

# SAFETY DATA SHEET

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NGHS / English



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## 1. IDENTIFICATION

### Product identifier

**Product Name** AZO® Urinary Pain Relief 95 mg (Product Code AQ)

### Other means of identification

**Product Code(s)** i-Health Product Code QG (WPS Id# 1384622)

### Recommended use of the chemical and restrictions on use

**Recommended Use** Urinary Pain Relief - Ingested

**Restrictions on use** See package Drug Facts Panel and/or package insert for restrictions on oral consumption of the product.

### Details of the supplier of the safety data sheet

**Supplier Identification** i-Health, Inc.

**Address** 25 Bacon Road  
Enfield, CT 06082  
USA

**Telephone** Phone: 800-722-3476

**E-mail** [ihealth.ra-info@dsm-firmenich.com](mailto:ihealth.ra-info@dsm-firmenich.com)

### Emergency telephone number

**Company Emergency Phone Number** 860-894-1200

## 2. HAZARDS IDENTIFICATION

### Classification

This product is an OTC drug regulated by the United States Food & Drug Administration intended for oral consumption.



**Appearance** Red brown**Physical state** Solid Tablet**Odor** Neutral**GHS Label elements, including precautionary statements****Danger****Hazard statements**

Harmful if swallowed

May cause cancer

**Precautionary Statements - Prevention**

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Wear protective gloves/protective clothing/eye protection/face protection

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

**Precautionary Statements - Response**

IF exposed or concerned: Get medical advice/attention

**Ingestion**

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

Rinse mouth

**Precautionary Statements - Storage**

Store locked up

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Other information**

Causes mild skin irritation.

**Unknown acute toxicity** 78.97 % of the mixture consists of ingredient(s) of unknown toxicity

10.07 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

78.97 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

78.97 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

78.97 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

78.97 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

**3. COMPOSITION/INFORMATION ON INGREDIENTS****Substance**

Not applicable.

### Mixture

Chemical name	CAS No	Weight-%	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)
Phenazopyridine hydrochloride	136-40-3	66.8	-	-
Maize starch	9005-25-8	5.59	-	-
Povidone	9003-39-8	2.1	-	-
Magnesium stearate	557-04-0	2.03	-	-

## 4. FIRST AID MEASURES

### Description of first aid measures

<b>General advice</b>	Show this safety data sheet to the doctor in attendance. IF exposed or concerned: Get medical advice/attention.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	This product is an OTC drug intended for oral consumption. If unintentionally ingested, Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

### Most important symptoms and effects, both acute and delayed

**Symptoms** No information available.

### Indication of any immediate medical attention and special treatment needed

**Note to physicians** Treat symptomatically.

## 5. FIRE-FIGHTING MEASURES

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
<b>Specific hazards arising from the chemical</b>	No information available.
<b>Hazardous Combustion Products</b>	Carbon oxides.

**Explosion Data**

Sensitivity to Mechanical Impact None.  
 Sensitivity to Static Discharge None.

**Special protective equipment for fire-fighters**

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

**6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures

**Personal precautions** Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

**Other Information** Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

**7. HANDLING AND STORAGE**

Precautions for safe handling

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing.

Conditions for safe storage, including any incompatibilities

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

Control parameters

**Exposure Limits**

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH	
Maize starch 9005-25-8	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust	
Magnesium stearate 557-04-0	TWA: 10 mg/m <sup>3</sup>	-		
Chemical name	Alberta	British Columbia	Ontario TWAEV	Quebec



Maize starch 9005-25-8	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> TWA: 3 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
Magnesium stearate 557-04-0	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> TWA: 3 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> TWA: 3 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>

**Other Exposure Guidelines** Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

**Appropriate engineering controls**

**Engineering controls** Showers  
Eyewash stations  
Ventilation systems.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection** No special protective equipment required.

**Hand protection** Wear suitable gloves.

**Skin and body protection** Wear suitable protective clothing.

**Respiratory protection** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

**Physical state** Solid  
**Appearance** Red brown  
**Odor** Neutral  
**Color** No information available  
**Odor Threshold** Not applicable

<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	No data available	None known	
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	No data available	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air		None known	
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	
Relative density	No data available	None known	
Water Solubility	Slightly soluble		
Solubility(ies)	No data available	None known	
Partition coefficient: n-octanol/water	0		
Autoignition temperature	No data available	None known	
Decomposition temperature	No data available	None known	
Kinematic viscosity	No data available	None known	



Dynamic viscosity	No data available	None known
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**Other Information**

Explosive properties	No information available
Oxidizing properties	No information available
Softening Point	No information available
Molecular Weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk Density	No information available
Particle Size	No information available
Particle Size Distribution	No information available

## 10. STABILITY AND REACTIVITY

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of Hazardous Reactions	None under normal processing.
Hazardous Polymerization	Hazardous polymerization does not occur.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous Decomposition Products	Carbon oxides.

## 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure****Product Information**

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).

**Symptoms related to the physical, chemical and toxicological characteristics**

Symptoms	No information available.
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**Numerical measures of toxicity****Acute toxicity**

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral)	635.30 mg/kg
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**Unknown acute toxicity** 78.97 % of the mixture consists of ingredient(s) of unknown toxicity  
 10.07 % of the mixture consists of ingredient(s) of unknown acute oral toxicity  
 78.97 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity  
 78.97 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)  
 78.97 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)  
 78.97 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

**Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Phenazopyridine hydrochloride	= 472 mg/kg ( Rat )	-	-
Povidone	= 100 g/kg ( Rat )	-	-

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Skin corrosion/irritation** No information available.  
**Serious eye damage/eye irritation** No information available.  
**Respiratory or skin sensitization** No information available.  
**Germ cell mutagenicity** No information available.  
**Carcinogenicity** Contains a known or suspected carcinogen. Classification based on data available for ingredients. May cause cancer.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Phenazopyridine hydrochloride 136-40-3	-	Group 2B	Reasonably Anticipated	X
Povidone 9003-39-8	-	Group 3	-	-

**Legend**

**IARC (International Agency for Research on Cancer)**

Group 2B - Possibly Carcinogenic to Humans  
 Group 3 - Not Classifiable as to Carcinogenicity in Humans

**NTP (National Toxicology Program)**

Reasonably Anticipated - Reasonably Anticipated to be a Human Carcinogen

**OSHA (Occupational Safety and Health Administration of the US Department of Labor)**

X - Present

**Reproductive toxicity** No information available.  
**STOT - single exposure** No information available.  
**STOT - repeated exposure** No information available.  
**Aspiration hazard** No information available.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity** The environmental impact of this product has not been fully investigated.



<b>Persistence and Degradability</b>	No information available.
<b>Bioaccumulation</b>	No information available.
<b>Mobility</b>	No information available.
<b>Other adverse effects</b>	No information available.

### 13. DISPOSAL CONSIDERATIONS

#### Waste treatment methods

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.
<b>California Waste Codes</b>	311

### 14. TRANSPORT INFORMATION

<b><u>DOT</u></b> Proper Shipping Name Hazard Class	NOT REGULATED NON-REGULATED N/A
<b><u>TDG</u></b>	Not applicable
<b><u>MEX</u></b>	Not applicable
<b><u>ICAO</u></b>	Not applicable
<b><u>IATA</u></b> Proper Shipping Name Hazard Class	Not applicable NON REGULATED N/A
<b><u>IMDG/IMO</u></b> Hazard Class	Not applicable N/A
<b><u>RID</u></b>	Not applicable
<b><u>ADR</u></b>	Not applicable
<b><u>ADN</u></b>	Not applicable

### 15. REGULATORY INFORMATION

#### Safety, health and environmental regulations/legislation specific for the substance or mixture

#### International Regulations

**The Montreal Protocol on Substances that Deplete the Ozone Layer** Not applicable

**The Stockholm Convention on Persistent Organic Pollutants** Not applicable

**The Rotterdam Convention** Not applicable

#### International Inventories

<b>TSCA</b>	Contact supplier for inventory compliance status.
<b>DSL/NDSL</b>	Contact supplier for inventory compliance status.
<b>EINECS/ELINCS</b>	Contact supplier for inventory compliance status.
<b>ENCS</b>	Contact supplier for inventory compliance status.
<b>KECL</b>	Contact supplier for inventory compliance status.
<b>PICCS</b>	Contact supplier for inventory compliance status.
<b>AICS</b>	Contact supplier for inventory compliance status.

#### Legend

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances

#### US Federal Regulations

##### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

##### SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

##### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

##### CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

#### US State Regulations

##### California Proposition 65

This product contains the following Proposition 65 chemicals.

Chemical name	California Proposition 65
Phenazopyridine hydrochloride - 136-40-3	Carcinogen

##### U.S. State Right-to-Know Regulations

This product may contain substances regulated by state right-to-know regulations.



Chemical name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Phenazopyridine hydrochloride 136-40-3	X	X	X		X
Maize starch 9005-25-8		X	X		

**16. OTHER INFORMATION**

**NFPA** Health hazards 1 Flammability 0 Instability 0 Physical and Chemical Properties -  
**HMIS** Health hazards 1\* Flammability 0 Physical hazards 0 Personal Protection X  
*Chronic Hazard Star Legend* \* = Chronic Health Hazard

**Prepared By** Product Stewardship  
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**Revision Note** No information available

**Disclaimer**

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**End of Safety Data Sheet**

