

Subpart B—Disclosure of Trade Secret Information to Health Professionals

350.40 Disclosure to health professionals.

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Subpart A—Trade Secrecy Claims

§ 350.1 Definitions.

Administrator and *General Counsel* mean the EPA officers or employees occupying the positions so titled.

Business confidentiality or *confidential business information* includes the concept of trade secrecy and other related legal concepts which give (or may give) a business the right to preserve the confidentiality of business information and to limit its use or disclosure by others in order that the business may obtain or retain business advantages it derives from its right in the information. The definition is meant to encompass any concept which authorizes a Federal agency to withhold business information under 5 U.S.C. 552(b)(4), as well as any concept which requires EPA to withhold information from the public for the benefit of a business under 18 U.S.C. 1905.

Chief Executive Officer of the tribe means the person who is recognized by the Bureau of Indian Affairs as the chief elected administrative officer of the tribe.

Claimant means a person submitting a claim of trade secrecy to EPA in connection with a chemical otherwise required to be disclosed in a report or other filing made under Title III.

Commission means the emergency response commission for the State in which the facility is located except where the facility is located in Indian Country, in which case, *commission* means the emergency response commission for the tribe under whose jurisdiction the facility is located. In the absence of an emergency response commission, the Governor and the chief executive officer, respectively, shall be the commission. Where there is a cooperative agreement between a State and a Tribe, the commission shall be the entity identified in the agreement.

Facility means all buildings, equipment, structure, and other stationary items that are located on a single site or on contiguous or adjacent sites and which are owned or operated by the same person (or by any person which controls, is controlled by, or under common control with, such person). *Facility* shall include man-made structures as well as all natural structures in which chemicals are purposefully placed or removed through human means such that it functions as a containment structure for human use. For purposes of emergency release notification, the term includes motor vehicles, rolling stock, and aircraft.

Indian Country means *Indian country* as defined in 18 U.S.C. 1151. That section defines Indian country as:

(a) All land within the limits of any Indian reservation under the jurisdiction of the United States government, notwithstanding the issuance of any patent, and including rights-of-way running through the reservation;

(b) All dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a State; and

(c) All Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same.

Indian tribe means those tribes federally recognized by the Secretary of the Interior.

Local emergency planning committee or *committee* means the local emergency planning committee appointed by the emergency response commission.

Petitioner is any person who submits a petition under this regulation requesting disclosure of a chemical identity claimed as trade secret.

Sanitized means a version of a document from which information claimed as trade secret or confidential has been omitted or withheld.

Senior management official means an official with management responsibility for the person or persons completing the report, or the manager of environmental programs for the facility or establishments, or for the corporation owning or operating the facility or establishments responsible for

certifying similar reports under other environmental regulatory requirements.

Specific chemical identity means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance. Where the trade name is reported in lieu of the specific chemical identity, the trade name will be treated as the specific chemical identity for purposes of this part.

State means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, the Northern Mariana Islands, and any other territory or possession over which the United States has jurisdiction and Indian Country.

Submitter means a person filing a required report or making a claim of trade secrecy to EPA under sections 303 (d)(2) and (d)(3), 311, 312, and 313 of Title III.

Substantiation means the written answers submitted to EPA by a submitter to the specific questions set forth in this regulation in support of a claim that chemical identity is a trade secret.

Title III means Title III of the Superfund Amendments and Reauthorization Act of 1986, also titled the Emergency Planning and Community Right-to-Know Act of 1986.

Trade secrecy claim is a submittal under sections 303 (d)(2) or (d)(3), 311, 312 or 313 of Title III in which a chemical identity is claimed as trade secret, and is accompanied by a substantiation in support of the claim of trade secrecy for chemical identity.

Trade secret means any confidential formula, pattern, process, device, information or compilation of information that is used in a submitter's business, and that gives the submitter an opportunity to obtain an advantage over competitors who do not know or use it. EPA intends to be guided by the Restatement of Torts, Section 757, Comment b.

Unsanitized means a version of a document from which information claimed as trade secret or confidential has not been withheld or omitted.

Working day is any day on which Federal government offices are open for normal business. Saturdays, Sundays, and official Federal holidays are not working days; all other days are.

[53 FR 28801, July 29, 1988, as amended at 55 FR 30644, July 26, 1990]

§350.3 Applicability of subpart; priority where provisions conflict; interaction with 40 CFR part 2.

(a) *Applicability of subpart.* Sections 350.1 through 350.27 establish rules governing assertion of trade secrecy claims for chemical identity information collected under the authority of sections 303 (d)(2) and (d)(3), 311, 312 and 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986, and for trade secrecy or business confidentiality claims for information submitted in a substantiation under sections 303 (d)(2) and (d)(3), 311, 312, and 313 of Title III. This subpart also establishes rules governing petitions from the public requesting the disclosure of chemical identity claimed as trade secret, and determinations by EPA of whether this information is entitled to trade secret treatment. Claims for confidentiality of the location of a hazardous chemical under section 312(d)(2)(F) of Title III are not subject to the requirements of this subpart.

(b) *Priority where provisions conflict.* Where information subject to the requirements of this subpart is also collected under another statutory authority, the confidentiality provisions of that authority shall be used to claim that information as trade secret or confidential when submitting it to EPA under that statutory authority.

(c) *Interaction with 40 CFR part 2, EPA's Freedom of Information Act procedures.* (1) No trade secrecy or business confidentiality claims other than those allowed in this subpart are permitted for information collected under sections 303 (d)(2) and (d)(3), 311, 312 and 313 of Title III.

(2) Except as provided in §350.25 of this subpart, request for access to chemical identities withheld as trade secret under this regulation is solely through this regulation and procedures hereunder, not through EPA's Freedom

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of Information Act procedures set forth at 40 CFR part 2.

(3) Request for access to information other than chemical identity submitted to EPA under this regulation is through EPA's Freedom of Information Act regulations at 40 CFR part 2.

§ 350.5 Assertion of claims of trade secrecy.

(a) A claim of trade secrecy may be made only for the specific chemical identity of an extremely hazardous substance under sections 303 (d)(2) and (d)(3), a hazardous chemical under sections 311 and 312, and a toxic chemical under section 313.

(b) Method of asserting claims of trade secrecy for information submitted under sections 303 (d)(2) and (d)(3).

(1) In submitting information to the local emergency planning committee under sections 303 (d)(2) or (d)(3), the submitter may claim as trade secret the specific chemical identity of any chemical subject to reporting under section 303.

(2) To make a claim, the submitter shall submit to EPA the following:

(i) A copy of the information which is being submitted under sections 303 (d)(2) or (d)(3) to the local emergency planning committee, with the chemical identity or identities claimed trade secret deleted, and the generic class or category of the chemical identity or identities inserted in its place. The method of choosing generic class or category is set forth in paragraph (f) of this section.

(ii) A sanitized and unsanitized substantiation in accordance with §350.7 for each chemical identity claimed as trade secret.

(3) If the submitter wishes to claim information in the substantiation as trade secret or business confidential, it shall do so in accordance with §350.7(d).

(4) Section 303 claims shall be sent to the address specified in §350.16 of this regulation.

(c) Method of asserting claims of trade secrecy for information submitted under section 311.

(1) Submitters may claim as trade secret the specific chemical identity of any chemical subject to reporting under section 311 on the material safe-

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ty data sheet or chemical list under section 311.

(2) To assert a claim for a chemical identity on a material safety data sheet under section 311, the submitter shall submit to EPA the following:

(i) One copy of the material safety data sheet which is being submitted to the State emergency response commission, the local emergency planning committee and the local fire department, which shall make it available to the public. In place of the specific chemical identity claimed as trade secret, the generic class or category of the chemical claimed as trade secret shall be inserted. The method of choosing generic class or category is set forth in paragraph (f) of this section.

(ii) A sanitized and unsanitized substantiation in accordance with §350.7 for every chemical identity claimed as trade secret.

(3) To assert a claim for a chemical identity on a list under section 311, the submitter shall submit to EPA the following:

(i) An unsanitized copy of the chemical list under section 311. The submitter shall clearly indicate the specific chemical identity claimed as trade secret, and shall label it "*Trade Secret.*" The generic class or category of the chemical claimed as trade secret shall be inserted directly below the claimed chemical identity. The method of choosing generic class or category is set forth in paragraph (f) of this section.

(ii) A sanitized copy of the chemical list under section 311. This copy shall be identical to the document in paragraph (c)(3)(i) of this section except that the submitter shall delete the chemical identity claimed as trade secret, leaving in place the generic class or category of the chemical claimed as trade secret. This copy shall be sent by the submitter to the State emergency response commission, the local emergency planning committee and the local fire department, which shall make it available to the public.

(iii) A sanitized and unsanitized substantiation in accordance with §350.7 for every chemical identity claimed as trade secret.

(4) If the submitter wishes to claim information in the substantiation as

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trade secret or business confidential, it shall do so in accordance with § 350.7(d).

(5) Section 311 claims shall be sent to the address specified in § 350.16 of this regulation.

(d) Method of asserting claims of trade secrecy for information submitted under section 312.

(1) Submitters may claim as trade secret the specific chemical identity of any chemical subject to reporting under section 312.

(2) To assert a claim the submitter shall submit to EPA the following:

(i) An unsanitized copy of the Tier II emergency and hazardous chemical inventory form under section 312. (The Tier I emergency and hazardous chemical inventory form does not require the reporting of specific chemical identity and therefore no trade secrecy claims may be made with respect to that form.) The submitter shall clearly indicate the specific chemical identity claimed as trade secret by checking the box marked "trade secret" next to the claimed chemical identity.

(ii) A sanitized copy of the Tier II emergency and hazardous chemical inventory form. This copy shall be identical to the document in paragraph (d)(2)(i) of this section except that the submitter shall delete the chemical identity or identities claimed as trade secret and include instead the generic class or category of the chemical claimed as trade secret. The method of choosing generic class or category is set forth in paragraph (f) of this section. The sanitized copy shall be sent by the submitter to the State emergency response commission, local emergency planning committee or the local fire department, whichever entity requested the information.

(iii) A sanitized and unsanitized substantiation in accordance with § 350.7 for every chemical identity claimed as trade secret.

(3) If the submitter wishes to claim information in the substantiation as trade secret or business confidential, it shall do so in accordance with § 350.7(d).

(4) Section 312 claims shall be sent to the address specified in § 350.16 of this regulation.

(e) Method of asserting claims of trade secrecy for information submitted under section 313.

(1) Submitters may claim as trade secret the specific chemical identity of any chemical subject to reporting under section 313.

(2) To make a claim, the submitter shall submit to EPA the following:

(i) An unsanitized copy of the toxic release inventory form under section 313 with the information claimed as trade secret clearly identified. To do this, the submitter shall check the box on the form indicating that the chemical identity is being claimed as trade secret. The submitter shall enter the generic class or category that is structurally descriptive of the chemical, as specified in paragraph (f) of this section.

(ii) A sanitized copy of the toxic release inventory form. This copy shall be identical to the document in paragraph (e)(2)(i) of this section except that the submitter shall delete the chemical identity claimed as trade secret. This copy shall also be submitted to the State official or officials designated to receive this information.

(iii) A sanitized and unsanitized substantiation in accordance with § 350.7 for every chemical identity claimed as trade secret.

(3) If the submitter wishes to claim information in the substantiation as trade secret or business confidential, it shall do so in accordance with § 350.7(d).

(4) Section 313 claims shall be sent to the address specified in § 350.16 of this regulation.

(f) Method of choosing generic class or category for sections 303, 311, 312 and 313. A facility owner or operator claiming chemical identity as trade secret should choose a generic class or category for the chemical that is structurally descriptive of the chemical.

(g) If a specific chemical identity is submitted under Title III to EPA, or to a State emergency response commission, designated State agency, local emergency planning committee or local fire department, without asserting a trade secrecy claim, the chemical identity shall be considered to have been voluntarily disclosed, and non-trade secret.

(h) A submitter making a trade secrecy claim under this section shall submit to entities other than EPA (e.g., a designated State agency, local

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emergency planning committee and local fire department) only the sanitized or public copy of the submission and substantiation.

§ 350.7 Substantiating claims of trade secrecy.

(a) Claims of trade secrecy must be substantiated by providing a specific answer including, where applicable, specific facts, to each of the following questions with the submission to which the trade secrecy claim pertains. Submitters must answer these questions on the form entitled “Substantiation to Accompany Claims of Trade Secrecy” in § 350.27 of this subpart.

(1) Describe the specific measures you have taken to safeguard the confidentiality of the chemical identity claimed as trade secret, and indicate whether these measures will continue in the future.

(2) Have you disclosed the information claimed as trade secret to any other person (other than a member of a local emergency planning committee, officer or employee of the United States or a State or local government, or your employee) who is not bound by a confidentiality agreement to refrain from disclosing this trade secret information to others?

(3) List all local, State, and Federal government entities to which you have disclosed the specific chemical identity. For each, indicate whether you asserted a confidentiality claim for the chemical identity and whether the government entity denied that claim.

(4) In order to show the validity of a trade secrecy claim, you must identify your specific use of the chemical claimed as trade secret and explain why it is a secret of interest to competitors. Therefore:

(i) Describe the specific use of the chemical claimed as trade secret, identifying the product or process in which it is used. (If you use the chemical other than as a component of a product or in a manufacturing process, identify the activity where the chemical is used.)

(ii) Has your company or facility identity been linked to the specific chemical identity claimed as trade secret in a patent, or in publications or other information sources available to

the public or your competitors (of which you are aware)? If so, explain why this knowledge does not eliminate the justification for trade secrecy.

(iii) If this use of the chemical claimed as trade secret is unknown outside your company, explain how your competitors could deduce this use from disclosure of the chemical identity together with other information on the Title III submittal form.

(iv) Explain why your use of the chemical claimed as trade secret would be valuable information to your competitors.

(5) Indicate the nature of the harm to your competitive position that would likely result from disclosure of the specific chemical identity, and indicate why such harm would be substantial.

(6)(i) To what extent is the chemical claimed as trade secret available to the public or your competitors in products, articles, or environmental releases?

(ii) Describe the factors which influence the cost of determining the identity of the chemical claimed as trade secret by chemical analysis of the product, article, or waste which contains the chemical (e.g., whether the chemical is in pure form or is mixed with other substances).

(b) The answers to the substantiation questions listed in paragraph (a) of this section are to be submitted on the form in § 350.27 of this subpart, and included with a submitter's trade secret claim.

(c) An owner, operator or senior official with management responsibility shall sign the certification at the end of the form contained in § 350.27. The certification in both the sanitized and unsanitized versions of the substantiation must bear an original signature.

(d) *Claims of confidentiality in the substantiation.* (1) The submitter may claim as confidential any trade secret or confidential business information contained in the substantiation. Such claims for material in the substantiation are not limited to claims of trade secrecy for specific chemical identity, but may also include claims of confidentiality for any confidential business information. To claim this material as confidential, the submitter shall clearly designate those portions of the substantiation to be claimed as

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confidential by marking those portions "Confidential," or "Trade Secret." Information not so marked will be treated as public and may be disclosed without notice to the submitter.

(2) An owner, operator, or senior official with management responsibility shall sign the certification stating that those portions of the substantiation claimed as confidential would, if disclosed, reveal the chemical identity being claimed as a trade secret, or would reveal other confidential business or trade secret information. This certification is combined on the substantiation form in §350.27 with the certification described in paragraph (c) of this section.

(3) The submitter shall submit to EPA two copies of the substantiation, one of which shall be the unsanitized version, and the other shall be the sanitized version.

(i) The unsanitized copy shall contain all of the information claimed as trade secret or business confidential, marked as indicated in paragraph (d)(1) of this section.

(ii) The second copy shall be identical to the unsanitized substantiation except that it will be a sanitized version, in which all of the information claimed as trade secret or confidential shall be deleted. If any of the information claimed as trade secret in the substantiation is the chemical identity which is the subject of the substantiation, the submitter shall include the appropriate generic class or category of the chemical claimed as trade secret. This sanitized copy shall be submitted to the State emergency response commission, a designated State agency, the local emergency planning committee and the local fire department, as appropriate, and made publicly available.

(e) *Supplemental information.* (1) EPA may request supplemental information from the submitter in support of its trade secret claim, pursuant to §350.11(a)(1). EPA may specify the kind of information to be submitted, or the submitter may submit any additional detailed information which further supports the truth of the information previously supplied to EPA in its initial substantiation, under this section.

(2) The submitter may claim as confidential any trade secret or confiden-

tial business information contained in the supplemental information. To claim this material as confidential, the submitter shall clearly designate those portions of the supplemental information to be claimed as confidential by marking those portions "Confidential," or "Trade Secret." Information not so marked will be treated as public and may be disclosed without notice to the submitter.

(3) If portions of the supplementary information are claimed confidential, an owner, operator, or senior official with management responsibility of the submitter shall certify that those portions of the supplemental information claimed as confidential would, if disclosed, reveal the chemical identity being claimed as confidential or would reveal other confidential business or trade secret information.

(4) If supplemental information is requested by EPA and the submitter claims portions of it as trade secret or confidential, then the submitter shall submit to EPA two copies of the supplemental information, an unsanitized and a sanitized version.

(i) The unsanitized version shall contain all of the information claimed as trade secret or business confidential, marked as indicated above in paragraph (e)(2) of this section.

(ii) The second copy shall be identical to the unsanitized substantiation except that it will be a sanitized version, in which all of the information claimed as trade secret or confidential shall be deleted. If any of the information claimed as trade secret in the supplemental information is the chemical identity which is the subject of the substantiation, the submitter shall include the appropriate generic class or category of the chemical claimed as trade secret.

§ 350.9 Initial action by EPA.

(a) When a claim of trade secrecy, made in accordance with §350.5 of this part, is received by EPA, that information is treated as confidential until a contrary determination is made.

(b) A determination as to the validity of a trade secrecy claim shall be initiated upon receipt by EPA of a petition under §350.15 or may be initiated at

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any time by EPA if EPA desires to determine whether chemical identity information claimed as trade secret is entitled to trade secret treatment, even though no request for release of the information has been received.

(c) If EPA initiates a determination as to the validity of a trade secrecy claim, the procedures set forth in §§ 350.11, 350.15, and 350.17 shall be followed in making the determination.

(d) When EPA receives a petition requesting disclosure of trade secret chemical identity or if EPA decides to initiate a determination of the validity of a trade secrecy claim for chemical identity, EPA shall first make a determination that the chemical identity claimed as trade secret is not the subject of a prior trade secret determination by EPA concerning the same submitter and facility, or if it is, that the prior determination upheld the submitter's claim of trade secrecy for that chemical identity at that facility.

(1) If EPA determines that the chemical identity claimed as trade secret is not the subject of a prior trade secret determination by EPA concerning the same submitter and the same facility, or if it is, that the prior determination upheld the submitter's claim of trade secrecy, then EPA shall review the submitter's claim according to § 350.11.

(2) If such a prior determination held that the submitter's claim for that chemical identity is invalid, and such determination was not challenged by appeal to the General Counsel, or by review in the District Court, or, if challenged, was upheld, EPA shall notify the submitter by certified mail (return receipt requested) that the chemical identity claimed as trade secret is the subject of a prior, final Agency determination concerning the same facility in which it was held that such a claim was invalid. In this notification EPA shall include notice of intent to disclose chemical identity within 10 days pursuant to § 350.18(c) of this subpart. EPA shall also notify the petitioner by regular mail of the action taken pursuant to this section.

§ 350.11 Review of claim.

(a) *Determination of sufficiency.* When EPA receives a petition submitted pursuant to § 350.15, or if EPA initiates a

determination of the validity of a trade secrecy claim for chemical identity, and EPA has made a determination, as required in paragraph (d)(1) of § 350.9, then EPA shall determine whether the submitter has presented sufficient support for its claim of trade secrecy in its substantiation. EPA must make such a determination within 30 days of receipt of a petition. A claim of trade secrecy for chemical identity will be considered sufficient if, assuming all of the information presented in the substantiation is true, this supporting information could support a valid claim of trade secrecy. A claim is sufficient if it meets the criteria set forth in § 350.13.

(1) *Sufficient claim.* If the claim meets the criteria of sufficiency set forth in § 350.13, EPA shall notify the submitter in writing, by certified mail (return receipt requested), that it has 30 days from the date of receipt of the notice to submit supplemental information in writing in accordance with § 350.7(e), to support the truth of the facts asserted in the substantiation. EPA will not accept any supplemental information, in response to this notice, submitted after the 30 day period has expired. The notice required by this section shall include the address to which supplemental information must be sent. The notice may specifically request supplemental information in particular areas relating to the submitter's claim. The notice must also inform the submitter of his right to claim any trade secret or confidential business information as confidential, and shall include a reference to § 350.7(e) of this regulation as the source for the proper procedure for claiming trade secrecy for trade secret or confidential business information submitted in the supplemental information requested by EPA.

(2) *Insufficient claim.* If the claim does not meet the criteria of sufficiency set forth in § 350.13, EPA shall notify the submitter in writing of this fact by certified mail (return receipt requested). Upon receipt of this notice, the submitter may either file an appeal of the matter to the General Counsel under paragraph (a)(2)(i) of this section, or, for good cause shown, submit additional material in support of its claim

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of trade secrecy to EPA under paragraph (a)(2)(ii) of this section. The notice required by this section shall include the reasons for EPA's decision that the submitter's claim is insufficient, and shall inform the submitter of its rights within 30 days of receiving notice to file an appeal with EPA's General Counsel or to amend its original substantiation for good cause shown. The notice shall include the address of the General Counsel, and the address of the office to which an amendment for good cause shown should be sent. The notice shall also include a reference to §350.11(a)(2)(i)-(iv) of this subpart as the source on the proper procedures for filing an appeal or for amending the original substantiation.

(i) *Appeal.* The submitter may file an appeal of a determination of insufficiency with the General Counsel within 30 days of receipt of the notice of insufficiency, in accordance with the procedures set forth in §350.17.

(ii) *Good Cause.* In lieu of an appeal to the General Counsel, the submitter may send additional material in support of its trade secrecy claim, for good cause shown, within 30 days of receipt of the notice of insufficiency. To do so, the submitter shall notify EPA by letter of its contentions as to good cause, and shall include in that letter the additional supporting material.

(iii) Good cause is limited to one or more of the following reasons:

(A) The submitter was not aware of the facts underlying the additional information at the time the substantiation was submitted, and could not reasonably have known the facts at that time; or

(B) EPA regulations and other EPA guidance did not call for such information at the time the substantiation was submitted; or

(C) The submitter had made a good faith effort to submit a complete substantiation, but failed to do so due to an inadvertent omission or clerical error.

(iv) If EPA determines that the submitter has met the standard for good cause, then EPA shall decide, pursuant to paragraph (a) of this section, whether the submitter's claim meets the

Agency's standards of sufficiency set forth in §350.13.

(A) If after receipt of additional material for good cause, EPA decides the claim is sufficient, EPA will determine whether the claim presents a valid claim of trade secrecy according to the procedures set forth in paragraph (b) of this section.

(B) If after receipt of additional material for good cause, EPA decides the claim is insufficient, EPA will notify the submitter by certified mail (return receipt requested) and the submitter may seek review in U.S. District Court within 30 days of receipt of the notice. The notice required by this paragraph shall include EPA's reasons for its determination, and shall inform the submitter of its right to seek review in U.S. District Court within 30 days of receipt of the notice. The petitioner shall be notified of EPA's decision by regular mail.

(v) If EPA determines that the submitter has not met the standard for good cause, then EPA shall notify the submitter by certified mail (return receipt requested). The submitter may seek review of EPA's decision in U.S. District Court within 30 days of receipt of the notice. The notice required in this paragraph shall include EPA's reasons for its determination, and shall inform the submitter of its right to seek review in U.S. District Court within 30 days of receipt of the notice. The petitioner shall be notified of EPA's decision by regular mail.

(b) Determination of trade secrecy. Once a claim has been determined to be sufficient under paragraph (a) of this section, EPA must decide whether the claim is entitled to trade secrecy.

(1) If EPA determines that the information submitted in support of the trade secrecy claim is true and that the chemical identity is a trade secret, the petitioner shall be notified by certified mail (return receipt requested) of EPA's determination and may bring an action in U.S. District Court within 30 days of receipt of such notice. The notice required in this paragraph shall include the reasons why EPA has determined that the chemical identity is a trade secret and shall inform the petitioner of its right to seek review in U.S. District Court within 30 days of

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receipt of the notice. The submitter shall be notified of EPA's decision by regular mail.

(2) If EPA decides that the information submitted in support of the trade secrecy claim is not true and that the chemical identity is not a trade secret:

(i) The submitter shall be notified by certified mail (return receipt requested) of EPA's determination and may appeal to the General Counsel within 30 days of receipt of such notice, in accordance with the procedures set forth in §350.17. The notice required by this paragraph shall include the reasons why EPA has determined that the chemical identity is not a trade secret and shall inform the submitter of its appeal rights to EPA's General Counsel. The notice shall include the address to which an appeal should be sent and the procedure for filing an appeal, as set forth in §350.17(a) of this subpart. The petitioner shall be notified of EPA's decision by regular mail.

(ii) The General Counsel shall notify the submitter by certified mail (return receipt requested) of its decision on appeal pursuant to the requirements in §350.17. The notice required by this paragraph shall include the reasons for EPA's determination. If the General Counsel affirms the decision that the chemical identity is not a trade secret, then the submitter shall have 30 days from the date it receives notice of the General Counsel's decision to bring an action in U.S. District Court. If the General Counsel decides that the chemical identity is a trade secret, then EPA shall follow the procedure set forth in paragraph (b)(1) of this section.

§ 350.13 Sufficiency of assertions.

(a) A substantiation submitted under §350.7 will be determined to be insufficient to support a claim of trade secrecy unless the answers to the questions in the substantiation submitted under §350.7 support all of the following conclusions. This substantiation must include, where applicable, specific facts.

(1) The submitter has not disclosed the information to any other person, other than a member of a local emergency planning committee, an officer or employee of the United States or a State or local government, an em-

ployee of such person, or a person who is bound by a confidentiality agreement, and such person has taken reasonable measures to protect the confidentiality of such information and intends to continue to take such measures. To support this conclusion, the facts asserted must show all of the following:

(i) The submitter has taken reasonable measures to prevent unauthorized disclosure of the specific chemical identity and will continue to take such measures.

(ii) The submitter has not disclosed the specific chemical identity to any person who is not bound by an agreement to refrain from disclosing the information.

(iii) The submitter has not previously disclosed the specific chemical identity to a local, State, or Federal government entity without asserting a confidentiality claim.

(2) The information is not required to be disclosed, or otherwise made available, to the public under any other Federal or State law.

(3) Disclosure of the information is likely to cause substantial harm to the competitive position of such person. To support this conclusion, the facts asserted must show all of the following:

(i) *Either:* (A) Competitors do not know or the submitter is not aware that competitors know that the chemical whose identity is being claimed trade secret can be used in the fashion that the submitter uses it, and competitors cannot easily duplicate the specific use of this chemical through their own research and development activities; or

(B) Competitors are not aware or the submitter does not know whether competitors are aware that the submitter is using this chemical in this fashion.

(ii) The fact that the submitter manufactures, imports or otherwise uses this chemical in a particular fashion is not contained in any publication or other information source (of which the submitter is aware) available to competitors or the public.

(iii) The non-confidential version of the submission under this title does not contain sufficient information to enable competitors to determine the

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specific chemical identity withheld therefrom.

(iv) The information referred to in paragraph (a)(3)(i)(A) of this section, is of value to competitors.

(v) Competitors are likely to use this information to the economic detriment of the submitter and are not precluded from doing so by a United States patent.

(vi) The resulting harm to submitter's competitive position would be substantial.

(4) The chemical identity is not readily discoverable through reverse engineering. To support this conclusion, the facts asserted must show that competitors cannot readily discover the specific chemical identity by analysis of the submitter's products or environmental releases.

(b) The sufficiency of the trade secrecy claim shall be decided entirely upon the information submitted under § 350.7, or § 350.11(a)(2)(ii).

§ 350.15 Public petitions requesting disclosure of chemical identity claimed as trade secret.

(a) The public may request the disclosure of chemical identity claimed as trade secret by submitting a written petition to the address specified in § 350.16.

(b) The petition shall include:

(1) The name, address, and telephone number of the petitioner;

(2) The name and address of the company claiming the chemical identity as trade secret; and

(3) A copy of the submission in which the submitter claimed chemical identity as trade secret, with a specific indication as to which chemical identity the petitioner seeks disclosed.

(c) EPA shall acknowledge, by letter to the petitioner, the receipt of the petition.

(d) Incomplete petitions. If the information contained in the petition is not sufficient to allow EPA to identify which chemical identity the petitioner is seeking to have released, EPA shall notify the petitioner that the petition cannot be further processed until additional information is furnished. EPA will make every reasonable effort to assist a petitioner in providing sufficient information for EPA to identify

the chemical identity the petitioner is seeking to have released.

(e) EPA shall make a determination on a petition requesting disclosure, in accordance with § 350.11 and § 350.17, within nine months of receipt of such petition.

§ 350.16 Address to send trade secrecy claims and petitions requesting disclosure.

The address and location to send all claims of trade secrecy under sections 303(d)(2) and (d)(3), 311, 312, and 313 of Title III and all public petitions requesting disclosure of chemical identities claimed as trade secret are posted on the following EPA Program Web sites, <http://www.epa.gov/ceppo> and <http://www.epa.gov/tri>. Any subsequent changes to the address and location will be announced in FEDERAL REGISTER Notices as these changes occur. Also, the changes will be posted on these Web sites. Submitters may also contact the Emergency Planning and Community Right-to-Know Hotline at (800) 424-9346 or (703) 412-9810, TDD (800) 553-7672, <http://www.epa.gov/epaoswer/hotline/> to obtain this information.

[68 FR 64724, Nov. 14, 2003]

§ 350.17 Appeals.

(a) *Procedure for filing appeal.* A submitter may appeal an EPA determination under § 350.11(a)(2)(i) or (b)(2)(i), by filing an appeal with the General Counsel. The appeal shall be addressed to: The Office of General Counsel, U.S. Environmental Protection Agency, Mailcode 2310A, 1200 Pennsylvania Avenue, NW., Washington DC 20460.

The appeal shall contain the following:

(1) A letter requesting review of the appealed decision; and

(2) A copy of the letter containing EPA's decision upon which appeal is requested.

(b) Appeal of determination of insufficient claim.

(1) Where a submitter appeals a determination by EPA under § 350.11(a)(2)(i) that the trade secrecy claim presents insufficient support for a finding of trade secrecy, the General Counsel shall make one of the following determinations:

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(i) The trade secrecy claim at issue meets the standards of sufficiency set forth in § 350.13; or

(ii) The trade secrecy claim at issue does not meet the standards of sufficiency set forth in § 350.13.

(2) If the General Counsel reverses the decision made by the EPA office handling the claim, the claim shall be processed according to § 350.11(a)(1). The General Counsel shall notify the submitter of the determination on appeal in writing, by certified mail (return receipt requested). The appeal determination shall include the date the appeal was received by the General Counsel, a statement of the decision appealed from, a statement of the decision on appeal and the reasons for such decision.

(3) If the General Counsel upholds the determination of insufficiency made by the EPA office handling the claim, the submitter may seek review in U.S. District Court within 30 days after receipt of notice of the General Counsel's determination. The General Counsel shall notify the submitter of its determination on appeal in writing, by certified mail (return receipt requested). The appeal determination shall include the date the appeal was received by the General Counsel, a statement of the decision appealed from, a statement of the decision on appeal and the reasons for such decision, and a statement of the submitter's right to seek review in U.S. District Court within 30 days of receipt of such notice. The petitioner shall be notified by regular mail.

(c) *Appeal of determination of no trade secret.* (1) If a submitter appeals from a determination by EPA under § 350.11(b)(2) that the specific chemical identity at issue is not a trade secret, the General Counsel shall make one of the following determinations:

(i) The assertions supporting the claim of trade secrecy are true and the chemical identity is a trade secret; or

(ii) The assertions supporting the claim of trade secrecy are not true and the chemical identity is not a trade secret.

(2) If the General Counsel reverses the decision made by the EPA office handling the claim, the General Counsel shall notify the submitter of its determination on appeal in writing, by

certified mail (return receipt requested). The appeal determination shall include the date the appeal was received by the General Counsel, a statement of the decision appealed from, a statement of the decision on appeal and the reasons for such decision. The General Counsel shall send the petitioner the notice required in § 350.11(b)(1).

(3) If the General Counsel upholds the decision of the EPA office which made the trade secret determination, the submitter may seek review in U.S. District Court within 30 days of receipt of notice of the General Counsel's decision. The General Counsel shall notify the submitter of the determination on appeal in writing, by certified mail (return receipt requested). The notice shall include the date the appeal was received by the General Counsel, a statement of the decision appealed from, the basis for the appeal determination, that it constitutes final Agency action concerning the chemical identity trade secrecy claim, and that such final Agency action may be subject to review in U.S. District Court within 30 days of receipt of such notice. The General Counsel shall notify the petitioner by regular mail.

[53 FR 28801, July 29, 1988, as amended at 68 FR 64724, Nov. 14, 2003]

§ 350.18 Release of chemical identity determined to be non-trade secret; notice of intent to release chemical identity.

(a) Where a submitter fails to seek review within U.S. District Court within 20 days of receiving notice of a determination of the General Counsel under § 350.17(b)(3) of this subpart that the trade secrecy claim is insufficient, or under § 350.17(c)(3) of this subpart that chemical identity claimed as trade secret is not entitled to trade secret protection, EPA may furnish notice of intent to disclose the chemical identity claimed as trade secret within 10 days by furnishing the submitter with the notice set forth in paragraph (d) of this section by certified mail (return receipt requested).

(b) Where a submitter fails to seek review within U.S. District Court within 20 days of receiving notice of an EPA determination under

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§ 350.11(a)(2)(iv)(B), or § 350.11(a)(2)(v) of this regulation, or fails to pursue appeal to the General Counsel within 20 days after being notified of its right to do so under § 350.11(a)(2)(i) or § 350.11(b)(2)(i), EPA may furnish notice of intent to disclose the chemical identity claimed as trade secret within 10 days by furnishing the submitter with the notice set forth in paragraph (d) of this section by certified mail (return receipt requested).

(c) Where EPA, upon initial review under § 350.9(d), determines that the chemical identity claimed as trade secret in a submittal submitted pursuant to this part is the subject of a prior final Agency determination concerning a claim of trade secrecy for the same chemical identity for the same facility, in which such claim was held invalid, EPA shall furnish notice of intent to disclose chemical identity within 10 days by furnishing the submitter with the notice set forth in paragraph (d) of this section by certified mail (return receipt requested).

(d) EPA shall furnish notice of its intent to release chemical identity claimed as trade secret by sending the following notification to submitters, under the circumstances set forth in paragraphs (a), (b), and (c) of this section. The notice shall state that EPA will make the chemical identity available to the petitioner and the public on the tenth working day after the date of the submitter's receipt of written notice (or on such later date as the Office of General Counsel may establish), unless the Office of General Counsel has first been notified of the submitter's commencement of an action in Federal court to obtain judicial review of the determination at issue, and to obtain preliminary injunctive relief against disclosure, or, where applicable, as described in paragraph (b) of this section, of commencement of an appeal to the General Counsel. The notice shall further state that if Federal court action is timely commenced, EPA may nonetheless make the information available to the petitioner and the public (in the absence of an order by the court to the contrary), once the court has denied a motion for a preliminary injunction in the action or has otherwise upheld the EPA determination, or, that if Federal

court action or appeal to the General Counsel is timely commenced, EPA may nonetheless make the information available to the petitioner and the public whenever it appears to the General Counsel, after reasonable notice to the submitter, that the submitter is not taking appropriate measures to obtain a speedy resolution of the action.

§ 350.19 Provision of information to States.

(a) Any State may request access to trade secrecy claims, substantiations, supplemental substantiations, and additional information submitted to EPA. EPA shall release this information, even if claimed confidential, to any State requesting access if:

- (1) The request is in writing;
- (2) The request is from the Governor of the State; and
- (3) The State agrees to safeguard the information with procedures equivalent to those which EPA uses to safeguard the information.

(b) The Governor of a State which receives access to trade secret information under this section may disclose such information only to State employees.

§ 350.21 Adverse health effects.

The Governor or State emergency response commission shall identify the adverse health effects associated with each of the chemicals claimed as trade secret and shall make this information available to the public. The material safety data sheets submitted to the State emergency response commissions may be used for this purpose.

§ 350.23 Disclosure to authorized representatives.

(a) Under section 322(f) of the Act, EPA possesses the authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to trade secret or confidential treatment under this part. Such authority may be exercised only in accordance with paragraph (b) of this section.

(b)(1) A person under contract or subcontract to EPA or a grantee who performs work for EPA in connection with

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Title III or regulations which implement Title III may be considered an authorized representative of the United States for purposes of this § 350.23. Subject to the limitations in this § 350.23(b), information to which this section applies may be disclosed to such a person if the EPA program office managing the contract, subcontract, or grant first determines in writing that such disclosure is necessary in order that the contractor, subcontractor or grantee may carry out the work required by the contract, subcontract or grant.

(2) No information shall be disclosed under this § 350.23(b) unless this contract, subcontract, or grant in question provides:

(i) That the contractor, subcontractor or the grantee and the contractor's, subcontractor's, or grantee's employees shall use the information only for the purpose of carrying out the work required by the contract, subcontract, or grant, and shall refrain from disclosing the information to anyone other than EPA without the prior written approval of each affected submitter or of an EPA legal office, and shall return to EPA all copies of the information (and any abstracts or extracts therefrom) upon request by the EPA program office, whenever the information is no longer required by the contractor, subcontractor or grantee for the performance of the work required under the contract, subcontract or grant, or upon completion of the contract, subcontract or grant;

(ii) That the contractor, subcontractor or grantee shall obtain a written agreement to honor such terms of the contract or subcontract from each of the contractor's, subcontractor's or grantee's employees who will have access to the information, before such employee is allowed such access; and

(iii) That the contractor, subcontractor or grantee acknowledges and agrees that the contract, subcontract or grant provisions concerning the use and disclosure of confidential business information are included for the benefit of, and shall be enforceable by,

both EPA and any covered facility having an interest in information concerning it supplied to the contractor, subcontractor or grantee by EPA under the contract or subcontract or grant.

(3) No information shall be disclosed under this § 350.23(b) until each affected submitter has been furnished notice of the contemplated disclosure by the EPA program office and has been afforded a period found reasonable by that office (not less than 5 working days) to submit its comments. Such notice shall include a description of the information to be disclosed, the identity of the contractor, subcontractor or grantee, the contract, subcontract or grant number, if any, and the purposes to be served by the disclosure. This notice may be published in the FEDERAL REGISTER or may be sent to individual submitters.

(4) The EPA program office shall prepare a record of disclosures under this § 350.23(b). The EPA program office shall maintain the record of disclosure and the determination of necessity prepared under paragraph (b)(1) of this section for a period of not less than 36 months after the date of the disclosure.

§ 350.25 Disclosure in special circumstances.

Other disclosure of specific chemical identity may be made in accordance with 40 CFR 2.209.

§ 350.27 Substantiation form to accompany claims of trade secrecy, instructions to substantiation form.

(a) The substantiation form to accompany claims of trade secrecy must be completed and submitted as required in § 350.7(a). The form is posted on the Chemical Emergency Preparedness and Prevention Office Web site, <http://www.epa.gov/ceppo> and the Toxics Release Inventory Program Division Web site, <http://www.epa.gov/tri>. Submitters may also contact the National Service Center for Environmental Publications (NSCEP) at (800) 490-9198 or (513) 489-8190 to obtain the form.

(b) Substantiation form to accompany claims of trade secrecy.

United States Environmental Protection Agency Washington, DC 20460		Form Approved OMB No. 2050-0078 Approval expires 10-31-90
Substantiation To Accompany Claims of Trade Secrecy Under the Emergency Planning and Community Right-To-Know Act of 1986		
Paperwork Reduction Act Notice Public reporting burden for this collection of information is estimated to vary from 27.7 hours to 33.2 hours per response, with an average of 28.8 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.		
Part 1. Substantiation Category		
1.1 Title III Reporting Section (check only one)		
<input type="checkbox"/> 303	<input type="checkbox"/> 311	<input type="checkbox"/> 312
1.2 Reporting Year 19 _____		
1.3 Indicate Whether This Form Is (check only one)		
1.3a. <input type="checkbox"/> Sanitized (answer 1.3.1a below)	1.3b. <input type="checkbox"/> Unsanitized (answer 1.3.1b. and 1.3.2b. below)	
1.3.1a. Generic Class or Category	1.3.1b. CAS Number [] [] [] [] [] [] - [] [] - []	
	1.3.2b. Specific Chemical Identity	
Part 2. Facility Identification Information		
2.1 Name		
2.2 Street Address		
2.3 City, State, and ZIP Code		
2.4 Dun and Bradstreet Number		
[] [] [] - [] [] [] - [] [] []		

Part 3. Responses to Substantiation Questions

3.1 Describe the specific measures you have taken to safeguard the confidentiality of the chemical identity claimed as trade secret, and indicate whether these measures will continue in the future.

3.2 Have you disclosed the information claimed as trade secret to any other person (other than a member of a local emergency planning committee, officer or employee of the United States or a State or local government, or your employee) who is not bound by a confidentiality agreement to refrain from disclosing this trade secret information to others?

Yes No

3.3 List all local, State, and Federal government entities to which you have disclosed the specific chemical identity. For each, indicate whether you asserted a confidentiality claim for the chemical identity and whether the government entity denied that claim.

Government Entity	Confidentiality Claim Asserted		Confidentiality Claim Denied	
	Yes	No	Yes	No

3.4 In order to show the validity of a trade secrecy claim, you must identify your specific use of the chemical claimed as trade secret and explain why it is a secret of interest to competitors. Therefore:

(i) Describe the specific use of the chemical claimed as trade secret, identifying the product or process in which it is used. (If you use the chemical other than as a component of a product or in a manufacturing process, identify the activity where the chemical is used.)

(ii) Has your company or facility identity been linked to the specific chemical identity claimed as trade secret in a patent, or in publications or other information sources available to the public or your competitors (of which you are aware)?

Yes **No**

If so, explain why this knowledge does not eliminate the justification for trade secrecy.

(iii) If this use of the chemical claimed as trade secret is unknown outside your company, explain how your competitors could deduce this use from disclosure of the chemical identity together with other information on the Title III submittal form.

3.4 (iv) Explain why your use of the chemical claimed as trade secret would be valuable information to your competitors.

3.5 Indicate the nature of the harm to your competitive position that would likely result from disclosure of the specific chemical identity, and indicate why such harm would be substantial.

3.6 (i) To what extent is the chemical claimed as trade secret available to the public or your competitors in products, articles, or environmental releases?

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3.6 (ii) Describe the factors which influence the cost of determining the identity of the chemical claimed as trade secret by chemical analysis of the product, article, or waste which contains the chemical (e.g., whether the chemical is in pure form or is mixed with other substances).

Part 4. Certification (Read and sign after completing all sections)

I certify under penalty of law that I have personally examined the information submitted in this and all attached documents. Based on my inquiry of those individuals responsible for obtaining the information, I certify that the submitted information is true, accurate, and complete, and that those portions of the substantiation claimed as confidential would, if disclosed, reveal the chemical identity being claimed as a trade secret, or would reveal other confidential business or trade secret information. I acknowledge that I may be asked by the Environmental Protection Agency to provide further detailed factual substantiation relating to this claim of trade secrecy, and certify to the best of my knowledge and belief that such information is available. I understand that if it is determined by the Administrator of EPA that this trade secret claim is frivolous, EPA may assess a penalty of up to \$25,000 per claim.

I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

4.1 Name and official title of owner or operator or senior management official

4.2 Signature (All signatures must be original)

4.3 Date Signed

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INSTRUCTIONS FOR COMPLETING THE EPA TRADE SECRET SUBSTANTIATION FORM

General Information

EPA requires that the information requested in a trade secret substantiation be completed using this substantiation form in order to ensure that all facility and chemical identifier information, substantiation questions, and certification statements are completed. Submitter-devised forms will not be accepted. Incomplete substantiations will in all likelihood be found insufficient to support the claim, and the claim will be denied. *Moreover, the statute provides that a submitter who fails to provide information required will be subject to a \$10,000 fine.* For the submitter's own protection, therefore, the EPA form must be used and completed in its entirety.

The statute for section 322 establishes a two-phase process in which the submitter must do the following:

1. At the time a report is submitted, the submitter must present a complete set of assertions that (if true) would be sufficient to justify the claim of trade secrecy; and
2. If the claim is reviewed by EPA, the submitter will be asked to provide additional factual information sufficient to establish the truthfulness of the assertions made at the time the claim was made.

In making its assertions of trade secrecy, a submitter should provide, where applicable, descriptive factual statements. Conclusory statements of compliance (such as positive or negative restatements of the questions) may not provide EPA with enough information to make a determination and may be found insufficient to support a claim.

WHAT MAY BE WITHHELD

Only the specific chemical identity required to be disclosed in sections 303, 311, 312, and 313 submissions may be claimed trade secret on the Title III submittal itself. (Other trade secret or confidential business information included in answer to a question on the substantiation may be claimed trade secret or confidential, as described below.)

Location information claimed as confidential under section 312(d)(2)(F) should *not* be sent to EPA; this should only be sent to the SERC, LEPC, and the fire department, as requested.

Sanitized and Unsanitized Copies

You must submit this form to EPA in sanitized and unsanitized versions, along with the sanitized and unsanitized copies of the submittal that gives rise to this trade secrecy claim (except for the section 303 submittal, and for MSDSs under section 311). The *unsanitized* version of this form contains specific chemical identity and CAS number and may contain other trade secret or confidential business information, which should be clearly labeled as such. Failure to claim other information trade secret or confidential will make that information publicly available. In the *sanitized* version of this form, the specific chemical identity and CAS number must be replaced with the chemical's generic class or category and any other trade secret or confidential business information should be deleted. *You should also send sanitized copies of the submittal and this form to relevant State and local authorities.*

Each question on this form must be answered. *Submitters are encouraged to answer in the space provided.* If you need more space to answer a particular question, please use additional sheets. If you use additional sheets, be sure to include the number (and if applicable, the subpart) of the question being answered and write your facility's Dun and Bradstreet Number on the lower right-hand corner of each sheet.

When the Forms Must be Submitted

The sanitized and unsanitized report forms and trade secret substantiations must be submitted to EPA by the normal reporting deadline for that section (e.g., section 313 submissions for any calendar year must be submitted on or before July 1 of the following year).

Where To Send the Trade Secrecy Claim

The address to send all trade secrecy claims is posted on the following EPA Program Web sites, <http://www.epa.gov/>

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ceppo and <http://www.epa.gov/tri>. This information can also be obtained by contacting the Emergency Planning and Community Right-to-Know Hotline at (800) 424-9346 or (703) 412-9810, TDD (800) 553-7672, <http://www.epa.gov/epaoswer/hotline/>.

Packaging of Claim(s)

A completed section 322 claim package must include four items, packaged in the following order:

1. An unsanitized trade secret substantiation form.
2. A sanitized trade secret substantiation form.
3. An unsanitized 312 or 313 report (it is not necessary to create an unsanitized section 303 submittal or MSDS for submission under section 311).
4. A sanitized (public) section 303, 311, 312, or 313 or report.

It is important to securely fasten together (binder clip or rubber band) each of the reporting forms and substantiations for the particular chemical being claimed trade secret. This process will make it clear that a claim is physically complete when submitted. When submitters submit claims for more than one chemical, EPA requests that the four parts associated with each chemical be assembled as a set and each set for different chemicals be kept separate within the package sent to EPA. Following these guidelines permits the Agency to make the appropriate determinations of trade secrecy, and to make public only those portions of each submittal required to be disclosed.

How to Obtain Forms and Other Information

Additional copies of the Trade Secret Substantiation Form may be obtained by writing to: Emergency Planning and Community Right-to-Know Program, U.S. Environmental Protection Agency, WH-562A, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

Instructions for Completing Specific Sections of the Form

Part 1. Substantiation Category

1.1 Title III Reporting Section. Check the box corresponding to the section for which this particular claim of trade secrecy is being made. Checking off more than one box for a claim is not permitted.

1.2 Reporting Year. Enter the year to which the reported information applies, not the year in which you are submitting the report.

1.3a Sanitized. If this copy of the submission is the "public" or sanitized version, check this box and complete 1.3.1a, which asks for generic class or category. Do not complete the information required in the unsanitized box (1.3b.).

1.3.1a Generic Class or Category. You must complete this if you are claiming the specific chemical identity as a trade secret and have marked the box in 1.3a. The generic chemical name must be structurally descriptive of the chemical.

1.3b Unsanitized. Check the box if this version of the form contains the specific chemical identity or any other trade secret or confidential business information.

1.3.1b CAS Number. You must enter the Chemical Abstract Service (CAS) registry number that appears in the appropriate section of the rule for the chemical being reported. Use leading place holding zeros. If you are reporting a chemical category (e.g., copper compounds), enter N/A in the CAS number space.

1.3.2b Specific Chemical Identity. Enter the name of the chemical or chemical category as it is listed in the appropriate section of the reporting rule.

Part 2. Facility Identification Information

2.1-2.3 Facility Name and Location. You must enter the name of your facility (plant site name or appropriate facility designation), street address, city, State and ZIP Code in the space provided. You may not use a post office box number for this location.

2.4 Dun and Bradstreet Number. You must enter the number assigned by Dun and Bradstreet for your facility or

each establishment within your facility. If the establishment does not have a D & B number, enter N/A in the boxes reserved for those numbers. Use leading place holding zeros.

Part 3. Responses to Substantiation Questions

The six questions posed in this form are based on the four statutory criteria found in section 322(b) of Title III. The information you submit in response to these questions is the basis for EPA's initial determination as to whether the substantiation is sufficient to support a claim of trade secrecy. EPA has indicated in §350.13 of the final rule the specific criteria that it regards as the legal basis for evaluating whether the answers you have provided are sufficient to warrant protection of the chemical identity. You are urged to review those criteria before preparing answers to the questions on the form.

Part 4. Certification

An *original* signature is required for each trade secret substantiation submitted to EPA, both sanitized and unsanitized. It indicates the submitter is certifying that the particular substantiation provided to EPA is complete, true, and accurate, and that it is intended to support the specific trade secret claim being made. Noncompliance with this certification requirement may jeopardize the trade secret claim.

4.1 Name and Official Title. Print or type the name and title of the person who signs the statement at 4.2.

4.2 Signature. This certification must be signed by the owner or operator, or a senior official with management responsibility for the person (or persons) completing the form. An *original* signature is required for each trade secret substantiation submitted to EPA, both sanitized and unsanitized. Since the certification applies to all information supplied on the forms, it should be signed only after the substantiation has been completed.

4.3 Date. Enter the date when the certification was signed.

[53 FR 28801, July 29, 1988, as amended at 68 FR 64724, Nov. 14, 2003]

APPENDIX A TO SUBPART A OF PART 350—RESTATEMENT OF TORTS SECTION 757, COMMENT B

b. Definition of trade secret. A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business (see section 759) in that it is not simply information as to single or ephemeral events in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract or the salary of certain employees, or the security investments made or contemplated, or the date fixed for the announcement of a new policy or for bringing out a new model or the like. A trade secret is a process or device for continuous use in the operation of the business. Generally it relates to the production of goods, as, for example, a machine or formula for the production of an article. It may, however, relate to the sale of goods or to other operations in the business, such as a code for determining discounts, rebates or other concessions in a price list or catalogue, or a list of specialized customers, or a method of bookkeeping or other office management.

Secrecy. The subject matter of a trade secret must be secret. Matters of public knowledge or of general knowledge in an industry cannot be appropriated by one as his secret. Matters which are completely disclosed by the goods which one markets cannot be his secret. Substantially, a trade secret is known only in the particular business in which it is used. It is not requisite that only the proprietor of the business know it. He may, without losing his protection, communicate it to employees involved in its use. He may likewise communicate it to others pledged to secrecy. Others may also know of it independently, as, for example, when they have discovered the process or formula by independent invention and are keeping it secret. Nevertheless, a substantial element of secrecy must exist, so that, except by the use of improper means, there would be difficulty in acquiring the information. An exact definition of a trade secret is not possible. Some factors to be considered in determining whether given information is one's trade secret are: (1) The extent to which the information is known outside of his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the value of the information to him and to his competitors; (5) the amount of effort or

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money expended by him in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Novelty and prior art. A trade secret may be a device or process which is patentable; but it need not be that. It may be a device or process which is clearly anticipated in the prior art or one which is merely a mechanical improvement that a good mechanic can make. Novelty and invention are not requisite for a trade secret as they are for patentability. These requirements are essential to patentability because a patent protects against unlicensed use of the patented device or process even by one who discovers it properly through independent research. The patent monopoly is a reward to the inventor. But such is not the case with a trade secret. Its protection is not based on a policy of rewarding or otherwise encouraging the development of secret processes or devices. The protection is merely against breach of faith and reprehensible means of learning another's secret. For this limited protection it is not appropriate to require also the kind of novelty and invention which is a requisite of patentability. The nature of the secret is, however, an important factor in determining the kind of relief that is appropriate against one who is subject to liability under the rule stated in this section. Thus, if the secret consists of a device or process which is a novel invention, one who acquires the secret wrongfully is ordinarily enjoined from further use of it and is required to account for the profits derived from his past use. If, on the other hand, the secret consists of mechanical improvements that a good mechanic can make without resort to the secret, the wrongdoer's liability may be limited to damages, and an injunction against future use of the improvements made with the aid of the secret may be inappropriate.

Subpart B—Disclosure of Trade Secret Information to Health Professionals

§ 350.40 Disclosure to health professionals.

(a) *Definitions. Medical emergency* means any unforeseen condition which a health professional would judge to require urgent and unscheduled medical attention. Such a condition is one which results in sudden and/or serious symptom(s) constituting a threat to a person's physical or psychological well-being and which requires immediate medical attention to prevent possible deterioration, disability, or death.

(b) The specific chemical identity, including the chemical name of a haz-

ardous chemical, extremely hazardous substance, or a toxic chemical, is made available to health professionals, in accordance with the applicable provisions of this section.

(c) *Diagnosis or Treatment by Health Professionals in Non-Emergency Situations.* (1) An owner or operator of a facility which is subject to the requirements of sections 311, 312, and 313, shall, upon request, provide the specific chemical identity, if known, of a hazardous chemical, extremely hazardous substance, or a toxic chemical to a health professional if:

(i) The request is in writing;

(ii) The request describes why the health professional has a reasonable basis to suspect that:

(A) The specific chemical identity is needed for purposes of diagnosis or treatment of an individual,

(B) The individual or individuals being diagnosed or treated have been exposed to the chemical concerned, and

(C) Knowledge of the specific chemical identity of such chemical will assist in diagnosis or treatment.

(iii) The request contains a confidentiality agreement which includes:

(A) A description of the procedures to be used to maintain the confidentiality of the disclosed information; and

(B) A statement by the health professional that he will not use the information for any purpose other than the health needs asserted in the statement of need authorized in paragraph (c)(1)(ii) of this section and will not release the information under any circumstances, except as authorized by the terms of the confidentiality agreement or by the owner or operator of the facility providing such information.

(iv) The request includes a certification signed by the health professional stating that the information contained in the statement of need is true.

(2) Following receipt of a written request, the facility owner or operator to whom such request is made shall provide the requested information to the health professional promptly.

(d) *Preventive Measures and Treatment by Local Health Professionals.* (1) An owner or operator of a facility subject to the requirements of sections 311, 312,