

8EHQ-0801-14950
Procter & Gamble

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8EHQ-01-14950

Document Control Office (7407)
Room G99 East Towner Attn: Section 8(e)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Contain NO CBI

RE: TSCA Section 8(e) Submission 8EHQ-0601-14950A

Dear Mr. Hefter,

This responds to your request for further information on 8EHQ-0601-14950A.

P&G filed a FIFRA section 3 registration on the test mixture. In response to our registration application, EPA's Office of Pesticide Programs required a 21-day dermal toxicity study. We conducted the study and have received the draft report. The draft report was the subject of 8EHQ-0601-14950A. This study on the test mixture will be submitted to the US EPA, Office of Pesticide Programs upon receipt of the final report.

As we noted in our submission of June 6, several observations from this study lead us to conclude that the grip strength changes observed in the study are not biologically significant or test article related. The changes seen in the treated groups are small relative to control and there is a lack of a dose-response relationship. Furthermore, there were no significant differences for any other clinical observations and no neuropathology observed in the test groups.

EPA has requested information regarding exposures to the test material which was the subject of 8EHQ-0601-14950A. The test mixture is not available commercially. Exposures to the test mixture are those which occur as part of the R&D development of the mixture. The R&D exposures to the test mixture employed standard safe handling practices, as are followed when working with all chemical substances. Hazard information is communicated during the R&D process.

The following responds to EPA request for CBI substantiation.

1. Procter & Gamble is asserting the claim of CBI on its own behalf.
2. We request EPA maintain the CBI information in TSCA 8(e) submission 8EHG-0601-14950A for an indefinite period. We choose this timeframe for CBI coverage because we are not able to define a point in time when the information claimed CBI would be disclosed to the public.
3. The confidential compositional information in 8EHG-0601-14950A has been previously disclosed to EPA as part of a FIFRA section 3 registration as noted above. The compositional information was also shared with the California EPA. Both of these disclosures were protected by a claim of confidentiality.
4. To protect the confidentiality of CBI information, security precautions have been taken to restrict access to information on a need-to-know basis. Other than the disclosures to US EPA, Office of Pesticide Programs and California EPA (both with confidentiality protection), the compositional information claimed CBI has not been shared outside the Company. Within the company, the making process and formulation are highly safeguarded both physically and through procedure. The exact formulation and process are contained in password-encoded systems or in locked and secured files that limit access without specific credentials and a need-to-know. Formulations within R&D are also considered confidential and not shared widely within the company or between R&D organizations.



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5. Outside of the disclosures noted in #3 above, we have not disclosed the CBI information in 8EHG-0601-14950A to others.
6. None of the CBI information within this TSCA 8(e) submission has been disclosed through promotional materials, advertising, professional or trade publications, or any other media or publications. The MSDS does not disclose the CBI information. The test substance is not for sale.
7. As far as we are aware, there have been no confidentiality determinations made by EPA, another federal agency, or a court regarding the CBI information in 8EHG-0601-14950A.
8. Disclosure of the CBI information in 8EHQ-0601-14950A, which includes making process and exact formulation of the test material, would substantially harm our competitive position within the marketplace by allowing competitors to see our potential breakthroughs in the research and development, processing and production of this formulation. We have invested several person-years of effort to develop the test mixture's composition and making process. Because of the long timeframes associated with registering FIFRA products, disclosure of the CBI information would provide our competitors a substantial advantage and shorten their time necessary to respond to the marketing of a FIFRA product such as the test mixture by several years.
9. The CBI information in 8EHQ-0601-14950A has not been disclosed via patents.
10. The test mixture is not available commercially. This formulation is currently an R&D material and has not been marketed. Potential marketing decisions are not complete at this time since sale of this formulation requires further registration procedures with state authorities. We would estimate the test mixture would not be marketed for at least a year, if at all.
11. The test mixture is not available to a competitor so it could not be reverse engineered. In addition, because of the complexity of the processing operations and the complex identity of some ingredients contained within the test mixture, we do not believe a competitor could identically recreate the test mixture without the CBI information in 8EHQ-0601-14950A.
12. Disclosure of the CBI information would disclose confidential processes used to manufacture the test substance and the identity and proportions of mixture components. We do not believe the information claimed CBI is related to the human health or environmental effects.
13. The test material is a mixture and does not have a Chemical Abstract Service Registry Number.
14. The confidential compositional information in 8EHQ-0601-14950A was described via a FIFRA section 3 registration and was accompanied by a claim of confidentiality.

If you wish further information, please contact me.

Very truly yours,

THE PROCTER AND GAMBLE COMPANY



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