

# Customized Source Materials Meet the Needs of Extract Manufacturers



#### **GREER TOUCHPOINT #27**

"To win as an extract manufacturer,
I want a collaborator, not a competitor."

In Touch. Within Reach."



### In Touch with Extract Manufacturers

Each manufacturing challenge is different, so the GREER® Source Materials team starts by listening. Then we put our experience and knowledge to work to find the solutions that help you meet your objectives. Because extract manufacturing is at the core of our business, that expertise allows us to more fully understand your needs and serve as a greater resource for your project. GREER professionals work alongside customers to provide personalized support on many levels. We can tailor the raw materials and manufacture them to customer-defined specifications under cGMPs.

## **GREER Provides Source Materials** in Useful Formulations



## GREER® Offers a Wide Array of Allergenic Source Materials

SOURCE Material	DESCRIPTION	FEATURES
Mites	GREER® offers house dust mites, formulated to meet customer-specified purity levels up to 99% pure	House dust mites are raised by GREER on a controlled medium to ensure consistency in its dedicated facility
Epithelia, Hair, Feathers & Dander	GREER offers danders, hair and epithelia of dog, cat, and many other species	All danders, hairs, epithelia, and feathers are collected from animals certified to be healthy and free from disease
Pollens	GREER offers a wide range of grass, tree, weed, and flower pollen, all micro- scopically inspected to ensure identity and purity	GREER pollens are collected via our worldwide network of experienced in-house and external collectors
Fungi & Smuts	GREER offers a wide range of fungi, prepared to meet customers' specifica- tions for cellular and culture filtrate	GREER fungi are grown on site from controlled seed cultures to assure lot-to-lot consistency
Venoms	GREER venoms are formulated to contain clinically relevant species and lyophilized (freeze-dried) to ensure stability and labeled potency	Consistency of product quality and potency is controlled by laboratory tests for protein, hyaluronidase, and phospholiphase activity, and comparison to in-house reference preparations
Foods	GREER offers a wide variety of fruits, vegetables, meats, seafood, egg, and dairy products	GREER food materials are obtained from sources that operate under food safety, USDA or FDA regulations
Insects	Our extensive collection network enables GREER to offer a variety of insect species, all verified by GREER scientists for identity and purity	GREER insects are collected live and then frozen immediately or laboratory-raised on a controlled diet to ensure consistency

## Within Reach with Quality Solutions

For greater control of what exactly is collected and for access to hard-to-find pollens, GREER® combines in-house and outsourced expertise.

- Extensive experience requirements for all collectors
- Exclusive collection capabilities in the US and Europe to access regionally-appropriate pollen species

#### **Source Material Pollen Collecting Process**

#### • Pollen is sent along with documentation of the collection process, such as date, Pollen time, area, and method **Collectors** • The pollen is received into quarantine and assigned a computer-generated lot number • Moisture test; specification <4.5% Microscopic examination for identity and purity Pollen Analytical testing for specific allergen content and other customer-specified assays **Testing** Quality control evaluation and release Nondefatted pollen is placed into released inventory and is available for Placed Into further processing Inventory Nondefatted pollen is stored under controlled and monitored conditions at <0° C</li> • Pollen may be defatted to aid in the efficiency of extraction Further Products may be lyophilized **Processing** • Products may be processed into liquid extracts • Production records review to confirm product and customer specifications QC Release Quality Control evaluation to ensure compliance



#### **GREER TOUCHPOINT #526**

"Working with a source materials partner who understands our regulatory requirements makes my job much easier."

### **Integrity is Integral**

GREER® is an FDA-licensed allergenic extract manufacturer that understands the regulatory requirements you face.

GREER prides itself on meeting domestic and international industry standards for quality, including current good manufacturing practices (cGMPs). In fact, many source materials supplied to GREER customers are the same materials used to manufacture finished GREER allergenic extracts. In addition, GREER is prepared to provide support for registration submissions. Other GREER points of excellence include:

- Pre-samples for customer evaluation
- Testing for heavy metals and pesticides upon request
- QA/QC oversight of product manufacture and release
- cGLP development & cGMP operations
- Lot-specific Certificates of Analysis
- Thorough documentation of processes and test results
- Source identities ensured by GREER scientists
- Confidential R&D project support

This level of control allows GREER the flexibility to address each customer's unique challenges.

#### In Touch with Extract Manufacturers



The GREER® Source Materials Group works as a confidential and trusted partner to develop solutions for our source materials customers. Solutions like:

- A breadth of high-quality allergenic source materials that help meet your varied needs
- A variety of formulations to fit your specific project
- Custom products
  - -Manufactured to customer-defined specifications under cGMPs
  - Lyophilized extracts, free of preservatives or buffer salts, available for any of the GREER raw materials
  - -Vialing and lyophilization of customer-supplied products
- Custom services
  - -Antibody production, such as Anti-Amb a, to meet project needs
  - Analytical testing for total protein, moisture, endotoxin, or other customer-requested tests
  - -Analytical testing for specific allergen content, such as Der p 1, Der f 1,Amb a 1, Fel d 1, Can f 1

Your GREER team is comprised of accomplished researchers who understand your challenges. We will use this collective experience and knowledge to find the solutions that fit each challenge.

For more information on how the experienced and knowledgeable GREER professionals can help you and your business, get in touch with GREER. Call the GREER Customer Service Representatives toll free: 800.378.3907 or write to sourcematerials@greerlabs.com.



Do you have a challenge or question you need help with, right away? Get in touch with GREER. Now.

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