Safety Data Sheet

Trade Name: Ten20® Conductive Paste

Version: 1.0 / en Revision Date: 10 February 2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade Name: Ten20® Conductive Paste

Other means of identification:
Manufacturer's item number(s):
10-20-8, 10-20-4, 10-20-4T, 10-20-4TK, 10-20-2, 10-20-2S, 10-20-1

Hazard components for labeling:
Ten20 contains no hazardous components

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses:
Conductive and adhesive paste for use in neuromonitoring procedures in conjunction with non-gelled neurodiagnostic electrodes to improve test results.

Uses advised against:
Do not use on injured skin / open wounds; adequate clinical data has not been collected to determine the safety and effectiveness of Ten20 Conductive Paste when used on unhealthy/damaged skin.

Do not use on patients with a history of skin allergies or a history of sensitivity to cosmetics or lotions.

Do not use with current-inducing electrodes; adequate clinical data has not been collected to determine the safety and effectiveness of Ten20 Conductive Paste when used with current-inducing electrodes.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Weaver and Company
565 Nucla Way, Unit B
Aurora, Colorado 80011
United States of America
+001.800.525.2130
regulatory@weaverandcompany.com

EC Representative:
Emergo Group
Prinsessegracht 20
2514 AP The Hague
The Netherlands
+31.70.345.8570

1.4 Emergency telephone number: +001.800.525.2130

Available during normal business hours only:
Monday – Thursday: 8:00 – 16:30 (GMT-7:00)
Friday: 8:00 – 15:00 (GMT-7:00)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Ten20 does not meet the criteria for classification in accordance with Regulation (EC) No. 1272/2008.

2.2 Labeling elements

Ten20 does not require additional labeling in accordance with Regulation (EC) No. 1272/2008.

2.3 Other hazards

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 healthy, 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.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable – this SDS is for a mixture.

3.2 Mixtures

Description of the mixture:

Mixture of Polyoxyethylene (20) Cetyl Ether, Water, Glycerin, Calcium Carbonate, 1,2-Propanediol, Potassium Chloride, Gelwhite®, Sodium Chloride, Polyoxyethylene (20) Sorbitol, Methylparaben, and Propylparaben.

Hazardous ingredients:

Ten20 does not contain any hazardous ingredients as defined by Regulation (EC) No. 1272/2008.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Immediate medical attention is typically not required.

Following inhalation:

Inhalation is not possible. Ten20 does not give off any dust/particulates or gases/vapors.

Following skin contact:

Ten20 is a topical product, meant for direct contact with healthy, intact skin. Any persistent redness, soreness, burning, itching, or swelling of the skin should be reported to a physician.

Following 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.

Following ingestion:
Ten20 is essentially non-toxic if accidently ingested. If irritation or discomfort is experienced, contact a physician.

Self-protection of the first aider:
No special self-protection is necessary for the first aider.

4.2 Most important symptoms and effects, both acute and delayed
Undetermined

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor
Treat symptomatically.

Special treatment
Special treatment is not required during first aid activities.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Ten20 is nonflammable.

5.2 Special hazards arising from the substance or mixture
Ten20 is nonflammable.

5.3 Advice for fire-fighters
Ten20 is nonflammable.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:
No special personal precautions, protective equipment, or emergency procedures are necessary.

For emergency personnel:
No special personal precautions, protective equipment, or emergency procedures are necessary.

6.2 Environmental precautions
No special environmental precautions are necessary.

6.3 Methods and material for containment and cleaning up

For containment:
No special containment measures are necessary.

For cleaning up:
Ten20 is water-soluble; use warm water to clean up.

Other information:
None.

6.4 References to other sections

None.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures:

Advice on safe handling
No special handling is required. Wipe up any spilled material and dispose of appropriately, according to local regulations.

Fire preventions
Ten20 is nonflammable; measures to prevent fires are not applicable.

Aerosol and dust generation preventions
Ten20 does not generate aerosol or dust; no such protective measures are applicable.

Environmental precautions
No environmental protective measures are necessary.

Advice on general occupational hygiene:
Wash skin after use.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:
Keep out of the reach of children.

Packaging materials:
There are no safety-related concerns with Ten20 contacting other packaging materials.

Requirements for storage rooms and vessels:
There are no safety-related requirements for storage rooms. However, in order to maintain product quality, Ten20 should be kept at room temperature, and, for multiple-use containers (tubes and jars), the lid should be kept tightly closed when not in use.

7.3 Specific end uses

Preferably apply to the electrode using surgical or rubber gloves. Excessive or un-gloved exposure may cause finger skin dryness and chapping. Wash from hands after applying to patient. Do not use on or near injured skin. Avoid eye contact. Do not use with current-inducing electrodes.

SECTION 8: Exposure controls / personal protection

8.1 Control parameters

Occupational exposure limits:
Not applicable.

Biological limit values:
Not applicable.

Exposure limits at intended use:
Not applicable.

8.2 Exposure controls

Appropriate engineering controls:
None required.

Personal protective equipment:
None required.

Environmental exposure controls:
None required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

(a) Appearance
- Physical state ..... semi-solid paste
- Color ..... off-white

(b) Odor ..... odorless
(c) Odor threshold ..... not applicable
(d) pH ..... slightly alkaline
(e) Melting point / Freezing point ..... approximately 44°C
(f) Initial boiling point and boiling range ..... unknown
(g) Flash point ..... unknown
(h) Evaporation rate ..... unknown
(i) Flammability ..... none
(j) Upper/lower flammability or explosive limits ..... not applicable
(k) Vapor pressure ..... unknown
(l) Vapor density ..... unknown
(m) Relative density ..... approximately 2.3 g/cm^3

(n) Solubility (in water) ..... partial
(o) Partition coefficient: n-octanol/water ..... unknown
(p) Auto-ignition temperature ..... unknown
(q) Decomposition temperature ..... unknown
(r) Viscosity ..... unknown
(s) Explosive properties ..... none
(t) Oxidizing properties ..... none

9.2 Other information
None available.

SECTION 10: Stability and reactivity

10.1 Reactivity
Ten20 is stable and non-reactive under normal conditions. Hazardous polymerization will not occur.

10.2 Chemical stability
Ten20 is stable and non-reactive under normal conditions. Hazardous polymerization will not occur.

10.3 Possibility of hazardous reactions
None known.

10.4 Conditions to avoid
None known.

10.5 Incompatible materials
None known.

10.6 Hazardous decomposition products
None known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

General information: When used properly, Ten20 is not expected to be toxic.

(a) Acute toxicity
Data unavailable for this hazard class.

(b) Skin corrosion/irritation
Method: Dermal Irritation Test per ISO 10993-10:2010
Species: New Zealand White Rabbits
Routes of exposure: Topical
Effective Dose: Approximately 0.5 mL
Exposure time: 4 hours

Results: Primary Irritation Index = 0 (negligible)

(c) Serious eye damage/irritation

Data unavailable for this hazard class.

(d) Respiratory or skin sensitization

Method: Closed Patch Test for Delayed-Type Hypersensitivity per ISO 10993-10:2010
Species: Hartley Guinea Pigs
Routes of exposure: Topical
Effective Dose: Approximately 0.4 mL
Exposure time: 9 exposures of 6 ± 0.5 hours each (54 ± 4.5 hours total)
Results: Grade (Magnusson and Kligman scale) = 0 (no visible change)

(e) Germ gell mutagenicity

Data unavailable for this hazard class.

(f) Carcinogenicity

Data unavailable for this hazard class.

(g) Reproductive toxicity

Data unavailable for this hazard class.

(h) STOT-single exposure

Data unavailable for this hazard class.

(i) STOT-repeated exposure

Data unavailable for this hazard class.

(j) Aspiration hazard

Data unavailable for this hazard class.

SECTION 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 Persistence and degradability

Ten20 is expected to degrade through biodegradation over time when exposed to the environment, as well as sewage treatment plants.

12.3 Bioaccumulative potential

No harmful effects are expected.

12.4 Mobility in soil

Ten20, if released to the environment, is not expected to transport to groundwater or far from the site of release.

12.5 Results of PBT and vPvB assessment
No assessment has been completed; a Chemical Safety Report is not required.

12.6 Other adverse effects
None known.

12.7 Additional information
None.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
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.

Packaging may be recyclable, even if contaminated with Ten20. Check with local recycling requirements to ensure that they will be accepted.

SECTION 14: Transportation information

General information: Ten20 does not require any special precautions when being transported.

14.1 UN number
Not applicable.

14.2 UN proper shipping name
Not applicable.

14.3 Transport hazard class(es)
Not applicable.

14.4 Packing group
Not applicable.

14.5 Environmental hazards
Not applicable.

14.6 Special precautions for user
Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code
Not applicable.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Ten20 is manufactured under a Quality System that is compliant to the US FDA Quality System Regulation (21 CFR 820), ISO 13485:2016, the EU Medical Device Directive, and the Canadian Medical Device Regulation.

No specific safety, health, or environmental regulations/legislation apply.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment is not required for Ten20 Conductive Paste.

SECTION 16: Other information

16.1 Revisions

Version 1.0 supersedes the Safety Data Sheet for Ten20 Conductive Paste dated July 26, 2017. The previous version has been revised to include requirements of Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008.

16.2 Abbreviations

"CFR" : Code of Federal Regulations (of the United States)
"EC" : European Community
"EU" : European Union
"SDS" : Safety Data Sheet
"STOT" : Specific Target Organ Toxicity
"Ten20" refers to the product name "Ten20 Conductive Paste"

16.3 Statement of Liability

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