

# **Safety Data Sheet**

**SDS No. 1163A** 

**Section 1 - Identification** 

1.1 Product identifier: EpoxAcoat® HT Part A
1.2 General Use: Formulated Epoxy Resin

**1.3 Manufacturer:** Smooth-On, Inc.,

5600 Lower Macungie Rd., Macungie, PA 18062 Phone (610) 252-5800, FAX (610) 252-6200

**1.4 Emergency Contact**: Chem-Tel Domestic: 800-255-3924 International: 813-248-0585

#### Section 2 - Hazards Identification

#### 2.1 Classification of the substance or mixture

Acute toxicity, dermal – Category 5, H313

### 2.2 GHS Label elements, including precautionary statements

Hazard Pictogram(s): Signal word: Warning

Health Hazard:	H313	May be harmful in contact with skin
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General	If medical advice is needed, have product container
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Precautions: P101 or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

Prevention P264 Wash with soap and water thoroughly after handling.

Precautions:

P270 Do not eat, drink or smoke when using this product.

P272 Contaminated work clothing should not be allowed

out of the workplace.

P280 Wear protective gloves/protective clothing/eye

protection/face protection.

Response P302 + P352 IF ON SKIN: Wash with plenty of soap and water

Precautions:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all

contaminated clothing. Rinse skin with water [or

shower].

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several

minutes. Remove contact lenses, if present and easy

to do. Continue rinsing.

P332 + P313 If skin irritation occurs: Get medical advice/attention.

P362 + P364

Take off contaminated clothing and wash it before reuse.

# Hazards not otherwise classified (HNOC) or not covered by GHS – none

# Section 3 - Composition / Information on Ingredients

#### 3.1 Substances

The following ingredients are hazardous according to Regulation 2012 OSHA Hazard Communication Standard: 29 CFR 1910.1200:

CAS	Component	Concentration
28064-14-4	Phenol-formaldehyde polymer glycidyl ether	25% - 100%

#### **Section 4 - First Aid Measures**

#### 4.1 Description of first aid measures

**Inhalation:** Remove source(s) of contamination and move victim to fresh air. If breathing has stopped, give artificial respiration, then oxygen if needed. Contact physician immediately.

**Eye Contact:** Flush eyes with plenty of water. If irritation persists, seek medical attention.

**Skin Contact:** In case of skin contact, wash thoroughly with soap and water.

**Ingestion:** Do not induce vomiting unless instructed by a physician. Never give anything by mouth to an unconscious person.

- 4.2 Most important symptoms and effects, both acute and delayed: None known.
- 4.3 After first aid, get appropriate in-plant, paramedic, or community medical support.

# **Section 5 - Fire-Fighting Measures**

- **5.1 Extinguishing Media:** Water Fog, Dry Chemical, and Carbon Dioxide Foam
- 5.2 Special hazards arising from the substance or mixture: None known.
- 5.3 Advice for firefighters: Use water spray to cool fire-exposed surfaces and to protect personnel. Shut off "fuel" to fire. If a leak or spill has not ignited, use water spray to disperse the vapors. Either allow fire to burn under controlled conditions or extinguish with foam or dry chemical. Try to cover liquid spills with foam. Because fire may produce toxic thermal decomposition products, wear a self-contained breathing apparatus (SCBA) with a full face piece operated in pressure demand or positive-pressure mode.

#### **Section 6 - Accidental Release Measures**

- **Personal precautions, protective equipment and emergency procedures:** Only properly protected personnel should remain in the spill area; dike and contain spill. Stop or reduce discharge if it can be done safely.
- **6.2** Environmental precautions: No special environmental precautions required.
- **6.3 Methods and material for containment and cleaning up:** absorb or scrape up excess into suitable container for disposal; wash area with dilute ammonia solution
- **6.4** Reference to other sections: if appropriate Sections 8 and 13 shall be referred to.

### Section 7 - Handling and Storage

- **7.1 Precautions for safe handling:** Use good general housekeeping procedures. Wash hands after use.
- 7.2 Conditions for safe storage, including any incompatibilities: Keep container(s) tightly closed and properly labeled. Store in cool, dry, well ventilated place away from heat, direct sunlight, strong oxidizers and any incompatibles. Store in approved containers and protect against physical damage. Keep containers securely sealed when not in use. Indoor storage should meet OSHA standards and appropriate fire codes. Containers that have been opened must be carefully resealed to prevent leakage. Empty containers retain residue and may be dangerous.
- **7.3** Specific end use(s): These precautions are for room temperature handling. Other uses including elevated temperatures or aerosol/spray applications may require added precautions.

# **Section 8 - Exposure Controls / Personal Protection**

- **8.1 Control parameters:** none defined
- 8.2 Exposure controls:

**Respiratory Protection:** Should a respirator be needed, follow OSHA respirator regulations 29 CFR 1910.134 and European Standards EN 141, 143 and 371; wear an MSHA/NIOSH or European Standards EN 141, 143 and 371 approved respirators equipped with organic vapor cartridges.

**Hand Protection:** Wear any liquid-tight gloves such as butyl rubber, neoprene or PVC. **Eye Protection:** Safety glasses with side shields per OSHA eye- and face-protection regulations 29 CFR 1910.133 and European Standard EN166. Contact lenses are not eye protective devices. Appropriate eye protection must be worn instead of, or in conjunction with contact lenses.

**Other Protective Clothing/Equipment:** Additional protective clothing or equipment is not normally required. Provide eye bath and safety shower.

**Comments:** Never eat, drink, or smoke in work areas. Practice good personal hygiene after using this material, especially before eating, drinking, smoking, using the toilet, or applying cosmetics. Wash thoroughly after handling.

# **Section 9 - Physical and Chemical Properties**

9.1 Information on basic physical and chemical properties:

Appearance: viscous liquid Odor/Threshold: Mild odor pH: N.A. (non-aqueous)

Melting Point/Freezing Point: N.A. Low/High Boiling Point: N.A.

Flash Point: >300 °F

**Evaporation Rate:** Not available **Flammability:** f.p. at or above 200 °F

**UEL/LEL:** Not available

Vapor Pressure: None (Polymeric Resin)

Vapor Density (Air=1): None

**Specific Gravity (H2O=1, at 4 °C):** 1.0-1.2

Water Solubility: Insoluble

Partition coefficient: Not available

**Auto-ignition temperature:** Not available **Decomposition temperature:** Not available

**Viscosity:** 5,000 – 20,000 centipoise

% Volatile: Nil

#### Section 10 - Stability and Reactivity

- **10.1 Reactivity:** No hazardous reactions if stored and handled as prescribed/indicated., No corrosive effect on metal. Not fire propagating.
- **10.2 Chemical stability:** These products are stable at room temperature in closed containers under normal storage and handling conditions.
- 10.3 Possibility of hazardous reactions: Hazardous polymerization cannot occur.
- 10.4 Conditions to avoid: none known
- 10.5 Incompatible materials: strong bases and acids
- **10.6 Hazardous decomposition products:** Thermal oxidative decomposition can produce carbon oxides, gasses/vapors, and traces of incompletely burned carbon compounds.

## **Section 11- Toxicological Information**

11.1 Information on toxicological effects:

Skin Corrosion/Irritation: no data

Serious Eye Damage/Irritation: no data

Respiratory/Skin Sensitization: no data

Germ Cell Mutagenicity: no data

Carcinogenicity: No component of this product at levels greater than or equal to 0.1% is

identified as a carcinogen or potential carcinogen by IARC, NTP, or OSHA.

Reproductive Toxicity: no data

Specific Target Organ Toxicity – Single Exposure: no data Specific Target Organ Toxicity – Repeated Exposure: no data

Aspiration Hazard: no data
Acute Toxicity: no data
Chronic Exposure: no data

Potential Health Effects - Miscellaneous: no data

### **Section 12 - Ecological Information**

- **12.1 Toxicity:** no data
- 12.2 Persistence and Degradability: no data
- 12.3 Bioaccumulative Potential: no data
- 12.4 Mobility in Soil: no data
- 12.5 Results of PBT and vPvB assessment: no data
- 12.6 Other Adverse Effects: no data

### **Section 13 - Disposal Considerations**

13.1 Waste treatment methods: Under RCRA it is the responsibility of the user of the product to determine at the time of disposal whether the product meets RCRA criteria for hazardous waste. Waste management should be in full compliance with federal, state and local laws. Empty containers retain product residue which may exhibit hazards of material, therefore to not pressurize, cut, glaze, weld or use for any other purposes. Return drums to reclamation centers for proper cleaning and reuse.

### **Section 14 - Transport Information**

Not classified by DOT, IATA or IMDG

- 14.1 UN number: none
- 14.2 UN proper shipping name: none
- 14.3 Transport hazard class(es): not applicable
- **14.4 Packing group:** not applicable
- 14.5 Environmental hazards: none known
- **14.6 Special precautions for user:** none known
- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: not

applicable

### **Section 15 - Regulatory Information**

15.1 Safety health and environmental regulations/legislation specific for the substance or mixture:

In the United States (EPA Regulations):

**TSCA Inventory Status (40 CFR710):** All components of this formulation are listed in the TSCA Inventory.

**SARA 302 Components:** No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313 Components:** No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 313.

SARA 311/312 Hazards: none

<u>California Proposition 65</u>: This product does not intentionally contain any chemicals known to the state of California to cause cancer, birth defects or other reproductive harm.

**15.2 Chemical safety assessment:** No chemical safety assessment has been carried out for this substance/mixture by the supplier.

#### 16 - Other Information

HMIS	
I	2
F	1
R	1



Revision: 1

Date Prepared: May 1, 2017

NFPA

Glossary: ACGIH-American Conference of Governmental Industrial Hygienists; ANSI-American National Standards Institute; Canadian TDG-Canadian Transportation of Dangerous Goods; CAS-Chemical Abstract Service; Chemtrec-Chemical Transportation Emergency Center (US); CHIP-Chemical Hazard Information and Packaging; DSL-Domestic Substances List; EC-Equivalent Concentration; EH40 (UK)-HSE Guidance Note EH40 Occupational Exposure Limits; EPCRA-Emergency Planning and Community Right-To-Know Act; ESL-Effects screening levels; GHS-Globally Harmonized System of Classification and Labelling of Chemicals; HMIS-Hazardous Material Information Service; IATA-International Air Transport Association; IMDG-International Maritime Dangerous Goods Code; LC-Lethal Concentration; LD-Lethal Dose; LEL-Lower Explosion Level; NFPA-National Fire Protection Association; OEL-Occupational Exposure Limit; OSHA-Occupational Safety and Health Administration, US Dept. of Labor; PEL-Permissible Exposure Limit; SARA (Title III)-Superfund Amendments and Reauthorization Act; SARA 313-Superfund Amendments and Reauthorization Act, Section 313; SCBA-Self-Contained Breathing Apparatus; STEL-Short Term Exposure Limit; TCEQ-Texas Commission on Environmental Quality; TLV-Threshold Limit Value; TSCA-Toxic Substances Control Act Public Law 94-469; TWA-Time Weighted Value; UEL-Upper Explosion Level; US DOT-US Department of Transportation; WHMIS-Workplace Hazardous Materials Information System.

**Disclaimer:** The information contained in this Safety Data Sheet (SDS) is considered accurate as of the version date. However, no warranty is expressed or implied regarding the accuracy of the data. Since the use of this product is not within the control of Smooth-On Inc., it is the user's obligation to determine the suitability of the product for its intended application and assumes all risk and liability for its safe use. This SDS is prepared to comply with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as prescribed by the United States (US) Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200), the Canadian Workplace Hazardous Materials Information System (WHMIS), and European Union Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 (REACH). Classifications of the chemical in accordance with 29 CFR 1910.1200, signal word, hazard and

precautionary statement(s), symbol(s) and other information are based on listed concentration of each hazardous ingredient. Unlisted ingredients are not "hazardous" per the OSHA Hazard Communication Standard (29 CFR 1910.1200), WHMIS and EC No 1907/2006 and are considered trade secrets under US Federal Law (29 CFR and 40 CFR), Canadian Law (Health Canada Legislation), and European Union Directives.



# **Safety Data Sheet**

**SDS No. 1163B** 

**Section 1 - Identification** 

1.1 Product identifier: EpoxAcoat® HT Part B
1.2 General Use: Epoxy Curing Resin
1.3 Manufacturer: Smooth-On, Inc.,

5600 Lower Macungie Rd., Macungie, PA 18062 Phone (610) 252-5800, FAX (610) 252-6200

**1.4 Emergency Contact**: Chem-Tel Domestic: 800-255-3924 International: 813-248-0585

#### Section 2 - Hazards Identification

#### 2.1 Classification of the substance or mixture

Skin irritation – Category 2, H315 Eye irritation – Category 2, H319

Acute toxicity, inhalation – Category 5, H333

### 2.2 GHS Label elements, including precautionary statements

Pictogram(s):

Signal Word: Warning

Health Hazards: H315 Causes skin irritation

H319 Causes serious eye irritation. H333 May be harmful if inhaled.

General P101 If medical advice is needed, have product container

Precautions: or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

Prevention P264 Wash skin thoroughly after handling.

Precautions:

P271 Use only outdoors or in a well-ventilated area.

Response P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

Precautions:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several

minutes. Remove contact lenses, if present and easy

to do. Continue rinsing.

P333 + P313 If skin irritation or rash occurs: Get medical

advice/attention.

P337 + P313 If eye irritation persists: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

Storage P403 + P235 Store in a well-ventilated place. Keep cool.

Precautions:

Disposal P501 Dispose of contents/container according to local,

Precautions: state and federal laws.

### Hazards not otherwise classified (HNOC) or not covered by GHS - none

### **Section 3 - Composition / Information on Ingredients**

#### 3.1 Substances

The following ingredients are hazardous according to Regulation 2012 OSHA Hazard Communication Standard: 29 CFR 1910.1200:

CAS	Component	Concentration
1761-71-3	Methylenebiscyclohexanamine, 4,4'-	60% - 80%
32610-77-8	TETA, reaction products with phenol/formaldehyde	>55%
112-24-3	Triethylenetetramine (TETA)	<20%
108-95-2	Phenol	15% - 20%

#### **Section 4 - First Aid Measures**

# 4.1 Description of first aid measures

**Inhalation:** Remove source(s) of contamination and move victim to fresh air. If breathing has stopped, give artificial respiration, then oxygen if needed. Contact physician immediately.

**Eye Contact:** Flush eyes with plenty of water. If irritation persists, seek medical attention. **Skin Contact:** In case of skin contact, wash thoroughly with soap and water.

**Ingestion:** Do not induce vomiting unless instructed by a physician. Never give anything by mouth to an unconscious person.

- 4.2 Most important symptoms and effects, both acute and delayed None known.
- 4.3 After first aid, get appropriate in-plant, paramedic, or community medical support.

# **Section 5 - Fire-Fighting Measures**

- **5.1 Extinguishing Media:** Water Fog, Dry Chemical, and Carbon Dioxide Foam
- 5.2 Special hazards arising from the substance or mixture: None known.
- 5.3 Advice for firefighters: Use water spray to cool fire-exposed surfaces and to protect personnel. Shut off "fuel" to fire. If a leak or spill has not ignited, use water spray to disperse the vapors. Either allow fire to burn under controlled conditions or extinguish with foam or dry chemical. Try to cover liquid spills with foam. Because fire may produce toxic thermal decomposition products, wear a self-contained breathing apparatus (SCBA) with a full-face piece operated in pressure demand or positive-pressure mode.

#### Section 6 - Accidental Release Measures

- **6.1 Personal precautions, protective equipment and emergency procedures:** Only properly protected personnel should remain in the spill area; dike and contain spill. Stop or reduce discharge if it can be done safely.
- **6.2** Environmental precautions: No special environmental precautions required.
- **6.3 Methods and material for containment and cleaning up:** absorb or scrape up excess into suitable container for disposal; wash area with dilute ammonia solution
- **6.4** Reference to other sections: if appropriate Sections 8 and 13 shall be referred to.

## Section 7 - Handling and Storage

- **7.1 Precautions for safe handling:** Use good general housekeeping procedures. Wash hands after use.
- 7.2 Conditions for safe storage, including any incompatibilities: Keep container(s) tightly closed and properly labeled. Store in cool, dry, well ventilated place away from heat, direct sunlight, strong oxidizers and any incompatibles. Store in approved containers and protect against physical damage. Keep containers securely sealed when not in use. Indoor storage should meet OSHA standards and appropriate fire codes. Containers that have been opened must be carefully resealed to prevent leakage. Empty containers retain residue and may be dangerous.
- **7.3** Specific end use(s): These precautions are for room temperature handling. Other uses including elevated temperatures or aerosol/spray applications may require added precautions.

# **Section 8 - Exposure Controls / Personal Protection**

- 8.1 Control parameters: none defined
- 8.2 Exposure controls:

**Respiratory Protection:** Should a respirator be needed, follow OSHA respirator regulations 29 CFR 1910.134 and European Standards EN 141, 143 and 371; wear an MSHA/NIOSH or European Standards EN 141, 143 and 371 approved respirators equipped with organic vapor cartridges.

**Hand Protection:** Wear any liquid-tight gloves such as butyl rubber, neoprene or PVC. **Eye Protection:** Safety glasses with side shields per OSHA eye- and face-protection regulations 29 CFR 1910.133 and European Standard EN166. Contact lenses are not eye protective devices. Appropriate eye protection must be worn instead of, or in conjunction with contact lenses.

**Other Protective Clothing/Equipment:** Additional protective clothing or equipment is not normally required. Provide eye bath and safety shower.

**Comments:** Never eat, drink, or smoke in work areas. Practice good personal hygiene after using this material, especially before eating, drinking, smoking, using the toilet, or applying cosmetics. Wash thoroughly after handling.

# **Section 9 - Physical and Chemical Properties**

9.1 Information on basic physical and chemical properties:

**Appearance:** paste

Odor/Threshold: Mild phenolic odor

pH: Not available

Melting Point/Freezing Point: N.A. Low/High Boiling Point: N.A.

Flash Point: N.A.

**Evaporation Rate:** Not available **Flammability:** f.p. at or above 200 °F

**UEL/LEL:** Not available

Vapor Pressure: < 1.0 mmHg @ 70 °F

Vapor Density (Air=1): >1

Specific Gravity (H2O=1, at 4 °C): N.A.

Water Solubility: insoluble

Partition coefficient: Not available

**Auto-ignition temperature:** Not available **Decomposition temperature:** Not available

Viscosity: Not available % Volatile: Not available

#### Section 10 - Stability and Reactivity

- **10.1 Reactivity:** No hazardous reactions if stored and handled as prescribed/indicated., No corrosive effect on metal. Not fire propagating.
- **10.2 Chemical stability:** These products are stable at room temperature in closed containers under normal storage and handling conditions.
- 10.3 Possibility of hazardous reactions: Hazardous polymerization cannot occur.
- 10.4 Conditions to avoid: none known
- 10.5 Incompatible materials: strong bases and acids
- **10.6 Hazardous decomposition products:** Thermal oxidative decomposition can produce carbon oxides, gasses/vapors, and traces of incompletely burned carbon compounds.

# **Section 11- Toxicological Information**

11.1 Information on toxicological effects:

Skin Corrosion/Irritation: Causes skin irritation

Serious Eye Damage/Irritation: Causes serious eye irritation.

Respiratory/Skin Sensitization: no data
Carcinogenicity: no data
Carcinogenicity: no data
Reproductive Toxicity: no data

Specific Target Organ Toxicity – Single Exposure: no data Specific Target Organ Toxicity – Repeated Exposure: no data

Aspiration Hazard: no data

**Acute Toxicity:** 

LD50, oral: >2,200 mg/kg (rat)

Inhalation: no data

LD50, dermal: > 1,000 mg/kg (Rabbit, calculation method)

**Chronic Exposure:** Absorption of phenolic solutions through the skin may be very rapid and can cause damage to the kidneys, liver, pancreas and spleen, and edema of the lungs.

Potential Health Effects - Miscellaneous: no data

### **Section 12 - Ecological Information**

- **12.1 Toxicity:** no data
- 12.2 Persistence and Degradability: no data
- 12.3 Bioaccumulative Potential: no data
- 12.4 Mobility in Soil: no data
- 12.5 Results of PBT and vPvB assessment: no data
- 12.6 Other Adverse Effects: no data

## **Section 13 - Disposal Considerations**

13.1 Waste treatment methods: Under RCRA it is the responsibility of the user of the product to determine at the time of disposal whether the product meets RCRA criteria for hazardous waste. Waste management should be in full compliance with federal, state and local laws. Empty containers retain product residue which may exhibit hazards of material, therefore to not pressurize, cut, glaze, weld or use for any other purposes. Return drums to reclamation centers for proper cleaning and reuse.

## **Section 14 - Transport Information**

Classified by DOT, IATA or IMDG

- **14.1 UN number:** 2735
- **14.2 UN proper shipping name:** Amines, liquid, corrosive, n.o.s. (4,4'-methylene biscyclohexanamine and polyoxypropylene triamine)
- 14.3 Transport hazard class(es): 8
- 14.4 Packing group: II
- 14.5 Environmental hazards: none known
- **14.6 Special precautions for user:** none known
- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: not applicable

### **Section 15 - Regulatory Information**

15.1 Safety health and environmental regulations/legislation specific for the substance or mixture:

In the United States (EPA Regulations):

**TSCA Inventory Status (40 CFR710):** All components of this formulation are listed in the TSCA Inventory.

**SARA 302 Components:** No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313 Components:** No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 313.

SARA 311/312 Hazards: none

<u>California Proposition 65</u>: This product does not intentionally contain any chemicals known to the state of California to cause cancer, birth defects or other reproductive harm.

**15.2 Chemical safety assessment:** No chemical safety assessment has been carried out for this substance/mixture by the supplier.

#### 16 - Other Information

HMIS	
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F	0
R	0



**NFPA** 

Revision: 2

Date Prepared: February 12, 2018

Glossary: ACGIH-American Conference of Governmental Industrial Hygienists; ANSI-American National Standards Institute; Canadian TDG-Canadian Transportation of Dangerous Goods; CAS-Chemical Abstract Service; Chemtrec-Chemical Transportation Emergency Center (US); CHIP-Chemical Hazard Information and Packaging; DSL-Domestic Substances List; EC-Equivalent Concentration; EH40 (UK)-HSE Guidance Note EH40 Occupational Exposure Limits; EPCRA-Emergency Planning and Community Right-To-Know Act; ESL-Effects screening levels; GHS-Globally Harmonized System of Classification and Labelling of Chemicals; HMIS-Hazardous Material Information Service; IATA-International Air Transport Association; IMDG-International Maritime Dangerous Goods Code; LC-Lethal Concentration; LD-Lethal Dose; LEL-Lower Explosion Level; NFPA-National Fire Protection Association; OEL-Occupational Exposure Limit; OSHA-Occupational Safety and Health Administration, US Dept. of Labor; PEL-Permissible Exposure Limit; SARA (Title III)-Superfund Amendments and Reauthorization Act; SARA 313-Superfund Amendments and Reauthorization Act, Section 313; SCBA-Self-Contained Breathing Apparatus; STEL-Short Term Exposure Limit; TCEQ-Texas Commission on Environmental Quality; TLV-Threshold Limit Value; TSCA-Toxic Substances Control Act Public Law 94-469; TWA-Time Weighted Value; UEL-Upper Explosion Level; US DOT-US Department of Transportation; WHMIS-Workplace Hazardous Materials Information System.

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precautionary statement(s), symbol(s) and other information are based on listed concentration of each hazardous ingredient. Unlisted ingredients are not "hazardous" per the OSHA Hazard Communication Standard (29 CFR 1910.1200), WHMIS and EC No 1907/2006 and are considered trade secrets under US Federal Law (29 CFR and 40 CFR), Canadian Law (Health Canada Legislation), and European Union Directives.