1. Product and Company Identification

<table>
<thead>
<tr>
<th>Material name</th>
<th>ALFENTANIL HYDROCHLORIDE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version #</td>
<td>01</td>
</tr>
<tr>
<td>Issue date</td>
<td>02-04-2014</td>
</tr>
<tr>
<td>CAS #</td>
<td>70879-28-6</td>
</tr>
<tr>
<td>Synonym(s)</td>
<td>Alfentanil Hydrochloride monohydrate * Propanamide, N-(1-(2-(4-ethyl-4,5-dihydro-5-oxo-1H-tetrazol-1-yl)ethyl)-4-methoxymethyl)4-piperidinyl)-n-phenyl-, hydrochloride monohydrate * Alfentanil Hydrochloride Analytical Research Standard-(FOR R&amp;D USE ONLY) * Hydroxymethylpiperidine Alfentanil ARS-(FOR R&amp;D USE ONLY) * N-Acetyl Alfentanil ARS-(FOR R&amp;D USE ONLY) * Methoxymethylpiperidine Alfentanil ARS-(FOR R&amp;D USE ONLY) * Dipropionyl Alfentanil ARS-(FOR R&amp;D USE ONLY)</td>
</tr>
</tbody>
</table>

Manufacturer information

Mallinckrodt
675 McDonnell Blvd.
Hazelwood, MO 63042
24 Hour Emergency 314-654-1600
Chemtrec 800-424-9300
Customer Service 888-744-1414

Item code

0620, 0622, 0625, 0626, 0628, 0682, 1682

2. Hazards Identification

Emergency overview

DANGER

Potent Narcotic. May be fatal if swallowed. May be fatal if inhaled. May be fatal if absorbed through skin. Causes central nervous system effects.

OSHA regulatory status

This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).

Potential health effects

Routes of exposure

Inhalation. Ingestion. Skin contact. Eye contact.

Eyes

Dust or powder may irritate eye tissue. May have a strong narcotic effect (pupil constriction) and the eye may serve as an absorption route into the body. Do not get this material in contact with eyes.

Skin

This product may be fatal if it is absorbed through the skin. May produce narcotic effects if absorbed through skin. Symptoms may parallel ingestion.

Inhalation

May be fatal if inhaled. Narcotic effect. May cause typical symptoms of narcosis (see Ingestion.) Dust irritates the respiratory system, and may cause coughing and difficulties in breathing. Inhalation of powder/dust may cause lung edema.

Ingestion

Highly toxic. May be fatal if swallowed. Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Dizziness. May cause central nervous system depression. Large doses can lead to respiratory or cardiac arrest and death. Do not ingest.

Target organs

Central nervous system. Heart.

Chronic effects

Causes central nervous system effects. May lead to habituation or addiction.

Signs and symptoms

Narcosis. Decrease in motor functions. Respiratory disorder.

3. Composition / Information on Ingredients

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS #</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALFENTANIL HYDROCHLORIDE</td>
<td>70879-28-6</td>
<td>100</td>
</tr>
</tbody>
</table>
4. First Aid Measures

First aid procedures

**Eye contact**
Immediately flush eyes with plenty of water for at least 15 minutes. If a contact lens is present, DO NOT delay irrigation or attempt to remove the lens. Get medical attention immediately.

**Skin contact**
Immediately flush skin with plenty of water. Remove and isolate contaminated clothing and shoes. Get medical attention immediately. Wash clothing separately before reuse.

**Inhalation**
If gas/fume/vapor/dust/mist from the material is inhaled, remove the affected person immediately to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical attention immediately.

**Ingestion**
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

**Notes to physician**
The principle sign of serious overdose to fentanyl include stupor and respiratory depression. Treatment for these effects due to fentanyl is the same as for overdose by other opioids: airway maintenance, ventilation support, and administration of a narcotic antagonist such as naloxone (Narcan®) beginning with 0.4 to 2 mg intravenously and repeating every three minutes as clinically indicated. Intramuscular or subcutaneous administration may be necessary if the intravenous route is not available.

**General advice**
In case of shortness of breath, give oxygen. Keep victim warm. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before re-use.

5. Fire Fighting Measures

**Flammable properties**
As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source.

**Extinguishing media**
Suitable extinguishing media
Water spray. Alcohol foam. Dry chemical powder. Carbon dioxide (CO2).

**Fire fighting equipment/instructions**
In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk. As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

**Specific methods**
Cool containers exposed to flames with water until well after the fire is out. Follow handling guidance appropriate for OEB-3 potent compounds, (see section 7).

6. Accidental Release Measures

**Personal precautions**
Ensure adequate ventilation. Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate protective equipment and clothing during clean-up. Avoid contact with spilled material. Avoid inhalation of dust from the spilled material. Ventilate closed spaces before entering them. Follow handling guidance appropriate for OEB-3 potent compounds, (see Section 7).

**Environmental precautions**
Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

**Methods for containment**
Stop the flow of material, if this is without risk. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Prevent entry into waterways, sewer, basements or confined areas.
Methods for cleaning up
Do not flush to sewer. Sweep up or vacuum up spillage and collect in suitable container for
disposal. Avoid dust formation. Collect dust using a vacuum cleaner equipped with HEPA filter.
Use only non-sparking tools. Clean surface thoroughly to remove residual contamination. All
clean-up operations should be witnessed by more than one individual. The amount of material
collected should be assessed and documented. For waste disposal, see section 13 of the MSDS.

7. Handling and Storage

Handling
Do not use in areas without adequate ventilation. DO NOT handle, store or open near an open
flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not breathe
dust. Keep formation of airborne dusts to a minimum. Provide appropriate exhaust ventilation at
places where dust is formed. Use personal protective equipment as required. Do not ingest. Do
not get this material in contact with eyes. Do not get this material in contact with skin. Do not get
this material on clothing. Wash thoroughly after handling. When using, do not eat, drink or smoke.
Avoid release to the environment. Handle and open container with care.

Storage
Store locked up. Keep container tightly closed. Store in a cool, dry place. Store in a well-ventilated
place. Keep away from heat and sources of ignition. Use care in handling/storage. Store in
accordance with local/regional/national/international regulation.

Further information
CONTROLLED SUBSTANCE: Location of storage area must comply with all Drug Enforcement
Agency regulations.

Alfentanil Hydrochloride has potent pharmacological activity and is classified as an OEB-3*
material. Handling practices for OEB-3 substances are described below.

LABORATORY: *Wear appropriate gloves, lab coat, and safety glasses. Use good lab practices.
*A designated area is required for handling compounds.
*Work surfaces are to be cleaned daily. If lab bench absorbent paper is used, it is to be changed
at least daily.
*High-energy operations such as milling, particle sizing, spraying or fluidizing should be done
within an approved emission control or containment system.
*Develop cleaning procedures and techniques that limit potential exposure.

*POWders HANDLING: To prevent contamination and overexposure, no open handling of
powder should be allowed. Powder handling operations are to be done in a powders weighing
hood, a glove box, or other equivalent ventilated containment system. In situations where these
ventilated containment hoods have not been installed, a non-ventilated enclosed containment
hood should be used. Pending changes resulting from additional air monitoring data, up to 300
mg can be handled outside of an enclosure provided that no grinding, crushing or other
dust-generating process occurs. An air-purifying respirator (P95 or other type providing a higher
level of protection) should be worn by all personnel in the immediate area in cases where
non-ventilated containment is used, where significant amounts of material (e.g., more than 2
grams) are used, or where the material may become airborne (as through grinding, etc.). Powder
should be put into solution or a closed or covered container after handling. If using a ventilated
enclosure that has not been validated, wear a half-mask respirator equipped with HEPA
cartridges until the enclosure is validated for use.

*SOLUTIONs HANDLING: *Solutions can be handled outside a containment system or without
local exhaust ventilation during procedures with no potential for aerosolization. If the procedures
have a potential for aerosolization, and air-purifying respirator (P95 or other type providing a higher
level of protection) is to be worn by all personnel in the immediate area.
*Solutions used for procedures where aerosolization may occur (e.g., vortexing, pumping) are to
be handled within a containment system or with local exhaust ventilation. In situations where this
is not feasible (may include animal dosing), an air-purifying respirator (P95 or other type providing
a higher level of protection) is to be worn by all personnel in the immediate area.
*If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped
with HEPA cartridges until the enclosure is validated for use.
*Ensure gloves are protective against solvents in use.
*PILOT PLANT and PRODUCTION: *Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties. Use good manufacturing practices (i.e., cGMPs).

*Protective garment (coveralls, Tyvek, lab coat) is not to be worn outside the work area.

*Clean/dirty/decontamination areas are to be established.

*Negative/positive air pressure relationships and buffer zones required (i.e., ante-room/degowning room/airlock).

*Area access is to be restricted.

*High-energy operations such as milling, particle sizing, spraying or fluidizing should be done within an approved emission control or containment system.

*Develop cleaning procedures and techniques that limit potential exposure.

*POWERS HANDLING: *Emphasis is to be placed on closed material transfer systems and process containment, with no open handling of powders. Use enclosures and containment measures to reduce potential exposures.

*Use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR) until processes have been monitored to show that respiratory protection is not required.

*SOLUTIONS HANDLING: *Enclose systems where possible. Processing tanks are to be kept covered. Process samples should be taken from sample ports if feasible.

*Wear a P95 Dust/Mist respirator or a respirator supplying a higher level of protection until processes have been monitored to show that respiratory protection is not required.

*Ensure gloves are protective against solvents in use.

*OEB - Mallinckrodt's Occupational Exposure Band: The classification of a compound or pharmaceutical ingredient into one of four ordinal categories of increasing potency and toxicity. This rating assigns a set of pre-determined handling and containment practices to a compound until a quantitative OEL is established.

8. Exposure Controls / Personal Protection

<table>
<thead>
<tr>
<th>Mallinckrodt</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALFENTANIL HYDROCHLORIDE (CAS 70879-28-6)</td>
<td>OEB</td>
<td>3 OEB</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OEG</td>
<td>3 µg/m³</td>
<td>8-hour time-weighted average</td>
</tr>
<tr>
<td></td>
<td>STEL</td>
<td>9 µg/m³</td>
<td>15-minute average, Notation: skin</td>
</tr>
</tbody>
</table>

**Engineering controls** To prevent contamination and overexposure, no open handling of powder should be allowed. Powder handling operations are to be done in a powder weighing hood, a glove box, or other equivalent ventilated containment system. In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used. Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs. See Section 7 for additional information on proper handling and venting requirements for potent compounds.

**Personal protective equipment**

**Eye / face protection** Chemical goggles are recommended. Provide eyewash station and safety shower.

**Skin protection** Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties.
Respiratory protection
An air-purifying respirator (P95 or other type providing a higher level of protection) should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.). If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use. See Section 7 for additional information on proper handling and respirator recommendations for potent compounds.

General hygiene considerations
When using, do not eat, drink or smoke. Do not breathe dust. Do not get in eyes. Do not get this material in contact with skin. Do not get this material on clothing. Wash hands after handling and before eating. Handle in accordance with good industrial hygiene and safety practice. See Section 7 for additional information on occupational control measures appropriate for OEB-3 potent compounds.

9. Physical & Chemical Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Granular. Powder.</td>
</tr>
<tr>
<td>Physical state</td>
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<tr>
<td>Form</td>
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<tr>
<td>Color</td>
<td>White.</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless.</td>
</tr>
<tr>
<td>Odor threshold</td>
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</tr>
<tr>
<td>pH</td>
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</tr>
<tr>
<td>Vapor pressure</td>
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<tr>
<td>Vapor density</td>
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<tr>
<td>Boiling point</td>
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<td>Melting point/Freezing point</td>
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<td>Solubility (water)</td>
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<td>Specific gravity</td>
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<tr>
<td>Relative density</td>
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<td>Flash point</td>
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<td>Flammability limits in air, upper, % by volume</td>
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</tr>
<tr>
<td>Flammability limits in air, lower, % by volume</td>
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<td>Auto-ignition temperature</td>
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<td>Molecular weight</td>
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<td>C21H33CIN6O3 . H20</td>
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<td>Concentration</td>
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<td>Specific activity</td>
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10. Chemical Stability & Reactivity Information

<table>
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<th>Property</th>
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</thead>
<tbody>
<tr>
<td>Chemical stability</td>
<td>Discoloration upon exposure to light.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None under normal conditions.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Not available.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Hazardous polymerization does not occur.</td>
</tr>
</tbody>
</table>
11. Toxicological Information

Toxicological data

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALFENTANIL HYDROCHLORIDE</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Rat</td>
<td>LD50 47.5 mg/kg, (Intravenous)</td>
</tr>
</tbody>
</table>

* Estimates for product may be based on additional component data not shown.

Acute effects: May be fatal if inhaled, absorbed through skin, or swallowed.
Local effects: Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal.
Chronic effects: May cause central nervous system disorder (e.g., narcosis involving a loss of coordination, weakness, fatigue, mental confusion and blurred vision) and/or damage. Chronic exposure may lead to tolerance, dependence, and unpleasant withdrawal symptoms upon abrupt discontinuation of use (e.g., sweating, restlessness, irritability, hallucinations).
Carcinogenicity: This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

12. Ecological Information

Ecotoxicity: This product has no known eco-toxicological effects.
Environmental effects: Not classified as an environmental hazard. An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Persistence and degradability: No data is available on the degradability of this product.

13. Disposal Considerations

Disposal instructions: Notify site Drug Enforcement Agency compliance officer and local DEA office for appropriate disposal procedures. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Follow handling guidance appropriate for OEB-3 potent compounds, (see Section 7). Dispose of contents/container (in accordance with related regulations).

14. Transport Information

DOT

Basic shipping requirements:
- UN number: UN2811
- Proper shipping name: Toxic solids, organic, n.o.s. (Propanamide, N-(1-(2-(4-ethyl-4,5-dihydro-5-oxo-1H-tetrazol-1-yl)ethyl)-4-methoxymethyl)4-piperidinyl)-n-phenyl-, hydrochloride monohydrate)
- Hazard class: 6.1(PGI, II)
- Packing group: II

Additional information:
- Special provisions: IB8, IP2, IP4, T3, TP33
- Packaging exceptions: 153
- Packaging non bulk: 212
- Packaging bulk: 242

IATA

- UN number: UN2811
- UN proper shipping name: Toxic solid, organic, n.o.s. (Propanamide, N-(1-(2-(4-ethyl-4,5-dihydro-5-oxo-1H-tetrazol-1-yl)ethyl)-4-methoxymethyl)4-piperidinyl)-n-phenyl-, hydrochloride monohydrate)
- Transport hazard class(es): 6.1(PGI, II)
- Packing group: II
- ERG code: 6L

IMDG

- UN number: UN2811

Material name: ALFENTANIL HYDROCHLORIDE
MSDS ID: ALFHC  Version #: 01  Revision date: 02-04-2014
**UN proper shipping name**
TOXIC SOLID, ORGANIC, N.O.S. (Propanamide, N-(1-(2-(4-ethyl-4,5-dihydro-5-oxo-1H-triazol-1-yl)ethyl)-4-methoxymethyl)4-piperidinyl)-n-phenyl-, hydrochloride monohydrate)

**Transport hazard class(es)**
6.1(PGI, II)

**Packing group**
EmS

**DOT**

![DOT Toxic 6](image)

**IATA; IMDG**

![IATA IMDG](image)

---

**15. Regulatory Information**

**US federal regulations**
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
CERCLA/SARA Hazardous Substances - Not applicable.
TSCA exempt status.

**CERCLA (Superfund) reportable quantity**
None

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

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

**SARA 302 Extremely hazardous substance**
No

**SARA 311/312 Hazardous chemical**
No

**Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)**
Schedule II - 9737

**Inventory status**

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

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

State regulations

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

16. Labeling Info

**Label Hazard Warning**

DANGER! Potent Narcotic. May be fatal if inhaled, absorbed through skin, or swallowed. Causes central nervous system effects.

**Label Precautions**

Do not breathe dust. Do not get in eyes, on skin, or on clothing. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling. Wear suitable protective clothing and gloves.

**Label First Aid**

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. If gas/fume/vapor/dust/mist from the material is inhaled, remove the affected person immediately to fresh air. In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.

17. Other Information

**NFPA ratings**

Health: 4  
Flammability: 0  
Instability: 0

**Disclaimer**

Mallinckrodt provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. MALLINCKRODT MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HERIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

This data sheet contains changes from the previous version in section(s):

This document has undergone significant changes and should be reviewed in its entirety.