

# **\*SAFETY DATA SHEET\***

		SECTION 1: PR	RODUCT IDENTIFICA	ATION AND	COMPANY IDEN	TIFICATION			
PRODUCT NAME:	McKesson Consult ® iFOBT Test								
MFR №.:	4485; 4486; 4487; 4487-HCCHP								
INTENDED USE:	McKesson Consult ® iFOBT Test, a Fecal Immunochemical Test (FIT) is a rapid, convenient qualitative immunoassay for the determination of human hemoglobin in feces, a vital tool in the diagnosis and therapy of gastrointestinal disorders. McKesson Consult ® iFOBT Test features an innovative sampling method that utilizes one card for collection of two (2) specimens of feces and ONLY one immunochemical specimen preparation tube/test cassette system for analysis.								
PRODUCT USE:	For In Vi	tro Diagnostic Use. Se	e product literature for detai	EMERGENCY:	1-800-451-8346 (3E Company) Day or Night				
DISTRIBUTED BY:	McKesso	McKesson Medical-Surgical Inc.							
ADDRESS:	9954 Mayland Drive, Suite 4000 Richmond, Virginia 23233								
TELEPHONE:	1-800-777-4908 Monday – Friday 8:00 am – 6pm EST								
			SECTION 2: HAZ/	ARDS IDEN	TIFICATION				
GHS CLASSIFIC	CATION	SIGNAL WORD	SYMBOL	HAZARD & PF	RECAUTIONARY STATE	EMENTS			
Not Hazardous		N/A	N/A	N/A					
This product has been classified as non-hazardous based on the physical and/or chemical nature and/or concentration of ingredients. Product has little to no hazards for Emergency Responders if spilled and has no unusual hazard if in a fire. Sodium azide (≤ 0.1%) is included as a preservative. Although it is not considered hazardous at this level, please note that accumulated sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Thorough flushing of plumbing is recommended.  While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.  As part of good industrial, personal hygiene & safety procedure, avoid all unnecessary exposure to the chemical components in this kit and ensure prompt removal from skin, eyes, and clothing. Significant health effects are NOT anticipated from routine use when adhering to the instructions listed in the Package Insert provided with kit.  This kit may contain material of human or animal origin and should be considered as potentially capable of transmitting infectious diseases. Human serum products and patient specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. Follow Universal Precautions as necessary.									
		SECTION	N 3: COMPOSITION	INFORMAT	ION OF INGREDI	ENTS			
PRODUCT DESCR	IPTION:	Mixture; Clear Color (E	Buffer Soln.); Liquid; Odorles	ss; Consisting of	the following ingredient	(s)			
CHEMICAL	NAME	IUPAC	SYNONYMS	C	OMPOSITION	IDENTIFIERS			
Sodium Azio  Molecular Fo		Sodium Azide	Sodium trinitride; Smite Sodium azoimio		≤ 0.1%	CAS 26628-22-8  PUBCHEM 33557  EC 247-852-1  UN 1687  RTECS VY8050000			



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## **SECTION 4: FIRST AID MEASURES**

EYES: In case of contact with eyes, immediately wash eyes under potable running water for at least 15 minutes, making sure that the eyelids are held open. If

pain or irritation occurs, obtain medical attention.

SKIN: In case of contact to the skin, remove any contaminated clothing and wash affected area with plenty of soap and water. If pain, irritation, or other

symptoms develop, obtain medical attention.

INGESTION: In case of ingestion, contact a poison control center or physician for instructions. Only induce vomiting if directed to do so by medical personnel. Never

give anything by mouth to an unconscious person.

INHALATION: Inhalation of any component in this kit is unlikely. If a component of this kit is inhaled and causes discomfort, move exposed individual to fresh air.

Seek medical attention if breathing is difficult or symptoms persist. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance.

SYMPTOMS: To the best of our knowledge, no symptoms, acute or delayed, have been reported.

## SECTION 5: FIRE FIGHTING MEASURES

Flash Point: Non Combustible
Auto-ignition Temperature: Not Applicable
Upper / Lower Explosion Limit: Not Applicable

Extinguishing Media: For small fires, use dry chemical, carbon dioxide, alcohol-resistant foam, or water spray

Special Fire Fighting Procedures: This material will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the surrounding fire.

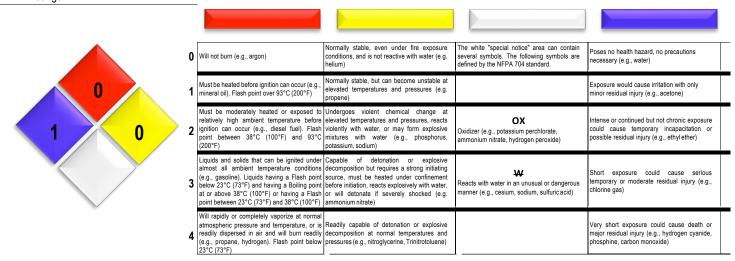
Utilize proper personal protective equipment when responding to any fire. Incipient fire responders should wear eye protection.

Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment.

Special Exposure Hazards: None Identified

Only trained and competent personnel shall attempt to extinguish a fire. Contact emergency response personnel as required. Be cautious of surrounding materials that may react with the extinguishing media.

#### NFPA Ratings:



## SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions: This kit contains materials of biological origin. Use Personal Protective Equipment during clean-up procedures. Use good laboratory

procedures; avoid eye and skin contact.

Environmental Precautions: No environmental hazard is anticipated provided that the material is handled and disposed of with due care. Contain spill to prevent

migration.

Spill and Leak Procedures: Large spills of this kit are unlikely. Personnel who have received basic chemical safety training can generally handle small-scale releases,

such as 1 container in this kit. Utilize safety glasses, nitrile gloves, and lab coat/apron when responding to spills involving the components of this kit. Absorb liquid with an appropriate inert, non-flammable absorbent and place in container suitable for disposal. Dispose of in accordance with applicable U.S. Federal, State, or local procedures or appropriate standards of Canada or the EU (see Section 13, Disposal

Considerations).



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SECTION 7: HANDLING & STORAGE

Handling: As with all chemicals, avoid getting components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or

drink while using this kit. This kit should be handled only by qualified clinical or laboratory personnel trained on the use of this kit. This kit should be handled as though capable of transmitting infectious diseases. Universal Precautions should be followed when using this kit. Not for use by the general

public.

Storage: Keep away from incompatible materials (Section 10). To maintain efficacy, when not in use, keep components tightly closed and store according to the

package insert instructions.

Specific Use: For in vitro diagnostic use only.

Other: Do not substitute reagents from kits from other manufacturers. The reagents in each kit are matched. Reagents from different kits must not be

interchanged or pooled. Mix the reagents well before use. If the kit does not yield expected results when controls are tested, the kit should be discarded. Traces of detergent or dried reactants on the test slide may adversely affect test performance and results. Replace vial closure when not being used.

Dropper Bulb(s) contain natural rubber.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### **Exposure Limits:**

	OSHA PEL	ACGIH TLV	DFG MAK	NIOSH
Sodium Azide				
EU Index:		0.29 mg/m <sup>3</sup> Ceiling (sodium		0.3 mg/m <sup>3</sup> Ceiling (sodium
011-004-00-7	none listed	azide);	0.2 mg/m <sup>3</sup> MAK (inhalable	azide);
EU Classification:	none noted	0.11 ppm Ceiling (hydrazoic	fraction)	0.1 ppm Ceiling (hydrazoic
Highly toxic (T+)		acid, vapor)		acid, vapor)
Very dangerous for the environment(N)				

#### **Occupational Exposure Controls:**

**Engineering Controls:** 

No special engineering controls are required when working with this kit. Use with adequate ventilation to ensure

exposure levels are maintained below the limits provided above.

#### Personal Protective Equipment (PPE):

Under normal conditions, the use of this product should not require respiratory protection. Respiratory Protection:

Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 Eye

Contact: or appropriate government standards.

Skin Wear Impervious gloves, such as latex or equivalent, should be worn to prevent skin contact and especially cover any cuts, abrasions or skin lesions. Dispose of gloves as bio-hazardous material. Wash hands thoroughly after removing gloves. Use extreme caution with any Contact:

sharp object to avoid percutaneous exposure to material. Wear outer protective garments such as a lab coat or gown. Refer U.S. OSHA

29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Other: Not Applicable

**Environmental Controls:** No special environmental controls are required.

#### SECTION 9: PHYSICAL & CHEMICAL CHARACTERISTICS

Characteristic	Buffer
Appearance	Clear
Odor	Odorless
рН	Neutral
Boiling Point	Not Available
Melting Point	Not available
Specific Gravity	Approximately 1
Vapor Pressure	Not available
Vapor Density	Not available



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Solubility in Water  Evaporation Rate  Auto-ignition Temperature  Decomposition Temperature		Soluble			
		<1			
		Not Available			
		Not Available			
Viscositv		Not Available			
	SECTION '	10: STABILITY AND	D REACTIVITY		
Characteristic			Buffer		
Stability:	Stable when store	ed according to approved I	l labeling (see Section 7).		
Conditions to Avoid:	materials. Sodium	ot freeze. Protect from prolonged exposure to heat, humidity, and light, ignition sources & incompatible rials. Sodium Azide may react with lead and copper plumbing to form highly explosive metal azides. Thorough ing of plumbing with water is recommended.			

Materials to Avoid (Incompatibility): Avoid contact with acid, metals, halogenated solvents, and dimethyl sulfate.

None, when stored as recommended.

Hazardous Decomposition or Byproducts: Under Fire conditions: carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride gas

Hazardous Reactions: NONE EXPECTED

## SECTION 11: TOXICOLOGICAL INFORMATION

Toxicity Data for Hazardous Ingredients: There are currently no toxicity data available for the components of this kit.

Routes of Exposure: Overexposures to components within this kit are not expected. Common routes of exposure may include ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture,

contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Potential Effects of Acute Overexposure,
By Route Of Exposure:

This kit may contain materials of human or animal origin and should be considered as potentially capable of transmitting infectious diseases.

INHALATION: Vapors, mists, sprays, or dusts of this kit can cause irritation to the respiratory tract.

CONTACT WITH SKIN or EYES: Contact can cause eye or skinirritation.

SKIN ABSORPTION: May be harmful if absorbed throughskin.

INGESTION: May cause nausea, diarrhea, vomiting, and headache, slight lowering of blood pressure, abdominal pain, and a general feeling

of apprehension and un-wellness, as well as, irritation of the mouth, throat, and other issues of the gastro-intestinal system may

occui.

INJECTION: Accidental injection of this kit may cause burning, reddening, and swelling in addition to the wound. Symptoms of such exposure

can include those described under "Inhalation", "Contact with Skin or Eyes," and "Ingestion".

Potential Effects of Chronic Exposure: Long-term skin or eye contact can result in dermatitis or eye irritation. Prolonged or repetitive exposure to Sodium

Azide may increase risk of cumulative effects.

Symptoms of Overexposure: Symptoms of overexposure to Sodium Azide may include: eye, skin, nose, and throat irritation, headache, nausea

and vomiting. Symptoms may be delayed for several hours after exposure.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly

investigated.

Medical Conditions Aggravated by Exposure: Persons with pre-existing skin disorders; eye problems or impaired respiratory system function can be more

susceptible to health effects associated with overexposures to the chemicals within this kit.

Irritation/Sensitization May cause sensitization by inhalation and skin contact.

Other Effects None identified.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or GHS



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SECTION 12: ECOLOGICAL INFORMATION

**Eco-toxicity** No adverse effects on the environment are expected from the components of this kit.

Persistence and Degradability, Mobility

& Bioaccumulation

Data are not available for the components of this kit.

There is limited potential for the components within this kit to accumulate in plant or animal systems.

## SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD:

Dispose of waste materials, unused components and contaminated packaging in compliance with country (i.e., Canada, EU) federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

WITH SPECIMEN:

Patient specimens and all materials coming into contact with them should be handled as if capable of transmitting infections and disposed of with proper precautions

## SECTION 14: TRANSPORT INFORMATION

#### U.S. Transportation

This substance is considered to be non-hazardous for transport.

#### **Canadian Transportation**

The above-listed DOT basic description applies to this product under the regulations of Transport Canada.

#### International Air Transportation

This substance is considered to be non-hazardous for air transport.

## SECTION 15: REGULATORY INFORMATION

## U.S. FEDERAL AND STATE REGULATIONS

U.S. SARA SECTION 311/312 FOR KIT:

Not applicable

**U.S. TSCA INVENTORY STATUS:** 

Sodium Azide listed on the TSCA Inventory.

OTHER U.S. FEDERAL REGULATIONS: Not applicable

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): NO INGREDIENTS LISTED

#### **CANADIAN REGULATIONS:**

CANADIAN DSL/NDSL INVENTORY STATUS: Sodium Azide is listed on the DSL Inventory.

CANADIAN WHMIS SYMBOLS: None Required

#### **HMIS RATINGS**



B: Safety Glasses and Gloves

#### **EU LABELING CLASSIFICATION**

Classification: Non-Hazardous-No hazard classification or danger symbol required.

Risk Phrases: N/A Safety Phrases:



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**SECTION 16: OTHER INFORMATION** 

Revision Date: August 28, 2015

This SDS has been updated to comply with GHS requirements

#### DISCLAIMER:

This information relates onto to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. The information and recommendations contained herein are to the best of the manufacturer's knowledge and belief accurate and reliable as of the date indicated. No representation warranty or guarantee, however, is made with regards to accuracy, reliability or completeness. Conditions of use of the material are under the control of the user; therefore, it is the user's responsibility to satisfy itself as to the suitability and completeness of such information for its own particular use. Appropriate warnings and safe-handling procedures should be provided to handlers and users..

# **NFPA 704**

#### CHEMTREC® (24 hours) 1-800-424-9300

(Toll-free in the U.S., Canada, and the U.S. Virgin Islands)
For calls originating elsewhere:
703-527-3887 (Collect calls are accepted)

## CHEMTEL, INC. (24 hours) 1-888-255-3924

(Toll-free in the U.S., Canada, Puerto Rico and the U.S. Virgin Islands)
For calls originating elsewhere:
813-248-0585 (Collect calls are accepted)

#### **INFOTRAC** (24 hours) 1-800-535-5053

(Toll-free in the U.S., Canada, and the U.S. Virgin Islands)
For calls originating elsewhere:
352-323-3500 (Collect calls are accepted)

#### 3E COMPANY (24 hours) 1-800-451-8346

(Toll-free in the U.S., Canada, and the U.S. Virgin Islands)
For calls originating elsewhere:
760-602-8703 (Collect calls are accepted)

The emergency response information services shown above have requested to be listed as providers of emergency response information and have agreed to provide emergency response information to all callers. They maintain periodically updated lists of state and Federal radiation authorities who provide information and technical assistance on handling incidents involving radioactive materials.

#### NATIONWIDE POISON CONTROL CENTER (United States Only)

Emergency and information calls are answered by the nearest Poison Center (24 hours): 1-800-222-1222 (toll-free in the U.S.).

#### NATIONAL RESPONSE CENTER (NRC)

The NRC, which is operated by the U.S. Coast Guard, receives reports required when dangerous goods and hazardous substances are spilled. After receiving notification of an incident, the NRC will immediately notify the appropriate Federal On-Scene Coordinator and concerned Federal agencies. Federal law requires that anyone who releases into the environment a reportable quantity of a hazardous substance (including oil when water is, or may be affected) or a material identified as a marine pollutant must **immediately** notify the NRC. When in doubt as to whether the amount released equals the required reporting levels for these materials, the NRC should be notified.

CALL NRC (24 hours) 1-800-424-8802 (Toll-free in the U.S., Canada, and the U.S. Virgin Islands) 202-267-2675 in the District of Columbia

Calling the emergency response telephone number, CHEMTREC®, CHEMTEL, INC., INFOTRAC or 3E COMPANY, does not constitute compliance with regulatory requirements to call the NRC.

#### **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 (Chemical Abstract Service) Number that uniquely identifies each compound.

**ACGIH** (American Conference of Governmental Industrial Hygienists): a professional association that establishes exposure limits.

**TLV** (Threshold Limit Value): an airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers can 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 that 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.

**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.

#### **Protective Equipment**

- A: Safety Glasses.
- B: Safety glasses and gloves.
- **C:** Safety glasses, gloves and body protection.
- **D:** Splash goggles with face shield, gloves and bodyprotection.
- E: Eye protection, gloves and dust mask respiratory protection.
- **F:** Eye protection, gloves, body protection and dust maskrespiratory protection.
- **G:** Eye protection, gloves and air purifying respiratory protection.

## HAZARD RATINGS:

## HAZARDOUS MATERIALS IDENTIFICATION SYSTEM (HMIS):

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 cause permanent injury and can be fatal); 4 (extreme acute exposure hazard; single overexposure can be fatal). \* Indicates chronichazard.

Flammability Hazard: **0** (minimal hazard); **1** (materials that require substantial preheating 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 (NFPA):

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 could cause 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:

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, LDo, TC, TCo, LCLo, and LCo, the lowest dose (or concentration) to cause lethal or toxic effects. BEI - Biological Exposure Indices, represent the levels of determinants that 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.

Data from several sources are used to evaluate the cancer-causing potential of the material. The sources and ratings are: IARC - the International Agency for Research on Cancer; 1 = Carcinogenic to humans, 2A, 2B = Probably carcinogenic to humans, 3 = Unclassifiable as to carcinogenicity in humans, and 4 = Probably not carcinogenic to humans. NTP - the National Toxicology Program; K = Known to be a human carcinogen, and R = Reasonably anticipated to be a human carcinogen. RTECS - the Registry of Toxic Effects of Chemical Substances. OSHA -Occupational Safety and Health Administration and CAL/OSHA - California's subunit of the Occupational Safety and Health Administration; Ca = Carcinogen defined with no further categorization. ACGIH - American Conference of Governmental Industrial Hygienists; A1 = Confirmed human carcinogen, A2 = Suspected human carcinogen, A3 = Confirmed animal carcinogen with unknown relevance to humans, A4 = Not classifiable as a human carcinogen, and A5 = Not suspected as a human carcinogen, NIOSH – U.S. National Institute for Occupational Safety and Health: Ca = Potential occupational carcinogen, with no further categorization. EPA - U.S. Environmental Protection Agency; A = Human carcinogen, B = Probable human carcinogen, C = Possible human carcinogen, D = Not classifiable as to human carcinogenicity, E = Evidence of Non-carcinogenicity for humans, K = Known human carcinogen, L = Likely to produce cancer in humans, CBD = Cannot be determined, NL = Not likely to be carcinogenic in humans, and I = Data are inadequate for an assessment of human carcinogenic potential.

#### 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.

Superfund Amendments and Reauthorization Act (SARA); the Canadian Domestic/Non-Domestic Substances List (DSL/NDSL); the U.S. Toxic Substance Control Act (TSCA); Marine Pollutant status according to the DOT; the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund); and various state regulations.

This section also includes information on the precautionary warnings that appear on a material's industrial package label.