MEMORANDUM:


FROM: William L. Anthony, Chemist Special Review Section II Chemical Branch II - Reregistration Support Health Effects Division [H7509C]

THRU: Francis B. Suhre, Section Head Special Review Section II Chemical Branch II - Reregistration Support Health Effects Division [H7509C]

TO: Venus Eagle, PM #71 Reregistration Branch Special Review & Reregistration Division [H7505C]

Atrazine is a List A Chemical. A Registration Standard and FRSTR were issued for atrazine on 9/85 and 10/88, respectively. The following product chemistry data were submitted under MRID #420-948-01:

Series 61: PRODUCT CHEMISTRY AND COMPOSITION
§61-3 Discussion of the Formation of Impurities

Series 62: ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS
§62-1 Preliminary analysis of Product Samples
§62-2 Certification of Ingredient Limits
§62-3 Analytical Methods to Verify Certified Limits

These data were submitted by OXON ITALIA S.p.A., Milano, Italia for their technical atrazine [EPA Reg. #35915-6].

§61-3 Discussion of Formation of Impurities.

See CONFIDENTIAL APPENDIX A for registrants comments on the
unlikelihood of nitrosamine and dioxin formation in their technical product. The potential formation of impurities other than nitrosamines and dioxins were not discussed.

Series 62: ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

§62-1 Preliminary Analysis of Product Samples
§62-3 Analysis Methods to verify Certified Limits

See CONFIDENTIAL APPENDIX B for registrants analysis of their atrazine batches.

§62-2 Certification of Ingredient Limits

A signed Certified Statement of Formula [Form OMB #2070-0060] was submitted by the Registrant. However, the upper and lower certified limits for each active ingredient and the upper certified limit for each impurity was not included in the form.

CONCLUSIONS

(1) Data provided in MRID #420-948-01 do not fulfill the requirements for Product Chemistry Guideline §61-3 [Discussion of Formation of Impurities]. Potential formation of impurities other than nitrosamines and dioxins were not discussed.

(2) Data provided in MRID #420-948-01 do not fulfill the requirements for §62-1 [Preliminary Analysis of Product Samples] and §62-3 [Analytical Methods to Verify Certified Limits]. The submission did not include a description of the analytical procedures used for determining several components of the technical grade active ingredient nor were experimental data (chromatograms, recoveries, etc.) provided in support of tabulated results. Information (including new data) must be submitted which shows all the impurities >01% in the TGAI, and which demonstrates closure. (Total percentage of identified components for each batch of the TGAI analyzed.)

(3) Date provided in MRID #420-948-01 do not fulfill the requirements for §62-2 [Certification of Ingredient Limits] because the upper and lower certified limits for each active ingredient and the upper maximum limit for each impurity detected in the technical grade product were not included in the certified Confidental Statement of Formula.

CC: With Confidential Appendix; RF;SF[atrazine];Reviewer; By std Update,
CC: Without Confidential Appendix: Circulation
RDI: FBS,4/16/92;MM,4/20/92;EZ,4/21/92.
H7509CX: WLA;wla;CM-2,Rm 812;X305-6309;4/21/92.
The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product impurities.
- Description of the product manufacturing process.
- Description of quality control procedures.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) ________.
- The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.