

§720.90 Data from health and safety studies.

(a) Information other than specific chemical identity. Except as provided in paragraph (b) of this section, EPA will deny any claim of confidentiality with respect to information included in a health and safety study, unless the information would disclose confidential business information concerning:

(1) Processes used in the manufacture or processing of a chemical substance or mixture.

(2) In the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.

(3) Information which is not in any way related to the effects of a substance on human health or the environment, such as the name of the submitting company, cost or other financial data, product development or marketing plans, and advertising plans, for which the person submits a claim of confidentiality in accordance with §720.80.

(b) Specific chemical identity—(1) Claims applicable to period prior to commencement of manufacture. A claim of confidentiality for the period prior to commencement of manufacture or import for the chemical identity of a chemical substance for which a health and safety study was submitted must be asserted in conjunction with a claim asserted under §720.85(a).

(2) Claims applicable to period after commencement of manufacture or import for commercial purposes. To maintain the confidential status of the chemical identity of a chemical substance for which a health and safety study was submitted after commencement of manufacture or import, the claim must be reasserted and substantiated in conjunction with a claim under §720.85(b). In addition to the questions set forth in §720.85(b)(3)(iv) of this part, the submitter must answer the following questions:

(i) Would disclosure of the chemical identity disclose processes used in the manufacture or processing of a chemical substance or mixture? Describe how this would occur. In responding to the question in §720.85(b)(3)(iv)(A), explain what harmful competitive effects would occur from disclosure of this process information.

(ii) Would disclosure of the chemical identity disclose the portion of a mixture comprised by any of the substances in the mixture? Describe how this would occur. In responding to the question in §720.85(b)(3)(iv)(A), explain what harmful competitive effects would occur from disclosure of this information.

(iii) Do you assert that disclosure of the chemical identity is not necessary to interpret any of the health and safety studies you have submitted? If so, explain how a less specific identity would be sufficient to interpret the studies.

(c) Denial of confidentiality claim. EPA will deny a claim of confidentiality for chemical identity under paragraph (b) of this section, unless:

(1) The information would disclose processes used in the manufacture or processing of a chemical substance or mixture.

(2) In the case of a mixture, the information would disclose the portion of the mixture comprised by any of the substances in the mixture.

(3) The specific chemical identity is not necessary to interpret a health and safety study.

(d) Use of generic names. When EPA discloses a health and safety study containing a specific chemical identity, which the submitter has claimed confidential, and if the Agency has not denied the claim under paragraph (c) of this section, EPA will identify the chemical substance by the generic name selected under §720.85.

https://ecfr.io/Title-40/pt40.33.716#se40.33.716_13

Extracted by GlobalMSDS Ltd

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