

# Product Safety Labs

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## Attachment to USDA/APHIS Annual Report of Research facility

Explanation of Column “E” Entries.

10/01/17 through 9/30/18

Registration Number: 22-R-0143

### **396 Guinea Pigs – Dermal Sensitization Test (OPPTS 870.2600):**

Three Hundred and fifteen (315) animals were used for Magnusson & Kligman Method studies and eighty one (81) were from Buehler Method studies. All exhibited either severe erythema with or without edema, or eschar and/or corrosion or blanching at the dose site, which may indicate necrosis of the skin. In all cases, the area of exposure and subsequent skin damage was  $\leq 1 \text{ in}^2$ . Use of topical anesthetic agents during dermal irritation tests is deemed inappropriate as it could lead to study complications such as delayed healing of the test site and likely impact the level of irritation (increase or decrease) which would result in questionable results. The use of analgesics in these particular studies would be inappropriate as well due to the resultant potential anti-inflammatory effects that could mask the indicators of irritation. The use of either of these agents could significantly compromise the results of the study.