

United States Department of Agriculture  
Agricultural Marketing Service | National Organic Program  
Document Cover Sheet

<https://www.ams.usda.gov/rules-regulations/organic/petitioned-substances>

Document Type:

**National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

**Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

**Petition for Amending the National List of the USDA's  
National Organic Program  
for inclusion of:**

***Pollen Extracts (*Secale cereale*)***

***A Non-organic agricultural substance allowed in processing***

Submitted date: July 7, 2022

Resubmission date: August 17, 2022

by

- Heather J. May, CEO, Graminex, L.L.C., 2300 County Road C, Deshler, OH 43516  
hmay@graminex.com
- Colleen E. May, CBO, Graminex, L.L.C., 2300 County Road C, Deshler, OH 43516  
bugs@graminex.com

### Item A.1

This is a petition to amend the National List of Allowed and Prohibited Substances (National List) at 7 C.F.R. § 205.606 for the following ingredients:

Pollen extracts (*Secale cereale*)

1. Water-soluble pollen extract (Water extraction)
2. Lipid-soluble pollen extract (Supercritical CO<sub>2</sub> extraction)

### Item A.2

N/A

### Item A.3

N/A

### Item B

#### 1. Substance Name

Pollen extracts (*Secale cereale*)

- Water-soluble pollen extract (Water extraction) (Graminex® G60®)
- Lipid-soluble pollen extract (Supercritical CO<sub>2</sub> extraction) (Graminex® NAX™)

#### 2. Petitioner and Manufacturer Information

Heather J. May, CEO  
Colleen E. May, CBO  
Graminex, L.L.C.  
2300 County Road C  
Deshler, OH 43516

Graminex was founded in 1997 and owns 6,500 acres of northwest Ohio farmland along with pollen harvesting, processing equipment, silos, and storage spread over 2 acres. Our pollen extracts are shipped worldwide mainly serving the dietary supplement market. We are third-generation farmers. Women-owned and operated.

#### 3. Intended or Current Use

Pollen extracts are an agricultural ingredient from *Secale cereale* pollen. They are produced by separately extracting the water and the lipid portions of rye (*Secale cereale*) pollen. The two pollen extracts are allergen-free and composed of vitamins, minerals, enzymes, fatty acids including omega-3, 6, 9, and phytosterols such as beta-sitosterol and campesterol, stigmaterol, and other phytonutrients, like quercetin, chlorogenic acid, and rutin. (Locatelli, 2018) The

intended use is, in general, as a functional ingredient, and more specifically, in vegan syrups. Vegan syrup is a growing area at the supermarket providing a vegan alternative to honey. The addition of pollen extracts to different flavors/origins of syrups imparts the 'pollen' aspect of honey without the need for bees, hence the allowance for vegan designation. The pollen extracts are functional ingredients used to provide the whole spectrum nutrient profile described above.

#### **4. Intended Activities and Application Rate**

The pollen extracts will be used at the following rate per 8 ounce bottle of syrup:

- 500mg Water-soluble pollen extract (*Secale cereale*)
- 25mg Lipid-soluble pollen extract (*Secale cereale*)

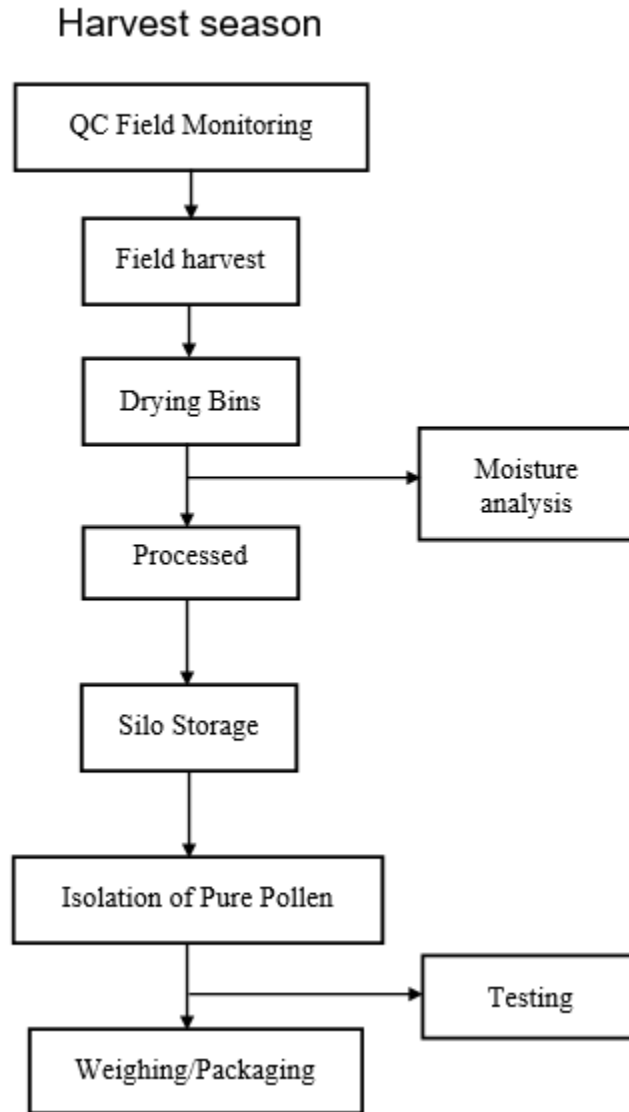
Here is a link to the syrups now available without pollen extracts. Adding the pollen extracts to these existing products will create a new generation of products.

<https://thesofco.com/our-products>

#### **5. Manufacturing Process**

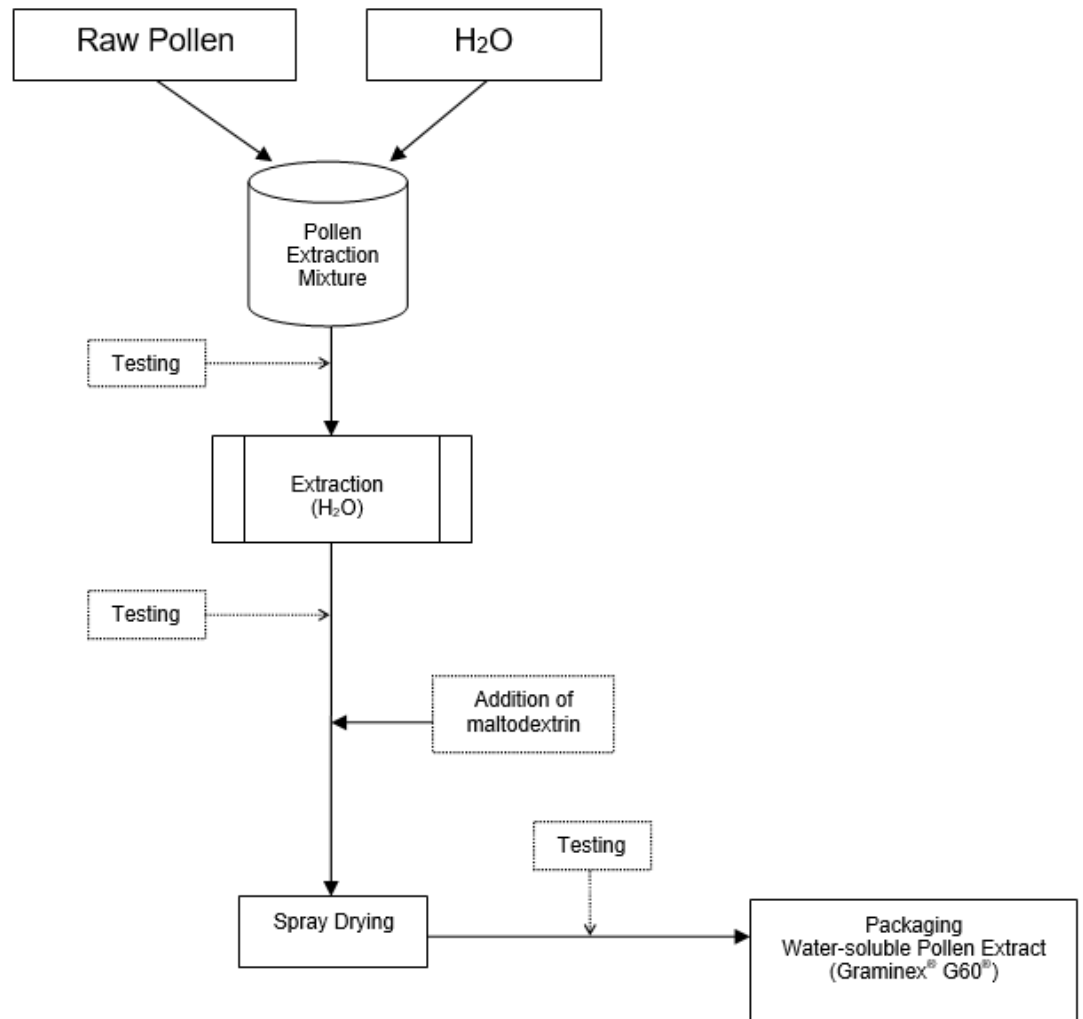
Each year we grow 400-600 acres of *Secale cereale*. We sow in the fall and harvest the pollen in the spring. We harvest the top 12-18" of the rye stalk which contains the pollen. The plant material then enters processing described below in the flow chart for Raw Pollen production.

## Graminex LLC Raw Pollen Production

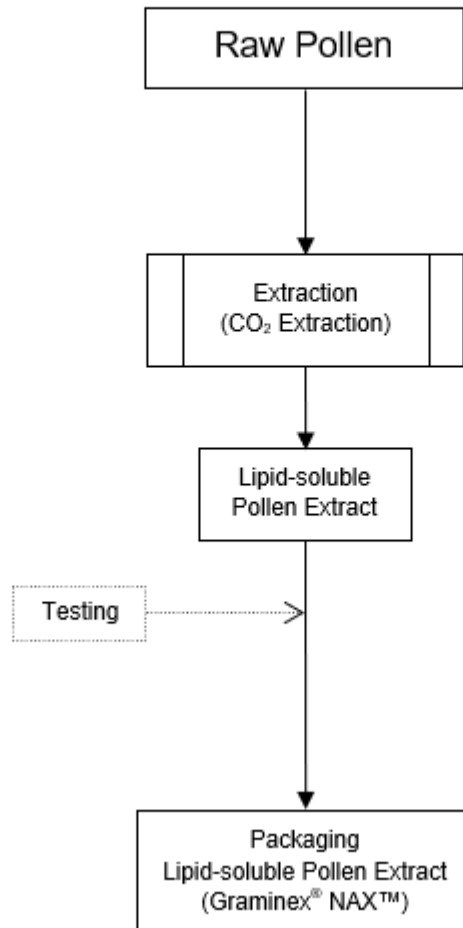


The Raw Pollen is then either water extracted or supercritical CO<sub>2</sub> extracted creating the water-soluble pollen extract and the lipid-soluble pollen extract, respectively. Both extracts are described in the below flow charts:

## Process Flow Chart Diagram for Water-soluble Pollen Extract (Graminex® G60®)



## Process Flow Chart Diagram for Lipid-soluble Pollen Extract (Graminex® NAX™)



### 6. Ancillary Substances

The Water-soluble Pollen Extract (Graminex® G60®) contains maltodextrin used as a spray dry carrier. The Lipid-soluble Pollen Extract (Graminex® NAX™) is pure and contains no excipients.

### 7. Previous Reviews

We are certified GMP by NSF.



## NSF INTERNATIONAL

789 N. Dixboro Road, Ann Arbor, Michigan 48105 USA  
+1 800 673 6275



GMP Registered  
Dietary Supplements

NSF International has assessed and confirmed compliance of

### Graminex L.L.C.

Facility: 2-300 County Road C, Deshler, OH, 43516, United States

### to NSF GMP Registration Program Requirements of NSF/ANSI 173, Section 8

which includes FSMA and cGMP (21 CFR 111), (21 CFR 117)

Print Date: May 23, 2022  
Certificate Number: 0W341-DS-4  
Initial Certification: July 28, 2003  
Expiration Date: May 23, 2023

**David Trosin**  
Senior Director Global Certification,  
Health Sciences



## 8. Regulatory Authority

We are registered in the State of Ohio, Department of Agriculture Certified – Registration No. REG6595. The Graminex facility is registered with the FDA #13138367404. As far as human consumption, pollen extracts were grandfathered in since they were used prior to October 15, 1994 and hence do not require a NDI.

## 9. Chemical Abstracts Service (CAS) Number and Product Labels

Pollen extracts (*Secale cereale*)

- Water-soluble pollen extract (Water extraction) (Graminex® G60®)
  - Maltodextrin: CAS# 9050-36-6
  - Pollen Extract: CAS# not applicable

### 25 kg Drum Label



Graminex L.L.C.  
PH (419) 278-1023  
FX (419) 278-1042

1 of X

Ship From: Graminex L.L.C  
2300 County Road C  
Deshler, OH 43516  
USA

Ship To:

Product: Graminex® G60® Flower Pollen  
Extract™

Qty Ordered: XXXkg  
Qty Packed: 25kg

Code No.: EM2000-00

Date: Month DD, YYYY

Batch #: XXXX-YY-XX-X

Customer PO# \_\_\_\_\_

Tare Weight: 3.438kg Net Weight: 25.000kg Gross Weight: 28.438kg

- Lipid-soluble pollen extract (Supercritical CO<sub>2</sub> extraction) (Graminex® NAX™)
  - Pollen Extract: CAS# not applicable

### 5 kg Pail Label



Graminex L.L.C.  
PH (419) 278-1023  
FX (419) 278-1042

1 of X

Ship From: Graminex L.L.C  
2300 County Road C  
Deshler, OH 43516  
USA

Ship To:

Product: Graminex® NAX™ 7% Paste

Qty Ordered: XXXkg  
Qty Packed: 5kg

Code No.: EM3000-05

Date: Month DD, YYYY

Batch #: XXXX-YY-XX-X

Customer PO# \_\_\_\_\_

Tare Weight: 1.232kg Net Weight: 5.000kg Gross Weight: 6.232kg

## 10. Physical and Chemical Properties

Graminex® G60® is a water-soluble fraction of rye (*Secale cereale*) pollen and is a beige fine hygroscopic powder with natural variations, a slightly acidic taste, and hay-like odor.

Graminex® NAX™ is a lipid-soluble fraction of rye (*Secale cereale*) pollen and is a dark, greenish-brown to almost black hygroscopic oily paste with natural variations, a bitter and acidic taste, and hay-like odor.

Both ingredients are non-allergenic, non-toxic, pesticide-free, gluten-free, Halal and Kosher certified.

## 11. Safety Information

Safety Data Sheets (SDS) for both ingredients below:

# SAFETY DATA SHEET

## Section 1: Product Identification

Product name : GRAMINEX® G60® FLOWER POLLEN EXTRACT™  
Product code : EM2000-00  
Other means of identification : Rye (*Secale cereale* L.); Flower Pollen Extract™  
Product type : Powder

### Relevant identified uses of the substance or mixture and uses advised against

Product use : Dietary Supplements, Nutraceuticals, Pharmaceuticals,  
Functional Foods and Beverages, Cosmetics  
Uses advised against : Not applicable  
Manufacturer : Graminex® L.L.C.  
2300 County Road C  
Deshler, OH 43516  
USA  
Phone: 1-419-278-1023

## Section 2: Hazards Identification

OSHA/HCS status : This product is not classified as a hazardous material according to the U.S. OSHA Hazard Communication Standard  
Hazard pictograms : Not applicable  
Signal word : Not applicable  
Hazard statements : Not applicable  
Precautionary Statement : Not applicable

## Section 3: Composition/Information on Ingredients

Substance/mixture : Mixture  
Product name : GRAMINEX® G60® FLOWER POLLEN EXTRACT™

Ingredient name	CAS number
Graminex® Pollen Extract™ Spissum	N/A
Maltodextrin	9050-36-6

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

## Section 4: First-Aid Measures

Description of necessary first aid measures

Product Code: EM2000-00	Date of Issue: 25 Aug 2021
Product Name: GRAMINEX® G60® FLOWER POLLEN EXTRACT™	Version: 4

Eye contact	: In case of contact immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.
Inhalation	: Individuals showing evidence of inhalation exposure should be removed to an uncontaminated area. Seek medical advice.
Skin contact	: Not expected to require first aid measures. Wash exposed area with soap and water. Get medical advice if irritation develops.
Ingestion	: Not expected to require first aid measures. If large amounts were swallowed give water to drink and get medical advice.

<b>Section 5: Fire Fighting measures</b>
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Fire	: This material is not considered to be a fire hazard.
Special Hazards arising from the material	: No further relevant information available.
Explosion	: Not considered to be an explosion hazard.
Fire Extinguishing Media	: Use suitable media for extinguishing surrounding fire.
Information for firefighters	: Wear self-contained, approved breathing apparatus, and full protective gear including eye protection and boots.

<b>Section 6: Accidental Release Measures</b>
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Personal precautions	: Use personal protective equipment.
Environmental precautions	: Prevent product from entering drains.
Methods for cleaning up	: Sweep up and shovel into suitable containers for disposal.

<b>Section 7: Handling and Storage</b>
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Precautions for safe handling	: Handle with good industrial hygiene practices and safety procedures. Wash thoroughly before and after using. Avoid contact with skin and eyes. Keep proper ventilation. Avoid breathing dust.
Precautions during storage and handling	: Avoid work operations that form dust.
Conditions for safe storage	: Store in PE bags in well closed containers at 2-8 °C.
Hazardous reactions with	: Not relevant
Hazardous decomposition products	: Not relevant

Product Code: EM2000-00

Date of Issue: 25 Aug 2021

Product Name: GRAMINEX® G60® FLOWER POLLEN EXTRACT™

Version: 4

## Section 8: Exposure Controls/Personal Protection

### Control parameters

#### Occupational exposure limits

Ingredient Name	Exposure limits	
	OSHA	ACGIH
Maltodextrin	PEL: 15mg/m <sup>3</sup> (TD)	TWA: 10 mg/m <sup>3</sup> (TD)
	PEL: 5 mg/m <sup>3</sup> (R)	TWA: 3 mg/m <sup>3</sup> (R)

#### Key to abbreviations

ACGIH = American Conference of Governmental Industrial Hygienists.

PEL = Permissible Exposure Limit

OSHA = Occupational Safety and Health Administration.

TWA = Time Weighted Average

R = Respirable

TD = Total dust

**Exposure controls** : Local exhaust or ventilation is recommended to keep employee exposures as low as possible.

**Personal protective equipment** : Gloves and semi mask, protective goggles when the work operations form dust

## Section 9: Physical and Chemical Properties

### Appearance

<b>Physical state</b>	: Fine powder
<b>Color</b>	: Light brown/Beige
<b>Odor</b>	: Hay-like
<b>Odor threshold</b>	: Not available
<b>Solubility</b>	: Somewhat soluble in water
<b>pH</b>	: 3.6 – 5.8 (1:10 in water)
<b>Vapor pressure</b>	: Not available
<b>Boiling point</b>	: Not available
<b>Melting point</b>	: Not available
<b>Decomposition Temperature</b>	: Not available
<b>Specific Gravity</b>	: Not available
<b>Viscosity</b>	: Not available
<b>Flash Point</b>	: Not available
<b>Flammability</b>	: Not Flammable
<b>Auto-ignition temperature</b>	: Not available

## Section 10: Stability and Reactivity

<b>Chemical Stability</b>	: This product is stable
<b>Possibility of hazardous reactions</b>	: Under normal conditions of storage and use, hazardous reactions will not occur.
<b>Conditions to Avoid</b>	: Avoid moisture
<b>Incompatible Materials</b>	: No data found
<b>Hazardous Decomposition Products</b>	: No data found

## Section 11: Toxicological Information

<b>Acute Toxicity</b>	: No data found
<b>Aspiration hazard</b>	: No data found
<b>Skin corrosion/irritation</b>	: No data found
<b>Serious eye damage/irritation</b>	: No data found
<b>Respiratory or skin sensitization</b>	: No data found

Product Code: EM2000-00	Date of Issue: 25 Aug 2021
Product Name: GRAMINEX <sup>®</sup> G60 <sup>®</sup> FLOWER POLLEN EXTRACT™	Version: 4

Germ cell mutagenicity	: No data found
Carcinogenicity	: No data found
Toxicity for Reproduction	: No data found
Specific target organ toxicity (single exposure)	: No data found
Specific target organ toxicity (repeated exposure)	: No data found
Routes of Entry	: No data found
Chronic Toxicity	: No data found

**Special Remarks**

Potential Acute Health Effects

Inhalation	: Exposure to dust may cause irritation
Skin	: May cause skin irritation
Eyes	: Exposure to dust may cause irritation

Potential Chronic Health Effects	: No data found
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**Section 12: Ecological Information**

Ecotoxicity	: No information found
Environmental fate	: No information found
Environmental Toxicity	: No information found
Biodegradation	: 100% Biodegradable

**Section 13: Disposal Considerations**

Waste Disposal	: No special handling required, 100% biodegradable, consult local authorities
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**Section 14: Transport Information**

DOT Classification	: Not classified
Identification	: Not applicable
Special Provisions for Transport	: No special precautions necessary

**Section 15: Regulatory Information**

U.S. OSHA	: Not Listed
California Proposition 65	: Not Listed
SARA 302	: Not Listed
SARA 313	: Not Listed
WHMIS Canada	: Not Listed

Product Code: EM2000-00	Date of Issue: 25 Aug 2021
Product Name: GRAMINEX® G60® FLOWER POLLEN EXTRACT™	Version: 4

### Section 16: Other Information

Created : 08 July 2015  
Last Updated : 25 Aug 2021  
Revision # : 4  
Prepared By : Graminex® Quality Department

**Disclaimer:**

*The information contained in this data sheet is based on present scientific and technical knowledge. The purpose of this information is to draw attention to the health and safety aspects concerning the products supplied by Graminex L.L.C., and to recommend precautionary measures for the storage and handling of the products. No warranty or guarantee is given in respect of the properties of the products. No liability can be accepted for any failure to observe the precautionary measures described in this data sheet or for any misuse of the products.*

**End of Safety Data Sheet**

# SAFETY DATA SHEET

## Section 1: Product Identification

Product name : GRAMINEX<sup>®</sup> NAX<sup>™</sup> 7% PASTE  
Product code : EM3000-05  
Other means of identification : Rye (*Secale cereale* L.); Flower Pollen Extract<sup>™</sup>  
Product type : Paste

### Relevant identified uses of the substance or mixture and uses advised against

Product use : Dietary Supplements, Nutraceuticals, Pharmaceuticals,  
Functional Foods and Beverages, Cosmetics

Uses advised against : Not applicable

Manufacturer : Graminex<sup>®</sup> L.L.C.  
2300 County Road C  
Deshler, OH 43516  
USA  
Phone: 1-419-278-1023

## Section 2: Hazards Identification

OSHA/HCS status : This product is not classified as a hazardous material  
according to the U.S. OSHA Hazard Communication Standard

Hazard pictograms : Not applicable  
Signal word : Not applicable  
Hazard statements : Not applicable  
Precautionary Statement : Not applicable

## Section 3: Composition/Information on Ingredients

Substance/mixture : Substance  
Product name : GRAMINEX<sup>®</sup> NAX<sup>™</sup> 7% PASTE

Ingredient name	CAS number
Graminex <sup>®</sup> NAX <sup>™</sup> 7% Paste	N/A

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.



#### Section 4: First-Aid Measures

##### Description of necessary first aid measures

- Eye contact : In case of contact immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.
- Inhalation : Individuals showing evidence of inhalation exposure should be removed to an uncontaminated area. Seek medical advice.
- Skin contact : Not expected to require first aid measures. Wash exposed area with soap and water. Get medical advice if irritation develops.
- Ingestion : Not expected to require first aid measures. If large amounts were swallowed give water to drink and get medical advice.

#### Section 5: Fire Fighting measures

- Fire : This material is not considered to be a fire hazard.
- Special Hazards arising from the material : No further relevant information available.
- Explosion : Not considered to be an explosion hazard.
- Fire Extinguishing Media : Use suitable media for extinguishing surrounding fire.
- Information for firefighters : Wear self-contained, approved breathing apparatus, and full protective gear including eye protection and boots.

#### Section 6: Accidental Release Measures

- Personal precautions : Use personal protective equipment.
- Environmental precautions : Prevent product from entering drains.
- Methods for cleaning up : Sweep up and shovel into suitable containers for disposal.

#### Section 7: Handling and Storage

- Precautions for safe handling : Handle with good industrial hygiene practices and safety procedures. Wash thoroughly before and after using. Avoid contact with skin and eyes. Keep proper ventilation. Avoid breathing dust.
- Precautions during storage and handling : Avoid work operations that form dust.
- Conditions for safe storage : Store in well closed containers at 2°C - 8 °C.
- Hazardous reactions with : Not relevant
- Hazardous decomposition products : Not relevant

Product Code: EM3000-05

Date of Issue: 25 Aug 2021

Product Name: GRAMINEX<sup>®</sup> NAX<sup>™</sup> 7% Paste

Version: 3

## Section 8: Exposure Controls/Personal Protection

### Control parameters

#### Occupational exposure limits

Ingredient Name	Exposure limits	
	OSHA	ACGIH
NAX <sup>™</sup> 7% Paste	Not available	Not available

#### Key to abbreviations

ACGIH = American Conference of Governmental Industrial Hygienists.

PEL = Permissible Exposure Limit

OSHA = Occupational Safety and Health Administration.

TWA = Time Weighted Average

R = Respirable

TD = Total dust

**Exposure controls** : Local exhaust or ventilation is recommended to keep employee exposures as low as possible.

**Personal protective equipment** : Gloves and semi mask, protective goggles when the work operations form dust

## Section 9: Physical and Chemical Properties

### Appearance

Physical state	: Lipid soluble paste
Color	: Dark green/brownish
Odor	: Hay-like
Odor threshold	: Not available
Solubility	: Not soluble in water
pH	: Not available
Vapor pressure	: Not available
Boiling point	: Not available
Melting point	: Not available
Decomposition Temperature	: Not available
Specific Gravity	: Not available
Viscosity	: Not available
Flash Point	: Not available
Flammability	: Not Flammable
Auto-ignition temperature	: Not available
	:

## Section 10: Stability and Reactivity

Chemical Stability	: This product is stable
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to Avoid	: Avoid moisture
Incompatible Materials	: No data found
Hazardous Decomposition Products	: No data found

## Section 11: Toxicological Information

Acute Toxicity	: LD50 > 5000 mg/kg
Aspiration hazard	: No data found
Skin corrosion/irritation	: No data found
Serious eye damage/irritation	: No data found
Respiratory or skin sensitization	: No data found

Product Code: EM3000-05	Date of Issue: 25 Aug 2021
Product Name: GRAMINEX® NAX™ 7% Paste	Version: 3

Germ cell mutagenicity : No data found  
 Carcinogenicity : No data found  
 Toxicity for Reproduction : No data found  
 Specific target organ toxicity (single exposure) : No data found  
 Specific target organ toxicity (repeated exposure) : No data found  
 Routes of Entry : No data found  
 Chronic Toxicity : No data found  
 :

**Special Remarks**

Potential Acute Health Effects

Inhalation : Exposure to this paste may cause irritation  
 Skin : May cause skin irritation  
 Eyes : Exposure to the eyes may cause irritation  
 Potential Chronic Health Effects : No data found  
 :

**Section 12: Ecological Information**

Ecotoxicity : No information found  
 Environmental fate : No information found  
 Environmental Toxicity : No information found  
 Biodegradation : 100% Biodegradable

**Section 13: Disposal Considerations**

Waste Disposal : No special handling required, 100% biodegradable, consult local authorities

**Section 14: Transport Information**

DOT Classification : Not classified  
 Identification : Not applicable  
 Special Provisions for Transport : No special precautions necessary

**Section 15: Regulatory Information**

U.S. OSHA : Not Listed  
 California Proposition 65 : Not Listed  
 SARA 302 : Not Listed  
 SARA 313 : Not Listed  
 WHMIS Canada : Not Listed

Product Code: EM3000-05	Date of Issue: 25 Aug 2021
Product Name: GRAMINEX® NAX™ 7% Paste	Version: 3

### Section 16: Other Information

Created : 08 July 2015  
Last Updated : 25 Aug 2021  
Revision # : 3  
Prepared By : Graminex® Quality Department

**Disclaimer:**

*The information contained in this data sheet is based on present scientific and technical knowledge. The purpose of this information is to draw attention to the health and safety aspects concerning the products supplied by Graminex L.L.C., and to recommend precautionary measures for the storage and handling of the products. No warranty or guarantee is given in respect of the properties of the products. No liability can be accepted for any failure to observe the precautionary measures described in this data sheet or for any misuse of the products.*

**End of Safety Data Sheet**

## 12. Research Information

The research information is mainly around prostate health. There is no information around the organic/non-organic nature of rye pollen as far as we are aware. All research was performed using non-organic pollen extracts. Here are three examples. (Graminex® G63® is a combination of Graminex® G60® and Graminex® NAX™ that creates a flowable powder for use in capsules and tablets.)

Locatelli M, Macchione N, Ferrante C, Chiavaroli A, Recinella L, Carradori S, Zengin G, Cesa S, Leporini L, Leone S, Brunetti L, Menghini L, Orlando G. Graminex Pollen: Phenolic Pattern, Colorimetric Analysis and Protective Effects in Immortalized Prostate Cells (PC3) and Rat Prostate Challenged with LPS. *Molecules*. 2018 May 11;23(5):1145. doi: 10.3390/molecules23051145. PMID: 29751604; PMCID: PMC6100541.

Di Pasquale AB, Cassani A, Masciovecchio S, Zasa G, Ranieri G, Romano G, Di Clemente L. Postoperative treatment with phytotherapy Graminex G63 (CERNILEN-Flogo®) after greenlight laser XPS (180W) photovaporization of the prostate (PVP), can affect patient's quality of life? *Eur Rev Med Pharmacol Sci*. 2020 Sep;24(17):9116-9120. doi: 10.26355/eurrev\_202009\_22858. PMID: 32965002.

Cai T, Verze P, La Rocca R, Anceschi U, De Nunzio C, Mirone V. The role of flower pollen extract in managing patients affected by chronic prostatitis/chronic pelvic pain syndrome: a comprehensive analysis of all published clinical trials. *BMC Urol*. 2017 Apr 21;17(1):32. doi: 10.1186/s12894-017-0223-5. PMID: 28431537; PMCID: PMC5401347.

## 13. Petition Justification Statement

The non-organic substance designation is necessary for use in organic handling because of our customer's intention to list the vegan syrups as certified USDA organic. We produce 99% of our rye pollen extracts for the dietary supplement market and this new foray into foods beckons this non-organic inclusion.

Graminex is the only producer of commercial scale non-solvent rye pollen extracts in the United States. Graminex's farms are located across four counties (Henry, Wood, Putnam, Hancock) in Northwest Ohio in the Lake Erie watershed. Austria and Sweden also produce non-organic rye pollen in a similar climate. Graminex produces 60-100MT of rye pollen production per year that serves both domestic and international demand. Graminex has not experienced any supply issues since its inception in 1997. We maintain three to five years of raw pollen inventory. And lastly, we are not aware of any trade related issues or issues that would impact consistency of supply.

Rye seed is available in common as well as breeder stock. Given that high pollen yield is core to our business, Graminex must use seed stock that maximizes the production of pollen. Since common rye seed develops self-incompatibility which means that the mature rye plants do no

produce copious amounts of pollen, Graminex must use breeder stock and this breeder stock is only available in non-organic form.

Graminex purchases our non-organic breeder seed stock from growers in Canada who maintain specialized heirloom varieties of rye seed that produce a good stand with high-yielding pollen potential. Purchasing certified breeder select seed allows Graminex to maintain high yielding crops necessary for the commercialization of rye pollen extract. This requires that new breeder select seed be brought in from Canada regularly. We are partnered through SeCan ([www.secan.com](http://www.secan.com)) with a grower in Hughenden, Canada that specializes in the Muskateer variety which has proven successful year after year, for over 25 years. In fact, Muskateer is one of the last heirloom varieties of rye seed available. Again, while common rye seed is available in organic form, the Breeder's Muskateer seed is not.

*A note from our partner, Single Origin Food Co. (SOFO):* SOFO has worked for over a year to create the world's first plant-based honey substitute with flower pollen in partnership with Graminex. Our Vegan Un-honey product has been developed to give bee cultures in the USA and around the world a chance to rebalance and become more aligned with traditional wild bee colonies by allowing for diversity within bee species to rebuild (as opposed to the mono bee culture we see in intensive honey farming which disturbs the flora of pollination and insect diversity).

We believe that having flower pollen as an ingredient within our plant-based un-honeys allows us to do this effectively and be taken seriously by consumers who care deeply about modern bee culture. Organic certification for us is incredibly important as all our nectars fly under this banner and we care immensely about organic farming and biodiversity. We want to continue supporting and being part of the USDA organic model, especially in all our Un-honey projects and we feel that the oldest naturally occurring and important ingredient ever produced by plants should be able to be added to the list of acceptable ingredients with your kind permission.

#### **14. References**

Locatelli M, Macchione N, Ferrante C, Chiavaroli A, Recinella L, Carradori S, Zengin G, Cesa S, Leporini L, Leone S, Brunetti L, Menghini L, Orlando G. Graminex Pollen: Phenolic Pattern, Colorimetric Analysis and Protective Effects in Immortalized Prostate Cells (PC3) and Rat Prostate Challenged with LPS. *Molecules*. 2018 May 11;23(5):1145. doi: 10.3390/molecules23051145. PMID: 29751604; PMCID: PMC6100541.