Safety Data Sheet

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

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

1.1 Product Identifier:

Trade Name (as labeled):	**Hydro-Cast® Tissue Treatment, Liquid**
Part/Item Number:	73010, 73015, 73017

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

Recommended Use:	Impression material
Restrictions on Use:	For professional use only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	1301 Smile Way York, PA, USA
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)-
Email address:	customer.service@sultanhc.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)

2. HAZARD(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS SDS Classification:

Health	Environmental	Physical
Reproductive toxicity Category 1B	Hazardous to the aquatic environment, acute toxicity Category 1 Hazardous to the aquatic environment, chronic toxicity Category 1	Flammable liquids Category 2

EU Classification (1999/45/EC as amended): Highly Flammable (F), Toxic (T), Dangerous for the Environment (N)

EU Risk (R) Phrases: R11, R50/53, R61, R62

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

2.2 Labeling Elements: Contains Butyl Benzyl Phthalate, and Ethanol

Signal Word: Danger

Hazard Statements	Precautionary Statements
H225 Highly flammable liquid and vapour H360Df May damage the unborn child. Suspected of damaging fertility. H410 Very toxic to aquatic life with long lasting effects	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P210 Keep away from heat, sparks, open flames, and hot surfaces. - No smoking. P233 Keep container tightly closed. P240 Ground/Bond container and receiving equipment. P241 Use explosion-proof electrical, ventilating, lighting, and equipment. P242 Use only non-sparking tools. P243 Take precautionary measures against static discharge. P273 Avoid release to the environment. P280 Wear protective gloves, protective clothing, eye protection, or face protection. P303 + P361 + P353 IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water. P308 + P313 IF exposed or concerned: Get medical advice/attention. P370 + P378 In case of fire: Use water fog, dry chemical, carbon dioxide or alcohol-resistant foam for extinction. 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: EUH 066 Repeated exposure may cause skin dryness of cracking.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. # EC#	IUPAC Name	CLP/GHS / EU Classification (1272/2008) (1999/45/EC)	WT %
Butyl Benzyl Phthalate	85-68-7 / 201-622-7	benzyl butyl phthalate	T, N R61, R62, R50/53 Repr. 1B (H360Df) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	80-90
Ethanol	64-17-5 / 200-578-6	ethanol	F R11 Flam. Liq. 2 (H225)	10-20
Acetone	67-64-1 / 200-662-2	acetone	F, Xi R11, R36, R66, R67 Flam. Liq. 2 (H225) Eye Irrit. 2A (H319) STOT SE 3 (H336) (EUH066)	1-5

The exact concentration is being withheld as a trade secret.

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

4. FIRST-AID MEASURES

4.1 Description of First Aid Measures:

Routes of Exposure	First Aid Instructions
Eye	Flush eyes with water for 15 minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Wash skin with soap and water. Remove contaminated clothing and launder before reuse. Get medical attention if irritation develop or persists.
Inhalation	If irritation develops, move to fresh air. Get medical attention if irritation persists.
Ingestion	If swallowed, wash mouth with water. Never give anything my mouth to an unconscious person. Get medical attention.

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

May cause eye and skin irritation. Inhalation of mists or aerosols may cause irritation. Swallowing may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Butyl benzyl phthalate has been shown to cause reproductive effects and birth defects in laboratory animals.

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

None expected under normal conditions of use.

Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media	
Use water fog, dry chemical, carbon dioxide or alcohol-resistant foam.	
5.2 Special Hazards Arising from the Substance or Mixture:	
Flammable liquid and vapors. Vapors may travel to a remote ignition source and flashback.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures:	Cool fire exposed containers and structures with water.
Precautions for Fire Fighters:	Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

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

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:			
For large spills, wear eye protection and gloves. Small spills do not require special precautions. Eliminate all ignition sources and ventilate the area.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**SKIN**	**RESPIRATORY**	**THERMAL**
			

6.2 Environmental Precautions:
Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities. This product is very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

6.3 Methods and Material for Containment and Cleaning up:
Ventilate area and remove ignition sources. Collect using an inert non-combustible absorbent material and place in appropriate containers 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 Handing:

Avoid contact with eyes, skin and clothing. Use in accordance with package instructions. Keep product away from heat and sources of ignition.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, well-ventilated area away from excessive heat and ignition sources.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Butyl Benzyl Phthalate	United States	None Established
	Germany	None Established
	United Kingdom	5 mg/m3 TWA UK OEL
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Ethanol	United States	1000 ppm OSHA PEL 1000 ppm ACGIH TLV STEL
	Germany	500 ppm TWA DFG MAK
	United Kingdom	1000 ppm UK OEL
	France	1000 ppm INRS VME, 5000 ppm VLCT
	Spain	1000 ppm TWA VLA-ED
	Italy	None Established
	European Union	None Established

Acetone	United States	1000 ppm OSHA PEL 500 ppm TWA ACGIH TLV, 750 ppm STEL
	Germany	500 ppm TWA DFG MAK, 1000 STEL
	United Kingdom	500 ppm UK OEL
	France	500 ppm INRS VME, 1000 ppm VLCT
	Spain	500 ppm TWA VLA-ED
	Italy	None Established
	European Union	None Established

Biological Exposure Limits: Acetone in urine. End of shift. 50mg/L

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate local or general ventilation to minimize exposure concentrations.

Individual Protection Measures (PPE)

Specific Eye/face Protection: Avoid eye contact. Safety glasses should be worn if contact is likely.
Specific Skin Protection: Wear impervious gloves such as nitrile rubber. Recommended glove: Nitrile rubber. Contact glove supplier for thickness and breakthrough times.
Specific Respiratory Protection: None required under normal use conditions.
Specific Thermal Hazards: Not applicable.

Recommended Personal Protective Equipment

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Colorless, viscous liquid	**Explosive limits:**	LEL: 2.5% (acetone) UEL: 19% (ethanol)
Odor:	Slight Alcohol	**Vapor pressure:**	Not available
Odor threshold:	0.136 (ethanol)	**Vapor density:**	>1
pH:	Not available	**Relative density:**	Not available
Melting/freezing point:	Not available	**Solubility:**	Partially miscible
Initial boiling point and range:	74-153°F / 23.3-67.2°C	**Partition coefficient: n-octanol/water:**	Not available

Flash point:	56.3°F / 13.5°C	**Auto-ignition temperature:**	Not available
Evaporation rate:	>1	**Decomposition temperature:**	Not available
Flammability:	Flammable	**Viscosity:**	Not available
Explosive Properties:	None	**Oxidizing Properties:**	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Not reactive

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: Contact with excessive heat, sparks and flame may cause fire.

10.4 Conditions to Avoid: Avoid contact with excessive heat, sparks and ignition sources.

10.5 Incompatible materials: Avoid oxidizing agents, acids and nitrates.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon oxides.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: May cause irritation with redness, stinging and tearing.

Skin: Prolonged skin contact may cause mild irritation.

Ingestion: Swallowing may cause nausea, vomiting and diarrhea and central nervous system depression.

Inhalation: Inhalation of vapors may cause respiratory irritation, coughing, shortness of breath, nausea, dizziness, drowsiness, unconsciousness and other central nervous system effects.

Chronic Health Effects: Prolonged overexposure to ethanol may cause liver damage. Prolonged over exposure to butyl benzyl phthalate may damage to the kidneys, liver, spleen and central nervous system.

Carcinogenicity: None of the other components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives. Ethanol: In a skin painting study with mice, a 50% solution was placed on the skin three times a day for 829 days. No skin tumors were observed. Butyl Benzyl Phthalates: In a 103 week study, rats and mice were exposure to 6,000 or 12,000 ppm of the butyl benzyl phthalate. No treatment-related neoplasms were observed in mice. The female rats

showed an increase incidence of mononuclear cell leukemias. The significance of these finding to humans are not known.

Mutagenicity: Butyl Benzyl Phthalate: Negative in AMES test. There were negative and equivocal responses in the mouse lymphoma assay and sister chromatid exchanges (SCE) in Chinese hamster ovary cells. 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.

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

Acute Toxicity Data:
Butyl Benzyl Phthalate: Oral Rat LD50 2,000 mg/kg, Skin rabbit LD50 >10,000 mg/kg
Ethanol: Oral Rat LD50 7,060 mg/kg, Inhalation Rat LC50 20,000 ppm/ 10 hr
Acetone: Oral rat LD50 5,800 mg/kg,, Inhalation Rat LC50 76 mg/L/4, Skin Rabbit 20 mg/kg

Reproductive Toxicity Data: Butyl Benzyl Phthalate: In a human epidemiology study, subjects exposed to the butyl benzyl phthalate have been shown to have reduced sperm rates and mobility. In a reproductive study with animals, rats were administered 0-1,640 mg/kg/day. Reduced body weight gain, liver effects, kidney effects and increased water consumption were observed in maternal animals. Fetal toxicity was observed at the highest dose level. NOAEL for maternal and developmental toxicity was 420 mg/kg/day. In another study, Butyl benzyl phthalate was applied to the skin of rats at 0-5-4.0 mL/kg. No reproductive effects were observed. When applied at 4 mL/kg, sperm mobility was affected.

Specific Target Organ Toxicity (STOT):

Single Exposure: Butyl Benzyl Phthalate: Not irritating to rabbit skin. Mildly irritating to rabbit eye. Acetone: In a three week study with guinea pigs, a 50% solution was placed on the skin dermally three times a week. Cataracts developed by the third month post-treatment.

Repeated Exposure: Ethanol: No adverse effects were observed in a 90 day inhalation study with rats at an exposure of 86 mg/m3. Liver damage was observed in an 85 day study with rats at a dose of 80 ml/kg/day. Butyl Benzyl Phthalate: In an oral study, Butyl benzyl phthalate was administered orally to rat in does of 188 to 1,500 mg/kg/day. Increases in liver weight were observed at 750 mg/kg/day in females and at 1,125 mg/kg/day in males. Kidney weight increased at 750 mg/kg/day and higher in males. A NOAEL of 375 mg/kg/day was established based on liver and kidney effects at 750 mg/kg/day.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:
Butyl Benzyl Phthalate:: 48 hr EC50 daphnia magna >760 ug/L
Ethanol: 96 hr LC50 fathead minnow 4,200 mg/L, 48 hr EC50 daphnia magna
Acetone: 96 hr LC50 Oncorhynchus mykiss/ (Rainbow trout) 5,540 mg/L, 48 hr EC50 daphnia magna 10 mg/L

12.2 Persistence and Degradability : Butyl benzyl phthalate is readily biodegradable (87% after 28 days). Ethanol: Readily biodegradable (84% after 20 days). Acetone: Readily Biodegradable (84% in 20 days).

12.3 Bio-accumulative Potential: Ethanol, butyl benzyl phthalate and acetone are expected to have a low potential to bioaccumulation.

12.4 Mobility in Soil: Acetone and ethanol are expected to have very high mobility in soil. Butyl benzyl phthalate is expected to have a low mobility in soil.

12.5 Other Adverse Effects: No adverse effects are expected.

12.6 Results of PBT/vPvB Assessment: Not required

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:
Regulations: Dispose in accordance with local and national environmental regulations.
Properties (Physical/Chemical) Affecting Disposal: None known.
Waste Treatment Recommendations: None needed

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, Acetone)	3	PG II	No
ADR/RID	UN1993	Flammable Liquid, n.o.s. (Ethanol, Acetone)	3	PG II	Yes
IMDG	UN1993	Flammable Liquid, n.o.s. (Ethanol, Acetone)	3	PG II	Marine Pollutant- Yes
IATA/ICAO	UN1993	Flammable Liquid, n.o.s. (Ethanol, Acetone)	3	PG II	Yes

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 111 lbs. based on the RQ for butyl benzyl phthalate of 100 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 requirements.

Clean Water Act (CWA): Butyl Benzyl Phthalate 80-90%

Clean Air Act (CAA): Not Listed

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 %
None		

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
Butyl Benzyl Phthalate	85-68-7	80-90%

International Regulations

EU REACH: The substances in this product comply with the EU REACH regulation as applicable.

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:
F Highly Flammable
N Dangerous for the Environment
T Toxic
Xi Irritant
R11 Highly Flammable
R36 Irritating to eyes.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
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.

CLP/GHS Classification and H Phrases for Reference (See Section 3)
Aquatic Acute 1 Hazardous to the aquatic environment, acute toxicity Category 1
Aquatic Chronic 1 Hazardous to the aquatic environment, chronic toxicity Category 1
Eye Irrit. 2A Serious eye irritation Category 2A
Flam. Liq. 2 Flammable liquids Category 2
Repr. 1B Reproductive toxicity Category 1B
STOT SE 3 Specific target organ toxicity - single exposure Category 3
H225 Highly flammable liquid and vapour.
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
H410 Very toxic to aquatic life with long lasting effects

Benzyl Butyl Phthalate is on the Candidate List of Substances of Very High Concern for Authorization.

Supersedes: 19 November 2012

Revision Summary: Comprehensive review, new format.
Date of SDS Preparation/Revision: 5 August, 2014

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