

MATERIAL SAFETY DATA SHEET

Effective Date: 3/27/09 Supersedes: 1/29/02 Page 1 of 10

Section 1: IDENTIFICATION

PRODUCT:

Product Name: Corneal Storage Media

(Optisol, Optisol GS, Dexsol, McCarey-Kaufman Media)

Product Description: Chondroitin-sulphate-based, commercial storage media 50004-OPT, 50006-OPT, 50003-DEX, 50001-MK

Intended Use: Storage and preservation of human tissue.

COMPANY IDENTIFICATION:

Bausch & Lomb, Incorporated 1400 N. Goodman Street Rochester, New York 14609

For Information: 1-800-553-5340

EMERGENCY TELEPHONE NUMBER:

24-Hour Emergency: 1-800-535-5053

Section 2: HAZARD(S) IDENTIFICATION

CLASSIFICATION (All Products): Eye irritation: Category 2B

Skin irritation: Category 3

LABELING (All Products):

Pictograms: (None required)

Signal Word: Warning

Hazard Exposure to this product through inhalation, ingestion, or skin contact may

Statements: cause irritation.

Precautionary Avoid generating splashes, sprays, or mists.

Statements: Avoid accidental injection.

Avoid contact with strong acids, bases, oxidizers.

Avoid release to the environment.

POTENTIAL HEALTH EFFECTS (All Products):

No adverse health effects should occur from routine use of this material in the manner specified by the manufacturer's instructions. The only likely symptom of exposure would be reddening or inflammation after accidental injection. The potential health effects from the individual components are as follows:

EYE:

Contact with the eyes may cause mild irritation, which is alleviated upon rinsing.

MATERIAL SAFETY DATA SHEET

Page 2 of 10

Section 2: HAZARD(S) IDENTIFICATION (cont.)

SKIN:

Contact with the skin may cause mild irritation, which is alleviated upon rinsing.

INHALATION:

Inhalation of a vapor or mist of this product's solutions may cause mild irritation. Symptoms are generally alleviated upon breathing fresh air.

INGESTION:

Ingestion of this product's solutions, especially in large volumes, may cause gastric distress.

INJECTION:

Injection of this product's solutions may cause local reddening, tissue swelling, and discomfort.

CHRONIC HEALTH EFFECTS

This product is not known to cause any significant chronic health effects.

CARCINOGENICITY:

NTP: No IARC: No OSHA: No

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

OPTISOL:

CAS#	Chemical Identitiy	Concentration, % W/W	EINECS / ELINCS #
9082-07-9	Chondroitin Sulfate	< 1	NA
9004-54-0	Dextran 40	< 1	232-677-5
Mixture	Optisol Base Powder	< 1	NA
144-55-8	Sodium Bicarbonate	< 1	205-633-8
1403-66-3	Gentamycin	< 1	215-765-8
Mixture	Amino Acids	< 1	NA
113-24-6	Sodium Pyruvate	< 1	204-024-4
56-85-9	L-Glutamine	< 1	200-292-1
60-24-2	2-Mercaptoethanol	< 1	200-464-6
7732-18-5	Purified Water	Balance	231-791-2

MATERIAL SAFETY DATA SHEET

Page 3 of 10

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS (cont.)

OPTISOL GS:

CAS#	Chemical Identitiy	Concentration, % W/W	EINECS / ELINCS #
9082-07-9	Chondroitin Sulfate	< 1	NA
9004-54-0	Dextran 40	< 1	232-677-5
Mixture	Optisol Base Powder	<1	NA
144-55-8	Sodium Bicarbonate	<1	205-633-8
1403-66-3	Gentamycin	< 1	215-765-8
3810-74-0	Streptomycin Sulfate	< 1	223-286-0
Mixture	Amino Acids	<1	NA NA
113-24-6	Sodium Pyruvate	< 1	204-024-4
56-85-9	L-Glutamine	< 1	200-292-1
60-24-2	2-Mercaptoethanol	<1	200-464-6
7732-18-5	Purified Water	Balance	231-791-2

DEXSOL:

CAS#	Chemical Identitiy	Concentration, % W/W	EINECS / ELINCS #
9082-07-9	Chondroitin Sulfate	< 1	NA
9004-54-0	Dextran 40	< 1	232-677-5
Mixture	Dexsol Base Powder	< 1	NA
144-55-8	Sodium Bicarbonate	<1	205-633-8
1403-66-3	Gentamycin	< 1	215-765-8
Mixture	Amino Acids	<1	NA
113-24-6	Sodium Pyruvate	< 1	204-024-4
56-85-9	L-Glutamine	< 1	200-292-1
60-24-2	2-Mercaptoethanol	< 1	200-464-6
7732-18-5	Purified Water	Balance	231-791-2

MATERIAL SAFETY DATA SHEET

Page 4 of 10

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS (cont.)

McCarey-Kaufman Medium:

CAS#	Chemical Identitiy	Concentration, % W/W	EINECS / ELINCS #
9004-54-0	Dextran 40	< 1	232-677-5
Mixture	MK Base Powder	<1	NA
75277-39-3	HEPES Buffer	<1	278-169-7
144-55-8	Sodium Bicarbonate	<1	205-633-8
143-74-8	Phenol Red	< 1	205-609-7
1403-66-3	Gentamycin	< 1	215-765-8
7732-18-5	Purified Water	Balance	231-791-2

NOTE: The remainder of this Safety Data Sheet applies to each of these products.

Section 4: FIRST AID MEASURES

EYE CONTACT:

If chemical is splashed in eyes, open person's eyes while under gentle running water. Use sufficient force to open eyelids. Have person "roll" eyes. Minimum flushing time is 15 minutes. Get medical attention if irritation or other symptoms develop or persist.

SKIN CONTACT:

Basic work place hygiene should prevent any problems. If contact with this product leads to reddening, inflammation, or irritation, flush the exposed area with running water. Remove any contaminated clothing, taking care not to contaminate eyes. Get medical attention if irritation or other symptoms develop or persist.

INHALATION:

If vapor or mist of this product is inhaled, causing irritation, remove person to fresh air. If necessary, use artificial respiration to support vital functions. Remove or cover gross contamination to avoid exposure to rescuers. Get medical attention.

INGESTION:

If chemical is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, <u>do not</u> induce vomiting. Person should drink milk, egg whites, or large quantities of water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow.

INJECTION:

Get medical attention if irritation or other symptoms develop or persist.

MATERIAL SAFETY DATA SHEET

Page 5 of 10

Section 5: FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA:

In the event of a fire, use the following suppression methods for surrounding materials: Carbon dioxide, dry chemical powder, appropriate foam or water fog.

HAZARDOUS COMBUSTION PRODUCTS:

During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.

SPECIAL FIRE FIGHTING INSTRUCTIONS:

As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:

For small releases (< 1 liter), take basic hygiene precautions. Ensure adequate ventilation. Lightweight chemical resistant gloves, a lab coat and eye protection should be worn.

Large releases (> 1 liter) which are not immediately controlled, should be responded to by trained personnel using preplanned procedures. Ensure adequate ventilation. Minimum Personal Protective Equipment should be Level D: lab coat, chemical resistant gloves, chemically resistant apron, boots, and splash goggles. Respiratory protection should not be necessary. However, a NIOSH approved air-purifying respirator, equipped with the appropriate cartridges, may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present.

Refer to Sections 7 and 8.

ENVIRONMENTAL PRECAUTIONS:

Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:

For small releases (< 1 liter): Absorb spilled liquid with paper towels. Wash contaminated area with soap and water, absorb with paper towels, and rinse with water.

Large releases (> 1 liter): Absorb spilled liquid with universal spill pads or other suitable absorbent materials. Decontaminate the area thoroughly.

Decontaminate equipment using soapy water before maintenance begins. Collect all rinsates and dispose of according to applicable Federal, State, or local procedures where adequate ventilation is provided.

Place all spill residue in a double plastic bag and seal. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13).

MATERIAL SAFETY DATA SHEET

Page 6 of 10

Section 7: HANDLING AND STORAGE

HANDLING:

Avoid contact with eyes. Avoid prolonged or repeated exposure to skin or mucous membranes, and breathing mists/vapors. Use in a well ventilated area. Wash thoroughly with soap and water after handling.

STORAGE:

Keep vials tightly closed when not in use. Store vials in a cool, dry location, away from direct sunlight, sources of intense heat, or where freezing is possible.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

CONTROL PARAMETERS:

		OCCUPATIONAL EXPOSURE LIMITS / GUIDELINES										
CAS#	COMPONENT NAME	OSHA PEL TWA /STEL		ACGIH TLV NIOSH REL TWA /STEL TWA /STEL		IRELAND TWA/STEL		HSE TWA/STEL		UNITS		
9082-07-9	Chondroitin Sulfate	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
9004-54-0	Dextran 40	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
Mixture	Optisol Base Powder	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
Mixture	Dexsol Base Powder	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
Mixture	MK Base Powder	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
75277-39-3	HEPES Buffer	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
143-74-8	Phenol Red	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
144-55-8	Sodium Bicarbonate	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
1403-66-3	Gentamycin	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
Mixture	Amino Acids	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
113-24-6	Sodium Pyruvate	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
56-85-9	L-Glutamine	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
60-24-2	2-Mercaptoethanol	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
7732-18-5	Purified Water	NE I	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA

N/E: Not Established

TWA: 8-Hour Time-Weighted Average

N/A: Not Applicable

ACGIH: American Conference of Governmental Industrial Hygienists

NIOSH: National Institute for Occupational Safety & Health

OSHA: Occupational Safety & Health Administration

PPM: Parts Per Million

STEL: Short-Term Exposure Limit

C: Ceiling Limit

REL: Recommended Exposure Limit

 $\label{eq:NOTE:limits/standards} \textbf{NOTE: Limits/standards shown for guidance only. } \textbf{Follow applicable regulations.}$

MATERIAL SAFETY DATA SHEET

Page 7 of 10

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION (cont.)

ENGINEERING CONTROLS:

Use with good general ventilation. No special controls required.

RESPIRATORY PROTECTION:

Respiratory protection is not generally needed when using this product. Maintain airborne contaminant concentrations below guidelines listed in Section 7. If respiratory protection is needed, use only protection authorized in 29 CFR 1910.134, or applicable State regulations. Use supplied air respiratory protection if oxygen levels are below 19.5% or are unknown.

EYE PROTECTION:

Splash goggles or safety glasses with side shields.

SKIN PROTECTION:

Wear chemical resistant gloves for routine industrial use.

ADDITIONAL PROTECTIVE CLOTHING & EQUIPMENT:

Use body protection appropriate for the task (i.e. laboratory coat, lab apron).

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid

> Color: Clear, orange-colored Odor: No distinctive odor

Odor Threshold: Not determined

pH-Value: 7.0 - 8.0

Melting Point: Not applicable

Freezing Point: 0 °C (32 °F) **Initial Boiling Point:** 100°C (212°F)

> Flash Point: Not applicable

Evaporation Rate (water=1):

Flammability (solid,gas): Not applicable

Explosion Limits: Not determined Vapor Pressure: 18 mm @ 20°C Vapor Density: Not determined

Specific Gravity (H₂O=1): 1.0

Solubility: Soluble in water

Partition Coefficient: Not applicable Not determined **Auto-Ignition Temperature: Decomposition Temperature:** Not determined

Viscosity: Not determined

MATERIAL SAFETY DATA SHEET

Page 8 of 10

Section 10: STABILITY AND REACTIVITY

REACTIVITY:

No known hazards.

CHEMICAL STABILITY:

Stable

POSSIBILITY OF HAZARDOUS REACTIONS:

Will not occur.

CONDITIONS TO AVOID:

Any conditions which are incompatible with water. Avoid mixing this product with incompatible chemicals.

INCOMPATIBLE MATERIALS:

This product is not compatible with strong acids or bases and strong oxidizers.

HAZARDOUS DECOMPOSITION:

Thermal decomposition of the components of this product may produce carbon dioxide, carbon monoxide, and oxides of nitrogen.

Section 11: TOXICOLOGICAL INFORMATION

TOXICITY DATA:

While not tested, this product is not expected to be toxic. Mild eye irritation may occur if this product is splashed in the eye.

IRRITANCY OF PRODUCT:

While not tested, this product is not expected to cause irritancy to the skin. Mild eye irritation may occur if this product is splashed in the eye.

SENSITIZATION TO THE PRODUCT:

No component is known to be a sensitizer.

REPRODUCTIVE TOXICITY INFORMATION:

Listed below is information concerning the effects of this product and its components on the human reproductive system.

<u>Mutagenicity:</u> Due to the dilute concentration of components, this product is not expected to cause mutation effects in humans.

<u>Teratogenicity:</u> Due to the dilute concentration of components, this product is not expected to cause teratogenic effects in humans.

Reproductive Toxicity: Due to the dilute concentration of components, this product is not expected to cause adverse reproductive effects in humans.

MATERIAL SAFETY DATA SHEET

Page 9 of 10

Section 11: TOXICOLOGICAL INFORMATION (cont.)

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:

No specific medical conditions are known to be aggravated by exposure to this product.

RECOMMENDATIONS TO PHYSICIANS:

This product is not expected to cause clinical symptoms. If such symptoms occur, treat the symptoms, while alleviating the cause. Biological Exposure Indices (BEIs) are not applicable to the components of this product.

Section 12: ECOLOGICAL INFORMATION

ENVIRONMENTAL STABILITY:

The components of this product will degrade in the environment into smaller organic and inorganic constituents.

EFFECT OF MATERIAL ON PLANTS or ANIMALS:

No unusual effects on plants or animals are expected if this product is released into the environment; however, as with all chemicals, work practices should be aimed at minimizing environmental releases.

EFFECT OF CHEMICAL ON AQUATIC LIFE:

This product is not known to cause adverse effects on aquatic life; however, as with all chemicals, work practices should be aimed at minimizing environmental releases.

Section 13: DISPOSAL CONSIDERATIONS

All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the sole responsibility of the waste generator.

Section 14: TRANSPORT INFORMATION

	US DOT	IATA	IMO	RID/ADR	Canadian DG
Shipping Name:	Not Regulated				
Hazard Class:	NA	NA	NA	NA	NA
UN Number:	NA	NA	NA	NA	NA
Package Group:	NA	NA	NA	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.

MATERIAL SAFETY DATA SHEET

Page 10 of 10

Section 15: REGULATORY INFORMATION

OSHA HAZARD COMMUNICATION STANDARD (29 CFR 1910.1200):

Corneal Storage Media (All Products) is considered non-hazardous under the Occupational Safety & Health Administration Hazard Communication Standard.

REACH:

This product is exempt from REACH requirements.

TOXIC SUBSTANCE CONTROL ACT (TSCA):

The chemicals in this product are listed on the TSCA Inventory.

SARA TITLE III (Superfund Amendments and Reauthorization Act):

SECTION 302 (Extremely Hazardous Substances): No Components Listed SECTION 311, 312 (Hazard Categories): No Components Listed SECTION 313 (Toxic Chemicals): No Components Listed

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 which would require a warning under the statute.

Section 16: OTHER INFORMATION

To the best of our knowledge, the information contained herein is accurate. However, neither Bausch & Lomb Incorporated nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Bausch & Lomb Incorporated or any of its subsidiaries be liable for any special, incidental or consequential damages.