UNITED STATES ENVIRONMENTAL PROTECTION AGENCY # 849 A

001970

DATE: 8 MAY 1977

SUBJECT: Arbotect 20 S and S
Reg. No. 618-II and IO Thiabendazole

FROM: Toxicology Branch

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TO: PM, Dr. E. Wilson

Registrant states in his letter of December 16, 1976 that Arbotect 20 S is the same formulation as TK-100 (Reg. No. 618-81). The TK-100 has the following composition:

| | | |
|---|---|---|
| Active: | Thiabendazole | 20% |
| [redacted] | | |

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Toxicity Review

1. Oral $LD_{50}$: Wells Laboratory Report D-4293 September 10, 1970.

10 rats per dose level (mixed sex), 5 dose levels (4.0, 5.0, 5.2, 5.6 and 7.0 grams/kg) were given by gavage. The $LD_{50}$ was determined to be 5.3 g/kg with 95% confidence limits from 5.1 to 5.5 g/kg. The slope of the mortality curve was 1.8.

Conclusion: This study at present is invalid since substance identification is incomplete. Substance is identified as MPXP-37 and not as TK-100. This study can be elevated to a core guideline study once substance identification is made.

2. Dermal $LD_{50}$ (rabbits): Wells Lab. Report D-4296 Sept. 10, 1970

4 animals (sex not specified) were exposed per dose level (5, 10, and 20 g/kg), skin was abraded. No deaths occurred, no toxic signs other than local skin reactions were observed over the 2 week period. The dermal $LD_{50}$ is greater than 20 g/kg.

Conclusion: This study is invalid since substance identification is incomplete. Substance is identified as Metasol MPXP-37, not as TX-100. This study will qualify as core minimal data after substance identification is complete.

Note: Study F-374 is not reviewed since a powder was used in that study.

EPA Form 1320-6 (Rev. 6-72)

3. Eye Irritation: Wells Lab. report No. F-370
October 19, 1973.

0.1 ml TX-100 Formulation was instilled in the eyes of six rabbits. The Draize irritation score was 0.0 in all eyes.

Conclusion: This study qualifies as core data even though no eye washings were carried out the zero irritation by a liquid formulation makes eye washing unnecessary.

Note: This is a perfect example of zero eye irritation by a solution with a pH of less than 2.0.

4. Dermal Irritation: Wells Lab. Report F-369
October 15, 1973.

TX-100 formulation was tested on 6 rabbits (abraded and unabraded skin). The method is referenced, USDA-FIFRA, CFR 7 part 362.3 (c). No irritation was observed, score 0.0.

Conclusion: This study is classified as core data.

Conclusion: *

Register Arbotect 20 S and Arbotect S after written assurance is obtained that the MPXP-37 formulation is identical to TX-100 and thus identical to Arbotect 20 S.

After this assurance is obtained the Oral $LD_{50}$, Dermal $LD_{50}$, and skin and eye irritation studies reviewed above all qualify as either core or core minimal data. These studies furthermore, support the registration and reregistration of the TX-100 formulation, with respect to acute toxicity requirements.

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Toxicology Branch
Registration Division

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* With letter of May 26, 1977 registrant stated that theMPXP-37, the TX-100 and the Arbotect 20S formulations are all identical; thus the studies submitted are all aceeptable and support the registration of Arbotect 20 S

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