

OMB 2020-0003
SAMPLE LETTER A
Generic

BY CERTIFIED U.S. MAIL; RETURN RECEIPT REQUESTED

(Name, title, and address of the [designated] representative of the affected business)

Re: Freedom of Information Act ("FOIA") Request XX-FOI-XXXXX-XX

Dear (Addressee):

The U.S. Environmental Protection Agency ("EPA" or "Agency") has received a request under the FOIA for certain records **[if submitted by the business whose information it is: that you submitted to EPA] [if submitted by an entity other than the business whose information it is: in EPA's possession] pertaining to [description of the information that is the subject of the advance or final confidentiality determination].** You have claimed (all or part) of this information as confidential business information ("CBI"). In accordance with applicable EPA regulations, 40 C.F.R. Part 2, Subpart B, EPA has determined that you might be expected to assert a claim that some or all of the information you submitted to EPA is confidential business information ("CBI"). Under the EPA regulations, 40 C.F.R. part 2, subpart B, the FOIA request has been initially denied to afford you an opportunity to claim this information as CBI and substantiate your claim(s) as described below.

This letter is to notify you that the EPA (appropriate legal office) will be making a(n) (advance or final) confidentiality determination concerning this information. If you feel that some or all of the above information is entitled to confidential treatment, please specify which portions of the information you consider confidential. Please attach a copy of those pages with brackets around the text that you claim to be CBI. Any information not specifically identified as subject to a confidentiality claim will be disclosed to the requestor without further notice to you.] For each item or class of information that you identify as being subject to your claim, please answer the following questions, giving as much detail as possible:

1. For what period of time do you request that the information be maintained as confidential, e.g., until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
2. Information submitted to EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question #1?
3. What measures have you taken to protect the information claimed as confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an

agreement not to disclose the information further? If so, why should the information still be considered confidential?

4. Is the information contained in any publicly available material such as the Internet, publicly available databases, promotional publications, annual reports, or articles? Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?
5. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
6. For each category of information claimed as confidential, explain with specificity why release of the information is likely to cause substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?
7. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If the business asserts that the information is voluntarily submitted information, please explain whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.
8. If you believe any information to be (a) trade secret(s), please so state and explain the reason for your belief. Please attach copies of those pages with brackets around the text that you claim to be (a) trade secret(s).
9. Any other issue you deem relevant (including, if pertinent, reasons why you believe that the information you claim to be CBI is not emission data or effluent data).

[For contract-related CBI: Enclosed is EPA Class Determination 1-95 entitled, *Confidentiality of Certain Business Information Submitted by Contractors and Prospective Contractors*, which addresses the treatment of different types of information related to contracts. You may consider reviewing Class Determination 1-95 as you develop your response.]

Please note that you bear the burden of substantiating your confidentiality claim(s). Conclusory allegations will be given little or no weight in the determination. If you wish to claim any of the information in your response as confidential, you must mark the response "CONFIDENTIAL" or with a similar designation, and must bracket all text so claimed. Information so designated will be disclosed by EPA only to the extent allowed by, and by means of the procedures set forth in, 40 C.F.R. Part 2, Subpart B. If you fail to claim the information as confidential, it may be made available to the public without further notice to you.

OMB 2020-0003
SAMPLE LETTER B
(Generic Substantiation)

BY CERTIFIED U.S. MAIL; RETURN RECEIPT REQUESTED

(Name, title, and address of the [designated] representative of the affected business)

Re: Freedom of Information Act ("FOIA") Request XX-FOI-XXXXX-XX

Dear (Addressee):

The U.S. Environmental Protection Agency ("EPA" or "Agency") is seeking to determine the entitlement to confidentiality of **[description of the information that is the subject of the advance or final confidentiality determination]** **[if submitted by the business whose information it is: that you submitted to EPA]** **[if submitted by an entity other than the business whose information it is: in EPA's possession.]** **[If information has been claimed as CBI: You have claimed (all or part) of this information as confidential business information ("CBI").]** **[If no claim has been made: In accordance with applicable EPA regulations, EPA has determined that you might be expected to assert a claim that some or all of [if submitted by the business whose information it is: the information you submitted to EPA] [if submitted by an entity other than the business whose information it is: this information in EPA's possession] is confidential business information ("CBI").]** Under the EPA regulations, 40 C.F.R. Part 2, subpart B, the FOIA request has been initially denied to afford you an opportunity to claim this information as CBI and substantiate your claim(s) as described below.

This letter is to notify you that the EPA (appropriate legal office) will be making a(n) (advance or final) confidentiality determination concerning this information. If you feel that some or all of the above information is entitled to confidential treatment, please specify which portions of the information you consider confidential. Please attach a copy of those pages with brackets around the text that you claim to be CBI. Any information not specifically identified as subject to a confidentiality claim will be disclosed to the public without further notice to you. For each item or class of information that you identify as being subject to your claim, please answer the following questions, giving as much detail as possible:

1. For what period of time do you request that the information be maintained as confidential, e.g., until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
2. Information submitted to EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question #1?
3. What measures have you taken to protect the information claimed as

confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information still be considered confidential?

4. Is the information contained in any publicly available material such as the Internet, publicly available databases, promotional publications, annual reports, or articles? Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?
5. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
6. For each category of information claimed as confidential, explain with specificity why release of the information is likely to cause substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?
7. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If the business asserts that the information is voluntarily submitted information, please explain whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.
8. If you believe any information to be (a) trade secret(s), please so state and explain the reason for your belief. Please attach copies of those pages with brackets around the text that you claim to be (a) trade secret(s).
9. Any other issue you deem relevant (including, if pertinent, reasons why you believe that the information you claim to be CBI is not emission data or effluent data).

[For contract-related CBI: Enclosed is EPA Class Determination 1-95 entitled, *Confidentiality of Certain Business Information Submitted by Contractors and Prospective Contractors*, which addresses the treatment of different types of information related to contracts. You may consider reviewing Class Determination 1-95 as you develop your response.]

Please note that you bear the burden of substantiating your confidentiality claim(s). Conclusory allegations will be given little or no weight in the determination. If you wish to claim any of the information in your response as confidential, you must mark the response "CONFIDENTIAL" or with a similar designation, and must bracket all text so claimed. Information so designated will be disclosed by EPA only to the extent allowed by, and by means of the procedures set forth in, 40 C.F.R. Part 2, Subpart B. If you fail to claim the information as confidential, it may be made available to the public without further notice to you.

Your comments must be postmarked or hand delivered to this office, or e-mailed to (e-mail address), by the 15th working day after your receipt of this letter. You may seek an extension of time to submit your comments to this office, but the request must be made before the end of the 15-day period. Except in extraordinary circumstances, no extension will be approved. Failure to submit your comments within that time will be regarded as a waiver of your confidentiality claim or claims, and EPA may release the information.

Should you have any questions concerning this matter, please call me at (telephone number).

Sincerely,

(Signature and Title and Office Name and Address)

[Enclosure]

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Re: Freedom of Information Act Request HQ-FOI-

Dear

The EPA Office of Pesticide Programs has received a request under the Freedom of Information Act (FOIA) from for . In accordance with 40 C.F.R. 2.204(d)(1), the request has been initially denied in order to afford you an opportunity to substantiate your confidentiality claim.

The information responsive to the request is enclosed. The EPA Office of General Counsel will be making a final confidentiality determination concerning this information. If you believe that some or all of the enclosed information is entitled to confidential treatment, please answer the following questions separately with respect to each portion claimed confidential:

1. For what period of time do you request that the information be maintained as confidential? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
2. Information submitted to EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question #1?
3. What measures have you taken to protect the information claimed as confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information still be considered confidential?
4. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.

5. Is the information contained in any publicly available material such as promotional publications, annual reports, articles, etc.? Is there any means by which a member of the public could obtain access to the information?
6. For each category of information claimed as confidential, discuss with specificity why release of the information is likely to cause substantial harm to your competitive position. Explain the nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?
7. Do you assert that the information is "voluntarily submitted" as defined at 40 C.F.R. 2.201(i)? If so, explain why and how disclosure would tend to lessen EPA's ability to obtain similar information in the future.
8. Any other issue you deem relevant.

Please note that you bear the burden of substantiating your confidentiality claim pursuant to 40 CFR 2.208(e). Conclusory allegations will be given little or no weight in the determination. If you wish to claim any information in your response to this letter as confidential, you must mark the response "CONFIDENTIAL" or with a similar designation, and must bracket all text so claimed. Information so designated will be disclosed by EPA only to the extent allowed by, and by means of the procedures set forth in, 40 CFR Part 2. If you fail to claim the information as confidential upon submission, it may be made available to the public without further notice to you.

If you wish to claim any information in your response to this letter as confidential, you must mark the response CONFIDENTIAL or with a similar designation, and must bracket all text so claimed. Information so designated will be disclosed by EPA only to the extent allowed by, and by means of the procedures set forth in 40 CFR Part 2. If you fail to claim the information as confidential upon submission, it may be made available to the public without further notice to you.

Your reply can be mailed to the following address:

Or your reply can be delivered to the following address:

Your comments must be postmarked or hand-delivered by the 15th working day after your receipt of this letter. If you intend to submit timely comments, please notify _____ by phone at _____, by email at _____ or by mail at the address above. Failure to submit timely comments will be regarded as a waiver of your confidentiality claim and EPA will release the information.

You may request an extension of the 15-day deadline. Except in extraordinary circumstances, no extension will be granted without the permission of the requestor. Should you have any questions in this matter, please contact _____.

Sincerely,

Enclosures

TSCA Health and Safety Filings Substantiation Questions

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.
2. List each data element in this filing that your company is claiming as CBI.
3. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.
4. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this agency at any other time? Identify the agency to which the information was disclosed and provide the date and circumstances of the disclosure. Was the disclosure accompanied by a claim of confidentiality?
5. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.
6. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s)? If so, explain the content of the agreement(s).

7. Does the information claimed as confidential appear or is it referred to in any of the following:
- Advertising or promotional material for the chemical substance or the resulting downstream material or end product;
 - Material safety data sheets or other similar materials (such as technical data sheets or product bulletins) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale);
 - Professional or trade publications; or
 - Any other media or publications, including electronic media including websites, marketing materials, available to the general public, customers, vendors or to your competitors.
- If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.
8. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.
9. Describe the substantial harmful effects that would result to your competitive position if the information claimed as confidential is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, unusual or specialized manufacturing or processing procedures, processes and your competitors' access to your customers. Address each piece of information claimed CBI separately.
10. If the substance name in the filing has been claimed as confidential, has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?
11. If the substance name in the filing has been claimed as confidential, is the substance listed on the TSCA Inventory. If so please provide the Chemical Abstracts Service Registry Number (CASRN) or TSCA accession number for the listing.

12. If the substance name in the filing has been claimed as confidential, is listed on the TSCA Inventory? Is the substance listed on the confidential or public portion of the Inventory?
13. If the substance name in the filing has been claimed as confidential, is the substance commercially available and if so, for how long has it been available on the commercial market?
 - a. If on the commercial market, are any of your competitors aware that the substance is commercially available in the U.S.?
 - b. If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established.
 - c. What is the substance used for and what type of product(s) does it appear in?
14. If the substance name in the filing has been claimed as confidential, describe whether a competitor could employ reverse engineering to identically recreate the substance (for example, from a product, mixture, or downstream material)?
15. If the substance name in the filing has been claimed as confidential, do you assert that the substance is either a polymer or a chemical substance of unknown or variable composition or complex reaction product or biological material (a UVCB substance)?
16. If the substance name in the filing has been claimed as confidential, do you assert that disclosure of this information you are claiming CBI would reveal:
 - a. confidential processes used in manufacturing the substance;
 - b. if a mixture, the actual and confidential portions of the substance in the mixture; or
 - c. information unrelated to the effects of the substance on human health or the environment?If your answer to any of the above questions is yes, explain how such information would be revealed.
17. If the substance name in the filing has been claimed as confidential, provide the Chemical Abstracts Service Registry Number (CASRN) for the substance, if known. Is your company applying for a CASRN now or in the near future?

18. Is the substance identity or any other information claimed as CBI the subject of FIFRA regulation or reporting? If so, explain.

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Re: Freedom of Information Act Request HQ-FOI-

Dear :

The EPA Office of Pesticide Programs has received a request under the Freedom of Information Act (FOIA) from for . In accordance with 40 C.F.R. 2.204(d)(1), the request has been initially denied in order to afford you an opportunity to substantiate your confidentiality claim.

The information responsive to the request is enclosed. The EPA Office of General Counsel will be making a final confidentiality determination concerning this information. If you believe that some or all of the enclosed information is entitled to confidential treatment, please answer the following questions separately with respect to each portion claimed confidential:

Questions 1-7 must be answered with respect to any confidentiality claims pertaining to the enclosed product chemistry information.

1. What value can your competitors derive from knowing the identity, percent by weight, certified limits, or parent process of each impurity? Is this impurity unique to your manufacturing process? Why would your competitors find this impurity preferable over whatever impurity results from their equivalent process?
2. Does published analytical methodology exist that could identify and quantify this impurity? If so, why do you believe that your competitors have not already performed such analysis?

3. What value can your competitors derive from knowing the description of materials used to produce the product, the description of the production process, or the preliminary production analysis? Why would your competitors find these processes preferable over their equivalent processes?

Questions 4-7 must be answered with respect to any confidentiality claims pertaining to the inert ingredients. Each question must be answered separately with respect to each inert ingredient:

4. What is the value that this inert ingredient brings to the product formulation? What characteristics of this ingredient are unique such that competitors might prefer it over whatever ingredients perform the equivalent function in their formulations? Is the use of this ingredient limited to your product, or does it have broader applications?
5. Why is it unlikely that your competitors have not already discovered the value of this ingredient? Are you aware of the use of this ingredient as an inert by your competitors?
6. To your knowledge, has the use of this inert ingredient in a pesticide been disclosed in a patent? If so, how would disclosure of the identity of the ingredient assist your competitors beyond what is already available through a patent?
7. Can the identity of this inert ingredient be determined by product sample analysis? If so, why do you believe that your competitors have not already performed such analysis?

Question 8 must be answered with respect to any confidentiality claims pertaining to the enclosed records:

8. For each category of information claimed as confidential, discuss with specificity why release of the information is likely to cause substantial harm to your competitive position. Explain the nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?

Questions 9 through 15 must be answered for each type of information that you claimed as confidential:

9. For what period of time do you request that the information be maintained as confidential? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
10. Information submitted to EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question

number 9?

11. What measures have you taken to protect the information? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose it further? If so, why should it still be considered confidential?
12. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
13. Is the presence of this information disclosed in any publicly available material such as Material Safety Data Sheets, promotional publications, annual reports, articles, etc.? Is there any means by which a member of the public could obtain access to the information?
14. Do you assert that the information is "voluntarily submitted" as defined at 40 CFR 2.201(i)? If so, explain why, and how disclosure would tend to lessen EPA's ability to obtain similar information in the future.
15. Any other issue you deem relevant.

Please note that you bear the burden of substantiating your confidentiality claim pursuant to 40 CFR 2.208(e). Conclusory allegations will be given little or no weight in the determination. Any information not specifically claimed confidential and not specifically supported by a substantiation of confidentiality claims will be released without further notice to you. Be advised that information described by Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 10(d)(1)(A), (B), and (C) is not automatically entitled to confidential treatment. Disclosure of such information would only be prohibited, by FIFRA section 10(b), if the information is eligible for confidential treatment as described by 40 CFR 2.208.

If you wish to claim any information in your response to this letter as confidential, you must mark the response "CONFIDENTIAL" or with a similar designation, and you must bracket all text so claimed. Information so designated will be disclosed by EPA only to the extent allowed by, and by means of, the procedures set forth in 40 CFR Part 2. If you fail to claim the information in your response as confidential upon submission, it may be made available to the public without further notice to you.

Your reply can be mailed to the following address:

Or your reply can be delivered to my attention at the following address:

Your comments must be postmarked or hand-delivered by the 15th working day after your receipt of this letter. If you intend to submit timely comments, please notify _____ by phone: _____, by fax: _____, by email: _____ or by mail at the address above. Failure to submit timely comments will be regarded as a waiver of your confidentiality claim and EPA will release the information.

You may request an extension of the 15-day deadline. Except in extraordinary circumstances, no extension will be granted without the permission of the requester.

Should you have any questions in this matter, please contact

Sincerely,

Enclosures