3401 Grays Ferry Avenue, Building 176, Philadelphia PA 19146
Website: www.allevi3D.com
Email: info@allevi3D.com

Safety Data Sheet

1. Identification

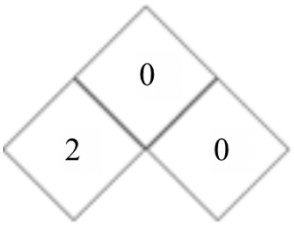
Product Name	Hyperelastic Bone™
Substance/Mixture	Mixture – methylene chloride, hydroxyapatite, 2-butoxyethanol, dibutyl phthalate
Company:	Allevi, Inc. and Dimension Inx
Address	3401 Grays Ferry Avenue, Building 176, Philadelphia PA 19146
Telephone	215-588-8937
Email	info@allevi3D.com

2. Hazards Identification

Classification of the substance or mixture		
Physical Hazards	Skin irritation, eye irritation, may cause respiratory irritation, may cause drowsiness or dizziness.	
Health Hazards	Suspected of causing cancer, may damage fertility or the unborn child, may cause damage to organs (liver, blood) through prolonged or repeated exposure if swallowed, may cause damage to organs (central nervous system) through prolonged or repeated exposure if swallowed.	
Environmental Hazards	Toxic to aquatic life.	
Label Elements, including precautionary statements		
Pictograms or hazard symbols		
Signal word	Danger	
Hazard Statements	H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H336 May cause drowsiness or dizziness. H351 Suspected of causing cancer. H360 May damage fertility or the unborn child. H373 May cause damage to organs (Liver,	

	Blood) through prolonged or repeated exposure if swallowed. H373 May cause damage to organs (Central nervous system) through prolonged or repeated exposure if inhaled. H401 Toxic to aquatic life.	
Precautionary statements	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray. P264 Wash skin thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313 IF exposed or concerned: Get medical advice/ attention. P332 + P313 If skin irritation occurs: Get medical advice/ attention. P337 + P313 If eye irritation persists: Get medical advice/ attention. P362 Take off contaminated clothing and wash before reuse. P403 + P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up. P501 Dispose of contents/ container to an approved waste disposal plant.	

NFPA ratings (scale 0-4):



Health = 2

Fire = 0

Reactivity = 0

HMIS-Ratings (scale 0 -4):

Health	2	Health = 2
Fire	0	Fire = 0
Reactivity	0	Reactivity = 0

Other Hazards not otherwise classified (HNOC) or not covered by GHS - none

Results of PBT and vPvB assessment:
PBT: Not required/not conducted
vPvB: Not required/not conducted

3. Composition/Information on Ingredients

Product Name	Methylene chloride	
Substance/Mixture	Substance	
Chemical composition	Methylene chloride	≥ 50% ≤ 70%
Chemical Formula	CH_2Cl_2	
Mean Molecular Weight	84.93	
CAS Number	75-09-2	
Notice through Official Gazettes Reference Numbers		
ENCS	200-838-9	
Index-No.	602-004-00-3	

Product Name	Hydroxyapatite
Substance/Mixture	Substance
Chemical formula	$HCa_5O_{13}P_3$
Mean molecular weight	502.31
CAS Number	12167-74-7

EC-No.	235-330-6

Product Name	2-Butoxyethanol	
Substance/Mixture	Substance	
Chemical composition	2-Butoxyethanol	≥ 10% ≤ 20%
Chemical Formula	$CH_3(CH_2)_3OCH_2CH_2OH$	
Mean Molecular Weight	118.17	
CAS Number	111-76-2	
Notice through Official Gazettes Reference Numbers		
ENCS	203-905-0	
Index-No.	603-014-00-0	

Product Name	Dibutyl phthalate	
Substance/Mixture	Substance	
Chemical composition	Dibutyl phthalate	≥ 5% ≤ 10%
Chemical Formula	C_6H_4-1,2-$[CO_2(CH_2)_3CH_3]_2$	
Mean Molecular Weight	278.34	
CAS Number	84-74-2	
Notice through Official Gazettes Reference Numbers		
ENCS	201-557-4	
Index-No.	607-318-00-4	
Registration number	01-2119493042-44-XXXX	

Dibutyl phthalate is included in the Candidate List of Substances of Very High Concern (SVHC) according to Regulation (EC) No. 1907/2006 (REACH)

4. First Aid Measure

After Inhalation:	Move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
After Skin Contact:	Wash off with soap and plenty of water. Consult a physician.
After Eye Contact:	Rinse thoroughly with plenty of water for at least 15 minutes. Consult a physician.
Ingestion	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Most important symptoms and effects, both acute and delayed	The most important known symptoms and effects are described in section 12.

Indication of any immediate medical attention and special treatment needed	No further relevant information available.

5. Fire-fighting Measures

Suitable Extinguishing Media:	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Specific hazards arising from the chemical:	Oxides of phosphorous, calcium oxide
Precautions for Firefighters:	Wear self-contained breathing apparatus for firefighting if necessary.
Further information:	No data available.

6. Accidental Release Measures

Personal Precautions, Protective equipment and emergency procedures	Use personal protective equipment. Avoid breathing vapors, mist or gas. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation. Evacuate personnel to safe areas. For personal protection see section 8.
Environmental Precautions:	Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.
Methods and materials for containment and cleaning up:	Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.
Reference to other sections:	For disposal see section 13.

7. Handling and Storage

Precautions for Safe Handling	
Technical Measures:	Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. For precautions see section 2.
Conditions for safe storage, including any incompatibilities	
Storage Conditions:	Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Recommended storage temperature: 2 – 8 ˚C Air -, heat-, and moisture-sensitive. Do not freeze.
Specific end use(s)	No further relevant information available.

8. Exposure Controls/Personal Protection

Component	CAS-No.	Value	Control Parameters	Basis
Methylene chloride	75-09-2	TWA	50.000000 ppm	USA. ACGIH Threshold Limit Values (TLV)
		Central nervous system impairment Carboxyhemoglobinemia Substances for which there is a Biological Exposure Index or Indices Confirmed animal carcinogen with unknown relevance to humans		

		TWA	50 ppm	USA. ACGIH Threshold Limit Values (TLV)
		Central nervous system impairment Carboxyhemoglobinemia Substances for which there is a Biological Exposure Index or Indices Confirmed animal carcinogen with unknown relevance to humans		
		Substance listed; for more information see OSHA document 1910.1052		
		Substance listed; for more information see OSHA document 1910.1052		
		See Table Z-2		
		PEL	25.000000 ppm	OSHA Specifically Regulated Chemicals/Carcinogens
		1910.1052 This section applies to all occupational exposures to methylene chloride (MC), Chemical Abstracts Service Registry Number 75-09-2, in general industry, construction and shipyard employment. Methylene chloride (MC) means an organic compound with chemical formula, CH2CL2. Its Chemical Abstracts Service Registry Number is 75-09-2. Its molecular weight is 84.9 g/mole. OSHA specifically regulated carcinogen.		
		STEL	125.000000 ppm	OSHA Specifically Regulated Chemicals/Carcinogens
		1910.1052 This section applies to all occupational exposures to methylene chloride (MC), Chemical Abstracts Service Registry Number 75-09-2, in general industry, construction and shipyard employment. Methylene chloride (MC) means an organic compound with chemical formula, CH2CL2. Its Chemical Abstracts Service Registry Number is 75-09-2. Its molecular weight is 84.9 g/mole. OSHA specifically regulated carcinogen.		
		PEL	25 ppm 87 mg/m3	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
		STEL	125 ppm 435 mg/m3	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
2-Butoxyethanol	111-76-2	TWA	20.000000 ppm	USA. ACGIH Threshold Limit Values (TLV)
		Upper Respiratory Tract Irritation Eye irritation Substances for which there is a Biological Exposure Index or Indices Confirmed animal carcinogen with unknown relevance to humans		
		TWA	5.000000 ppm 24.000000 mg/m3	USA. NIOSH Recommended Exposure Limits
		Potential for dermal absorption		
		TWA	50.000000 ppm 240.000000 mg/m3	USA. Occupational Exposure Limits (OSHA)

				– Table Z-1 Limits for Air Contaminants
		Skin designation The value in mg/m3 is approximate.		
		PEL	20 ppm 97 mg/m3	USA. ACGIH Threshold Limit Values (TLV)
		Skin		
Dibutyl phthalate	84-74-2	TWA	5.000000 mg/m3	USA. ACGIH Threshold Limit Values (TLV)
		Upper Respiratory Tract Irritation Eye irritation Testicular damage		
		TWA	5 mg/m3	USA. ACGIH Threshold Limit Values (TLV)
		Upper Respiratory Tract Irritation Eye irritation Testicular damage		
		TWA	5.000000 mg/m3	USA. Occupational Exposure Limits (OSHA) – Table Z-1 Limits for Air Contaminants
		TWA	5.000000 mg/m3	USA. NIOSH Recommended Exposure Limits
		PEL	5 mg/m3	California permissible exposure limits for chemical contaminants (Title 8, Article 107)

Personal protective equipment	
Eye/face protection:	Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. For precautions see section 2.
Skin protection:	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
Body protection:	Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection:	Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type AXBEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Control of environmental exposure:	Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

9. Physical and Chemical Properties

Appearance	Form: liquid
Odor	Stench.
Odor Threshold	No data available
pH	No data available
Melting point/freezing	No data available
Initial boiling point and boiling range	39˚C (102˚F)
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limits	No data available
Vapor pressure	No data available
Vapor density	1.5 – 1.8 g/cm3 at 25˚C (77˚F)
Relative density	No data available
Water solubility	No data available
Partition coefficient: n-octanol/water	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

10. Stability and Reactivity

Reactivity	No data available
Chemical Stability	Stable under recommended storage conditions
Possibility of hazardous reactions	No data available
Conditions to avoid	No data available
Incompatible materials	Strong oxidizing agents
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions. – Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride gas Other decomposition products – No data available In the event of fire: see section 5

11. Toxicological Information

Acute toxicity:	LD50 Oral – rat – male and female - > 5000 mg/kg Inhalation: no data available LD50 Dermal – rabbit – male and female - > 2000 mg/kg
Skin corrosion/irritation:	Skin – rabbit Result: No skin irritation – 4h (OECD Test Guideline 404)
Serious eye damage/irritation:	Eyes – rabbit Result: No eye irritation
Respiratory or skin sensitization:	No data available
Germ cell mutagenicity:	Mouse Lymphocyte Result: negative
Carcinogenicity:	IARC: No component of this product present at levels greater than of equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. OSHA: OSHA specifically regulated carcinogen (Methylene chloride)
Reproductive toxicity:	No data available
Specific target organ toxicity – single exposure:	No data available
Specific target organ toxicity – repeated exposure:	No data available
Aspiration hazard:	No data available
Additional Information:	RTECS: Not available To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Stomach – Irregularities – Based on Human Evidence Stomach – Irregularities – Based on Human Evidence (Methylene chloride) Stomach – Irregularities – Based on Human Evidence (2-Butoxyethanol) Central nervous system – (Dibutyl phthalate)

12. Ecological Information

Toxicity	No data available
Persistence/degradability:	No data available
Bioaccumulative Potential:	No data available
Mobility in Soil	No data available
Results of PBT and vBvB assessment	PBT/vPvB assessment was not available as chemical safety assessment not required/not conducted
Other adverse effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Toxic to aquatic life.

13. Disposal Considerations

Waste Treatment methods	Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed

	professional waste dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.
Uncleaned packaging	Dispose of as unused product.

14. Transport Information

DOT (US)	UN number: 1593 Class: 6.1 Packing group: III Proper shipping name: dichloromethane, solution Reportable Quantity (RQ): 200 lbs Poison inhalation hazard: no
IMDG	UN number: 1593 Class: 6.1 Packing group: III EMS-No: F-A, S-A Proper shipping name: DICHLOROMETHANE, SOLUTION
IATA	UN number: 1593 Class: 6.1 Packing group: III Proper shipping name: dichloromethane, solution

15. Regulatory information

SARA 302 Components	No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 Components	The following components are subject to reporting levels established by SARA Title III, Section 313: Methylene chloride CAS-No. 75-09-2 Revision date 2007-07-01 Dibutyl phthalate CAS-No. 84-74-2 Revision date 2007-07-01 2-Butoxyethanol CAS-No. 111-76-2 Revision date 1993-04-24
Section 311/312:	Acute Health Hazard, Chronic Health Hazard
Massachusetts Right to Know Components	Methylene chloride CAS-No. 75-09-2 Revision date 2007-07-01 Dibutyl phthalate CAS-No. 84-74-2 Revision date 2007-07-01 2-Butoxyethanol CAS-No. 111-76-2 Revision date 1993-04-24
Pennsylvania Right to Know Components	Methylene chloride CAS-No. 75-09-2 Revision date 2007-07-01

	Dibutyl phthalate CAS-No. 84-74-2 Revision date 2007-07-01 2-Butoxyethanol CAS-No. 111-76-2 Revision date 1993-04-24 Pentacalcium hydroxide tris(orthophosphate) CAS-No. 12167-74-7 MAXPRENE MX2, PLGA, PLA-co-PGA CAS-No. 30846-39-0
New Jersey Right to Know Components	Methylene chloride CAS-No. 75-09-2 Revision date 2007-07-01 Dibutyl phthalate CAS-No. 84-74-2 Revision date 2007-07-01 2-Butoxyethanol CAS-No. 111-76-2 Revision date 1993-04-24 Pentacalcium hydroxide tris(orthophosphate) CAS-No. 12167-74-7 MAXPRENE MX2, PLGA, PLA-co-PGA CAS-No. 30846-39-0
California Prop. 65 Components	WARNING! This product contains a chemical known to the State of California to cause cancer. Methylene chloride CAS-No. 75-09-2 Revision date 2007-09-28 WARNING! This product contains a chemical known to the State of California to cause birth defects or other reproductive harm. Dibutyl phthalate CAS-No. 84-74-2 Revision date 2008-06-17

16. Other Information

This information is based on our present knowledge. Prior to use, please investigate not only the hazards and toxicity information but also the laws and regulations of the organization, area and country where the products are to be used, which shall be given the first priority. The products are supposed to be used promptly after purchase in consideration of safety. Some new information or amendments may be added afterwards. If the products are to be used far behind the expected time of use or you have any questions, please feel free to contact us. The stated cautions are for normal handling only. In case of special handling, sufficient care should be taken, in addition to the safety measures suitable for the situation. All chemical products should be treated with the recognition of "having unknown hazards and toxicity", which differ greatly depending on the conditions and handling when in use and/or the conditions and duration of storage. The products must be handled only by those who are familiar with specialized knowledge and have experience or under the guidance of those specialists throughout use from opening to storage and disposal. Safe usage conditions shall be set up on each user's own responsibility. Allevi, Inc. and its affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. This document and information shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.