

## SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 and Regulation (EC) No. 2020/878

**Issuing date:** 20-May-2022

**Revision date:** 29-09-2023

**Version:** 2.0

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product code(s):** 133001007

**Product name:** Lactose Intolerance Test

**REACH registration number:** No registration number is given yet for this substance 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

**Recommended use:** For in vitro diagnostic purposes.

**Use description code:** Not available.

**Uses advised against:** Not for consumer use.

### 1.3. Details of the supplier of the safety data sheet

#### **Supplier**

STAB VIDA, Lda.

Madan Parque - Rua dos Inventores, Salas 2.18.

2825-182 Caparica

PORTUGAL

Tel: (+351) 938 437 766

Fax: (+351) 21 043 8608

For further information, please contact: drvida@stabvida.com

### 1.4. Emergency telephone number

**Poison Information Centre Emergency Phone (CIAV):** + 351 800 250 250

## 2. HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

#### Classification according to Regulation (EC) No. 1272/2008 [CLP]

**Physical hazards:** Not classified

**Health hazards:** - Aspiration hazard (Category 1), H304 (May be fatal if swallowed and enters airways)

- Acute toxicity (oral, dermal, inhalation) hazard (Category 4), H315 (Skin Irrit), H319 (Eye Irrit)

**Environmental Hazards:** Not classified

**Additional information:** Not applicable

### 2.2. Label elements

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

**Hazard pictograms:**


**Signal word:** Danger; Warning.

**Hazard statements:**

- H304 – May be fatal if swallowed and enters airways.
- H315 – Harmful in contact with skin. Skin Irrit. 2
- H319 – Harmful if swallowed. Eye Irrit. 2

**Precautionary Statements - EU (§28, 1272/2008):**

- P280 – Wear protective gloves/ protective clothing;
- P301 + P310 – If swallowed: Immediately call a Poison Center/medical assistance;
- P331 – Do not induce vomiting;
- P405 – Store locked up;
- P501 – Dispose of contents/ container to an approved waste disposal plant.

Supplemental Hazard information (EU)

EUH066 – Repeated exposure may cause skin dryness or cracking.

**2.3. Other hazards**

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**3.1. Substances/Mixture**

Mixture	Product Identifier	Classification according to Regulation (EC) No. 1272/2008 [CLP]
LC-LaCl-LB (Potassium hydroxide, KOH)	CAS No 1310-58-3 EC No 215-181-3	Acute toxicity hazard (Category 4), H315 e H319
n-Hexadecane (Cetane)	CAS No 544-76-3 EC-No 208-878-9	Aspiration hazard (Category 1), H304
Phenol red (Sodium Salt)	CAS No 34487-61-1 EC-No 252-057-8	Not classified

## 4. FIRST AID MEASURES

**4.1. Description of first aid measures**

**General advice:** Consult a physician. Show this safety data sheet to the doctor in attendance.

**Eye contact:** Rinse cautiously with water for several minutes. After initial flushing, remove any contact lenses, if present and easy to do so, and continue rinse with water for an additional 15minutes. If symptoms persist, call a physician.

**Skin contact:** Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. If symptoms persist, call a physician.

**Ingestion:** Never give anything by mouth to an unconscious person. Rinse mouth with water. Drink plenty of water. If symptoms persist, call a physician.

After swallowing: caution if victim vomits. Risk of aspiration. Keep airways free. Pulmonary failure possible after aspiration of vomit. Call a physician immediately.

**Inhalation:** Move to fresh air. If symptoms persist, call a physician.

**Notes to Physician** No information available.

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

**Main symptoms:** The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

#### **4.3. Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

### **5. FIREFIGHTING MEASURES**

#### **5.1. Extinguishing media**

**Suitable extinguishing media:** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable extinguishing media:** No information available.

#### **5.2. Special hazards arising from the substance or mixture**

**Specific hazards arising from the chemical:**

- Carbon oxides;
- Combustible;
- Vapours are heavier than air and may spread along floors;
- Forms explosive mixtures with air on intense heating;
- Development of hazardous combustion gases or vapours possible in the event of fire.

#### **5.3. Advice for firefighters**

**Special protective equipment for fire-fighters**

Firefighters should wear self-contained breathing apparatus and full protective gear. Use of personal protection equipment.

#### **5.4. Further information**

Prevent fire extinguishing water from contaminating surface water or the ground water system.

### **6. ACCIDENTAL RELEASE MEASURES**

#### **6.1. Personal precautions, protective equipment and emergency procedure**

Do not breathe vapors, aerosols. Avoid contact with skin and eyes. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. Always wear recommended Personal Protective Equipment. See section 8 for more details.

### **6.2. Environmental precautions**

Avoid release to the environment. Do not let product enter drains. See Section 12 for additional Ecological Information

### **6.3. Methods and material for containment and cleaning up**

Take up liquid spill into absorbent material. Keep in appropriate and closed containers for disposal. Dispose of materials or solid residues at an authorized site. Never return spills to original containers for re-use. Clean up affected area. Ventilate the exhibit area to dissipate residual vapours.

### **6.4. Reference to other sections**

For personal protection, see Section 8 for more information.

For disposal, see Section 13 for more information.

## **7. HANDLING AND STORAGE**

### **7.1. Precautions for safe handling**

Use personal protective equipment as required. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Ensure adequate ventilation. Smoking, eating and drinking should be prohibited in the application area.

### **7.2. Conditions for safe storage, including any incompatibilities**

Keep container tightly closed in a dry and well-ventilated place. Keep in properly labelled containers.

### **7.3. Specific end use(s)**

**Specific use(s):** Apart from the use(s) mentioned in Section 1.2, no other specific uses are stipulated.

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### **8.1. Control parameters**

**Exposure limits:** Contains no substances with occupational exposure limits.

**Derived No effect Level (DNEL):** No information available.

**Predicted No Effect Concentration (PNEC):** No information available.

### **8.2. Exposure controls**

**Appropriate engineering controls:** Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. Ensure adequate ventilation, especially in contained areas.

#### **Personal protective equipment**

**Eye protection:** Tightly fitting safety goggles

**Hand protection:** Wear suitable protective gloves, i.e., compatible chemical-resistant gloves

**Skin and body protection:** Wear suitable protective clothing

**Respiratory protection:** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

<b>Thermal hazards:</b>	No data available
<b>Hygiene measures:</b>	Handle in accordance with good industrial hygiene and safety practice. Keep away from food and drink. When using do not eat, drink or smoke.
<b>Environmental controls:</b>	<b>exposure</b> No special environmental precautions required. Discharge into the environment must be avoided.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

<u>Property</u>	<u>Values</u>	<u>Notes</u>
<b>Appearance</b>	<b>Form:</b> Liquid <b>Colour:</b> colourless	-
<b>Odour</b>	No data available	-
<b>pH</b>	8.8	-
<b>Melting/freezing point</b>	No data available	-
<b>Boiling point/boiling range</b>	No data available	-
<b>Flash point</b>	No data available	-
<b>Evaporation rate</b>	No data available	-
<b>Flammability (solid, gas)</b>	No data available	-
<b>Flammability Limits in Air</b> <b>upper flammability limit</b> <b>lower flammability limit</b>	No data available	-
<b>Vapor pressure</b>	No data available	-
<b>Vapor density</b>	No data available	-
<b>Relative density</b>	No data available	-
<b>Water solubility</b>	No data available	-
<b>Solubility in other solvents</b>	No data available	-
<b>Partition coefficient: n-octanol/water</b>	No data available	-
<b>Autoignition temperature</b>	Not determined	-
<b>Decomposition temperature</b>	No data available	-
<b>Viscosity, kinematic</b>	No data available	-

<u>Property</u>	<u>Values</u>	<u>Notes</u>
Explosive properties	No data available	-

## 9.2. Other information

No data available

## 10. STABILITY AND REACTIVITY

### 10.1. Reactivity

No information available.

### 10.2. Chemical stability

Stable under recommended storage conditions.

### 10.3. Possibility of hazardous reactions

None under normal processing.

### 10.4. Conditions to avoid

No information available.

### 10.5. Incompatible materials

None known based on information supplied.

### 10.6. Hazardous decomposition products

None known based on information supplied.

## 11. TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

#### Acute toxicity

<b>Product Information</b>	Product does not present an acute toxicity hazard based on available information.
<b>Inhalation</b>	There is no data available for this product.
<b>Eye contact</b>	May cause eyes irritation.
<b>Skin contact</b>	May cause skin irritation.
<b>Ingestion</b>	There is no data available for this product.

#### Chronic toxicity

<b>Corrosivity</b>	There is no data available for this product.
<b>Sensitization</b>	There is no data available for this product.
<b>Neurological effects</b>	There is no data available for this product.
<b>Reproductive toxicity</b>	There is no data available for this product.
<b>Mutagenic effects</b>	There is no data available for this product.
<b>Target Organ Effects</b>	There is no data available for this product.

## 12. ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecotoxicity effects:** As supplied, the preparation is not expected to present significant adverse environmental effects.

### 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

No information available.

### 12.7 Other adverse effects

No information available.

## 13. DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

**Waste from residues/unused products:** Dispose of in accordance with local regulations.

**Contaminated packaging:** Do not reuse empty containers. Empty containers should be taken to an approved waste handling site for recycling or disposal.

## 14. TRANSPORT INFORMATION

### ADR / IATA / DOT / IMDG

Not classified as dangerous in the meaning of transport regulations.

### 14.1. UN number

Not regulated

### 14.2. UN proper shipping name

Not regulated

### 14.3. Transport hazard class(es)

Not regulated

### 14.4. Packing group

Not regulated

### 14.5. Environmental hazard

Not applicable

### 14.6. Special precautions for user

None

## 15. REGULATORY INFORMATION

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

## European Union

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII) None

### Persistent Organic Pollutants

Not applicable.

### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable.

### International Inventories

TSCA	Contact supplier for inventory compliance status
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AICS	Contact supplier for inventory compliance status

Legend:

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

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

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

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

### 15.2. Chemical safety assessment

No information available.



## 16. OTHER INFORMATION

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 and Regulation (EC) No. 2020/878

Last revision date                    29-Sep-2023  
Prepared by                            STAB VIDA  
Revision note                         Contact [drvida@stabvida.com](mailto:drvida@stabvida.com) for latest revision.

### Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text. 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 OF FITNESS FOR ANY PARTICULAR PURPOSE.

--- END OF SAFETY DATA SHEET ---