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May 26, 1987

8EHQ-0587-0653

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Document Control Officer (TS-790)  
(Attn.: Section 8(e) Coordinator)  
Office of Toxic Substances  
U. S. Environmental Protection Agency  
401 M Street, S. W.  
Washington, D. C. 20460

Re.: 8EHQ-0287-0653 and FYI-OTS-0187-0527. IRGAFORM® 1266

Dear Sir/Madam:

This letter contains no Confidential Business Information. It is in response to Joseph J. Merenda's letter of April 17, 1987, which we received on April 28, 1987.

Other than those already reported to EPA via the updated Material Safety Data Sheet, CIBA-GEIGY Corporation has no additional toxicity or exposure studies for IRGAFORM 1266, nor are any such studies in progress or planned.

The Company's rationale as to why the findings contained in FYI-OTS-0187-0527 were not reported formally under TSCA Section 8(e) centers on the fact that the 10 line "FLASH REPORT" was considered inconclusive to reasonably support that IRGAFORM 1266 presented a substantial risk of injury to health or the environment. The "FLASH REPORT" did not contain pivotal information necessary to make an informed review of this chemical, which is structurally related to phenidone. The Company's rationale, in brief, is as follows:

The related compound, phenidone, produced similar reproductive and blood abnormalities but also caused significant decreases in body weight and food consumption, which made it uncertain whether the effects were truly compound related. In the 1984 review of the 8(e) submission of phenidone, EPA stated "the reported adverse effects are most probably real (treatment related) in that they were dose related" (emphasis added). However, the Agency also recognized the existence of a confounding factor as evidenced by the following statement: "It is not clear that these changes were direct toxic effects or resulted from impaired nutrition (either general malnutrition from decreased food consumption or local impairment of nutrition of stored spermatozoa as the result of damage to the epididymides)" (emphasis added).

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The "FLASH REPORT" on IRGAFORM 1266 indicated that the male reproductive effects occurred in the high dose group only (were not dose-related) and no information was given about the general health of rats in the high dose group (body weight, food consumption, or mortality). We were uncertain, therefore, as to whether these effects were due to a direct action of the test compound or were attributable to general toxicity in the high dose group resulting in malnutrition and significant weight reductions. Therefore, we considered it necessary to await the final report, which was targeted for completion in about a month, in order to determine the significance of the observations. The "FLASH REPORT" on IRGAFORM 1266, which was the only information in our possession at the time of our initial FYI submission, was insufficient to make a judgment relative to an 8(e) reporting obligation. We therefore decided to voluntarily submit this preliminary information as an FYI.

Once the final report containing the complete data was received and evaluated, it was concluded that the male reproductive effects were not related to a general systemic toxicity or malnutrition, and appeared to be a direct, specific effect. At this time, the final report was submitted under Section 8(e).

CIBA-GEIGY Corporation feels it acted prudently and responsibly in this matter and believes its initial reporting of the information as FYI, and subsequently under 8(e), is evidence of its good faith and diligence in reporting substantial risk information to the Agency in a timely manner.

Very truly yours,

*a. Di Battista*

Anthony Di Battista  
Manager, Toxic Substances Compliance  
Safety, Health & Ecology

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