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IMMUNOTOXICOLOGY STUDY OF TINUVIN® 144
ADMINISTERED BY THE DERMAL ROUTE 89-878000007

SUMMARY OF DRAFT REPORT

CONTAINS NO CBI

April 14, 1987

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The results of this study seem to confirm those of the previous reported study, although the lowest observed effect level (LOEL) of 70 mg/kg. In agreement with the previous study, increased spleen weight and decreased thymus weight were observed, as were alterations in the total and differential leukocyte counts.

Other significant findings in the present study include a decreased response to mitogen stimulation by both T- and B-cells and a decrease in the mixed leukocyte response (MLR) assay, an indicator that the test material can modulate recognition of (and response to) allogenic (i.e., non-self) cells. These results may be consistent with the interpretation that the test material is acting as an adjuvant, rather than as an immunosuppressor, as previously concluded. 0.7 mg/kg was clearly a no-observable-effect level (NOEL).

In this study, mice were treated daily for 14 days on intact or abraded abdominal skin, in contrast to the previous reported study in which rats were dosed orally for 28 days. The vehicle used for the test material in the present study was a mixture of acetone and olive oil (4:1). Dose levels were 0.7, 7, and 70 mg/kg/day, applied once per day.

No biologically significant differences were seen between animals dosed on abraded vs. nonabraded skin. However, since the animals were gang-housed and post-treatment preening and grooming of cage mates was reported, it is possible that the effects seen reflect a resulting oral dosing whose effects transcended those due to any absorption difference between intact and abraded skin.

An additional dermal study is planned in which ingestion will be prevented.

*Tinuvin® 144 is bis(1,2,2,6,6-pentamethyl-4-piperidiny)(3,5-di-tert-butyl-4-hydroxybenzyl)butylpropanedioate; (63843-89-10)).

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CERTIFICATE OF AUTHENTICITY

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