



MATERIAL SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI and Canadian WHMIS Standards

PART I *What is the material and what do I need to know in an emergency?*

1. PRODUCT IDENTIFICATION

TRADE NAME (AS LABELED):

SURGILENS CORNEAL SHIELD

PRODUCT USE:

Ocular Postsurgical Healing

MANUFACTURED FOR:

BAUSCH & LOMB

BY:

9342 Jeronimo Road
Irvine, CA 92718

EMERGENCY PHONE:

CHEMTREC: 800-424-9300, Intl: 1-202-483-7616

MORE INFO? CUSTOMER SERVICE:

1-800-338-2020

DATE OF PREPARATION:

July 13, 1998 (Updated Company information Jan. 2002)

NOTE: This product is defined as an "Article" under the U.S. Federal OSHA Hazard Communication Standard (29 CFR 1910.1200), and the Canadian Workplace Hazardous Materials Standard. As an article, this product presents negligible health and physical hazards under reasonably anticipated circumstances of use. Subsequently, a Material Safety Data Sheet is not required for this product under Standards cited above. This document is prepared to provide persons using this product with additional safety information.

2. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% w/w	EXPOSURE LIMITS IN AIR					
			ACGIH		OSHA		IDLH	OTHER
			TLV	STEL	PEL	STEL		
Gelatin	9004-70-8	1-2	NE	NE	NE	NE	NE	NE
Sodium Carboxymethyl Cellulose	9004-32-4	< 1	NE	NE	NE	NE	NE	NE

NE = Not Established

C = Ceiling Limit

See Section 16 for Definitions of Terms Used

NOTE: All WHMIS required information is included. It is located in appropriate sections based on the ANSI Z400.1-1993 format.

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: This product consists of a clear, colorless, pliable, thin lens. This product does not have any unusual health, fire, or reactivity hazards. If involved in a fire, this product may decomposes and generate carbon monoxide, carbon dioxide, and other organic compounds.

HEALTH EFFECTS OR RISKS: An Explanation in **Lay Terms.**

ACUTE: There is no health hazard anticipated to occur to medical personnel during routine use of this product. In terms of patient-care, it is important to note that this product should not be used on individuals who have the following conditions:

- Corneal Anesthesia
- Evidence of Acute External Ocular Infections
- Intraocular Infections
- Monocular Vision
- Dysthyroid Ophthalmopathy
- Nasolacrimal Duct Obstruction
- Blepharitis
- Chalazion
- Lax Lids
- Dry Eye Syndrome
- Hypersensitivity to Collagen
- Hypersensitivity to Bovine-Derived Products

CHRONIC: Not applicable.

TARGET ORGANS: None.

HAZARDOUS MATERIAL INFORMATION SYSTEM			
HEALTH	(BLUE)	0	
FLAMMABILITY	(RED)	0	
REACTIVITY	(YELLOW)	0	
PROTECTIVE EQUIPMENT			NA
EYES	RESPIRATORY	HANDS	BODY
None needed under normal circumstances of use.			

See Section 16 for Definition of Ratings

PART II *What should I do if a hazardous situation occurs?*

4. FIRST-AID MEASURES

This product is not anticipated to cause injury to medical personnel under normal circumstances of use or handling. Persons using this product should consult a physician or other medical professional in the unlikely event that an accident involving this product results in injury.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not applicable.

AUTOIGNITION TEMPERATURE: Not applicable.

FLAMMABLE LIMITS (in air by volume, %):

Lower (LEL): Not applicable.

Upper (UEL): Not applicable.

FIRE EXTINGUISHING MATERIALS:

Water Spray: YES

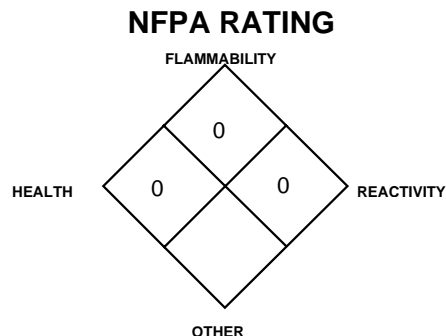
Foam: YES

Halon: YES

Carbon Dioxide: YES

Dry Chemical: YES

Other: Any "ABC" Class



See Section 16 for Definition of Ratings

5. FIRE-FIGHTING MEASURES (Continued)

UNUSUAL FIRE AND EXPLOSION HAZARDS: This product is not flammable. If involved in a fire, this product will decompose and produce toxic gases carbon monoxide, carbon dioxide.

Explosion Sensitivity to Mechanical Impact: Not applicable.

Explosion Sensitivity to Static Discharge: Not applicable.

SPECIAL FIRE-FIGHTING PROCEDURES: Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment.

6. ACCIDENTAL RELEASE MEASURES

RELEASE RESPONSE: Due to the nature of this product, no special accidental release measures are normally required. Uncontrolled releases involving other materials released near this product should be responded to by appropriately trained personnel using pre-planned procedures.

PART III *How can I prevent hazardous situations from occurring?*

7. HANDLING and STORAGE

WORK, STORAGE AND HANDLING PRACTICES: Medical personnel should review *Care and Handling Instructions* before using this product. Sterile, sealed packages containing this product should be stored at a controlled room temperature, 15-30°C (59-86°F). Avoid exposing this product to heat above 40°C (104°F) or temperatures at or below freezing, 0°C (32°F).

Medical personnel should not resterilize this product; all open and unused shields must be discarded. Medical personnel must also carefully screen patients for any known hypersensitivities to collagen or bovine-derived products. In addition, patients should be monitored for reactions to the product. The following steps summarize the recommended instructions for use:

1. Anesthetize and hydrate the eye before applying the product. The shield should be lifted from the protective case using blunt forceps.
 2. Partially fill the holding well with a sterile, hydrating fluid (e.g. Balanced Salt Solution).
 3. Return the product to holding well and add sterile hydrating fluid to cover the shield. Allow the product to hydrate for a minimum of five minutes.
 4. Moisten the eye with sterile hydrating fluid. Apply the shield to the eye using blunt forceps. Hydrate the eye and shield thoroughly. The eye may be patched, as determined by the physician. No ointment should be used.
-

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS: No special ventilation and engineering controls are required for use of this product.

RESPIRATORY PROTECTION: No special respiratory protection is required for use of this product. Respiratory protection is required for firefighters, as authorized in the Federal OSHA Standard (29 CFR 1910.134) or applicable U.S. State or Canadian regulations.

EYE PROTECTION: No special eye protection is required for use of this product.

HAND PROTECTION: No special hand protection is normally required for use of this product.

BODY PROTECTION: No special body protection is required for use of this product.

9. PHYSICAL and CHEMICAL PROPERTIES

RELATIVE VAPOR DENSITY (air = 1): Not applicable.

SPECIFIC GRAVITY (water = 1): Not determined.

SOLUBILITY IN WATER: Soluble.

VAPOR PRESSURE, mm Hg @ 20°C: Not applicable.

EVAPORATION RATE (n-BuAc = 1): Not applicable.

MELTING/FREEZING POINT: Not applicable.

BOILING POINT: Not applicable.

pH: Not applicable.

9. PHYSICAL and CHEMICAL PROPERTIES (Continued)

ODOR THRESHOLD: Not applicable.

COEFFICIENT OF OIL/WATER DISTRIBUTION (PARTITION COEFFICIENT): Not applicable.

APPEARANCE AND COLOR: Clear, colorless, pliable, thin lens

HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance is a distinguishing characteristic of this product.

10. STABILITY and REACTIVITY

STABILITY: Stable.

DECOMPOSITION PRODUCTS: If exposed to extremely high temperatures, this product will decompose to generate carbon dioxide, carbon monoxide, and a variety of organic compounds.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Strong oxidizers.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid exposure or contact to extreme temperatures, incompatible chemicals.

PART IV *Is there any other useful information about this material?*

11. TOXICOLOGICAL INFORMATION

TOXICITY DATA: The specific toxicology data available for components greater than 1% in concentration are listed below. It is important to note the data are for the components of this product, and not for the product itself.

GELATIN:

TDLo - Intraperitoneal - mouse: 700 mg/kg: female 7-13 day(s) after conception: Specific Developmental Abnormalities - urogenital system; growth statistics

SODIUM CARBOXYMETHYL CELLULOSE:

LD₅₀ - Oral - rat: 27000 mg/kg

LC₅₀ - Inhalation - rat: >5800 mg/m³/4 hours

LD₅₀ - Oral - mouse: >27 gm/kg

LD₅₀ - Oral - rabbit: >27 gm/kg

LD₅₀ - skin - rabbit: >2 gm/kg

SODIUM CARBOXYMETHYL CELLULOSE (continued):

LD₅₀ - Oral - guinea pig: 16000 mg/kg

TDLo - Oral - rat: 227 gm/kg/13 weeks (continuous); changes in liver weight, changes in urine composition, changes in sodium levels

TDLo - Subcutaneous - rat: 1900 mg/kg/19 weeks (intermittent):

Tumorigenic - neoplastic

TD - Subcutaneous - rat: 8600 mg/kg/19 weeks (intermittent); neoplastic

TD - Subcutaneous - rat: 33 gm/kg/22 weeks (intermittent): neoplastic

TDLo - Oral - rat: 140 mg/kg: male 14 day(s) pre-mating: Reproductive -

Paternal Effects - prostate, seminal vesicle, Cowper's gland, accessory glands

SUSPECTED CANCER AGENT: This product's components are not found on the following lists: U.S. FEDERAL OSHA Z LIST, NTP, IARC, and CAL/OSHA and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies

IRRITANCY OF PRODUCT: This product is not irritating under normal circumstances of use or handling.

SENSITIZATION TO THE PRODUCT: This product contains no known sensitizer after prolonged or repeated contact.

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

Mutagenicity: This product is not reported to produce mutagenic effects in humans.

Embryotoxicity: This product is not reported to produce embryotoxic effects in humans.

Teratogenicity: This product is not reported to cause teratogenic effects in humans.

Reproductive Toxicity: This product is not reported to cause reproductive effects in humans. Clinical studies on mice exposed to relatively high doses of Gelatin (a component of this product) via intraperitoneal exposure provided reproductive toxicity data; intraperitoneal exposures are not anticipated to occur when this product is used as intended.

A *mutagen* is a chemical which causes permanent changes to genetic material (DNA) such that the changes will propagate through generational lines. An *embryotoxin* is a chemical which causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A *teratogen* is a chemical which causes damage to a developing fetus, but the damage does not propagate across generational lines. A *reproductive toxin* is any substance which interferes in any way with the reproductive process.

ACGIH BIOLOGICAL EXPOSURE INDICES: Currently, there are no ACGIH Biological Exposure Indices (BEIs) associated with the components of this product.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: In terms of effect on medical personnel, no medical conditions are known to be aggravated by this product. Refer to Section 3 (Hazard Identification) for information related to patent medical conditions which could be affected by use of this product.

RECOMMENDATIONS TO PHYSICIANS: Treat symptoms.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: This product is biodegradable. The following environmental data are available for the components of this product:

SODIUM CARBOXYMETHYL CELLULOSE: Inherently biodegradable.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: This product is not anticipated to harm terrestrial plant or animal life.

EFFECT OF CHEMICAL ON AQUATIC LIFE: This product is not anticipated to harm aquatic plant or animal life. The following aquatic toxicity data are available for the components (in pure form) of this product.

SODIUM CARBOXYMETHYL CELLULOSE:

No Observable effect concentration (rainbow trout) = saturated solution/96 hours

No Observable effect concentration (daphnia) = saturated solution/96 hours

No Observable effect concentration (algae) = saturated solution/96 hours

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: The shields will dissolve in the eyes; subsequently, waste-handling is not normally pertinent to this product. If unused product is disposed, the shields may be disposed of as permitted by local waste-handling authority.

U.S. EPA WASTE NUMBER: Not applicable.

14. TRANSPORTATION INFORMATION

THIS MATERIAL IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION.

PROPER SHIPPING NAME: Not applicable.

HAZARD CLASS NUMBER and DESCRIPTION: Not applicable.

UN IDENTIFICATION NUMBER: Not applicable.

PACKING GROUP: Not applicable.

DOT LABEL(S) REQUIRED: Not applicable.

NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (1996): Not applicable.

MARINE POLLUTANT: The components of this product are not designated by the DOT to be Marine Pollutants (49 CFR 172.101, Appendix B).

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: THIS MATERIAL IS NOT CONSIDERED AS DANGEROUS GOODS.

15. REGULATORY INFORMATION

ADDITIONAL U.S. REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA THRESHOLD PLANNING QUANTITY: Not applicable.

U.S. CERCLA REPORTABLE QUANTITY (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: The components of this product are on the TSCA inventory.

OTHER U.S. FEDERAL REGULATIONS: U.S. Federal law restricts this device to sale by, or on the order of, a physician. Additionally, this product meets the definition of an "Article" under the U.S. Federal OSHA Hazard Communication Standard (29 CFR 1910.1200). For further information, the definition of "Article" is provided below.

Article means a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical, and does not pose a physical hazard or health risk to employees.

15. REGULATORY INFORMATION (Continued)

U.S. STATE REGULATORY INFORMATION: The components of this product are not covered under specific State regulations, as denoted below:

Alaska - Designated Toxic and Hazardous Substances: No.

California - Permissible Exposure Limits for Chemical Contaminants: No.

Florida - Substance List: No.

Illinois - Toxic Substance List: No.

Kansas - Section 302/313 List: No.

Massachusetts - Substance List: No.

Michigan - Critical Materials Register: No.

Minnesota - List of Hazardous Substances: No.

Missouri - Employer Information/Toxic Substance List: No.

New Jersey - Right to Know Hazardous Substance List: No.

North Dakota - List of Hazardous Chemicals, Reportable Quantities: No.

Pennsylvania - Hazardous Substance List: No.

Rhode Island - Hazardous Substance List: No.

Texas - Hazardous Substance List: No.

West Virginia - Hazardous Substance List: No.

Wisconsin - Toxic and Hazardous Substances: No.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No component of this product is on the California Proposition 65 lists.

LABELING (Precautionary Statements): This product is an article; no label information is required under OSHA 29 CFR 1910.1200 or ANSI Z400.1 to address the chemical hazards.

ADDITIONAL CANADIAN REGULATIONS:

CANADIAN DSL INVENTORY: The components of this product are on the DSL inventory.

OTHER CANADIAN REGULATIONS: This product meets the definition of an article under WHMIS Regulations (Hazardous Products Act, 6&7, Part II (Sections 11 and 12).

CANADIAN ENVIRONMENTAL PROTECTION AGENCY (CEPA) PRIORITIES SUBSTANCES LISTS: No component of this product is on the Priorities Substances Lists.

CANADIAN WHMIS SYMBOLS: Not applicable.

16. OTHER INFORMATION

PREPARED BY:

CHEMICAL SAFETY ASSOCIATES, Inc.
9163 Chesapeake Drive, San Diego, CA 92123-1002
(619) 565 - 0302

DATE OF PRINTING:

January 22, 2002

<p>The information contained herein is based on data considered accurate. However, no warranty is expressed or implied regarding the accuracy of these data or the results to be obtained from the use thereof. Bausch & Lomb assumes no responsibility for injury to the vendee or third persons proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Additionally, Bausch & Lomb assumes no responsibility for injury to vendee or third persons proximately caused by abnormal use of the material even if reasonable safety procedures are followed. Furthermore, vendee assumes the risk in his use of the material.</p>

DEFINITIONS OF TERMS

A large number of abbreviations and acronyms appear on a MSDS. Some of these which are commonly used include the following:

CAS #: This is the Chemical Abstract Service Number which uniquely identifies each constituent. It is used for computer-related searching.

EXPOSURE LIMITS IN AIR:

ACGIH - American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits. **TLV** - Threshold Limit Value - an airborne concentration of a substance which represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour Time Weighted Average (**TWA**), the 15-minute Short Term Exposure Limit, and the instantaneous Ceiling Level (**C**). Skin absorption effects must also be considered.

OSHA - U.S. Occupational Safety and Health Administration.

PEL - Permissible Exposure Limit - This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL," is placed next to the PEL which was vacated by Court Order. **IDLH** - Immediately Dangerous to Life and Health - This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury. **The DFG** - **MAK** is the Republic of Germany's Maximum Exposure Level, similar to the U.S. PEL. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (**OSHA**). NIOSH issues exposure guidelines called Recommended Exposure Levels (**RELs**). When no exposure guidelines are established, an entry of **NE** is made for reference.

HAZARD RATINGS:

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM: Health Hazard: **0** (minimal acute or chronic exposure hazard); **1** (slight acute or chronic exposure hazard); **2** (moderate acute or significant chronic exposure hazard); **3** (severe acute exposure hazard; onetime overexposure can result in permanent injury and may be fatal); **4** (extreme acute exposure hazard; onetime overexposure can be fatal). Flammability Hazard: **0** (minimal hazard); **1** (materials that require substantial pre-heating before burning); **2** (combustible liquid or solids; liquids with a flash point of 38-93°C [100-200°F]); **3** (Class IB and IC flammable liquids with flash points below 38°C [100°F]); **4** (Class IA flammable liquids with flash points below 23°C [73°F] and boiling points below 38°C [100°F]). Reactivity Hazard: **0** (normally stable); **1** (material that can become unstable at elevated temperatures or which can react slightly with water); **2** (materials that are unstable but do not detonate or which can react violently with water); **3** (materials that can detonate when initiated or which can react explosively with water); **4** (materials that can detonate at normal temperatures or pressures).

NATIONAL FIRE PROTECTION ASSOCIATION: Health Hazard: **0** (material that on exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials); **1** (materials that on exposure under fire conditions could cause irritation or minor residual injury); **2** (materials that on intense or continued exposure under fire conditions could cause temporary incapacitation or possible residual injury); **3** (materials that can on short exposure could cause serious temporary or residual injury); **4** (materials that under very short exposure causes death or major residual injury). Flammability Hazard and Reactivity Hazard: Refer to definitions for "Hazardous Materials Identification System".

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the National Fire Protection Association (**NFPA**). Flash Point - Minimum temperature at which a liquid gives off sufficient vapors to form an ignitable mixture with air. Autoignition Temperature: The minimum temperature required to initiate combustion in air with no other source of ignition. LEL - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. UEL - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: **LD₅₀** - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; **LC₅₀** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** concentration expressed in parts of material per million parts of air or water; **mg/m³** concentration expressed in weight of substance per volume of air; **mg/kg** quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include **TDLo**, the lowest dose to cause a symptom and **TCLo** the lowest concentration to cause a symptom; **TDo**, **LDLo**, and **LDo**, or **TC**, **TCo**, **LCLo**, and **LCo**, the lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** The sources are: **IARC** - the International Agency for Research on Cancer; **NTP** - the National Toxicology Program, **RTECS** - the Registry of Toxic Effects of Chemical Substances, **OSHA** and **CAL/OSHA**. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** **BEI** - ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV. **Ecological Information:** **EC** is the effect concentration in water. **BCF** = Bioconcentration Factor, which is used to determine if a substance will concentrate in lifeforms which consume contaminated plant or animal matter. Coefficient of Oil/Water Distribution is represented by **log K_{ow}** or **log K_{oc}** and is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

This section explains the impact of various laws and regulations on the material. **U.S.:** **EPA** is the U.S. Environmental Protection Agency. **DOT** is the U.S. Department of Transportation. **SARA** is the Superfund Amendments and Reauthorization Act. **TSCA** is the U.S. Toxic Substance Control Act. **CERCLA (or Superfund)** refers to the Comprehensive Environmental Response, Compensation, and Liability Act. Labeling is per the American National Standards Institute (**ANSI Z129.1**). **CANADA:** **CEPA** is the Canadian Environmental Protection Act. **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **TC** is Transport Canada. **DSL/NDSL** are the Canadian Domestic/Non-Domestic Substances Lists.