

| 1. | SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING | | |
|-------|---|---|--|
| 1.1 | Product identifier | | |
| | Product code(s) & Product Name | 640 Monoclonal Rh Control | |
| | CAS No. | Mixture | |
| | EINECS No. | Mixture | |
| | Product Description | A solution of sodium chloride, buffer salts, potentiators and bovine serum albumin. | |
| 1.2 | Relevant identified uses of the substance or mixture and uses advised against | | |
| | Identified Use(s) | Control reagent used with Lorne Rhesus blood grouping reagents. | |
| | Uses Advised Against | Anything other than the above. | |
| 1.3 | Details of the supplier of the safety data sheet | , , | |
| | Company Identification | Lorne Laboratories Ltd | |
| | | Unit 1 Cutbush Park Industrial Estate | |
| | | Danehill | |
| | | Lower Earley | |
| | | Berkshire RG6 4UT | |
| | | United Kingdom | |
| | Telephone | +44(0) 0118 921 2264 | |
| | Fax | +44(0) 0118 986 4518 | |
| | E-Mail (competent person) | Info@lornelabs.com | |
| 1.4 | Emergency telephone number | +44(0) 0118 921 2264 | |
| | | Available 0900 – 1700 (GMT) | |
| | Languages spoken | English | |
| 2. | SECTION 2: HAZARDS IDENTIFICATION | | |
| 2.1 | Classification of the substance or mixture | | |
| 2.1.1 | Regulation (EC) No. 1272/2008 (CLP) | Not classified as hazardous for supply/use. | |
| 2.2 | Label elements | According to Regulation (EC) No. 1272/2008 (CLP) | |
| | Hazard Pictogram(s) | None assigned | |
| | Signal Word(s) | None assigned | |

Precautionary Statement(s)

Hazard Statement(s)

2.3 Other hazards

3.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures Substances in preparations / mixtures

EC Classification Regulation (EC) No. 1272/2008 (CLP)

| Chemical identity of the | %W/W | CAS No. | EC No. | REACH Registration | Hazard Statement(s) |
|--------------------------|------|------------|-----------|-------------------------|-------------------------|
| substance | | | | No. | |
| Sodium Azide | 0.09 | 26628-22-8 | 247-852-1 | Not yet assigned in the | Acute Tox. 2; H300 |
| | | | | supply chain | Aquatic Acute 1; H400 |
| | | | | | Aquatic Chronic 1; H410 |

None assigned

None assigned

None known.



4. SECTION 4: FIRST AID MEASURES 4.1 Description of first aid measures Inhalation Remove from exposure. Remove victim to fresh air and keep at rest in a position comfortable for breathing. Keep warm and at rest. Get medical advice/attention if you feel unwell. Skin Contact Wash affected skin with soap and water. Remove contaminated clothing and wash clothing before reuse. If irritation (redness, rash, blistering) develops, get medical attention. Eye Contact Flush eyes with water for at least 15 minutes while holding eyelids open. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Ingestion Rinse mouth. Give plenty of water to drink. Do not give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell. 4.2 Most important symptoms and effects, both acute None known. and delayed 4.3 Indication of any immediate medical attention and Treat symptomatically. special treatment needed 5. SECTION 5: FIRE-FIGHTING MEASURES 5.1 Extinguishing media Suitable Extinguishing Media Non-flammable. As appropriate for surrounding fire. Water spray, foam, dry powder or CO2. Do not use water jet. Direct water jet may spread the fire. Unsuitable extinguishing Media 5.2 Special hazards arising from the substance or Combustion or thermal decomposition will evolve toxic vapours. mixture 5.3 Advice for fire-fighters Fight fire with normal precautions from a reasonable distance. Fire fighters

6. SECTION 6: ACCIDENTAL RELEASE MEASURES 6.1 Personal precautions, protective equipment and Ensure adequate ventilation. Avoid all contact. Ensure suitable personal emergency procedures protection during removal of spillages. See Section: 8 6.2 **Environmental precautions** Avoid release to the environment. 6.3 Methods and material for containment and cleaning Absorb spillage in suitable inert material. Transfer to a lidded container for disposal or recovery. Ventilate the area and wash spill site after material pick-up up is complete. Avoid release to the environment. 6.4 Reference to other sections See Section: 8, 13

or water courses.

should wear complete protective clothing including self-contained breathing apparatus. Avoid all contact. Do not allow run-off from fire fighting to enter drains

7. SECTION 7: HANDLING AND STORAGE 7.1 Avoid all contact. Use personal protective equipment as required. Ensure Precautions for safe handling adequate ventilation. Keep good industrial hygiene. Wash hands thoroughly after handling. Contaminated clothing should be thoroughly cleaned. 7.2 Conditions for safe storage, including any Keep only in the original container/package in a cool well-ventilated place. Keep incompatibilities away from food, drinks and animal food. Storage temperature Storage temperature should be controlled to between 2 and 8°C. Storage life Keep only in the original container/package in a cool well-ventilated place. Incompatible materials None known. 7.3 Specific end use(s) See Section: 1.2



| 8. | SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION | | |
|-------|---|---|--|
| 8.1 | Control parameters | | |
| 8.1.1 | Occupational Exposure Limits | None assigned. | |
| 8.1.2 | Biological limit value | Not established. | |
| 8.1.3 | PNECs and DNELs | Not established. | |
| 8.2 | Exposure controls | | |
| 8.2.1 | Appropriate engineering controls | Ensure adequate ventilation. Good hygiene practices and housekeeping measures. | |
| 8.2.2 | Individual protection measures, such as personal protective equipment (PPE) | Use personal protective equipment as required. Avoid all contact. Keep good industrial hygiene. Wash hands before breaks and after work. Keep work clothes separately. Wash contaminated clothing before reuse. Do not eat, drink or smoke at the work place. | |
| | Eye/face protection | Not normally required. Recommended: Wear eye protection with side protection (EN166). | |
| | Skin protection | Prolonged, direct contact: Wear impervious gloves (EN374). | |
| | Respiratory protection | Not normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protective equipment should conform to the appropriate EN standard. | |
| 8.2.3 | Thermal hazards Environmental Exposure Controls | None anticipated. Avoid release to the environment. | |

9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

| 9.1 | Information on basic physical and chemical properties | | |
|-----|---|-------------------------|--|
| | Appearance | Liquid, Straw coloured. | |
| | Odour | Not established. | |
| | Odour Threshold | Not established. | |
| | рН | 7 | |
| | Melting Point/Freezing Point | Not established. | |
| | Initial boiling point and boiling range | Not established. | |
| | Flash Point | Not established. | |
| | Evaporation Rate | Not established. | |
| | Flammability (solid, gas) | Not established. | |
| | Upper/lower flammability or explosive limits | Not applicable. | |
| | Vapour pressure | Not established. | |
| | Vapour density | Not established. | |
| | Relative density | Not established. | |
| | Solubility(ies) | Miscible with water. | |
| | Partition coefficient: n-octanol/water | Not established. | |
| | Auto-ignition temperature | Not established. | |
| | Decomposition Temperature | Not established. | |
| | Viscosity | Not established. | |
| | Explosive properties | Not explosive | |
| | | | |



| | Oxidising properties | Not oxidising. | |
|------|--|---|--|
| 9.2 | Other information | None known. | |
| 10. | SECTION 10: STABILITY AND REACTIVITY | | |
| 10.1 | Reactivity | Stable under normal conditions. | |
| 10.2 | Chemical stability | Stable for 24 months after the date of production when stored at between 2 and 8°C. | |
| 10.3 | Possibility of hazardous reactions | None known. Hazardous polymerisation will not occur. | |
| 10.4 | Conditions to avoid | Keep away from heat, sources of ignition and direct sunlight. | |
| 10.5 | Incompatible materials | Strong acids, strong oxidizing agents. | |
| 10.6 | Hazardous decomposition product(s) | Combustion or thermal decomposition will evolve toxic vapours. | |
| 11. | SECTION 11: TOXICOLOGICAL INFORMATI | ON | |
| 11.1 | Information on toxicological effects (Substances in preparations / mixtures) Acute toxicity | | |
| | Ingestion | Based on available data, the classification criteria are not met. | |
| | 3 | Acute Toxicity Estimate Mixture Calculation: LD50 >2000 mg/kg bw/day | |
| | Inhalation | Based on available data, the classification criteria are not met. | |
| | | Acute Toxicity Estimate Mixture Calculation: LD50 >20 mg/l. | |
| | Skin Contact | Based on available data, the classification criteria are not met. | |
| | | Acute Toxicity Estimate Mixture Calculation: LD50 >2000 mg/kg bw/day | |
| | Skin corrosion/irritation | Based on available data, the classification criteria are not met. | |
| | Serious eye damage/irritation | Based on available data, the classification criteria are not met. | |
| | Respiratory or skin sensitization | Based on available data, the classification criteria are not met. | |
| | Germ cell mutagenicity | Based on available data, the classification criteria are not met. | |
| | Carcinogenicity | Based on available data, the classification criteria are not met. | |
| | Reproductive toxicity | Based on available data, the classification criteria are not met. | |
| | STOT - single exposure | Based on available data, the classification criteria are not met. | |
| | STOT - repeated exposure | Based on available data, the classification criteria are not met. | |
| | Aspiration hazard | Based on available data, the classification criteria are not met. | |
| 11.2 | Other information | None known. | |
| 12. | SECTION 12: ECOLOGICAL INFORMATION | | |

| 12.1 | Toxicity | Based on available data, the classification criteria are not met. |
|------|------------------------------------|--|
| | | Estimated LC50 (96 hour) Fish > 100 mg/l |
| 12.2 | Persistence and degradability | Not established. Some of the ingredients are expected to be resistant to |
| | | biodegradation. |
| 12.3 | Bioaccumulative potential | Not established. Predicted to be be unlikely. |
| 12.4 | Mobility in soil | The product has high mobility in soil. Miscible with water. |
| 12.5 | Results of PBT and VPVB assessment | Not classified as PBT or vPvB. None of the substances in this product fulfil the |
| | | criteria for being regarded as a PBT or vPvB substance. |
| 12.6 | Other adverse effects | None known. |
| | | |

13. SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

13.2 Additional Information

Disposal should be in accordance with local, state or national legislation. Empty containers may contain hazardous residues. Containers shall be disposed of by incineration as soon as possible.

SECTION 14: TRANSPORT INFORMATION



Not classified according to the United Nations 'Recommendations on the Transport of Dangerous Goods'. ADR/RID IMDG IATA/ICAO 14.1 UN number None assigned. None assigned. None assigned. 14.2 UN proper shipping name None assigned. None assigned. None assigned. 14.3 Transport hazard class(es) None assigned. None assigned. None assigned. 14.4 Packing group None assigned. None assigned. None assigned. 14.5 **Environmental hazards** Not classified. Not classified. Not classified. 14.6 Special precautions for user See Section: 2 14.7 Transport in bulk according to Annex II of Not applicable. Not applicable. Not applicable. MARPOL73/78 and the IBC Code 14.8 **Additional Information** None. SECTION 15: REGULATORY INFORMATION 15. 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture 15.1.1 EU regulations Authorisations and/or Restrictions On Use None. 15.1.2 National regulations Germany

15.2 Chemical Safety Assessment

Water hazard class: 1 None.

16. SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements: 1-16.

References: Existing Safety Data Sheet (SDS).

This Safety Data Sheet was prepared in accordance with EC Regulation (EC) 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830.

LEGEND

14.

| LTEL | Long Term Exposure Limit |
|------|---|
| STEL | Short Term Exposure Limit |
| DNEL | Derived No Effect Level |
| PNEC | Predicted No Effect Concentration |
| PBT | PBT: Persistent, Bioaccumulative and Toxic |
| vPvB | vPvT: very Persistent and very Toxic |
| OECD | Organisation for Economic Cooperation and Development |

Training advice: Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required.

Disclaimers

Customers are urged to ensure that the product is entirely suitable for their own purpose. It is the customers' responsibility to ensure that a suitable and sufficient assessment of the risks created by the use of the product is undertaken. The use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagent is in use.

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Annex to the extended Safety Data Sheet (eSDS)

Not applicable

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ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830



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