

SAMPLE LETTER A: Generic Substantiation, FOIA

Approved OMB xxx
Approval expires XXXX

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 [INSERT FOIA #]

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 the EPA] [if submitted by an entity other than the business whose information it is: in EPA’s possession]* pertaining to *[a detailed description of the information or specific list of documents that is/are the subject of the advance or final confidentiality determination]*. *[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, 40 C.F.R. Part 2, Subpart B, the 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 the 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 at 40 C.F.R. Part 2, Subpart B, the FOIA request has been initially denied to afford you an opportunity to provide comments to [If no claim has been made: claim this information as CBI and] substantiate your claim(s) as described below.*

The purpose of this letter is to notify you that the EPA (*appropriate legal office*) will be making a(n) (*advance* or *final*) confidentiality determination concerning the information you have claimed as CBI. If you feel that some or all of the information is entitled to confidential treatment, you must make the showings below with specific reference to those portions of the information you consider confidential.

Please be specific by page (including Bates Stamp, if applicable), paragraph, and sentence when identifying and substantiating the information subject to your claim. Where your claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that you claim to be CBI. Please note that if a page, document, group, or class of documents claimed by you to be CBI contains a significant amount of information which (*appropriate legal office*) determines is not CBI, your CBI claim regarding that page, document, group, or class of documents may be denied. Please be advised that any information not specifically identified as

subject to a confidentiality claim and substantiated as such in your response to this letter may be disclosed to the requester without further notice to you.

In making its final confidentiality determination, the EPA will consider the relevant substantive criteria in its CBI regulations, under 40 C.F.R. § 2.208(a)-(d), as well as the U.S. Supreme Court's decision in *Food Marketing Institute v. Argus Leader Media (Argus)*, 139 S. Ct. 2356 (2019), which evaluated the definition of "confidential" as used in Exemption 4. In the *Argus* decision, the Court held that at least where "[1] commercial or financial information is both customarily and actually treated as private by its owner and [2] provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4." *Argus*, 139 S. Ct. at 2366.

Thus, for each item or class of information that you claim as CBI, please answer the following questions, giving as much detail as possible. EPA will use your responses to these questions to determine whether the information has been shown to be entitled to confidential treatment:

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 the EPA becomes stale over time. Please explain why EPA should protect the information you claim as confidential for the time period specified in your answer to question #1.
3. Has EPA, another federal agency, or court made any determination as to the confidentiality of the information? If so, please attach a copy of the determination.
4. Is the information contained in any publicly available material such as patents or patent applications, publicly available databases (including state databases), promotional publications, annual reports, or articles? Yes/No

If you answered "yes", please identify the publicly available information and its location (e.g., patent number or website address).

5. Has your company taken reasonable measures to protect the information claimed as CBI? If so, please identify the measure or internal controls your business has taken to protect the information claimed as confidential:
 - a. Non-disclosure agreement required prior to access. Yes/No
 - b. Access is limited to individuals with a need-to-know. Yes/No
 - c. Information is physically secured (e.g. locked in a room or cabinet) or electronically secured (encrypted, password protected, etc.). Yes/No
 - d. Other internal control measures(s). Yes/No. (*If yes, please explain.*)

6. Does your company customarily keep the information private or closely-held? If so, please explain the basis for your response.
7. At the time you submitted the information you claimed as CBI, did EPA provide any express or implied assurance of confidentiality? If so, please provide the specific assurance(s) you received. For example, expressed assurances indicating that information will not be publicly disclosed could include legal authorities (regulation or statute), direct communications, class determinations, etc. Examples of implicit assurances could include a description of the specific context in which the information was received.
8. Did the Agency provide any expressed or implied indications at the time the information was submitted that EPA would publicly disclose the information?
9. If you believe any submitted information to be a trade secret, please state and explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be a trade secret.
10. [Potential Question based on circumstance: Are there any means by which a member of the public could obtain access to the information or readily discover the information claimed as confidential through reverse engineering?]
11. [Potential Question based on the type of CBI claim: Please explain why the information claimed as confidential is not emissions data under the Clean Air Act, effluent data under the Clean Water Act, health and safety data under the Toxics Substances Control Act, or any other information that is prohibited from protection under regulation or statute.]
12. Explain any other issue or additional information you deem relevant to EPA's determination.

Please note that *you bear the burden of substantiating your CBI and trade secret claim(s)*. Generalized or conclusory statements will be given little or no weight in EPA's determination on the confidentiality of the information you claim to be CBI.

Your comments must be postmarked or hand delivered to this office, or emailed to [*email 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 your request must be made before the end of the 15-day period. Except in extraordinary circumstances, no extension will be approved without the consent of the FOIA requester. Failure to submit your comments within that time will be regarded as a waiver of your confidentiality claim(s), and the EPA may release the information.

If you wish to claim any information that you provide in your response to this letter to be claimed as CBI, you must mark the response with "**CONFIDENTIAL BUSINESS INFORMATION**" or with a similar designation, and you must bracket all text in the response that you so claim. Information so designated will be disclosed by the 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 provided in your response as confidential, it may be made available to the public without further notice to you.

Should you have any questions concerning this matter, please call me at [*telephone number*].

Sincerely,

[Signature and Title; Office Name and Address]

[Enclosure]

SAMPLE LETTER B: Generic Substantiation, Non-FOIA

Approved OMB 2020-0003
Approval expires xxxx

Request for Substantiation From an Affected Business

By Certified U.S. Mail; Return Receipt Requested

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

Re: _____

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 the 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, 40 C.F.R. Part 2, Subpart B, the 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 the 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”).]*

The purpose of this letter is to notify you that the EPA *[appropriate legal office]* will be making a(n) *[advance or final]* confidentiality determination concerning the information you have claimed as CBI. If you feel that some or all of the information is entitled to confidential treatment, you must make the showings below with specific reference to those portions of the information you consider confidential.

Please be specific by page (including Bates Stamp, if applicable), paragraph, and sentence when identifying and substantiating the information subject to your claim. Where your claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that you claim to be CBI. Please note that if a page, document, group or class of documents claimed by you to be CBI contains a significant amount of information which our *[appropriate legal office]* determines is not CBI, your CBI claim regarding that page, document, group, or class of documents may be denied. Any information not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter may be disclosed without further notice to you.

In making its final confidentiality determination, the EPA will consider the relevant substantive criteria in its CBI regulations, under 40 C.F.R. § 2.208(a)-(d), as well as the U.S. Supreme Court's decision in *Food Marketing Institute v. Argus Leader Media (Argus)*, 139 S. Ct. 2356 (2019), which evaluated the definition of "confidential" as used in Exemption 4. In the *Argus* decision, the Court held that at least where "[1] commercial or financial information is both customarily and actually treated as private by its owner and [2] provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4." *Argus*, 139 S. Ct. at 2366.

Thus, for each item or class of information that you claim as CBI, please answer the following questions, giving as much detail as possible. EPA will use your responses to these questions to determine whether the information has been shown to be entitled to confidential treatment: 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 the EPA becomes stale over time. Please explain why EPA should protect the information you claim as confidential for the time period specified in your answer to question #1.
3. Has EPA, another federal agency, or court made any determination as to the confidentiality of the information? If so, please attach a copy of the determination.
4. Is the information contained in any publicly available material such as patents or patent applications, publicly available databases (including state databases), promotional publications, annual reports, or articles? Yes/No

If you answered "yes", please identify the publicly available information and its location (e.g., patent number or website address).

5. Has your company taken reasonable measures to protect the information claimed as CBI? If so, please identify the measure or internal controls your business has taken to protect the information claimed as confidential:
 - a. Non-disclosure agreement required prior to access. Yes/No
 - b. Access is limited to individuals with a need-to-know. Yes/No
 - c. Information is physically secured (e.g. locked in a room or cabinet) or electronically secured (encrypted, password protected, etc.). Yes/No
 - d. Other internal control measures(s). Yes/No. (*If yes, please explain.*)
6. Does your company customarily keep the information private or closely-held? If so, please explain the basis for your response.
7. At the time you submitted the information you claimed as CBI, did EPA provide any express or implied assurance of confidentiality? If so, please explain the specific assurance(s) you received. For example, expressed assurances indicating that

information will not be publicly disclosed could include legal authorities (regulation or statute), direct communications, class determinations, etc. Examples of implicit assurances could include a description of the specific context in which the information was received.

8. Did the Agency provide any expressed or implied indications at the time the information was submitted that EPA would publicly disclose the information?
9. If you believe any submitted information to be a trade secret, please state and explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be a trade secret.
10. [Optional Question for Program to include if applicable: Are there any means by which a member of the public could obtain access to the information or readily discover the information claimed as confidential through reverse engineering?]
11. [Optional Question for Program to include if applicable: Please explain why the information claimed as confidential is not emissions data under the Clean Air Act, effluent data under the Clean Water Act, health and safety data under the Toxics Substances Control Act, or any other information that is prohibited from protection under regulation or statute.]
12. Explain any other issue or additional information you deem relevant to EPA's determination.

[If applicable to a EPA class determination: Enclosed is the EPA Class Determination [class determination number] entitled, [name of the class determination], which addresses the treatment of [description of class determination]. You may consider reviewing Class Determination [#] as you develop your response.]

Please note that *you bear the burden of substantiating your confidentiality and trade secret claim(s)*. Generalized or conclusory statements will be given little or no weight in EPA's determination on the confidentiality of the information you claim to be CBI.

Your comments must be postmarked or hand delivered to this office, or emailed to [email 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 the EPA may release the information.

If you wish to claim any information that you provide in your response to this letter to itself be confidential, you must mark the response "**CONFIDENTIAL**" or with a similar designation, and must bracket all text in the response that you so claim. Information so designated will be disclosed by the 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 provided

in your response as confidential, it may be made available to the public without further notice to you.

If you wish to claim any information that you provide in your response to this letter to be claimed as CBI, you must mark the response with “**CONFIDENTIAL BUSINESS INFORMATION**” or with a similar designation, and you must bracket all text in the response that you so claim. Information so designated will be disclosed by the 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 provided in your response as confidential, it may be made available to the public without further notice to you.

Should you have any questions concerning this matter, please call me at [*telephone number*].

Sincerely,

[Signature and Title ; Office Name and Address]

[Enclosure]

SAMPLE LETTER C: FIFRA, FOIA

OMB 2020-0003
Expires: XXXX
Inert Ingredients

Request for Substantiation From an Affected Business

By Certified U.S. Mail; Return Receipt Requested

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

RE: Confidential Business Information Determination

Dear [ADDRESSEE]:

The U.S. Environmental Protection Agency (“EPA”) Office of Pesticide Programs has received a request under the FOIA for certain records *[if submitted by the business whose information it is: that you submitted to the EPA] [if submitted by an entity other than the business whose information it is: in EPA’s possession]* pertaining to *[a detailed description of the information or specific list of documents that is/are the subject of the advance or final confidentiality determination]*. *[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, 40 C.F.R. Part 2, Subpart B, the 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 the 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 at 40 C.F.R. Part 2, Subpart B, the FOIA request has been initially denied to afford you an opportunity to provide comments to *[If no claim has been made: claim this information as CBI and]* substantiate your claim(s) as described below.

The purpose of this letter is to notify you that the EPA Office of General Counsel will be making a(n) *[advance or final]* confidentiality determination concerning the information you have claimed as CBI. If you feel that some or all of the information is entitled to confidential treatment, you must make the showings below with specific reference to those portions of the information you consider confidential.

Please be specific by page (including Bates Stamp, if applicable), paragraph, and sentence when identifying and substantiating the information subject to your claim. Where your

claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that you claim to be CBI. Please note that if a page, document, group, or class of documents claimed by you to be CBI contains a significant amount of information which the Office of General Counsel determines is not CBI, your CBI claim regarding that page, document, group, or class of documents may be denied. Any information not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter may be disclosed to the requester without further notice to you.

In making its final confidentiality determination, the EPA will consider the relevant substantive criteria in its CBI regulations, under 40 C.F.R. § 2.208(a)-(d), as well as the U.S. Supreme Court's decision in *Food Marketing Institute v. Argus Leader Media (Argus)*, 139 S. Ct. 2356 (2019), which evaluated the definition of "confidential" as used in Exemption 4. In the *Argus* decision, the Court held that at least where "[1] commercial or financial information is both customarily and actually treated as private by its owner and [2] provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4." *Argus*, 139 S. Ct. at 2366.

Thus, for each item or class of information that you claim as CBI, please answer the following questions, giving as much detail as possible. EPA will use your responses to these questions to determine whether the information has been shown to be entitled to confidential treatment:

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 the EPA becomes stale over time. Please explain why EPA should protect the information you claim as confidential for the time period specified in your answer to question #1.
3. Has EPA, another federal agency, or court made any determination as to the confidentiality of the information? If so, please attach a copy of the determination.
4. Is the information contained in any publicly available material such as patents or patent applications, publicly available databases (including state databases), promotional publications, annual reports, or articles? Yes/No

If you answered "yes", please identify the publicly available information and its location (e.g., patent number or website address).

5. Has your company taken reasonable measures to protect the information claimed as CBI? If so, please identify the measure or internal controls your business has taken to protect the information claimed as confidential:
 - a. Non-disclosure agreement required prior to access. Yes/No

- b. Access is limited to individuals with a need-to-know. Yes/No
 - c. Information is physically secured (e.g. locked in a room or cabinet) or electronically secured (encrypted, password protected, etc.). Yes/No
 - d. Other internal control measures(s). Yes/No. (*If yes, please explain.*)
6. Does your company customarily keep the information private or closely-held? If so, please explain the basis for your response.
 7. At the time you submitted the information you claimed as CBI, did EPA provide any express or implied assurance of confidentiality? If so, please explain the specific assurance(s) you received. For example, expressed assurances indicating that information will not be publicly disclosed could include legal authorities (regulation or statute), direct communications, class determinations, etc. Examples of implicit assurances could include a description of the specific context in which the information was received.
 8. Did the Agency provide any expressed or implied indications at the time the information was submitted that EPA would publicly disclose the information?
 9. If you believe any submitted information to be a trade secret, please state and explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be a trade secret.
 10. [Optional Question for Program to include if applicable: Are there any means by which a member of the public could obtain access to the information or readily discover the information claimed as confidential through reverse engineering?]
 11. Explain any other issue or additional information you deem relevant to EPA's determination.

Please note that *you bear the burden of substantiating your confidentiality and trade secret claim(s)*. Generalized or conclusory statements will be given little or no weight in EPA's determination on the confidentiality of the information you claim to be CBI.

Your comments must be postmarked or hand delivered to this office, or emailed to [*email 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 the EPA may release the information.

If you wish to claim any information that you provide in your response to this letter to itself be confidential, you must mark the response "**CONFIDENTIAL**" or with a similar designation, and must bracket all text in the response that you so claim. Information so designated will be disclosed by the 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 provided

in your response as confidential, it may be made available to the public without further notice to you.

If you wish to claim any information that you provide in your response to this letter to be claimed as CBI, you must mark the response with “**CONFIDENTIAL BUSINESS INFORMATION**” or with a similar designation, and you must bracket all text in the response that you so claim. Information so designated will be disclosed by the 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 provided in your response as confidential, it may be made available to the public without further notice to you.

Should you have any questions concerning this matter, please call me at [*telephone number*].

Sincerely,

[Signature and Title ; Office Name and Address]

[Enclosure]

SAMPLE LETTER D: FIFRA; Non-FOIA

OMB 2020-0003
Expires

Request for Substantiation From an Affected Business

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 Request [INSERT NUMBER]

Dear [INSERT NAME]:

The U.S. Environmental Protection Agency (“EPA”) Office of Pesticide Programs 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 the 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, 40 C.F.R. Part 2, Subpart B, the 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 the 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”).]

The purpose of this letter is to notify you that the EPA Office of General Counsel will be making a(n) [advance or final] confidentiality determination concerning the information you have claimed as CBI. If you feel that some or all of the information is entitled to confidential treatment, you must make the showings below with specific reference to those portions of the information you consider confidential.

Please be specific by page (including Bates Stamp, if applicable), paragraph, and sentence when identifying and substantiating the information subject to your claim. Where your claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that you claim to be CBI. Please note that if a page, document, group, or class of documents claimed by you to be CBI contains a significant amount of information which the Office of General Counsel determines is not CBI, your CBI claim regarding that page, document, group, or class of documents may be denied. Any information not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter may be disclosed to the requester without further notice to you.

In making its final confidentiality determination, the EPA will consider the relevant substantive criteria in its CBI regulations, under 40 C.F.R. § 2.208(a)-(d), as well as the U.S. Supreme Court's decision in *Food Marketing Institute v. Argus Leader Media (Argus)*, 139 S. Ct. 2356 (2019), which evaluated the definition of "confidential" as used in Exemption 4. In the *Argus* decision, the Court held that at least where "[1] commercial or financial information is both customarily and actually treated as private by its owner and [2] provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4." *Argus*, 139 S. Ct. at 2366.

Thus, for each item or class of information that you claim as CBI, please answer the following questions, giving as much detail as possible. EPA will use your responses to these questions to determine whether the information has been shown to be entitled to confidential treatment:

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?

Questions 8 through 17 must be answered for each type of information that you claimed as confidential:

8. 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.
9. Information submitted to the EPA becomes stale over time. Please explain why EPA should protect the information you claim as confidential for the time period specified in your answer to question #1.
10. Has EPA, another federal agency, or court made any determination as to the confidentiality of the information? If so, please attach a copy of the determination.
11. Is the information contained in any publicly available material such as patents or patent applications, publicly available databases (including state databases), promotional publications, annual reports, or articles? Yes/No

If you answered “yes”, please identify the publicly available information and its location (e.g., patent number or website address).

12. Has your company taken reasonable measures to protect the information claimed as CBI? If so, please identify the measure or internal controls your business has taken to protect the information claimed as confidential:
 - a. Non-disclosure agreement required prior to access. Yes/No
 - b. Access is limited to individuals with a need-to-know. Yes/No
 - c. Information is physically secured (e.g. locked in a room or cabinet) or electronically secured (encrypted, password protected, etc.). Yes/No
 - d. Other internal control measures(s). Yes/No. (*If yes, please explain.*)
13. Does your company customarily keep the information private or closely-held? If so, please explain the basis for your response.
14. At the time you submitted the information you claimed as CBI, did EPA provide any express or implied assurance of confidentiality? If so, please explain the specific assurance(s) you received. For example, expressed assurances indicating that information will not be publicly disclosed could include legal authorities (regulation or statute), direct communications, class determinations, etc. Examples of implicit assurances could include a description of the specific context in which the information was received.

15. Did the Agency provide any expressed or implied indications at the time the information was submitted that EPA would publicly disclose the information?
16. If you believe any submitted information to be a trade secret, please state and explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be a trade secret.
17. Explain any other issue or additional information you deem relevant to EPA's determination.

Please note that *you bear the burden of substantiating your CBI and trade secret claim(s)*. Generalized or conclusory statements will be given little or no weight in EPA's determination on the confidentiality of the information you claim to be CBI. 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 (b), if the information is eligible for confidential treatment as described by 40 CFR 2.208(a)-(d).

Your comments must be postmarked or hand delivered to this office, or emailed to [*email 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 your request must be made before the end of the 15-day period. Except in extraordinary circumstances, no extension will be approved without the consent of the FOIA requester. Failure to submit your comments within that time will be regarded as a waiver of your confidentiality claim(s), and the EPA may release the information.

If you wish to claim any information that you provide in your response to this letter to be claimed as CBI, you must mark the response with "**CONFIDENTIAL BUSINESS INFORMATION**" or with a similar designation, and you must bracket all text in the response that you so claim. Information so designated will be disclosed by the 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 provided in your response as confidential, it may be made available to the public without further notice to you.

Should you have any questions concerning this matter, please call me at [*telephone number*].

Sincerely,

[SIGNATORY AND TITLE]

Enclosures

OMB 2020-0003
Approval expires

By Certified U.S. Mail; Return Receipt Requested

MAY CONTAIN CONFIDENTIAL BUSINESS INFORMATION

[*Technical Contact Name, title, Company, and Address*]

Re: Notice of Review and Request for Substantiation of Confidential Business Information Claim(s)

Document Type:

Document Identifying Number:

Date of Submission:

Type of claim(s) to be reviewed:

- specific chemical identity
- all other CBI claims

Dear [*Addressee*]:

Under section 14(f) of the Toxic Substances Control Act (TSCA), EPA shall require any person to “reassert and substantiate or resubstantiate the [CBI] claim” under certain circumstances. EPA will review such CBI claim (1) to determine whether the information qualifies for protection under Exemption 4 when requested to be disclosed under a Freedom of Information request; (2) if the Administrator has a reasonable basis to believe the information does not qualify for protection under TSCA; or (3) for any chemical substance that EPA determines under TSCA section 5(b)(4)(A) presents an unreasonable risk of injury to health or the environment. 15 U.S.C. § 2613(f).

This letter is to notify you that the U.S. Environmental Protection Agency (EPA) Office of General Counsel will be making a final confidentiality determination concerning information you have claimed as CBI, as identified above. All CBI claims must be substantiated.

If you feel that some or all of the information checked above is entitled to confidential treatment, you must substantiate as described below with specific reference to those portions of the information you consider confidential.

Substantiating a CBI Claim.

There are two different sets of substantiation questions for CBI claims: (I) questions for all CBI claims in the submission; and (II) questions for chemical identity CBI claims. Please use the appropriate question set. In some instances, your TSCA submission may contain both types of CBI claims or a CBI claim may require completing both sets of substantiation questions. For example, if you assert a CBI claim to protect a chemical substance's identity, then you must answer both question sets. EPA has identified the appropriate question set(s) via the checkboxes at the top of this letter. In some instances, for example TSCA section 8(a) Chemical Data Reporting (CDR) Rule submissions, you may have already provided up-front substantiations for some or all of the CBI claims. If you have already substantiated your CBI claim at the time of submission, and believe that your previously submitted substantiation remains accurate and up to date, you may choose to rely on that substantiation by referring to or preferably physically attaching your substantiation to your response to this letter.

I. REQUIRED FOR ALL CBI CLAIMS.

If you are asserting ANY information in the submission as CBI, please answer the following questions.

In supporting your CBI claim(s), please be specific by page, paragraph, sentence, or by data element when identifying and substantiating the information subject to your claim. Where your claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that you claim to be CBI.

In some cases, it may be appropriate to group the information into a class of information rather than responding to each item claimed as CBI. See EPA webpage [INSERT WEBPAGE] for suggested approaches to providing substantiations of materials grouped. For any information that is not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter, it shall be determined that you have waived your CBI claim, pursuant to 40 C.F.R. § 2.205(d).

For each item or class of information that you continue to claim as CBI, please answer the following questions, giving as much detail as possible. Your substantiation response to these questions will be used by the EPA to determine whether the information has been shown to be entitled to confidential treatment:

1. Will disclosure of the information claimed as confidential likely cause in substantial harm to your business's competitive position? Yes/No.

If you answered yes, please describe with specificity the substantial harmful effects that would result to your competitive position if the CBI-claimed information 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, or unusual processes and your competitor's access to your customers.

2. To the extent you have disclosed information to others (both internally and externally), what precautions has your business taken? Please identify any measures or internal controls your business has taken to protect the information claimed as confidential.
 - A. Non-disclosure agreement required prior to access. Yes/No
 - B. Access is limited to individuals with a need-to-know. Yes/No
 - C. Information is physically secured (e.g. locked in room or cabinet) or electronically secured (encrypted, password protected, etc.). Yes/No
 - D. Other internal control measure(s). If so, please explain.
3. Does the information claimed as confidential appear in any public documents, including (but not limited to) safety data sheet, advertising or promotional material, professional or trade publication, patents or patent applications, or any other media or publications available to the general public? Yes/No.

If you answered yes, please identify the publicly available information and its location (e.g., patent number or website address) and explain why the information should nonetheless be treated as confidential.

4. Are there any means by which a member of the public or competitor could obtain access to the information or readily discover the information claimed as confidential through reverse engineering?
5. Does the information claimed to be CBI contain (a) trade secret(s)¹ ? Yes/No

If yes, please explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be (a) trade secret(s).
6. If you assert a claim of confidentiality that is less than 10 years (see TSCA section 14(f) (3)), then please indicate the number of years (between 1-10 years) or specific date after which the claim is withdrawn.²
7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? Yes/No.

¹ "Trade secret" is defined as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983).

² Information with withdrawn CBI claims will be made available to the public without further notice.

If yes, please explain the outcome of that determination and provide EPA with a copy of the previous confidentiality determination or any information that will assist the Agency in identifying the prior determination.

II. REQUIRED FOR ONLY CHEMICAL IDENTITY CBI CLAIMS.

If you are claiming a specific chemical identity as CBI, please answer the additional following questions. If you are not substantiating a chemical identity CBI claim, then you do not need to respond to the questions below.

1. Is the chemical substance on the confidential portion of the TSCA Inventory? Yes/No.
2. Commerce:
 - A. Has the chemical substance (or mixture) been offered for commercial distribution? Yes/No.
 - B. Is the chemical substance known by the public or your competitors to be in U.S. commerce? Yes/No.

If you answered yes, please explain why the information should nonetheless be treated as confidential.

3. Disclosure of the specific chemical name would release:
 - A. Confidential process information. Yes/No.
 - B. Confidential portion of a mixture information. Yes/No.

If you answered yes to either question, please explain.

Asserting a CBI claim in your substantiation response.

Businesses may claim their substantiation response as CBI. Information claimed as confidential should be clearly marked by bracketing, circling, or underlining. All pages containing such information must also be stamped "CONFIDENTIAL BUSINESS INFORMATION" or with similar designation in order to assert a confidentiality claim. Care should be taken to ensure that these markings do not obscure the text.

Certification

You must include the following statement in the submission.

I hereby certify to the best of my knowledge and belief that all information provided in this submission is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

- (i) My company has taken reasonable measures to protect the confidentiality of the information;
- (ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and
- (iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

Timely Responses and Postal Requirements

Your substantiation response must be postmarked or hand delivered to this office **by the 15th working day after your receipt of this letter**. While it is anticipated that there will be a means for sending these to the Agency electronically in the future, at this point substantiations should be sent via US Mail or courier.

Filings should be directed to the below address.

TSCA Confidential Business Information Center (7407M)
WJC East; Room 6428; Attn: TSCA CBI Substantiations
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Courier Deliveries:

U.S. EPA
Office of Pollution Prevention and Toxics
Confidential Business Information Center (CBIC)
Attn: TSCA CBI Substantiations
1201 Constitution Avenue, NW
WJC East; Room 6428
Washington, DC 20004-3302
(202) 564-8930

You may seek an extension of time to submit your substantiation response to this office, but the request must be made before the end of the 15-day period. Requests for an extension may be directed to Ms. Quoc Nguyen, Office of General Counsel, Nguyen.Quoc@epa.gov.

Failure to timely submit your substantiation response will be regarded as a waiver of your confidentiality claim or claims, and the EPA may release the information.

Should you have any questions concerning this matter, please contact Mr. Scott Sherlock, (202) 564-8257 and Sherlock.Scott@epa.gov; or Ms. Jessica Barkas, (202) 250-8880 and Barkas.Jessica@epa.gov.

Sincerely,

[Signature and Title ; Office Name and Address]