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**TSCA NON-CONFIDENTIAL BUSINESS INFORMATION**

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Givaudan<sup>®</sup>

March 11, 2011

Via email and USPS

Matthew G. Leopard, Director  
Information Management Division  
USEPA Headquarters  
Ariel Rios Building  
1200 Pennsylvania Avenue, N. W.  
**Mail Code:** 7407M  
Washington, DC 20460



Re: Withdrawal of Confidentiality Claims

Dear Mr. Leopard,

We are writing in response to three letters from you dated February 8, 2011 regarding claims of confidentiality for the identity of five chemical substances that were the subject of reports under Section 8(e) of the Toxic Substances Control Act ("TSCA") dated March 27, 2006, July 1, 2008, and April 21 and May 19, 2009. Givaudan hereby withdraws all claims of confidentiality made with respect to the Section 8(e) reports in question. This withdrawal relates only to the five reports referenced in your letters, not to any other submission that Givaudan may have made under TSCA.

Please note this withdrawal of confidentiality is intended only to allow EPA to reveal to the public the information that was claimed confidential at the time of the reports in question. Givaudan is not relinquishing any property rights in the studies in question.

If you have any questions regarding this letter, please contact our counsel, Thomas B. Johnston, McKenna Long & Aldridge LLP, at (202) 496-7656.

Sincerely,

Greg Adamson, Ph.D.  
Vice President Regulatory Affairs & Product Safety  
Givaudan Fragrances Corporation

cc: Mr. Scott M. Sherlock (OPPTS)  
Mr. Ryan Wallace (OPPTS)



**TSCA CONFIDENTIAL  
BUSINESS INFORMATION  
- DOES NOT CONTAIN NATIONAL  
SECURITY INFORMATION (E.O. 12065)**

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09 MAY 21 AM 10:00  
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OPTIC CTR

May 19, 2009



Via Courier

~~CONTAINS TSCA CONFIDENTIAL  
BUSINESS INFORMATION~~ RPW

TSCA Confidential Business Information Center (7407M)  
EPA East - Room 6428 Attn: Section 8(e)  
U.S. Environmental Protection Agency  
1201 Constitution Avenue, N.W.  
Washington, DC 20004-3302



**Re: Givaudan Fragrances Corporation; Submission of Preliminary Test Results  
Under Section 8(e) of TSCA for Benzenepropanal,  $\alpha$ -methyl-4-(2-  
methylpropyl)-, CASRN 6658-48-6**

Dear Sir or Madam:

Givaudan Fragrances Corporation (Givaudan) is hereby advising the U.S. Environmental Protection Agency (EPA) of preliminary findings from a feeding study in rats with 3-(4-Isopropylphenyl)-2-methylpropanal, which has Chemical Abstracts Service Registry Number (CASRN) 6658-48-6. This notice is in accord with section 8(e) of the Toxic Substances Control Act (TSCA) as interpreted in *TSCA Section 8(e) Notification of Substantial Risk; Policy Clarification and Reporting Guidance* (68 Fed. Reg. 33,129, Jun. 3, 2003) and *TSCA Section 8(e) Reporting Guidance; Correction, Clarification of Applicability, and Announcement Regarding the Issuance Questions and Answers* (70 Fed. Reg. 2162, Jan. 12, 2005). Providing this information in a timely manner to the Agency is consistent with Givaudan's commitment to product stewardship.

The preliminary presentation of unaudited results from a fourteen-day, oral gavage study in mature male Crl:WI(HAN) rats conducted by the BASF corporation, Ludwigshafen Germany, was made to Givaudan on April 30, 2009. Three groups of five animals per group were dosed with either 1000 mg/kg/day respectively of the test substance, or a positive or negative control. The negative control consisted of only the vehicle, corn oil; the positive control was 50 mg/kg/day of 4-(1,1-dimethylethyl)- $\alpha$ -methylbenzenepropanal, CASRN 80-54-6. Givaudan previously submitted section 8(e) notices reporting testicular effects for the positive control in 1990 and 1991.

The purpose of the subject study was to examine the effects of the test substance on the reproductive organs of male rats. At the start of dosing, the rats weighed on average 290 g. Gross pathology, clinical observations, histopathology of all reproductive organs, including sperm morphology and motility of terminally sacrificed animals were completed. Below, we provide a summary of the preliminary findings presented to Givaudan.

Givaudan Fragrances  
Corporation

717 Ridgedale Avenue East Hanover, NJ 07930  
T 973 576 9500 Audlix 973 576 9300

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There was one animal exposed to the test substance that exhibited reduced size of the seminal vesicles at terminal sacrifice, no other gross macroscopic lesions were noted in any of the animals

At the dose of 1000 mg/kg/day of the test substance all five remaining animals survived the treatment period. All animals exhibited salivation after treatment, and one of five exhibited piloerection after treatment. All animals of the test substance group exhibited treatment-related effects of significant reduction of body weight gain that was on average only 13% of that of the negative controls over the duration of the in life dosing phase. All five animals exhibited significantly ( $P < 0.05$ ) reduced relative organ weights of the cauda epididymus (76% of control). One animal exhibited histopathologic evidence of multifocal degeneration of the testicals although specific cellular involvement was not specified. All animals of the test substance group exhibited significantly reduced sperm count in both those found in the testicles as well as the epididymus. There was also a significantly increased number of sperm with abnormal morphology (92.8% vs 3.5% in negative control animals), and significant reduction in sperm motility (0% motile sperm vs 87% motile in negative controls)

Effects observed in the control groups were as expected. Animals in the positive control group showed effects that were similar to those observed in animals treated with the test substance, although the potency was higher with the positive control (50mg/kg/day). Significant reduction in sperm motility (0% motile in positive controls vs 87% motile in negative control animals), and abnormal morphology (91.7% in positive controls vs 3.5% in negative control animals). There was diffuse testicular degeneration noted upon histopathologic examination of all animals in the positive control group, as well as oligozoospermia in the same animals. Three positive control animals also exhibited spermatogenic granuloma formation. All positive control animals exhibited reduced testicular size but no other gross macroscopic lesions. No adverse observations were made on the reproductive organs of the animals in the negative control group.

Enclosed, please find a copy of this letter with confidential information redacted. In addition we enclose a CBI copy of the answered CBI substantiation questions according to the instructions located in the TSCA section 8(e) website:

<http://www.epa.gov/oppt/tscas8e/pubs/confidentialbusinessinformation.htm>

The completed study report has not been issued to Givaudan. If there are any questions, please do not hesitate to contact me at 973-576-9404.

Sincerely,



Greg Adamson, Ph.D.  
Vice President Regulatory Affairs & Product Safety  
Givaudan Fragrances Corporation

Enclosures

cc: J. Zangaro, Esq.