EPA Reviewer: M. Hashim **Date:** May 17, 2005

Risk Manager (EPA): 25

STUDY TYPE: Dermal Sensitization – guinea pigs; OPPTS 870.2600

TEST MATERIAL: SP1022 (Triclopyr-Triethylamine salt 14.8%), Lot #870IP506-2A, Gray granules

CITATION: Moore, G. (2006). Dermal Sensitization Study in Guinea Pigs (Buehler Method) Product Safety Laboratories, Dayton, NJ 08810, Study #: 18017 dated 1-30-06 MRID 46791908. Unpublished.

SPONSOR: SePRO Corporation, Carmel, IN 46032-4565.

EXECUTIVE SUMMARY: Buehler Method- In a dermal sensitization study (MRID 46791908), SP1022 (Triclopyr-Triethylamine salt 14.8%) was tested for a potential of eliciting a sensitization reaction in albino guinea pigs (Strain: Hartley albino, Source: Elm Hill Breeding Labs, Chelmford, MA Twenty test and ten control animals were used for the study. Following a screening test, 70% w/w mixture (in dist. Water) was used for 3 (weekly) inductions. Animals were challenged with a 53% w/w mixture, twenty seven days after the first induction. Animals were evaluated for dermal reaction at 24 and 48 hours after the challenge. A historical positive control test was used for validation (Study #18271 dated 10-14-05).

The test and the control animals showed no significant reaction (incidence as 0 / 20 test, and 0 / 10 controls). The product is not a dermal sensitizer.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary dermal irritation study (OPPTS 870.2600) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

PROCEDURE: Buehler Method- In a dermal sensitization study SP1022 were tested for a potential to induce a sensitization reaction in albino guinea pig (Strain: Hartley albino, Source: Elm Hill Breeding Labs, Chelmford, MA Twenty test and ten control animals were used for the study. Following a screening test, a 70% w/w mixture (in dist. Water) was used for 3 (weekly) inductions. Animals were challenged with a 53% w/w mixture twenty seven days after the first induction. Animals were evaluated for dermal reaction at 24 and 48 hours after the challenge.

II. RESULTS and DISCUSSION:

A. The test and control animals showed no significant reaction (incidence as 0 / 20 test, and 0 / 10 controls).

The product is not a contact sensitizer.

B. Positive control: A historical positive control test was used for validation (Study #18271 dated 10-14-05).

C. Reviewer's Conclusion - TRB agrees with the study author that the test substance is not a dermal sensitizer.