

Safety data sheet**according to Regulation (EC) No 1907/2006, Article 31, Annex II
according to Regulation (EU) No 2020/878**Printing date: 25.05.2021
Revision date: 25.05.2021
Version number: 4 (replaces version 3)**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** Reagent HIPPUstrip**Other names:** REAGENT**UFI:** Not apply.**1.2 Relevant identified uses of the substance or mixture and uses advised against**

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

Application of the substance / the mixture: Preparation for in vitro diagnostic use.**Uses advised against:** Any other than the above mentioned.**1.3 Details of the supplier of the safety data sheet****Supplier:**

TestLine Clinical Diagnostics s.r.o.

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

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

Company Identification Number: 479 13 240

Phone/Fax: +420 541 243 390

E-mail: pospisiljar@testlinecd.com / Website: www.testlinecd.com**Further information obtainable from:**

Ing. Karel Královec, Studio2K

Phone: +420 777 145 808, E-mail: bl@studio2k.cz, Website: www.bezpecnostni-listy.eu**1.4 Emergency telephone number**Phone: +420 224 919 293 or +420 224 915 402; E-mail: tis@vfn.cz

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

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

National helpdesks contact details - <https://echa.europa.eu/support/helpdesks>.Links to Poison Centers and Clinical Toxicologists all over the World: <https://www.eapcct.org/index.php?page=links>.**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture**

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

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

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

Classification according to Regulation (EC) No 1272/2008

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

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Acute Tox. 4 H302 Harmful if swallowed.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Dam. 1 H318 Causes serious eye damage.

STOT SE 3 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.

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:**

GHS02

GHS05

GHS07

Signal word: Danger**Hazard-determining components of labelling:**

butan-1-ol

acetone

indan-1,2,3-trione

Hazard statements:

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.

Precautionary statements:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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P233	Keep container tightly closed.
P261	Avoid breathing vapours.
P280	Wear protective gloves/eye protection/face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
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/doctor.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P405	Store locked up.
P501	Dispose of contents/container to hazardous or special waste collection point.

Additional information:

Restricted to professional users.

Labelling of packages where the contents do not exceed 125 ml

Hazard pictograms:



Signal word: Danger

Hazard-determining components of labelling:

butan-1-ol
acetone
indan-1,2,3-trione

Hazard statements:

H318 Causes serious eye damage.

Precautionary statements:

P280 Wear eye protection/face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.

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: 71-36-3 EINECS: 200-751-6 Index number: 603-004-00-6 Reg.-No: 01-2119484630-38-XXXX	butan-1-ol Flam. Liq. 3, H226 Eye Dam. 1, H318 Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335-H336	48.5%
CAS: 67-64-1 EINECS: 200-662-2 Index number: 606-001-00-8 Reg.-No: 01-2119471330-49-XXXX	acetone Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336 EUH066	47.5%
CAS: 485-47-2 EINECS: 207-618-1	indan-1,2,3-trione Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	4.2%

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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!

In case of doubt, 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:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

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.

Upon irregular breathing or respiratory arrest, perform artificial respiration or secure breathing support.

If the person is unconscious, place in a stable side position and consult a physician.

After skin contact:

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

After eye contact:

Open the eyelids, possibly remove the contact lenses, and thoroughly rinse the affected eyes with clean flowing water for about 15 minutes. Seek medical assistance immediately.

After swallowing:

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

Information for doctor: Symptomatic treatment.

4.2 Most important symptoms and effects, both acute and delayed

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

Upon inhalation:

Central nervous system affection.

Upon ingestion:

Digestive tract problems, stomach and bowels irritation.

Discomfort and vomiting.

4.3 Indication of any immediate medical attention and special treatment needed

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

For special medical advice, contact the Toxicology Information Centre.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

Carbon dioxide (CO₂), extinguishing foam, extinguishing powder, water spray. 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 can be released:

Carbon monoxide (CO) a carbon dioxide (CO₂).

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:

Cool with water the products in enclosed packaging, which is near the fire. If possible, remove the products in un-damaged packaging from the danger area. Store the contaminated extinguishing water separately and do not let it into the sewerage. Remove

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the extinguishing water or used extinguishing materials together with the remnants of the fire according to the corresponding regulations.

* SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:

Ensure adequate ventilation.
Remove possible causes of ignition - do not smoke.
Use personal protective equipment.
Avoid contact with eyes and skin.
Avoid inhalation of vapors.
Prevent entry of unauthorized and unprotected persons.

For emergency responders: No relevant information available.

6.2 Environmental precautions

No special measures required.
Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

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

Possibly wipe the leaked product with a paper towel and place it into a waste vessel.
Thoroughly wash the affected spot and the tools used with a suitable detergent, it is possible to use a larger quantity of water.
Protect health against exposure of contained substances from the atmosphere, see the limit values of exposure, which are stated in Section 8.
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

* SECTION 7: Handling and storage

7.1 Precautions for safe handling

Before use, it is necessary to familiarize oneself with the contents of Sections 2, 6, 8, and 11 of the safety data sheet.
Use personal protective equipment.
Avoid inhalation of vapors.
Avoid contact with eyes.
Avoid long-term or intense skin contact.
Ensure good ventilation.
Use working methods according to operating instructions.
General hygiene measures for the handling of chemicals are applicable.
Before a pause and after ending the work, wash the hands and take off the polluted working clothes. Keep these clothes separately.
Remove contaminated clothing and protective equipment before entering areas in which food is consumed.
Do not eat, drink, smoke, or snuff during use.

Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.
Possibly perform measures for protection against electrostatic discharge.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and receptacles:

Store in a cool location.
Store only in unopened original receptacles.

Information about storage in one common storage facility:

Do not store together with strong oxidizing agents, acids and toxic metals.
Keep away from food, drink and animal feedingstuffs.

Further information about storage conditions:

Store in a dry and well ventilated place.
Keep containers tightly sealed.
Adhere to regulations and directives for flammable liquid storage.
Protect from frost.

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.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

67-64-1 acetone

IOELV Long-term value: 1210 mg/m³, 500 ppm

Regulatory information:

IOELV: COMMISSION DIRECTIVE (EU) 2019/1831

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

DNELs:

71-36-3 butan-1-ol

Oral	DNEL - Short term exposure, systemic effects	3,125 mg/kg/d (workers)
Inhalative	DNEL - Long term exposure, systemic effects	310 mg/m ³ (workers)
	DNEL - Long term exposure, local effects	55 mg/m ³ (consumers)

67-64-1 acetone

Oral	DNEL - Long term exposure, systemic effects	62 mg/kg/d (consumers)
		Overall rating factor = 2
Dermal	DNEL - Long term exposure, systemic effects	62 mg/kg/d (consumers)
		Overall rating factor = 20
Inhalative	DNEL - Long term exposure, systemic effects	186 mg/kg/d (workers)
		200 mg/m ³ (consumers)
		Overall rating factor = 200
	DNEL - Short term exposure, systemic effects	1,210 mg/m ³ (workers)
		2,420 mg/m ³ (workers)

PNECs:

71-36-3 butan-1-ol

PNEC - Freshwater	0.082 mg/l
PNEC - Marine water	0.0082 mg/l
PNEC - Sewage treatment plant	2,476 mg/l
PNEC - Sediment, freshwater	0.178 mg/kg
PNEC - Sediment, marine water	0.0178 mg/kg
PNEC - Soil	0.015 mg/kg
PNEC - Water (sporadic release)	2.25 mg/l

67-64-1 acetone

PNEC - Freshwater	10.6 mg/l
	Rating factor = 50
PNEC - Marine water	1.06 mg/l
	Rating factor = 500
PNEC - Sewage treatment plant	100 mg/l
PNEC - Sediment, freshwater	30.4 mg/kg
PNEC - Sediment, marine water	30.4 mg/kg
PNEC - Soil	29.5 mg/kg
PNEC - Water (sporadic release)	21 mg/l
	Rating factor = 100

Ingredients with biological limit values:

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

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

8.2 Exposure controls

Appropriate engineering controls:

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

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.
Keep away from foodstuffs, beverages and feed.

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Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Do not inhale gases/fumes/aerosols.

Eye/face protection:



Use enclosed protective goggles with sidewalls or a face shield (EN 166).

It is necessary to have bottles with a preparation for eye rinsing available at the workplace or to have an eye shower within reach.

Body protection:



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

Hand protection



Protective gloves (EN ISO 374-1).

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

Material of gloves:

Not determined.

For example protective surgical gloves.

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

Penetration time of glove material:

Not determined.

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

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

Respiratory protection:

Unnecessary during regular use.



In case of insufficient ventilation and exceeding permitted exposure limits, use a suitable half-mask (EN 149+A1) with a filter (EN 14387+A1), upon high concentrations, use an insulation breathing apparatus (EN 137, EN 138).

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:	Fluid.
Colour:	Light yellow.
Odour:	Light aromatic, fermentation.
Melting point/freezing point:	Not determined.
Boiling point or initial boiling point and boiling range:	Not determined.
Flammability:	The mixture is highly flammable.
Lower and upper explosion limit	
Lower:	2.6 Vol % (*)
Upper:	13.0 Vol % (*)
Flash point:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Decomposition temperature:	Not determined.
pH:	Not determined.
Viscosity	
Kinematic viscosity:	Not determined.

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Dynamic viscosity:	Not determined.
Solubility water:	Miscible.
Partition coefficient n-octanol/water (log value):	Not determined.
Vapour pressure at 20 °C:	23.3 kPa (*)
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 determined.
Oxidising properties:	No.
Evaporation rate:	Not determined.
Information with regard to physical hazard classes	
Explosives:	Void.
Flammable gases:	Void.
Aerosols:	Void.
Oxidising gases:	Void.
Gases under pressure:	Void.
Flammable liquids:	
Highly flammable liquid and vapour.	
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:	(*) Value for acetone.

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 The product does not polymerise.

10.4 Conditions to avoid

Prevent contact with incompatible materials.

Protect against heating, open flames, and ignition sources.

Protect against frost.

10.5 Incompatible materials Acids, acid chlorides, acid anhydrides, oxidizing agents, alkali metals, reducing agents.

10.6 Hazardous decomposition products

Carbon monoxide (CO) a carbon dioxide (CO₂).

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: Harmful if swallowed.

Relevant toxicological values for classification:		
ATE (Acute Toxicity Estimates)		
Oral	LD50	1,462 mg/kg
71-36-3 butan-1-ol		
Oral	LD50	790 mg/kg (rat)

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Dermal	LD50	3,430 mg/kg (rabbit)
Inhalative	LC50/4 h	24 mg/l (rat)
	LC0/4 h	> 17.76 mg/l (rat) Páry
67-64-1 acetone		
Oral	LD50	3,000 mg/kg (mouse)
		5,800 mg/kg (rat)
Dermal	LD50	20,000 mg/kg (rabbit)
		Inhalative
485-47-2 indan-1,2,3-trione		
Oral	LD50	600 mg/kg (rat)

Specific symptoms in biological assay:

Strong irritant effect - rabbit skin - 24 hours (acetone).

Strong irritant effect - rabbit eyes - 24 hours (acetone).

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/irritation: Causes serious eye damage.

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

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

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

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

STOT-single exposure: May cause respiratory irritation. May cause drowsiness or dizziness.

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: Upon vapour inhalation, narcotic effects may appear.

Acute effects:

Acute oral toxicity, Hazard category 4.

Serious eye damage - Eye Dam. 1.

Skin irritation - Skin Irrit. category 2.

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

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

11.2 Information on other hazards

Endocrine disrupting properties:

None of the ingredients is listed.

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.

71-36-3 butan-1-ol

LC50/96 h	1,376 mg/l (fish) (OECD 203 - Fish, Acute Toxicity Test) Pimephales promelas
EC50/48 h	1,328 mg/l (daphnia) (OECD 202 - Daphnia sp. Acute Immobilisation Test) Daphnia magna
ErC50/96 h	225 mg/l (algae) (OECD 201 - Alga, Growth Inhibition Test) Pseudokirchneriella subcapitata
EC50/17 h	4,390 mg/l (bacteria) Pseudomonas putida
NOEC/21 d	4.1 mg/l (daphnia) (OECD 211 - Daphnia magna Reproduction Test) Daphnia magna

67-64-1 acetone

LC50/96 h	5,540 - 8,300 mg/l (fish) Lepomis macrochirus
EC50/48 h	6,100 - 12,700 mg/l (daphnia) Daphnia magna

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EC5/16 h	1,700 mg/l (bacteria) Pseudomonas putida
EC5/8 d	530 mg/l (bacteria) Microcystis aeruginosa
EC50/96 h	7,500 mg/l (algae) Selenastrum capricornutum
NOEC/NOEL/48 h	3,400 mg/l (algae) Pseudokerchneriella subcapitata

12.2 Persistence and degradability

71-36-3 butan-1-ol

Biodegradability in water 98 %/28 d (OECD 301 B - CO2 Evolution Test)
the substance is readily biodegradable

67-64-1 acetone

Biodegradability in water 91 %/28 d (OECD 301 B - CO2 Evolution Test)
the substance is readily biodegradable

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

12.3 Bioaccumulative potential

71-36-3 butan-1-ol

log Pow 1 (OECD 117 - Partition Coefficient (n-octanol/water))
significant bioaccumulation is not expected

67-64-1 acetone

log Pow -0.24
bioaccumulation is not expected

Bioconcentration factor (BCF):

71-36-3 butan-1-ol

BCF 3.16 (estimated value)

67-64-1 acetone

BCF 0.19

12.4 Mobility in soil

71-36-3 butan-1-ol

Koc 2.4 (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

COD-value:

67-64-1 acetone

COD 2.1 g O2/g

BOD5-value:

67-64-1 acetone

BOD5 1.76 - 1.9 g O2/g

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.

Must not reach sewage water or drainage ditch undiluted or unneutralised.

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.

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

Soaked polluted cloths, paper or other organic materials represent a fire hazard and should be controlled, collected and disposed of.

Waste disposal key:

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

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

European waste catalogue and hazardous properties of waste:	
18 02 05*	chemicals consisting of or containing hazardous substances
15 01 10*	packaging containing residues of or contaminated by hazardous substances
15 01 02	plastic packaging
HP3	Flammable
HP4	Irritant - skin irritation and eye damage
HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP6	Acute Toxicity

Uncleaned packaging

Recommendation:

Dispose of packaging according to regulations on the disposal of packagings.

Non contaminated packagings may be reused.

Non contaminated packagings may be recycled.

Dispose of packaging that cannot be cleaned in the same manner as the mixture.

Empty container completely. Dispose of hazardous waste pursuant to corresponding local directives in adequate equipment. Put other waste away according to the material type into collection vessels for sorted waste.

Regulations:

Commission Decision No 2014/955/EU of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council.

Commission Regulation (EU) No 1357/2014, replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, as amended.

SECTION 14: Transport information

14.1 UN number or ID number ADR, IMDG, IATA	UN1993
14.2 UN proper shipping name ADR IMDG, IATA	1993 FLAMMABLE LIQUID, N.O.S. (ACETONE, BUTANOLS), special provision 640D FLAMMABLE LIQUID, N.O.S. (ACETONE, BUTANOLS)
14.3 Transport hazard class(es) ADR	 Class: 3 (F1) Flammable liquids. Label: 3
IMDG, IATA	 Class: 3 Flammable liquids. Label: 3
14.4 Packing group ADR, IMDG, IATA	II
14.5 Environmental hazards Marine pollutant:	No.
14.6 Special precautions for user	Unless specified otherwise, general measures for safe transport must be followed.

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Hazard identification number (Kemler code):	Persons employed in transporting dangerous goods must be trained.
EMS Number:	All persons involved in transporting must observe safety regulations.
Stowage Category:	Warning: Flammable liquids.
	33
	F-E, <u>S</u> -E
	B
14.7 Maritime transport in bulk according to IMO instruments Not applicable.	
Transport/Additional information:	
ADR	
Limited quantities (LQ):	1L
Excepted quantities (EQ):	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
Transport category:	2
Tunnel restriction code:	D/E
IMDG	
Limited quantities (LQ):	1L
Excepted quantities (EQ):	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL PROVISION 640D (ACETONE, BUTANOLS), 3, II

SECTION 15: Regulatory information

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

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

Seveso category: P5c FLAMMABLE LIQUIDS

Qualifying quantity (tonnes) for the application of lower-tier requirements: 5.000 t

Qualifying quantity (tonnes) for the application of upper-tier requirements: 50.000 t

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

67-64-1	acetone
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Legal regulations of the European Community:

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

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

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

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

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

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

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

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SECTION 16: Other information

Warning:

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

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

Relevant phrases:

H225 Highly flammable liquid and vapour.
H226 Flammable liquid and vapour.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
EUH066 Repeated exposure may cause skin dryness or cracking.

Training hints:

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

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

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

Recommended restriction of use:

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

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

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

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

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

Flammable liquids	On basis of test data
Acute toxicity - oral Skin corrosion/irritation Serious eye damage/eye irritation Specific target organ toxicity (single exposure)	Calculation method

Department issuing SDS:

Ing. Karel Královec, Studio2K
Phone: +420 777 145 808, E-mail: info@studio2k.cz, Websites: www.studio2k.cz / www.bezpecnostni-listy.eu

First issue of SDS: 19.03.2014

Date of previous version: 29.04.2018

Version number of previous version: 3

Reasons for alterations:

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

Revised sections: 1, 2, 3, 4, 6, 7, 8, 9, 11, 12, 13, 15, 16.

Internal code formula: 810.004

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)

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DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Flam. Liq. 3: Flammable liquids – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Sources:

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

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

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

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