



## Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Bisacodyl USP Micronized

55-2553

### Section 1: Identification

**Product Name** Bisacodyl USP Micronized  
**Commercial Name** Not available.  
**Product Use** Not available.  
**Restrictions On Use** Not available.

**Product Code** 55-2553

**Company** PCCA  
9901 South Wilcrest  
Houston, TX 77099  
Phone: 1-800-331-2498  
Fax: 1-800-874-5760

In case of emergency contact:  
**CHEMTREC (24hr) 1-800-424-9300**

### Section 2: Hazard(s) Identification

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

**CFR 1910.1200**

**Signal Word** WARNING

**Hazard Statement(s)** Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.

**Pictogram(s) or Symbol(s)**



#### Precautionary Statement(s):

**Prevention** Wear eye/face protection. Avoid breathing dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear eye protection/face protection. Wear protective gloves. Wear eye protection/face protection. Wear protective gloves.

**Response** If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. 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.

**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.

### Section 3: Composition/Information on Ingredients

**Substance/Mixture** Substance  
**Components** Bisacodyl USP Micronized  
**% By Weight** 100  
**CAS#** 603-50-9  
**Molecular Weight** 361.4 g/mole  
**Chemical Formula** C<sub>22</sub>H<sub>19</sub>NO<sub>4</sub>  
**Synonym(s)** 4,4'-(2-Pyridinylmethylene)bisphenol diacetate

#### Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
1) Bisacodyl	603-50-9	100	Not available.	ORAL (LD50):Acute: 4320mg/kg [Rat].17500 mg/kg[Mouse].

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**Section 4: First-Aid Measures**

<b>Inhalation</b>	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Do not use mouth-to-mouth method if the substance is inhaled. Oxygen or artificial respiration if needed. Call a physician if symptoms develop or persist.
<b>Skin Contact</b>	Remove contaminated clothing. Rinse skin with water/shower. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
<b>Eye Contact</b>	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Symptoms/Effects</b>	
<b>Acute</b>	Pharmacologically active material. Occupational exposure may cause physiological effects.
<b>Delayed</b>	Pharmacologically active material. Occupational exposure may cause physiological effects.

**Immediate Medical Attention**

Provide general supportive measures and treat symptomatically. Treatment of stimulant laxative overdose may include the following: Administer activated charcoal as a slurry. Perform gastric lavage soon after ingestion (within one hour). Protect airway by 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.

**Section 5: Fire-Fighting Measures****Suitable Extinguishing Media**

Water. Foam. Dry chemical or CO<sub>2</sub>. Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable Extinguishing Media**

Not available.

**Products of Combustion**

No unusual fire or explosion hazards noted

**Firefighters Special Equipment and Precautions**

Wear suitable protective equipment. Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials.

**Section 6: Accidental Release Measures**

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS Methods and materials for containment and cleaning up: Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS. Environmental precaution Avoid discharge into drains, water courses or onto the ground.

**Section 7: Handling and Storage**

**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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. **Storage:** Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

**Section 8: Exposure Controls/Personal Protection**

<b>Exposure Limits</b>	Not available
<b>Engineering Controls</b>	For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

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**Personal Protection**

Eye/face protection: Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. Skin protection Hand protection: Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Other: Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Respiratory protection: Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls. Thermal hazards: Wear appropriate thermal protective clothing, when necessary. General hygiene considerations: Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

**Section 9: Physical and Chemical Properties**

<b>Appearance</b>	White. Off-white powder. Solid.		
<b>Odor</b>	Odorless.		
<b>Odor Threshold</b>	Not available.		
<b>Melting Point</b>	267.8 - 275 °F (131 - 135 °C)	<b>pH</b>	Not available.
<b>Freezing Point</b>	Not available.	<b>Vapor Pressure</b>	< 0.0000001 kPa at 25 °C
<b>Boiling Point/Range</b>	Not available.	<b>Vapor Density</b>	Not available.
<b>Decomposition temperature</b>	Not available.	<b>Viscosity</b>	Not available.
<b>Partition Coefficient: n-octanol/water</b>	Not available.	<b>Evaporation Rate</b>	Not available.
<b>Flash Point</b>	Not available.	<b>Autoignition temperature</b>	707 °F (375 °C)
<b>Flammability</b>	Not available	<b>Flammability or Explosive Limits:</b>	
		<b>Lower</b>	Not available.
		<b>Upper</b>	Not available.
<b>Solubility(ies)</b>	Practically insoluble in water.		
<b>Other</b>	Acetone: 95%: Soluble. Alkaline solutions: Practically insoluble. Benzene: Soluble. Chloroform: Soluble. Ethanol: Sparingly soluble. Ether: Slightly soluble. Methanol: Sparingly soluble. Propylene glycol: Soluble. Chemical family Pyridine derivative; diphenylmethane derivative. Molecular formula C22H19NO4 Molecular weight 361.39		

**Section 10: Stability and Reactivity**

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability</b>	Material is stable under normal conditions.
<b>Hazardous Polymerization</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to Avoid</b>	Contact with incompatible materials
<b>Incompatible Materials</b>	Oxidizing agents
<b>Hazardous Decomposition Products</b>	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions

**Section 11: Toxicological Information****RTECS** SM8750000**Acute Toxicity**

Acute Oral LD50 Rat &gt; 3 g/kg

**Skin Corrosion/Irritation**

Causes skin irritation.

**Serious Eye Damage/Irritation**

Causes serious eye irritation

**Respiratory or Skin Sensitization**

Not available

**Germ Cell Mutagenicity**

Not available.

**Carcinogenicity**

Not available.

**Reproductive Toxicity**

Not available.

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**Routes of Entry**

Inhalation. Skin. Eye. Ingestion.

**Symptoms Related to Exposure**

Laxatives: Abdominal pain. Cramping. Nausea. Belching. Constipation. Diarrhea. Vomiting. Thirst. Weight loss. Faintness. Confusion. Tiredness. Irregular heartbeat. Bone pain. Muscle loss. Swelling

**Potential Health Effects**

Pharmacologically active material. Occupational exposure may cause physiological effects.

**Target Organ(s)** May cause respiratory irritation**Section 12: Ecological Information****Ecotoxicity**

Not available.

**Persistence and Degradability**

Not readily biodegradable

**Bioaccumulative Potential**

Not available.

**Mobility in Soil**

Not available.

**Other Adverse Effects**

Not available.

**Section 13: Disposal Considerations****Waste Disposal**

Dispose in accordance with all applicable regulations. 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. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. 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).

**Disposal of Container**

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**Other Considerations**

Not available.

**Section 14: Transport Information****DOT Classification**

Not a DOT controlled material (United States). This material is not classified dangerous good according to international transportation regulations (ADR/RID-IMDG-ICAO/IATA).

**Section 15: Regulatory Information****Regulations**

US federal regulations: This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052) Not regulated. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Not listed. YesSARA 311/312 Hazardous chemical Skin corrosion or irritation Serious eye damage or eye irritation Specific target organ toxicity (single or repeated exposure) Classified hazard categories SARA 313 (TRI reporting) Not regulated. Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Not regulated. Safe Drinking Water Act (SDWA) US state regulations California Proposition 65 California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

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**Other**

WHMIS Not controlled under WHMIS (Canada). (Canada);DSCL (EEC) R36/37/38- Irritating to eyes, respiratory system and skin.;Gloves.;Lab coat.;Dust respirator. Be sure to use an approved/certified respirator or equivalent.;Splash goggles.

**Section 16: Other Information**

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Dishman Pharmaceuticals & Chemicals LTD shall not be held liable for any damage from handling or from contact with the above product.