propper Manufacturing Co., Inc.

PROFESSIONAL INFORMATION REPORT **84-4**

SAFETY TESTING OF PROPPER
Once-A-Day® Bowie & Dick Test Indicator

NAmSA® NORTH AMERICAN SCIENCE ASSOCIATES, INCORPORATED
2261 Tracy Road • Northwood, Ohio 43619-1397
Phone 419/666-9455

Lab. No. 84T-04649-00
Lot No. Not Supplied
P. O. No. 34628

Propper Mfg. Co.
36-04 Skillman Avenue
Long Island City, NY 11101
Attn: Dr. Thomas Augurt

Material: Once-a-Day Bowie and Dick Test Indicator

Test: Cytotoxicity by the MEM Elution Method (on substrate samples sterilized in contact with the test material)

Method: The sterilization indicators under study were evaluated for their potential to transfer cytotoxic leachables to various substrates in contact with the indicators during a sterilization cycle. The MEM elution method of Wilsnack, et. al.* was employed with modifications for use in this study design as described below.

Sample Preparation - was completed by placing the center portion of one sterilization indicator in contact with each of the following substrates:
British Towel conforming to BS1781TL6 (3-1/2" x 1" section)
U.S. Towel (3-1/2" x 1" section)

NOTE: Towel sections were prepared by laundering in hot water without detergent followed by boiling in deionized water for final rinse and drying at room temperature.

Separate test packs were prepared for each substrate sample, and similar packs without the test indicators were prepared for use as controls.

Sterilization of test and control packs was performed at 250°F for 30 minutes in a pre-vacuum sterilizer.

Extraction of each sterilized substrate test sample and control was carried out in 10 ml of Minimum Essential Medium (MEM) with 5% bovine serum. Extracts were held at 37°C for 24 hours and then composites were prepared of the test extracts and the control extracts respectively. An aliquot of MEM extraction fluid was similarly treated for use as an additional negative control and a routine positive control sample was also prepared in a similar manner.

Cell Cultures of L-929 mouse fibroblasts, propagated to confluency in MEM with 5% serum, were employed for final evaluation of each composite extract. Growth medium was removed from each cell culture and replaced by 5 ml of either test or control extract. Cultures were incubated at 37°C for 24 hours and then examined microscopically for signs of cytotoxic effect (CTE).

Results:

Test sample extract	Non-toxic (No CTE)
Control extract	Non-toxic
Negative control	Non-toxic
Positive control	Toxic

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(see page 2)

Completed _____ Tech. _____ Approved by _____

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Conclusions:

Under the conditions of this test, the Once-a-Day Bowie and Dick Test Indicators did not impart cytotoxic properties to the various substrate samples sterilized in contact with them.

*Wilsnack, R.E. 1976. Quantitative cell culture biocompatibility testing of medical devices and correlation to animal tests. Biomaterials, Medical Devices and Artificial Organs. Vol. 4, No. 3 and 4, pp. 235-261

Wilsnack, R.E., F.J. Meyer and J.G. Smith. 1973. Human cell culture toxicity testing of medical devices and correlation to animal tests. Biomaterials, Medical Devices and Artifical Organs. Vol. 1, No. 3, pp. 545-562.

/ss Completed 6-11-84 Tech. BH/SKS Approved by [signature]