

# SAFETY DATA SHEET

Otsuka America Pharmaceutical, Inc.  
2440 Research Blvd  
Rockville, MD 20850

Pranactin® Citric  
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Emergency Contact Information:

Otsuka Medical Information  
1-888-637-3835

SECTION 1:	IDENTIFICATION
<b>Product Identifier:</b>	Pranactin® Citric
<b>Manufacturer:</b>	Otsuka America Pharmaceutical, Inc
<b>Distributor Name:</b>	Otsuka America Pharmaceutical, Inc
<b>Phone:</b>	1-888-637-3835
<b>Emergency Contact:</b>	1-888-637-3835
<b>Recommended Use</b>	<p>Description of the Pranactin®-Citric Diagnostic Drug Component</p> <p>The diagnostic drug component of the kit is <sup>13</sup>C-urea, a synthetic urea contained in a granulated powder (<b>Pranactin-Citric</b>) for reconstitution with potable water to provide a clear solution <b>for oral administration</b>. The carbon in the drug component is predominantly Carbon-13, a stable, naturally occurring, non-radioactive isotope of carbon; the relative abundance of Carbon-13 is greater than or equal to 99%.</p> <p>Each 3 gram dose of Pranactin-Citric is supplied in a polyethylene-lined foil pouch and contains 75 mg of <sup>13</sup>C-urea, citric acid, aspartame and mannitol. <sup>13</sup>C-urea is the diamide of <sup>13</sup>C-carbonic acid and is highly soluble in water (1 gram per mL at 25°C). It has the following chemical formula: <sup>13</sup>CH<sub>4</sub>N<sub>2</sub>O. An average adult body normally contains about 9 grams of urea, which is a product of protein metabolism. Urea in the body is referred to as natural isotopic abundance urea since it is composed of 98.9% <sup>12</sup>C-urea and 1.1% <sup>13</sup>C-urea.</p>
<b>Restrictions on use:</b>	Is not approved for use in patients younger than 3 years of age.
SECTION 2:	HAZARD(S) IDENTIFICATION
<b>Hazards:</b>	None known under normal conditions.
<b>Unknown Toxicity:</b>	Drug does not contain ingredients with unknown toxicity.
<b>Carcinogenicity:</b>	Pranactin Citric is not on the following lists: NTP, IARC, Federal OSHA Z list & California OSHA, and therefore is neither considered to be suspected to be a cancer causing agent by these agencies.

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<b>SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS</b>	
<b>Chemical ingredient</b>	<b>% CAS #</b>
Citric Acid Anhydrous:	<70 77-92-9
Mannitol:	<30 69-65-8
Aspartame:	<10 22839-47-0
13C Urea:	<5 58069-82-2

  

<b>SECTION 4: FIRST-AID MEASURES</b>	
<b>Inhalation:</b>	Fresh air. Rest and medical observation are recommended
<b>Skin:</b>	Rinse skin with plenty of water. Refer for medical attention if excessive redness occurs
<b>Eyes:</b>	First, rinse with plenty of water for 15 minutes (remove contact lenses if easily possible) then take to doctor.
<b>Ingestion:</b>	Rinse mouth. Drink several ounces or more of water. Refer for medical attention if abdominal pain or sore throat occurs. This product is approved by the FDA for ingestion according to the product directions for use.

  

<b>SECTION 5: FIRE-FIGHTING MEASURES</b>	
<b>Flammable Limits in air:</b>	0.28 – 2.29 kg/m <sup>3</sup> (dust) for citric acid. Unknown for Pranactin-Citric formulation.
<b>Extinguishing Media:</b>	Use Water Fog, Carbon Dioxide, Foam or Dry Chemical for surrounding fire. Use water spray to cool fire exposed containers.
<b>Special Fire Fighting Proc:</b>	Wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full face-piece operated in the positive pressure mode.
<b>Unusual Fire Hazard:</b>	Fire or excessive heat may cause production of hazardous decomposition products.

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<b>SECTION 6: ACCIDENTAL RELEASE MEASURES</b>	
<b>In case of material spill:</b>	Sweep spilled substance into dry containers. If appropriate, moisten first to prevent dusting. Wash away remainder with plenty of water.
<b>Waste Disposal</b>	Dilute individual pouch contents with large quantities of water and rinse down drain. Consult local Water Board to confirm proper disposal in your area.
<b>SECTION 7: HANDLING AND STORAGE</b>	
<b>Precautions to be taken in Handling and Storage:</b>	Do not breach container. Store at room temperature 15 to 30 °C (59 - 86°F); avoid excessive humidity. Store separated from strong oxidants, strong bases, metal nitrates and metals.
<b>SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION</b>	
Chemical Ingredient Exposure Limits:	
Citric Acid, Anhydrous	PNOS 15 mg/m <sup>3</sup> Total (OSHA), PNOS 10 mg/m <sup>3</sup> Inhalable (ACGIH)
Mannitol	PNOS 15 mg/m <sup>3</sup> Total (OSHA), PNOS 10 mg/m <sup>3</sup> Inhalable (ACGIH)
Aspartame	PNOS 15 mg/m <sup>3</sup> Total (OSHA)
<sup>13</sup> C Urea	10 mg/m <sup>3</sup> AIHA-WEEL
<u>Abbreviations:</u>	
PNOS = particulate not otherwise specified	
Mg/m <sup>3</sup> = milligrams per cubic meter	
Total = collected without size selective sampler	
Inhalable = may cause health effects anywhere in the respiratory tract	
OSHA = Occupational Safety and Health Administration	
ACGIH = American Conference of Governmental Industrial Hygienists	
AIHA = American Industrial Hygiene Association	
WEEL = Workplace Environmental Exposure Level	

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<b>SECTION 9:</b>	<b>PHYSICAL AND CHEMICAL PROPERTIES</b>
Appearance:	White Granules
Upper or lower flammability or explosive limits:	No information available
Odor:	Odorless
Vapor Pressure:	No information available
Odor threshold:	No information available
Vapor density:	No information available
pH:	2.2 (3g in 4oz water)
Relative density:	No information available
Melting point:	No information available
Solubility In Water:	Highly Soluble
Initial BP & BR:	No information available
Flash point:	No information available
Evaporation rate:	No information available
Flammability:	1
Partition coefficient:	No information available
Auto-ignition temperature:	No information available
Decomposition temperature:	No information available
Viscosity:	No information available
<b>SECTION 10:</b>	<b>STABILITY AND REACTIVITY</b>
<b>Reactivity :</b>	1
	Metal nitrates, alkali carbonate & bicarbonates, potassium tartrate. Will

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**Materials to Avoid:** corrode copper, zinc, aluminum, and their alloys

**Stability:** Stable

**Conditions To Avoid:** High temperatures, sparks and open flames

**Hazardous** None known under normal conditions

**Decomposition**

**Products:**

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<b>SECTION 11: TOXICOLOGICAL INFORMATION.</b>	
<b>Description of symptoms from lowest to most severe exposure:</b>	
Skin:	(Yes) Skin irritant, redness, itching & pain.
Eyes:	(Yes) Severe eye irritant, redness & pain.
Ingestion:	(Yes) Ingestion of dry, undiluted product may cause nausea, vomiting, diarrhea, abdominal pain, and sore throat.
<b>Effects of short or long term exposure:</b>	
Skin:	(Yes) Skin irritant, redness, itching & pain.
Eyes:	(Yes) Severe eye irritant, redness & pain.
Ingestion:	(Yes) Ingestion of dry, undiluted product may cause nausea, vomiting, diarrhea, abdominal pain, and sore throat.
<b>The numerical measure of toxicity:</b>	No information available.
<b>Acute Toxicity Level:</b>	No information available.
<b>Carcinogenicity:</b>	Pranactin Citric is not on the following lists: NTP, IARC, Federal OSHA Z list & California OSHA, and therefore is neither considered to be suspected to be a cancer causing agent by these agencies.
<b>Phenylketonurics:</b>	Contains Phenylalanine (one of the protein components of Aspartame), 84 mg, may cause headache.
<b>SECTION 12: ECOLOGICAL INFORMATION</b>	
None available at this time	

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<b>SECTION 13: DISPOSAL CONSIDERATIONS*</b>
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Dilute individual pouch contents with large quantities of water and rinse down drain. Consult local Water Board to confirm proper disposal in your area.
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<b>SECTION 14: TRANSPORT INFORMATION*</b>
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Not regulated for transportation.
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<b>SECTION 15: REGULATORY INFORMATION*</b>
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No information is available for national or regulatory information of the chemical or mixtures (including OSHA, Department of Transportation, Environmental Protection Agency, or Consumer Product Safety Commission regulations).
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<b>SECTION 16: OTHER INFORMATION</b>
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<b>DATE OF PREPARATION AND REVISION NUMBER:</b> November 25, 2015 Version 1, Rev. 0.0
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\*Note: Since other Agencies regulate this information, OSHA will not be enforcing Sections 12 through 15 (29 CFR 1910.1200(g)(2)).