



DENTSPLY Professional

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Document Number: 82387-1214
Date Revised: 09 December 2014

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

1.1 Product Identifier:

Trade Name (as labeled): Midwest Plus™ Handpiece Lubricant
Part/Item Number: 380130

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

Recommended Use: Lubricating Oil
Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: DENTSPLY Professional
Manufacturer/Supplier Address: 901 West Oakton St.
Des Plaines, IL 60018
Manufacturer/Supplier Telephone Number: 800-989-8826 or 717-767-8502 (Product Information)
Email address: ProfessionalMSDS@dentsply.com

1.4 Emergency Telephone Number:

Transportation Emergency Contact Number: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Aspiration Toxicity Category 1 (H304)	Not Hazardous	Not Hazardous

EU Classification: Harmful (Xn), R65

2.2 Label Elements:



Signal Word: Danger!

Hazard Phrases	Precautionary Phrases
H304 May be fatal if swallowed and enters airways.	P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor. P331 Do NOT induce vomiting. P405 Store locked up. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
1-Decene, Homopolymer, Hydrogenated	68037-01-4	500-183-1	Not Classified	30-40
1-Dodecene Polymer with 1-Decene	151006-60-9	436-190-0	Xn, R65 Asp Tox Cat 1 (H304)	30-40
1-Dodecene, Polymer with 1-Decene and 1-Octene	163149-28-8	605-315-2	Xn, R65 Asp Tox Cat 1 (H304)	30-40

The exact concentration is being withheld as a trade secret.

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

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

Eye	Immediately flush eyes with large quantities of water, while holding the eyelids apart. Get medical attention if irritation persists.
Skin	Wash skin thoroughly with soap and water. If symptoms develop and persist, get medical attention.
Inhalation	Immediately remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration.
Ingestion	Aspiration hazard: DO NOT induce vomiting. Keep the victim calm and warm. If conscious, rinse mouth with water. Never give anything by mouth to an unconscious or convulsing person. If vomiting occurs spontaneously, keep head below hips to prevent aspiration into the lungs. Immediately call poison control center or go to a hospital emergency room.

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

Aspiration into lungs during swallowing or vomiting may cause fatal or harmful lung damage.

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

Immediate medical attention is required for ingestion.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:

Use carbon dioxide, foam or dry chemical. Do not use water jet, as it may spread fire

5.2 Special Hazards Arising from the Substance or Mixture:

Decomposition may release carbon monoxide, carbon dioxide and low molecular weight hydrocarbons.

5.3 Advice for Fire-Fighters:**Fire Fighting Procedures:**

Use water to cool exposed containers and structures and disperse flammable vapors.

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.. Do not allow run-off from firefighting to enter drains or water courses.

Recommended Protective Equipment for Fire Fighters:**EYES/FACE****HANDS****RESPIRATORY****THERMAL**

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

Recommended Personal Protective Equipment for Containment and Clean-up:**EYES/FACE****HANDS****RESPIRATORY****SKIN****6.2 Environmental Precautions:**

Prevent entry into sewers and waterways. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Soak up with inert absorbent material. Clean contaminated surface thoroughly. Clean up spills immediately, observing precautions in Protective Equipment section. Collect using an absorbent material and place in an appropriate 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. Do not breathe vapors or mists. 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 can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in cool place. Store in a closed container away from incompatible materials.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:**Occupational Exposure Limits:**

1-Decene Homopolymer Hydrogenated	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
1-Dodecene Polymer with 1-Decene	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
1-Dodecene, Polymer with 1-Decene and 1-Octene	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to minimize exposures levels.

Individual Protection Measures (PPE):



Specific Eye/face Protection: Chemical safety glasses with side shields or chemical splash goggles are recommended to avoid eye contact where splashing is possible.

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

Specific Respiratory Protection: None should be needed for normal use. If indoor air concentrations are excessive, an approved respirator with dust/mist cartridges or supplied air respirator should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Clear liquid with slight odor	Explosive limits:	LEL: Not available UEL: Not available
Odor:	Weak, characteristic odor	Vapor pressure (mmHg):	Not available
Odor threshold:	Not available	Vapor density:	Not available
pH:	Not available	Relative density:	0.825 g/cm ³
Melting/freezing point:	Not available	Solubility(ies):	Not available
Initial boiling point and boiling range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	>400 °F/>204.4 °C ASTM D-92	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability (solid, gas):	Not available	Viscosity:	Not available

Explosive Properties:	Not available	Oxidizing Properties:	Not available
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9.2 Other Information: None known.

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal conditions.

10.3 Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4 Conditions to Avoid: Keep away from heat, sparks and all ignition sources.

10.5 Incompatible materials: Strong oxidizing agents, acids, and alkalines.

10.6 Hazardous Decomposition Products: Decomposition may release oxides of carbon and low molecular weight hydrocarbons.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Contact with liquid may cause mild irritation.

Skin: Prolonged contact with skin may cause mild irritation.

Ingestion: Aspiration into the lungs during ingestion or vomiting may cause chemical pneumonitis, pulmonary edema/hemorrhage, and possible death. Ingestion may also cause mucous membrane and gastrointestinal irritation and nervous system depression with symptoms of headache, dizziness, narcosis, nausea, vomiting, and diarrhea.

Inhalation: Inhalation of vapors may cause mucous membrane and respiratory irritation.

Chronic Health Effects: None known.

Irritation: No data available.

Corrosivity: No data available.

Sensitization: No data available.

Carcinogenicity: None of the components of this product 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.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing conditions may be at increased risk from exposure.

Acute Toxicity Data:

Product: No toxicity data available

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

Specific Target Organ Toxicity (STOT):

Single Exposure: No data available.

Repeated Exposure: No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

No ecotoxicity data available

12.2 Persistence and Degradability: No data is currently available

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

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

Waste Treatment Recommendations: Dispose in accordance with national and local 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	Not applicable
ADR/RID	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA/ICAO	None	Not Regulated	None	None	Not applicable

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:

Immediate Hazard:	Yes	Pressure Hazard:	No
Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	No		

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 contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
None		

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

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

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

EU REACH: 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.

New Zealand Inventory of Chemicals: 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 – 1 Physical Hazard– 0

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

Xn Harmful

R65 May cause lung damage if swallowed.

Asp Tox Cat 1 Aspiration Toxicity Category 1

H304May be fatal if swallowed and enters airways.

Revision Date: 09 December 2014

Revision Summary: Converted MSDS to Reach SDS. Updated all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.



DENTSPLY Professional

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Document Number: 82381-1214
Date Revised: 09 December 2014

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

1.1 Product Identifier:

Trade Name (as labeled): Midwest Plus™ Handpiece Cleaner
Part/Item Number: 380140

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

Recommended Use: Cleaner, Lubricant
Restrictions on Use: For Professional Use Only.

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: DENTSPLY Professional
Manufacturer/Supplier Address: 901 West Oakton St.
Des Plaines, IL 60018
Manufacturer/Supplier Telephone Number: 800-989-8826 or 717-767-8502 (Product Information)
Email address: ProfessionalMSDS@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
Not Hazardous	Not Hazardous	Not Hazardous

EU Classification: None

2.2 Label Elements:

Signal Word: None Required

Hazard Phrases	Precautionary Phrases
None Required	None Required

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Non-Hazardous Proprietary Blend	Mixture	Mixture	Not Applicable	100%

The exact concentration is being withheld as a trade secret.

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

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

Eye	Flush eyes with large quantities of water, while holding the eyelids apart. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. If irritation develops, get medical attention. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. If irritation occurs, get medical attention.
Ingestion	In the case of unintended ingestion, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if any adverse effects occur.

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

May cause mild eye irritation. May cause skin irritation with prolonged contact. Inhalation of vapors or mist may cause upper respiratory irritation.

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

Immediate medical attention should not be required except in cases of high quantities of ingestion or inhalation.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES





5.1 Extinguishing Media: Use water, carbon dioxide, alcohol foam or dry chemical.

5.2 Special Hazards Arising from the Substance or Mixture:

Decomposition may release carbon monoxide and carbon dioxide.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures:	Use water to cool exposed containers and structures. Fight fire from safe distance or protected location.
Precautions for Fire Fighters:	Do not enter fire area without proper protection. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus. Do not allow run-off from firefighting to enter drains or water courses.



Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Avoid contact with skin, eyes or clothing. Avoid breathing mists. Wear appropriate protective clothing.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

6.2 Environmental Precautions:

Prevent entry into sewers and waterways. Report releases as required by local, state, and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Contain and collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Prevent spill from entering sewers and water courses. Report releases as required by local, state and federal authorities.

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. Avoid breathing mists. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Do not reuse containers. Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well-ventilated area away from heat, direct sunlight and all sources of ignition. Store away from incompatible materials. Keep container closed to prevent contamination.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:**Occupational Exposure Limits:**

Non-Hazardous Proprietary Blend	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposure levels below the occupational exposure limits. Use explosion-proof equipment where required.

Individual Protection Measures (PPE):



Specific Eye/face Protection: Chemical safety glasses or chemical splash goggles are recommended to avoid eye contact.

Specific Skin Protection: Wear impervious gloves such as butyl rubber or neoprene gloves to avoid prolonged skin contact.

Specific Respiratory Protection: None should be needed for normal use. If the airborne concentrations are excessive, an approved organic vapor 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.

Recommended Personal Protective Equipment

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Water-white sudsy liquid with slightly opaque color.	Explosive limits:	LEL: Not determined UEL: Not determined
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Odor:	Mild odor characteristic of isopropanol.	Vapor pressure (mmHg):	Not determined
Odor threshold:	Not determined	Vapor density:	Not Determined
pH:	6.5	Relative density:	~1.004
Melting/freezing point:	Not determined	Solubility(ies):	Completely miscible
Initial boiling point and boiling range:	80.4-100°C (176.72-212°F)	Partition coefficient: n-octanol/water:	Not determined
Flash point:	Not determined	Auto-ignition temperature:	Not determined
Evaporation rate:	Between 1.5 and 1.75	Decomposition temperature:	Not determined
Flammability (solid, gas):	Not applicable	Viscosity:	Not applicable
Explosive Properties:	Not an explosive	Oxidizing Properties:	Not an oxidizer

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.
10.2 Chemical Stability: Stable at normal temperatures and conditions.
10.3 Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
10.4 Conditions to Avoid: None known
10.5 Incompatible materials: Avoid oxidizing agents.
10.6 Hazardous Decomposition Products: Decomposition may release carbon monoxide and carbon dioxide.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

<p><u>Potential Health Effects:</u></p> <p><u>Eyes:</u> Contact may cause moderate irritation with redness, tearing and stinging.</p> <p><u>Skin:</u> Repeated or prolonged contact may cause irritation, drying, defatting of the skin and dermatitis.</p> <p><u>Ingestion:</u> Ingestion of large amounts may cause gastrointestinal upset.</p> <p><u>Inhalation:</u> Inhalation of vapors may cause cause irritation of the mucous membranes and upper respiratory tract.</p> <p><u>Chronic Health Effects:</u> None known.</p>
<p><u>Irritation:</u></p> <p>Product: Skin irritation (rabbit): Not corrosive. Direct contact can cause mild to severe redness and swelling. Eye irritation (rabbit): 0.1 ml applied to the eye without washing may produce minimal to moderate transient eye irritation.</p>

<u>Corrosivity:</u> This product is not a corrosive material.
<u>Sensitization:</u> No data available. This product is not expected to cause sensitization.
<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Directive.
<u>Mutagenicity:</u> No data available. This product is not expected to cause mutagenic activity.
<u>Medical Conditions Aggravated by Exposure:</u> Individuals with pre-existing skin, respiratory, liver and kidney disease may be at increased risk from exposure.
<u>Acute Toxicity Data:</u> Product: Oral Rat LD50: >5.0 g/kg, Dermal Rabbit LD50: \geq 2.0 g/kg.
<u>Reproductive Toxicity Data:</u> No data available. This product is not expected to cause reproductive harm.
<u>Specific Target Organ Toxicity (STOT):</u> <u>Single Exposure:</u> No data available <u>Repeated Exposure:</u> No data available

12. ECOLOGICAL INFORMATION

12.1 Toxicity: No ecotoxicity data available
12.2 Persistence and Degradability: No data available.
12.3 Bio-accumulative Potential: No data available.
12.4 Mobility in Soil: No data available.
12.5 Results of PBT and vPvB Assessment: Not applicable.
12.6 Other Adverse Effects: None

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

<u>Regulations:</u> Dispose in accordance with all national and local regulations.
<u>Properties (Physical/Chemical) Affecting Disposal:</u> Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.
<u>Waste Treatment Recommendations:</u> Dispose in accordance with national and local 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	Not applicable
ADR/RID	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA/ICAO	None	Not Regulated	None	None	Not applicable

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 an approved drug 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:

Immediate Hazard:	No	Pressure Hazard:	No
Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	No		

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 contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
None		

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

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

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

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 – 1 Flammability – 0 Physical Hazard – 0

Full text of Classification abbreviations used in Section 2 and 3:
None

Date Revised: 09 December 2014

Revision Summary: Converted MSDS to Reach SDS. Updated all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.