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OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

MEMORANDUM

SUBJECT: EPA ID# 55947-RUU. Prodiamine (Barricade® F Herbicide). Need for nitrosamine analysis. DP Barcode D180860. CB# 10269.

FROM: Richard Loranger, Ph.D., Branch Senior Scientist  
Chemistry Branch Tolerance Support  
Health Effects Division (H7509C)

*R. Loranger*

THRU: Debra Edwards, Ph.D., Acting Chief  
Chemistry Branch Tolerance Support  
Health Effects Division (H7509C)

*Debra Edwards*  
*9/16/92*

TO: Joanne Miller/Eugene Wilson, PM Team 23  
Fungicide Herbicide Branch  
Registration Division (H7505C)

In a letter dated 7/7/92 Sandoz Agro, Inc. has submitted an argument against the need for nitrosamine data to support registration of their product Barricade F Herbicide containing 2.0% of the active ingredient prodiamine [ $N^3, N^3$ -di-n-propyl-2,4-dinitro-6-(trifluoromethyl)-m-phenylenediamine] and assorted fertilizers. We are somewhat perplexed by this request in that nitrosamine data have been submitted and reviewed (K. Dockter, 8/13/92) and the product apparently has been conditionally registered. Nevertheless, since registration of similar prodiamine/fertilizer products is likely to be submitted in the future, we will review the submitted argument as to its applicability to such products.

The key points of Sandoz' argument are summarized below.

1. The source of prodiamine in Barricade F is Barricade 65 MC, stated to be chemically identical to Barricade 65 WG. Nitrosamine data have been submitted to and accepted by the Agency for Barricade 65 WG that had been in storage for six months. These data showed no detectable (<0.04 ppm) levels of nitrosodipropylamine (NDPA) in the stored 65% ai product. [We concur with this statement. This nitrosamine analysis was reviewed by K. Dockter (12/9/91), who concluded that no detectable NDPA was present in the Barricade 65 WG.]

2. Barricade F is formulated by mechanically mixing the 65% prodiamine formulation with the granular fertilizer ingredients. The Barricade 65 MC component remains largely intact such that its chemical behavior should not be altered significantly. To the extent that the micro environment of the Barricade 65 MC is changed, the most pronounced effect will be to dilute the reactants necessary to form nitrosamines. Assuming the nitrosation reaction is first order in amine and second order in the nitrosating agent and that concentrations are diluted 32 fold (i.e., 65% ai in Barricade 65 MC down to 2% ai in Barricade F), the reaction rate will be slowed  $32 \times 32^2 = 32,768$  fold relative to that in the Barricade 65 MC.

3. None of the inerts added to the formulation is a nitrosating agent. The nitrogen sources in the fertilizer are urea/formaldehyde condensate, urea, and ammonia. Furthermore, Sandoz claims that the ammonia could act as a scavenger of nitrosating agents.

#### CONCLUSION

Acceptable nitrosamine data showing <0.05 ppm nitrosodipropylamine have been submitted for the Barricade F formulation (K. Dockter, 8/13/92 review). Therefore, the request for a waiver of such data is moot. However, taken in conjunction with the nitrosamine analysis of the Barricade F formulation, the argument presented by Sandoz is reasonable to support waiving the requirement for such analyses of similar end use products of prodiamine. Therefore, nitrosamine analyses will not be required to obtain registrations of granular end use products of prodiamine containing fertilizers provided the following conditions are met:

- (1) The Barricade 65 WG/MC formulation is used as the source of prodiamine.
- (2) The formulation process is solely dry mixing of the Barricade 65 and granular fertilizer ingredients at ambient or typical room temperatures.
- (3) No nitrates, nitrites or other nitrosating agents are added as ingredients of the formulation or packaging.

cc: Circu, RF, Loranger, K. Dockter, Nitrosamine SF, Prodiamine SF  
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