1. Identification

Product identifier: Bisacodyl

Other means of identification:
- Catalog number: 1074007
- Chemical name: Phenol, 4,4’-(2-pyridinylmethylene)bis-, diacetate (ester)

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:
- Skin corrosion/irritation Category 2
- Serious eye damage/eye irritation Category 2A
- Specific target organ toxicity, single exposure Category 3 respiratory tract irritation

OSHA hazard(s):
- Not classified.

Label elements:

Signal word: Warning

Hazard statement: Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.

Precautionary statement:
- Prevention: Wash thoroughly after handling. Wear protective gloves. Wear eye/face protection. Use only outdoors or in a well-ventilated area.
- Response: If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.
- Storage: Store in a well-ventilated place. Keep container tightly closed. Store locked up.
- Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

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

3. Composition/information on ingredients

Substance
4. First-aid measures

Inhalation
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. 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. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed
Irritant effects.

Indication of immediate medical attention and special treatment needed
Treatment of stimulant laxative overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as a slurry. Perform gastric lavage soon after ingestion (within one hour). Protect airway be placement in Trendelenburg and left lateral decubitus position or by endotracheal intubation. Control any seizures first. Manage severe diarrhea with restriction of solid food intake and administration of a polyionic solution to maintain a high fluid intake until diarrhea resolves. [Meditext 2010]

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. Dry chemical or CO2. Foam. Use fire-extinguishing media appropriate for surrounding 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. Use water spray to cool unopened containers.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

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. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.

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. Clean surface thoroughly to remove residual contamination.

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.

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

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

Exposure guidelines
No exposure standards allocated.

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.
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.

**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 to off-white crystalline powder.

**Physical state**
Solid.

**Form**
Powder.

**Odor**
Odorless.

**Odor threshold**
Not available.

**pH**
Not available.

**Melting point/freezing point**
267.8 - 275 °F (131 - 135 °C) / 280.4 °F (138 °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**
\(< 0.0000001 \text{ kPa at 25 °C}\)

**Vapor density**
Not available.

**Relative density**
Not available.

**Solubility in water**
Practically insoluble.

**Partition coefficient (n-octanol/water)**
Not available.

**Auto-ignition temperature**
707 °F (375 °C)

**Viscosity**
Not available.

**Other information**

- **Chemical family**
  Pyridine derivative; diphenylmethane derivative.

- **Molecular formula**
  C22H19NO4

- **Molecular weight**
  361.39

- **Solubility (other)**
  Soluble in chloroform, in benzene, in acetone, and in propylene glycol; sparingly soluble in ethanol and in methanol; slightly soluble in ether; practically insoluble in alkaline solutions.

10. Stability and reactivity

**Reactivity**
No reactivity hazards known.

**Chemical stability**
Material is stable under normal conditions.

**Possibility of hazardous reactions**
No dangerous reaction known under conditions of normal use.
Conditions to avoid
None known.

Incompatible materials
Oxidizing agents.

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

11. Toxicological information

Information on likely routes of exposure

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Based on available data, the classification criteria are not met.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>May cause irritation to the respiratory system.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>Causes skin irritation.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Causes serious eye irritation.</td>
</tr>
</tbody>
</table>

Symptoms related to the physical, chemical, and toxicological characteristics

Delayed and immediate effects of exposure

Medical conditions aggravated by exposure

Acute toxicity

<table>
<thead>
<tr>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bisacodyl (CAS 603-50-9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Dog</td>
<td>&gt; 15 g/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>17.5 g/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>&gt; 3 g/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation
Causes skin irritation.

Serious eye damage/eye irritation
Causes serious eye irritation.

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
Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity
Ames assay
Result: Negative.
Micronucleus test in mouse erythrocytes
Result: Negative.
Syrian hamster embryo cell mutagenicity test
Result: Negative.

Carcinogenicity
Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

< 8000 mg/kg/day Carcinogenicity study
Result: No bisacodyl-related neoplasms were observed.
Species: Mouse
Test Duration: 26 weeks

Reproductive toxicity
Due to lack of data the classification is not possible. Studies in rats at doses up to 70 times the human dose have not revealed evidence that bisacodyl causes harm to the fetus; however, at this same dosage level bisacodyl has caused lower litter survival rates.

Specific target organ toxicity - single exposure
Respiratory tract irritation.

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

<table>
<thead>
<tr>
<th>Product</th>
<th>EC50</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bisacodyl (CAS 603-50-9)</td>
<td></td>
<td>Crustacea &gt; 1.93 mg/l, 48 hours</td>
<td></td>
</tr>
</tbody>
</table>

| Persistence and degradability | Not readily biodegradable. |
| Bioaccumulative potential     | Not available. |
| Mobility in soil              | Not available. |
| Other adverse effects         | Not available. |

13. Disposal considerations

Disposal instructions
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 available.

Waste from residues / unused products
Dispose of in accordance with local regulations. 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
Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

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.

All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
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>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
</tbody>
</table>

Material name: Bisacodyl

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<th>Country(s) or region</th>
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</thead>
<tbody>
<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>No</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>No</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>Yes</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

<table>
<thead>
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<tr>
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<td>02</td>
</tr>
<tr>
<td>Further information</td>
<td>Not available.</td>
</tr>
<tr>
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Revision Information This document has undergone significant changes and should be reviewed in its entirety.