

Safety Data Sheet

(according to European Directive 2006/1907/EC and OSHA 29CFR 1910.1200)

for Nuprep[®] Skin Prep Gel

revised March 20, 2012
supersedes July 26, 2011

I. IDENTIFICATION OR THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

- I.1. Identification of the Substance/Preparation: Nuprep[®] Skin Prep Gel
- I.2. Use of Substance/Preparation: abrasive skin prepping gel intended for use when a reduction of skin impedance would enhance a test result

I.3. Company Identification:



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2. HAZARD IDENTIFICATION

- 2.1. Health hazards beyond those associated with over-abrasion of skin or minor skin sensitivity have not been demonstrated. Nuprep is to be used topically on healthy, intact skin only. Over-abrading the skin can cause serious topical injury to the patient, including permanent scarring. Nuprep should never be used on patients with a history of skin allergies or a history of sensitivity to cosmetics or lotions. The use of any topical abrasive product or technique carries a risk of infection at the electrode site.
- 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. Mixture of Water, Aluminum Oxide, 1,2-Propanediol, Sodium Polyacrylate, Methylparaben, Propylparaben, FD&C Blue 1, FD&C Red 40, and FD&C Yellow 5

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: Nuprep is non-toxic if ingested. If irritation or discomfort is experienced, contact a physician.
- 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. Nuprep 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: Always apply gently with a soft material, such as a cotton swab or gauze pad. Do not use on or near injured skin. Avoid eye contact. Do not use with current-inducing electrodes.

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
 - ColorLight Green
 - OdorOdorless
- 9.2. Important Health, Safety, and Environmental Information
 - pH.....Approximately 7.0
 - Density.....Approximately 1.2 g/cm³
 - Water SolubilityPartial
- 9.3. Other Information
 - None available

10. STABILITY AND REACTIVITY

General Information: Nuprep 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, Nuprep is not expected to be toxic.

12. ECOLOGICAL INFORMATION

- 12.1. Ecotoxicity: Nuprep is not expected to have a negative effect on aquatic organisms or other environmentally relevant organisms.

- 12.2. Mobility: Nuprep, if released to the environment, is not expected to transport to groundwater or far from the site of release.
- 12.3. Persistence and Degradability: Nuprep 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: Nuprep 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 Nuprep, 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 Nuprep. Check with local recycling requirements to ensure that they will be accepted.

14. TRANSPORT INFORMATION

- 14.1. Nuprep 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. Nuprep is manufactured under a Quality System that is compliant to the US FDA Quality System Regulation (21 CFR 820), ISO 13485:2003, the EU Medical Device Directive (93/42/EEC, amended by 2007/47/EC), and to the Canadian Medical Device Regulation.

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 Weaver and Company assumes no responsibility for any loss, damage or expense, direct or consequential, arising from their use.