MATERIAL SAFETY DATA SHEET (MSDS)

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

1.1. Product identifier

Product name: ***Listeria* MonlabTest (MO-804025)**
Composition: Test + Sample diluent

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

Relevant identified uses:

- TEST: Medical device for professional in vitro diagnostic use only. Use for detection of *Listeria* in stool samples, indicative of listeriosis.
- SAMPLE DILUENT: Use for Listeria antigens extraction from stool samples. This buffer is only provided with the product which has to be used (*Salmonella* Test).

Uses advised against: No information available

1.3. Company/undertaking identification

MONLAB, SL
Selva de Mar, 48
08019 Barcelona (Spain)
Telephone +34 93 433 58 60
Fax +34 93 436 38 94

1.4. Emergency telephone number: 112 (EU)

SECTION 2: HAZARD IDENTIFICATION

2.1. Classification of the substance or mixture: Non-hazardous preparation (Directive 1999/45/EC).

2.1.1. Classification according to Regulation (EC) No 1272/2008 [CLP]: Non-hazardous.

2.1.2. Classification according to Directive 1999/45/EC: Non-hazardous.

2.1.3. Additional information: See SECTION 16.

2.2. Label elements

Signal Word: None

2.3. Other hazards: No information available

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Substances: No information available.

3.2. Mixtures

Mixture description: Contains biological buffer, salt, detergent and <0.1% of sodium azide as preservative.
Hazardous components: No information available.

NOTE: Sample diluent is not dangerous preparation (Directive 1999/45/EC).
The device consists in a strip composed of several layers: an absorbent material pre-dryed with a coloured latex-antibodies conjugate against the product antigens, a nitro-cellulose membrane with coated antibodies against the product antigens and cellulose absorbent. Contains sodium azide as preservative.

For full text of R-phrases and H-phrases: see SECTION 16.

SECTION 4: FIRST-AID MEASURES

4.1. Description of first aid measures

- **Following eye contact**: Rinse thoroughly with plenty of water for at least 15 minutes. Consult a physician.
- **Following skin contact**: Wash off immediately with soap and plenty of water. Consult a physician.
- **Following ingestion**: Clean mouth with water and drink afterwards plenty of water. Consult a physician.
- **Following inhalation**: Ensure sufficient ventilation of workplace. Consult a physician.

4.2. Most important symptoms and effects, both acute and delayed: No information available.

4.3. Indication of any immediate medical attention and special treatment needed: Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

- **Suitable Extinguishing Media**: Water or CO_2. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- **Extinguishing media which must not be used for safety reasons**: No information available.

5.2. Special hazards arising from the substance or mixture: Thermal decomposition can lead to release of irritating gases and vapors.

5.3. Advice for firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures: Prevent contact with skin, eyes and clothes. Use personal protective equipment. Ensure adequate ventilation.

6.2. Environmental precautions: Given the way dispensation there is no possibility of accidental spillage in sufficient quantity to be dangerous. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up: Soak up with inert absorbent material. Clean contaminated surface thoroughly.

6.4. Reference to other sections: If appropriate Sections 8 and 13 shall be referred to.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling: Good Laboratory Practices (disposal gloves). Not to eat, drink and smoke in work areas. Avoid contact and contamination with skin, eyes and clothes. Use disposal gloves.

7.2. Conditions for safe storage, including any incompatibilities: Store in a dry place at +2ºC to +30ºC. Avoid storage near to heat sources.

7.3. Specific end use(s): Only use provided diluent for sample dilution.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters: Any specific protection and prevention measures should not be taken during use of the product.

Exposure limits: No information available.

8.2. Exposure controls: All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

Personal protective equipment: Handle with disposable gloves (EN 374), wear appropriate protective safety eyewear and clothing, such as a lab coat.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance/Physical State Test: White solid with yellow lines. Solid reaction strip that could be placed into a plastic cassette depending on the format used.
Sample diluent: Transparent slightly yellowish.

Odor	No information available	**Explosion Limits**	No data available
pH	No data available	**Vapor Density**	No data available
Boiling Point	No data available	**Relative density**	No data available
Flash Point	No data available	**Solubility**	No data available
Vapor Pressure	No data available	**Flammability**	No data available
Melting Point	No data available	**Viscosity**	No data available
Autoignition Temperature	No data available	**Explosive Properties**	No data available
Partition Coefficient (n-octanol/water)	No data available	**Oxidizing Properties**	No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. **Reactivity**: No known hazardous reactivity.

10.2. **Chemical stability**: Under storage at normal ambient temperatures the product is stable. No known hazardous reactions.

10.3. **Possibility of hazardous reactions**: None known.

10.4. **Conditions to avoid**: Direct contact with a flame. Temperatures outside the range of 2-30 ° C. Avoid storing in places with high humidity.

10.5. **Incompatible materials**: The stool sample should be treated only with buffer that is provided with the product before testing.

10.6. **Hazardous decomposition products**: No known hazardous decomposition products.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. **Information on toxicological effects**

- **Acute toxicity:** Product does not present an acute toxicity hazard based on known or supplied information Oral DL_{50} Rat: 27mg/kg; Dermal LD_{50} Rabbit: 20mg/kg.
- **Skin corrosion/irritation:** No data available.
- **Serious eye damage/irritation:** No data available.
- **Respiratory or skin sensitisation:** No data available.
- **Germ cell mutagenicity:** No data available.
- **Carcinogenicity:** A4-Not classifiable as a Human Carcinogen.
- **Reproductive toxicity:** No data available.
- **Summary of evaluation of the CMR properties:** No data available.
- **STOT-single exposure:** No data available.
- **STOT-repeated exposure:** No data available.
- **Aspiration hazard:** No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. **Toxicity**: No data available. The product should be discarded in a proper biohazard container after testing. Do not allow product to reach ground water, water bodies or sewage system.

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 data available for assessment.

12.6. **Other adverse effects**: No information available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

- **Waste from Residues:** After testing, the product must be disposed of compliance with the respective national regulations. One option would be possible inactivation of infectious agents in the product after use. Performed in autoclave at a pressure and a certain temperature.
- **Non-contaminated packaging:** The containers can be recycled.

SECTION 14: TRANSPORT INFORMATION

- **Maritime transport (IMDG/IMO):** Not dangerous preparations not required transport regulations.
- **Land transport (ADR):** Not dangerous preparations not required transport regulations.
- **Air Transport (IATA):** Not dangerous preparations not required transport regulations.

SECTION 15: REGULATORY INFORMATION

15.1. **Safety, health and environmental regulations/legislation specific for the substance or mixture**: This product does not require special labelling, in accordance with the appropriate EC directives. These products are used for in vitro diagnosis, so they must meet the criteria described in Directive 98/79/CE, do not carry the CE marking for marketing outside the EU.
National Regulations: Please ask your national/regional authorities.

15.2. **Chemical Safety Assessment**: A Chemical Safety Assessment/Report has not been conducted.

SECTION 16: SECTION 16: OTHER INFORMATION

- **Recommendations:** Consult instructions for use prior to product use. Professional use only for *in vitro* diagnosis.
- **References:** RD 255/2003, of February 28, approving the Regulation on classification, packaging and labeling of dangerous preparations, which incorporates into Spanish law Directive 1999/45/CE, Directive 2001/60/CE and partly Directive 2001/58/CE. Directive 91/155/CE.
- **Contact:**
  MONLAB, SL Selva de Mar 48 08019 Barcelona (Spain)
  Tel. +34 93 433 58 60 Fax: +34 93 436 38 94 email: mn.mk.calidad@monlab.com