



**PALS® Clinical Electrode with DermaFlow Hydrogel
Safety Data Sheet According to (EC) No 1907/2006
(Global Harmonised System – GHS)**

1	<p>Identification of Substance/Preparation</p> <p>Company Identification</p> <p>Emergency Telephone</p>	<p>Name: DermaFlow® Hydrogel Brands: PALS® Clinical Intended Use: Stimulation Hydrogel</p> <p>Axelgaard Manufacturing Co., Ltd. 520 Industrial Way Fallbrook, CA 92028-2244 USA</p> <p>Telephone: +1 (760) 451-8000 E-mail: support@axelgaard.com Website: www.axelgaard.com</p> <p>+1 (760) 451-8000 Office Hours Only: Monday – Thursday 7:00 am – 5:30 pm PST</p>										
2	<p>Hazards Identification</p>	<p>Main Hazards: Not classified as hazardous.</p> <p>Routes of Entry: Skin contact.</p> <p>Carcinogenic Status: Not considered a carcinogen under OSHA, ACGIH, NTP, or IARC guidelines.</p> <p>Target Organs: None.</p> <p>Health Effects – Eyes: Avoid eye contact.</p> <p>Health Effects – Skin: No adverse effects are expected.</p> <p>Health Effects – Ingestion: Not an expected route of entry during normal handling and use, do not ingest.</p> <p>Health Effects – Inhalation: No adverse effects expected during normal handling and use.</p>										
3	<p>Composition / Information on Ingredients</p>	<table border="0"> <thead> <tr> <th>Component</th> <th>CAS-No.</th> </tr> </thead> <tbody> <tr> <td>Glycerin, non-tallow</td> <td>56-81-5</td> </tr> <tr> <td>Water</td> <td>7732-18-5</td> </tr> <tr> <td>Poly(acrylate) Co-polymer</td> <td>40623-75-4</td> </tr> <tr> <td>Propylene Glycol</td> <td>57-55-6</td> </tr> </tbody> </table> <p>Trade Secret: The exact percentage (concentration) of composition has been withheld as a trade secret.</p>	Component	CAS-No.	Glycerin, non-tallow	56-81-5	Water	7732-18-5	Poly(acrylate) Co-polymer	40623-75-4	Propylene Glycol	57-55-6
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4	First Aid Measures	<p>Skin: If a skin irritation develops, discontinue use. Obtain medical treatment as needed.</p> <p>Eyes: If eye contact occurs, flush with water for fifteen minutes. Obtain medical attention if soreness or redness persists.</p> <p>Inhalation: Seek medical attention if symptoms occur.</p> <p>Ingestion: If ingestion occurs, see a physician.</p> <p>Advice to Physicians: Treat symptomatically.</p>
5	Fire Fighting Measures	<p>Extinguishing media: Water spray, carbon dioxide, dry chemical or appropriate foam.</p> <p>Special fire fighting procedures: Wear self-contained breathing apparatus.</p> <p>Unusual fire and explosion hazards: May release hazardous vapors during a fire.</p>
6	Accidental Release Measures	No specific measures necessary.
7	Handling and Storage	<p>Keep tightly closed to prevent evaporation of water.</p> <p>Store in cool, dry place.</p> <p>Keep away from heat.</p>
8	<p>Exposure Controls</p> <p>Personal Protection</p> <p>Environmental Exposure Controls</p>	<p>No exposure controls required</p> <p>Respiratory protection: None required.</p> <p>Hand protection: None required under normal use.</p> <p>Eye protection: Use safety glasses.</p> <p>Skin protection: Normal work wear.</p> <p>No environmental exposure controls required.</p>



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9	<p>Physical and Chemical Properties</p> <p>Important Health, Safety and Environmental Information</p>	<p>The hydrogel is a blue viscoelastic gel on a PET (polyethylene terephthalate) liner.</p> <p>Color: Blue Odor: Slight pH: 3.5 (+/- 0.5) Boiling Point/Range: Not applicable Flash Point: Not applicable Flammability: Not applicable Explosion Properties: Not applicable Oxidizing Properties: Not applicable Vapor Pressure: Not applicable Relative Density: Not applicable Solubility: Not applicable Solubility in Water: Not applicable Partition coefficient: n-octanol/water: Not applicable Viscosity: Not applicable Vapor Density: Not applicable Evaporation Rate: Not applicable</p>
10	Stability and Reactivity	<p>Stability: Stable under normal conditions. Conditions to Avoid: Heat – High temperatures. Materials to Avoid: None known. Hazardous Polymerization: Will not occur. Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, oxides of nitrogen, and oxides of sulfur.</p>
11	Toxicological Information	<p>AG2500 series hydrogel has passed ISO 10993-1 requirements for skin contact. It demonstrated no cytotoxicity, no irritation, and no sensitization upon skin contact.</p> <p>Acute Toxicity: Low order of acute toxicity. Chronic Toxicity/ Carcinogenicity: Not expected to cause long term adverse health effects. Genotoxicity: Not expected to cause any mutagenic effects. Reproductive / Development Toxicity: Not expected to cause adverse reproductive effects.</p>

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12	Ecological Information	<p>Ecotoxicity</p> <p>Aquatic Toxicity: No relevant studies identified. Soil Toxicity: No relevant studies identified. Micro-Macro Organisms Toxicity: No relevant studies identified.</p> <p>Sewage Treatment Plant Impact: No relevant studies identified. Mobility: No relevant studies identified.</p> <p>Persistence and Degradability: No relevant studies identified. Bioaccumulative Potential: No relevant studies identified.</p> <p>Mobility: No relevant studies identified.</p> <p>Persistence and Degradability: No relevant studies identified. Bio-Accumulation: No relevant studies identified.</p> <p>CSA Report: Not applicable.</p>
13	Disposal Considerations	Dispose of in accordance with all applicable local and national regulations.
14	Transport Information	<p>DOT CFR 172.101: Not regulated. UN Shipping Name: Not regulated. UN Class: None. UN Number: None. UN Packaging Group: None.</p> <p>Consult the appropriate national/local regulators for transport by: IMDG (sea) ADR (road) RID (rail) ICAO/IATA (air)</p>



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15	Regulatory Information	<p>EU Label Information</p> <p>Directive 67/548/EEC: Classification and labeling have been performed per directive; not applicable.</p> <p>Directive 1999/44/EC: Classification and labeling have been performed per directive; not applicable.</p> <p>EC Annex I Classification: This product is not classified.</p> <p>R Phrases: None.</p> <p>S Phrases: None.</p> <p>US Regulations (Federal, State) and International Chemical Registration Laws</p> <p>Chemical Safety Assessment (CSA-EU) is not required for hydrogel.</p> <p>EINECS Listing: All ingredients in this product have not been verified for listing on the European Inventory of Existing Commercial Chemical Substances (EINECS). This product is considered an article.</p> <p>Canadian Workplace Hazardous Materials Information System (WHMIS): This product is not listed.</p> <p>OSHA or EPA regulations: This product is not considered hazardous.</p> <p>California Proposition 65: This product does not contain any materials which the State of California has found to cause cancer, birth defects or other reproductive harm.</p> <p>TSCA Listing: This product contains ingredients that are listed on or exempt from listing on the EPA Toxic Substance Control Act Chemical Inventory. This product is considered an article.</p> <p>NFPA Rating: Health: 1 Fire: 0 Reactivity: 0</p>
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16	Other Information	<p>Prepared by: Axelgaard Manufacturing Co., Ltd. Regulatory Affairs Department Prepared on: November 16, 2022</p> <p>The above information is believed to be correct, but does not purport to be all-inclusive and shall be used only as a guide. Axelgaard Manufacturing Company, Ltd. shall not be held liable for any damage resulting from the handling of or contact with the above product. License granted to make unlimited paper copies of this SDS for internal use only.</p>
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