

Product Safety Labs

Attachment to USDA/APHIS Annual Report of Research facility

Explanation of Column "E" Entries.

10/01/18 through 9/30/19

Registration Number: 22-R-0143

1102 Guinea Pigs – Dermal Sensitization Test (OPPTS 870.2600):

One thousand one hundred and two (1102) animals were used for Magnusson & Kligman 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.