

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): **VITRASERT**

SYNONYMS: **Cytovene®
Ganciclovir**

PRODUCT USE: Intravitreal Implant

DOSE: Not applicable

MANUFACTURED FOR: **BAUSCH & LOMB, Rochester, NY 14609**

BY: AMP, Inc., Irvine, CA 92718

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

MORE INFO? CUSTOMER SERVICE: 1-800-338-2020

2. COMPOSITION and INFORMATION ON INGREDIENTS

Vitrasert contains a compound called Ganciclovir. Ganciclovir is a synthetic nucleoside analogue of 2'-deoxyguanosine that inhibits replication of the herpes virus, both in vitro and in vivo. Sensitive human viruses include cytomegalovirus (CMV), herpes simplex virus-1 and -2 (HSV-1, HSV-2), Epstein-Barr Virus, and varicella zoster virus. The product is in the form of small implants for the eyes, which are supplied in individual unit boxes in sterile Tyvek packaging. The composition of the implants is described in the following table.

CHEMICAL NAME	CAS #	% w/w	EXPOSURE LIMITS IN AIR					OTHER
			ACGIH		OSHA			
			TLV	STEL	PEL	STEL	IDLH	
Ganciclovir: 9-[[2-hydroxy-1-(hydroxymethyl)-ethoxy]methyl]guanine	Not Established	4.5 mg/tablet	NE	NE	NE	NE	NE	Manufacturer Recommended Occupational Exposure Limit: 5 µg/m ³ (Syntex)
Magnesium Stearate	557-04-0	< 1	10 mg/m ³ (for stearates; A4, Not Classifiable as a Human Carcinogen)	NE	NE	NE	NE	NE
Polyvinylalcohol Polymer	9002-89-5 (for monomer)	> 1	NE	NE	NE	NE	NE	NE
Ethylene-Vinyl Acetate Co-Polymer	108-05-4 (for monomer)	Balance	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 is an off-white colored tablet. This product is odorless. Acute over-exposures, prolonged over-exposures, or repeated exposures to this product may cause adverse effects on the reproductive and blood systems. This product is a possible human carcinogen and reproductive toxin. The product is not flammable. Emergency responders must wear proper personal protective equipment.

SYMPTOMS OF OVER-EXPOSURE BY ROUTE OF EXPOSURE: No adverse health effects should occur from routine use of this material in the manner specified by the manufacturer's instructions. The health effects describe below are usually associated with therapeutic use of this product. These health effects may also be observed in accidental over-exposures in occupational use situations.

INHALATION: Because of the form and size of this product, inhalation is not anticipated to be a significant route of occupational exposure. Inhalation of dusts or particulates generated from this product may cause mild irritation of the nose and throat. Symptoms are generally alleviated upon breathing fresh air.

CONTACT WITH SKIN or EYES: Contact with the skin is not reported to be irritating. However, prolonged or repeated skin exposures may cause reddening and irritation in sensitive individuals.

This product is designed to be implanted in the eyes for the treatment of specific eye disorders. The product is not reported to be irritating, however therapeutic effects of such exposure include the following health effects: decrease in visual acuity, cataract formation, hemorrhages in eye tissue, and other adverse effects of the eye tissue. Other health effects which have been reported during therapeutic use of this product include the following: headaches, central nervous system effects, acne, rashes, dry skin, hair loss, changes in the senses (hearing, taste), digestive system problems, blood and lymphatic system disorders, and metabolic system changes.

Though over-exposure via eye contact is not anticipated to be a significant route of occupational over-exposure, if eye contact occurs, then the exposure symptoms described in the paragraph above may be observed. Additionally, contact with broken or abraded skin with this product may cause adverse health effects.

SKIN ABSORPTION: Skin absorption is not anticipated to be a significant route of exposure for the components of this product.



INGESTION: Ingestion is not anticipated to be a significant route of occupational exposure for this product. If ingestion of this product occurs, symptoms which may develop can include nausea, vomiting, diarrhea and gastric distress. Ingestion may also cause the development of symptoms described under "Contact with Skin or Eyes".

INJECTION: Injection of this product's solutions may cause local reddening, tissue swelling, and discomfort. Symptoms described under "Contact with Skin or Eyes" may also occur after injection over-exposures.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms.

ACUTE: Over-exposures to small quantities of this product for brief periods of time is not reported to cause any immediate, observable effect. Over-exposure to large quantities of this product via eye-contact, contact with broken skin, or ingestion can include visual disturbances, central nervous system effects, and systemic problems.

CHRONIC: Clinical studies involving animals exposed to Ganciclovir, the active component of this product, indicate carcinogenic effects and adverse effects on the reproductive system. Refer to Section 11 (Toxicological Information) on this MSDS for additional information.

HAZARDOUS MATERIAL SYSTEM			
HEALTH		(BLUE)	2
FLAMMABILITY		(RED)	1
REACTIVITY		(YELLOW)	0
PROTECTIVE EQUIPMENT			X
EYES	RESPIRATORY	HANDS	BODY
	See Section 8		See Section 8
For routine industrial applications			

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

4. FIRST-AID MEASURES

SKIN EXPOSURE: The practice of basic work place hygiene should prevent any problems. If contact with this product occurs, flush the exposed area with running water for 15 minutes. Remove any contaminated clothing, taking care not to contaminate eyes. Victim must seek medical attention.

EYE EXPOSURE: If the product contaminates the eyes via an occupational exposure, open person's eyes while under gentle running water. Use sufficient force to open eyelids. Have person "roll" eyes. Minimum flushing is for 15 minutes. Victim must seek medical attention.

INHALATION: If dusts or particulates of this product are 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.

INGESTION: If chemical is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not 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.

Persons who may be over-exposed to a chemical, must be taken for medical attention. Rescuers should be taken for medical attention, if necessary. Take copy of label and MSDS to physician or health professional with the person.

5. FIRE-FIGHTING MEASURES

FLASH POINT, °C (method): Not applicable.

AUTOIGNITION TEMPERATURE, °C: Not applicable.

FLAMMABLE LIMITS (in air by volume, %): Lower (LEL): Not applicable.

Upper (UEL): Not applicable.

FIRE EXTINGUISHING MATERIALS: In the event of a fire, use suppression methods for surrounding materials.

Water Spray: YES

Carbon Dioxide: YES

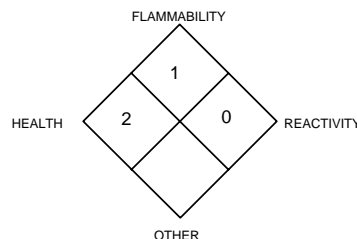
Foam: YES

Dry Chemical: YES Halon: YES

Other: Any "ABC" Class.

UNUSUAL FIRE AND EXPLOSION HAZARDS: This product presents a slight fire hazard at elevated temperatures. When involved in a fire, this material may decompose and produce irritating fumes and toxic gases including carbon monoxide, carbon dioxide, and oxides of nitrogen and magnesium.

NFPA RATING



Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural fire fighters must wear self-contained Breathing Apparatus and full protective equipment. If possible, fire-response actions should avoid generating dusts or particulates of this product.

6. ACCIDENTAL RELEASE MEASURES

SPILL and LEAK RESPONSE: For small releases of this product (i.e. one tablet) wear double latex or nitrile gloves, safety glasses, and appropriate body protection. Large or uncontrolled releases should be responded to by trained personnel using pre-planned procedures. Proper protective equipment should be used, including double latex or nitrile gloves, full body gown, and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of the air-purifying respirator. SCBA must be worn in environments in which oxygen levels are below 19.5% or are unknown.

In case of a spill, clear the affected area, protect people, and respond with trained personnel. If necessary, sweep-up or vacuum spilled material. Avoid generating dusts of this product. Triple rinse area thoroughly with soap and water. Place all spill residue in a double plastic bag. Dispose of in accordance with Federal, State, and local waste disposal regulations.

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

7. HANDLING and STORAGE

WORK PRACTICES and HYGIENE PRACTICES: As with all chemicals, avoid getting this material ON YOU or IN YOU. Wash hands after handling this product. Do not eat or drink while handling this product. Wash hands thoroughly after handling this product or equipment and containers which contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with product.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Operations of risk associated with the use of this product include:

- Opening packets containing this product.
- Opening damaged packages containing this material.
- Placement of implant.

DO NOT CLIP OR CRUSH NEEDLE WITH WHICH THIS PRODUCT WAS IN CONTACT. Use of this product should meet the following provisions.

- Work should be performed in a designated area for working with hazardous drugs;
- Containment devices, such as a Biological Safety Cabinet, should be used;
- Contaminated waste must be properly handled; and,
- Work areas must be regularly decontaminated.

STORAGE and HANDLING PRACTICES: Employees must be trained to properly use the product. Ensure packages of this product are properly labeled. Store the product away from incompatible materials. Store product in original container. Recommended storage temperature is 15-30 °C (59-86 °F). Protect from light. Protect from exposures to excessive heat.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear gloves (double-gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials, and other disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION and ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. Admixtures or manipulations of this drug should be carried out in an antineoplastic drug safety cabinet. The cabinet should be regularly cleaned following the manufacturer's recommendations, but no less frequently than weekly. All surfaces should be thoroughly washed with water and detergent and triple rinsed. During decontamination, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS for the clean-up of a large spill. HEPA filters on the antineoplastic drug safety cabinet should be changed every six months. Technicians should be aware of the risks associated with this drug via training, and should use the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS for the clean-up of large spills. The safety cabinet should be tested and certified as recommended by the National Sanitation Foundation in Standard Number 49.

RESPIRATORY PROTECTION: A full-face respirator with a HEPA filter should be used until a Biological Safety Cabinet is installed. A respirator is not required for routine conditions of use with a Biological Safety Cabinet.

EYE PROTECTION: Chemical splash goggles, or regular splash goggles, with a full face-shield.

HAND PROTECTION: Double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff.

BODY PROTECTION: A full body gown which is closed at the front and has long sleeves. The gown should be made of Tyvek^(TM), PE-Coated Tyvek^(TM) and SARANEX^(TM).

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

9. PHYSICAL and CHEMICAL PROPERTIES

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

EVAPORATION RATE (water = 1): Not applicable.

SPECIFIC GRAVITY (water = 1): >1.0

FREEZING/MELTING POINT: 242-255°C, (467-472°F -decomposition)

SOLUBILITY IN WATER: Soluble.

BOILING POINT: Not applicable.

VAPOR PRESSURE, mm Hg @ 25 °C: 4.3 mg/mL

pH: Not applicable.

ODOR THRESHOLD: Not available.

LOG OIL/WATER DISTRIBUTION COEFFICIENT: Not available.

APPEARANCE AND COLOR: This product is an odorless, off-white, crystalline solid.

HOW TO DETECT THIS SUBSTANCE (warning properties): This product does not have any unique warning properties.

10. STABILITY and REACTIVITY

STABILITY: Stable.

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

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is not compatible with strong oxidizers.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid exposure to elevated temperatures and contact with incompatible chemicals.

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

11. TOXICOLOGICAL INFORMATION

TOXICITY DATA: The following toxicity data are available for the components of this product.

Ganciclovir:

LD₅₀ (oral, mice) > 2000 mg/kg

LD₅₀ (oral, dog) > 1000 mg/kg

Ethylene Vinyl Acetate Copolymer:

LD₅₀ (oral, rat) > 1000 mg/kg

Magnesium Stearate:

LD₅₀ (oral, rat) > 10000 mg/kg

LC₇₀ (inhalation, rat) = 200 mg/L (one hour)

LC₂₀ (inhalation, rat) = 2 mg/L (two weeks)

Draize test (eye, rabbit) = Non-irritating

Draize Test (skin, rabbit) = Non-irritating

Long Term Chronic Ingestion: Increased

incidence of stone formation in the lower

urinary tract, reduced liver weights, and death

were seen in rats.

Polyvinylalcohol Polymer: No toxicology information is currently available for this component.

SUSPECTED CANCER AGENT: The components of this product are not found on the following lists: NTP, IARC, Federal OSHA, Z List, and CAL/OSHA, and therefore they are not considered to be, nor suspected to be, cancer causing agents by these agencies. However, the following information is available for Ganciclovir (the active component of this product) from clinical studies of laboratory animals.

Ganciclovir: Ganciclovir was carcinogenic in mice after daily oral doses of 20 mg/kg/day and 1000 mg/kg/day. The tissues most affected by doses of 100 mg/kg/day in mice were the preputial gland in males, in the reproductive system and liver in females, and the fore-stomach in both males and females. All Ganciclovir-induced tumors were of epithelial or vascular origin, except for histiocytic sarcoma of the liver. No carcinogenic effect occurred at doses of 1 mg/kg/day. The preputial and clitoral glands, fore-stomach, and harderian glands of mice do not have human counterparts. Based on these results, Ganciclovir should be handled as a potential human carcinogen.

IRRITANCY OF PRODUCT: While not tested, this product is not reported to cause irritancy to the skin or eyes.

SENSITIZATION TO THE PRODUCT: No component of this product is reported to be a sensitizer with repeated or prolonged use..

11. TOXICOLOGICAL INFORMATION (Continued)

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

Mutagenicity: Ganciclovir (the active component of this product) increased mutations in mouse lymphoma cells and DNA damage in lymphocytes in vitro at concentrations between 50-500 and 25-2000 µg/mL, respectively. In the mouse micronucleus assay, Ganciclovir was clastogenic at doses of 150 and 500 mg/kg (2.8 to 10 times greater than the anticipated dosage to humans), but not 50 mg/kg (the approximate level of human dosage). Ganciclovir was not mutagenic in the Ames Salmonella assay of concentrations of 500-5000 µg/mL.

Embryotoxicity: This product is not reported to produce embryotoxic effects in humans. Refer to the following paragraph for additional information.

Teratogenicity: Ganciclovir (the active component of this product) has been shown to be embryotoxic in rabbits and mice following intravenous administration and teratogenic in rabbits. Fetal resorptions were observed in at least 85% of rabbits and mice administered 60 mg/kg/day and 108 mg/kg/day, respectively. Effects observed in rabbits include: fetal growth retardation, embryoletality, teratogenicity, and maternal toxicity. In mice, the observed effects were maternal and fetal toxicity and embryoletality.

Reproductive Toxicity: Ganciclovir (the active component of this product) caused decreased mating behavior, decreased fertility, and an increased incidence of embryoletality in female mice following doses of 90 mg/kg/day. Ganciclovir caused decreased fertility in male mice and hypospermatogenesis in mice and dogs.

*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.*

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

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: No specific medical conditions are known to be aggravated by occupational over-exposures to this product.

RECOMMENDATIONS TO PHYSICIANS: Refer to adverse reaction information provided with this product. Employees should receive routine medical surveillance before job placement, periodically (following acute exposures), and at the job termination or transfer.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

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: Because of the size of the product, no unusual effects on plants or animals are expected if this product is released into the environment; however, because of the potential for harm to contaminated plants and animals.

EFFECT OF PRODUCT ON AQUATIC LIFE: This product is not known to cause adverse effects on aquatic life; however, because of the potential for harm to contaminated aquatic plant and animal life.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Reusable equipment should be cleaned with soap and water.

EPA WASTE NUMBER: Not applicable to the product.

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: Not applicable (49 CFR 172.101, Appendix B).

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

15. REGULATORY INFORMATION

SARA REPORTING REQUIREMENTS: No component of this product is subject to the reporting requirements of Sections 302, 304 and 313 of Title III of the Superfund Amendments and Reauthorization Act, as follows:

SARA Threshold Planning Quantity: Not applicable.

TSCA INVENTORY STATUS: Magnesium Stearate is listed on the TSCA Inventory. The polymer compounds are exempted from this Act.

CERCLA REPORTABLE QUANTITY (RQ): Not applicable.

OTHER FEDERAL REGULATIONS: Employers should refer to the OSHA Technical Instructions, TED 1.15, when employees are working with hazardous drugs.

STATE REGULATORY INFORMATION: No component of this product is covered under specific State regulations, as denoted below:

Alaska - Designated Toxic and Hazardous Substances: None.

California - Permissible Exposure Limits for Chemical Contaminants: None.

Florida - Substance List: None.

Illinois - Toxic Substance List: None.

Kansas - Section 302/313 List: None.

Massachusetts - Substance List: None.

Minnesota - List of Hazardous Substances: None.

Missouri - Employer Information/Toxic Substance List: None.

New Jersey - Right to Know Hazardous Substance List: None.

North Dakota - List of Hazardous

Chemicals, Reportable Quantities: None.

Pennsylvania - Hazardous Substance List: None.

Rhode Island - Hazardous Substance List: None.

Texas - Hazardous Substance List: None.

West Virginia - Hazardous Substance List: None.

Wisconsin - Toxic and Hazardous

Substances: None.

CALIFORNIA PROPOSITION 65: No component of this solution is on the California Proposition 65 lists.

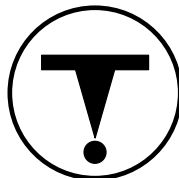
LABELING (Precautionary Statements): **WARNING!** Possible Human Carcinogen. Possible Human Reproductive Toxin. May cause blood disorders. Animal studies indicate over-exposure to this product can cause cancer, birth defects, and other reproductive harm. Avoid contact with skin, eyes, and mucous membranes. Avoid generating dusts. Product must be administered only by a qualified health-care professional. Avoid contact with strong oxidizers. Flush contaminated skin and eyes for 15 minutes, and seek prompt medical attention. Consult Material Safety Data Sheet before use.

In addition to standard pharmacy labeling practices, all syringes and IV bags containing this product should be labeled as follows:

SPECIAL HANDLING AND DISPOSAL REQUIRED

TARGET ORGANS: Eyes, reproductive system, blood system.

WHMIS SYMBOLS:



16. OTHER INFORMATION

PREPARED BY:

Bausch & Lomb
Rochester, NY 14609
(800)338-2020

DATE OF PRINTING:

May 22, 2008

Updated Company information on 5/22/08 – No technical information was changed.

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 vend 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.

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**. Skin adsorption 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.

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the **National Fire Protection Association (NFPA)**. **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:

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. Data from several sources are used to evaluate the cancer-causing potential of the material. 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 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 death. **BEI** - 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.

REGULATORY INFORMATION:

This section explains the impact of various laws and regulations on the material. **EPA** is the U.S. Environmental Protection Agency. **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **DOT** and **TC** are the U.S. Department of Transportation and the Transport Canada, respectively. Other acronyms used are: **Superfund Amendments and Reauthorization Act (SARA)**; the **Toxic Substance Control Act (TSCA)**; Marine Pollutant status according to the **DOT**; California's Safe Drinking Water Act (**Proposition 65**); the **Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund)**; and various state regulations. This section also includes information on the precautionary warnings which appear on the materials package label.