CREATIVEMATERIALS

www.creativematerials.com

ISO 9001 CERTIFIED

Creative Materials, Inc.
12 Willow Road
Ayer, MA 01432

T 978.391.4700
F 978.391.4705

113-09

ELECTRICALLY CONDUCTIVE MEDICAL ELECTRODE INK

DESCRIPTION: 113-09 is a silver/silver chloride, medical grade, electrically conductive ink and coating suitable for application by screen printing, dipping and syringe dispensing. This product features excellent adhesion to Kapton, Mylar, glass and a variety of other surfaces. Unlike conventional conductive materials, this product is very resistant to flexing and creasing. Some applications for 113-09 include, but are not limited to, transdermal drug delivery, ECG electrodes, tens electrodes and muscle stimulator electrodes.

TYPICAL CURED PROPERTIES:

Viscosity	12,000 - 16,000 cps
Filler	Silver/Silver Chloride
Crease Resistance	Excellent
Volume Resistivity (ohm-cm)	0.0002
Sheet Resistivity (ohm/sq)	0.05
Solderable	No
Hydrolytic Stability	Excellent
Useful Temperature Range	-55°C to +200°C
Thermal Stability	Good to 325°C

SUGGESTED HANDLING & CURING: 113-09 is ready to use as supplied. Further thinning may be accomplished by adding small amounts of CMI Thinner # 102-03 and/or butyl cellosolve acetate. Prior to using, be certain to resuspend silver. Best properties, for most applications, result when cured for several minutes at 100°C. Good properties are obtained on a variety of substrates by dry and curing at temperatures ranging from 50°C to 150°C. End user is advised to experimentally determine temperature and time best suited for individual applications.

STORAGE: Shelf Life: 6 months at 25°C.

SAFETY & HANDLING: Use with adequate ventilation. Keep away from sparks and open flames. Avoid prolonged contact with skin and breathing of vapors. Wash with soap and water to remove from skin.

REVISION DATE: 08/29/22 REVISION: D

Creative Materials, Inc.
12 Willow Road
Ayer, MA 01432

T 978.391.4700
F 978.391.4705

TOXIKON
RIGHT. FROM THE START.℠

TEST RESULT CERTIFICATE

Sponsor	Creative Materials, Inc	**Technical Initiation**	10/27/2021
Address	12 Willow Rd. Ayer MA 01432	**Technical Completion**	10/30/2021
Contact	Jonathan Knotts	**Report Date**	12/13/2021
P.O. Number	00796207	**Final Non-GLP Report**	21-03538-N1

Test Article	Printed electrode array with 112-15A , 113-09, and 127-24FB on polyethylene terephthalate film.
Lot/Batch #	663180
Study	Primary Skin Irritation Test – Direct
Comments	Physical State: Solid Color: Blue and Silver Sterility: Not Sterile Storage condition: Room Temperature Intended Use: Research and development - device

REFERENCES: The study was conducted based upon the following references: ISO 10993-10, 2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization. ISO 10993-12, 2021, Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials. ISO 10993-23, 2021, Biological Evaluation of Medical Devices - Part 23: Tests for Irritation.

ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The skin of three albino rabbits was prepared for testing. Two application sites for both test article and control were prepared by clipping the skin of the trunk free of hair within 24 hours before application of the test article. The sites of application were not abraded deliberately or accidentally during preparation. Areas of untreated skin served as the control sites. The animals were treated by introducing the test article (2.5 × 2.5 cm) under gauze patches. The test article was kept in contact with the skin for 4 hours by wrapping with an impervious bandaging. At the end of the exposure period, the wrapping and test article were removed. The animals were observed for signs of erythema and edema at 60 minutes, and then at 24, 48, and 72 hours after bandage removal. Observations were scored according to the Classification System for Scoring Skin Reactions. Observation values were calculated by averaging the scores for each individual animal. This was performed by adding the scores for each animal for erythema and edema at 24, 48, and 72 hours. This total was divided by 6 (2 test sites times 3 observation periods). A similar assessment was made of the control sites. The control score was subtracted from the test article score. Then, this calculated value for each animal was added together for a total of three animals. The total was divided by 3 to obtain the Primary Irritation Index. A test article with a Primary Irritation Index of less than 0.5 is considered a negligible irritant. Test article with indices of 0.5 to less than 2.0 are slight irritants. Test articles with indices of 2.0 to less than 5.0 are moderate irritants. Any test articles with an index of 5.0 or more are considered severe irritants. Dermal irritants are those test articles that produce reversible changes in the derma. Those test articles that destroy the structure of the intact skin or change it irreversibly are considered corrosive.

RESULTS: All animals gained in body weight. No signs of erythema or edema were present at the 60 minute, 24, 48, or the 72 hour observation points. None of the control sites of any animal at any of the observation periods showed signs of erythema or edema.

CONCLUSION: The test article was tested for its potential to produce primary dermal irritation after a single topical 4 hour application to the skin of albino rabbits. The Primary Irritation Index was 0.0. The test article was considered a negligible irritant.

AUTHORIZED PERSONNEL:

Alex Howlett, B.S.
Quality Assurance

Shirley Lister, B.S., LATG
Study Director