



SAFETY DATA SHEET

122000005011

Ultravist®

Version 3.0

Revision Date 07/02/2014

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product information

Product Name: Ultravist®
MSDS Number: 122000005011

Use : Medical Product

Company

BAYER HEALTHCARE LLC
Bayer HealthCare Pharmaceuticals
100 Bayer Boulevard PO Box 915
Whippany, NJ 07981-0915
USA
1888-84-BAYER

In case of emergency: 1888-84-BAYER
Chemtrec: (800) 424-9300

2. HAZARDS IDENTIFICATION

Emergency Overview

Colour: clear, Colorless to light yellow **Form:** liquid **Odour:** odourless.

GHS Classification:

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

GHS Label element:

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Hazard Communication (29CFR 1910.1200)

This material is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This material is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

Label Ingredients: Water; Iopromide; Trometamol; Hydrochloric acid; Sodium
Calciumedetate;

Other Ingredients

Weight percent	Components	CAS-No.
55%	Iopromide	73334-07-3

4. FIRST AID MEASURES

If inhaled: Not applicable.

In case of skin contact: In case of skin contact, wash affected areas with soap and water.

In case of eye contact: Rinse immediately with plenty of water for at least 15 minutes.

If swallowed: If ingested, seek medical attention.

Contact Number: Use the Bayer Emergency Number in Section 1

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray jet, Foam, Dry powder, Carbon dioxide (CO₂)

Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting: Fire may cause evolution of: Carbon dioxide (CO₂) Carbon monoxide (CO) nitrogen oxides (NO_x) Hydrogen iodide

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.

Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment.

Methods for cleaning up: Soak up with inert absorbent material. Flush with plenty of water.

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Additional advice: No special precautions required.

Further Accidental Release Notes No special precautions required.

7. HANDLING AND STORAGE**Handling:**

Avoid contact with skin, eyes and clothing.

Containers should be kept tightly closed to prevent contamination.

No special protective measures against fire required.

Storage:

Storage temperature: 59 - 86 °F (15 - 30 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Respiratory protection:**

No personal respiratory protective equipment normally required.

Eye protection:

None for normal use.

Skin and body protection:

No special skin protection requirements during normal handling and use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	liquid
Colour:	clear, Colorless to light yellow
Odour:	odourless
Odour Threshold:	No applicable information is available
Melting point:	No applicable information is available
Boiling point/boiling range:	No applicable information is available
Density:	No applicable information is available
Bulk density:	No applicable information is available
Vapour pressure:	No applicable information is available
Viscosity, dynamic:	No applicable information is available
Viscosity, kinematic:	No applicable information is available
Flow time:	No applicable information is available
Surface tension:	No applicable information is available

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Miscibility with water:	No applicable information is available
Water solubility:	soluble
pH:	6.5 - 8
Relative density:	No applicable information is available
Partition coefficient:	No applicable information is available
Solubility(ies):	No applicable information is available
Flash point:	Not applicable
Flammability (solid, gas):	No applicable information is available
Ignition temperature:	No applicable information is available
Explosion limits:	No applicable information is available

10. STABILITY AND REACTIVITY

Conditions to avoid: no data available

Materials to avoid: Strong oxidizing agents

Hazardous reactions: None known.

Thermal decomposition:

no data available

Hazardous decomposition products:

Iodine vapors

Oxidizing properties:

No statements available.

Impact Sensitivity:

no data available

11. TOXICOLOGICAL INFORMATION

Acute toxicity (other routes of administration):

Iopromide

LD50 intravenous mouse: > 40,000 mg/kg

LD50 intravenous rat: > 31,000 mg/kg

LD50 intravenous dog: > 21,000 mg/kg

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Skin irritation:

Intravenous administration of iopromide (370 or 420 mg/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 mg/mL) caused very slight to moderate reddening or swelling at the injection site in guinea pigs.

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.

Eye irritation:

Not an ocular irritant. Ocular tolerance studies of iopromide (300 mg/mL) in rabbits showed no ocular irritation.

Genotoxicity in vitro:

Iopromide
Ames test Salmonella typhimurium
Result: negative

Carcinogenicity:

Iopromide
Result: Animal testing did not show any carcinogenic effects.

Reproductive toxicity:

Iopromide
Result: No toxicity to reproduction

Teratogenicity:

Iopromide
Result: No indication of teratogenic effects.

Pharmaceutic effects:

Contrast agent

CMR classification:

Carcinogenicity: No studies to assess the carcinogenic potential of iopromide have been conducted.

Mutagenicity: 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.

Teratogenicity: Reproduction studies performed with iopromide in rats and rabbits at doses up to 3.7g/kg (2.2 times the maximum recommended dose for a 50kg human, or approximately 0.7 times the human 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 g/kg but this was considered to have been secondary to maternal toxicity.

Reproductive toxicity: Iopromide (370 mg/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 mg/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.

Carcinogenicity:

No Carcinogenic substances as defined by IARC, NTP and/or OSHA

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STOT - single exposure:

no data available

STOT - repeated exposure:no data available

12. ECOLOGICAL INFORMATION**General advice:**

Do not allow to enter surface waters or groundwater.

Toxicity to fish:

Iopromide

LC50 > 10,000 mg/l

Test species: Danio rerio (zebra fish) Duration of test: 48 h

LC50 > 10,000 mg/l

Test species: Leuciscus idus (Golden orfe) Duration of test: 48 h

Toxicity to daphnia and other aquatic invertebrates:

Iopromide

EC50 > 10,000 mg/l

Test species: Daphnia Duration of test: 48 h

Toxicity to bacteria:

Iopromide

EC50 > 10,000 mg/l

tested on: Photobacterium phosphoreum

Duration of test: 30 min

Biodegradability:Not readily biodegradable.

13. DISPOSAL CONSIDERATIONSWaste disposal should be in accordance with existing federal, state and local environmental control laws.

14. TRANSPORT INFORMATION**Land transport (CFR)**

Non-Regulated

US Sea transport (IMDG)

Non-Regulated

US Air transport (ICAO / IATA cargo aircraft only)

Non-Regulated

US Air transport (ICAO / IATA passenger and cargo aircraft)

Non-Regulated

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International IATA - -
IMDG - -

15. REGULATORY INFORMATION

US. Toxic Substances Control Act This product is exempt from TSCA under Section 3
 (2)(B)(vi) when used for pharmaceutical application.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A) Components
 None

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required Components
 None

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components
 None

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists

Weight percent	Components	CAS-No.
60 - 100%	Water	7732-18-5
15 - 40%	Iopromide	73334-07-3

New Jersey Environmental Hazardous Substances List and/or New Jersey RTK Special Hazardous Substances Lists

Weight percent	Components	CAS-No.
0.1 - 1%	Hydrochloric acid	7647-01-0

California Prop. 65

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating Non-Hazardous

16. OTHER INFORMATION

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.