

In accordance with Regulation (EC) No 1907/2006 Revision date: 17/12/2014 Version number: 04

| 1. Identification of the substance or preparation and the company/ undertaking | | | | |
|--|---|---|---|--|
| 1.1 | Product Identifier | | | |
| | Product Name: | Mast C.E.M.O. Sele | ctatab [™] | |
| | Product Code: | MS60 | | |
| 1.2 | Relevant identified uses of the su | evant 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 | of supplier of the product and safety data sheet | | |
| | Manufacturer/supplier: | Mast Group Ltd., Ma Derby Road, Bootle, Merseyside, UK. L20 1EA Telephone: +44 (0) ⁷ Email: uksales@ma Web: www.mastgrp. | 151 933 7277 stgrp.com | |
| | | 2 | . Hazards identification | |
| 2.1 | Classification of the substance o | r mixture | | |
| | CLP Classification – Regulation (EC) No. 1272/2008: | | | |
| | | Physical hazards: | Based on available data, there are no physical hazards | |
| | | Heath hazards: | Based on available data, there are no health hazards | |
| | Envi | onmental hazards: | Based on available data, there are no environmental hazards | |
| 2.2 | Label elements | | | |
| | | Pictogram: | None | |
| | | Signal word: | None | |
| | I | Hazard statements: | None | |
| | Precau | tionary statements: | None | |
| 2.3 | 3 Classification according to EU Directive 67/548/EEC or 1999/45/EC | | | |
| | | Hazard symbol: | None | |
| | | R-phrase(s): | None | |
| | | S-phrase(s): | None | |
| 2.4 | .4 Other hazards | | | |
| | | | No information available | |



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3. Composition/information on ingredients

Composition: A multi-component freeze-dried tablet containing amphotericin B in an inert carrier.

Hazardous ingredients:

| Component | CAS-No. | EC-No. | Concentration | CLP Classification – 1272/2008/EC | Classification to – 67/548/EEC |
|-------------------------|------------|-----------|---------------|---|--|
| Amphotericin B | 1397-89-3 | 215-742-2 | <2% | Skin Irritant Cat. 2; Eye Irritant Cat. 2; Specific target organ toxicity - single exposure Cat. 3. H315 - Causes skin irritation H319 - Causes serious eye irritation. H335 - May cause respiratory irritation | Xi – Irritant. R36/37/38 - May be irritating to eyes, respiratory system and skin. |
| Clindamycin | 21462-39-5 | 244-398-6 | <2% | None | None |
| Trimethoprim lactate | 23256-42-0 | 245-533-1 | <1% | None | None |

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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6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Wear appropriate protective equipment. Avoid dust formation.

Accidental release measures

6.2 Environmental precautions

Should not be released into the environment.

6.

6.3 Methods and materials for containment 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. Avoid dust formation.

7.2 Conditions for safe storage, including any incompatabilities

Store at 2°C to 8°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 has no occupational exposure limits.

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. Product may be handled with forceps. |
| | Respiratory protection: | If required use a nuisance type particle respirator type P1 EU EN 143. |
| General hygiene measures: | eral hygiene measures: Handle in accordance with good laboratory practice. Wash hands before breaks and at the end of the working day. | |



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9. Physical and Chemical properties

9.1 Information on basic physical and chemical properties

Physical appearance: Odour: Odour threshold: Colour: pH value: Melting point/freezing point: Initial boiling point/range: Flash point: Evaporation rate: Flammability (solid, gas): Explosive limits: Vapour pressure: Vapour density: Relative density: Solubility in water: Solubility in other solvents: Partition coefficient (n-octanol/water): Auto-ignition temperature: Decomposition temperature: Viscosity: Vapour density: Explosive properties Oxidising properties:

Lyophilised tablet. No detectable odour. Not applicable. White to off-white colour. Not applicable. No data available. Soluble to partially soluble in water. No data available. This product is not explosive in normal circumstances. No data available.

9.2 Other information

No data available.

10. Stability and reactivity

10.1 Reactivity

No known on information available.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

Hygroscopic. Avoid exposure to sunlight.

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 For amphotericin B - LD₅₀ Oral - rat - >5,000 mg/kg Acute toxicity: For further information see RTECS: BU2625000 For clindamycin - LD₅₀ Oral - rat - 2,193 mg/kg, LD₅₀ Intramuscular - rat - 273 mg/kg LD₅₀ Intraperitoneal - rat - 745 mg/kg, LD₅₀ Subcutaneous - rat - 2,618 mg/kg For further information see RTECS: no data available. For trimethoprim - no data available. For further information see RTECS: no data available. Skin corrosion/irritation: No data available. Serious eye damage/ eye irritation: No data available. Respiratory or skin sensitisation: May cause allergic respiratory and skin reactions. Germ cell mutagenicity: No data available. IARC: No component of this product is present at levels greater than or equal to 0.1% is Carcinogenicity: 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: Inhalation - May be harmful if inhaled. May cause respiratory tract irritation. Ingestion - May be harmful if swallowed. Skin - May be harmful if absorbed through skin. May cause skin irritation. Eyes - May cause eye irritation. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. Ecological information

12.1 Toxicity

This product is not hazardous to the environment or that are not degradable in waste water treatment plants.

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

None known.

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 contaminated waste, e.g. used plates, according to local microbiological rules. | | | |
| 14. Transport information | | | | |
| 14.1 <u>UN Number</u> | | | | |
| ADR/RID: IMDG: IATA: | Not dangerous for shipping | | | |
| 14.2 <u>UN proper shipping name</u> | | | | |
| 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: | 17/05/2001 | | | |
| 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. | | | |