



MATERIAL SAFETY DATA SHEET

In accordance with EU Regulation (EC) No 1272/2008 and Annex II 2020/878.

Revision notes compared to previous version:

Version	Description of the modification
01	Creation
02	- Addition of the subsection 11.2 Information on other hazards - Addition of gloves breakthrough time

Manufacturer/Supplier	LaCAR MDx technologies SA
Address	LaCAR MDx technologies Liège Science Park Rue des Chasseurs Ardennais,10 4031 Liège Belgium
Contact	+32 4 287 39 44 customer@lacar-mdx.com

24 reactions	
LC-FII-LP	2X Lysis Buffer 1X Reaction Buffer 1X Ctrl Positive 1X Ctrl Negative
LC-FVL-LP	
LC-MTHFR-LP	
LC-FII&FVL-LP	
LC-Lacl-LP	
LC-2ndMTHFR-LP	
LC-HLAB27-LP	
LC-LaclDuplex-LP	
LC-HLAB27direct-LP	
LC-Hbs/C-LP	
LC-PAI1-LP	
LC-HFE-LP	
LC-CYP2C9-LP	2X Lysis Buffer 4X Reaction Buffer 1X Ctrl Positive 1X Ctrl Negative
LC-DPD4mut-LP	2X Lysis Buffer 3X Reaction Buffer 1X Ctrl Positive 1X Ctrl Negative
LC-HLACD-LP	2X Lysis Buffer 1X Ctrl Positive 1X Ctrl Negative
LC-CYP2C19-LP	
LC-TPMT-LP	

96 reactions		
LC-FII-LP	2X Lysis Buffer 2X Reaction Buffer 1X Ctrl Positive 1X Ctrl Negative	
LC-FVL-LP		
LC-MTHFR-LP		
LC-FII&FVL-LP		
LC-Lacl-LP		
LC-2ndMTHFR-LP		
LC-HLAB27-LP		
LC-LaclDuplex-LP		
LC-Hbs/C-LP		
LC-HFE-LP		2X Lysis Buffer 4X Reaction Buffer 1X Ctrl Positive 1X Ctrl Negative
LC-HLAB27direct-LP ^{a)}		2X Reaction Buffer 1X Ctrl Positive 1X Ctrl Negative
LC-DPD4mut-LP		2X Lysis Buffer 8X Reaction Buffer 1X Ctrl Positive 1X Ctrl Negative
LC-HLACD-LP ^{a)}	6X Reaction Buffer 1X Ctrl Positive 1X Ctrl Negative	
LC-SMA-LP ^{a)}	2X Reaction Buffer 1X Ctrl Positive	

a) No lysis buffer is provided within the kit. However, the lysis buffer is required to perform the test. Thus, the lysis buffer shall be ordered separately under the reference LC-LB (Lysis Buffer)

1. SECTION 1: IDENTIFICATION OF THE MIXTURE AND THE COMPANY

1.1 Product identifier

See the first page for the products list and their composition.

REACH Reg. number: Not relevant (mixture)

1.2 Relevant identified uses and uses advised against

Identified uses: In vitro diagnostic use only

1.3 Safety data sheet supplier details

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Liège Science Park
Rue des Chasseurs Ardennais,10
4031 Liège, Belgium
Tel: +32 (0) 4 287 39 44
E-mail: customer@lacar-mdx.com

1.4 Emergency telephone number

Call your local emergency center.

International: +1 703 527 3887

2. SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture


The lysis buffer contains potassium hydroxide KOH.

According to the EU Regulation (EC) No 1272/2008, the potassium hydroxide (KOH) is classified as dangerous.

No other chemicals contained in the kit are classified as hazardous. Nevertheless, all materials provided with the kit need to be manipulated with appropriate precautions and good practices required in a laboratory.

Hazardous ingredient	CAS No EC No	Classification according to Regulation EC No 1272/2008	Signal word	Specific Conc. Limits (%)
Potassium hydroxide KOH	CAS No: 1310-58-3 EC No: 215-181-3	Acute tox. 4 Skin corr. A1	Danger	Skin Irrit. 2; H315: 0,5 % ≤ C < 2 % Eye Irrit. 2; H319: 0,5 % ≤ C < 2 % Skin Corr. 1A; H314: C ≥ 5 % Skin Corr. 1B; H314: 2 % ≤ C < 5 %

2.2 Label elements

Substance	Hazard pictogram	Signal word	Hazard statement code(s)	Precautionary statement
Potassium hydroxide KOH (CAS No: 1310-58-3 EC No: 215-181-3)	 GHS07	Danger	H315: Causes skin irritation. H319: Causes serious eyes irritation.	P280: Wear protective gloves/eye protection/face protection. P264: Wash skin thoroughly after handling. 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. P362+P364: Take off contaminated clothing and wash before reuse. P332 + P313: If skin irritation occurs: Get medical advice/attention.

2.3 Other hazards

Not known.

3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance

Not applicable.

3.2 Mixtures

CAS No	EC No	Index No.	% [weight]	Substance name	Classification 1278/2008	SCL, M-factor, ATE
1310-58-3	215-181-3	019-002-00-8	1,64	Potassium hydroxide KOH	Acute tox. 4 Skin corr. A1	Skin Irrit. 2; H315: 0,5 % ≤ C < 2 % Eye Irrit. 2; H319: 0,5 % ≤ C < 2 %

4. SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General note: In case of concern, or if symptoms persist, call a doctor/physician.

Following inhalation: Move to fresh air. Get medical attention if any discomfort occurs.

Following skin contact: Wash contact areas with soap and water. Get medical attention if irritation develops or persists.

Following eye contact: Immediately flush eyes with plenty of water for at least 15 minutes. If irritation occurs, get medical assistance.

Following ingestion: Rinse mouth thoroughly with water and give large amounts of milk or water, if the person is conscious. Never give anything by mouth to an unconscious person. Get medical attention if any discomfort continues.

Self-protection of the first aider: Ensure that the medical personnel are aware of the material(s) involved and take precautions to protect themselves.

4.2 Most important symptoms and effects, both acute and delayed

No symptoms known up to now, not applicable.

4.3 Indication of any immediate medical attention and special treatment needed

First aid, symptomatic treatment.

5. SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide (CO₂).

Unsuitable extinguishing media: There are no common extinguishing agents inappropriate.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: no hazardous combustion products are contained in the mixture.

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid inhalation and contact with skin and eyes.

Wear appropriate protective equipment and clothing during clean-up. See section 8 of the MSDS for personal protective equipment.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

For containment: Stop the flow of material if this is safe to do so.

For cleaning up: Flush the place of release abundantly with running water and wash away into sewer if permitted or absorb with blotting paper and throw in a container provided for waste. Ventilate the exhibit area to dissipate residual vapors.

Never return spills to original containers for re-use.

Other information: No other information.

6.4 Reference to other sections

Observe protective measures in sections 7, 8 and 13.

7 SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice for safe handling: Avoid inhalation and contact with skin or eyes. Wear approved safety gloves. Observe good laboratory hygiene practices.

Measures to prevent fire: General measures of preventive fire protection.

7.2 Conditions for safe storage, including any incompatibilities

No technical protective measures are necessary. Store in closed original container. Keep container tightly closed.

7.3 Specific end use(s)

Observe instructions for use.

8 SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The mixture does not contain substances above concentration limits fixing and occupational exposure limit.

8.2 Exposure controls

Personal protective equipment: Wear goggles and a lab coat. Work in well-ventilated rooms.

Hand protection: Use gloves when handling solutions.

Substances contained in the product have no effect on the gloves. Wearing gloves is mainly to prevent contamination from operator to the product.

Gloves used by LaCAR have the following characteristics:

1. Glove material: Nitrile
2. Glove thickness (cuff): 0.09 mm
3. Glove thickness (finger): 0.18 mm
4. Breakthrough time: >30 min.

9 SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Color	Colorless
Odor	Odorless
Melting point/freezing point	No data available
Boiling point	No data available
Flammability	Non flammable
Lower and upper explosion limit	No data available
Flash point	No data available
Auto-ignition temperature	Does not ignite
Decomposition temperature	No data available
pH	No data available
Viscosity	No data available
Solubility	No data available
Partition coefficient n-octanol/water	No data available
Vapor pressure	No data available
Density	No data available
Relative vapor density	No data available
Particle characteristics	Not applicable to liquid

9.2 Other information

No data available.

10 SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No hazardous reaction known.

10.2 Chemical stability

This product is stable, no dangerous decomposition products known.

10.3 Possibility of hazardous reactions

There is no hazardous polymerization/reaction for the intended use.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Respect the expiration date and the instructions provided with the kit. None known.

11 SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity: No acute toxicity.

Skin corrosion/irritation: A concentration between 0.5% and 2% potassium hydroxide causes skin irritation.

Serious eye damage/irritation: A concentration between 0.5% and 2% potassium hydroxide causes eye irritation.

Respiratory or skin sensitization: No sensitizing.

Germ cell mutagenicity: No evidence of mutagenic activity.

Carcinogenicity: No known carcinogenic chemicals are contained in this product.

Reproductive toxicity: The mixture does not contain any substances that are classified as toxic for reproduction.

STOT-single exposure: No data available.

STOT-repeated exposure: No data available.

Aspiration hazard: No data available.

11.2 Information on other hazards

11.2.1 **Endocrine disrupting properties:** Not listed.

11.2.2 **Other information:** No other information.

12 SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Comply with local environmental regulations.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No bioaccumulative potential.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

There are no PBT/vPvB substances contained in the mixture.

12.6 Endocrine disrupting properties

No data available.

12.7 Other adverse effects

No data available.

13. SECTION 13: Disposal considerations

13.1 Waste treatment methods:

Waste codes: Not regulated.

Disposal instructions: Disposal recommendations are based on material as supplied. Disposal must be in accordance with current applicable laws and regulations, and material characteristics at time of disposal.

Since emptied containers may retain product residue, follow the label warnings even after container is emptied.

Waste of residues: Dispose in accordance with local regulations.

14. SECTION 14: Transport information

14.1 **UN number or ID number:** Not applicable

14.2 **UN proper shipping name:** Not applicable

14.3 **Transport hazard class(es):** None

14.4 **Packing group:** Not applicable

14.5 **Environmental hazards:** Not applicable

14.6 **Special precautions for user:** None

14.7 **Maritime transport in bulk according to IMO instruments:** Not applicable

15. SECTION 15: Regulatory information

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

EU regulations: REACH regulation (EC) No1907/2006 in its latest version

CLP regulation (EC) No 1272/2008 in its latest version

National regulations: Refer to the national legal regulation.

15.2 Chemical safety assessment

For these mixtures no chemical safety assessment has been carried out.

16. SECTION 16: Other information

(i) Indication of changes: See front page.

(ii) Abbreviations and acronyms:

CAS Chemical Abstracts Service (division of the American Chemical Society)

CLP Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

EC European Committee

IMO International Maritime Organisation

PBT Persistent, Bioaccumulative and Toxic

REACH Regulation (EC) 2020/878 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

STOT Specific Target Organ Toxicity

UN United Nations

vPvB very Persistent and very Bioaccumulative

(iii) Key literature references and sources for data:

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

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

Hazard calculation for the mixture has been performed as a cumulative assessment in accordance with 1272/2008 Annex I, where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI.

DISCLAIMER

This MSDS completes but does not replace the technical instructions for use. The information that it contains is based on our present knowledge about the product concerned on the day it was updated. It does not represent any guarantee of the properties of the product. We also draw the user's attention to the risks that may be run when a product is used for uses other than the ones for which it was designed. In no event does this MSDS dispense the user from knowing and applying all the legislation that regulates his activity. The sole aim of all the regulatory provisions mentioned herein is to help the recipient to satisfy the obligations incumbent upon him when using a dangerous product. This list must not be considered exhaustive. It does not relieve the user from ensuring that he must meet other obligations under texts other than those mentioned in this MSDS, which govern the possession and use of the product, for which he is solely responsible.