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October 29, 1992

Document Processing Center (TS-790)
Office of Toxic Substances
US Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP ID No.: 8ECAP - 0004

Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc. (RPI, CN 5266, Princeton, NJ 08543-5266) and its subsidiary Rhône-Poulenc Ag Company (RPAC), the following information is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for a TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA. This information is from one of the twenty studies identified in Attachment 1 of RPI's CAP Agreement with EPA, and thus, no copies of the report are enclosed as per Unit II.A.4 of the CAP Agreement.

This letter provides information on M&B 46030 and . The CAS number and chemical index name for M&B 46030 are 120068-37-3 and 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile. The CAS number and chemical index name for are

. These chemicals are manufactured in Europe and imported by RPAC for pesticide research and development.

No claims of confidentiality are made for M&B 46030 in this submission. Please note that RPAC released previous confidentiality claims for M&B 46030 on September 8, 1992. However, RPAC claims the alpha-numeric designation, the CAS number, and the specific chemical identity of as confidential business information (CBI). may be identified confidentially as a "heterocycle". The title of the report is "M&B 46030 and : Preliminary Teratology Study in the Rabbit". The following is a summary of the adverse effects observed in this study.

This study is being submitted under Section 8(e) because of the observed clinical signs of toxicity. M&B 46030 was administered by gavage to artificially inseminated New Zealand White Rabbits at doses of 4, 10, or 20 mg/kg/day. was administered by gavage to artificially inseminated New Zealand White Rabbits at dosages of 4, 10, or 50 mg/kg/day.

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Animals were dosed on days 6 through 19 of gestation. The general condition of the animals was markedly impaired by treatment, and all animals in all groups were terminated. Treatment-related clinical signs included increased respiration rate, ataxia or uncoordinated movement, lethargy, tremor, convulsions, and reduced fecal output. In addition, females in all groups exhibited marked weight loss.

The results with M&B 46030 in this study were previously reported to EPA under Section 8(e) on January 15, 1991 (EPA Document Control Number: 8EHQ-0191-1162S). The results for were submitted under Section 8(e) on November 27, 1991 (EPA Document Control Number 8EHQ-1291-1824S). The report was submitted to EPA on November 27, 1991. Although both compounds were tested in the same study, we became aware of the results on each compound at different times, and thus, two different TSCA Section 8(e) submissions were made. Six other TSCA Section 8(e) notices have been submitted on M&B 46030. The EPA Document Control Numbers for these submissions are 8EHQ-0391-1199S, 8EHQ-0591-1232S, 8EHQ-0791-1284S, 8EHQ-0791-1285S, 8EHQ-0891-1315S, and 8EHQ-0392-2540S. Also several Section 8(e) notices will be submitted on this compound under the CAP.

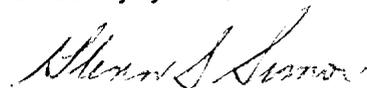
SUPPORT INFORMATION OF CONFIDENTIALITY CLAIMS FOR ONLY

1. Claims of confidentiality are being made on behalf of RPAC.
2. RPAC asserts this claim of confidentiality until such time as the chemical is approved for use in the United States. In the event that this chemical is never approved, RPAC asserts that the CBI information should be provided permanent protection. The structure and use of this 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 this 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 individual 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 this chemical have every right to know as much about the chemical's 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, chemical name, and CAS number** 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 this specific chemical structure. However, the generic chemical structure is covered by a patent that is currently pending.
10. This 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 and manufacture this compound.
13. The CAS number for this chemical is provided in the first page of this letter. This number is claimed as confidential as it provides access to the chemical name.
14. Currently, this chemical is not the subject of FIFRA regulation or reporting.
15. RPAC is not claiming "health and safety data" as CBI. Rather, we are claiming the exact chemical name as CBI.

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

Sincerely yours,



Glenn S. Simon, PhD, DABT
Director of Toxicology