



Safety Data Sheet

SDS No. 25A

Section 1 - Identification

1.1 Product identifier: Part A for: EA-40; EpoxAcast® 650, 655, 690; EpoxAcoat® Red and Grey; EpoxAmite® 100; Epsilon® PRO; MetalSet® A4; MT-13®; PC-3® Series; Sonite® EG-2; Super Instant®; Tarbender®; XTC-3D®; Habitat Cast N Coat

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
SDS@Smooth-On.com

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 |
| General Precautions: | P101 | If medical advice is needed, have product container or label at hand. |
| | P102 | Keep out of reach of children. |
| | P103 | Read label before use. |
| Prevention Precautions: | P264 | Wash with soap and water thoroughly after handling. |
| | 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 Precautions: | P302 + P352 | IF ON SKIN: Wash with plenty of soap and water |
| | 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 |
|------------|---|---------------|
| 25085-99-8 | Oxirane, 2,2'-((1-methylethylidene)bis(4,1-phenyleneoxymethylene))bis-, homopolymer | 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

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 : 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.

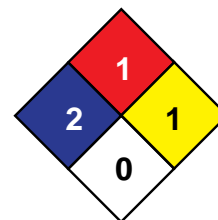
SARA 311/312 Hazards: none

California Proposition 65: 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 | |
|------|---|
| H | 2 |
| F | 1 |
| R | 1 |



NFPA

Revision: 4

Date Prepared: February 22, 2017

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. 1112B

Section 1 - Identification

1.1 Product identifier: Part B for: Free Form® Habitat® Black and Free Form® Habitat® Fire Safe and Habitat® Cast N Coat

1.2 General Use: Epoxy Curative

1.3 Manufacturer: Smooth-On, Inc.,
5600 Lower Macungie Rd., Macungie, PA 18062
Phone (610) 252-5800, FAX (610) 252-6200
SDS@Smooth-On.com

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

Eye irritation – Category 2

2.2 GHS Label elements, including precautionary statements

Hazard Pictogram(s):
Signal Word: Warning



| | | |
|-------------------------|--------------------|--|
| Health Hazards: | H315 | Causes skin irritation |
| | H317 | May cause an allergic skin reaction |
| | H319 | Causes serious eye irritation |
| General Precautions: | P101 | If medical advice is needed, have product container or label at hand. |
| | P102 | Keep out of reach of children. |
| | P103 | Read label before use. |
| Prevention Precautions: | P262 | Do not get in eyes, on skin, or on clothing. |
| | P264 | Wash skin thoroughly after handling. |
| | P271 | Use only outdoors or in a well-ventilated area. |
| Response Precautions: | P302 + P352 | IF ON SKIN: Wash with plenty of soap and water. |
| | 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, state and federal laws. |
| Precautions: | | |

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 |
|------------|--|---------------|
| 68953-36-6 | Tall oil fatty acid reaction products with tetraethylene pentamine | 15% - 25% |
| 112-57-2 | Tetraethylene pentamine | < 5% |

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. Avoid water contamination.

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 : high viscosity paste

Odor/Threshold: Mild ammonia odor

pH: N.A. (non-aqueous)

Melting Point/Freezing Point: N.A.

Low/High Boiling Point: N.A.

Flash Point: >485 °F

Evaporation Rate: Not available

Flammability: f.p. at or above 200 °F

UEL/LEL: Not available

Vapor Pressure: < 10 mmHg @ 70 °F

Vapor Density (Air=1): >1

Specific Gravity (H₂O=1, at 4 °C): 1.8

Water Solubility: negligible

Partition coefficient: Not available

Auto-ignition temperature: Not available

Decomposition temperature: Not available

Viscosity: dough

% 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 regulated 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.

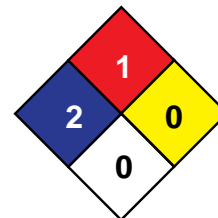
SARA 311/312 Hazards: none

California Proposition 65: 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 | |
|------|---|
| H | 2 |
| F | 1 |
| R | 0 |



NFPA

SDS Version: 4

Date Prepared: February 22, 2017

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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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.