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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: DEET: Review of 6(a)(2) data of domestic animal studies
in horses

Caswell No.	346	MRID No.	429351-01 429351-02
EPA Case No.	007000	EPA ID No.	080301-00114
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Registration Division (H7505C)

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THROUGH: James Rowe, Ph.D. *James N. Rowe 10/22/93*
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and
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Toxicology Branch II has been requested to review a set of data which has been classified as 6(a)(2) data and which consisted of two domestic animals studies on DEET in horses. The reports of these two studies are drafts which are being audited within Miles Quality Assurance Department for GLP compliance. Since these submissions are not the final reports, this reviewer has evaluated the summary data and validated them with the appropriate individual data. An individual Data Evaluation Report (DER) for each draft will not be prepared until the submission and evaluation of the final reports. Based on the data presented in the drafts, the following conclusions are derived:

Citation: Kohlenberg, M.L. (1993) General safety evaluation for the topical use of DEET formulation on horses. Draft Report by Miles Inc., Agriculture Division, Animal Health Products Toxicology. Study No. TR-93C-009. Aug. 15, 1993. Submitted to EPA by Miles Inc.; EPA MRID No. 429351-01.

Two groups of horses (5/group) were topically sprayed formulated DEET (23%) for two weeks (5 consecutive days/week); one group received 4 oz/day (\approx 130 gm), and the other group received 8 oz/day (\approx 230 gm). A control group of 5 horses received ethanol at 4 oz/day (\approx 110 gm). An attempt was made to expose the treated horses to the sun each day, and in rainy days, the treated horses were placed in a roofed enclosure. The results indicated that essentially all the DEET treated horses had oily hair and "flaking of epidermis", which occurred in most treated horses after approximately 8 days after treatment. Based on the raw individual animal data the "flaking of the epidermis" most frequently occurred on the chest, neck, shoulder, or hips of the treated horses.

Citation: Kohlenberg, M.L. (1993) Safety evaluation for the topical use of DEET formulation on horses. Draft Report by Miles Inc., Agriculture Division, Animal Health Products Toxicology. Study No. TR-93C-001. Feb. 15, 1993. Submitted to EPA by Miles Inc.; EPA MRID No. 429351-02.

Two groups of horses (5/group) were topically sprayed formulated DEET (23%) for 5 days; one group received 4 oz/day (\approx 117 gm), and the other group received 8 oz/day (\approx 220 gm). A control group of 5 horses received ethanol at 4 oz/day (\approx 120 gm). The treated horses were placed in a roofed enclosure for the entire study period (2 weeks). Under the conditions of the study, neither DEET nor ethanol produced any effect on the treated horse at all.

Discussion: Based on the results presented in the draft report, when DEET was topically sprayed on the horses for 2 weeks (at \approx 120 gm/day or \approx 220 gm/day) and exposed to the sun for a few hours/day (weather permitted), the treated animals showed signs of "flaking epidermis". In contrast, in animals which were treated with similar amounts of DEET for 5 days without exposure to the sun no effects were seen. In the opinion of this reviewer, the reported increase in the incidence of the "flaking of epidermis" could not be considered as a severe adverse effects and would not raise a toxicological concern for this product. However, this reviewer does wish the registrant to present a final report which contains all the individual animal data and the means of the amount of the test product sprayed onto each horse in addition to the group means.