

8EHQ - 0904 - 15196



# Acetophenone Task Force

1203 Nineteenth Street, N.W., Suite 300  
Washington, D.C. 20036-2401

04 SEP -2 AM 7:25

August 24, 2004

Via Certified Mail

Return Receipt Number 7003 2260 0001 8137 3306

**CONTAINS NO CBI**

Donald J. Rodier  
Acting Chief  
Office of Pollution Prevention and Toxics  
High Production Volume Chemicals Branch  
U.S. Environmental Protection Agency  
Ariel Rios Building; MC 7403M  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460-0001



Re: Toxic Substances Control Act -- Section 8(e)

Dear Mr. Rodier:

This letter responds to your August 11, 2004, letter requesting a copy of the complete report of the Organization for Economic Cooperation and Development (OECD) 422 Combined Repeated Dose Toxicity Study and Reproduction/Developmental Screening Study in Sprague-Dawley Rats with Acetophenone (CAS No. 98-86-2) submitted by the Acetophenone Task Force.<sup>1</sup> We are surprised by your letter and your statement that EPA has not yet received a response to its request for the Task Force to submit a full copy of the report. Indeed, the Task Force responded immediately to EPA's initial request and obtained confirmation from Richard Hefter, EPA, in a July 10, 2003, e-mail that the Task Force did not need to submit the full study report. A copy of that e-mail is appended.

If you have any questions, please call Lynn L. Bergeson, legal counsel to the Task Force, at (202) 557-3801, or e-mail her at lbergeson@lawbc.com.

2004 SEP 15 AM 9:43  
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OPPT/EDD

<sup>1</sup> The Task Force on September 9, 2002, and September 26, 2002, submitted information on this study under TSCA Section 8(e) and submitted the final report for this study on March 5, 2003.



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# Acetophenone Task Force

Donald J. Rodier  
August 24, 2004  
Page 2

Sincerely,  
ACETOPHENONE TASK FORCE

By: William J. Moffatt  
William J. Moffatt  
Chair

Attachment

cc: Acetophenone Task Force (w/attachment) (via e-mail)

FW Acetophenone Task Force.txt

-----Original Message-----

From: Hefter.Richard@epamail.epa.gov [mailto:Hefter.Richard@epamail.epa.gov]  
Sent: Thursday, July 10, 2003 4:37 PM  
To: Lisa Burchi  
Subject: Re: Acetophenone Task Force

Lisa:

At this time we can go with what has been sent in. Since this is a SIDS case we may want to see the full report in the future if we have any questions when we are reviewing the SIDS documents.

Lisa Burchi  
<lurchi@lawbc.co To: Richard  
Hefter/DC/USEPA/US@EPA m> cc:  
Subject: Acetophenone Task Force  
07/02/03 02:37 PM

Rich: As we discussed, appended is the letter from EPA regarding the Acetophenone Task Force's Section 8(e) submission. The Task Force is seeking confirmation that the study report it submitted is sufficient and that the Task Force does not need to provide the full 800 page report.

I hope that this information is helpful. As always, please let me know if you have any questions.

<<TSCA 8(e).pdf>>

Lisa R. Burchi  
BERGESON & CAMPBELL, P.C.  
1203 Nineteenth Street, NW  
Suite 300  
Washington, D.C. 20036-2401  
lburchi@lawbc.com  
(313) 824-0391 (phone)  
(313) 824-0392 (fax)

Please visit our web site at <http://www.lawbc.com>  
Page 1

FW Acetophenone Task Force.txt

This electronic transmission from the law firm of Bergeson & Campbell, P.C. may be highly confidential and subject to legally enforceable privileges. If you are not an addressee, you are strictly prohibited from reading or disclosing it. Please immediately telephone us at (202) 557-3800 or e-mail us at [info@lawbc.com](mailto:info@lawbc.com), and return the transmission to us at once if you are not an addressee.

(See attached file: TSCA 8(e).pdf)

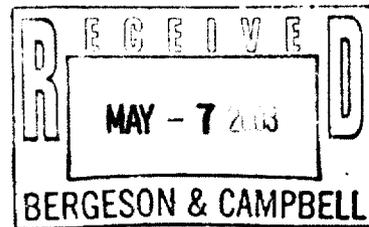


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

May 2, 2003

OFFICE OF  
PREVENTION PESTICIDES AND  
TOXIC SUBSTANCES

Acetophenone Task Force  
Attn: Lynn L. Bergeson  
Legal Counsel  
1203 Nineteenth Street, NW Suite 300  
Washington, DC 20036-2401



SUBJECT: 8EHQ-0303-15196C

Dear TSCA 8(e) Submitter:

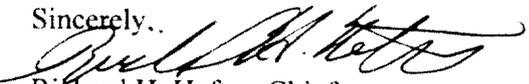
As part of EPA's responsibility to evaluate and publicize TSCA 8(e) submissions, the Office of Pollution Prevention and Toxics conducts preliminary screens of all 8(e)s and routinely requests additional information from submitters to complete this preliminary screen. It is noted that the above referenced 8(e) submission contained only the first 42 pages of a 799-page report. Please submit the remaining pages of this report, which consist of data tables and appendices, or indicate how the public may gain access to the full report.

Enclosed is the first page of your submission and a copy of "Support Information for Confidentiality Claims". Please cite the assigned 8EHQ number and address your response to:

Document Processing Center (7407M)  
EPA East - Room 6428 Attn: Section 8(e)  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW (or 1201 Constitution Avenue, NW for courier service)  
Washington, D.C. 20460-0001

Questions regarding this request should be directed to Mr. Terry O'Bryan of my staff at (202) 564-7656 or email [OBRYAN.TERRY@EPA.GOV](mailto:OBRYAN.TERRY@EPA.GOV)

Sincerely..

  
Richard H. Hefter, Chief  
High Production Volume Chemicals Branch

Enclosures

8EHQ-0303-15196

Acetophenone Task Force

C  
MKT  
264861

1203 Nineteenth Street, N.W., Suite 300  
Washington, D.C. 20036-2481



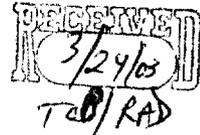
~~Privileged and Confidential~~

Ed. G...  
3/12/03

March 5, 2003

Via Certified Mail  
Return Receipt Number 7002 1000 0005 0845 2695

TSCA Section 8(e) Coordinator  
Document Control Officer (MC-7407)  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460-0001



Re: Toxic Substances Control Act -- Section 8(e)

Dear TSCA Section 8(e) Coordinator:

This letter supplements the September 9, 2002, and September 26, 2002, letters from the Acetophenone Task Force (ATF),<sup>1</sup> c/o Mr. William J. Moffatt, JLM Chemicals, Inc., 3350 West 131st Street, Blue Island, Illinois 60406-2365, to the U.S. Environmental Protection Agency (EPA) regarding its submission, pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA), of preliminary results of an Organization for Economic Cooperation and Development (OECD) ~~22~~ Combined Repeated Dose Toxicity Study and Reproduction/Developmental Screening Study in Sprague-Dawley Rats with Acetophenone (CAS No. 98-86-2). The study was conducted as part of the ATF's sponsorship of acetophenone in the OECD Screening Information Data Set (SIDS) Program and has now been issued in final. Although there is no new information regarding this chemical from this study that is considered to present a substantial risk to human health or the environment under TSCA Section 8(e) that was not already provided in our September 9, 2002, and September 26, 2002, letters, the ATF is submitting to EPA the final version of the study.

RECEIVED  
OFFICE OF  
TOXICS

Contain NO CBI

<sup>1</sup> The ATF is comprised of the following companies: JLM Chemicals, Inc. and Aceto Corporation.

Contain NO CBI

### **Support Information for Confidentiality Claims**

Information submitted under specific reporting requirements of the Toxic Substances Control Act (TSCA), or in support of TSCA, is subject to the provisions of Section 14 of TSCA and to EPA's Regulations on the Confidentiality of Business Information (see 40\*CFR Part 2). You must comply with the following procedures to assert a claim of confidentiality for the information solicited in the letter attaching this statement and the substantiation questions that follow. Failure to follow these procedures fully at the time you submit the information to EPA will be interpreted by the Agency as a waiver of your claim of confidentiality.

#### **Asserting a Claim**

Information claimed as confidential must be clearly marked by boxing, circling or underlining. All pages containing such information should also be stamped "CONFIDENTIAL." Care should be taken to ensure that these markings do not obscure the submission's text.

#### **Sanitized Copy**

Two versions must be filed of any documents submitted to the US EPA containing information claimed as confidential. One copy should be complete, with the information being claimed as confidential marked in the manner described above. The other copy should have all of the information claimed as confidential excised. This version will be placed in EPA's Public Files. See 43 Federal Register, page 1113, titled, "X. Confidentiality Claims," March 16, 1978.

#### **Substantiating claims of Confidentiality**

Detailed written responses to the following questions must be provided to substantiate your confidentiality claim(s). Your responses should be as specific as possible, with examples as appropriate, and should provide substantiation arguments for all types of information (e.g., sales, or production/ importation volumes, chemical identity, company identity) you claim as confidential. EPA must receive a response to these questions within twenty (20) business days of your receipt of this mailing.

### **Substantiation Questions**

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.
2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.
3. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.
4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.
5. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).
6. Does the information claimed as confidential appear or is it referred to in any of the following:
  - a. Advertising or promotional material for the chemical substance or the resulting and product;
  - b. Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale);
  - c. Professional or trade publications; or
  - d. Any other media or publications available to the public or to your competitors.

If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.
7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.

8. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitors access to your customers. Address each piece of information claimed CBI separately.
9. Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?
10. Is this substance/product commercially available and if so, for how long has it been available on the commercial market?
  - a. If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?
  - b. If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established.
  - c. What is the substance used for and what type of product(s) does it appear in.
11. Describe whether a competitor could employ reverse engineering to identically recreate the substance?
12. Do you assert that disclosure of this information you are claiming CBI would reveal:
  - a. confidential processes used in manufacturing the substance;
  - b. if a mixture, the actual portions of the substance in the mixture; or
  - c. information unrelated to the effects of the substance on human health or the environment?

If your answer to any of the above questions is yes, explain how such information would be revealed.
13. Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.
14. Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.