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Medical Materials & Technologies
BIOCOMPATIBILITY SUMMARY
Product Name: 3M™ Medical Tape 4579
Effective: December 2024

The finished product 3M™ Medical Tape 4579 contruction has been subjected to the following preclinical biocompatibility evaluations per ISO 10993 standards under FDA GLP Regulations (21 CFR Part 58):

Cytotoxicity Study Using the ISO Agarose Overlay Method

MTDID 69241 was evaluated to determine the potential for cytotoxicity in an Agarose Overlay Test. This study was conducted based on the requirements of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity. The clear film on the test article was removed and excluded from the preparation prior to cutting. Triplicate wells were dosed with a 1 cm x 1 cm portion of the test article. The acrylate adhesive side was dosed against the solidified agarose surface. Triplicate wells were dosed with a 1 cm length portion of high-density polyethylene as a negative control. Triplicate wells were dosed with a 1 cm x 1 cm portion of latex as a positive control. Each article was placed on an agarose surface directly overlaying a subconfluent monolayer of L-929 mouse fibroblast cells. After incubating at 37°C in the presence of 5% CO2 for 24-26 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis. The test article showed no evidence of causing any cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity). ***Study Number 24-307***

Cytotoxicity Study Using the ISO Elution Method

MTDID 69241 was evaluated for potential cytotoxic effects using an *in vitro* mammalian cell culture test. This study was conducted following the guidelines of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium (1X MEM) at 37°C for 72 hours. The clear film and white paper backing were removed and excluded from the preparation. The negative control, reagent control, and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37°C in the presence of 5% CO2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. The test article extract showed no evidence of causing cell lysis or toxicity. ***Study number 24-308***

ISO Skin Irritation Study in Rabbits

MTDID 69241 was evaluated for primary skin irritation in rabbits in an ISO Skin Irritation Study. This study was conducted in accordance with the guidelines of ISO 10993-23, Biological evaluation of medical

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devices - Part 23: Tests for irritation. Two 25 mm x 25 mm sections portions of the test article and control article were topically applied to the skin of each of three rabbits and left in place for a minimum of 23 hours and a maximum of 24 hours. The clear film and the white release liner were removed prior to testing. The test article was applied so that the adhesive was in contact with the skin. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single sample application. There was no to very slight erythema and no edema observed on the skin of the animals treated with the test article. The Primary Irritation Index for the test article was calculated to be 0.7. The response of the test article was categorized as slight or minimally irritating. ***Study number 24-309***

ISO Guinea Pig Maximization Sensitization Test

MTDID 69241 was evaluated for the potential to cause delayed dermal contact sensitization in a guinea pig maximization test. This study was conducted based on the requirements of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for skin sensitization. MTDID 69241 was extracted in 0.9% sodium chloride USP and sesame oil, NF at 50°C for 72 hours. The clear film and white paper backing were removed and excluded from the preparation. Each extract was intradermally injected and occlusively patched to ten test guinea pigs (per extract). The extraction vehicle was similarly injected and occlusively patched to five control guinea pigs (per vehicle). Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract and the vehicle control. All sites were scored for dermal reactions at 24 and 48 hours after patch removal. The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig and was not considered a sensitizer in the guinea pig maximization test. ***Study number 24-310***

In addition, the CAM12 residual monomer on 3M™ Medical Tape 4579, used with a similar medical tape, has been subjected to the following preclinical biocompatibility evaluations per ISO 10993 standards under FDA GLP Regulations (21 CFR Part 58):

Cytotoxicity Study Using the ISO Agarose Overlay Method

MTDID 66047 (ST241217-06), MTDID 66047 (ST241217- 07), MTDID 66047 (ST241217-08), and MTDID 66047 (ST241217-10) were evaluated to determine the potential for cytotoxicity in an Agarose Overlay Test. This study was conducted based on the requirements of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity. The clear film on the test article was removed and excluded from the preparation prior to cutting. Triplicate wells were dosed with a 1 cm x 1 cm portion of the test article. The acrylate adhesive side was dosed against the solidified agarose surface. Triplicate wells were dosed with a 1 cm length portion of high-density polyethylene as a negative control. Triplicate wells were dosed with a 1 cm x 1 cm portion of latex as a positive control. Each article was placed on an agarose surface directly overlaying a subconfluent monolayer of L-929 mouse fibroblast cells. After incubating at 37°C in the presence of 5% CO2 for 24-26 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis. The test articles

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showed no evidence of causing any cell lysis or toxicity. The test article extracts met the requirements of the test since the grade was less than a grade 2 (mild reactivity). ***Study Number 25-009***

Cytotoxicity Study Using the ISO Elution Method

MTDID 66047 (ST241217-06), MTDID 66047 (ST241217- 07), MTDID 66047 (ST241217-08), and MTDID 66047 (ST241217-10) were evaluated for potential cytotoxic effects using an *in vitro* mammalian cell culture test. This study was conducted following the guidelines of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium (1X MEM) at 37°C for 72 hours. The clear film and white paper backing were removed and excluded from the preparation. The negative control, reagent control, and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37°C in the presence of 5% CO2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. The test article extracts showed no evidence of causing cell lysis or toxicity. ***Study number 25-010***

ISO Skin Irritation Study in Rabbits

MTDID 66047 (ST241217-06), MTDID 66047 (ST241217- 07), MTDID 66047 (ST241217-08), and MTDID 66047 (ST241217-10) were evaluated for primary skin irritation in rabbits in an ISO Skin Irritation Study. This study was conducted in accordance with the guidelines of ISO 10993-23, Biological evaluation of medical devices - Part 23: Tests for irritation. Two 25 mm x 25 mm sections portions of the test article and control article were topically applied to the skin of each of three rabbits and left in place for a minimum of 23 hours and a maximum of 24 hours. The clear film and the white release liner were removed prior to testing. The test article was applied so that the adhesive was in contact with the skin. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single sample application. There was very slight erythema and no edema observed on the skin of the animals treated with the test articles. The Primary Irritation Index for the test articles were calculated to be 0.6 for MTDID 66047 (ST241217-10) and 1 for MTDID 66047 (ST241217-06), MTDID 66047 (ST241217- 07), and MTDID 66047 (ST241217-08). The response of the test article was categorized as slightly irritating. ***Study number 25-011***

ISO Guinea Pig Maximization Sensitization Test

MTDID 66047 (ST241217-06), MTDID 66047 (ST241217- 07), MTDID 66047 (ST241217-08), and MTDID 66047 (ST241217-10) were evaluated for the potential to cause delayed dermal contact sensitization in a guinea pig maximization test. This study was conducted based on the requirements of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for skin sensitization. MTDID 66047 (ST241217-06), MTDID 66047 (ST241217- 07), MTDID 66047 (ST241217-08), and MTDID 66047 (ST241217-10) were extracted in 0.9% sodium chloride USP and sesame oil, NF at 50°C for 72 hours. The clear film and white

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paper backing were removed and excluded from the preparation. Each extract was intradermally injected and occlusively patched to ten test guinea pigs (per extract). The extraction vehicle was similarly injected and occlusively patched to five control guinea pigs (per vehicle). Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract and the vehicle control. All sites were scored for dermal reactions at 24 and 48 hours after patch removal. The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig and was not considered a sensitizer in the guinea pig maximization test. ***Study number 25-012***

It is the responsibility of our customers to determine final suitability of our products for their application. Final testing of a converted device made with this material is the responsibility of the customer.