

Safety Data Sheet*(according to European Directive 2006/1907/EC and OSHA 29CFR 1910.1200)***for Electro-Gel (EEG Electrode Gel)**

Revised February 1, 2016

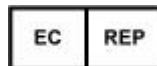
Supersedes April 30, 2015

1. IDENTIFICATION OR 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:



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Available during normal business hours only:
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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.

- 2.2 This preparation is not classified as dangerous according to Directive 1999/45/EC 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.

- 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 StateGel
ColorOff white.
OdorBasically Odorless
- 9.2. Important Health, Safety, and Environmental Information
pHApproximately 4.5
ViscosityApproximately 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.

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

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 13485:2003 and the EU Medical Device Directive (93/42/EEC, amended by 2007/47/EC).

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.