OFFICE OF CIVIL ENFORCEMENT
WASHINGTON, D.C. 20460

April 1, 2024

SENT VIA ELECTRONIC MAIL TO david@chaosdesigns.us

DELIVERY AND READ RECEIPTS REQUESTED

Mr. David Clayton
CEO
PathoGreen, LLC
PO Box 23003
Hilton Head Island, SC 29926

Re: Stop Sale, Use, or Removal Order to PathoGreen LLC, Docket No. FIFRA-HQ-2024-5004 and Request for Information

Dear Mr. Clayton:

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

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 PathoGreen 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).

PathoGreen must comply with all terms and conditions in this Order; 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 PathoGreen 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 section 14 of FIFRA, 7 U.S.C. § 136*l*.

If you choose to assert a claim of Confidential Business Information (CBI) you must substantiate how your CBI claims satisfies 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 via phone at (202) 564-2496 or email at Ibrahim.Abdul@epa.gov and legal questions regarding the SSURO 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

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Christina Cobb, Chief
Pesticides and Tanks Enforcement Branch
Waste and Chemical Enforcement Division
Office of Enforcement and Compliance Assurance

Enclosures: Enclosures: Stop Sale, Use, or Removal Order, Docket No. FIFRA-HQ-2024-5004
Information Request
Confidential Business Information Assertion and Substantiation

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENFORCEMENT AND COMPLIANCE ASSURANCE

IN THE MATTER OF:	)	
PathoGreen, LLC	)	**STOP SALE, USE, OR REMOVAL ORDER**
Hilton Head, South Carolina	)	
	)	**Docket No. FIFRA-HQ-2024-5004**
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 the Director and Associate Director of the Waste and Chemical Enforcement Division, Office of Enforcement and Compliance Assurance. The Director Redelegated this authority to the Branch Chief of the Pesticides and Tanks Enforcement Branch within in the Waste and Chemical Enforcement Division.

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, 7 U.S.C. §§ 136a(a), 136j(a)(1)(A), subject to certain exemptions not applicable here.

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. The term "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 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).

12. Regulations at 40 C.F.R. § 152.25(f) establish the conditions for pesticides to qualify as minimum risk pesticides exempt from Section 3 registration including, inter alia, specific ingredient and claims qualifications on product labeling. To qualify for the exemption, the product must not bear claims to control or mitigate microorganisms that pose a threat to human health, including viruses. 40 C.F.R. § 152.25(f)(3)(ii).

13. The term "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).

14. The term "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).

15. If a label references a company's website, either by listing a web address or URL, including a Quick Response Code (QR Code), or using similar identifiers that direct to a website, then the website becomes "labeling" under FIFRA and is subject to EPA review. *See* 7 U.S.C. § 136(p)(2).

III. BASIS FOR THE ORDER

16. PathoGreen, LLC ("Respondent"), is a limited liability company with its principal place of business in Hilton Head, South Carolina. Therefore, Respondent is a "person" as that term is defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s).

17. On February 14, 2024, the EPA observed Respondent's line of Path-Away products (collectively, "Path-Away") being offered for sale to the public on Respondent's website at https://pathogreen.com.

18. As used in this SSURO, the term "Path-Away," means any product containing Path-Away Anti-Pathogenic Solution including but not limited to:

a. Path-Away Protectant Solution – One Gallon Refills;
b. Path-Away Anti-Pathogenic Aerosol Solution – 32 oz. Disinfecting Spray;
c. Path-Away Anti-Pathogenic Aerosol Solution – 2 oz. Hand + Mask Spray;
d. Path-Away All Natural Healing Pet Spray – 4 oz. All Natural Healing Pet Spray; and
e. Path-Away All Natural Healing Pet Spray – 1 Gallon Pet Solution Refill.

19. According to Respondent's website, a company called Global Infection Control Consultants is the purported manufacturer of Path-Away and Respondent is the only official distributor of Path-Away.

20. As of the date of this Order, Path-Away products are available for purchase on Respondent's website, where a person visiting the site may find the product(s), select the product(s) for purchase, select a quantity, place the product(s) in a virtual cart, enter a shipping address, submit payment information, and complete the sales transaction.

21. On February 14, 2024, the EPA observed the following general and product-specific claims, which indicate Respondent's intent that Path-Away products be used to control or mitigate microorganisms that pose a threat to human health:

a. "Path-Away is an antipathogenic solution";
b. "effective against 170 different fungus, bacteria, viruses and yeast";
c. "tested and proven effective against COVID-19, H1N1, MRSA, SARS, Mycobacterium Tuberculosis, Clostridium Difficile, and more;"
d. "Kills 99.9% of bacteria & viruses";
e. "provides protection against many forms of bacteria and viruses";
f. "use it also for plane seats, seats at the doctor's office, and on shopping cart handles";
g. "works amazingly on mange".

22. Respondent's website at https://pathogreen.com/images/COVID-19.pdf features a study provided by the purported manufacturers of Path-Away. The study purports to demonstrate the product's success against Covid-19 at 3% concentration. The study also cites to EPA guidance entitled, *Emerging Viral Pathogen Guidance for Antimicrobial Pesticides,* and claims that it "will clarify for you that Path-Away Anti-Pathogenic Aerosol Solution meets current criteria for use on the ongoing COVID-19 (SARS-CoV2) situation."

23. Photographs posted on Respondent's web site show that labels affixed to the following products include some of the above-described public health claims:

a. Path-Away Anti-Pathogenic Aerosol Solution – 32 oz. Disinfecting Spray
b. Path-Away Anti-Pathogenic Aerosol Solution – 2 oz. Hand + Mask Spray
c. Path-Away All-Natural Healing Pet Spray – 4 oz.

24. Photographs posted on Respondent's web site show that labels affixed to the following products include the URL www.pathogreen.com:

a. Path-Away Protectant Solution – One Gallon Refills;
b. Path-Away All Natural Healing Pet Spray – 1 Gallon Pet Solution Refill.

25. Respondent's web site features multiple notices and studies from Global Infection Control Consultants each of which include the claim that Path-Away "was declared 'exempt from registration' by qualifying as a minimum risk pesticide."

26. Upon review of the Path-Away product safety data sheet available on Respondent's website, the EPA observed "proprietary citrus extract" and "ascorbic acid" listed as the active ingredients in Path-Away.

27. Neither "proprietary citrus extract" nor "ascorbic acid" is on the list of permitted active ingredients in products that are minimum risk pesticides under 40 C.F.R. § 152.25(f).

28. Photographs of Path-Away Protectant Solution and Path-Away Healing Pet Spray, offered for sale on Respondent's web site, depict product labels that list ingredients that differ from those listed on the above-described safety data sheet: the active ingredient listed on the product labels is citric acid. Although citric acid is on the accepted list of active ingredients for minimum risk pesticides and could make the products exempt from registration, such exemption is not available for products for which public health claims are made. *See* 40 C.F.R. § 152.25(f)(3)(ii).

29. Because the labeling claims for Path-Away products indicate that the products are intended to mitigate microorganisms including viruses and bacteria, the Path-Away products are "pesticides" as that term is defined by Section 2(u) of FIFRA. *See* 7 U.S.C. § 136(u).

30. Because the active ingredients in certain Path-Away products are not on the list of permitted active ingredients for minimum risk pesticides, those Path-Way products do not qualify for exemption from pesticide registration as minimum risk pesticides. *See* 40 C.F.R. § 152.25(f).

31. Because the labeling claims for Path-Away products contain human health claims, Path-Away products do not qualify for exemption from pesticide registration as minimum risk pesticides. *See* 40 C.F.R. § 152.25(f).

32. Path-Away products were never and are not currently registered with the EPA.

33. Therefore, the EPA has reason to believe that Respondent is selling and distributing, 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).

IV. ORDER

34. 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 Respondent's ownership, custody or control, wherever such products are located:

a. Path-Away Protectant Solution – One Gallon Refills;
b. Path-Away Anti-Pathogenic Aerosol Solution – 32 oz. Disinfecting Spray;
c. Path-Away Hand + Mask Spray;
d. Path-Away All Natural Healing Pet Spray – 4 oz.;
e. Path-Away All Natural Healing Pet Spray – 1 Gallon Pet Solution Refill; and
f. Any other unregistered pesticide product related to or containing Path-Away products.

35. This SSURO 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.

36. Respondent shall not sell; offer for sale; hold for sale; ship; deliver for shipment; receive; or, having received, deliver; offer for delivery; move; or remove the Path-Away products, other than in accordance with the provisions of this Order or such further Orders as may be issued by the EPA in connection with Path-Away.

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

a. Respondent must submit a written request to move Path-Away products and receive written approval from the EPA before any movement occurs;
b. The request must be submitted to Abdul Ibrahim 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, including proper pesticide disposal procedures.

38. Any movement or removal of Path-Away 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 and/or misbranded pesticide in violation of section 12 of FIFRA. 7 U.S.C. § 136j.

V. OTHER MATTERS

39. This SSURO shall be effective immediately upon receipt by an agent, owner, or operator of Respondent.

40. It is unlawful for any person to violate any order issued under section 13 of FIFRA, 7 U.S.C. § 136j(a)(2)(I).

41. 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.

42. The issuance of this SSURO shall not constitute a waiver by the EPA of any enforcement or other authority available to the Agency under federal law.

43. This SSURO shall remain in effect unless terminated or modified in writing by the EPA.

44. If any provision of this SSURO is subsequently held to be invalid, illegal, or unenforceable, the validity, legality, and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and shall remain in full effect.

45. Respondent may seek federal judicial review of this SSURO pursuant to Section 16 of FIFRA, 7 U.S.C. § 136n.

46. For any additional information about this SSURO, please contact Erika McDonald, Attorney-Advisor, by telephone at 202-564-2240 or by email at mcdonald.erika@epa.gov.

CHRISTIN A COBB

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Date

Christina Cobb, Chief
Pesticides and Tanks Enforcement Branch
Waste and Chemical Enforcement Division
Office of Enforcement and Compliance Assurance

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. "PathoGreen," "Respondent," "You," or "Your" means the PathoGreen company, including but not limited to its predecessors, successors, subsidiaries, parent companies, affiliates, d/b/a, divisions, branches, 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 all unit sizes and all quantities and forms in which Path-Away is offered for sale, held for sale, or otherwise distributed or sold including but not limited to the following products:

a. Path-Away Protectant Solution – One Gallon Refills;
b. Path-Away Anti-Pathogenic Aerosol Solution – 32 oz. Disinfecting Spray;
c. Path-Away Hand + Mask Spray;
d. Path-Away All Natural Healing Pet Spray – 4 oz.;
e. Path-Away All Natural Healing Pet Spray – 1 Gallon Pet Solution Refill; and
f. Any other unregistered pesticide product related to or containing Path-Away products.

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 PathoGreen. 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 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 operation 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, Internet Service Provider or network. 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 the 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. The 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. **General Company Information**. Provide the following, along with supporting documentation where applicable, for the years 2020 to the date of this information request:

a. A narrative description of the relationship between PathoGreen and Global Infection Control Solutions (and/or any of its representatives), including any former or current contractual obligations as they relate to Path-Away;
b. A narrative description of the relationship between PathoGreen and any other business entity engaged in supplying, manufacturing, producing, labeling, selling or distributing Path-Away from 2020 to the date of this request, including any former or current contractual obligations;
c. A list of any other outlets, besides pathogreen.com, where you sell Path-Away;
d. All records related to any manufacturing agreement and/or purchasing contracts between you and your source of Path-Away. This includes all documents which discuss the terms, location, or process by which Path-Away products are sold, produced, shipped, or otherwise transferred to you from any source.

III.2. Information Regarding Path-Away. For calendar years 2020, 2021, 2022, 2023, and 2024 (to date) please provide the following for each Path-Away product:

a. A complete inventory of all Path-Away products including product names, internal product codes, quantities, container sizes, and locations where the products are held;
b. The name of the product, date, and return address for every shipment of Path-Away you received;
c. A description of the process, if any, PathoGreen uses to repackage Path-Away in any way that alters the original container or label on the product when received from your source.

III.3. Sales/Distribution Records. For calendar years 2020, 2021, 2022, 2023, and 2024 (to date) please provide the following for each instance that PathoGreen "distributed" or "sold" Path-Away:

a. Name of product;
b. Purchase date;
c. Dates Path-Away was shipped to the purchaser;
d. Quantity of purchase;
e. Cost of product;
f. Total cost of purchase (e.g., if purchaser bought two products in one transaction for $10, the total cost of purchase would be $20); and
g. Copy of any documentation (e.g, safety data sheets) included with each product package.

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 make 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. 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 the 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 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.

IV. CERTIFICATION

I certify under penalty of law that I have personally examined and am familiar with the information and records submitted in response to this Information Request. I certify that to the best of my knowledge and belief all information and records submitted in response to this Request are true, accurate, and complete, and that all records submitted herewith are complete and authentic unless otherwise indicated. 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