
40 C.F.R. § 703.5

Requirements for asserting and maintaining confidentiality claims.

Any person who submits information under TSCA or these implementing regulations may assert a business confidentiality claim to information included in such submission except where such a claim is disallowed by applicable regulation under this subchapter. Such claim must be made concurrent with submission of the information. If no such claim accompanies the submission, EPA will not recognize a confidentiality claim, and the information in or referred to in that submission may be made available to the public (e.g., by publication of specific chemical name and CASRN on the public portion of the TSCA Inventory) without further notice.

(a) *Supporting statement and certification.* (1) A person asserting a confidentiality claim must submit a statement that the person has:

- (i) Taken reasonable measures to protect the confidentiality of the information;
- (ii) Determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (iii) A reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and
- (iv) A reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(2) The person must also certify that these four statements and any information required to substantiate the confidentiality claim in accordance with paragraph (b) of this section are true and correct.

(b) *Substantiation.* (1) Confidentiality claims must be substantiated at the time of submission to EPA, unless exempt under paragraph (b)(5) of this section. In the case of information collected by EPA or on behalf of EPA in person at the site of a TSCA inspection under section 11 of the Act, the affected company must assert its confidentiality claim(s) in writing at the time the information is collected, and then must provide substantiation of its confidentiality claims and the supporting statement and certification described in paragraph (a) of this section within ten business days after the inspection ends. Confidentiality claims lacking required substantiation after ten business days will be treated as deficient under paragraph (e) of this section. Unless otherwise directed by EPA, such information or materials must be submitted via CDX. In the case of an unusually voluminous document collection under section 11 of the Act, the affected company may request additional time to assert claims and provide substantiation, which EPA may grant at its discretion. The inspection is considered to have ended when the inspector physically exits the regulated facility on the last day of the inspection.

(2) Information in substantiations may be claimed as confidential. Such claims must be accompanied by the certification described in paragraph (a) of this section but need not be themselves separately substantiated.

(3) Substantiation questions for all claims. Unless otherwise specified elsewhere in this subchapter (e.g., 40

CFR part 711), answers to the following questions must be provided for each confidentiality claim in a TSCA submission:

(i) Please specifically explain what harm to the competitive position of your business would be likely to result from the release of the information claimed as confidential. How would that harm be *substantial*? Why is the substantial harm to your competitive position *likely* (i.e., probable) to be caused by release of the information rather than just *possible*? If you claimed multiple types of information to be confidential (e.g., site information, exposure information, environmental release information, etc.), explain how disclosure of each type of information would be likely to cause substantial harm to the competitive position of your business.

(ii) Has your business taken precautions to protect the confidentiality of the disclosed information? If yes, please explain and identify the specific measures, including but not limited to internal controls, that your business has taken to protect the information claimed as confidential. If the same or similar information was previously reported to EPA as non-confidential (such as in an earlier version of this submission), please explain the circumstances of that prior submission and reasons for believing the information is nonetheless still confidential.

(iii)

(A) Is any of the information claimed as confidential required to be publicly disclosed under any other Federal law? If yes, please explain.

(B) Does any of the information claimed as confidential otherwise appear in any public documents, including (but not limited to) safety data sheets; advertising or promotional material; professional or trade publications; State, local, or Federal agency files; or any other media or publications available to the general public? If yes, please explain why the information should be treated as confidential. If this chemical is patented and the patent reveals the information you are claiming confidential, please explain your reasons for believing the information is nonetheless still confidential.

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