



# MATERIAL SAFETY DATA SHEET

**Bayer HealthCare Pharmaceuticals Inc**  
6 West Belt  
Wayne, NJ 07470

**TRANSPORTATION EMERGENCY**  
CALL CHEMTREC..... : (800) 424-9300  
  
INTERNATIONAL..... : (703) 527-3887

**NON-TRANSPORTATION**  
BAYER EMERGENCY PHONE : (888) 84-  
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## Section 1: Product and Company Identification

**Product Name:** Ultravist  
**Material Number:** PH003001

## Section 2: Composition/Information on Ingredients

### HAZARDOUS INGREDIENTS

<u>Ingredient Name/ CAS Number</u>	<u>Exposure Limits</u>	<u>Concentration</u>	
		<u>Min.</u>	<u>Max.</u>
Iopromide 73334-07-3	OSHA (PEL): ACGIH (TLV):	26%	55%
TRIS(HYDROXYMETHYL)AMINOMETHANE 77-86-1	OSHA (PEL): ACGIH (TLV):	0.1%	0.3%
EDTA, CALCIUM DISODIUM 62-33-9	OSHA (PEL): ACGIH (TLV):		0.1%

## Section 3: Hazards Identification

**EMERGENCY OVERVIEW**

**Color:** Clear, Colorless to light yellow    **Form:** Liquid    **Odor:** Odorless

### POTENTIAL HEALTH EFFECTS

## HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE

### Carcinogenic Components:

<b>NTP:</b>	None
<b>IARC:</b>	None
<b>OSHA:</b>	None

### Section 4: First Aid Measures

<b>First Aid for Eye:</b>	In case of contact, flush eyes with plenty of water for at least 15 minutes.
<b>First Aid for Skin:</b>	In case of skin contact, wash affected areas with soap and water.
<b>First Aid for Inhalation:</b>	Not applicable.
<b>First Aid for Ingestion:</b>	If ingested, seek medical attention.

### Section 5: Fire Fighting Measures

<b>Flash Point:</b>	Not Established
<b><u>Flammable Limits:</u></b>	
<b>Upper Explosion Limit (UEL %):</b>	Not Applicable
<b>Lower Explosion Limit (LEL %):</b>	
<b>Auto-ignition Temperature:</b>	Not Applicable
<b><u>Extinguishing Media:</u></b>	
<b>Suitable:</b>	Water, Carbon Dioxide, Foam, Dry Chemical, as appropriate for the source of the fire.
<b>Special Fire Fighting Procedures:</b>	Toxic and irritating gases/fumes may be given off during burning or thermal decomposition.

### Section 6: Accidental Release Measures

<b>Spill or Leak Procedures:</b>	Use appropriate personal protective equipment during clean up. Absorb material and place in appropriate containers for disposal. Wash spill area with soap and water.
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## Section 7: Handling and Storage

### Storage Temperature:

**Minimum:** 59 °F (15 °C)  
**Maximum:** 86 °F (30 °C)

**Handling/Storage Precautions:** Containers should be kept tightly closed to prevent contamination.

## Section 8: Exposure Controls/Personal Protection

### Personal Protection Equipment

**Eye Protection Requirements:** None for normal use.

**Skin Protection Requirements:** No special skin protection requirements during normal handling and use.

**Hand Protection Requirements:** No gloves required during normal handling and use.

**Protective Clothing Requirements:** No special protective clothing required.

**Ventilation Requirements:** Under normal conditions of use, special ventilation is not required.

**Respirator Requirements:** Under normal conditions of use, respiratory protection is not required.

## Section 9: Physical and Chemical Properties

**Physical Form:** Liquid  
**Color:** Clear, Colorless to light yellow  
**Odor:** Odorless  
**pH:** 6.5 - 8  
**Solubility in Water:** Soluble

## Section 10: Stability and Reactivity

**Stability:** Stable

**Hazardous Polymerization:** Will not occur

**Substances to Avoid:** Strong oxidizing agents

**Decomposition Products:** Iodine vapors

## Section 11: Toxicological Information

### Toxicity Data for Ultravist

<b>Acute oral toxicity:</b>	Not applicable.
<b>Acute dermal toxicity:</b>	Not applicable.
<b>Acute inhalation toxicity:</b>	Not applicable.
<b>Eye Irritation:</b>	Not an ocular irritant. Ocular tolerance studies of iopromide (300 mgI/mL) in rabbits showed no ocular irritation.
<b>Skin Irritation:</b>	Intravenous administration of iopromide (370 or 420 mgI/mL) caused negligible local incompatibility reactions (discoloration and slight reddening) at or near the injection site in rabbits. Similarly, intradermal or epidermal administration of iopromide (300 mgI/mL) caused very slight to moderate reddening or swelling at the injection site in guinea pigs.
<b>Repeated Dose Toxicity:</b>	Repeated intravenous dosing of iopromide (370 mgI/mL) in laboratory animals resulted in no direct signs of compound-related toxicity following daily intravenous administration for up to 5 weeks at dose levels up to 3700 mgI/kg. However, nausea, increased water consumption, and increased urine specific gravity suggesting slight to moderate osmotic nephrosis were seen in some dogs given the highest dose.
<b>Carcinogenicity:</b>	No studies to assess the carcinogenic potential of iopromide have been conducted.
<b>Mutagenicity:</b>	An in vitro Ames test, an in vitro human lymphocytes analysis of chromosome aberrations, an in vivo mouse micronucleus assay, and an in vivo mouse dominant lethal assay did not reveal evidence that iopromide is a genetic toxicant.
<b>Developmental Toxicity/Teratogenicity:</b>	Reproduction studies performed with iopromide in rats and rabbits at doses up to 3.7gI/kg (2.2 times the maximum recommended dose for a 50kg huma, or approximately 0.7 times the huma dose following normalization of the data to body surface area estimates) have revealed no evidence of direct harm to the fetus. Embryo lethality was observed in rabbits that received 3.7 gI/kg but this was considered to have been secondary to maternal toxicity.
<b>Toxicity to Reproduction/Fertility:</b>	Iopromide (370 mgI/mL) did not affect fertility or reproduction performance of male and female rats, or the fetal and postnatal development and reproductive capacity of offspring, when given at dose levels up to 3700 mgI/kg either by daily intraperitoneal administration prior to mating and during the early stages of pregnancy or by daily intravenous administration during late pregnancy, parturition and lactation.

### Toxicity Data for Iopromide

**Toxicity Note:** Intravenous (I.V.) LD50: 21,403 mg/kg (rat); 34 gm/kg (mouse).

**Section 12: Ecological Information**

**Ecological Data for Ultravist**

**Biodegradation:** Not readily biodegradable

**Ecological Note:** No data available for this product.

**Ecological Data for Iopromide**

**Ecological Note:** No data available for this component.

**Section 13: Disposal Considerations**

**Waste Disposal Method:** Waste disposal should be in accordance with existing federal, state and local environmental control laws.

**Section 14: Transportation Information**

**Domestic Surface Transportation (DOT)**

**Hazard Class or Division:** Non-Regulated

**Marine Transportation (IMO / IMDG)**

**Hazard Class Division:** Non-Regulated

**Number:**

**Air Transportation (ICAO / IATA)**

**Hazard Class Division:** Non-Regulated

**Number:**

**Section 15: Regulatory Information**

**United States Federal Regulations**

**OSHA Hazcom Standard Rating:** Not subject to OSHA

**TSCA Inventory List:** This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical application.

**CERCLA Hazardous Substance:**

Component(s)  
None

Reportable Quantity

**SARA Title III**

**SARA Section 302 Extremely Hazardous Substances:**

Component(s)/  
CAS Number

Concentration  
Min.      Max.

None

**SARA Section 313 Toxic Chemicals:**

<u>Component(s)/ CAS Number</u>	<u>Reporting Threshold</u>	<u>Concentration</u>	
		<u>Min.</u>	<u>Max.</u>
None			

The following chemicals are specifically listed by individual states; other product specific health and safety data in other sections of the MSDS may also be applicable for state requirements. For details on your regulatory requirements you should contact the appropriate agency in your state.

**State Right-to-Know Information**

<u>Component(s)/ CAS Number</u>	<u>State Code</u>	<u>Concentration</u>	
		<u>Min.</u>	<u>Max.</u>
Water 7732-18-5	PA-N, NJ-N	60%	100%
Iopromide 73334-07-3	NJ-N	15%	40%

The following component(s) are listed under New Jersey Special Hazards:

Hydrochloric Acid, NF 7647-01-0	NJ-S	0.1%	1%
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The following component(s) are listed under Massachusetts Extra-ordinary Hazards:

Hydrochloric Acid, NF 7647-01-0	MA-X	0.1%	1%
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**State Code Translation Table**

PA-N = Pennsylvania Non-hazardous  
NJ-N = New Jersey Other - includes predominant ingredients  
NJ-S = New Jersey Special Health Hazardous Substance List  
MA-X = Massachusetts Extra-ordinary Hazardous Substance List

**Section 16: Other Information**

Contact: Product Safety Department  
Phone: (888) 84-BAYER  
MSDS Number: 000000003001  
Version Date: 04/10/2008  
MSDS Version: 1.3

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