

1. Product and Company Identification

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| Material name | OptiMARK® |
| Version # | 01 |
| Revision date | 02-21-2012 |
| CAS # | Mixture |
| Synonym(s) | Gadoversetamide Injection |
| Manufacturer information | Mallinckrodt 675 McDonnell Blvd. Hazelwood, MO 63042 United States 24 Hour Emergency 314-654-1600 Chemtrec 800-424-9300 Customer Service 888-744-1414 |

2. Hazards Identification

| | |
|--|---|
| Emergency overview | The hazard warnings associated with this product are based on the individual ingredients included in the finished dosage form of the pharmaceutical product. The supplied package insert (approved labeling) provides the necessary drug safety information. Avoid any exposure. Handle in accordance with good industrial hygiene and safety practice. |
| OSHA regulatory status | As per 29 CFR 1910.1200(b)(5)(iii), any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and regulations issued under that Act, when they are subject to the labeling requirements under that Act by the Food and Drug Administration are exempted from the requirements of the Hazard Communication Standard. All Mallinckrodt finished products are labeled in compliance with the requirements of the Food and Drug Administration (FDA) and must be used in the prescribed manner. Each package of the finished pharmaceutical product is supplied with a package insert (approved labeling) which provides necessary drug safety information. |
| Potential health effects | |
| Routes of exposure | Ingestion. Skin contact. Eye contact. |
| Eyes | Direct contact may irritate. |
| Skin | The hazardous properties of the product are considered limited. May cause minor irritation on skin contact. |
| Inhalation | Health injuries are not known or expected under normal use. |
| Ingestion | Ingestion of large amounts may produce gastrointestinal disturbances including irritation, nausea, and diarrhea. |
| Chronic effects | None known. |
| Potential environmental effects | Ecological injuries are not known or expected under normal use. |

3. Composition / Information on Ingredients

| Non-hazardous components | CAS # | Percent |
|---------------------------------|--------------|----------------|
| WATER | 7732-18-5 | 64.5 |
| GADOVERSETAMIDE | 131069-91-5 | 33 |
| VERSETAMIDE | 129009-83-2 | 2.5 |

4. First Aid Measures

First aid procedures

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| Eye contact | Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists. |
| Skin contact | Rinse skin with water/shower. Get medical attention if irritation develops and persists. |
| Inhalation | Not likely, due to the form of the product. |
| Ingestion | If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. Rinse mouth. |
| General advice | If you feel unwell, seek medical advice (show the label where possible). |

5. Fire Fighting Measures

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| Flammable properties | Not flammable by OSHA criteria. |
| Extinguishing media | |
| Suitable extinguishing media | Use any media suitable for the surrounding fires. |
| Fire fighting equipment/instructions | As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. |

6. Accidental Release Measures

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| Personal precautions | No special precautions are necessary beyond normal good hygiene practices. See Section 8 of the MSDS for additional personal protection advice when handling this product. |
| Environmental precautions | No special environmental precautions required. |
| Methods for cleaning up | Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Large Spills: Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the MSDS. |

7. Handling and Storage

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| Handling | Handle and open container with care. Do not handle until all safety precautions have been read and understood. Avoid contact with eyes. Avoid contact with skin. Do not ingest. When using, do not eat, drink or smoke. Wash thoroughly after handling. |
| Storage | Keep container tightly closed. Protect from freezing. Store between 20°C (68°F) and 25°C (77°F). Protect from light. Use care in handling/storage. Store in accordance with local/regional/national/international regulation. |

8. Exposure Controls / Personal Protection

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| Engineering controls | General ventilation normally adequate. |
| Personal protective equipment | |
| Eye / face protection | Safety glasses. Provide eyewash station and safety shower. |
| Skin protection | Wear appropriate chemical resistant clothing. Wear protective gloves. |
| Respiratory protection | No personal respiratory protective equipment normally required. |
| General hygiene considerations | Handle in accordance with good industrial hygiene and safety practice. |

9. Physical & Chemical Properties

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| Appearance | Clear. |
| Physical state | Liquid. |
| Form | Liquid. |
| Color | Colourless to light yellow. |
| Odor | Odorless. |

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|---|---------------------------|
| Odor threshold | Not available. |
| pH | 5.5 - 6.8 |
| Vapor pressure | 0 hPa estimated |
| Vapor density | Not available. |
| Boiling point | 212 °F (100 °C) estimated |
| Melting point/Freezing point | 32 °F (0 °C) estimated |
| Solubility (water) | Not available. |
| Specific gravity | 1.16 @ 25 °C |
| Relative density | Not available. |
| Flash point | Not available. |
| Flammability limits in air, upper, % by volume | Not available. |
| Flammability limits in air, lower, % by volume | Not available. |
| Auto-ignition temperature | Not available. |
| VOC | 64.5 % estimated |
| Percent volatile | 64.5 % estimated |

10. Chemical Stability & Reactivity Information

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| Chemical stability | Material is stable under normal conditions. |
| Conditions to avoid | None under normal conditions. |
| Incompatible materials | Not available. |
| Hazardous decomposition products | Carbon monoxide. Carbon dioxide. Nitrogen oxides (NOx). |

11. Toxicological Information

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| Sensitization | Not a skin sensitizer. |
| Local effects | May cause eye irritation. Mild skin irritation. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. |
| Chronic effects | None known through occupational exposure. |
| Carcinogenicity | This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. |

12. Ecological Information

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|--------------------------------------|--|
| Ecotoxicity | This product has no known eco-toxicological effects. |
| Environmental effects | Not classified as an environmental hazard. Ecological injuries are not known or expected under normal use. |
| Persistence and degradability | No data is available on the degradability of this product. |

13. Disposal Considerations

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| Disposal instructions | This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations. Disposal recommendations are based on uncontaminated material. |
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14. Transport Information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200 (b)(5)(iii).
TSCA exempt status.

Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2))

Not regulated

DEA Essential Chemical Code Number

Not regulated

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

Not regulated

DEA Exempt Chemical Mixtures Code Number

Not regulated

CERCLA (Superfund) reportable quantity

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance No

Section 311 hazardous chemical No

Inventory status

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|--|-------------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | No |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | No |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

State regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

16. Labeling Info

Label Hazard Warning Mallinckrodt finished products are labeled in compliance with the requirements of the Food and Drug Administration (FDA) and must be used in the prescribed manner. Each package of the finished pharmaceutical product is supplied with a package insert (approved labeling) which provides necessary drug safety information.

Label Precautions

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Label First Aid

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17. Other Information

Recommended use Diagnostic imaging agent.

NFPA ratings Health: 0
Flammability: 0
Instability: 0

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