Product Safety Data Sheet, Medronate II

Conforms to EU 93/112 and ISO 11014-1



1. Product and company Identification

Product names: N165, Medronate II

Synonyms: Methylene diphosphonic acid as the sodium salt

Application: Diagnostic imaging products for injection into humans

Supplier: GE Healthcare Limited, The Grove Centre, White Lion Road, Amersham, Bucks, UK

Telephone: +44 (0)1494 544000 Fax +44 (0)1494 543588

2. Composition/information on ingredients

Composition: White freeze dried powder

Contents: Low toxicity components at mg level in 10 ml glass vials

CAS No.: Mixture, Not applicable

3. Hazards identification

Emergency overview: Not considered to be hazardous

Hazard classification: Not applicable

4. First-aid measures

Skin contact: Wash thoroughly with soap and warm water

Inhalation: First aid not required

Eyes: Rinse eyes with water

Ingestion: First aid not required

Information to medical personnel: Not applicable

5. Fire-fighting measures

Flammability: Not applicable

6. Accidental release measures

Personal protection: None required

Clean up procedures: Clean up with moist cloth beware of broken glass

Environmental precaution: None required

7. Handling and storage

Handling precautions: None required

Storage conditions: Store in original vials at +2 to +25°C

8. Exposure controls/personal protection

Ventilation: None required when not reconstituted with radioactive material Protective gloves: None required when not reconstituted with radioactive material Eye protection: None required when not reconstituted with radioactive material Protective clothing: None required when not reconstituted with radioactive material

9. Physical and chemical properties

Appearance, colour: White Freeze dried solid in glass vial

Solubility: Readily soluble in water pH: neutral when reconstituted with water

10. Stability and reactivity

Stability: Stable

Reactivity: Not applicable

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11. Toxicological information

LD₅₀: rabbit 50mg/kg Acute Effects: Not applicable at this concentration

Local Effects: Not applicable at this concentration

Sensitisation: Not applicable at this concentration

Other Effects: Not applicable at this concentration

12. Ecological information

Environmental Fate: Not applicable at this concentration

Biodegradability: Not applicable at this concentration

Bioaccumulation potential: Not applicable at this concentration

13. Disposal consideration

Clean-up procedure: Clean up with moist cloth beware of broken glass

Waste disposal method: Normal waste route if non-radioactive

14. Transport information

ADR Classification: Non Hazardous

Transport conditions: Can be transported between –20 and +25 °C in the original transport packaging, The sales pack must

never be used as the only distribution/transportation pack. Ensure packages are not subject to

prolonged exposure to sunlight.

15. Regulatory information

Health Hazard Classification: Not applicable
Fire an Explosion Hazard Classification: Not applicable

Environmental Hazard Classification: Not applicable

R-phrases: Not applicable S-phrases: Not applicable

16. Other information

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warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequences of its use. Each individual should make a

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Status: Medronate II Version 1.2

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