

SAFETY DATA SHEET



In accordance with Regulation (EC) No 1907/2006
Revision date: 18/05/2015
Version number: 03

1. Identification of the substance or preparation and the company/ undertaking

1.1 Product Identifier

Product Name: MASTALEX™RA80

Product Code: RST601/ RST602

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

Recommended uses: *In vitro* diagnostic product; Laboratory chemical

Uses advised against: No information available

1.3 Details of supplier of the product and safety data sheet

Manufacturer/supplier: Mast Group Ltd., Mast House,
Derby Road,
Bootle,
Merseyside,
UK.
L20 1EA
Telephone: +44 (0) 151 933 7277
Email: uksales@mastgrp.com
Web: www.mastgrp.com

2. Hazards identification

2.1 Classification of the substance or mixture

CLP Classification – Regulation (EC) No. 1272/2008: Not hazardous. All hazardous components are present below a level requiring hazard labelling.

Physical hazards: Based on available data, there are no physical hazards

Health hazards: Based on available data, there are no health hazards

Environmental hazards: Based on available data, there are no environmental hazards

2.2 Label elements

Pictogram: None

Signal word: None

Hazard statements: None

Precautionary statements: None

2.3 Classification according to EU Directive 67/548/EEC or 1999/45/EC

Hazard symbol: None

R-phrases: None

S-phrases: None

2.4 Other hazards

The kit positive control contains donor human serum and the latex reagent is coated with purified human IgG. Each donor used in its preparation has been tested by FDA approved methods for the presence of HIV antibodies and HBs and HCV antigens and found to be negative.

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3. Composition/information on ingredients

Composition: A multi-component diagnostic kit, containing antibody coated latex reagent, positive and negative controls, diluent, test cards and mixing sticks. RST602 contains antibody coated latex reagent only. The latex reagent and controls contain 0.095% sodium azide as preservative.

Hazardous ingredients:

Component	CAS-No.	EC-No.	Concentration	CLP Classification – 1272/2008/EC	Classification to – 67/548/EEC
Sodium azide	26628-22-8	247-852-1	0.095%	Acute toxicity, Oral Cat. 2; Acute toxicity, Dermal Cat. 1; Acute aquatic toxicity Cat. 1; Chronic aquatic toxicity Cat. 1. H300 + H310 Fatal if swallowed or in contact with skin. H410 Very toxic to aquatic life with long lasting effects. EUH032 Contact with acids liberates very toxic gas.	T+ - Very toxic; N - Dangerous for the environment. R27 Very toxic in contact with skin. R28 Very toxic if swallowed. R32 Contact with acids liberates very toxic gas. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

4. First-aid measures

4.1 Description of First Aid measures

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance.

Eye contact: Rinse thoroughly with plenty of water for 10 to 15 minutes, also under the eyelids. Obtain medical attention if irritation persists.

Skin Contact: Wash off skin thoroughly with soap and plenty of water. Obtain medical attention if irritation persists.

Ingestion: Rinse mouth out with plenty of water. Obtain medical attention if symptoms occur.

Inhalation: Move person to fresh air. Obtain medical attention immediately if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indicate any immediate medical attention and special treatment needed

No information available.

5. Fire fighting measures

5.1 Extinguishing medium

Suitable extinguishing media: Use water spray, CO₂, foam or dry powder as the extinguisher medium.

Extinguishing media which must not be used for safety reasons: No information available

5.2 Special hazards arising from the substance or mixture

Combustible material. Thermal decomposition may lead to release of irritating gases and vapours.

5.3 Advice for firefighters

Wear suitable self contained breathing apparatus for fire fighting if necessary.

5.4 Additional information

No data available.

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6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

None specifically required as provided. In use when using ultra-freezer (minus 60°C to minus 80°C) wear suitable protective gloves and eye protection.

6.2 Environmental precautions

Should not be released into the environment.

6.3 Methods and materials for contamination and cleaning up

Sweep up or vacuum up spillage in suitable container for disposal. Avoid dust formation.

6.4 Further information

No data available.

7. Handling and storage

7.1 Precautions for safe handling

Avoid contact with eyes, skin and clothing. Avoid ingestion and inhalation.

7.2 Conditions for safe storage, including any incompatibilities

Store at unopened packs at 10°C to 25°C. Keep tightly closed in the container provided. Protect from direct sunlight and moisture.

7.3 Specific end use(s)

This product is for laboratory use only and should only be used by suitably trained laboratory personnel.

8. Exposure controls and personal protection

8.1 Control parameters

Components with workspace control parameters: This product contains sodium azide which has the following exposure limit values:
LTEL 0.1mg.m⁻³ ; STEL 0.3mg.m⁻³ ; Sk - EH40/2005 Workplace Exposure Limits (UK)
OELV (8 hr) 0.1mg.m⁻³ ; STEL: 0.3mg.m⁻³ ; Skin - Schedule 1 of 2011 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 (Eire)

8.2 Exposure controls

Engineering controls: No engineering protection required.

Personal protective measures:

Body protection:	Wear standard microbiology laboratory coat.
Eye/face protection:	Safety glasses with side shields conforming to EN 166.
Skin and hand protection:	Handle with suitable gloves conforming to EN 374.
Respiratory protection:	None specifically.

General hygiene measures: Handle in accordance with good laboratory practice.
Wash hands before breaks and at the end of the working day.

Sodium Azide may react with lead and copper plumbing to form highly explosive metal azides.

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9. Physical and Chemical properties

9.1 Information on basic physical and chemical properties

Physical appearance:	Latex reagent and control reagents - liquid.
Odour:	Odourless.
Odour threshold:	Not applicable.
Colour:	Latex reagent - milky white suspension; Control reagents - clear, colourless liquid.
pH value:	Latex reagent - pH 8.2±0.2.
Melting point/freezing point:	No data available.
Initial boiling point/range:	No data available.
Flash point:	No data available.
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Explosive limits:	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	No data available.
Solubility in water:	Soluble in water.
Solubility in other solvents:	No data available.
Partition coefficient (n-octanol/water):	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Vapour density:	No data available.
Explosive properties	This product is not explosive in normal circumstances.
Oxidising properties:	No data available.

9.2 Other information

No data available.

10. Stability and reactivity

10.1 Reactivity

Sodium Azide may react with lead and copper plumbing to form highly explosive metal azides.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

None under normal use conditions.

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11. Toxicological information

11.1 Information on toxicological effects

Overall product information: This product does not present an acute toxicity based on known or supplied information.

11.2 Toxicological data for the components

Acute toxicity: **For solid sodium azide:** LD50 Oral - Rabbit - 10 mg/kg; LC50 Inhalation - Rat - 37 mg/m³
Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: other.
Behavioural: convulsions or effect on seizure threshold. Lungs, Thorax, or Respiration:
Structural or functional change in trachea or bronchi. LD50 Dermal - Rabbit - 20 mg/kg

Skin corrosion/irritation: No data available.

Serious eye damage/ eye irritation: No data available.

Respiratory or skin sensitisation: No data available.

Germ cell mutagenicity: No data available.

Carcinogenicity: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity: No data available.

Specific target organ toxicity – single exposure: No data available.

Specific target organ toxicity – repeated exposure: No data available.

Aspiration hazard: No data available.

Potential health effects: For additional information see RTECS: VY8050000
Sodium azide may cause nausea, headache, Vomiting. Laboratory experiments in animals have shown sodium azide to produce a profound hypotensive effect, demyelination of myelinated nerve fibres in the central nervous system, testicular damage, blindness, attacks of rigidity, and hepatic and cerebral effects. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. Ecological information

12.1 Toxicity

No data available.

For sodium azide - toxicity to daphnia and other aquatic invertebrates. EC50 - Daphnia pulex (Water flea) - 4.2 mg/l - 48 h.

12.2 Persistence and degradability

Expected to be biodegradable.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects.

No data available.

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13. Disposal considerations

Disposal considerations: Dispose of in accordance with local and national regulations.
Dispose of all used contaminated waste, e.g. used plates, according to local microbiological rules.

14. Transport information

14.1 UN Number

ADR/RID: IMDG: IATA: Not dangerous for shipping

14.2 UN proper shipping name

ADR/RID: IMDG: IATA: Not dangerous for shipping

14.3 Transport hazard class(es)

ADR/RID: IMDG: IATA: Not dangerous for shipping

14.4 Packaging group

ADR/RID: IMDG: IATA: Not dangerous for shipping

14.5 Environmental hazards

ADR/RID: IMDG: IATA: None known.

14.6 Special precautions for user

No data available

15. Regulatory information

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

No data available.

15.2 Chemical safety assessment

Chemical safety assessment reports are not required for mixtures/IVD products.

16. Other information

Original origination date: 25/07/1994

Reason for change to document: Updated in accordance with Regulation (EC) No 1907/2006 to incorporate CLP Classification – Regulation (EC) No. 1272/2008 information.

The above information is believed to be correct but does not purport to be all inclusive and shall be used as a guide only. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product and is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. Mast Group Ltd. shall not be held liable for any damage resulting from handling or from contact with the above product. See our website at www.mast.grp.com and/or the reverse side of our invoice for additional terms and conditions of sale.