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December 2012

Summary of Cytotoxicity Test Results

Test Product: PurTect

Active: 0.8% Chloroxylenol

Testing of Study #121020-450, entitled **"EVALUATION OF IN-VITRO CYTOTOXICITY OF ONE TEST PRODUCT USING THE ISO 10993-5 DIRECT CONTACT TEST"**, has been completed.

One Test Product, PurTect Ointment (Chloroxylenol 0.8%, Petrolatum 63%; Lot Number: 1L12A1), was evaluated for its cytotoxicity using the Neutral Red Uptake (NRU) Direct Contact methodology described in ISO 10993-5:2009(E) "Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity". Testing was initiated on November 09, 2012 and completed on December 07, 2012.

METHODOLOGY: The test product was evaluated at eight concentrations. Each concentration was plated in six replicates. The test product dilutions were prepared using DMSO (Dimethylsulfoxide) in a water bath temperature of 45 °C - 50 °C. The dissolvable concentrations of product in DMSO were additionally diluted in medium using the dose factor of 1.21. Balb/c 3T3 cells (ATCC #CCL-163) were plated onto 96-well plate and incubated at 37 ° C ± 2 ° C. Cells were 60% confluent in 24 hours of incubation. Following incubation, culture medium was replaced with 100µL aliquots of test product dilutions and samples and controls. Plates were returned to incubation for 24 hours at 37 ° C ± 2 ° C. Due to the viscous consistency of the petrolatum-based test product and very low water solubility, 100 µL of 100% product concentration was plated onto cells and overlaid with 100µL of medium. After 24-hour treatment, plates were examined microscopically. The observed cell characteristics were graded "1" or, slightly irritating. Quantitative NRU evaluation of cell viability was carried out using the VERSAmax™ microplate reader set at 540 nm. Sodium Dodecyl Sulfate (SDS) served as a positive control. The SDS IC50 was calculated using the following model: log (inhibitor) vs. response – Variable slope (four parameters). Y=Bottom + (Top-Bottom)/(1+10^((LogIC50-X)*HillSlope)) implemented in the GraphPad Prism 5 software. The IC50 was 0.083 mg/mL meeting the test acceptance criterion. The mean OD_{540} of the blanks was > 0.3 and the values for the right and the left blanks did not differ by more than 15% from the mean of all blanks, meeting the acceptance criteria of this test. VERSAmax and GraphPad Prism 5.0 software printouts as well as product information and experimental raw data will be stored in the study file at BioScience Laboratories Inc.

RESULTS: The average viability of 3T3 cells treated with 100% concentration of the test product, PurTect Ointment (Lot Number: 1L12A1), was 71.326%. Since the cell viability exceeded 70%, the IC50 for the test product were not calculated.

CONCLUSION: The test product, PurTect Ointment (Lot Number: 1L12A1), can be considered non-cytotoxic.

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