8EHQ-0295-13331

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February 6, 1995

(A)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
P 253 155 587

OPPT Document Processing Center (7407)
ATTN: Section 8(e) Coordinator
Office of Pollution Prevention and Toxics (OPPT)
US Environmental Protection Agency
Washington, DC 20460

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RECEIVED

RE: TSCA Section 8(e) Notice

COMPANY SANITIZED

Dear Sir or Madam:

This notice is being submitted by Rhône-Poulenc Ag Company (RPAC) to the Environmental Protection Agency (EPA) in accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), 15 USC § 2607 (e).

We are submitting the results of a Chernoff-Kavlock assay on . Only limited quantities of this compound have been synthesized for research and development purposes.

RPAC claims the alpha-numeric designation and the specific chemical identity of the substance at issue to be confidential business information (CBI). The chemical substance may be nonconfidentially identified as a "heterocycle".

In the Chernoff-Kavlock assay, pregnant CD-1 mice (20 females/group) are dosed by gavage on gestation days 6 through 13, inclusive. Mice are allowed to litter naturally, and pup viability and growth is observed on postnatal days 1 through 4. For , no evidence of maternal or pup toxicity was noted at doses of 100 or 500 mg/kg/day. However, pup weights for females in the 500 mg/kg/day group were statistically lower than control on postnatal day 1 (1.44 g compared to a control of 1.49 g) but comparable to control on postnatal day 4. On postnatal day 4, pup weights for females in the 100 mg/kg/day were statistically higher than control (2.52 g compared to a control of 2.35 g).

SUPPORT INFORMATION OF CONFIDENTIALITY CLAIMS

1. Claims of confidentiality are being made on behalf of RPAC.

2. RPAC asserts this claim of confidentiality until such time as a specific chemical is approved for use in the United States. In the event that the chemical is never approved, RPAC asserts that the CBI information should be provided permanent protection. The structure and

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use of the chemical are unique. Disclosure of this information would provide our competitors with information on facets of our business that would be detrimental to our competitive position.

3. The information claimed as confidential has not been previously disclosed to any other governmental agency or to EPA.

4. This information has been disclosed to only a very limited number of investigators outside of RPAC who have performed either toxicity or efficacy testing. These individuals operate under a strict secrecy agreement. Any individuals who may work with the chemical will have all health/toxicology information disclosed to them as well, but only on the basis of strict secrecy and respect for the CBI nature of the information.

5. Any individuals to whom the CBI is revealed are warned of the nature of the information. Further, they are informed of their obligations to maintain secrecy should they terminate their employment with RPAC.

6. None of the information claimed as confidential appears in or is referred to in any advertising or promotional materials for the chemical or the end product containing it, professional or trade publications, or any other media available to the public or to our competitors. Appropriate warnings do appear on safety data sheets, as RPAC considers that individuals who are requested to work with the chemicals have every right to know as much about the chemicals' toxicity as possible. Further, the information is only considered to be CBI with respect to the general public, insofar as our competitors could use the information in an unfairly competitive nature.

7. No previous confidentiality determinations have been made by EPA, other Federal agencies or courts in connection with this information.

8. RPAC believes that disclosure of this information to the general public would be likely to result in substantial harm to its competitive position. Disclosure of the **alpha numeric designation** and **chemical name** would provide some competitors with information about the specific chemistry of this area of our research and our business. Further, the type of toxicological testing being reported in the TSCA 8(e) notice would provide competitive information about this chemical's status in the research and development process and, therefore, the time remaining until commercialization.

9. A patent has not been issued for the specific chemical structure. However, the generic chemical structure is covered by a patent that is currently pending.

10. The chemical is not available commercially. It is in the earliest stages of research and development for pesticide use and is unlikely to be developed into a commercial product.

11. We believe that disclosure of the chemical name would allow a competitor to synthesize this chemical. RPAC has invested a large amount of time and money into research of this particular chemical family, and information on specific chemical structures would harm our competitive position.

12. Disclosure of the chemical structure might reveal information on processes used to synthesize this compound.

13. CAS number has not yet been assigned.

14. Currently, the chemical is not the subject of FIFRA regulation or reporting.

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Further questions regarding this submission may be directed to the undersigned at 919-549-2222.

Sincerely,

Glenn S. Simon

Glenn S. Simon, PhD, DABT
Director of Toxicology