

Petition to Add Shea Butter to 40 CFR 152.25(f)(2) Inert Ingredients List

Date: July 22, 2025

To:

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From:

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Subject: Petition to Amend 40 CFR 152.25(f)(2) to Add Shea Butter (*Vitellaria paradoxa* Nut Fat, CAS No. 68920-03-6) as an Approved Inert Ingredient for Minimum Risk Pesticides under FIFRA Section 25(b)

Docket ID: [Request Docket ID or Reference EPA-HQ-OPP-2019-0701, if applicable]

I. Introduction

Six Hogs, LLC (DBA Meadowborn), a manufacturer of all-natural skin care products, hereby petitions the U.S. Environmental Protection Agency (EPA) to amend **40 CFR 152.25(f)(2)** to include shea butter (*Vitellaria paradoxa* nut fat, CAS No. 68920-03-6) as an approved inert ingredient for minimum risk pesticides under Section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This amendment would allow manufacturers to use shea butter in exempt pesticide products, such as topical insect-repellent lotions, without requiring federal registration, thereby reducing regulatory burden while maintaining safety for human health and the environment.

Shea butter is a natural, plant-derived fat widely used in cosmetics and food, with a well-established safety profile. Its inclusion in **40 CFR 152.25(f)(2)** would align with the EPA's goal of promoting low-risk ingredients in minimum risk pesticides, benefiting manufacturers and consumers seeking natural, effective products.

II. Description of Shea Butter

- Chemical Name:** Shea butter (*Vitellaria paradoxa* nut fat)
- CAS Number:** 68920-03-6 (refined or unrefined, depending on supplier specifications)
- Source:** Extracted from the nuts of the shea tree (*Vitellaria paradoxa*), native to Africa.
- Composition:** A complex mixture of fatty acids (primarily stearic acid, oleic acid), triglycerides, and minor components (e.g., triterpenes, tocopherols, sterols). Typical composition:
 - Stearic acid: 35–45%
 - Oleic acid: 40–55%
 - Linoleic acid: 3–8%
 - Palmitic acid: 3–7%
 - Minor components: Tocopherols, phenolic compounds, triterpenes (e.g., lupeol, amyrin)
- Physical Properties:** Semi-solid fat at room temperature, creamy texture, off-white to yellowish color, mild nutty odor (unrefined) or neutral (refined).
- Intended Use:** Inert ingredient in minimum risk pesticide products, such as topical skin care lotions with insect-repellent claims, serving as an emollient and moisturizer to enhance skin application and product stability.

III. Safety Data

Shea butter has a well-documented safety profile, supported by its use in food, cosmetics, and pharmaceuticals. Below is a summary of relevant safety data, with references to existing regulatory approvals and studies:

A. Toxicological Data

- **Acute Toxicity:**
 - **Oral LD50:** >5,000 mg/kg (rat), indicating low oral toxicity (Cosmetic Ingredient Review [CIR], 2005).
 - **Dermal LD50:** >2,000 mg/kg (rabbit), indicating low dermal toxicity (CIR, 2005).
 - **Inhalation:** Not relevant for topical use, as shea butter is non-volatile.
- **Skin and Eye Irritation:**
 - Non-irritating to skin in human patch tests (CIR, 2005).
 - Minimal to no eye irritation in rabbit studies (CIR, 2005).
- **Sensitization:**
 - Low sensitization potential; rare allergic reactions reported in individuals with nut allergies, but incidence is minimal (CIR, 2005; FDA, 2018).
- **Chronic Toxicity:**
 - No evidence of chronic toxicity or carcinogenicity in long-term use as a food or cosmetic ingredient (FDA GRAS, 21 CFR 184.1702).
- **Regulatory Status:**
 - **FDA GRAS:** Approved as a direct food additive (21 CFR 184.1702) for use in confections and frostings.
 - **Cosmetic Use:** Deemed safe by the CIR for use in cosmetics at concentrations up to 60% (CIR, 2005).
 - **International:** Approved for food and cosmetic use in the EU, Canada, and other jurisdictions.

B. Environmental Data

- **Biodegradability:** Shea butter is a natural, plant-derived fat, readily biodegradable under aerobic conditions (OECD Guideline 301, estimated).
- **Environmental Fate:** Minimal environmental impact due to its use in topical products with low environmental release. No significant effects on aquatic organisms or soil ecosystems expected.
- **Non-Target Organisms:** No adverse effects on pollinators, birds, or other non-target species, as shea butter is not applied to crops or environmental surfaces.

C. Existing Studies

- **Cosmetic Ingredient Review (CIR), 2005:** "Final Report on the Safety Assessment of Shea Butter." Concluded shea butter is safe for use in cosmetics, with low toxicity and irritation potential.
- **FDA GRAS Notice (21 CFR 184.1702):** Confirms shea butter's safety for food use, supporting its low-risk profile.
- **Literature:** Studies on shea butter's fatty acid composition and dermatological benefits (e.g., Alander, J., 2004, *Lipid Technology*) demonstrate its safety for topical application.

Note: Additional pesticide-specific toxicological or environmental studies may be required. Six Hogs, LLC (DBA Meadowborn) is prepared to provide or fund such studies if requested by the EPA.

IV. Justification for Inclusion

Shea butter qualifies as a minimum risk inert ingredient under **40 CFR 152.25(f)(2)** for the following reasons:

1. **Low Toxicity:**
 - Extensive safety data from food and cosmetic use (FDA GRAS, CIR) confirm shea butter's low acute and chronic toxicity, minimal irritation, and low sensitization potential, aligning with the EPA's criteria for minimum risk inerts.
 - Comparable to approved inerts like cocoa butter (CAS No. 8002-31-1) and mango butter (*Mangifera indica* seed oil, CAS No. 68956-68-3), which are plant-derived fats with similar safety profiles.
 2. **Environmental Safety:**
 - Shea butter's biodegradability and minimal environmental release (due to topical use) ensure no significant impact on ecosystems or non-target organisms, consistent with other approved inerts like sunflower oil (CAS No. 8001-21-6).
 3. **Regulatory Precedent:**
 - Shea butter's FDA GRAS status (21 CFR 184.1702) and CIR approval for cosmetics provide a strong foundation for its safety, similar to other inerts listed in **40 CFR 152.25(f)(2)** (e.g., cocoa butter, also GRAS).
 - The EPA's addition of chitosan in 2022 (Federal Register, Vol. 87, No. 213) demonstrates willingness to expand the list when safety data is sufficient.
 4. **Industry and Consumer Benefits:**
 - Adding shea butter would allow manufacturers to formulate all-natural, minimum risk pesticide products (e.g., insect-repellent lotions) without EPA registration, reducing costs and time to market.
 - Consumers demand natural ingredients like shea butter for their moisturizing and skin-soothing properties, enhancing product appeal.
 - Supports small businesses like Six Hogs, LLC (DBA Meadowborn) by enabling compliant formulations with popular ingredients.
 5. **Similarity to Approved Inerts:**
 - Shea butter's composition (fatty acids, triglycerides) is similar to cocoa butter and mango butter, both approved in **40 CFR 152.25(f)(2)**. Its safety profile and use in topical applications align with these inerts.
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V. Proposed Regulatory Text

We propose the following amendment to **40 CFR 152.25(f)(2)**, Table of Inert Ingredients, under the “Edible fats and oils” category:

Addition:

- Name:** Shea butter (*Vitellaria paradoxa* nut fat)
- CAS No.:** 68920-03-6
- Use:** Inert ingredient in minimum risk pesticide products, serving as an emollient and moisturizer in topical formulations.

Proposed Text:

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§ 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation.  
  
(f) Minimum risk pesticides—(2) Permitted inert ingredients. Only the inert ingredients listed in the following table may be used in  
[Table]  
  
Name | CAS No.  
Shea butter (*Vitellaria paradoxa* nut fat) | 68920-03-6  
...
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VI. Economic and Practical Benefits

- Manufacturer Benefits:** Adding shea butter to **40 CFR 152.25(f)(2)** allows Six Hogs, LLC (DBA Meadowborn) and other manufacturers to formulate compliant minimum risk pesticide products (e.g., insect-repellent skin lotions) without costly EPA registration, saving \$5,000–\$100,000+ in fees and testing costs per product.
- Consumer Appeal:** Shea butter is a popular, all-natural ingredient valued for its moisturizing and skin-protecting properties, enhancing the marketability of exempt products.
- Regulatory Efficiency:** Expanding the inert ingredients list aligns with the EPA’s goal of promoting low-risk pesticides, reducing regulatory burden while ensuring safety.

VII. Supporting Documentation

- References:**
 - Cosmetic Ingredient Review (CIR). (2005). Final Report on the Safety Assessment of Shea Butter. *International Journal of Toxicology*, 24(Suppl. 4), 1–10.
 - FDA. (2018). GRAS Notice for Shea Butter (21 CFR 184.1702).
 - Alander, J. (2004). Shea Butter – A Multi-Functional Ingredient for Food and Cosmetics. *Lipid Technology*, 16(9), 202–205.
 - OECD Guideline 301: Ready Biodegradability (for environmental fate estimation).
- Additional Data:** Six Hogs, LLC (DBA Meadowborn) is prepared to provide or fund pesticide-specific toxicological or environmental studies if requested by the EPA, including acute toxicity, irritation, or biodegradability data.
- Confidential Business Information (CBI):** This petition contains no CBI. All data provided is public or derived from publicly available sources. If additional proprietary data is submitted, a sanitized version will be provided for public disclosure.

VIII. Request for Action

Six Hogs, LLC (DBA Meadowborn) respectfully requests that the EPA:

- Review this petition to add shea butter (*Vitellaria paradoxa* nut fat, CAS No. 68920-03-6) to **40 CFR 152.25(f)(2)**.
- Publish the petition in the **Federal Register** for a 60-day public comment period.
- Initiate rulemaking to amend **40 CFR 152.25(f)(2)**, incorporating the proposed text.
- Provide guidance on any additional data required to support the petition.

We are available to discuss this petition, provide further data, or respond to public comments. Please contact Collin Jones, Vice President, at 606-627-5202 or collin.jones@webbedsphere.com, or submit inquiries to BPPDFRNotices@epa.gov.

IX. Certification

We certify that, to the best of our knowledge, all information provided in this petition is accurate and complete. We understand that the EPA may request additional data to support the inclusion of shea butter in **40 CFR 152.25(f)(2)**.

Signed,

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Date: July 22, 2025