


Safety Data Sheet

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

for Ten20[®] Conductive Paste

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: Ten20[®] Conductive Paste
- I.2. Use of Substance/Preparation: conductive and adhesive paste for use in neuromonitoring procedures in conjunction with non-gelled neurodiagnostic electrodes to improve test results
- I.3. Company Identification:
- | | | | |
|-------------------------------------------------------------------------------------|------------------------------------------------------------|----|-----|
|  | <table border="1"><tr><td>EC</td><td>REP</td></tr></table> | EC | REP |
| EC | REP | | |
| Weaver and Company | Emergo Europe | | |
| 565 Nucla Way, Unit B | Molenstraat 15 | | |
| Aurora, CO 80011-9319 | 2513 The Hague, The Netherlands | | |
| USA | Tel +31 70 345 8570 | | |
| Tel +1 800 525 2130 | Fax +31 70 346 7299 | | |
| Fax +1 303 367 5118 | | | |
| Email: nlee@doweaver.com | | | |
| Website: www.doweaver.com | | | |
- I.4. Emergency Telephone: +1 800 525 2130

2. HAZARD IDENTIFICATION

- 2.1. Health hazards beyond those associated with drying and chapping of skin or minor skin sensitivity have not been demonstrated. Ten20 Conductive Paste is to be used to adhere electrodes topically on health, intact skin only. Ten20 Conductive Paste should never be used on patients with a history of skin allergies or a history of sensitivity to cosmetics or lotions. The use of Ten20 Conductive Paste, in conjunction with typical procedures used to reduce skin impedance, carries with it the risk for 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 Polyoxyethylene (20) Cetyl Ether, Water, Glycerin, Calcium Carbonate, 1,2-Propanediol, Potassium Chloride, Gelwhite, Sodium Chloride, Polyoxyethylene (20) Sorbitol, 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: Ten20 is essentially 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. Ten20 is a nonflammable paste.

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 or 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: Preferable apply to the electrode using surgical or rubber gloves. Excessive or un-gloved exposure may cause finger skin dryness and chapping. Wash hands after applying to patient. 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 StateSolid Paste

ColorOff-white

OdorOdorless

9.2. Important Health, Safety, and Environmental Information

Melting Point44°C

DensityApproximately 2.3 g/cm³

Water SolubilityPartial

9.3. Other Information

None available

10. STABILITY AND REACTIVITY

General Information: Ten20 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, Ten20 is not expected to be toxic.

12. ECOLOGICAL INFORMATION

- 12.1. Ecotoxicity: Ten20 is not expected to have a negative effect on aquatic organisms or other environmentally relevant organisms.
- 12.2. Mobility: Ten20, if released to the environment, is not expected to transport to groundwater or far from the site of release.
- 12.3. Persistence and Degradability: Ten20 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: Ten20 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 Ten20, 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 Ten20. Check with local recycling requirements to ensure that they will be accepted.

14. TRANSPORT INFORMATION

- 14.1. Ten20 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. Ten20 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.