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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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APR 18 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: **Prodiamine technical and Prodiamine 75WP; review of additional information submitted by the Registrant.**

Caswell No: 727A
HED Project No: 1-0738
Accession No: 256459

FROM: **Timothy F. McMahon, Ph.D., Toxicologist** 4/15/91
Review Section I, Toxicology Branch II (HFAS)
Health Effects Division (H7509C)

TO: **Eugene Wilson PM 23**
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THRU: **Yiannakis M. Ioannou, Ph.D., Section Head** J.M. Joannou 4/15/91
Review Section I, Toxicology Branch II (HFAS)
Health Effects Division (H7509C)

and

Marcia Van Gemert, Ph.D., Branch Chief Marcia Gemert 4/16/91
Toxicology Branch II (HFAS)
Health Effects Division (H7509C)

Registrant: **Sandoz Crop Protection Corporation**

Action Requested: **Review of the Registrant's response to Agency review of Acute Dermal Irritation Studies with Prodiamine technical and Prodiamine 75WP in Rabbits.**

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Conclusions:

In the initial reviews of the registrant's reports, "Irritant Effects on Rabbit Skin of Prodiamine Technical" (HRC report # 84621 D/VCL 51/SE; EPA accession # 256459) and "Irritant Effects on Rabbit Skin of Prodiamine 75WP" (HRC report # 84622 D/VCL 56/SE; EPA accession # 256459), the completeness of the assessment of dermal irritation from application of the test article was questioned, based upon staining of the skin from test article application. No such staining had been reported in either the acute dermal toxicity study or the delayed contact hypersensitivity study with Prodiamine.

In response to this concern, the registrant replied (MRID# 417863-01) that a typographical error was made in section III, Results, of the original DER for Prodiamine technical, and that the terms erythema and edema were transposed. Yellow staining was present in the acute dermal toxicity study with Prodiamine technical (as found from examination of raw data), but as the purpose of this study was assessment of systemic toxicity, no mention was made of this in the final report. In the delayed contact hypersensitivity study with Prodiamine, staining was not observed due to the dilution of the material used in this study (20% w/w in acetone). For the study in question, the registrant agreed that no assessment could be made of dermal irritation immediately after removal of skin patches due to staining. However, the registrant stated that "Should any irritation have been present at the initial examination it is only likely to have been of a very slight (grade 1) level," and that "A well defined erythema (grade 2) would almost certainly have not been completely masked by the yellow color." The registrant commented additionally that at 24 hours and for the remaining time points through 72 hours, scoring for both erythema and edema was zero in this study, thus allowing a Toxicity Category IV classification. This classification was previously assigned in the original reviews.

Based upon the response of the registrant to the concerns raised in the initial reviews of the acute dermal irritation of Prodiamine technical and Prodiamine 75WP, these studies are upgraded from core supplementary to core minimum data.