



Retisert™
(fluocinolone acetonide intravitreal implant)
MATERIAL SAFETY DATA SHEET

Effective Date: 6/2/05 Supersedes: None

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Section 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Retisert™ (fluocinolone acetonide intravitreal implant) 0.59 mg	For Information: (9-011) 353-51-859631
Product Code:	NDC 24208-416-01	For Emergency: 1-800-535-5053 or 1-352-323-3500
Chemical Family:	Corticosteroid	
Manufactured By:	Bausch & Lomb - Ireland	
Address:	Unit 424/425 Industrial Estate Waterford, Ireland	

Section 2: COMPOSITION / INFORMATION ON INGREDIENTS

CAS #	COMPONENT NAME	% w/w	OCCUPATIONAL EXPOSURE LIMITS / GUIDELINES					UNITS					
			OSHA PEL TWA /STEL	ACGIH TLV TWA /STEL	NIOSH REL TWA /STEL	IRELAND TWA /STEL	HSE TWA /STEL						
Tablet Core													
Active:													
67-73-2	Fluocinolone Acetonide ¹	< 6	NE	NE	NE	NE	NE	NA					
Inactives:													
9002-89-5	Polyvinyl Alcohol (98% hydrolyzed)	< 5	NE	NE	NE	NE	NE	NA					
232-674-9	Microcrystalline Cellulose ²	< 20	15*5**	NE	10	NE	10*5**	NE	10*4**	20	10*4**	20	mg/m ³
557-04-0	Magnesium Stearate	< 1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
7732-18-5	Purified Water	< 2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
Polymer Coating:													
9002-89-5	Polyvinyl Alcohol (98% hydrolyzed)	< 10	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
NA	Silicone Elastomer	< 45	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
NA	Silicone Adhesive	< 20	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
Suture tab:													
9002-89-5	Polyvinyl Alcohol (98% hydrolyzed)	< 20	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA

1. Bausch & Lomb, Inc. has adopted an Occupational Exposure Limit, as established by SafeBridge Consultants, Inc., of 0.04 ug/m3 as an 8-hour TWA.

* Total Dust (as cellulose) ** Respirable Dust (as cellulose)

N/E: Not Established
N/A: Not Applicable
OSHA: Occupational Safety & Health Administration
NIOSH: National Institute for Occupational Safety & Health
ACGIH: American Conference of Governmental Industrial Hygienists

TWA: 8-Hour Time-Weighted Average
STEL: Short-Term Exposure Limit
C: Ceiling Limit
REL: Recommended Exposure Limit
MG/M³: Milligrams Per Cubic Meter
PPM: Parts Per Million

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Section 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Retisert™ is a surgically implanted drug delivery system composed of a white to off white central core consisting of 0.59 mg of fluocinolone acetonide (FA) compressed into a tablet. The tablet is encased in a silicone elastomer cup containing a release orifice and attached to a yellowish to light brown suture tab. It is intended for the treatment of non-infectious posterior uveitis. It is anticipated that implant contents may irritate skin, eyes, mucous membranes, and other contaminated tissues. This product is contraindicated in individuals with known or suspect hypersensitivity to any of the ingredients of this preparation and to other corticosteroids. Use only in accordance with product literature.

PRECAUTIONS:

Retisert™ is a surgical implant, indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, and must be used in accordance with product literature. The active drug substance in this implant is a synthetic corticosteroid (fluocinolone acetonide). This product is contraindicated in individuals with known or suspect hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

The toxicological properties of this material have not been fully characterized; therefore, laboratory control systems and work practices should be in place to minimize the potential for skin contact, eye contact, ingestion, and inhalation in the event that the integrity of this implant becomes compromised or damaged. It is anticipated that implant contents may irritate skin, eyes, and mucous membranes.

POTENTIAL HEALTH EFFECTS**EYE:**

Non-irritating to the external surfaces of the eyes when used as directed. Implant contents are irritating to the eyes.

SKIN:

Non-irritating to the skin and mucous membranes when used as directed. Implant contents may cause allergic skin reaction.

INGESTION:

Ingestion of the implant contents (i.e., through poor hygiene practices) may be harmful.

INHALATION:

If dusts of this material are inhaled, they may cause irritation of the nose and upper respiratory system. Symptoms of such over exposure may include sneezing, coughing, and nasal congestion.

CHRONIC HEALTH EFFECTS

Refer to Section 11. The toxicological properties of this product have not been fully characterized.

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Section 3: HAZARDS IDENTIFICATION (cont.)**TARGET ORGANS:**

The toxicological properties of this material have not been fully investigated

Section 4: FIRST AID MEASURES**EYES:**

In the event that the implant contents come in contact with the outside of the eye, immediately flush with plenty of water for at least 15 minutes. Seek medical attention.

SKIN:

In the event that the implant contents come in contact with the skin, immediately wash with soap and flush with copious amounts of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing separately before reuse. Seek medical attention.

INGESTION:

If this product is swallowed, obtain medical attention immediately.

INHALATION:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention immediately.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:

This product is contraindicated in individuals with known or suspect hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

RECOMMENDATIONS TO PHYSICIANS:

Treat symptoms and eliminate overexposures.

Section 5: FIRE FIGHTING MEASURES**FLAMMABLE PROPERTIES:****Flash Point:**

Not Flammable.

Autoignition Temperature:

Not Applicable.

Flammable Limits (in air by volume %):

Not Applicable

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Section 5: FIRE FIGHTING MEASURES (cont.)**EXTINGUISHING MEDIA:**

Use water spray or fog, foam, carbon dioxide, or dry chemical.

HAZARDOUS COMBUSTION PRODUCTS:

This material must be substantially pre-heated before ignition can occur. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon monoxide, carbon dioxide, and nitrogen and sulfur oxides)

SPECIAL FIRE FIGHTING INSTRUCTIONS:

Fire fighters must wear Self-Contained Breathing Apparatus and full protective equipment.

Section 6: ACCIDENTAL RELEASE MEASURES**SPILL AND LEAK RESPONSE:****Undamaged Implants:**

Use proper personal protection (refer to Section 8). Collect product and place in a suitable container and seal tightly. Dispose of in accordance with Section 13.

Damaged Implants (with exposed contents):

Trained personnel using pre-planned procedures should respond to releases involving damaged or compromised implants.

Proper protective equipment including PVC or other plastic gloves, safety glasses, and a disposable laboratory coat should be used for cleaning up a damaged implant with exposed contents. Provide adequate ventilation. In the event that dust is generated, a NIOSH-certified air-purifying respirator with HEPA cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air-purifying respirators may not provide adequate protection.

Prior to initiating cleanup, ensure that all sources of ignition have been eliminated. Exercise caution to avoid creating dust. Use a vacuum equipped with HEPA filtration to vacuum up any visible particulate. DO NOT SWEEP. Wet a Kim Wipe (or other suitable towelette) with a small amount of methanol to improve absorption of residual materials and carefully wipe down the contaminated area. Rinse the area thoroughly with soapy water. Place all spill residues and contaminated PPE in an appropriate, labeled container and seal. Dispose of in accordance with Section 13 of this document.

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Section 7: HANDLING AND STORAGE

STORAGE AND HANDLING PRACTICES:

Caution should be exercised in handling Retisert™ in order to avoid damage to the implant, which may result in an increase rate of drug release or inadvertent exposure to contents. Retisert™ should be handled only by the suture tab, in accordance with product literature.

Store in the original container at 15°- 25° C (59°-77°F). Protect from freezing.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS:

No special ventilation requirements when used in accordance with product literature. Operations that may compromise the integrity of the implant (crushing, cutting, etc.) must be conducted in a powder handling hood, with a verifiable airflow, that is designed to accommodate potent drug compounds. Decontaminate work surfaces routinely to prevent accumulation of dusts.

RESPIRATORY PROTECTION:

No respiratory protection required when handling implants in accordance with product literature.

EYE PROTECTION:

Use approved safety goggles or safety glasses.

HAND PROTECTION:

Handle implants in accordance with product literature. If an implant is damaged, use appropriate chemical resistant gloves (i.e., PVC or other plastic glove materials).

ADDITIONAL PROTECTIVE CLOTHING & EQUIPMENT:

Disposable laboratory coat, emergency eye wash & shower units

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES:

Appearance / Physical State: White to off-white tablet encased in a silicone elastomer cup with a yellowish to light brown suture tab

Odor: Odorless

CHEMICAL PROPERTIES:

Boiling Point: Not Determined

Vapor Pressure: Not Determined

Solubility (In Water): Insoluble

Solubility (In Methanol): Soluble

Evaporation Rate (n-BuAc=1) Not Applicable

Specific Gravity (H₂O = 1): Not Determined

Melting Point: Not Determined

Vapor Density: Not Determined

Odor Threshold: Not Applicable

Freezing Point: Not Determined

pH: Not Determined

Molecular Weight: Not Applicable

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Section 10: STABILITY AND REACTIVITY**STABILITY:**

Stable

INCOMPATIBLE MATERIALS AND CONDITIONS TO AVOID:

Avoid exposure to or contact with extreme temperatures, light, and incompatible chemicals.

HAZARDOUS POLYMERIZATION:

Will not occur.

HAZARDOUS DECOMPOSITION:

When exposed to extreme temperatures, this material may generate fluorine, magnesium oxide, carbon monoxide, carbon dioxide, and nitrogen and sulfur oxides.

Section 11: TOXICOLOGICAL INFORMATION

RTECS No.: TU3830000

Fluocinolone Acetonide

Toxicity Data:	ORL-RAT	LD50: > 4 GM/KG
	ORL-MOUSE	LD50: > 4 GM/KG

CARCINOGENICITY, MUTAGENICITY, REPRODUCTIVE EFFECTS:

Long-term animal studies have not been performed on Retisert™ to evaluate the carcinogenic and mutagenic potential, or the effect on fertility of fluocinolone acetonide.

Fluocinolone acetonide was not genotoxic *in vitro* in the Ames test, the mouse lymphoma TK assay, or *in vivo* in the mouse bone marrow micronucleus assay.

PREGNANCY, TERATOGENIC EFFECTS: PREGNANCY CATEGORY C.

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Fluocinolone acetonide, when administered subcutaneously at a dose of 0.13 mg/kg/day (approximately 10,000 times the daily clinical dose of Retisert™), during days 6 to 18 of pregnancy in the rabbit, induced abortion at the end of the third and at the beginning of the fourth gestational week. When administered subcutaneously to rats and rabbits during gestation at a maternal toxic dose 50 µg/kg/day (approximately 4,000 times the clinical dose or Retisert™), fluocinolone acetonide caused abortions and malformations in a few surviving fetuses.

There are no adequate and well-controlled studies in pregnant women. Retisert™ should be used during pregnancy **only** if the potential benefit justifies the potential risk to the fetus.

Refer to product literature for additional information.

The toxicological effects of Retisert™ have not been fully characterized.

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Section 12: ECOLOGICAL INFORMATION

No data available on the environmental impact of this product.

Section 13: DISPOSAL CONSIDERATIONS
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Waste disposal must be in accordance with appropriate Federal, State and local regulations.

Section 14: TRANSPORT INFORMATION
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	US DOT	IATA	IMO	RID/ADR	Canadian TDG
Shipping Name:	Not Regulated*	Not Regulated	No information available	No information available	No information available
Hazard Class:	NA	NA			
UN Number:	NA	NA			
Package Group:	NA	NA			

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR, Part 173) are not applicable to this product.

Section 15: REGULATORY INFORMATION

FDA Designations:

Prescription Medication Only
NDC 24208-416-01 (0.59 mg)

OSHA HAZARD COMMUNICATION STANDARD (29 CFR 1910.1200):

Retisert™ contents are considered hazardous under the Occupational Safety & Health Administration Hazard Communication Standard.

CERCLA (Comprehensive Response Compensation, and Liability Act):

(Fluocinolone acetonide) Not Listed

SARA TITLE III (Superfund Amendments and Reauthorization Act):

- **SECTION 302 (Extremely Hazardous Substances):** (Fluocinolone acetonide) Not Listed
- **SECTION 311/312 HAZARD CLASS(s):** (Fluocinolone acetonide) Acute, Chronic
- **SECTION 313 (Toxic Chemicals):** (Fluocinolone acetonide) Not Listed

TOXIC SUBSTANCE CONTROL ACT (TSCA):

CAS# 67-73-2, Fluocinolone Acetonide, is listed on the TSCA Inventory.
CAS# 9002-89-5, Polyvinyl Alcohol (98% hydrolyzed), is listed on the TSCA Inventory
CAS# 232-674-9, Microcrystalline Cellulose, is listed on the TSCA Inventory.
CAS# 557-04-0, Magnesium Stearate, is listed on the TSCA Inventory.

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Section 15: REGULATORY INFORMATION (cont.)**CALIFORNIA PROPOSITION 65:**

This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels that would require a warning under the statute.

Section 16: OTHER INFORMATION**LABEL PRECAUTIONARY STATEMENTS:**

WARNING! THE TOXICOLOGICAL PROPERTIES OF THIS PRODUCT HAVE NOT BEEN FULLY INVESTIGATED. USE ONLY IN ACCORDANCE WITH PRODUCT LITERATURE.

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