SAFETY DATA SHEET

1. Identification

Product identifier
Glyburide

Other means of identification
Catalog number
1295505
Chemical name
Benzamide, 5-chloro-N-[2-[4-[[[(cyclohexylamino)carbonyl]amino]sulfonyl]phenyl]ethyl]-2-methoxy-
Synonym(s)
Glibenclamide

Recommended use
Specified quality tests and assay use only.

Recommended restrictions
Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information
Company name
U. S. Pharmacopeia
Address
12601 Twinbrook Parkway
Rockville
MD
20852-1790
US
Telephone
RS Technical Services 301-816-8129
Website
www.usp.org
E-mail
RSTECH@usp.org
Emergency phone number
CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards
Not classified.
Health hazards
Not classified.
OSHA hazard(s)
Not classified.

Label elements
Hazard symbol
No symbol.
Signal word
Not available.
Hazard statement
Not available.
Precautionary statement
Prevention
Not available.
Response
Not available.
Storage
Not available.
Disposal
Not available.

Hazard(s) not otherwise classified (HNOC)
Not classified.

3. Composition/information on ingredients

Substance
Hazardous components
Chemical name
Glyburide

<table>
<thead>
<tr>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glibenclamide</td>
<td>10238-21-8</td>
<td>100</td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation
Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. Get medical advice/attention if you feel unwell. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed

Not available.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. For severe hypoglycemia, obtain immediate emergency medical assistance. For recent ingestion, induce vomiting if patient is alert. Perform gastric lavage. Repeat oral charcoal doses may enhance total body clearance and elimination. Monitor vital signs. Monitor arterial blood gas or pulse oximetry. Monitor blood glucose level. Monitor serum electrolytes, blood urea nitrogen, and serum creatinine as required. For cerebral edema, administer mannitol and dexamethasone. For hypokalemia, administer potassium supplements. For severe hypoglycemia, keep patient hospitalized for 6 to 91 hours for observation. (USP DI)

General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media

Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire-fighting equipment/instructions

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods

Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate protective equipment and clothing during clean-up.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glyburide (CAS 10238-21-8)</td>
<td>TWA</td>
<td>1 micrograms/m3</td>
</tr>
</tbody>
</table>

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.
Individual protection measures, such as personal protective equipment

**Eye/face protection**
Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Skin protection**

**Hand protection**
Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

**Other**
For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

**Respiratory protection**
Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Thermal hazards**
Not available.

**General hygiene considerations**
Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

**Appearance**
White or almost white crystalline powder.

**Physical state**
Solid.

**Form**
Powder.

**Odor**
Odorless.

**Odor threshold**
Not available.

**pH**
Not available.

**Melting point/freezing point**
332.6 - 347 °F (167 - 175 °C)

**Initial boiling point and boiling range**
Not available.

**Flash point**
Not available.

**Evaporation rate**
Not available.

**Flammability (solid, gas)**
Not applicable.

**Upper/lower flammability or explosive limits**

| Flammability limit - lower (%) | Not available. |
| Flammability limit - upper (%) | Not available. |
| Explosive limit - lower (%)    | Not available. |
| Explosive limit - upper (%)    | Not available. |

**Vapor pressure**
< 0.0000001 kPa at 25 °C

**Vapor density**
Not available.

**Relative density**
Not available.

**Solubility in water**
Practically insoluble.

**Partition coefficient (n-octanol/water)**
5.3

**Auto-ignition temperature**
Not available.

**Decomposition temperature**
Not available.

**Viscosity**
Not available.

**Other information**

**Chemical family**
Sulfonylurea.

**Molecular formula**
C23H28ClN3O5S

**Molecular weight**
494

**Solubility (other)**
Sparingly soluble in methylene chloride, in ether, and in dichloromethane; slightly soluble in alcohol and in methanol.

10. Stability and reactivity

**Reactivity**
No reactivity hazards known.
Chemical stability
Stable at normal conditions.

Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
None under normal conditions.

Incompatible materials
Strong oxidizing agents

Hazardous decomposition products
SOx. NOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

**Ingestion**
Based on available data, the classification criteria are not met.

**Inhalation**
Due to lack of data the classification is not possible.

**Skin contact**
Due to lack of data the classification is not possible.

**Eye contact**
Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics

Delayed and immediate effects of exposure

Cross sensitivity
Persons sensitive to one of the sulfonylureas, sulfonamide-, or thiazide-type medications may be sensitive to glyburide as well.

Medical conditions aggravated by exposure

Acute toxicity
Based on available data, the classification criteria are not met.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glyburide (CAS 10238-21-8)</td>
<td>Mouse</td>
<td>3250 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>&gt; 20 g/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation
Due to lack of data the classification is not possible.

Serious eye damage/eye irritation
Due to lack of data the classification is not possible.

Respiratory sensitization
Due to lack of data the classification is not possible.

Skin sensitization
Due to lack of data the classification is not possible.

Germ cell mutagenicity
Based on available data, the classification criteria are not met.

Mutagenicity
DNA damage/alkaline elution assay
Result: Negative.
Micronucleus test
Result: Negative.
S. typhimurium Ames assay
Result: Negative.

Carcinogenicity
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Based on available data, the classification criteria are not met.

300 mg/kg/day Carcinogenicity study
Result: No carcinogenic effects.
Species: Rat
Test Duration: 18 months

Reproductive toxicity
Based on available data, the classification criteria are not met.

Reproductive
Reproductive test
Result: No evidence of impaired fertility or harm to fetus (in doses up to 500 times the human dose)
Species: Rat

Specific target organ toxicity - single exposure
Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure
Due to lack of data the classification is not possible.

Aspiration hazard
Based on available data, the classification criteria are not met.
12. Ecological information

Ecotoxicity
No ecotoxicity data noted for the ingredient(s).

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
Not available.

Mobility in soil
Not available.

Other adverse effects
Not available.

13. Disposal considerations

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.

Local disposal regulations
Not available.

Hazardous waste code
Not regulated.

Waste from residues / unused products
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT
Not regulated as a hazardous material by DOT.

IATA
Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
No information available.

15. Regulatory information

US federal regulations
CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

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

SARA 302 Extremely hazardous substance
No

SARA 311/312 Hazardous chemical
No

Other federal regulations
Safe Drinking Water Act (SDWA)
Not regulated.

Food and Drug Administration (FDA)
Not regulated.

US 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.

International Inventories

<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>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</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>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</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>Yes</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>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>Yes</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>Yes</td>
</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)

16. Other information, including date of preparation or last revision

Issue date: 11-09-2006
Revision date: 11-30-2012
Version #: 02
Further information: Not available.

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Revision Information

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