SAFETY DATA SHEETS

This SDS packet was issued with item: 075453006

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).

075315015 075315049 075445101 075453030 075453089 075453097 075453105

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)

Date Issued: 9 August 2004 Document Number: 203 Date Revised: 18 December 2013 Revision Number: 7

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

1.1 Product Identifier: Trade Name (as labeled): PermaSoft® Liquid N811000, N811100, N811500, N812000, N812100, **Part/Item Number:** N812500, N814002, N814005 1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against: **Recommended Use: Denture Liner 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		
Eye Irritant Category 2 Reproductive Toxicity Category 1B	Aquatic Acute Category 1	Flammable Liquid Category 3		

EU Classification: Toxic (T) Dangerous for the Environment (N), R10, R50, R61, R62

2.2 Label Elements:



Signal Word: Danger

Contains: Dibutyl Phthalate

Hazard Phrases	Precautionary Phrases
Hazard Phrases H226 Flammable Liquid and vapor. H319 Causes serious eye irritation. H360df May damage the unborn child. Suspected of damaging fertility. H400 Very toxic to aquatic life.	Precautionary PhrasesP201 Obtain special instructions before use.P202 Do not handle until all safety precautions have been read and understoodP210 Keep away from heat, sparks, open flames, and hot surfaces. No smoking.P233 Keep container tightly closed.P240 Ground and bond container and receiving equipment P241 Use explosion-proof electrical, ventilating and lighting equipment.P242 Use only non-sparking tools.
	 P242 Ose only non-sparking tools. P243 Take precautionary measures against static discharge. P264 Wash thoroughly after handling. P280 Wear protective gloves, eye protection and face protection. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with 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. P337 + P313 If eye irritation persists: Get medical
	 attention. P308 + P313 IF exposed or concerned: Get medical attention. P370 + P378 In case of fire: Use carbon dioxide, alcohol foam or dry chemical to extinguish. P273 Avoid release to the environment. P391 Collect spillage P403 + P235 Store in a well-ventilated place. Keep cool. 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

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Dibutyl Phthalate	84-74-2	201-557-4	T, N R50, R61, R62 Repr. 1B H360,	60-90
			Aquatic Acute 1 H400	

Ethyl Acetate	141-78-6	205-500-4	F, Xi R11, R36, R66, R67 Flam. Liq. 2 H225,	5-15
			Eye Irrit. 2A H319 STOT SE 3 H336	
Ethanol (Ethyl Alcohol)	64-17-5	200-578-6	F R11 Flam. Liq. 2 H225	1-10

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 Descripti	on of First Aid Measures:
Eye	Immediately flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Immediately wash skin thoroughly with soap and water. If rash, irritation or symptoms develop, get medical attention. Launder clothing before re-use. (Discard contaminated shoes).
Inhalation	Immediately remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get immediate medical attention.
Ingestion	Get immediate medical attention. Immediately call poison control center or go to a hospital emergency room. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious or convulsing person.

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

May cause eye and skin irritation. Inhalation of vapors or mist may cause respiratory irritation and central nervous system effects such as headache, dizziness, drowsiness, nausea and unconsciousness. Prolonged and/or repeated overexposure may cause anemia, kidney and liver damage. May cause adverse reproductive effects based on studies with laboratory animals.

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

Immediate medical attention is required for ingestion and inhalation.

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

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use carbon dioxide, alcohol foam or dry chemical.		
5.2 Special Hazards Arising from the Substance or Mixture:			
	This product is flammable and forms explosive mixtures with air. Vapors are heavier than air and will travel along surfaces to remote ignition sources and flash back. Closed containers may explode if exposed to extreme heat.		
5.3 Advice for Fire-Fighters	5.3 Advice for Fire-Fighters:		
Fire Fighting Procedures:	Use water to cool exposed containers and structures and disperse flammable vapors. Do not allow run-off from firefighting to enter drains or water courses.		
Precautions for Fire	Firefighters should wear full emergency equipment and an approved positive pressure self-		
Fighters:	contained breathing apparatus.		

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

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Remove all sources of ignition. Ventilate area with explosion proof equipment. Wear appropriate protective clothing as described in Section 8. Avoid contact with eyes, skin, and clothing. If spill has not ignited, use water spray to disperse the vapors and protect personnel attempting to stop leak.

Recommended Personal Protective Equipment for Containment and Clean-up:



6.2 Environmental Precautions:

Do not flush into sewer! Do not allow spills to enter sewers, waterways or the environment. Report releases as required by local, state and federal authorities.

6.3 Methods and Material for Containment and Cleaning up:

Eliminate all ignition sources. Contain and collect using inert absorbent materials and place in appropriate containers for disposal. Use non-sparking tools and equipment.

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 Handing:

Avoid contact with the eyes, skin and clothing. Avoid breathing vapors. 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. Keep product away from heat, sparks, flames and all other sources of ignition. Do not permit smoking in use or storage areas. Use with non-sparking tools and explosion proof equipment. Electrically bond and ground containers for transfer.

Do not cut, drill, grind or weld on or near containers, even empty containers. Empty containers retain product residues can be hazardous. Follow all SDS precautions when handling empty containers.

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7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in accordance with regulations for the storage of flammable liquids. Store in a dry, well-ventilated area away from heat, direct sunlight and all sources of ignition. Store away from oxidizers and other incompatible materials.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:				
Occupational Exposure Lin	nits:			
Ethanol	United States	1000 ppm STEL ACGIH TLV 1000 ppm TWA OSHA PEL		
	Germany	500 ppm TWA, 1000 ppm STEL DFG MAK		
	United Kingdom	1000 ppm TWA UK WEL		
	European Union	Belgium: 1000 ppm TWA		
Dibutyl Phthalate	United States	5 mg/m ³ TWA ACGIH TLV 5 mg/m ³ TWA OSHA PEL		
	Germany	0.05 mg/m ³ TWA DFG MAK		
	United Kingdom	5 mg/m ³ TWA UK OEL 10 mg/m ³ STEL UK OEL		
	European Union	None Established		
Ethyl Acetate	United States	400 ppm TWA ACGIH TLV 400 ppm TWA OSHA PEL		
	Germany	400 ppm TWA DFG MAK		
	United Kingdom	200 ppm TWA UK OEL 400 ppm STEL UK OEL		
	European Union	None Established		

Biological Exposure Limits:

None

8.2 Exposure Controls:

Appropriate Engineering Controls: Use ventilation that is adequate to keep employee exposure to airborne concentrations below exposure limits. Use explosion-proof equipment where required

Individual Protection Measures (PPE):

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

Specific Skin Protection: Wear impervious gloves such as 4HTM. Clothing with long sleeves may be needed when working with large quantities.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded 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		
	CCUUM/				

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Light colored liquid	Explosive limits:	LEL: 2.0% (as ethyl acetate) UEL: 19% (as ethyl alcohol)
Odor:	Slight odor	Vapor pressure (mmHg):	Not available
Odor threshold:	Not available	Vapor density:	9.6 @ 20°C
рН:	Not available	Relative density:	1.02
Melting/freezing point:	Not available	Solubility(ies):	Partially
Initial boiling point and boiling range:	171° F (77°C)	Partition coefficient: n- octanol/water:	Not available
Flash point:	74°F (23°C)	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability (solid, gas):	Not applicable	Viscosity:	Not available
Explosive Properties:	Vapors may be explosive in confined areas.	Oxidizing Properties:	None

9.2 Other Information: None available.

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal conditions.

10.3 Possibility of Hazardous Reactions: None know.

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

10.5 Incompatible materials: Avoid oxidizing agents and inorganic acids.

10.6 Hazardous Decomposition Products: Decomposition may release carbon monoxide and carbon dioxide.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Contact may cause irritation with redness, tearing and stinging.

<u>Skin:</u> May cause skin irritation with redness and itching. Repeated or prolonged contact may cause drying, defatting of the skin and dermatitis.

<u>Ingestion</u>: Ingestion may cause mucous membrane and gastrointestinal irritation with nausea, vomiting and diarrhea. May cause nervous system depression with symptoms of headache, dizziness, nausea, vomiting, weakness, fatigue, confusion, and unconsciousness.

<u>Inhalation:</u> Inhalation of vapors may cause mucous membrane and respiratory irritation and central nervous system depression with symptoms of headache, dizziness, drowsiness, nausea, vomiting, and unconsciousness. High vapor concentrations may cause burning sensation of the nose and throat and watering of the eyes.

<u>Chronic Health Effects</u>: Repeated skin contact may cause dermatitis. Prolonged overexposure to ethyl acetate may cause anemia with leukocytes and damage to the kidney and liver.

Irritation: Ethanol: Not irritating to rabbit skin, Irritating to rabbit eyes.

Corrosivity: No data available. This product is not expected to be corrosive.

<u>Sensitization</u>: No data available. This product is not expected to cause sensitization. Dibutyl was not sensitizing in a guinea pig maximization test.

<u>Carcinogenicity</u>: Ethanol: Ingestion of alcoholic beverages is known to cause cancer in humans (IARC group 1). None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Directive.

<u>Mutagenicity</u>: Ethanol: Negative in AMES test, in-vivo rat cytogenetic assay. Positive in a sister chromatid and exchange CHO cells, human lymphocytes cytogenetic assay, in-vivo mouse cytogenetic assay and rat dominant lethal assay. Dibutyl was negative in an in vitro bacterial gene mutation assay.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing skin, respiratory, liver and kidney disease may be at increased risk from exposure.

Acute Toxicity Data:

Ethanol: Oral rat LD50-7060 mg/kg; Inhalation Rat LC50 – 117-125 mg/L/4 hr

Dibutyl Phthalate: LD50 oral rat 6279 mg/kg; LD50 skin rabbit 4200 mg/kg; LC50 inhalation mouse 15.68 mg/L/4 hr Ethyl Acetate: LD50 oral rat 5620 mg/kg; LC50 Inhalation Rat 200 gm/m3; LD50 Skin Rabbit > 20000 mg/kg

<u>Reproductive Toxicity Data:</u> Ethanol: Repeated ingestion of ethanol by pregnant mothers has been shown to adversely affect the central nervous system of the fetus, resulting in fetal alcohol syndrome. These effects include mental and physical retardation, disturbances of learning, motor and language deficiencies, behavioral disorders and small head size. Dibutyl phthalate has been shown to cause adverse reproductive effects and birth defects in studies with laboratory animals.

Specific Target Organ Toxicity (STOT):

<u>Single Exposure</u>: May cause nervous system depression with symptoms of headache, dizziness, nausea, vomiting, weakness, fatigue, confusion, and unconsciousness.

<u>Repeated Exposure</u>: Ethanol: Ethanol when consumed as a beverage has been found to cause damage to the liver, nervous system and reproductive system. Prolonged overexposure to ethyl acetate may cause damage to the kidney and liver.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Dibutyl Phtalate: LC50 Pimephales promelas (Fathead minnow) 0.92 mg/L/96 hr; EC50 daphnia magna 4.8 mg/L/48 hr; EC50 Pseudokirchnerella subcapitata 0.75 mg/L/ 96 hr

Ethanol: LC50 rainbow trout 13000 mg/L/96 hr; LC50 daphnia magna 9268-14221 mg/L/48 hr; EC50 Chlorella pyrenoidosa (Green algae; growth inhibition) 9310 mg/L/48 hr

Ethyl Acetate: LC50 Pimephales promelas (fathead minnow) 230 mg/l/96 hr.

12.2 Persistence and Degradability: Ethanol and dibutyl phthalate are readily biodegradable in screening tests.

12.3 Bio-accumulative Potential: Ethanol has an estimated BCF of 3. Ethyl acetate has an estimated BCF of 3.2.

12.4 Mobility in Soil: Dibutyl phthalate is expected to have a low mobility in soil. Ethyl acetate is expected to have high mobility in soil.

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:

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: Treat 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	UN1993	Flammable Liquid n.o.s. (Ethanol, Ethyl Acetate)	3	III	No
ADR/RID	UN1993	Flammable Liquid n.o.s. (Ethanol, Ethyl Acetate)	3	III	No
IMDG	UN1993	Flammable Liquid n.o.s. (Ethanol, Ethyl Acetate)	3	III	No
IATA/ICAO	UN1993	Flammable Liquid n.o.s. (Ethanol, Ethyl Acetate)	3	III	No

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 - product is transported only in packaged form.

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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 has a Reportable Quantity (RQ) of 11 lbs. based on the RQ for Dibutyl Phthalete of 10 lbs. Releases above the RQ must be reported to the National Response Center. 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.

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:	Yes	Reactivity Hazard:	No
Fire Hazard:	Yes		

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

Components	C.A.S. #	WT %
Dibutyl Phthalate	84-74-2	60-90

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 %	
Dibutyl Phthalate	84-74-2	60-90	

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not covered by 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.

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China Inventory of Existing Chemicals and 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 – 3 Physical Hazard-0 Full text of Classification abbreviations used in Section 2 and 3: F Flammable N Dangerous for the Environment T Toxic Xi Irritant R10 Flammable R11 Highly flammable. R36 Irritating to eyes. R50 Very toxic to aquatic organisms. R61 May cause harm to the unborn child. R62 Possible risk of impaired fertility. R66 Repeated exposure may cause skin dryness or cracking. R67 Vapors may cause drowsiness and dizziness Flam. Liq. 2 Flammable Liquid Category 2 Eye Irrit. 2A Eye Irritant Category 2A STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3 Repro 1B Toxic tot Reproduction Category 1B Aquatic Acute 1 Aquatic Acute Toxicity Category 1 H225 Highly flammable liquid and vapor. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. H360df May damage the unborn child. Suspected of damaging fertility. H400 Very toxic to aquatic life. Supersedes: 1 February 2012 Revision Summary: Converted SDS 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 International Prosthetics

Safety Data Sheet

Safety Data Sheet (conforms to with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 2015/830), US 29CFR1910.1200, Canada Hazardous Products Regulation

Date Issued: 9 August 2004 Document Number: 203 Date Revised: 15 April 2019 Revision Number: 9

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

1.1 Product Identifier:

Trade Name (as labeled):

Part/Item Number:

PermaSoft[®] Liquid

N811000, N811100, N811500, N812000, N812100, N812500, N814002, N814005

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

Reco	ommended Use:	Denture Liner
Rest	rictions on Use:	For Professional Use Only
1.3 Details of	f the Supplier of the Safety Data Sheet:	
Man	nufacturer/Supplier Name:	Dentsply Sirona Prosthetics
Man	ufacturer/Supplier Address:	570 West College Ave.
		York, PA 17401
Man	ufacturer/Supplier Telephone Number:	717-845-7511 (Product Information)
Ema	il address:	Prosthetics_MSDS@Dentsplysirona.com
1.4 Emergen	cy Telephone Number:	

Emergency Contact Telephone Number:

800-243-1942

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:				
Health	Environmental	Physical		
Eye Irritant Category 2 (H319) Reproductive Toxicity Category 1B (H360d)	Aquatic Acute Category 1 (H400)	Flammable Liquid Category 3 (H226)		

2.2 Label Elements:



Signal Word: Danger

Contains: Dibutyl Phthalate

Hazard Phrases	Precautionary Phrases
Hazard Phrases H226 Flammable Liquid and vapor. H319 Causes serious eye irritation. H360df May damage the unborn child. Suspected of damaging fertility. H400 Very toxic to aquatic life.	Precautionary PhrasesP201 Obtain special instructions before use.P202 Do not handle until all safety precautions have beenread and understoodP210 Keep away from heat, hot surfaces, sparks, openflames, and other ignition sources. No smoking.P233 Keep container tightly closed.P240 Ground and bond container and receiving equipmentP241 Use explosion-proof electrical, ventilating andlighting equipment.P242 Use only non-sparking tools.P243 Take precautionary measures against static discharge.P264 Wash thoroughly after handling.P280 Wear protective gloves, eye protection and faceprotection.P303 + P361 + P353 IF ON SKIN (or hair): Take offimmediately all contaminated clothing. Rinse skin withwater.P305 + P351 + P338 IF IN EYES: Rinse cautiously withwater for several minutes. Remove contact lenses, ifpresent and easy to do. Continue rinsing.P337 + P313 IF exposed or concerned: Get medicalattention.P370 + P378 In case of fire: Use carbon dioxide, alcoholfoam or dry chemical to extinguish.P273 Avoid release to the environment.P391 Collect spillageP403 + P235 Store in a well-ventilated place. Keep cool.P405 Store locked up.P501 Dispose of contents and container in accordance with

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS # / REACH Registration #	Classification	WT %
Dibutyl Phthalate	84-74-2	201-557-4 /	/ Repro. 1B, H360df, 60-90 Aquatic Acute 1, H400	

Ethyl Acetate	141-78-6	205-500-4 /	Flam. Liq., 2 H225, Eye Irrit. 2A, H319 STOT SE 3, H336	5-15
Ethanol (Ethyl Alcohol)	64-17-5	200-578-6 /	Flam. Liq. 2, H225	1-10

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	Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Wash skin thoroughly with soap and water. If rash, irritation or symptoms develop, get medical attention. Launder clothing before re-use. (Discard contaminated shoes).
Inhalation	Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get immediate medical attention.
Ingestion	Get medical attention. Call poison control center or go to a hospital emergency room. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious or convulsing person.

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

Causes eye irritation. May cause skin irritation. Inhalation of vapors or mist may cause respiratory irritation and central nervous system effects such as headache, dizziness, drowsiness, nausea and unconsciousness. Prolonged or repeated overexposure may cause anemia, kidney and liver damage. May cause adverse reproductive effects based on studies with laboratory animals.

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 carbon dioxide, alcohol foam or dry chemical.		
5.2 Special Hazards Arising from the Substance or Mixture:			
This product is flammable and forms explosive mixtures with air. Vapors are heavier than air and will travel along surfaces to remote ignition sources and flash back. Closed containers may explode if exposed to extreme heat.			
5.3 Advice for Fire-Fighters:			
Fire Fighting Procedures/Precautions for Fire Fighters:Use water to cool exposed containers and structures and disperse flammable vapors. Do not allow run-off from firefighting to enter drains or water courses. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus.			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Remove all sources of ignition. Ventilate area with explosion

proof equipment. Wear appropriate protective clothing as described in Section 8. Avoid contact with eyes, skin, and clothing. If spill has not ignited, use water spray to disperse the vapors and protect personnel attempting to stop leak.

6.2 Environmental Precautions:

Do not flush into sewer! Do not allow spills to enter sewers, waterways or the environment. Report releases as required by local, state and federal authorities.

6.3 Methods and Material for Containment and Cleaning up:

Eliminate all ignition sources. Contain and collect using inert absorbent materials and place in appropriate containers for disposal. Use non-sparking tools and equipment.

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 vapors. 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. Keep product away from heat, sparks, flames and all other sources of ignition. Do not permit smoking in use or storage areas. Use with non-sparking tools and explosion proof equipment. Electrically bond and ground containers for transfer.

Do not cut, drill, grind or weld on or near containers, even empty containers. Empty containers retain product residues can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in accordance with regulations for the storage of flammable liquids. Store in a dry, well-ventilated area away from heat, direct sunlight and all sources of ignition. Store away from oxidizers and other incompatible materials.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Ethanol	1000 ppm STEL ACGIH TLV 1000 ppm TWA OSHA PEL
	500 ppm TWA, 1000 ppm STEL DFG MAK
	1000 ppm TWA UK WEL
	Belgium: 1000 ppm TWA

Dibutyl Phthalate	5 mg/m ³ TWA ACGIH TLV 5 mg/m ³ TWA OSHA PEL	
	0.05 ppm TWA DFG MAK (Inhalable fraction and vapor) 0.1 ppm STEL DFG MAK (Inhalable fraction and vapor)	
	5 mg/m ³ TWA UK OEL 10 mg/m ³ STEL UK OEL	
Ethyl Acetate	400 ppm TWA ACGIH TLV 400 ppm TWA OSHA PEL	
	400 ppm TWA DFG MAK 800 ppm STEL DFG MAK	
	200 ppm TWA UK OEL 400 ppm STEL UK OEL	

Biological Exposure Limits:

None

8.2 Exposure Controls:

Appropriate Engineering Controls: Use ventilation that is adequate to keep employee exposure to airborne concentrations below exposure limits. Use explosion-proof equipment where required

Individual Protection Measures (PPE):

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

Specific Skin Protection: Wear impervious gloves such as 4HTM. Clothing with long sleeves may be needed when working with large quantities.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded 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

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Light colored liquid	Explosive limits:	LEL: 2.0% (as ethyl acetate) UEL: 19% (as ethyl alcohol)
Odor:	Slight odor	Vapor pressure (mmHg):	Not available
Odor threshold:	Not available	Vapor density:	9.6 @ 20°C
рН:	Not available	Relative density:	1.02
Melting/freezing point:	Not available	Solubility(ies):	Partially
Initial boiling point and boiling range:	171° F (77°C)	Partition coefficient: n- octanol/water:	Not available
Flash point:	74°F (23°C)	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available

Flammability (solid, gas):	Not applicable	Viscosity:	Not available
Explosive Properties:	Vapors may be explosive in confined areas.	Oxidizing Properties:	None

9.2 Other Information: None available.

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal conditions.

10.3 Possibility of Hazardous Reactions: None know.

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

10.5 Incompatible materials: Avoid oxidizing agents and inorganic acids.

10.6 Hazardous Decomposition Products: Decomposition may release carbon monoxide and carbon dioxide.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Contact may cause irritation with redness, tearing and stinging.

<u>Skin:</u> May cause skin irritation with redness and itching. Repeated or prolonged contact may cause drying, defatting of the skin and dermatitis.

<u>Ingestion:</u> Ingestion may cause mucous membrane and gastrointestinal irritation with nausea, vomiting and diarrhea. May cause nervous system depression with symptoms of headache, dizziness, nausea, vomiting, weakness, fatigue, confusion, and unconsciousness.

<u>Inhalation:</u> Inhalation of vapors may cause mucous membrane and respiratory irritation and central nervous system depression with symptoms of headache, dizziness, drowsiness, nausea, vomiting, and unconsciousness. High vapor concentrations may cause burning sensation of the nose and throat and watering of the eyes.

<u>Chronic Health Effects</u>: Repeated skin contact may cause dermatitis. Prolonged overexposure to ethyl acetate may cause anemia with leukocytes and damage to the kidney and liver.

Irritation: Ethanol: Not irritating to rabbit skin, Irritating to rabbit eyes.

<u>Corrosivity</u>: No data available. This product is not expected to be corrosive.

<u>Sensitization</u>: No data available. This product is not expected to cause sensitization. Dibutyl was not sensitizing in a guinea pig maximization test.

<u>Carcinogenicity</u>: Ethanol: Ingestion of alcoholic beverages is known to cause cancer in humans (IARC group 1). None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

<u>Mutagenicity</u>: Ethanol: Negative in AMES test, in-vivo rat cytogenetic assay. Positive in a sister chromatid and exchange CHO cells, human lymphocytes cytogenetic assay, in-vivo mouse cytogenetic assay and rat dominant lethal assay. Dibutyl was negative in an in vitro bacterial gene mutation assay.

Aspiration Hazard: Not an aspiration hazard.

Acute Toxicity Data:

Ethanol: LD50 oral rat 7060 mg/kg; LC50: inhalation rat 117-125 mg/L/4 hr.

Dibutyl Phthalate: LD50 oral rat 6279 mg/kg; LD50 skin rabbit 4200 mg/kg; LC50 inhalation mouse 15.68 mg/L/4 hr Ethyl Acetate: LD50 oral rat 5620 mg/kg; LC50 inhalation rat 200 gm/m3; LD50 skin rabbit > 20000 mg/kg

<u>Reproductive Toxicity Data:</u> Ethanol: Repeated ingestion of ethanol by pregnant mothers has been shown to adversely affect the central nervous system of the fetus, resulting in fetal alcohol syndrome. These effects include mental and physical retardation, disturbances of learning, motor and language deficiencies, behavioral disorders and small head size. Dibutyl phthalate has been shown to cause adverse reproductive effects and birth defects in studies with laboratory animals.

<u>Specific Target Organ Toxicity Single Exposure (STOT-SE)</u>: May cause nervous system depression with symptoms of headache, dizziness, nausea, vomiting, weakness, fatigue, confusion, and unconsciousness.

<u>Specific Target Organ Toxicity Repeated Exposure (STOT-RE:</u> Ethanol: Ethanol when consumed as a beverage has been found to cause damage to the liver, nervous system and reproductive system. Prolonged overexposure to ethyl acetate may cause damage to the kidney and liver.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Dibutyl Phtalate: LC50 Pimephales promelas (Fathead minnow) 0.92 mg/L/96 hr; EC50 daphnia magna 4.8 mg/L/48 hr; EC50 Pseudokirchnerella subcapitata 0.75 mg/L/ 96 hr

Ethanol: LC50 rainbow trout 13000 mg/L/96 hr; LC50 daphnia magna 9268-14221 mg/L/48 hr; EC50 Chlorella pyrenoidosa (Green algae; growth inhibition) 9310 mg/L/48 hr

Ethyl Acetate: LC50 Pimephales promelas (fathead minnow) 230 mg/l/96 hr.

12.2 Persistence and Degradability: Ethanol and dibutyl phthalate are readily biodegradable in screening tests.

12.3 Bio-accumulative Potential: Ethanol has an estimated BCF of 3. Ethyl acetate has an estimated BCF of 3.2.

12.4 Mobility in Soil: Dibutyl phthalate is expected to have a low mobility in soil. Ethyl acetate is expected to have high mobility in soil.

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 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	UN1993	Flammable Liquid n.o.s. (Ethanol, Ethyl Acetate)	3	III	No

ADR/RID	UN1993	Flammable Liquid n.o.s.	3	III	No
		(Ethanol, Ethyl Acetate)			
IMDG	UN1993	Flammable Liquid n.o.s.	3	III	No
		(Ethanol, Ethyl Acetate)			
IATA/ICAO	UN1993	Flammable Liquid n.o.s.	3	III	No
		(Ethanol, Ethyl Acetate)			

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 - product is transported only in packaged form.

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 has a Reportable Quantity (RQ) of 11 lbs. based on the RQ for Dibutyl Phthalete of 10 lbs. Releases above the RQ must be reported to the National Response Center. 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.

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, Chronic Health and Fire Hazard.

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

Components	C.A.S. #	WT %
Dibutyl Phthalate	84-74-2	60-90

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: Dibutyl Phthalate (60-90 %).

International Regulations

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: 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.

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 – 3 Physical Hazard–0 *Chronic health hazard. Full text of Classification abbreviations used in Section 2 and 3: Flam. Liq. 2 Flammable Liquid Category 2 Eye Irrit. 2A Eye Irritant Category 2A STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3 Repro 1B Toxic to Reproduction Category 1B Aquatic Acute 1 Aquatic Acute Toxicity Category 1 H225 Highly flammable liquid and vapor. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. H360df May damage the unborn child. Suspected of damaging fertility. H400 Very toxic to aquatic life.

Supersedes: 10 November 2016 Date Updated: 15 April 2019 Revision Summary: Changes to Sections 1 and 2.

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