MB Research Laboratories

1765 wentz road, p. o. box 178
spinnerstown, pa 18968
phone (215) 536-4110 fax (215) 536-1816
office@mbresearch.com

COLUMN E EXPLANATION - 2021
Facility Registration No: 23-R-0061

Guinea Pigs: The 160 guinea pigs listed in Column E of the Annual Report were used on guinea pig sensitization evaluations, in compliance with Organization for Economic Co-operation and Development (OECD), U.S. Environmental Protection Agency (EPA) and/or International Organization for Standardization (ISO) testing guidelines. The purpose of these studies is to assess the sensitization potential of a substance following repeated dermal exposure. Dermal irritation and toxicity can occur during these studies. The test guideline citations for these studies are as follows:

- OECD Guidelines for Testing of Chemicals
  - Test Guideline No. 406, Skin Sensitization, Adopted by the Council on July 17, 1992
- EPA Health Effects Test Guidelines
  - OCSPP 870.2600, Skin Sensitization, effective March 2003
- ISO 10993-10 International Standard
  - Biological evaluation of medical devices - test for irritation and skin sensitization, effective August 2010

These are regulatory-driven protocols and there are no current provisions in these test guidelines to permit the use of analgesia or anesthetics. NSAIDs and opioids are known to interfere with dendritic cell and T-cell responses, which are key events in the adverse outcome pathway (AOP) for delayed-type hypersensitivity (skin sensitization) reactions. Any pharmacologic control of pain that would lead to either enhancement or mitigation of delayed-type hypersensitivity is contraindicated by the interests of hazard identification for risk assessment and public health protection.

Rabbits: The 9 rabbits listed in Column E of the Annual Report were used in dermal irritation/corrosion studies in compliance with Consumer Product Safety Commission (CPSC), EPA, and/or OECD testing guidelines. The purpose of these studies is to determine the irritant or corrosive effect of a substance when applied to the skin. Dermal irritation and toxicity can occur during these studies. The test guideline citations for these studies are as follows:

- CPSC Federal Hazardous Substance Act
  - 16 CFR 1500.41, Primary Dermal Irritation
- OECD Guidelines for Testing of Chemicals
  - Test Guideline No. 404, Acute Dermal Irritation/Corrosion, Adopted by the Council July 28, 2015
- EPA Health Effects Test Guidelines
  - OCSPP 870.2500, Acute Dermal Irritation, effective August 1998

These are regulatory-driven protocols and there are no current provisions in the test guidelines to permit the use of analgesia or anesthetics. Opioids and NSAIDs are known modulators of wound-healing. Skin recovery from chemical irritation, or wound-healing, is an important aspect of skin irritation studies, and is a measure of reversibility. Any pharmacologic control of pain that would lead to either enhancement or mitigation of healing is contraindicated by the interests of hazard identification for risk assessment and public health protection.

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