

P.O. Box 9612 North Amherst MA 01059-9612

413-253-6565 ◆Fax: 413-253-6866 ◆www.ecoorganicsfertilizer.com

November 18, 2002

Ms. Toni Strother USDA/AMS/TM/NOP Rm. 4008-S, Ag. Stop 0268 1400 Independence Ave., SW. Washington, DC 2025-0200

Dear Ms. Strother:

As I relayed to you on your voice mail, a call to Ms. Kim Burton informed us that our petition of June 26, 2002, for the inclusion of our soy protein isolate in the National Organic List should really have been on behalf of the sodium hydroxide and hydrochloric acid employed to release the soy protein from its structural matrix.

Accordingly, we are petitioning, under Regulation 205.601 Synthetic substances allowed for use in crop production (j) (1), which lists sodium hydroxide 'limited to that amount necessary for extraction," to include as well hydrochloric acid under the same definition. These substances are used only in the manufacturing process and are not part of the final product.

In the event that further details of the manufacturing process are necessary beyond those provided in our petition of June 26, 2002, we are, of course, prepared to provide these.

We look forward to the early positive response to our petition.

Sincerely,

Haim B. Gunner

President

HBG/hms

# EcoOrganics Inc.

Environmental Balance Through Science
P.O. Box 9612, North Amherst, MA 01059-9612
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# **Fax**

Xx Urg	Soy Protein Isolate Petition  ent For Review   Please Co		☐ Please Comment		☐ Please Reply	☐ Please Recycle
Re:			CC:	[Click here and type name]		
Phone:	202-	690-2624		Date:	6/27/02	
Fax:	202-	205-7808		Pages:	1	
To:	Ms.	Toni Strother, USI	DAVNOP	From:	Haim B. Gunner	

Comments: Dear Ms. Strother

With respect to our soy protein isolate petition of 6/.26/02, we request that consideration of our petition be placed on fast track review, since sales to significant components of our current and future clientele are conditioned by our receiving organic registration for this material. Absent such registration serious harm could attach to the future of our company, Thank you for your help in this regard.

Haim B. Gunner



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Ms. Toni Strother USDA/AMS/TM/NOP Rm. 4008-S, Ag. Stop 0268 1400 Independence Ave., SW. Washington, DC 20250-0200 June 26, 2002

Dear Ms. Strother:

In accordance with the helpful counsel you have provided in our recent telephone conversations we are petitioning for the inclusion of our soy protein isolate in the National Organic List as noted below.

### Item A

We request the nonsynthetic substance, soy protein isolate, be included for use in organic crop production..

#### Item B

- 1. The substance's common name: Soy protein isolate.
- 2. Manufacturer: Archer Daniels Midland Company, 4666 East Faries Parkway, Decatur, IL 62525. Phone: 217-424-5200.
- 3. Intended use: Organic crop production, turf, landscape and horticultural applications.
- 4. As noted in 3 above. Rate: dependent on crop requirements proportional to the nitrogen content. Method of application: as a dispersible spray or in pelletized form.
- 5. Source: Soybean. Method of manufacture: as shown in the attached processing chart.
- 6. As shown in the attached letter from OMRI of May 29, 2002.
- 7. Not applicable.
- 8. Not applicable.
- 9. Not applicable.
- 10. MSDS attached
- 11. The rationale for OMRI's decision to recommend the inclusion of this material in the prohibited list was the use of sodium hydroxide (NaOH) and hydrochloric acid (HCl) food grade to release the protein from its surrounding matrix. However, humic acid (and kelp as well) though using NaOH is presently exempted from exclusion. Indeed, humic acid is an artifact with no existence as such in nature. Humic acids are identified after harsh alkaline extraction from what are termed humic substances, complex, mixtures of organic materials in soils, coals, and peat. Humic acid is specifically defined as that fraction of humic substances insoluble in water under acidic condition (pH less than 2) but soluble at higher

- pH. We contend that the gentle release of the soy protein isolate which remains unchanged from its natural structure provides a favorable contrast to the harsh chemical treatment necessary to produce humic acid derivatives.
- 12. The availability of soy protein isolate as an organic crop fertilizer and its availability as a growth enhancer and soil biostimulant make it an exceptionally valuable amendment to organic growers and those concerned with environmental health maintenance. In our letter to OMRI of December 5, 2001 (copy attached) we present our responses to questions OMRI raises as to how soy protein isolate meets the criteria of the U.S. Organic Food Production Act of 1990. In this letter, we provide evidence, among other data, confirming the beneficial effects of soy protein isolate to the environment, and to the crop and recreational turf ecosystems.
- 13. Commercial Confidential Information Statement: The use of soy protein isolate as fertilizer is covered by Patent No. 6406511 issued on June 18, 2002 to EcoOrganics, Inc.

We trust that the information provided will be adequate to support our application for inclusion of soy protein isolate for organic crop production.

Thank you for your help in this regard.

Yours/sincerely, Junes

Haim B. Gunner, Ph.D.

President

Encls.

HBG/mc

APR-19-2001 11:53

P.02/03

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# Soybean Processing

May 29, 2002

Haim Gunner EcoOrganics Inc P.O. Box 9612 North Amherst, MA 01059-9612

Dear Dr. Gunner:

Thank you for applying to the Organic Materials Review Institute (OMRI) for brand name product review.

The OMRI Review Panel has reviewed the product, BioSOF\* Plus, and have recommended that it be Prohibited for use in organic production. This decision indicates that the product does not meet organic standards based on OMRI's Generic Materials List and review policy contained in the most current OMRI Operating Manual, as well as our understanding of the documentation provided to support your application. The reason for prohibiting the product is that the soybeans are chemically treated with prohibited substances (specifically, sodium hydroxide and hydrochloric acid) that change the molecular structure of the soybeans.

OMRI has never listed plant extract products that are produced with sodium hydroxide and hydrochloric acid. Furthermore, the only exception to allowing alkali extraction at all is specifically annotated within the National Organic Rule under ketp and humic acid derivatives. Therefore, OMRI feels that in order for this product to be allowed in organic production the material should be petitioned to the National Organic Program. For information on that procedure go to www.ams.usda.gov/nop.

Furthermore, the Review Panel acknowledged that the manufacturing process submitted was not complete due to information gaps that were not explained (black circles on the flow chart). However, the information that was provided was enough for the Review Panel to vote on this product.

Prohibited listings are circulated to subscribing certifiers, but not to individual, corporate, or organizational subscribers unless it is requested. Please be aware that organic certifiers retain the right to make final certification decisions. These certifiers may choose to not accept OMRI's recommendation. Growers still need to contact their certifiers for information on the organic status of any given material. OMRI is not responsible for any losses that may occur as a result of this listing.

This letter serves as the Final Response Letter to EcoOrganics Inc regarding the status of BioSOF\* Plus. If EcoOrganics Inc wishes to appeal this decision, please refer to the "Appeals" section of the most current OMRI Operating Manual.

Again, thank you for your participation in the OMRI Brand Name Products Review Program.

Sincerely.

Kathleen Downey
Executive Director



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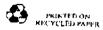
Marty Mesh Florida Certified Organic Growers & Consumers Gainesville, FL

> Zea Sonnabend California Certified Organic Farmers Watsonville, CA

Tim Sullivan, 1.D. Mississippi River Basin Alliunce Minneapolis, MN

Joran Viers New Mexico Organic Commodity Commission Albuquerque, NM

Affiliations listed for identification



# Material Safety Data Sheet

May be used to comply with

OSHA's Hazard Communication Standard. 29 CFR 1910.1200. Standard must be consulted for specific requirements.

IDENTITY (As Used on Label and List)

Sov Protein Isolate

U.S. Department of Labor

Occupational Safety and Health Administration (Non-Mandatory Form) Form Approved OMB No. 1218-0072

Note: Blank spaces are not permitted. If any item is not applicable, or no information is available, the

space must be marked to indicate that.

217-424-5200

**Emergency Telephone Number** 

Telephone Number for Information 217-424-5200

Date Prepared **NOVEMBER 1998** 

Signature of Preparer (optional)

### Section I

Manufacturer's Name ARCHER DANIELS MIDLAND COMPANY

Address (Number, Street, City, State, and ZIP Code)

**4666 FARIES PARKWAY DECATUR, IL 62525** 

# Section II - Hazard Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity;

Common Name(s))

OSHA PEL

**ACGIHTLY Other Limits Recommended** 

%(optional)

SOY PROTEIN ISOLATE CAS #9010-10-0

OSHA DUST LEVELS LESS THAN 15 mg/m²

### \*\*NFPA RATING: HEALTH-0: FLAMMABILITY-0: REACTIVITY-0 Section III - Physical/Chemical Characteristics

**Boiling Point** 

N/A

Specific Gravity (H2O = 1)

N/A

Vapor Pressure (mm Hg.)

N/A

**Melting Point** 

N/A

Vapor Density (AIR = 1)

N/A

**Evaporation Rate** 

(Butyl Acctate = 1)

N/A

Solubility in Water INSOLUBLE

Appearance and Odor OFF WHITE TO LIGHT BROWN

# Section IV - Fire and Explosion Hazard Data

Flash Point (Method Used)

Flammable Limits NA

LEL. NA

UEL. N/A

Extinguishing Media

SAND, DRY CHEMICAL, WATER THROUGH FOGGING TO LIMIT DUSTING

Special Fire Fighting Procedures

NONE

N/A

Unusual Fire and Explosion Hazards NONE

## SOY PROTEIN ISOLATE MSDS - PAGE 2 Section V - Reactivity Data

Stability

Unstable

Conditions to Avoid

N/A

Stable X

Incompatibility (Materials to Avoid)

NONE

Hezardous Decomposition or Byproducts NONE

Hezerdous

**Polymerization** 

May Occur

Conditions to Avoid

Will Not Occur

NOT APPLICABLE

X

Section VI - Health Hazard Data

Route(s) of Entry:

Inhalation? YES

Skin7 NO

Investion? YES

Health Hazards (Acute and Chrunic)

NO HEALTH HAZARD, MATERIAL IS FOOD INGREDIENT.

Carcinogenicity: NO

NTP?

IARC Monographs?

**OSHA Regulated?** 

Signs and Symptoms of Exposure:

NOT APPLICABLE

Medical Conditions Generally Aggravated by Exposure: MATERIAL IS NON HAZARDOUS. DUST MASK MAY BE WORN.

Emergency and First Aid Procedures:

EYES: FLUSH WITH WATER / SALINE FOLLOWED BY APPROPRIATE MEDICAL CARE AS NEEDED.

Section VII - Precautions for Safe Handling and Use

Steps to Be Taken in Case Material is Released or Spilled:

MATERIAL IS NON HAZARDOUS. IF DUSTING OCCURS IN CONFINED AREA, A DUST MASK SHALL BE WORN.

Waste Disposal Method:

NON CONTAMINATED WASTE MATERIAL CAN BE DISPOSED OF AS NON-HAZARDOUS SOLID WASTE.

Precautions to Be taken in Handling and Storing:

AVOID OPEN FLAMES OR OTHER IGNITION SOURCES (I.E., ELECTRICAL EQUIPMENT; SWITCH GEAR).

Other Precautions: NONE

Section VIII - Control Measures

Respiratory Protection (Specify Type): DUST MASK IF LEVELS EXCEED 15 mg/m²

Ventilation

Local Exhaust: NOT REQUIRED

Special: N/A

Mechanical (General): N/A

Other: N/A

Protective Gloves N/A

**Eye Protection: SAFETY GLASSES** 

Other Protective Clothing or Equipment: NONE

Work/Hygicaic Practices N/A

Page 2

\* U.S.G.P.O.: 1986 - 491 - 529/45775



Environmental Balance Through Science P.O. Box 9612, North Amherst, MA 01059-9612 Telephone: 413-253-6565 Fax: 413-253-6866

December 5, 2001

Ms. Cindy Douglas Product Review Coordinator OMRI Box 11558 Eugene, OR 97440-3758

Dear Ms. Douglas,

We have reviewed the issues raised in your letter of Nov. 28 with respect to the status of our BioSOF\* Plus fertilizer and understand from our brief conversation that your major concern is that the "acid-base digestion that the soybeans go through to make the product may or may not render the product synthetic".

As I indicated in my letter of Nov. 6<sup>th</sup>, there is in fact no "digestion" to which the residual soy protein isolates has been subjected. It is a process of solubilization to permit the proteins removal from the associated fiber, which is subsequently centrifuged away from the protein and soluble carbohydrates, a completely mechanical event. After a final pH adjustment, a final centrifugation separates the residual protein from the soluble carbohydrates. This residual protein is referred to as protein isolate and is indeed the unchanged protein from the original soybean matrix. The incidental neutralization of the alkali-acid interaction implies no change or degradation in the protein structure. The resultant NaCl is in fact "allowed" as indicated on page 58 of your January 2001 Interim report.

With respect to the criteria you cite from the U.S. Organic Food Production Act of 1990, the following apply:

- 1. "the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems". We find no record that soybean protein isolate, a readily biodegradable organic material, has had or shows the potential for detrimental chemical interactions with organic farming systems. The maximum residual sodium, as a result of the neutralization process, amounts to no more than 900-1200mg/100g of final product, an inconsequential concentration in soil systems where the application rate is typically between 1-1.5lbs/1,000 square feet.
- 2. "the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment". From our previous submissions, you will have learned of the very low

levels of heavy metals and the concentrations of nitrogen, phosphorous, potassium, calcium and magnesium (see attached). Our own field data show only the conventional decomposition sequences yielding exceptional plant growth responses with no signs of any toxicity or residual contamination.

3. "the probability of environmental contamination during manufacture, use, misuse, or disposal of such substance". Our primary supplier, ADM, Decatur, IL, is bound by all local and national regulations with respect to environmental contamination and is fully committed to compliance.

4. "the effect of the substance on human health". Soy protein isolate was in fact originally designed for specialty food applications and is widely used as a non-fat dry milk replacer in various foods such as margarine, butters and confections. It also has nutritional applications in baby foods and sauces. Our finding was the novel recognition that its especially high nitrogen concentration, organic compositions and sprayable application rendered it a particularly attractive fertilizer.

- 5. "the effects of the substance on biological and chemical interactions in the agroccosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops, and livestock". As cited above, our data indicate a very positive impact on the biological and chemical interactions in the agroecosystem, with enhanced turf and vegetable yields, in particular we have seen up to a 600-fold increase in microbial numbers, subsequent to application. The insignificant concentration of salt residual in the product would not have any meaningful impact on the salt index and solubility of the soil. We may only infer from the human food potential of this product the lack of any negative impact on livestock.
- 6. "the alternatives to using the substance in terms of practices or other available materials". Other substances that would qualify as organic in a similar category as our materials would be fish meal and blood meal. These, however, are animal derived whereas our soybean material is completely a natural plant organic material.
- 7. "its compatibility with a system of sustainable agriculture". As a soybean-derived material, completely organic with high nitrogen fertilizing capacity, it would appear to us to be readily compatible with a system of sustainable agriculture, in affect, completing the cycle of crop production and crop return as a soil fertilizer.

We trust that the foregoing will help in resolving the status of our products and we look forward to your early response in this regard. Nonetheless, should there be any further question, we shall be happy to respond.

President

CC Dr. Brian Baker

HBG/dab



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June 18, 2003

Mr. Richard Mathews
Program Manager
USDA-AMS-TMP-NOP
Room 4008-South Building
1400 Independence Avenue, SW
Washington, DC 20250-0020

RE: Request to Amend Regulations

Dear Mr. Mathews,

As you will notice from the voluminous copies of the attached correspondence, we have been attempting to achieve organic registration for our soy protein isolates for the past three years. Though we have received much help and guidance from members of your staff, particularly Miss Toni Strother, and from your committee member Kim Burton, the issue of achieving organic registration remains stranded around regulation 205-601 (j) 1. You will note that this regulation permits the use of potassium hydroxide or sodium hydroxide for aquatic plant extracts. Though we have petitioned for the acceptance of sodium hydroxide and hydrochloric acid as substances to be allowed under regulation 205-601 in the manufacture of our soy protein isolate for fertilizer use, we were ultimately informed in a telephone conversation by Ms. Kim Burton that our petition should have been directed to the change of item (j) 1 from "aquatic plant extracts" to simply "plant extracts". We therefore formally petition for this change as a means of facilitating the registration of our soy protein isolate as an organic material suitable as a plant or soil amendment.

To provide an overview of the process in which we have been engaged, we are including the following:

- 1. our letter to OMRI of December 5, 2001 responding to questions that they had raised
- 2. our letter of June 26, 2002 petitioning for the inclusion of our soy protein isolate in the NOM list
- 3. the flow sheet for the production of our soy protein isolate
- 4. the material safety data sheet.

As you see, this process is now approaching its third year of review and we again emphasize the urgency in achieving organic registration for an exceptionally worthy product whose market potential is impaired because of its lack of official organic status. We look forward to your early response.

Sincerely.

Haim B. Gunner, Ph. D.

President

Encl.

HBG/dab