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 form in paragraph (b) of this section must be completed and submitted as required in § 350.7(a).

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

United States Environmental Protection Agency
Washington, DC 20460

EPA

Substantiation To Accompany Claims of Trade Secrecy Under the Emergency Planning and Community Right-To-Know Act of 1986

Form Approved
OMB No. 2050-0078
Approval expires 10-31-90

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)

☐ **303** ☐ **311** ☐ **312** ☐ **313**

1.2 Reporting Year 19 _____

1.3 Indicate Whether This Form Is (check only one)

1.3a. ☐ **Sanitized**

(answer 1.3.1a below)

1.3.1a. Generic Class or Category

1.3b. ☐ **Unsanitized**

(answer 1.3.1b. and 1.3.2b. below)

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

☐☐ – ☐☐☐ – ☐☐☐☐

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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

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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?

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

All trade secrecy claims should be sent to the following address: U.S. Environmental Protection Agency, Emergency Planning and Community Right-to-Know Program, P.O. Box 70266, Washington, DC 20024–0266.

In addition, you must send sanitized copies of the report form and substantiation to relevant State and local authorities. States will provide addresses where the copies of the reports are to be sent.

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 wthin 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.

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

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 hazardous 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,