

SAFETY DATA SHEET



Lactose Intolerance Quick Test (Chromogen Solution)

The safety data sheet is in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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

Date issued	07.12.2015
Revision date	12.11.2017

1.1. Product identifier

Product name	Lactose Intolerance Quick Test (Chromogen Solution)
Article no.	602 010, 602 012

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

Use of the substance / preparation	Laboratory reagents intended to perform near patient testing of lactase activity from biopsy specimen.
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1.3. Details of the supplier of the safety data sheet

Company name	Biohit Oyj
Postal address	Laippatie 1
Postcode	00880
City	HELSINKI
Country	Finland
Telephone number	+358 9 773 861
Email	info@biohit.fi
Website	http://www.biohithealthcare.com

1.4. Emergency telephone number

Emergency telephone	Description: Immediately seek medical attention by calling your local Poison Information Centre
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SECTION 2: Hazards identification

2.1. Classification of substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP / GHS]	Eye Dam. 1; H318 Skin Corr. 1B; H314
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2.2. Label elements

Hazard pictograms (CLP)



Signal word	Danger
Hazard statements	H314 Causes severe skin burns and eye damage. H318 Causes serious eye damage.
Precautionary statements	P280 Wear protective gloves / protective clothing / 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. P302+P352 IF ON SKIN: Wash with plenty of soap and water.

2.3. Other hazards

PBT / vPvB	Not relevant.
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SECTION 3: Composition / information on ingredients

3.2. Mixtures

Substance	Identification	Classification	Contents
Acetic acid ...%	CAS No.: 64-19-7 EC No.: 200-580-7 Index No.: 607-002-00-6	Flam. Liq. 3; H226; Skin Corr. 1A; H314;	= 30 %
Thimerosal	CAS No.: 54-64-8 EC No.: 200-210-4 Index No.: 080-004-00-7	Acute tox. 2; H300,H330; Acute tox. 1; H310; STOT RE2; H373; Aquatic Acute 1; H400; Aquatic Chronic 1; H410;	0,002 %

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Remove affected person from source of contamination. Call a POISON CENTER or doctor/physician.
Skin contact	Rinse the skin immediately with lots of water. Remove contaminated clothes and rinse skin thoroughly with water. Call a POISON CENTER or doctor/physician.
Eye contact	Important! Immediately rinse with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor/physician.
Ingestion	Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

4.2. Most important symptoms and effects, both acute and delayed

General symptoms and effects	Irritation and corrosion, Bronchitis, Shortness of Breath, Gastric spasms, Nausea, Vomiting, Circulatory collapse, Shock.
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4.3. Indication of any immediate medical attention and special treatment needed

Medical treatment	Treat symptoms.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
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5.2. Special hazards arising from the substance or mixture

Fire and explosion hazards	Heating may cause an explosion. When heated and in case of fire, corrosive vapours/ gases may be formed. Vapours are heavier than air and may spread near ground to sources of ignition.
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5.3. Advice for firefighters

Personal protective equipment	Use personal protective equipment as required. Wear respiratory protection. Wear protective gloves / protective clothing / eye protection / face protection.
Fire fighting procedures	Water spray should be used to cool containers.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal protection measures	Use protective gloves, goggles and suitable protective clothing. Provide adequate ventilation. Do not breathe vapour.
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6.2. Environmental precautions

Environmental precautionary measures	Avoid discharge into drains.
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6.3. Methods and material for containment and cleaning up

Clean up	Collect spillage in containers, seal securely and deliver for disposal according to local regulations.
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6.4. Reference to other sections

Other instructions	None.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling	Avoid contact with skin and eyes. When using do not eat, drink or smoke. Read and follow manufacturer's recommendations. Provide good ventilation. Do not pipet patient samples or reagents by mouth.
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7.2. Conditions for safe storage, including any incompatibilities

Storage	Protect from heat and direct sunlight. Do not freeze. Store in closed original container in a dry place. Store 2-8°C Keep upright.
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7.3. Specific end use(s)

Specific use(s)	No data recorded.
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SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Substance	Identification	Value	TWA Year
Acetic acid ...%	CAS No.: 64-19-7		
Thimerosal	CAS No.: 54-64-8	TWA (8h) : 0,01 mg/m3	
Other Information about threshold limit values	Not relevant.		
Occupational exposure limit, intended use	Limit value type: Inhalation TWA (8h): 25 mg/l Value: 25 mg/l Source: Acetic Acid 30%		

8.2. Exposure controls

Safety signs



Eye / face protection

Required Properties	Wear tight-fitting goggles or face shield.
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Hand protection

Hand protection	Wear protective gloves. Impermeable material.
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Skin protection

Additional skin protection measures	Wear apron or protective clothing in case of splashes.
Skin protection remark	Provide eyewash, quick drench.

Respiratory protection

Recommended respiratory protection	Filter apparatus type: Self-contained breathing apparatus.
Additional respiratory protection measures	Under normal conditions of use respiration protection should not be required.
Respiratory protection, comments	In case of inadequate ventilation use suitable respirator.

Hygiene / environmental

Specific hygiene measures	Wash hands after handling. Wash at the end of each work shift and before eating, smoking and using the toilet. Wash contaminated clothing before reuse.
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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid.
Colour	Colourless.
Odour	Pungent.
Odour limit	Comments: No data recorded.
pH	Status: In delivery state Comments: No data recorded.
Melting point / melting range	Comments: No data recorded.
Flammability (solid, gas)	None.
Lower explosion limit with unit of measurement	Value: 4 %
Upper explosion limit with units of measurement	Value: 19.9 %
Explosion limit	Comments: No data recorded.
Vapour pressure	Comments: No data recorded.
Vapour density	Comments: No data recorded.
Specific gravity	Value: 1,039 g/ml Comments: No data recorded.
Solubility	Medium: Water Comments: No data recorded.
Partition coefficient: n-octanol/water	Comments: No data recorded.
Spontaneous combustibility	Comments: No data recorded.
Decomposition temperature	Comments: No data recorded.
Viscosity	Comments: No data recorded.
Oxidising properties	No data recorded.

9.2. Other information

SECTION 10: Stability and reactivity

10.1. Reactivity

10.2. Chemical stability

Stability	Stable under normal temperature conditions and recommended use.
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10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	Not known.
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10.4. Conditions to avoid

Conditions to avoid	Avoid contact with: Oxidising materials. Will react violently with: Metals. Bases. Alkali hydroxides, non metallic Halides, Ethanolamine, Acetic anhydride, Aldehydes, Alcohols, Halogen-halogen compounds, Shlorosulfonic acid, Nitric Acid, Alkalines, Cyanides. Strong alkalis.
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10.5. Incompatible materials

Materials to avoid	Avoid contact with oxidising agents (e.g. nitric acid, peroxides and chromates). Strong acids. Phosphorous halides. Chromosulfuric acid. Chromium (VI) oxide.
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10.6. Hazardous decomposition products

Hazardous decomposition products	No data recorded.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Other information regarding health hazards

Inhalation	May cause an asthma-like shortness of breath. Irritating to respiratory system.
Skin contact	Causes severe burns.
Eye contact	Risk of corneal damage. Contact with concentrated chemical may very rapidly cause severe eye damage, possibly loss of sight.
Ingestion	Causes burns. However, ingestion may cause nausea, stomach pain and vomiting.
Assessment of acute toxicity, classification	No data recorded.
Skin corrosion / irritation, other information	No data recorded.
Mutagenicity	No data recorded.
Carcinogenicity, other information	No component of this product present at levels greater than or equal to 0,1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity	No data recorded.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	No information available.
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12.2. Persistence and degradability

Persistence and degradability, comments	No data recorded.
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12.3. Bioaccumulative potential

Bioaccumulation, evaluation No data recorded.

12.4. Mobility in soil

Mobility evaluation No data recorded.

12.5. Results of PBT and vPvB assessment

PBT assessment results This product does not contain any PBT or vPvB substances.

12.6. Other adverse effects

Other adverse effects, comments Harmful effect due to pH shift. Caustic even in diluted form.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Specify the appropriate methods of disposal Dispose of waste and residues in accordance with local authority requirements.

SECTION 14: Transport information

14.1. UN number

Comments Not relevant.

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

14.6. Special precautions for user

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

SECTION 15: Regulatory information

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

15.2. Chemical safety assessment

Chemical safety assessment performed No

SECTION 16: Other information

Supplier's notes	The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.
List of relevant H-phrases (Section 2 and 3)	H226 Flammable liquid and vapour. H300 Fatal if swallowed. H310 Fatal in contact with skin. H314 Causes severe skin burns and eye damage. H318 Causes serious eye damage. H330 Fatal if inhaled. H373 May cause damage to organs through prolonged or repeated exposure H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.
Classification according to Regulation (EC) No 1272/ 2008 [CLP / GHS]	Eye Dam. 1; H318 Skin Corr. 1B; H314
Version	2