1. IDENTIFICATION OF SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product Name: VLyte Reagent Pack
Product Code: OEM-VT-EN-001
Product Line: OEM Product Line

Relevant identified uses of the substance or mixture and uses advised against:
Relevant identified uses: For diagnostic use only.

Supplier: Sensa Core Medical Instrumentation Pvt Ltd,
Plot No.3, Export Promotion Industrial Park,
Telangana, INDIA

Emergency Telephone Number: +91 – 8455 – 223400

2. HAZARDS IDENTIFICATION

This Reagent pack is not identified as dangerous but may cause severe irritation and harmful if swallowed or inhaled.

Potential Acute Health Effects: Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of inhalation.

Potential Chronic Health Effects: Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of inhalation.

CARCINOGENIC EFFECTS: Not available.
MUTAGENIC EFFECTS: Not available.
TERATOGENIC EFFECTS: Not available.
DEVELOPMENTAL TOXICITY: Not available

Adverse Human Health: Causes skin and serious eye damage.

Effects and Symptoms:
- Material may be irritating to the mucous membranes and upper respiratory tract.
- May be harmful by inhalation, ingestion, or skin absorption.
- May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- May cause respiratory system irritation.
- To the best of our knowledge, the toxicological properties have not been thoroughly investigated.
3. COMPOSITION/INFORMATION OF INGREDIENTS

This product does not contain any ingredients considered hazardous by OSHA.

Description 1 : Basic Calibrator (Cal A) 800 ml
Electrolytes, Buffer, Preservative in aqueous solution.

Description 2 : Acidic Calibrator (Cal B) 280 ml
Electrolytes, Buffer, Preservative in aqueous solution.

4. FIRST AID MEASURES

Inhalation : Discontinue the exposure, remove casualty to fresh air, keep at rest and seek medical advice.
Skin Contact : Take off all contaminated clothing. After contact with skin, wash immediately with soap and water.
Ingestion : Rinse mouth with water, drink 1/2 liter of lukewarm water, seek medical attention immediately, do not induce vomiting.
Eye Contact : In case of Contact with eyes, rinse immediately with plenty of water and seek medical advice.

Notes to Physician: None Determined.

5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media : Use Water Spray or Alcohol Foam.
Unusual Hazards : None Known.

Special Protective Equipment for Fire Fighters: Wear self contained breathing apparatus for firefighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions : Use personal protective equipment. Evacuate personnel to safe areas.
Environmental Precautions : Prevent further leakage or spillage if safe to do. Prevent product from entering drains.
Methods for Cleaning up : Never return spills in original container for reuse. Sweep up or vacuum (if powder) or soak up with Absorbent material (if liquid), then place into a suitable clean, dry, closed container, and label disposal.

7. HANDLING AND STORAGE

Handling : Handle in accordance with good industrial hygiene and safety practice and Protect from contamination.
Storage : Store in accordance with information listed on the product insert.
Other Precautions : Light Sensitive
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Measures: Use process enclosures, local exhaust ventilation, or other engineering controls to control levels below recommended exposure limits.

Personal Protective Equipment

Respiratory protection: Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow the OSHA regulation, 29CFR1910.134. Always use a NIOSH approved respirator when necessary.

Hand protection: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Skin and body protection: Wear appropriate body protection to prevent skin contact.

Eye protection: Wear appropriate eye protection to prevent eye contact.

Hygiene measures: Avoid contact with skin, eyes and clothing.

Work/Hygienic/ Maintenance: Do not take internally.

9. PHYSICAL AND CHEMICAL PROPERTIES

Odor: Odorless

Physical state: Liquid

Solubility in water: Soluble

Color: Colorless

pH: 7.0

Melting point / freezing point: No information available

Initial boiling point and boiling range (°C): No information available

Flash point (°C): No information available

Evaporation rate: No information available

Flammability (solid, gas): No information available

Upper/lower flammability or explosive limits: No information available

Vapour pressure: No information available

Vapour density: No information available

Relative density (kg.m-3): No information available

Explosive properties: No information available

Oxidizing properties: No information available

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Polymerization: Not applicable.

Hazardous decomposition products: Carbon oxides.

Materials to avoid: Strong acids and strong bases. Strong oxidizing agents.
11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects: The toxicological effects of this product have not been thoroughly studied.

Carcinogenicity : Not Applicable

Irritation : Repeated or prolonged exposure may cause irritation of eyes and skin

12. ECOLOGICAL INFORMATION

The environmental impact of this product has not been fully investigated

Bioaccumulation : Not determined.
Aquatic toxicity : No data is available
Ecotoxicity effects : No data is available

13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products:

Waste disposal is in accordance with appropriate National, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous.

14. TRANSPORT INFORMATION

Is product hazardous to ship? : No

DOT:

Proper shipping name: None UN Number: N/A Hazard class: N/A Packing group: N/A

ICAO/IATA:

Proper shipping name: None UN Number: N/A Hazard class: N/A Packing group: N/A

15. REGULATORY INFORMATION

1. Safety, health and environmental regulations/legislation specific for the substance or mixture.
2. The list of chemicals/solutions offered by Sensa Core Medical Instrumentation Pvt Ltd. Products in this list do not require a Safety Data Sheet (SDS).
3. According to OSHA regulations, substances containing more than 1% of a hazardous material or more than 0.1% of an extremely hazardous material require availability of an SDS (VLyte Reagent consists less than 1% hazardous material or less than 0.1% Extremely hazardous material).
4. According to the GHS revision 6.0 we had implemented the above changes of this SDS (Safety data Sheet).
16. OTHER INFORMATION

Reason for revision : According to the GHS Rev.06
References : GHS Rev.06
Additional advice : None
Prepared by : Sensa Core Medical Instrumentation Pvt Ltd, Telangana, India, Phone : +91-8455-223400

The information, data and recommendations contained herein are based upon information believed by Sensa Core Medical Instrumentation’s Operations after reasonable investigation and research, to be accurate; however, Sensa Core Medical Instrumentation’s Operations does not warrant the accuracy of this information. All materials and mixtures may present unknown hazards and should be used with caution. When necessary or appropriate, independent opinions regarding the risk of handling or exposure should be obtained from trained professionals. Sensa Core Medical Instrumentation’s operations disclaim any warranty against patent infringement and the implied warranties of merchantability and fitness for a particular purpose. Customer's sole and exclusive remedy shall be replacement of the product or return of the product and refund of the purchase price, at Sensa Core Medical Instrumentation but, Sensa Core is not responsible for any damages caused by improper use and handling of the product.

Operation's option: In no case shall Sensa Core Medical Instrumentation’s Operations be liable for incidental or consequential damages, including lost profits.

End of Safety Data Sheet

Approved By:

Dr. H. C. B. Kalachar (Ph.D)
Chemistry Department/
Quality Assurance