



OFFICE OF CIVIL ENFORCEMENT

WASHINGTON, D.C. 20460

April 17, 2024

**SENT VIA ELECTRONIC MAIL to
amartin@gicllc.com and kevin.martin77@yahoo.com
DELIVERY AND READ RECEIPTS REQUESTED**

Global Infection Control Consultants, LLC
ATTN: Arthur V. Martin, President
ATTN: Kevin M. Martin, CEO
PO Box 61325
Miami, FL 33261

**Re: Stop Sale, Use, or Removal Order to Global Infection Control Consultants
Docket No. FIFRA-HQ-2024-5017
and Request for Information**

Dear Sirs:

Enclosed is a Stop Sale, Use, or Removal Order (SSURO or "Order") issued by the U.S. Environmental Protection Agency (EPA) to Global Infection Control Consultants, LLC (GICC) concerning its line of Path-Away products. The enclosed SSURO requires GICC to immediately cease the sale and distribution of Path-Away products and is effective immediately upon receipt by GICC.

Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or "the Act"), 7 U.S.C. § 136k(a), authorizes the EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe, on the basis of inspection or tests, that the pesticide or device is in violation of any provision of FIFRA, or has been or is intended to be distributed in violation of any provision of the Act.

The EPA has reason to believe that GICC has previously and intends to continue selling and distributing unregistered pesticide products in violation of Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

GICC must comply with all terms and conditions in the SSURO; any violation may result in the imposition of civil penalties up to \$24,255 per violation or of criminal penalties. The issuance of this Order shall not act as a waiver by the EPA of any enforcement or other authority available to the Agency under federal law, including authority to seek civil penalties under Section 14(a) of FIFRA, 7 U.S.C. § 136l(a), for the violations alleged in this Order or any other violation.

Request for Information under FIFRA § § 8 and 9

Also enclosed is an Information Request made pursuant to sections 8(b) and 9(a) of FIFRA, 7 U.S.C. §§ 136f(b), 136g(a), which authorize the EPA to inspect and have access to various records related to the distribution and sale of pesticides and devices for the purposes of enforcing FIFRA. The EPA is asking that GICC submit information electronically in accordance with the enclosed Information Request within 30 days of receipt of this correspondence.

Failure to provide the requested records, refusing to allow the copying of the records requested, and knowingly falsifying records submitted to the EPA are violations under FIFRA. 7 U.S.C. §§ 136j(a)(2)(B), (M). Violations of FIFRA are punishable by civil or criminal penalties under FIFRA section 14, 7 U.S.C. § 136l.

If you choose to assert a claim of Confidential Business Information (CBI) you must substantiate how your CBI claims satisfy the criteria and procedures for CBI claims set forth in 40 C.F.R. Part 2, Subpart B (enclosed as “Confidential Business Information Assertion and Substantiation”).

Please direct all general and technical questions regarding this Information Request to Abdul Ibrahim, General Engineer, via phone at (202) 564-2496 or email at Ibrahim.Abdul@epa.gov and legal questions regarding the Order to Erika McDonald, Attorney-Advisor, via phone at (202) 564-2063 or e-mail at McDonald.Erika@epa.gov. Thank you for your cooperation.

Sincerely,

Christina Cobb, Chief
Pesticides and Tanks Enforcement Branch
Waste and Chemical Enforcement Division
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency

Enclosures: Stop Sale, Use, or Removal Order, Docket No. FIFRA-HQ-2024-5017
Information Request
Confidential Business Information Assertion and Substantiation

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENFORCEMENT AND COMPLIANCE ASSURANCE**

IN THE MATTER OF:)	
)	
)	
Global Infection Control Consultants, LLC)	STOP SALE, USE, OR REMOVAL ORDER
Miami, FL)	
)	Docket No. FIFRA-HQ-2024-5017
Respondent.)	
)	

I. AUTHORITY

1. The U.S. Environmental Protection Agency (EPA or “the Agency”) regulates pesticides and pesticide devices pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA or “the Act”), 7 U.S.C. §§ 136-136y.

2. Section 13(a) of FIFRA authorizes the EPA Administrator to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe, on the basis of inspection or tests, that the pesticide or device is in violation of any provision of FIFRA or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of the Act. 7 U.S.C. § 136k(a).

3. This authority was delegated from the EPA Administrator to Branch Chiefs in the Waste and Chemical Enforcement Division, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance.

II. GOVERNING LAW

4. Sections 3(a) and 12(a)(1)(A) of FIFRA provide that it is unlawful for any person in any state to distribute or sell to any person a pesticide that is not registered with the EPA under FIFRA, subject to certain exemptions. 7 U.S.C. §§ 136a(a), 136j(a)(1)(A).

5. Section 2(s) of FIFRA defines a “person” as “any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.” 7 U.S.C. § 136(s).

6. Section 2(gg) of FIFRA defines “to distribute or sell” as “to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver.” 7 U.S.C § 136(gg).

7. Section 2(u) of FIFRA defines a “pesticide,” in part, as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.” 7 U.S.C. § 136(u)

8. Regulations at 40 C.F.R. § 152.15(a)(1) and (b) further define the term “pesticide” as any substance intended for a pesticidal purpose, and thus requiring registration, if the person who distributes or sells the substance claims, states, or implies (by labeling or otherwise) that the substance can or should be used as a pesticide; or the substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than use for pesticidal purpose.

9. The term “active ingredient” refers to an ingredient in a pesticide other than a plant regulator, defoliant, desiccant, or nitrogen stabilizer, that will prevent, destroy, repel, or mitigate any pest. 7 U.S.C. §136(a).

10. “Pest” means any insect, rodent, nematode, fungus, weed, any other form of terrestrial or aquatic plant or animal life or virus, bacteria, prion, or other micro-organisms (except viruses, bacteria, or other micro-organisms on or in living man or other living animals and those on or in processed food or processed animal feed, beverage, drugs, and cosmetics) which the Administrator declares to be a pest under section 25(c)(1). 7 U.S.C. § 136(t). 40 C.F.R. § 152.5.

11. The regulation set forth at 40 C.F.R. § 152.5 provides that “[a]n organism is declared to be a pest under circumstances that make it deleterious to man or the environment,” including if the

organism is “[a]ny fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs [] and cosmetics [].”

12. The term “antimicrobial pesticide” includes pesticides intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms or protect inanimate objects or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime. 7 U.S.C. § 136(mm).

13. The EPA promulgated regulations at 40 C.F.R. § 152.25(f) establishing specific conditions for products to qualify as “minimum risk pesticides” exempt from Section 3 registration including, inter alia, specific inert and active ingredients and certain types of product claims. To qualify for the exemption, the product must not bear claims to control or mitigate microorganisms that pose a threat to human health, including disease transmitting bacteria or viruses. *See* 40 C.F.R. § 152.25(f)(3)(ii).

14. “Label” means “the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.” 7 U.S.C. § 136(p)(1).

15. “Labeling” includes “all labels and all other written, printed, or graphic matter accompanying the pesticide or device at any time, or to which reference is made on the label or in literature accompanying the pesticide or device.” 7 U.S.C. § 136(p)(2).

III. BASIS FOR THE ORDER

16. Respondent Global Infection Control Consultants (GICC or “Respondent”) is a “person” as that term is defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s).

17. On May 15, 2023, the EPA’s Office of Inspector General informed the Office of Civil Enforcement that GICC was making public health claims about a product that was not registered with

the EPA called Path-Away.

18. The EPA subsequently began an investigation and determined that Path-Away was being offered for sale by a number of distributors, including one at www.powerwashstore.com.

19. Pursuant to the Path-Away investigation, EPA credentialed inspectors conducted a for-cause inspection at Mobi Clean Inc., dba Power Wash Store, located at W147 N9415 Held Drive, Menomonee Falls, WI on January 9, 2024.

21. During the inspection, EPA inspectors observed a pallet containing 47 one-gallon containers of Path-Away Antipathogenic Solution (Path-Away). A Power Wash Store executive told inspectors that the company purchased and received one 275-gallon tote and two 55-gallon drums of Path-Away from GICC.

22. Labels on the Path-Away products included claims that Path-Away is effective in mitigating pathogens, such as the term “anti-pathogenic solution.”

20. EPA inspectors obtained purchase orders showing sales of the following products from GICC to Power Wash Store:

- a. One 275-gallon tote of Path-Away to be delivered by GICC to Jarman’s Midwest Cleaning Systems, dated October 26, 2020.
- b. One 55-gallon drum of Path-Away to be delivered by GICC to Supreme Power Wash in San Antonio, Texas, dated December 3, 2020.
- c. One 55-gallon drum of Path-Away to be delivered by GICC to PWS-Charlotte in Midland, North Carolina, dated January 13, 2021.

21. During the inspection, an executive for Power Wash Store told EPA inspectors that GICC authorized Power Wash Store to contract with Jarman’s Midwest Cleaning Solutions to repackage Path-Away from the bulk containers to one-gallon containers and that GICC provided a digital copy of the label to be printed and applied to the one-gallon containers by Jarman’s Midwest Cleaning Solutions. EPA inspectors also obtained a series of emails between GICC, Power Wash Store, and Jarman’s Midwest Cleaning Solutions arranging for the repackaging, sale, and distribution of Path-Away into U.S.

commerce. One such email, from GICC, included a label attached as a Portable Document Format (pdf) file that matched the labels on the Path-Away containers at the Power Wash Store warehouse described above.

22. During the inspection, EPA inspectors also obtained emails from GICC to Power Wash Store that included a number of studies provided by GICC as putative support for labelling claims that Path-Away is effective in preventing the spread of various pathogens and viruses including MRSA, SARS-Cov-2 (the virus that causes COVID-19 infections), E. coli, Candida, Staphylococcus, and Clostridium difficile. The EPA observed that the same health claims for Path-Away, and the supporting studies, are visible on GICC's web site at <https://path-away.com/index.php/performance>.

22. In documentation collected during the inspection, Jarman's Midwest Cleaning Solutions asked Power Wash Store if Path-Away is an EPA-registered pesticide and whether Jarman's Midwest Cleaning Solutions should be registered with the EPA in order to legally repackage Path-Away. In its emailed response to Power Wash Store, GICC provided a letter, dated January 12, 2015, from a state pesticide regulator in California expressing an opinion that Path-Away qualified as a minimum risk pesticide exempt from FIFRA registration. The state regulator's opinion included a copy of a label for Path-Away from 2015 that differed from the labels collected by EPA inspectors in the 2024 inspection described above. For instance, the 2015 label did not contain the term "anti-pathogenic solution."

23. Accordingly, based on the 2024 inspection, Path-Away is currently labeled with a different label than the one California reviewed in 2015.

24. As of the date of this Order, Path-Away is still offered for sale through third-party distributors including but not limited to the following:

- a. GC Organic Solutions at <https://www.gcorganicsolutions.com/online-store>
- b. Home Vet at <https://www.homevet.com/product/path-away-8-oz-spray/>
- c. Innovative Poultry Products at <https://shop.innovativepoultryproducts.com/path-away/>
- d. OBI Disinfection at <https://obidisinfection.com/product/path-away-sanitizer-32oz/>

25. The web site Path-Away.com advertises a list of products identified as the “full product line” at <https://path-away.com/index.php/full-product-line> and includes the following products:

- a. Path-Away Anti-Pathogenic Aerosol Solution
- b. Path-Away Protectant Solution
- c. Path-Away Hand & Mask Spray
- d. Path-Away Textile Protectant
- e. Path-Away Poultry Protectant
- f. Path-Away Dairy Protectant
- g. Path-Away +
- h. Path-Away Health & Wellness Additive
- i. Path-Away Pet Protectant
- j. Path-Away Cannabis Control

26. Company details on the same web page identify GICC and include a link to <https://giccllc.com/>.

27. Based on the inspections and labeling claims described above, Path-Away is a “pesticide” as that term is defined by Section 2(u) of FIFRA, 7 U.S.C. § 136(u), and must be registered with the EPA before being distributed or sold.

28. Based on the human health claims made for Path-Away, it is not exempt from FIFRA’s registration requirements as a minimum risk pesticide.

29. Path-Away has not been and is not currently registered with the EPA.

30. Therefore, the EPA has reason to believe that GICC sold or distributed and continues to sell and distribute unregistered pesticides, in violation of Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

IV. ORDER

31. Pursuant to Section 13(a) of FIFRA, Respondent is ordered to immediately cease any distribution, sale, use, or removal of the following products, collectively referred to as Path-Away, within the Respondent’s ownership, custody, or control, wherever such products are located:

- a. Path-Away Anti-Pathogenic Aerosol Solution

- b. Path-Away Protectant Solution
- c. Path-Away Hand & Mask Spray
- d. Path-Away Textile Protectant
- e. Path-Away Poultry Protectant
- f. Path-Away Dairy Protectant
- g. Path-Away +
- h. Path-Away Health & Wellness Additive
- i. Path-Away Pet Protectant
- j. Path-Away Cannabis Control

32. This Order pertains to all unit sizes and to all quantities and forms in which Path-Away is offered for sale, held for sale, or otherwise distributed or sold.

33. Path-Away shall not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, received, delivered, offered for delivery, moved, used, or removed for any reason unless in accordance with this Order, any written modifications to this Order, or as otherwise approved by the EPA in writing according to the following paragraph.

34. Movement of Path-Away may occur only as follows:

- a. Respondent must submit a written request to move Path-Away and receive written approval from the EPA before any movement occurs;
- b. The request must be submitted to Abdul Ibrahim via email at Ibrahim.Abdul@epa.gov;
- c. The request must include an explanation of the purpose or reason for the movement or removal;
- d. The request must provide a written accounting of the products to be moved (i.e., product name or identifier, container size, number of containers, and total quantity), the address of the facility from where the products will be moved, and the address of the destination facility;
- e. If the movement or removal is for the purposes of disposal, Respondent must provide written proof of disposal to the EPA, including quantity of product disposed and proof of compliance with all applicable federal, state, and local laws.

35. Any movement or removal of any Path-Away Products made without prior written authorization from the EPA or not in accordance with the above paragraph constitutes a violation of this Order and may constitute the distribution or sale of an unregistered pesticide in violation of section 12 of FIFRA. 7 U.S.C. § 136j.

V. OTHER MATTERS

36. This Order shall be effective immediately upon receipt by Respondent or an authorized agent and shall remain in effect until revoked, terminated, suspended, or closed in writing by the EPA.

37. Respondent may seek judicial review of this Order pursuant to section 16 of FIFRA. 7 U.S.C. § 136n.

38. Noncompliance with this Order is a violation of FIFRA and may result in civil or criminal penalties pursuant to section 14 of FIFRA. 7 U.S.C. §§ 136j(a)(2)(I), 136l.

39. The issuance of this Order shall not constitute a waiver by the EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.

40. Respondent may assert a business confidentiality claim (CBI claim) covering all or part of the information provided as part of this Order if such information meets the requisite criteria and is submitted according to 40 C.F.R. § 2.203(b). Information properly subject to a CBI claim may be made available to the public only in accordance with 40 C.F.R. pt. 2, subpt. B. Otherwise, information submitted to the EPA may be made available to the public without further notice.

41. For any additional information about this SSURO, please contact Erika McDonald, attorney, by telephone at (202) 564-2240 or by email at Mcdonald.Erika@epa.gov.

Date

Christina Cobb, Chief
Pesticides and Tanks
Enforcement Branch Waste and
Chemical Enforcement Division
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

INFORMATION REQUEST

I. DEFINITIONS

For the purpose of this Information Request, all terms used herein share those meanings of terms set forth in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y, its implementing regulations, and the Stop Sale, Use and Removal Order (SSURO) enclosed with this correspondence. Otherwise, the following definitions shall apply:

- I.1.** “GICC” means Global Infection Control Consultants, LLC, including but not limited to its predecessors, successors, subsidiaries, parent companies, affiliates, d/b/a, divisions, branches, brands, offices, franchises, facilities, committees, trusts, partnerships, and joint ventures in which it has any interest; all entities for which it is acting as an agent or contractor; and its past or present officers, directors, trustees, managers, employees, agents, consultants, contractors, attorneys, representatives, and any other persons acting on its behalf.
- I.2.** “Path-Away” means any product manufactured by GICC or Holista Colltech containing a solution with the active ingredients either citric acid, ascorbic acid, or “proprietary citrus extract” as the active ingredient, in any and all unit sizes, all forms, and any using alternative names, which GICC sold, offered for sale, held for sale, imported, exported, or otherwise distributed or currently sells or distributes including but not limited to the following products:
- k. Path-Away Anti-Pathogenic Aerosol Solution
 - l. Path-Away Protectant Solution
 - m. Path-Away Hand & Mask Spray
 - n. Path-Away Textile Protectant
 - o. Path-Away Poultry Protectant
 - p. Path-Away Dairy Protectant
 - q. Path-Away +
 - r. Path-Away Health & Wellness Additive
 - s. Path-Away Pet Protectant
 - t. Path-Away Cannabis Control
- I.3.** “And” as well as “or” shall be construed either conjunctively or disjunctively as necessary to bring within the scope of this Information Request all information which might otherwise be construed to be outside its scope.
- I.4.** “Furnish,” “provide,” “describe,” “identify” or “indicate” means turning over to the EPA either original or duplicate copies of the requested information in the possession, custody, or control of GICC. Where specific information is not memorialized in any document but is nonetheless responsive to a request, you must respond to the request with a written response. If such requested information is not in your possession, custody or control then

indicate where such information or documents may be obtained.

- I.5. "Record" means an original or copy of all documents, contracts, agreements, memoranda, notes, papers, letters, maps, books, photographs, microfilms, electronic messages and attachments, calendars, outlines, drafts, ledgers, bills, invoices, purchase orders, shipping orders, statements of receipt or shipment, work orders, work requests, electronic data processing files and output, films, sound recordings, or other material, regardless of physical form or characteristics, made or received by Respondent concerning or in connection with Respondent's facilities and any pesticide or device. It also includes electronically stored data from which information can be obtained either directly or by translation through detection devices or readers, including but not limited to information stored on a computer hard drive, magnetic tape, cassette, disk, CD, network, or cloud storage service. All records must be produced in usable form with instructions for reading such data.
- I.6. "Shipped" means when the product left the store to be sent to the person who purchased the product.
- I.7. "Delivered" means when the product was left with the person who purchased the product at the address specified by that person.

II. INSTRUCTIONS

- II.1. A response must be submitted within 30 days of receipt of this Request. Requests for additional time must be made in writing within five calendar days of receipt of this Request and provide a justification for the request.
- II.2. Identify the person(s) responding to this request. Include names, titles, telephone numbers, and email addresses.
- II.3. Identify the person(s) consulted in preparing the responses to this request (including names, titles, telephone numbers and email addresses), as well as all documentation consulted, examined or referred to in preparing the answers to this request and provide copies of all such documents.
- II.4. The response and all record submissions required by this Information Request should be provided electronically (i.e., email or online file sharing such as Dropbox, Google Drive, OneDrive, etc.) and in an electronic format that is searchable and fully accessible in Microsoft Office or Adobe Acrobat. For any files provided in PDF, all text must be made searchable and optical character recognition performed. If another format is used, it must be approved by EPA at least 15 days before the response is due.
- II.5. Provide a record index or list that identifies each record submitted, the specific request the file is responding to, the file software, file name(s), size(s), and the date(s) of creation.
- II.6. Address each numbered request separately and precede each response with the number of

the corresponding request and a list of all records submitted in response to the request, including the full record name(s) with the file software, file size(s), author, and date(s) of creation.

- II.7.** You must provide a complete answer must be provided for each request to the best of Respondent's ability, even if the information sought was never reduced to writing or if the records are no longer available. If the appropriate response is "none" or "not applicable," that must be stated. Submission of cursory responses when other responsive information is available will be considered non-compliance with this Request. Incomplete, evasive, or ambiguous answers shall constitute failure to respond to this IRL and may result in enforcement action.
- II.8.** If responsive information or records are not within Respondent's possession, custody, or control, indicate where the information or records may be obtained. Responsive information or records must be obtained from current and former employees and/or agents if needed.
- II.9.** All records that respond in whole or in part to any part or clause of any request shall be produced in their entirety, including all attachments and enclosures. A written reason and general subject matter explanation must be provided if anything is redacted or deleted from a responsive record.
- II.10.** If information is not known or available at the date of submission of the response, but later becomes known or available, supplemental responses must be submitted to the EPA. If after submitting the response any portion of the submitted information is found to be false, misleading, or misrepresents the truth, Respondent must immediately notify the EPA.
- II.11.** EPA has not determined whether recipient is a "small business" under the Small Business Regulatory Enforcement and Fairness Act ("SBREFA"). If this company is a "small business" under SBREFA, please see additional information provided in the EPA's Small Business Information Sheet (<https://www.epa.gov/compliance/small-business-resources-information-sheet>) which includes information on compliance assistance and about contacting the SBREFA Ombudsman to comment on federal enforcement. Any decision to participate in such program or to seek compliance assistance does not relieve any obligation to respond to an EPA information request or other enforcement action in a timely manner. Further, participation does not create any new rights or defenses under law and will not affect the EPA's decision to pursue an enforcement action.
- II.12.** The information requested herein must be provided notwithstanding its possible characterization as confidential information or trade secrets. Records or information provided to the EPA may be entitled to a claim of business confidentiality ("CBI claim"). Additional information on asserting or substantiating a CBI claim is included with this correspondence.
- II.13.** The response should be accompanied by the certification enclosed with this Information Request signed by a responsible company official or representative.

III. Information and Records Requested

- III.1.** Provide a narrative description of the corporate structure of GICC and any subsidiaries, contractors and brands.
- III.2.** Provide a narrative description of the relationship between GICC and Holista Colltech, including any import documentation and former or current contractual obligations between March, 2020 and the date of this request.
- III.3.** Provide a complete inventory of all Path-Away products including product names, internal product codes, quantities, container sizes, and locations where the products are held
- III.4.** Provide the following records for each corresponding Path-Away product sold or distributed from March 2020 to the date of this Request:
 - a. Product name and internal product code;
 - b. Product description;
 - c. Date of sale or distribution, shipment, and delivery;
 - d. Quantity purchased;
 - e. Purchase price;
 - f. Location where product was shipped from;
 - g. Product composition, including active and inert ingredients; and
 - h. All labels, safety data sheets, compositional analyses, promotional marketing materials or advertisements, studies, product bulletins, and all other records created, distributed, or used by GICC to promote or inform the sale, distribution, or use of each Path-Away product.
- III.5.** Provide a narrative description of the manufacturing process for Path-Away including the location and date the product was last manufactured.
 - a. If the product is produced by a contract manufacturer, provide the directions and specifications issued to the manufacturer.
 - b. If the product is pre-manufactured, mixed, packaged, or labeled, identify the supplier and any records from the supplier detailing the product's composition.
- III.6.** Identify the person(s) responding to this request and any person(s) consulted in preparing responses to this request (including names, titles, telephone numbers, and email addresses).

IV. CERTIFICATION

I certify under penalty of law that I have personally examined and am familiar with the documents and information submitted in response to this Information Request; that, to the best of my knowledge and belief, the submitted information is true, accurate and complete; and that all documents submitted herewith are complete and authentic. I am aware that there are significant penalties for submitting false information, including the possibility of fine or imprisonment.

Executed on the _____ day of _____, 202__

Signature

Name

Title

Employer

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

CONFIDENTIAL BUSINESS INFORMATION (CBI) ASSERTION AND SUBSTANTIATION REQUIREMENTS

Assertion Requirements

Respondent may assert a business confidentiality claim covering all or part of the information requested in the attached letter, as provided in 40 C.F.R. § 2.203(b). To make a confidentiality claim, submit the requested information and indicate that you are making a claim of confidentiality. Any document for which a claim of confidentiality is made should be marked by placing on or attaching a cover sheet, stamped or typed legend, or other suitable form of notice employing language such as “trade secret,” “proprietary,” or “company confidential” and a date, if any, when the information should no longer be treated as confidential. Information covered by such a claim will be disclosed by the EPA only to the extent permitted and by means of the procedures set forth by 40 C.F.R. pt. 2. Allegedly confidential portions of otherwise non confidential documents should be clearly identified. The EPA will construe the failure to furnish a confidentiality claim with your response to the attached letter as a waiver of that claim, and the information may be made available to the public without further notice.

Please segregate personnel, medical and similar files from all responses and include such information on separate sheet(s) marked as “Personal Privacy Information.”

Substantiation Requirements

All confidentiality claims are subject to the EPA verification and must be made in accordance with 40 C.F.R. § 2.208, which provides that Respondent satisfactorily show that it has taken reasonable measures to protect the confidentiality of the information, that Respondent intends to continue to do so, and that the information is not and has not been reasonably obtainable by legitimate means without Respondent’s consent.

Pursuant to 40 C.F.R. pt. 2, subpt. B, the EPA may at any time send a letter asking that Respondent substantiate a CBI claim. Respondent must provide EPA with a response within the number of days set forth in the EPA request letter. Failure to submit comments within that time will be regarded as a waiver of the confidentiality claim or claims, and the EPA may release the information. The EPA will ask Respondent to specify which portions of the information considered confidential. **Respondent must be specific by page, paragraph, and sentence when identifying the information subject to a CBI claim.** Any information not specifically identified as subject to a CBI claim may be disclosed in response to a Freedom of Information Act request without further notice. For each item or class of information that you identify as being subject to CBI, the EPA will ask for answers to the following questions, with as much detail as possible:

1. For what period of time should 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. Why should the information claimed as confidential be protected for the time period specified in the answer to question

#1?

3. What measures have been taken to protect the information claimed as confidential? Has it been disclosed 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 would customarily not be 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 Respondent's 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 competitors make use of this information to Respondent's detriment?
7. Does Respondent assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for this assertion. If it is asserted that the information is voluntarily submitted, explain whether and why disclosure of the information would tend to lessen the availability to the EPA of similar information in the future.
8. Any other issue(s) Respondent deems relevant.

If Respondent receives a request for a substantiation letter from the EPA, Respondent bears the burden of substantiating the confidentiality claim. Conclusory allegations will be given little or no weight in the determination. In substantiating a CBI claim(s), the EPA will require that a bracket be placed around all text so claimed and marked as "CBI." 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. pt. 2, sub B. Information not subject to a CBI claim may be made available to the public without further notice.