatic life with long lasting effects. EUH071 Corrosive to the respiratory H410 tract.

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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	Calculation	
	method	

First issue of SDS: 30.09.2022 Internal code formula: 1670.002 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

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

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

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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.

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SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: Phosphoric acid < 10 %

Unique Formula Identifier (UFI): Not Applicable

REACH registration number: No registration number is given yet for this substance / substances in this mixture since the annual import quantity is less than one tonnage per annum or the transition period for its registration according to Article 23 of REACH has not yet expired.

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

Relevant identified uses

For research use only

Use Description Code

SU22 - Professional uses: Public domain (administration, education,

entertainment, services, craftsmen), PROC15 - Use as laboratory reagent, PC21 - Laboratory chemicals, SU24 - Scientific research and development

Uses advised against

Not for consumer use

1.3 Details of the supplier of the safety data sheet

BioVendor - Laboratorní medicína a.s.

Karásek 1767/1 621 00 Brno Czech Republic

Identification number: 63471507

Tel: +420 549 124 185 E-mail: <u>info@biovendor.com</u> Website: <u>www.biovendor.com</u>

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 [CLP] Physical hazards Not Hazardous

Health hazards

Skin corrosion/irritation Category 1
Serious eye damage/eye irritation Category 1

Environmental hazards

Not Hazardous

Additional information

No information available

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

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Hazard pictograms



Signal Word: Danger

Hazard Statements:

H314 - Causes severe skin burns and eye damage H318 - Causes serious eye damage

Precautionary Statements:

P260 - Do not breathe dust/fume/gas/mist/vapours/spray P264 - Wash hands thoroughly after handling

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

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

P310 - Immediately call a POISON CENTER or doctor/physician

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing P301

+ P330 + P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting

P363 - Wash contaminated clothing before reuse

P501 - Dispose of contents/ container to an approved waste disposal plant

2.3 Other hazards

Not Applicable

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Mixtures

Chemical Name	CAS No	EINECS-No.	2	REACH registration number	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Phosphoric acid	7664-38-2	-	5-10	-	Not classified

Chemical Name	Specific concentration limit (SCL)	M-Factor	Acute Toxicity Estimate
Phosphoric acid	Eye Irrit. 2 10%<=C<25% Skin Corr. 1B C>=25%	-	-
	Skin Irrit. 2 10%<=C<25%		

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

Skin contact: Wash off immediately with plenty of water for at least 15 minutes. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Immediate medical attention is required.

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Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Immediate medical attention is required.

Ingestion: Never give anything by mouth to an unconscious person. Do not induce vomiting without medical advice. Get medical attention if symptoms occur.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. If symptoms persist, call a doctor.

Notes to Physician: Treat symptomatically.

4.2 Most important symptoms and effects, both acute and delayed

H314 - Causes severe skin burns and eye damage H318 - Causes serious eye damage

4.3 Indication of any immediate medical attention and special treatment needed

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

SECTION 5 FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray. Carbon dioxide (CO2). Foam. Dry chemical. **Unsuitable extinguishing media**: No information available.

5.2 Special hazards arising from the substance or mixture

No data

5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective suit

5.4 Further information

None

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment, and emergency procedures

Ensure adequate ventilation

Avoid contact with skin, eyes or clothing Use personal protection equipment See section 8 for more information

6.2 Environmental precautions

No special environmental precautions required. Avoid discharge into drains and waterways whenever possible.

6.3 Methods and material for containment and cleaning up

Soak up with inert absorbent material.

6.4 Reference to other sections

See section 8 for more information.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Always wear recommended Personal Protective Equipment. See section 8 for more information. Do not get in eyes, on skin, or on clothing. Do not ingest. If during normal use the material presents a respiratory hazard, use adequate ventilation and/or wear appropriate respirator

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7.2 Conditions for safe storage, including any incompatibilities

Keep in a dry, cool and well-ventilated place. Keep in properly labelled containers. Store in accordance with local regulations.

7.3 Specific end use(s)

For research use only

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECT	SECTION 8	EXPOSURE	CONTROLS /	PERSONAL	PROTECTION
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8.1 Control parameters

Chemical Name	EU OEL (TWA)	EU OEL (STEL)	EU Skin Notation
Phosphoric acid 7664- 38-2	None	None	None
Chemical Name	Austria	Belgium (TWA)	Czech Republic
		0 (
Phosphoric acid 7664- 38-2	1 mg/m3	1 mg/m3	mg/m3 TWA mg/m3 Ceiling Irritant
•	1 mg/m3	. ,	mg/m3 TWA

Chemical Name	Denmark (TWA)	Finland OEL (TWA)	France OEL (VME)
Phosphoric acid 7664- 38-2	1 mg/m3	None	0.2 ppm 1 mg/m3

Chemical Name	Germany OEL (TWA)	Ireland (TWA)	Italy OEL (TWA)
Phosphoric acid 7664- 38-2	2 mg/m3 exposure factor 2	1 mg/m3	1 mg/m3

Chemical Name	Lithuania OEL (TWA)	Netherlands OEL (MAC)	Norway
Phosphoric acid 7664- 38-2	1 mg/m ³	1 mg/m ³	1 mg/m ³ TWA 3 mg/m ³ STEL

Chemical Name	Poland	Portugal	Spain OEL (TWA)
Phosphoric acid 7664-	mg/m ³ TWA	mg/m ³ TWA	1 mg/m ³
38-2	mg/m ³ STEL	mg/m ³ STEL	

Chemical Name	Sweden - Occupational Exposure Limits - TLVs (LLVs)		United Kingdom
Phosphoric acid 7664-38-2	1 mg/m ³ TLV NGV	4 mg/m ³ STEL 2 mg/m ³ TWA	1 mg/m ³ TWA

Engineering Measures Ensure adequate ventilation, especially in confined areas.

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8.2 Exposure controls

8.2.1 Personal protective equipment

a) Eye/face protection



Tight sealing safety goggles.

b) Skin protection



Body protection

Wear laboratory coat for body protection.



Hand protection

Wear suitable gloves, Glove material: Compatible chemical-resistant gloves.

c) Respiratory protection



In case of insufficient ventilation wear respirators and components tested and approved under appropriate government standards.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls

No special environmental precautions required. Avoid discharge into drains and waterways whenever possible.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	liquid	
Colour	No data	
Odour	No data	
Molecular Weight	No data	
Melting point / melting range	°C No data	°F No data
Boiling point / boiling range	°C No data	°F No data
Flammability (solid, gas)	No data	
Lower explosion limit	No data	
Upper explosion limit	No data	

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Flash point	°C No data	°F No data
Autoignition Temperature	°C No data	°F No data
Decomposition temperature	°C No data	°F No data
рН	No data	
Evaporation rate	No data	
Viscosity	No data	
Solubility	No data	
Partition coefficient: n-octanol/water	No data	
Vapour Pressure	No data	
Specific gravity	No data	
Relative density	No data	
Vapour density	No data	
Explosive properties	No data	
Oxidising properties	No data	
Particle characteristics	No data	

9.2 Other information

Information with regards to physical hazard classes

No information available

Other safety characteristics

No information available

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

None known

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

Hazardous reaction has not been reported

10.4 Conditions to avoid

Oxidising agent.

10.5 Incompatible materials

Flammable liquid. Oxidiser. poisons. Acids.

10.6 Hazardous decomposition products

No known hazardous decomposition products.

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SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Phosphoric acid	= 1530 mg/kg (Rat)	= 2740 mg/kg(Rabbit)	>850mg/m ³ (Rat)

11.1.1 Principal Routes of Exposure

Skin corrosion/irritation: Causes severe burns

Serious eye damage/irritation: Causes serious eye damage

Respiratory or skin sensitisation: Data are conclusive but insufficient for classification

Specific target organ toxicity (STOT) - single exposure:

Data are conclusive but insufficient for classification

Specific target organ toxicity (STOT) - repeated exposure:

Data are conclusive but insufficient for classification

Carcinogenicity: Data are conclusive but insufficient for classification

Germ cell mutagenicity: Data are conclusive but insufficient for classification

Reproductive Toxicity: Data are conclusive but insufficient for classification

Aspiration Hazard: Data are conclusive but insufficient for classification

11.2 Additional Information

Endocrine disrupting properties

No information available

Other information

No information available

SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity

The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates	Toxicity to fish	Microtox Data	log Pow
Phosphoric acid	No data	No data	No data	No data	No data
	available	available	available	available	available

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Endocrine disrupting properties

This product does not contain any known or suspected endocrine disruptors

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Phosphoric acid < 10 %

12.7 Other adverse effects

No information available.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Disposal methods

The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in according to approved disposal technique. Disposal of this product, its solutions or of any byproducts, shall comply with the requirements of all applicable local, regional or national/federal regulations.

SECTION 14 TRANSPORT INFORMATION

14.1 IATA / ADR / DOT-US / IMDG

Classified as dangerous in the meaning of transport regulations

14.2 UN number

1760

14.3 UN proper shipping name

Corrosive liquid, n.o.s. (Phosphoric Acid solution)

14.4 Transport hazard class(es)

8

14.5 Packaging group

Ш

14.6 Environmental hazards

Not Applicable

14.7 Special precautions for user

Not Applicable

14.8 Maritime transport in bulk according to IMO instruments

Not Applicable.

SECTION 15 REGULATORY INFORMATION

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

None

15.2 Substances of Very High Concern

None

15.3 Substance subject to authorisation per REACH Annex XIV

None

15.4 Restricted substances under EC 1907/2006, Annex XVII

Chemical Name	Weight-%	EU - REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances
Phosphoric acid	5-10	Use restricted. See item 75.B

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15.5 Regulation (EC) No 649/2012 (Rotterdam Convention - export/import of dangerous chemicals)

None

15.6 Regulation (EU) No 2019/1021 (Stockholm Convention – persistent organic pollutants)
None

15.7 EU - Substances Depleting the Ozone layer (1005/2009)

None

15.8 German Water hazard classes (Wassergefährdungsklassen)

Chemical Name	Weight-%	Water hazard class (WGK)
Phosphoric acid	5-10	hazard class 1 - slightly hazardous to water

15.9 Other International Inventories

Chemical Name	EINECS (European Union)	ELINCS (European List of Notified Chemical Substances)	ENCS (Japan)	PICCS (Philippines)
Phosphoric acid	Listed	-	Listed	Listed

Chemical Name	AICS (Australia)	South Korea (KECL)	Canada (DSL)	NDSL
Phosphoric acid	Listed	Listed	Listed	-

15.10 Chemical Safety Assessment

No Chemical safety assessment has been carried out

SECTION 16 OTHER INFORMATION

Date of issue: 18.08.2025 Revision notes: None

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Skin corrosion/irritation Category 1 Calculation method Serious eye damage/eye irritation Category 1 Calculation method

Abbreviations and acronyms

TWA - Time-Weighted Average

OELs - Occupational Exposure Limits

STEL - Short Term Exposure Limit

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

KECL - Korean Existing and Evaluated Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

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Phosphoric acid < 10 %

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

CEPA - Canadian Environmental Protection Act

EPA - Environmental Protection Agency

OSHA - Occupational Safety and Health Administration of the US Department of Labour

IATA - International Air Transport Association

DOT - Department of Transportation

IMDG - International Maritime Dangerous Goods

ACGIH - American Conference of Governmental Industrial Hygienists

NIOSH - National Institute for Occupational Safety and Health

AIHA - American Industrial Hygiene Association

HMIS - Department of Defense Hazardous Materials Information System

NTP - National Toxicology Program

IARC - International Agency for Research on Cancer

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No. 1907/2006.

The above information was acquired by diligent search and/or investigation and the recommendations are based on prudent application of professional judgment. The information shall not be taken as being all inclusive and is to be used only as a guide. All materials and mixtures may present unknown hazards and should be used with caution.

Since the Company cannot control the actual methods, volumes, or conditions of use, the Company shall not be held liable for any damages or losses resulting from the handling or from contact with the product as described herein.

The information in this sds does not constitute a warranty, expressed or implied, including any implied warranty of merchantability or fitness for any particular purpose.

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