002336

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

MEMORANDUM

12/15/82

TO: William Miller (16)
Registration Division (TS-767)

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

THRU: Orville E. Paynter, Ph.D.
Chief, Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Comments on the responses of Monogram Industries, Inc., in their letter (Accession No. 247945) dated July 13, 1982, to William Miller regarding the registration of "No-Go", Reg. No. 45987-R CASWELL Nos.: 526 & ~~1326~~ 1328

These comments refer to the sponsor's responses to a Toxicology Branch memo of 11/12/81 as identified in the above-mentioned letter.

A. Toxicology Responses

Company Response: (1) This response states that the product studied by Bio-Technics Laboratories as Monogram Animal Repellant No. 100 was later assigned the trademark "No-Go" and is the same product described in their application for registration.

Tox Reply: This explanation is accepted as adequately documenting that the product tested in toxicology studies was the same as that for which registration was requested. Consequently, classification of each submitted test is changed to Core-Minimum.

Company Response: (2) This response includes three report changes (on Pages 41, 44 and 58) and refers to a cover letter from Bio-Technics Laboratories dated February 19, 1982, which accompanied their revised testing report to Monogram Industries, Inc. Changes to the test report are discussed in (3) and (4), below, and will not be addressed here.

This response also referred to the cover letter dated 2/19/82, mentioned in the paragraph immediately above, for an explanation to a Toxicology Branch statement regarding test observations, which questioned why all skin responses were graded as completely negative although histopathologic evaluation of skin sections revealed the presence of acute inflammation and focal purulent crusting, both of which should have been obvious upon gross examination.

Tox Reply: The explanation in the cover letter that "the technician performing the test saw minor physical trauma from the wrappings in both the test and control animals, which he considered not test related", does not address failure of the observer in the test to note what should have been obvious skin reactions.

Company Response: (3) This response indicates that the revised test report states on Page 58 that the dose for the dermal irritation test was 0.5 gm, rather than 0.5 ml.

Tox Reply: This change is appropriate and the dosage is now correctly stated.

Company Response: (4) This response indicates that on Page 41 of the revised test report, the reader is referred to the Appendix, Page 44, for the particle size distribution of the material tested in the acute inhalation toxicity test.

Tox Reply: Inclusion of this information in the revised report is acknowledged.

This information reveals that only 31.1% of the particles were 10 u and below in size, thus indicating that about 70% of the test material particles were not of respirable size.

Summary:

Replies are made to Toxicology Responses 1, 2, 3 and 4 as stated by Monogram Industries, Inc., in their letter of July 13, 1982 to William Miller. Toxicity testing of their product "No-Go" is now accepted and the tests reviewed in a Toxicology Branch memo of 11/12/81 are reclassified as Core-Minimum.

12/8/82

Winnie Teeters

Winnie Teeters, Ph.D. 12/15/82
Toxicology Branch
Hazard Evaluation Division (TS-769)