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COLUMN E EXPLANATION - 2016
Facility Registration No: 23-R-0061

Guinea Pigs: The sixty-five guinea pigs listed in Column E were used on guinea pig sensitization evaluations, in compliance with OECD and/or EPA testing guidelines. The purpose of this study is to assess the sensitization potential of a substance following repeated dermal exposure. Dermal irritation and occasional abnormal systemic observations can occur during these studies. These are regulatory driven protocols and there are no current provisions in the test guideline to permit the use of analgesia or anesthetics. The citings for these test guidelines are as follows:

- Organization for Economic Cooperation and Development (OECD) Guidelines for Testing of Chemicals, Guideline #406, Skin Sensitization, Adopted by the Council on July 17, 1992.
- EPA Health Effects Test Guidelines, OPPTS 870.2600 final guideline, March 2003

Currently, the Local Lymph Node Assay (LLNA) using mice is an accepted method for sensitization studies. However, this study requires the radioactive procedures. In 2002, MB was awarded a Small Business Innovative Research (SBIR) Phase II grant for the development and commercialization of a Local Lymph Node Assay using mice but eliminating the need for radioactive procedures. MB Research is currently conducting these studies for commercial clients. However, the regulatory agencies, i.e., EPA, and OECD, have not yet adopted this LLNA version as an approved test guideline for sensitization studies, so it cannot be used as an alternative to either the Magnusson-Kligman or Buehler Methods.

Rabbits: The twenty rabbits listed in Column E of the Annual Report were used in EPA, OECD or FHSA dermal or ocular irritation/corrosion studies and dermal toxicity studies in which the use of anesthetics has the potential to mask or worsen the responses being investigated. The purpose of these studies is to determine the irritant or corrosive effect of a substance when applied to the skin or eye. In cases where there is reason to believe that ocular or dermal reactions may be severe, MB recommends to the study sponsor that only one rabbit be tested. In cases where the reaction is severe, the sponsor is notified and the animals are humanely euthanized in accordance with the 2013 American Veterinary Medical Association (AVMA) Guidelines. The citings for these studies are as follows:

- OECD Guidelines for Testing of Chemicals:
  - Guideline #402, Acute Dermal Toxicity in Rabbits, Adopted February 24, 1987
  - Guideline #404, Acute Dermal Irritation/Corrosion, Adopted by the Council April 24, 2002
  - Guideline #405, Acute Eye Irritation/Corrosion, Adopted by the Council on April 24, 2002
- EPA Office of Chemical Safety and Pollution Prevention (OCSPP), Health Effects Test Guidelines:
  - Guideline #870.2400, Acute Eye Irritation, effective August 1998
  - Guideline #870.2500, Acute Dermal Irritation, effective August 1998
  - Guideline #870.1200, Acute Dermal Toxicity, effective August 1998
- FHSA - Federal Hazardous Substance Act
  - 16 CFR 1500.40, Acute Dermal Toxicity
  - 16 CFR 1500.41, Primary Dermal Irritation
  - 16 CFR 1500.42, Primary Eye Irritation