

Product Name: Ultiva
Issued: Jun-10-2013

SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Ultiva

Synonyms: Ultiva (Remifentanil Hydrochloride for Injection), 1 mg; Ultiva (Remifentanil Hydrochloride) for injection, 2mg; Ultiva (Remifentanil Hydrochloride) for Injection, 5 mg; Remifentanil Hydrochloride for Injection

Trade name: Ultiva

List Number: 4498; 4504; 4507; M801; M802; M803

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: Manufactured for:
AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
1-800-255-5162
+1-847-937-7433

Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433

E-mail Address: AbbVie.SDS@abbvie.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Reproductive toxicity Category 2
Specific target organ systemic toxicity (repeated exposure) Category 1

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger: T - Toxic

Risk Phrases: R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed

R62 - Possible risk of impaired fertility

Section 2. Hazards identification

2.2 Label elements



Signal Word: Danger

Hazard Statements:
H361 - Suspected of damaging fertility or the unborn child
H372 - Causes damage to organs through prolonged or repeated exposure

P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P501 - Dispose of contents/container to an approved waste disposal plant

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Glycine 56-40-6	85-95	Present		Not Hazardous*	No data available
Remifentanil Hydrochloride 132539-07-2	5-15	NA	R67 T, R48/25 R62	STOT SE 3 (H336) Repr. 2 (H361) STOT RE 1 (H372)	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16
For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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Skin Contact:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Protection of First-aiders:	Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms:	No signs and symptoms from occupational exposure are known. Clinical data suggests the following: headaches, vomiting, nausea, slow heart rate, decreased blood pressure, rash, muscle weakness, numbness, respiratory depression. Reported to cause the following: chest pain, chest discomfort, seizures, hypoxemia. Direct contact may cause: opioid effects.
Medical Conditions Aggravated by Exposure:	None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: kidney, central nervous system, testes, respiratory system, cardiovascular system.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician:	Specific narcotic antagonist, eg. nalorphine hydrobromide or naloxone hydrochloride are antidotes for respiratory depression produced by active ingredient.
Additional Information:	A Schedule II Controlled drug. Can cause euphoria and dependence.

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8

6.2. Environmental precautions

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Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Glycine 56-40-6	Not Applicable	None
Remifentanil Hydrochloride 132539-07-2	1 mcg /m ³ , STEL	None

8.2. Exposure controls

Engineering Controls: No special provisions are required under normal product use conditions. Use inside a process enclosure when handling the bulk formulation.

Respiratory Protection: Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

Gloves: Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

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Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	White to off-white Solid
Odor:	Not determined.
Odor Threshold:	Not determined
pH:	2.5-3.5 for the reconstituted product.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	Not determined.
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Not determined.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	Not determined.
Vapor Density (Air = 1):	Not determined.
Specific Gravity:	Not determined.
Solubility(ies):	Not determined.
Partition coefficient: n-octanol/water	Not determined.
Autoignition Temp. (°C):	Not determined.
Decomposition temperature (°C):	Not determined.
Viscosity (centipoise):	Not determined.
Explosion Severity:	Not determined.
Oxidizer Properties:	Not determined.

9.2. Other information

Not determined

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition products

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Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Unlikely
Dermal: Yes
Inhalation: Unlikely

Acute Toxicity - Oral: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Glycine 56-40-6	LD50 =	4920	mg/kg	Mice Rats
Remifentanil Hydrochloride 132539-07-2	LD50 >	2000	mg/kg	Rats

Acute Toxicity - Dermal: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Remifentanil Hydrochloride 132539-07-2	LD50 >	2000	mg/kg	Rabbits

Acute Toxicity - Inhalation: Not determined.

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Remifentanil Hydrochloride 132539-07-2	LD50 (it) =	8	mcg/kg	Rats	
	LD50 (iv) =	17.2 113-114	mg/kg	Rats Mice Dogs	

Corrosivity: Not determined.

Dermal Irritation: Active Ingredient : Did not produce skin irritation in rabbits.

Eye Irritation: Active Ingredient : Produced mild eye irritation in rabbits. Transient eye irritation in animals testing.

Sensitization: Active Ingredient : Negative in the Buehler assay in guinea pigs at challenge concentrations.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Active Ingredient : May cause drowsiness or dizziness
Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Remifentanil Hydrochloride 132539-07-2	Kidney Testes Central Nervous System Liver	Rats Dogs	0.5 -2.5	mg/kg	Intravenous	28 days

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Reproductive Effects:

Active Ingredient : In animals adverse reproductive effects include: male reproductive system.

Based on these experimental results, protection against maternal toxicity will provide adequate protection against potential embryo-fetal toxicity and teratogenicity

Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration
Remifentanil Hydrochloride 132539-07-2	Rats	0.5	mg/kg	Intravenous	Premating in Males

Carcinogenicity:

Not determined.

Mutagenicity:

Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Remifentanil Hydrochloride 132539-07-2	Negative	Negative	Positive with activation Negative without activation	No Data.

Aspiration hazard:

Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

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Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

14.1. UN Number: Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

Section 15. Regulatory Information

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

International Inventories

Chemical Name	EINECS/ELINCS	TSCA	DSL	NDSL	PICCS
Glycine 56-40-6	Present	X	X	Not listed.	X
Remifentanil Hydrochloride 132539-07-2	-	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Glycine 56-40-6	Present	-	X	X	Present	HSR003783
Remifentanil Hydrochloride 132539-07-2	-	-	-	-	-	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

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Chemical Name	Percent	NTP:	IARC:	ACGIH:
Glycine	85-95	Not Listed	Not Listed	Not Listed
Remifentanil Hydrochloride	5-15	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Glycine	85-95	No	Not Applicable	Not applicable
Remifentanil Hydrochloride	5-15	No	Not Applicable	Not applicable

Immediate Health: Yes

Delayed Health: No

Fire: No

Sudden Pressure: No

Reactivity: No

RCRA Status: Not determined.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class: Not determined.

Health: 1

Fire: 1

Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases: R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed, R62 - Possible risk of impaired fertility

Full text of H-Statements referred to under sections 2 and 3

H336 - May cause drowsiness or dizziness, H372 - Causes damage to organs (a,b,c) through prolonged or repeated exposure if inhaled, H361 - Suspected of damaging fertility or the unborn child if inhaled

Document Authored By: Global Occupational Toxicology (D-03QC)

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