Nonsynthetic Affidavit

* **CCOF Client:** Upon request by CCOF, submit one affidavit for each nonsynthetic nonagricultural material. Forward this affidavit to the material manufacturer. They must complete and sign this form.
* **Material Manufacturer:** A qualified, authorized contact must complete this form so CCOF can review this material for the CCOF certified client’s use. Confidentiality will be maintained[[1]](#footnote-2).

1. **Material Details**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Nonorganic ingredient (material) name: | |  | |
| 1. Manufacturer business name and contact info (phone/email): | | |  |
| 1. CCOF Client Name: |  | | |

* 1. Attach a complete ingredient statement.  Attached
  2. Attach a complete production process flow diagram or written description of how the material is made. Include all steps in the production of this material and include any solvents, adjuvants, carriers, preservatives, incidentals, ancillaries, processing aids or other materials used in its production, including solvent removal steps.  Attached

|  |  |  |
| --- | --- | --- |
| 1. The material listed above conforms to the following criteria: | **True** | **False** |
| 1. Genetic engineering, genetically modified organisms, and excluded methods[[2]](#footnote-3) as defined in NOP 205.2 were **not** used in the production of this material. |  |  |
| 1. Ionizing radiation as described in 21 CFR 179.26 was **not** used in the processing of this material. |  |  |
| 1. Sewage sludge was **not** used in the production of this material |  |  |

1. **Nonsynthetic Classification Criteria**

Nonsynthetic is a substance that is derived from a natural source, such as minerals, plants, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). Extracted materials must not be transformed into a different substance via chemical change; must not have been altered into a form that does not occur in nature; and any synthetic materials used to separate, isolate, or extract the substance must have been removed from the final material (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final material. Products of naturally occurring biological processes such as fermentation and composting are statutorily considered natural and nonsynthetic.

1. Is the substance manufactured, produced, or extracted from a natural source (naturally occurring mineral or biological matter)?

Yes  No (Prohibited)

1. Describe the natural ingredient(s) used to produce your final product:

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1. Has the substance undergone a chemical change so that it is chemically or structurally different than how it naturally occurs in the source material?

Yes  No (Allowed – Nonsynthetic)

1. Is the chemical change created by a naturally occurring biological process such as composting, fermentation, or enzymatic digestion; or by the heating or burning of biological matter?

Yes (Allowed – Nonsynthetic)  No (Prohibited – Synthetic)  Not applicable (no chemical change)

1. Is the substance extracted?

No. Do not complete section C. Skip to Section D.  Yes. Complete section C

1. **Extracted Substance Production Process**

The following questions apply to substances produced via extraction.

1. At the end of the extraction process, has the material been transformed into a different substance via chemical change?

Yes (Synthetic – Prohibited)  No

1. Has the extracted material been altered into a form that does not occur in nature?

Yes (Synthetic – Prohibited)  No

1. Have all synthetic materials used to separate, isolate, or extract the substance been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product?

Yes (Nonsynthetic – Allowed)  No (Synthetic – Prohibited)

Not applicable (no synthetic materials used to separate, isolate, or extract the substance)

1. **Manufacturer Statement**

Pursuant to NOP 205.2, 205.105, and 205.605-606, I, on behalf of the named manufacturer, hereby attest that the information provided in this form is accurate and truthful to the best of my knowledge. Note that per NOP 205.100(c)(2), any person falsifying statements to an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

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| --- | --- | --- | --- |
|  |  |  | |
| **Manufacturer Representative Name** *(please print clearly)* | **Title** | **Email Address** | |
|  | | |  |
| **Manufacturer Representative’s Authorized Signature (Digital, Ink, or E-Verified)** | | | **Date** |

1. **NOP Definitions**

Refer to [NOP Program Handbook](https://www.ams.usda.gov/sites/default/files/media/Program%20Handbk_TOC.pdf) 5033 and 5033-1 and NOP 205.2 for further information.

* Nonsynthetic (natural) – A substance that is derived from mineral, plant or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). Nonsynthetic is used as a synonym for natural as the term is used in the Act.
* Chemical change – A process (i.e. chemical reaction) whereby a substance is transformed into one or more other distinct substances.
* Extract – To separate, withdraw, or obtain one or more constituents of an organism, substance, or mixture by use of solvents (dissolution), acid-base extraction, or mechanical or physical methods.
* Naturally occurring biological process – A process that occurs due to the action of biological organisms or subcomponents of biological organisms, such as enzymes. Examples of naturally occurring biological processes include, but are not limited to, fermentation, composting, manure production, anaerobic digestion, or enzymatic processes.

1. 1Confidentiality of Information: CCOF CS safeguards the confidentiality of any business-related information concerning any client, products, or suppliers obtained during the course of certification. CCOF CS does not disclose any proprietary information to third parties without the client’s written consent prior to release, except to the authorized representatives of the Secretary, the applicable State Organic Program's Governing State Official, or other authorized representatives of accreditation agencies where necessary to implement the NOP, the State Organic Program, or the CCOF CS certification program. CCOF CS may disclose proprietary information as required by other laws of the United States or other countries in which it performs certification activities, State law or other laws of local governments. [↑](#footnote-ref-2)
2. ***Excluded Methods (NOP 205.2)***. *A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.* [↑](#footnote-ref-3)