



SECTION 1: IDENTIFICATION

Product Name: Medonic™ M-Series Lyse
Part Number: 501-212

Application of the substance / mixture: For In Vitro Diagnostic Use

Manufacturer/Supplier

Address: Produced for Boule Medical AB by:
Clinical Diagnostic Solutions, Inc.
1800 NW 65th Avenue
Plantation FL, 33313, USA
www.boule.se

Phone No: +1 954 791 1773

Fax No: +1 954 791 7118

SECTION 2: HAZARD(S) IDENTIFICATION

Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910

This mixture does not have any hazardous classification.

The mixture has been reviewed in accordance with 29 CFR 1910. The product does not contain any substances at concentrations considered to be hazardous to human health or the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CAS-No.	Component	Classification	Concentration
-	Proprietary Mixture	-	-

SECTION 4: FIRST AID MEASURES

Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact



Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Most important symptoms and effects, both acute and delayed

None

Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: FIREFIGHTING MEASURES

• Suitable extinguishing agents

Dry chemical, carbon dioxide (CO₂), water spray or regular foam.

- Caution: CO₂ will displace air in confined spaces and may cause an oxygen-deficient atmosphere.

• Special hazards arising from the substance or mixture

There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.

SECTION 6: ACCIDENTAL RELEASE MEASURES

• Personal precautions, protective equipment and emergency procedures

Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible. Keep unprotected people away.

• Environmental precautions

Prevent liquid from entering sewage system, storm drains, surface waters, and soil.

• Methods and material for containment and cleaning up

Block small volumes of spilled or spattered product with paper towels or similar materials.

- Contain larger spills by placing absorbents around the outside edges of the spill. Absorb with any material Suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:

- Detergent or similar cleansing agent.

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

SECTION 7: HANDLING AND STORAGE

• **Precautions for safe handling:** Use personal protective equipment required by the Laboratory.

• **Measure to prevent fire:** No special measures required.

• **Storage requirements:** Store only in the original container. Store in a cool (5 - 35 °C), dry place away from away from heat and direct sunlight.

• **Further information about storage conditions:** Protect from heat and direct sunlight.



SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with Occupational Exposure Limits

Substance name	Concentration	CAS No	Occupational exposure limits
None listed			

Exposure controls

Personal protective equipment

Always maintain good housekeeping and follow general precautionary measures. Do not eat, drink or store food and beverages in areas where chemicals or specimens are used. Wash hands before breaks, after handling reagents and specimens, and at the end of the work shift.

· Breathing equipment:

Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

Small-volume spills (e.g. small enough to clean up with a paper towel or small sorbent pad) - respiratory protection should not be necessary if room is well ventilated.

Hazardous Materials Emergencies or Firefighting - use NIOSH/NFPA-approved respiratory protection.

· Hand protection:

Wear water-resistant gloves if hand contact with the material is anticipated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

· Material of gloves and breakthrough time of the glove material:

The glove material must be suitable for use in a clinical chemistry laboratory and have a measured breakthrough time of at least 30 minutes, such as those with a Class 2 protection index per EN374 (or equivalent standard applicable in your region). NOTE: This recommendation applies only to the product stated in this Safety Data Sheet. When dissolving in or mixing with other substances, contact the supplier of approved gloves.

· Eye protection:

Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

· Body protection:

Normal use: protect personal clothing from spatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution). Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.



SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Property	Value
Physical state	Liquid
Color	Tinted yellow
Odor	Odorless
pH-value at 20 °C (68 °F)	7.0
Melting point	Not determined
Boiling point	Not determined
Flash point	Not applicable
Flammability (solid, gas)	Non flammable
Auto igniting	Product is not self-igniting.
Danger of explosion	Product does not present an explosion hazard.
Vapor density	Not applicable
Density at 20 °C (68 °F)	1 g/mL
Solubility in water	Completely soluble

SECTION 10: STABILITY AND REACTIVITY

- **Thermal decomposition / conditions to be avoided**
No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions:** Reacts with strong acids and bases.
- **Conditions to avoid:** Sunlight, warmth, heat and fire.
- **Incompatible materials:** Strong acids and bases.
- **Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

Acute toxicity

No data available

Dermal

No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity



No data available

SECTION 12: ECOLOGICAL INFORMATION

- **Toxicity:** No further relevant information available.
- **Marine pollutant:** No
- **Additional Ecological Information**
- **General notes:** Do not allow undiluted product or large quantities of it to reach ground water, water course, or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable
- **vPvB:** Not applicable

SECTION 13: DISPOSAL CONSIDERATIONS

Recommendation for disposal of unused product:

Dispose in accordance with federal, state and local regulations.

Recommendation for disposal of packaging:

Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and Institutional policies.

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

- Recommended cleansing agent: Water with cleansing agents, if necessary.

SECTION 14: TRANSPORT INFORMATION

DOT (US):

Not dangerous goods

IMDG:

Not dangerous goods

IATA:

Not dangerous goods

SECTION 15: REGULATORY INFORMATION

- **SARA 302/304 (40CFR355.30 / 40CFR355.40):**
The product does not contain listed substances.
- **SARA 313 (40CFR372.65):**
The product does not contain listed substances.

SARA 311/312 Hazards

No SARA Hazards

- **California Proposition 65 (USA):**
- **Chemicals known to cause cancer:**
The product does not contain listed substances.
- **Chemicals known to cause female reproductive toxicity:**
None of the ingredients is listed.
- **Chemicals known to cause male reproductive toxicity:**



None of the ingredients is listed.

• **Chemicals known to cause developmental reproductive toxicity:**

None of the ingredients is listed.

Pennsylvania Right to Know Components

Tetradonium Bromide	CAS 1119-97-7
Sodium dihydrogenorthophosphate monohydrate	CAS 10049-21-5
Disodium hydrogenorthophosphate	CAS 7558-79-4
Sodium Sulfate	CAS 7757-82-6
Sodium Chloride	CAS 7647-14-5
Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS 55965-84-9
Dodecyltrimethylammonium chloride	CAS 112-00-5

New Jersey Right to Know Components

Tetradonium Bromide	CAS 1119-97-7
Sodium dihydrogenorthophosphate monohydrate	CAS 10049-21-5
Disodium hydrogenorthophosphate	CAS 7558-79-4
Sodium Sulfate	CAS 7757-82-6
Sodium Chloride	CAS 7647-14-5
Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS 55965-84-9
Dodecyltrimethylammonium chloride	CAS 112-00-5

Massachusetts Right to Know Components

Disodium hydrogenorthophosphate	CAS 7558-79-4
Sodium Sulfate	CAS 7757-82-6

SECTION 16: OTHER INFORMATION

Abbreviations and acronyms

CAS No:	Chemical Abstracts Service number.
CMR properties:	Carcinogenic, Mutagenic or toxic for Reproduction
STOT SE	Specific target organ toxicity - single exposure
LC ₅₀ :	Lethal Concentration. In ecotoxicology, the LC ₅₀ is the concentration which kills 50 % of a population of one species, within a specified period of time.
LD ₅₀ :	Lethal Dose. The LD ₅₀ is the dose of a substance which kills 50 % of a population of one species and is expressed as weight (mg, g) or as weight per weight of test animal (mg/kg).
pH:	pH is a measure of the acidity or basicity of an aqueous solution.
pKa:	The symbol for the acid dissociation constant at logarithmic scale.
ppm:	parts per million.
vPvB substance:	Very persistent and very bioaccumulative substance.
WEL:	Workplace Exposure Limits.

• **Contact**

General information about this product:
Clinical Diagnostic Solutions, Inc.
1800 NW 65th Ave.
Plantation, FL 33313