

## ELECTRO-CAP INTERNATIONAL INC.

1011 WEST LEXINGTON ROAD

EATON, OHIO 45320

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Toll Free: 800-527-2193

[www.electro-cap.com](http://www.electro-cap.com)

### Safety Data Sheet

(according to European Directive 2017/745 and OSHA 29CFR 1910.1200)

### for Electro-Gel (EEG Electrode Gel)

Revised June 26, 2024

Supersedes February 1, 2016

#### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

- 1.1. Identification of the Substance/Preparation: Electro-Gel
- 1.2. Use of Substance/Preparation: Electro-Gel serves as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.
- 1.3. Company Identification:

1.4.



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| EC | REP |
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Starrenhoflaan 44/0017  
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Tel +32 (0)3 605 74 00

- 1.5. Emergency Telephone: +1 800 527 2193  
Available during normal business hours only:  
Monday – Friday: 8:00 – 16:30 Eastern Standard Time

#### 2. HAZARD IDENTIFICATION

- 2.1 Health hazards beyond those associated with drying and chapping of skin or minor sensitivity have not been demonstrated, however, Electro-Gel should be used cautiously on patients with a history of skin allergies. Electro-Gel is to be used as a conductive gel between the electrodes and healthy intact skin only. The use of Electro-Gel as a conductor between the scalp and the electrodes, in conjunction with typical procedures used during neurodiagnostic procedures, carries a slight risk for infection at the electrode site, if the skin is damaged during the procedure.

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- 2.2 This preparation is not classified as dangerous according to Directive 2017/745 or OSHA 29CFR 1910.1200.

### **3. COMPOSITION/INFORMATION ON INGREDIENTS**

- 3.1. Electro-Gel is a mixture of the following components: Water, Sodium Chloride, Aragum T-1998 (Gum Acacia, Guar Gum, and Xanthan Gum), Potassium Bitartrate (Cream of Tartar), Glycerin, Methylparaben and Propylparaben.

### **4. FIRST AID MEASURES**

- 4.1. Eye Contact: Rinse eyes thoroughly with warm water for 10 to 15 minutes. Avoid rubbing the eyes. If eye irritation continues, contact a physician immediately.
- 4.2. Ingestion: Electro-Gel is non-toxic; however ingestion could result in nausea, vomiting and/or diarrhea.
- 4.3. Skin Irritation: Any persistent redness, soreness, burning, itching, or swelling of the skin should be reported immediately to a physician.

### **5. FIRE-FIGHTING MEASURES**

- 5.1. Electro-Gel is a nonflammable gel.

### **6. ACCIDENTAL RELEASE MEASURES**

- 6.1. No special measures are required.

### **7. HANDLING AND STORAGE**

- 7.1. Handling: No special handling is required. Wipe up any spilled material and dispose of appropriately according to local regulations.
- 7.2. Storage: Keep container tightly closed when not in use. Store at room temperature. Keep out of the reach of children.

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- 7.3. Specific Uses: Use gel for the purposes intended in accordance with printed instructions for use. Electro-Gel is applied by inserting the gel into the electrodes by using a syringe and 16g blunted needle. Wash from hands after applying to patient. Routine clean up with tap water. Local exhaust is not required with normal use.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1. Exposure Limit Values: Not applicable.
- 8.2. Exposure Controls: None required.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

- 9.1. General Information  
Physical State..... Gel  
Color..... Off white.  
Odor ..... Basically Odorless
- 9.2. Important Health, Safety, and Environmental Information  
pH..... Approximately 4.5  
Viscosity ..... Approximately 350 cps  
Water Solubility ..... Partial
- 9.3. Other Information  
None available

### 10. STABILITY AND REACTIVITY

General Information: Electro-Gel is stable and non-reactive under normal conditions.  
Hazardous polymerization will not occur.

- 10.1. Conditions to Avoid: None known
- 10.2. Materials to Avoid: None known
- 10.3. Hazardous Decomposition Products: None known

### 11. TOXICOLOGICAL INFORMATION

- 11.1. When used properly, Electro-Gel is not expected to be toxic.

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### 12. ECOLOGICAL INFORMATION

- 12.1. Ecotoxicity: Electro-Gel is not expected to have a negative effect on aquatic organisms or other environmentally relevant organisms.
- 12.2. Mobility: Electro-Gel, if released to the environment, is not expected to transport to groundwater or far from the site of release.
- 12.3. Persistence and Degradability: Electro-Gel is expected to degrade through biodegradation over time when exposed to the environment, as well as sewage treatment plants.
- 12.4. Bioaccumulative Potential: No harmful effects are expected.
- 12.5. Results of PBT assessment: Not applicable.
- 12.6. Other Adverse Effects: Electro-Gel is not expected to have any adverse effects on the environment when used properly.

### 13. DISPOSAL CONSIDERATIONS

- 13.1. No special handling is required for disposal of Electro-Gel, either from surplus or waste resulting from its use. Follow national or regional regulations regarding waste management.
- 13.2. Packaging may be recyclable, even if contaminated with Electro-Gel. Check with local recycling requirements to ensure that they will be accepted.

### 14. TRANSPORT INFORMATION

- 14.1. Electro-Gel does not require any special precautions when being transported.
- 14.2. Transport by Sea (IMDG)..... Not regulated
- 14.3. Transport by Road (ADR/USDOT)..... Not regulated
- 14.4. Transport by Rail (RID) ..... Not regulated
- 14.5. Transport by Air (ICAO/IATA) ..... Not regulated

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### **15. REGULATORY INFORMATION**

- 15.1. Electro-Gel is manufactured under a Quality System that is compliant to the US FDA Quality System Regulation (21 CFR 820), ISO 13485:2016 and the EU Medical Device Directive (93/42/EEC, amended by 2017/745).

### **16. OTHER INFORMATION**

- 16.1. The statements, technical information, and recommendations contained herein are reliable and based on present-day knowledge, but they are given without warranty or guarantee of any kind, express or implied, and Electro-Cap International, Inc. assumes no responsibility for any loss, damage or expense, direct or consequential, arising from their use.