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**USEPA TSCA Section 8(e) CBI Guidance**

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**USEPA Guidance Regarding Confidential Business Information (“CBI”) Claims and TSCA §8(e) Submissions****What can TSCA 8(e) Submitters Claim as “Confidential Business Information” (CBI)?**

Submitters may claim confidentiality for proprietary information within a TSCA 8(e) submission, but should also submit a detailed written explanation to substantiate all confidential business information (CBI) claims. Also, submitters must submit a sanitized copy of the submission (from which confidential information has been deleted) to be placed in the TSCA Public Docket. (See Confidential Business Information - "Support Information for Confidentiality Claims" below.) This guidance is referenced in Part VIII. X. of the June 3, 2003 TSCA 8(e) Guidance.

**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).

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6. Does the information claimed as confidential appear or is it referred to in any of the following:
- Advertising or promotional material for the chemical substance or the resulting and product;
  - 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);
  - Professional or trade publications; or
  - 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?
- If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?
  - 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.
  - 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:
- confidential processes used in manufacturing the substance;
  - if a mixture, the actual portions of the substance in the mixture; or
  - 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.

