

SAFETY DATA SHEETS

This SDS packet was issued with item:

072768182

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

072768232 072768281



MATERIAL SAFETY DATA SHEET

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product Name: Triad® TruTray™ Custom Tray Material
Product Number: 89902, 89904, 89905
MSDS Code Number: 93

Manufacturer: Dentsply Prosthetics
Address: 570 West College Ave.
York, PA 17405-0872
Information Telephone Number: 717-845-7511
Emergency Telephone Number: 800-424-9300 Chemtrec
Email: Prosthetics_MSDS@Dentsply.com

Product Use: Resin used in removable dental appliances.

Date of Last Revision: June 5, 2009

SECTION 2 HAZARDS IDENTIFICATION

Emergency Overview: CAUTION! May cause eye and skin irritation. May cause allergic skin reaction (sensitization).

EU Preparation Classification (1999/45/EC): Xi R43

SECTION 3 COMPOSITION INFORMATION ON INGREDIENTS

Ingredient	CAS No./EINECS No.	Percent	EC Substance Classification (67/548/EEC)
Non-hazardous Material	Proprietary	50-80	Not Applicable
Dichlorodimethyl silane-, reaction products with silica	68611-44-9 / 271-893-4	1-5	Not Applicable
Silazane Treated Silica	68909-20-6 / 272-697-1	1-5	Not Applicable
Methacryloxypropyl trimethoxysilane	2530-85-0 / 219-785-8	1-5	Xn R22, R43
Urethane Dimethacrylate	72869-86-4 / 276-957-5	<25	R52/53

See Section 16 for further information on EU Classification.

SECTION 4 FIRST AID MEASURES

Eye Contact: Immediately flush victim's eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention.

Skin Contact: Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops. Launder clothing before re-use. (Discard contaminated shoes).

Ingestion: If conscious, wash mouth out with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.

Inhalation: If irritation develops, remove to fresh air. Get medical attention if symptoms persist.

SECTION 5 FIRE FIGHTING PROCEDURES

Extinguishing Media: Water fog, foam, carbon dioxide, water spray or dry chemical.

Firefighting Procedures: Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus. Cool exposed intact containers with water spray.

Unusual Fire/Explosion Hazards: High temperatures and sunlight may cause a polymerizing reaction to occur. Decomposition may release acrid smoke or fumes.

Known or Anticipated Hazardous Products of Combustion: Acrid fumes, carbon and nitrogen oxides.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Accidental Release Measures Exposure to sunlight or artificial light will cause the paste to polymerize. Spread the paste to maximize the surface area. Once the material is hard, pick up and place into a container for disposal. Spill and release reporting requirements vary. Consult local authorities regarding requirements.

Personal Precautions: Avoid contact with skin, eyes or clothing.

Environmental Precautions: Prevent entry into sewers and waterways.

SECTION 7 HANDLING AND STORAGE

Handling: Avoid contact with the eyes, skin and clothing. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.

Storage: Store in a tightly closed container in a cool, well ventilated location away from incompatible materials. Do not store near high temperatures or ignition sources. Prevent contact with moisture. Refrigeration prolongs shelf life. Store away from food or beverages.

SECTION 8 EXPOSURE CONTROL/PERSONAL PROTECTION

Occupational Exposure Limits:

Non-hazardous Material	None Established
Dichlorodimethyl silane, reaction products with silica (as PNOC)	15 mg/m ³ (total dust) TWA OSHA PEL 5 mg/m ³ (respirable fraction) TWA OSHA PEL
Silazane Treated Silica	0.8 mg/m ³ TWA (manufacturer recommended)
Methacryloxypropyl trimethoxysilane	None Established
Urethane Dimethacrylate	None Established

Engineering Controls: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits or when grinding polymerized (cured) materials.

Personal Protective Equipment:

Eye Protection: Chemical safety glasses or chemical splash goggles.

Skin Protection: Wear impervious gloves such as rubber to prevent skin contact.

Respiratory Protection: If the product is heated and ventilation is inadequate, wear an approved respiratory appropriate for the exposure conditions.

Other Protective Clothing or Equipment: Impervious clothing as needed to prevent contact. A safety shower and eye wash should be available in the immediate work area.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Faint yellow, translucent paste.

Boiling Point: N/A (polymerizes)

Freezing Point: <-40°C(<-40°F)

Solubility in Water: Negligible

Vapor Pressure (mmHg): <1

Evaporation Rate: Not available

% Volatile by Volume: Negligible

Flammable Limits in Air:

LEL: N/A

UEL: N/A

Melting Point: N/A

Specific Gravity: 1.5

pH: Not determined

Vapor Density: >1

Viscosity: Not determined

Flashpoint: Not applicable

Autoignition Temperature: Not applicable

SECTION 10 STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: Polymerizes to form a hard plastic in 2 hours at 100°C (212°F) with low exotherm.

Incompatibility with Other Materials: Oxidizing agents, reducing agents, inert gases, oxygen scavengers, free radical initiators. Avoid excessive heat, flames, ignition sources and direct sunlight.

Hazardous Decomposition Products: Acrid fumes, carbon and nitrogen oxides.

SECTION 11 TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: May cause irritation, redness and tearing.

Skin: May cause irritation, redness, and swelling. May cause allergic skin reaction (sensitization).

Ingestion: None expected under normal use conditions.

Inhalation: None expected under normal use.

Chronic Health Effects: None expected under normal use.

Carcinogenicity: None of the components are listed as possible carcinogens by NTP, IARC, ACGIH, the EU Dangerous Substances Directive, or OSHA.

Medical Conditions Aggravated by Exposure: Individuals with pre-existing skin disorders may be at increased risk from exposure.

Acute Toxicity Data:

Non-hazardous materials No data available

Silazane Treated Silica Oral Rat LD50: >5000 mg/kg

Methacryloxypropyl trimethoxysilane Oral Rat LD50: >2000 mg/kg; Skin rat LD50: >2000 mg/kg

Dichlorodimethyl silane-, reaction products with silica Oral Rat LD50: >5000 mg/kg

Urethane Dimethacrylate Oral Rat LD50: >2000 mg/kg

SECTION 12 ECOLOGICAL INFORMATION

Non-hazardous materials No data available

Silazane Treated Silica No data available

Methacryloxypropyl trimethoxysilane No data available

Dichlorodimethyl silane-, reaction products with silica No data available

Urethane Dimethacrylate

96h/LC50 zebra fish: 10.1 mg/l, not readily biodegradable

SECTION 13 DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations. Exposure to sunlight or artificial light will cause the material to polymerize into a hard plastic.

SECTION 14 TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated

DOT Hazard Class: N/A

UN Number: N/A

DOT Labels Required (49CFR172.101): N/A

IATA Shipping Name: Not Regulated

IATA Hazard Class: N/A

UN Number: N/A

IATA Hazard Labels Required: N/A

IMDG Shipping Name: Not Regulated

IMDG Class: N/A

UN Number: N/A

IMDG Label: N/A

SECTION 15 REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

CERCLA: Report spills required under federal, state and local regulations.

SARA TITLE III:

Hazard Category For Section 311/312: Acute Health

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: This product is a medical device and not subject to chemical notification requirements.

U.S. STATE REGULATIONS

California Proposition 65: This product contains the following substances known to the State of California to cause cancer: None

INTERNATIONAL REGULATIONS:

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

Canadian WHMIS Classification: This product is a medical device and not subject to labeling under WHMIS.

European Community Labeling:



Irritant

R43 May cause sensitization by skin contact.
S24/25 Avoid contact with skin and eyes.
S36/37 Wear suitable protective clothing and gloves.

European Inventory of New and Existing Chemicals Substances (EINECS): This product is a medical device and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

SECTION 16 OTHER INFORMATION

HMIS Hazard Rating:

Health – 1 Flammability – 1 Physical Hazard – 1

EU Classes and Risk Phrases for Reference (See Sections 2 and 3):

Xi Irritant

R36/37/38 Irritating to eyes, respiratory system and skin.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Revision Summary:

Added e-mail address to Section 1. Switched Sections 2 and 3. Updated exposure limits. Updated Canadian WHMIS classification.

Revision Date: 06/05/2009

Supersedes: 07/14/2006

**DENTSPLY International
DENTSPLY PROSTHETICS**

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010), US 29CFR1910.1200, Canada Hazardous Products Regulation

Date Issued: 25 June 1997
Document Number: 093
Date Revised: 23 September 2015
Revision Number: 7

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled): Triad® TruTray™ Custom Tray Material
Part/Item Number: 89902, 89904, 89905

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use: Resin for fabricating custom dental trays
Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: DENTSPLY Prosthetics
Manufacturer/Supplier Address: 570 West College Ave.
York, PA 17401
Manufacturer/Supplier Telephone Number: 717-845-7511 (Product Information)
Email address: Prosthetics_MSDS@Dentsply.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Skin Sensitization Category 1 (H317)	Not Hazardous	Not Hazardous

2.2 Label Elements:



Signal Word: Warning

Contains: Urethane Dimethacrylate

Hazard Phrases	Precautionary Phrases
H317 May cause an allergic skin reaction.	P261 Avoid breathing dust or fume. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P333+P313 If skin irritation or rash occurs: Get medical attention. P363 Wash contaminated clothing before reuse. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS # REACH Registration #	Classification	WT %
Non-hazardous Ingredients	Proprietary	Proprietary	Not Applicable	Balance
Glass	65997-17-3	266-046-0	Carc 1B (H350)*	60-70
Urethane Dimethacrylate	72869-86-4	276-957-5	Skin Sens 1B (H317)	< 25
Dichlorodimethyl silane-, reaction products with silica	68611-44-9	271-893-4	Not Applicable	1-5
Methacryloxypropyl trimethoxysilane	2530-85-0	219-785-8	Not Applicable	1-5

*Carcinogen classification is not applicable to non-fibrous forms.

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS Classifications.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

Eye	Rinse thoroughly with water, while holding the eye lids open to be sure the material is washed out. Get medical attention if irritation occurs and persists.
Skin	Remove clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation or rash develops. Launder contaminated clothing before re-use.
Inhalation	If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	Do not induce vomiting. If conscious, wash mouth out with water. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if you feel unwell.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

May cause eye and skin irritation. Prolonged or repeated contact may cause allergic skin reaction (sensitization). Individuals with sensitivity to methacrylates may develop an allergic reaction when exposed to this product.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention should not be required.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use water fog, foam, carbon dioxide, water spray or dry chemical.
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5.2 Special Hazards Arising from the Substance or Mixture:

High temperatures and sunlight may cause a polymerizing reaction to occur. Decomposition may release acrid smoke and fumes; carbon and nitrogen oxides.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures:	Cool fire exposed containers and structures with water.
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Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.
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6. ACCIDENTAL RELEASE MEASURES**6.1 Personal Precautions, Protective Equipment and Emergency Procedures:**

Avoid contact with skin, eyes or clothing. Avoid breathing dust, mist or fumes. Wear appropriate protective clothing as described in Section 8.

6.2 Environmental Precautions:

Avoid releases to the environment. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Exposure to sunlight or artificial light will cause the paste to polymerize. Spread the paste to maximize the surface area. Once the material is hard, pick up and place into a container for disposal.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE**7.1 Precautions for Safe Handling:**

Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Empty containers retain product residues and contaminants that can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in a tightly closed container in a cool, well-ventilated location away from incompatible materials. Do not store near high temperatures. Prevent contact with moisture. Refrigeration prolongs shelf life. Store away from food or beverages.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Glass	5 mg/m ³ or 1 f/cc TWA ACGIH TLV 15 mg/m ³ TWA OSHA PEL (total dust), 5 mg/m ³ TWA (respirable fraction)
Urethane Dimethacrylate	None Established
Dichlorodimethyl Silane-, reaction products with silica (as PNOC)	5 mg/m ³ (Respirable fraction), 15 mg/m ³ (total dust) TWA OSHA PEL
	4 mg/m ³ TWA DFG MAK (Inhalable)
	Belgium: 3 mg/m ³ TWA
Methacryloxypropyl trimethoxysilane	None Established

*PNOC exposure limits only apply if dust is generated.

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits or when grinding polymerized (cured) materials.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety glasses or goggles recommended.

Specific Skin Protection: Wear impervious gloves such as rubber to prevent skin contact.

Specific Respiratory Protection: None should be needed for normal use. If the product is heated, grinded, or ventilation is inadequate, an approved respirator with dust/mist cartridges or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.

Specific Thermal Hazards: None required

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Faint yellow, translucent paste in the uncured state.	Explosive limits:	Not applicable
Odor:	Characteristic odor.	Vapor pressure (mmHg):	< 1
Odor threshold:	Not determined	Vapor density: (Air=1)	>1
pH:	Not determined	Relative density:	1.5
Melting/freezing point:	<-40°C(<-40°F)	Solubility:	Negligible
Initial boiling point and range:	Not applicable (polymerizes)	Partition coefficient: n-octanol/water:	Not available

Flash point:	Not applicable	Auto-ignition temperature:	Not applicable
Evaporation rate:	Not available	Decomposition temperature:	Not determined
Flammability:	Not Flammable	Viscosity:	Not determined
Explosive Properties:	Not explosive	Oxidizing Properties:	Not an oxidizer

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Polymerization can occur.
10.2 Chemical Stability: Unstable if heated. Polymerizes to form a hard plastic in 2 hours at 100°C (212°F) with low exotherm.
10.3 Possibility of Hazardous Reactions: Polymerization can occur if heated above 100°C (212°F)
10.4 Conditions to Avoid: Avoid heating greater than 100°C (212°F). Avoid excessive heat, flames, ignition sources and direct sunlight.
10.5 Incompatible materials: Oxidizing agents, reducing agents, inert gases, oxygen scavengers, and free radical initiators. Avoid excessive heat, flames, ignition sources and direct sunlight.
10.6 Hazardous Decomposition Products: Thermal decomposition may release acrid smoke and fumes; carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects: <u>Eyes:</u> May cause slight irritation, redness and tearing. <u>Skin:</u> May cause slight irritation, redness, rash and swelling. May cause allergic skin reaction (sensitization). <u>Ingestion:</u> None expected under normal use conditions. <u>Inhalation:</u> None expected under normal use.
Chronic Health Effects: None expected under normal use.
Irritation: This product is not classified as an irritant.
Corrosivity: This product is not classified as a corrosive material.
Sensitization: This product is classified as a skin sensitizer.
Carcinogenicity: Fiberglass is classified by the EU as a carcinogen category 1B. However, this classification does not apply to non-fibrous forms of fiberglass. None of the other components of this product at 0.1% or greater are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.
Mutagenicity: No data available. This product is not expected to cause mutagenic activity.

Acute Toxicity Data:

Non-hazardous Ingredients: No data available.

Glass: No data available.

Urethane Dimethacrylate: Oral rat LD50 > 5000 mg/kg

Dichlorodimethyl silane-, reaction products with silica: No data available.

Methacryloxypropyl trimethoxysilane: Oral rat LD50 > 2000 mg/kg, inhalation rat LC50 > 2.28 mg/L, dermal rat LD50 > 2000 mg/kg

Reproductive Toxicity Data: No data available. This product is not expected to cause adverse reproductive effects.

Specific Target Organ Toxicity Single Exposure (STOT-SE):

No data available.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE):

No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Urethane Dimethacrylate: Daphnia magna EC50 > 1.2 mg/L/48hr

Methacryloxypropyl trimethoxysilane: Danio rerio LC50 > 100 mg/L/96hr

This product is not expected to be harmful to the aquatic environment.

12.2 Persistence and Degradability: Urethane Dimethacrylate is not readily biodegradable

12.3 Bio-accumulative Potential: No data is currently available

12.4 Mobility in Soil: No data is currently available

12.5 Results of PBT and vPvB Assessment: Not required

12.6 Other Adverse Effects: None known

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Waste Treatment Recommendations: Treat in accordance with local, regional and national regulations.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	None
ADR/RID	None	Not Regulated	None	None	None
IMDG	None	Not Regulated	None	None	None
IATA/ICAO	None	Not Regulated	None	None	None

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification requirements.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories: Acute Health.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product does not contain substances known to the state of California to cause cancer and/or reproductive toxicity.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: All components requiring registration have been pre-registered.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 2 Flammability – 0 Physical Hazard– 1

Full text of Classification abbreviations used in Section 2 and 3:

Carc 1 Carcinogen Category 1

Skin Sens. 1 Skin Sensitizer Category 1

H317 May cause an allergic skin reaction.

H350 May cause cancer

Supersedes: 16 August 2012

Date Updated: 23 September 2015

Revision Summary: Updated format and all sections to comply with REACH regulations.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.