

May 25, 2017

Via email: nosb@ams.usda.gov

National List Manager
USDA/AMS/NOP, Standards Division
1400 Independence Avenue SW
Room 2642-So., Ag Stop 0268
Washington, DC 20250-0268

Please accept this Petition to amend the National List of Allowed and Prohibited Substances (National List) at 7 CFR 205, by adding SULFUR to Section 205.601(h) as a slug or snail bait.

Thank you for your consideration.

Sincerely,

OR-CAL, INC.



Brooke Baker, Regulatory Specialist
29454 Meadowview Road
Junction City, OR 97448
541-689-4413
brooke@orcalinc.com

Hickman Regulatory Services



Molly E. Hickman, Agent for OR-CAL, Inc.
3501 Shady Timber Street #2105
Las Vegas, NV 89129
541-316-5873
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**OR-CAL, INC.
29454 Meadowview Road
Junction City, OR 97448**

**PETITION TO AMEND THE NATIONAL LIST OF ALLOWED AND PROHIBITED SUBSTANCES
(National List) at 7 CFR 205**

TO ADD SULFUR to Section 205.601(h) AS A SLUG OR SNAIL BAIT

Item A.1—Indicate which section or sections the petitioned substance will be included on and/or removed from the National List.

Included as a synthetic substance allowed for use in organic crop production, § 205.601(h) as a slug and snail bait.

Item A.2—OFPA Category – Crop and Livestock Materials

Copper and Sulfur compounds.

Item A.3—Inert Ingredients

Not applicable.

Item B—Provide concise and comprehensive responses in providing all of the following information on the substance being petitioned.

1. Substance name.

Sulfur/elemental sulfur (synthetically produced)

2. Petitioner/Manufacturer Information.

Brooke Baker, Regulatory Specialist
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brooke@orcalinc.com

3. Intended or Current Use.

Elemental sulfur is currently NOP Listed under section 205.601 (e)(5) as insecticide (including acaricides or miticides), 205.601(i) as plant disease control, and 205.601(j)(2) as plant or soil amendment.

Elemental sulfur is under evaluation for inclusion in the National List for use as a pesticide on domestic livestock. Petitioner: Georgia Gulf Sulfur Corporation of Valdosta, Georgia.

The current Petition is for consideration for listing Sulfur under section 205.601(h) as slug and snail bait.

4. Intended Activities and Application Rate.

Please see Appendix A – EPA-registered label pesticide label, EPA Reg. No. 71096-16.

5. Manufacturing Process.

Sulfur is obtained from multiple sources of supply – all approved on the registered end-use bait's EPA Confidential Statements of Formula – as a byproduct of coal, natural gas, and petroleum refinement.

Please see Appendix B – Technical Evaluation Report USDA/AMS, March 16, 2017 in re: Petition of Georgia Gulf Sulfur Corporation, Valdosta, Georgia.

6. Ancillary Substances.

Not applicable; not petitioned for organic handling or processing.

7. Previous Reviews.

Not applicable – first instance for consideration as a slug and snail bait.

8. Regulatory Authority.

Please see Appendix A – EPA-registered pesticide label, EPA Reg. No. 71096-16.

Please see Appendix C – EPA Sulfur RED Facts May 1991.

9. Chemical Abstract Service (CAS) Number and Product Labels.

Sulfur (elemental): CAS No. 7704-34-9

Please see Appendix A – EPA registered pesticide label, EPA Reg. No. 71096-16.

10. Physical and Chemical Properties.

Please see Appendix B – Technical Evaluation Report USDA/AMS, March 16, 2017 in re: Petition of Georgia Gulf Sulfur Corporation, Valdosta, Georgia.

11. Safety Information.

Please see Appendix B – Technical Evaluation Report USDA/AMS, March 16, 2017 in re: Petition of Georgia Gulf Sulfur Corporation, Valdosta, Georgia.

12. Research Information.

Please see Appendix B – Technical Evaluation Report USDA/AMS, March 16, 2017 in re: Petition of Georgia Gulf Sulfur Corporation, Valdosta, Georgia.

13. Petition Justification Statement.

A. Inclusion of a Synthetic on the National List, Section 205.601(h), Sulfur as a slug and snail bait.

Explain why the synthetic substance is necessary for the production or handling of an organic product.

Sulfur is already included on the National List for the following purposes:

In section 205.601(e)(5) as insecticide (including acaricides or miticides).

In section 205.601(i) as plant disease control.

In section 205.601(j)(2) as plant or soil amendment.

Also, Sulfur is under evaluation for inclusion in the National List for use as a pesticide on domestic livestock. Petitioner: Georgia Gulf Sulfur Corporation of Valdosta, Georgia.

This commonly used synthetic chemical is well-known by organic growers and used (or under evaluation for use) for multiple purposes, as allowed by the NOP. Cultural and other alternative non-synthetic methods are simply not as effective (*see Neudorff discussion, below*).

Currently, there is only one listed slug and snail bait – ferric phosphate. Organic growers need another choice. Furthermore, it is our understanding that the ferric phosphate baits are manufactured in Europe. During a growing season of high pest pressure, high demand, or port disruption, resupply efforts may be delayed. Sulfur-based slug and snail baits are made domestically, making them more readily available during times of high need and/or low supply.

Describe any nonsynthetic substances, synthetic substances on the National List, or alternative cultural method that could be used in place of the petitioned synthetic substance.

As stated in the Ferric Phosphate Petition submitted by Neudorff North America, May 2003:

“Cultural methods used to control slugs and snails are tedious, inefficient processes. Supply can also be a problem with some of the control methods. For an organic farmer with a large farm, it is virtually impossible to adequately control slugs using the methods currently acceptable to organic gardening.

“Slugs can be captured in traps and killed manually by the farmer. These traps can consist of: a) holes in the ground with a covering; b) boards; and c) various manufactured traps that use bait, e.g beer, yeast. There are also biological controls for slugs. Various birds will eat slugs and snails. The problem with using animals as control methods is that they also tend to damage the crop. There are fly and beetle species that might provide control, however, the supply is not consistent. Predatory snails can destroy pest snails. However, due to the fact that these snails are not native, their use is restricted to areas where they are naturalized. A predatory nematode is available in Europe and Britain but is not currently sold in the US. Botanicals, attractants and repellents that have proven effective against mollusks, have not been developed into commercial products (Quarles, 1997).

“The remaining control methods for slugs are the synthetic chemicals: the carbamates and metaldehyde. Both of these chemicals are far more toxic to mammals than ferric phosphate. Neither occurs naturally in the environment.

“Without an adequate control method for slugs and snails, organic farmers suffer significant annual crop loss to the pests. Approval of ferric phosphate as an active ingredient to control pest slugs and snails, would improve the viability of these organic farms and ensure a continuous supply of quality organic products to the market.”

We have no reason to believe any these claims have changed. In evaluating the petition to include ferric phosphate, NOP determined the availability of these alternative methods did not overrule the Listing petition. For these reasons, we ask NOP to consider the continued availability of these alternative methods as not fatal to our Petition.

Finally, the Listing of ferric phosphate as a slug and snail bait does not immediately overrule the inclusion of another slug and snail bait in the National List.

Describe the beneficial effects the to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a nonsynthetic substance or alternative cultural method.

Prior consideration of Sulfur for initial inclusion (and subsequent sunset evaluation) on the National List was found acceptable for multiple categories of use. Clearly, these prior evaluations indicate Sulfur has met all conditions of 'beneficial use instead of the use of a nonsynthetic substance or alternative cultural method.'

See also, Neudroff discussion, above.

The product is as or more effective than ferric phosphate and other alternative non-synthetic methods, as a slug and snail bait.

Studies indicate sulfur-based molluscicides are shown to provide an earlier response than ferric phosphate baits. See Appendix D, ORCAL BioSul Efficacy Trial Report, Webco R&D, 2012.

Studies indicate no significant difference between commonly used metaldehyde baits and Petitioner's sulfur-based molluscicide bait. See Appendix D, OR-CAL AG SLUG & SNAIL BAIT HYDRANGEA FIELD TRIAL, Webco R&D, 2012.

14. Confidential Business Information Statement

This petition does not contain any confidential business information.

APPENDIX A
EPA REGISTERED LABEL
OR-CAL BIO-SUL SLUG AND SNAIL BAIT
EPA REG NO 71096-16



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 6, 2016

Molly E. Hickman
Agent for OR-CAL, Inc.
OR-CAL, Inc.
29454 Meadowview Road
Junction City, OR 97448

Subject: Label Amendment – Adding me-too crops, other minor revisions, adding supplemental label
Product Name: OR-CAL Bio-Sul Slug and Snail Bait
EPA Registration Number: 71096-16
Application Date: 07/25/2016
Decision Number: 521084

Dear Ms. Hickman:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 71096-16
Decision No. 521084

with FIFRA section 6. If you have any questions, please contact Lisa Pahel by phone at (703) 347-0459, or via email at pahel.lisa@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Erik Kraft for". The signature is fluid and cursive.

Erik Kraft, Acting Product Manager 24
Fungicide and Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

MASTER LABEL- amendment 10042016

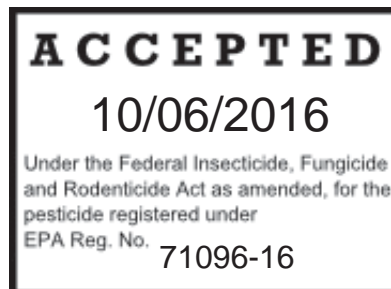
OR-CAL
BIO-SUL
SLUG AND SNAIL BAIT

ACTIVE INGREDIENT:

Sulfur.....1.0%
OTHER INGREDIENTS..... 99.0%
TOTAL 100.0%

SUBLABEL A: Home and Garden Use

SUBLABEL B: Commercial Agriculture use



KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA REGISTRATION NUMBER: 71096-16

EPA ESTABLISHMENT NUMBER: 66876-OR-001

REGISTRANT: OR-CAL, Inc.
29454 Meadowview Rd.
Junction City, OR 97448
541/689-5026

Home & Garden Use: NET WEIGHT: 1 oz., 13 oz., 26 oz, 0.5 lb, 1 lb, 1.25 lbs, 1.5 lbs. 2 lbs, 2.5 lbs., 3 lbs., 3.2 lbs., 3.5 lbs., 4.25 lbs., 5 lbs., 5.5 lbs, 6 lbs., 7 lbs., 8.5 lbs., 10 lbs., 20 lbs., 25 lbs., XX ozs. and XX lbs.

Commercial Agriculture Use: NET WEIGHT: 10 lbs, 20 lbs., 25 lbs., 40 lbs., 50 lbs., 55 lbs., 100 lbs., 2000 lbs.

SUBLABEL A: Home and Garden Use

**OR-CAL
BIO-SUL
SLUG AND SNAIL BAIT**

Active Ingredient:	By Weight
Sulfur.....	1.0%
Other Ingredients:.....	<u>99.0%</u>
Total	100.0%

EPA Registration Number 71096-16

EPA Establishment Number 66876-OR-001

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center at: 1-800-858-7378 for information about this product (including health concerns or pesticide incidents).

See side/back panel/booklet/bag for additional precautionary statements.

NET WEIGHT: 1 oz., 13 oz., 26 oz., 0.5 lb., 1 lb., 1.25 lb, 1.5 lbs, 2 lbs., 2.5 lbs., 3 lbs., 3.2 lbs., 3.5 lbs., 4.25 lbs., 5 lbs., 5.25 lbs., 5.5 lbs., 6 lbs., 7 lbs., 8.5 lbs., 10 lbs., 20 lbs., 25 lbs., XX oz and XX lbs.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling. Applicators must wear: long-sleeved shirt and long pants, shoes plus socks, chemical resistant gloves made out of any waterproof material, and protective eyewear,

Environmental Hazards

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Sweeping any product that lands on a driveway, sidewalk, or street, back onto the treated area of the lawn or garden will help to prevent run off to water bodies or drainage systems.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not enter or allow others to enter until dusts have settled.

HOME AND GARDEN

Not for use on crops grown for sale.

RESTRICTIONS: Do not apply when weather conditions favor drift from treated areas. Do not place in piles.

HOW TO APPLY: Scatter the slug and snail bait pellets on the soil around or near the plants to be protected. For broadcast application, use standard broadcast spreaders. For row application, use standard granular spreaders. Apply bait evenly at approximately 1 lb. per 1000 square feet, or for smaller areas, 0.15 oz or 1 level teaspoon, per square yard, and reapply as the bait is consumed or at least every three weeks. Do not place in piles. If the ground is dry, wet it before applying bait. The product works best when soil is moist but with little or no standing water.

Reapply as the bait is consumed or at least every three weeks. Apply more heavily if the infestation is severe, if the area is heavily watered or after long periods of heavy rain. See specific directions for different plant types and for inside greenhouses.

WHEN TO APPLY: Evening is the best time to apply the bait, as slugs and snails travel and feed mostly by night or early morning.

WHERE TO APPLY: Treat all likely areas of infestation, especially around the perimeter of garden plots because these pests travel into plant areas from daytime refuges. They favor damp places around vegetable plants such as bean, tomatoes, lettuce, cabbage, celery and squash. Other favorite areas are flower garden, rockeries, hedges, lawns, citrus groves, ivy patches, and other ground cover where they obtain shelter by day.

Vegetables

The bait can be used to protect the following vegetables from slug and snail damage: artichokes, asparagus, beans, beets, blackeyed peas, broccoli, Brussels sprouts, cabbage, cantaloupe, carrots, cauliflower, celery, collards, corn, cowpeas, cucumbers, eggplants, garlic, kale, lettuce, onions, parsley, peas, peppers, potatoes, pumpkin, radishes, rutabagas, spinach, squash, Swiss chard, tomatoes, and turnips. Scatter the bait around the perimeter of the vegetable plot at approximately 0.5-1 lb per 1000 square feet, or for smaller areas, 0.15 oz. or 1 level teaspoon, per square yard, to provide a protective "barrier" for slugs and snails entering the garden plot. If slugs or snails are inside the rows, then scatter the bait on the soil around the base of the plants and between rows.

Fruits and Nuts including Citrus

The bait can be used to protect the following fruits and nuts from slugs and snails: apples, avocados, apricots, cherries, citrus, dates, figs, grapes, melons, nectarines, olives, papayas, peaches, pears, plums, pomegranates, prunes, quince, almonds, macadamia nuts, pistachio nuts, walnuts. For seedlings, spread the bait around the base of the stem. Apply at 0.15 oz, or 1 level teaspoon, per square yard, in a 6 inch circular band around the base of the plants to be protected. For older trees, spread the bait around the base of the tree to intercept slugs and snails traveling to the trunk. Apply the bait at approximately 0.5-1 lb. per 1000 square feet for orchards using standard fertilizer granular spreaders.

Berries

The bait can be used to protect the following berries from slugs and snails: strawberries, blackberries, blueberries, boysenberries, currants, dewberries, gooseberries, huckleberries, loganberries, raspberries. Spread the bait around the perimeter of the plot to intercept slugs and snails migrating toward the berries. Use a rate of approximately 0.5-1 lb. per 1000 square feet, or for smaller areas, 0.15 oz., or 1 level teaspoon, per square yard, and scatter by hand or with granular spreaders. If slugs and snails are already in the plots, then carefully spread bait between the furrows near the base of the plants. For small plots, treat around the base of the plants to be protected. Do not spread over the entire area but apply selectively.

Outdoor Ornamentals

Scatter bait in a 6 inch circular band around the base of the plants to be protected at the rate of 0.15 oz., or 1 level teaspoon, per square yard. If plants are next to a grassy area, spread the bait between the ornamentals and the grass. Slugs and snails traveling to the plants will encounter the bait before reaching the plant. In these situations, scatter the bait around the perimeter of the plot at approximately 1 lb. per 1000 square feet to intercept snails and slugs traveling to the plot.

Greenhouses

Where slugs or snails are a problem in greenhouses, scatter the bait in the plant pots or plants being damaged or around pots on greenhouse benches. Apply about ½ teaspoon per 9 inch pot.

Lawns

The bait can be used to protect lawns. When slugs or snails are detected, scatter the bait at a rate of approximately 0.5-1 lb. per 1000 square feet, or for smaller areas, 0.15 oz., or 1 level teaspoon, per square yard. Use a granular spreader to scatter bait where the slugs or snails are observed.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store this product in its original container and keep in a secure storage area out of reach of children and domestic animals.

CONTAINER HANDLING: **If empty:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or place in trash. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

(Alternate Warranty statement for sub-registrant)

NOTICE: To the extent consistent with applicable law, buyer assumes all risks of use, storage or handling of this product not in accordance with directions.

[Insert sub-registrant company name] **Guarantee:** If for any reason you, the consumer, are not satisfied with the product, mail us original proof of purchase to obtain a full refund of your purchase price.

Questions, Comments or Medical Information

1-800-225-2883 www.ortho.com

(Warranty statement for basic registrant)

CONDITIONS FOR SALE

Important: Read these entire Directions and Conditions for Sale before using OR-CAL BIO-SUL Slug & Snail Bait. Disclaimer: Manufacturer warrants that this product conforms to the chemical description on the label and is reasonably fit for the specific purposes referred to in the Directions for Use. Manufacturer makes no other express or implied warranty. To the extent consistent with applicable law, the manufacturer shall not be liable for consequential, special or indirect damage resulting from the use or handling of this product.

Manufactured by:
OR-CAL, Inc.
29454 Meadowview Road
Junction City, OR 97448
PH: 541/689-4413

The following claims and product information, may or may not be presented on the product's label and labeling:

- Low Application rate
- Now Covers Up to XXX Square Feet
- Quick Facts
- Product Facts
 - What It Does: Kills slugs and snails
 - Where to Use: For use around vegetables, fruit trees and certain nuts as listed on this label, citrus, berries, ornamentals, shrubs, flowers, trees, lawns, gardens and in greenhouses.
- Read the Label First.
- The highly compressed granules (pellets) are easy to use and economical.
- Easy-to-use (ready-to-use) RTU granular (pellet) formulation.
- Easy to apply granules.
- Small pellets for even coverage.
- Kills Snails & Slugs.
- Treats (will treat) x,xxx sq. ft.
- Remains effective after rain or sprinkling for up to 3 weeks.
- Proven snail & (and) slug killer (kill, control).
- Convenient. Easy-to-use. Requires no mixing, spraying, or special applicators.
- Money back Guarantee. If you are not satisfied with this product, we will gladly refund your original purchase price.
- Can be used in vegetable gardens.
- For use around vegetables, fruit trees and certain nuts as listed on this label, citrus, berries, ornamentals, shrubs, flowers, trees, lawns, gardens, and in greenhouses.
- Use around flowers, gardens, fruit trees and certain nuts as listed on this label.
- Sulfur occurs naturally in the soil.
- Can be used by domestic animal (pet) owners.

- Can be used around domestic animals (pets) and wildlife.
- Can be used around domestic animals (pets) and wildlife when used as directed
- Dual-Action Formula. Attracts and kills (snails & slugs).
- Highly attractive (bait)(to snails and slugs).
- Attracts/Lures snails & slugs (from plants) fast.
- Begins to kill (snails & slugs) fast/within 1-3 days.
- Begins killings (snails & slugs) fast/within 1-3 days.
- Snails & slugs begin to die within 1-3 days after eating bait.
- Kills/Controls (snails & slugs) fast/within 1-3 days.
- Visible results fast/within 1-3 days.
- Stops plant damage fast/within 1-3 days.
- Protects plants (from snails & slugs) within 1-3 days.
- Begins to kill fast/within 1-3 days & effective/lasts/protects for up to 3 weeks
- Works fast and provides long lasting control until granules are dissolved by rain.
- Fast –acting and long-lasting for use around domestic animals (pets) and wildlife.
- Fast & Long-Lasting (snail & slug) bait/killer/control that can be used around domestic animals (pets) and wildlife.
- Read Entire Container Label Before Using this Product.
- The active ingredient in this product is exempt from the requirement for a tolerance.
- For broadcast application standard broadcast applicators may be used, such as (but not limited to): Cyclone
- Baits and Kills
- For household home garden use.
- Kills a wide variety of slugs and snails
- Effective against a wide variety of slugs and snails
- Lures slugs and snails from hiding places and plants.
- No slime trails
- No messy cleanup.
- Dead snails, no slime trails.
- Attracts and kills slugs and snails.
- May be used up to and including day of harvest.
- Easy to see Pellet
- Effective for up to 3 weeks
- Protects/Defends plants for up to 3 weeks.
- Protects/Defends against plant damage (from snails and slugs) for up to 3 weeks.
- Rain-resistant formula.
- Provides/Returns sulfur and calcium to the soil/plants.
- Unique, patented formula/formulation.
- Protecting your plants from snails & slugs has never been easier.
- Guaranteed Results
- Convenient/Easy-to-use (Shake 'N Feed) applicator.
- Packaging made from xx% recycled/recyclable materials
- No/Low odor formula.
- Kills/Controls Giant African Land Snail
- This product contains iron, which may stain surfaces such as sidewalks, patios, wooden decks, driveways, and clothing. Sweep concrete surfaces immediately to prevent staining. If concrete is wet when contact occurs, staining may be impossible to prevent.

INFORMATION ABOUT OR-CAL BIO-SUL SLUG AND SNAIL BAIT and HOW IT WORKS

This product is a unique blend of the active ingredient, sulfur, with slug and snail bait additives. Sulfur is an element found in nature and used in many fertilizers. The bait will degrade and become a part of the soil.

The bait is attractive to slugs and snails and lures them from their hiding places. Ingestion of the bait will cause them to cease feeding. After eating the bait, the slugs and snails cease feeding, become less mobile and begin to die within one to three days. Dead slugs and snails may not be visible as they often crawl away to secluded places to die. Plant protection will be observed in the decrease in plant damage.

This product is effective against a wide variety of slugs and snails and will give protection to home lawns, gardens, greenhouses, outdoor ornamentals, vegetable gardens, fruits and certain nuts as listed on this label, berries, citrus and crop plants. The bait can be scattered on the lawn or on the soil around any vegetable plants, flowers, fruit or nut trees or bushes to be protected.

SUBLABEL B: Commercial Agriculture Use

OR-CAL
BIO-SUL
Slug & Snail Bait

Active Ingredient:	By weight
Sulfur.....	1.0%
Other Ingredients.....	99.0%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Registration Number 71096-16

EPA Establishment Number 66876-OR-001

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center at: 1-800-858-7378 for information about this product (including health concerns or pesticide incidents).

NET WEIGHT: 10 lbs, 20 lbs, 25 lbs, 40 lbs, 45 lbs, 50 lbs, 55 lbs, 100 lbs, 2000 lbs

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

Personal Protective Equipment (PPE) Requirements: Applicators and other handlers must wear: long-sleeved shirts and long pants, shoes plus socks, chemical resistant gloves made out of any waterproof material, and protective eyewear. Follow manufacturer's instructions for maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RESTRICTIONS: Do not apply when weather conditions favor drift from treated areas. Do not place in piles.

Do not apply this product in a manner that will contact workers or other persons, either directly or through drift. Only protected workers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribe agency representative responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about Personal Protective Equipment (PPE) and the restricted-entry interval. The requirement in this box only apply to uses of this product that are covered by the Worker Protection Standard (WPS).

Do not enter or allow worker entry into the treated areas during the restricted-entry interval (REI) of 24 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is: coveralls or long sleeved shirt and long pants, chemical-resistant gloves made of any waterproof materials, shoes plus socks, and protective eyewear.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Do not enter or allow others to enter until dusts have settled.

COMMERCIAL AGRICULTURE

HOW TO APPLY: Scatter or spread the slug and snail bait pellets on the soil around or near the plants to be protected.

For broadcast application, use standard broadcast spreaders.

For aerial application, use aerial equipment calibrated to give correct dosage within the application rates on this label; do not apply when weather conditions favor drift from treated areas. Do not allow dust to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals. For aerial applications, use upwind swath displacement and apply only when wind speed is 3 -- 10 mph as measured by an anemometer. If application includes a no-spray zone, do not release product at a height greater than 10 feet above the ground or the crop canopy. The applicator also must use all other measures necessary to control drift.

For row application, use standard granular spreaders. Scatter by hand when applicable.

Apply the higher rates if the infestation is severe or if the area is heavily watered or after long periods of heavy rain. Reapply as the bait is consumed or at least every three weeks. Do not place in piles. If the ground is dry, wet it before applying bait. The product works best when soil is moist but with little or no standing water. See specific directions for different plant types and for inside greenhouses.

WHEN TO APPLY: Evening is the best time to apply the bait, as slugs and snails travel and feed mostly at night or early morning.

WHERE TO APPLY: All likely areas of infestation should be treated, especially around the perimeter of garden plots because these pests travel into plant areas from daytime refuge sites. They favor damp places around vegetable plants such as beans, tomatoes, lettuce, cabbage, celery and squash, and in weeds or ditches around field margins. Other favorite areas are flower gardens, rockeries, hedges, citrus groves, ivy patches, and other ground cover where they obtain shelter by day.

Vegetables

The bait can be used to protect the following vegetables from slug and snail damage: artichokes, asparagus, beans, beets, blackeyed peas, broccoli, Brussels sprouts, cabbage, cantaloupe, carrots, cauliflower, celery, collards, corn, cowpeas, cucumbers, eggplants, garlic, kale, lettuce, onions, parsley, peas, peppers, potatoes, pumpkin, radishes, rutabagas, spinach, squash, Swiss chard, tomatoes, and turnips. Broadcast the product directly and evenly or spread the bait around the perimeter of the vegetable plantings at the rate of 20-44 lbs per acre (0.5-1 lb per 1,000 square feet) to provide a protective "barrier" for slugs and snails entering the vegetable plantings. If slugs or snails are inside the rows, then scatter the bait on the soil around the base of the plants and between rows.

Fruits and Nuts including Citrus

The bait can be used to protect the following fruits and nuts from slugs and snails: apples, avocados, apricots, cherries, citrus, dates, figs, grapes, melons, nectarines, olives, papayas, peaches, pears, plums, pomegranates, prunes, quince, almonds, macadamia nuts, pistachio nuts, walnuts. For seedlings, broadcast directly and evenly or spread the bait around the base of the stem. Apply at 0.15 oz, or 1 level teaspoon, per square yard, in a 6 inch circular band around the base of the plants to be protected. For older trees, broadcast directly and evenly or spread the bait around the base of the tree to intercept slugs and snails traveling to the trunk. Apply the bait at 20-44 lbs. per acre (0.5-1 lb. per 1000 square feet) for orchards, using standard fertilizer granular spreaders. Use the higher rates for heavy infestations.

Berries

The bait can be used to protect the following berries from slugs and snails: strawberries, blackberries, blueberries, boysenberries, currants, dewberries, gooseberries, huckleberries, loganberries, raspberries. Broadcast directly and evenly or spread the bait around the perimeter of the plot to intercept slugs and snails migrating toward the berries. Use a rate of 20-44 lbs. per acre (0.5-1 lb. per 1000 square feet) and scatter by hand or with granular spreaders. If slugs and snails are already in the plots, then carefully spread or broadcast bait between the furrows near the base of the plants. For small plots, treat around the base of the plants to be protected. Do not spread over the entire area but apply selectively.

Field Crops

The bait can be used to protect the following field and seed crops from slugs and snails: alfalfa, beans, cotton, field corn, sweet corn, soybeans, sugar beets, sugar cane, asparagus, beets, broccoli, Brussels sprouts, cabbage, carrots, cauliflower, cucumbers, flax, hops, lettuce, onions, peanuts, peas, peppers, potatoes, radishes, small grains (barley, oats, rye, wheat), sorghum, strawberries, tomatoes, turnips. At the seedling and later stages, apply the bait between the rows and around the perimeter of the field. Broadcast or spread pellets at a rate of 20-44 lbs. per acre (0.5-1 lb per 1,000 square feet). Use the higher dosage rate for heavier infestations.

Artichokes

The bait can be used to protect artichokes from slugs and snails. At the seedling and later stages, apply the bait within the rows and around the perimeter of the field. Broadcast or spread pellets at a rate of 10-44 lbs. per acre (0.23-1 lb per 1,000 square feet). Use the higher dosage rate for heavier infestations.

Outdoor Ornamentals

Scatter bait in a 6 inch circular band around the base of the plants to be protected at the rate of 0.15 oz., or 1 level teaspoon, per square yard. If plants are next to a grassy area, broadcast or spread the bait between the ornamentals and the grass. Slugs and snails traveling to the plants will encounter the bait before reaching the plant. In these situations, broadcast or spread the bait around the perimeter of the plot at approximately 1 lb. per 1000 square feet to intercept snails and slugs traveling to the plot.

Greenhouses

Where slugs or snails are a problem in greenhouses, scatter the bait in the plant pots or plants being damaged or around pots on greenhouse benches. Apply about ½ teaspoon per 9 inch pot.

Outdoor Container-Grown Nursery Plants

Where slugs or snails are a problem in outdoor nurseries, scatter the bait in the plant containers at the rate of 1 tablespoon per container of plants being damaged, or scatter on the soil near the containers at the rate of 1 teaspoon per square yard (24-44 lbs. per acre).

Lawns

The bait can be used to protect lawns. When slugs or snails are detected, broadcast or spread the bait at a rate of approximately 0.54 lb. per 1000 square feet (24-44 lbs per acre). Use the higher rate for heavy infestations. Scatter by hand or with a granular or standard broadcast spreader where the slugs or snails are observed.

Grass, Clover, Vetch - Grown for Seed Production and Wheat

The bait can be used to protect grass, clover, and vetch grown for seed production and wheat. When slugs or snails are detected, broadcast or spread the bait at a rate of approximately 0.23 to 1 lb per 1000 square feet (10-44 lbs. per acre). Use the higher rate for heavy infestations. Scatter by hand or with a granular or standard broadcast spreader where the slugs or snails are observed.

Non-Crop Areas

The bait can be used to protect the following non-crop areas: fallow land; barrier strips; non-food or non-feed brush; weed or dense vegetative areas; railroad, pipeline, highway, power and telephone rights of way and road sides; guardrails and fences; lumberyards; storage areas; industrial facility sites, including yards and walkways around industrial building; parking areas, parks, golf courses; airports. Apply at a rate of

approximately 20-44 lbs. per acre (0.5-1 lb. per 1,000 square feet). Use the higher rate for heavy infestations.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store this product in its original container and keep in a secure storage area out of reach of children and domestic animals.

PESTICIDE DISPOSAL: Clean container properly after emptying. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Completely empty drum, bag, box or tote into application equipment. Then dispose of empty drum, bag, box or tote by offering for recycling, if available, or in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

CONDITIONS FOR SALE

Important: Read these entire Directions and Conditions for Sale before using OR-CAL BIO-SUL Slug & Snail Bait. Disclaimer: Manufacturer warrants that this product conforms to the chemical description on the label and is reasonable fit for the specific purposes referred to in the Directions for Use. Manufacturer makes no other express or implied warranty. To the extent consistent with applicable law, the manufacturer shall not be liable for consequential, special or indirect damage resulting from the use or handling of this product.

Manufactured by:
OR-CAL, Inc.
29454 Meadowview Road
Junction City, OR 97448
PH: 541/689-4413

The following claims and product information, may or may not be presented on the product's label and labeling:

-Quick Facts

-NOTE: This package is sold by weight. Contents may have settled during shipment.

-Low Application rate

-Now Covers Up to XXX Square Feet

-Product Facts

-What It Does: Kills slugs and snails

-Where to Use: For use around vegetables, fruit and certain nuts as listed on this label, citrus, berries, ornamentals, shrubs, flowers,

Trees, lawns, gardens and in greenhouses.

-Read the Label First.

-The highly compressed granules (pellets) are easy to use and economical.

-Easy-to-use (ready-to-use) RTU granular (pellet) formulation.

-Easy to apply granules.

-Small pellets for even coverage.

-Kills Snails & Slugs.

-Treats (will treat) x,xxx sq. ft.

-Remains effective after rain or sprinkling for up to 3 weeks.

-Proven snail & (and) slug killer (kill, control).

-Convenient. Easy-to-use. Requires no mixing, spraying, or special applicators.

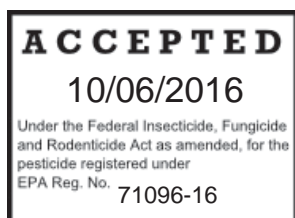
- Money back Guarantee. If you are not satisfied with this product, we will gladly refund your original purchase price.
- Can be used in vegetable gardens.
- For use around vegetables, fruit trees and certain nuts as listed on this label, citrus, berries, ornamentals, shrubs, flowers, trees, lawns, gardens, and in greenhouses.
- Use around flowers, gardens, fruit trees and certain nuts as listed on this label.
- Sulfur occurs naturally in the soil.
- Can be used by domestic animal (pet) owners.
- Can be used around domestic animals (pets) and wildlife.
- Can be used around domestic animals (pets) and wildlife when used as directed
- Dual-Action Formula. Attracts and kills (snails & slugs).
- Highly attractive (bait)(to snails and slugs).
- Attracts/Lures snails & slugs (from plants) fast.
- Begins to kill (snails & slugs) fast/within 1-3 days.
- Begins killings (snails & slugs) fast/within 1-3 days.
- Snails & slugs begin to die within 1-3 days after eating bait.
- Kills/Controls (snails & slugs) fast/within 1-3 days.
- Visible results fast/within 1-3 days.
- Stops plant damage fast/within 1-3 days.
- Protects plants (from snails & slugs) within 1-3 days.
- Begins to kill fast/within 1-3 days & effective/lasts/protects for up to 3 weeks
- Works fast and provides long lasting control until granules are dissolved by rain.
- Fast –acting and long-lasting for use around domestic animals (pets) and wildlife.
- Fast & Long-Lasting (snail & slug) bait/killer/control that can be used around domestic animals (pets) and wildlife.
- Read Entire Container Label Before Using this Product.
- The active ingredient in this product is exempt from the requirement for a tolerance.
- For broadcast application standard broadcast applicators may be used, such as (but not limited to): Cyclone
- Baits and Kills
- Kills a wide variety of slugs and snails
- Effective against a wide variety of slugs and snails
- Lures slugs and snails from hiding places and plants.
- No slime trails
- No messy cleanup.
- Dead snails, no slime trails.
- Attracts and kills slugs and snails.
- May be used up to and including day of harvest.
- Easy to see Pellet
- Effective for up to 3 weeks
- Protects/Defends plants for up to 3 weeks.
- Protects/Defends against plant damage (from snails and slugs) for up to 3 weeks.
- Rain-resistant formula.
- Provides/Returns sulfur and calcium to the soil/plants.
- Unique, patented formula/formulation.
- Protecting your plants from snails & slugs has never been easier.
- Guaranteed Results
- Packaging made from xx% recycled/recyclable materials
- No/Low odor formula.
- Kills/Controls Giant African Land Snail
- This product contains iron, which may stain surfaces such as sidewalks, patios, wooden decks, driveways, and clothing. Sweep concrete surfaces immediately to prevent staining. If concrete is wet when contact occurs, staining may be impossible to prevent.

INFORMATION ABOUT OR-CAL BIO-SUL SLUG & SNAIL BAIT and HOW IT WORKS

This product is a unique blend of the active ingredient, sulfur, with slug and snail bait additives. Sulfur is an element found in nature and used in many fertilizers. The bait will degrade and become a part of the soil.

The bait is attractive to slugs and snails and lures them from their hiding places. Ingestion of the bait will cause them to cease feeding. After eating the bait, the slugs and snails cease feeding, become less mobile and begin to die within one to three days. Dead slugs and snails may not be visible as they often crawl away to secluded places to die. Plant protection will be observed in the decrease in plant damage.

This product is effective against a wide variety of slugs and snails and will give protection to home lawns, gardens, greenhouses, outdoor ornamentals, vegetable gardens, fruits, certain nuts as listed on this label, berries, citrus and crop plants. The bait can be scattered on the lawn or on the soil around any vegetable plants, flowers or fruit trees or bushes to be protected.



SUPPLEMENTAL LABEL
OR-CAL BIO-SUL SLUG AND SNAIL BAIT
EPA Reg. No. 71096-16

This supplemental label expires on December 21, 2019 and may not be used or distributed after that date

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. The labeling must be in possession of the user at the time application. Read the label affixed to the container for OR-CAL BIO-SUL Slug and Snail Bait before applying. Use of OR-CAL BIO-SUL Slug and Snail Bait according to this labeling is subject to the use precautions and limitations imposed by the label affixed to the container for OR-CAL BIO-SUL Slug and Snail Bait.

Scatter or spread the slug and snail bait pellets on the soil around or near the plants to be protected. *For broadcast application*, use standard broadcast spreaders. *For aerial application*, use aerial equipment calibrated to give correct dosage within the application rates on this label; do not apply when weather conditions favor drift from treated areas. Do not allow dust to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals. For aerial applications, use upwind swath displacement and apply only when wind speed is 3 -- 10 mph as measured by an anemometer. If application includes a no-spray zone, do not release product at a height greater than 10 feet above the ground or the crop canopy. The applicator also must use all other measures necessary to control drift. *For row application*, use standard granular spreaders. Scatter by hand when applicable. This product contains iron, which may stain surfaces such as sidewalks, patios, wooden decks, driveways, and clothing. Sweep concrete surfaces immediately to prevent staining. If concrete is wet when contact occurs, staining may be impossible to prevent.

Additional pest controlled: Giant African Land Snail.

Additional Crop Use Site by Category	Application rate
Vegetables: Celery, collards, cowpeas, pumpkin	20-44 lbs per acre (0.5-1 lb per 1,000 square feet)
Fruits and Nuts: Dates, figs, nectarines, olives, papayas, pomegranates, prunes, quince, almonds, macadamia nuts, pistachio nuts, walnuts	20-44 lbs per acre (0.5-1 lb per 1,000 square feet)
Berries: Currants, dewberries, gooseberries, huckleberries	20-44 lbs per acre (0.5-1 lb per 1,000 square feet)
Field Crops: Alfalfa, cotton, flax, hops, peanuts, small grains (barley, oats, rye, wheat), sorghum	20-44 lbs per acre (0.5-1 lb per 1,000 square feet)
Clover, Vetch: Grown for Seed Production and Wheat	10-44 lbs per acre (0.23-1 lb per 1,000 square feet)

APPENDIX B

Technical Evaluation Report USDA/AMS, March 16, 2017

In re: Petition of Georgia Gulf Sulfur Corporation, Valdosta, Georgia

Sulfur

Livestock

Identification of Petitioned Substance

Chemical Names:

Sulfur, Sulphur

Other Name:

Elemental sulfur, Octasulfur, cyclo-S₈, cyclo-octasulfur, cyclooctasulfur, octathiocane, cyclic octaatomic sulfur, orthorhombic sulfur

Trade Names:

Sulfur ground, sulfur powder, sulfur flowers, sulfur, 325 mesh

CAS Numbers:

10544-50-0; 1326-66-5; 7704-34-9

Other Codes:

Pubchem: 66348; InCHI = 1S/S8/c1-2-4-6-8-7-5-3-1; InCHI key = JLQNHAFVFCURHW-UHFFFAOYSA-N; Canonical Smiles = S1SSSSSS1; EC number = 215-437-4, 927-196-9; UNII = 70D1KFU70

Summary of Petitioned Use

A petition was received by the NOP to add sulfur for use as an insecticide (miticide, acaricide) in organic livestock production (§205.603(b)). Sulfur (elemental) is currently allowed for use in the production of organic crops as an insecticide, for plant disease control, and as a plant or soil amendment.

Characterization of Petitioned Substance

Composition of the Substance:

Sulfur is a naturally occurring chemical element. It has been given the symbol S and has an atomic number of 16. It is an abundant, multivalent nonmetal.

Source or Origin of the Substance:

Commercial elemental sulfur was once mined and extracted from salt domes where it sometimes occurs in nearly pure form, but this method has been in decline since the late 20th century. Today, almost all elemental sulfur is produced as a byproduct of coal, natural gas and petroleum refinement (Davis and Detro, 1992). Desulfurization of diesel fuel, gasoline, and jet fuel to meet today's air pollution standards requires the reduction of sulfur concentration from levels exceeding 500 parts per million (ppm) to less than 15 ppm (Song, 2003). Residual sulfur is removed from petroleum, natural gas and coal by the Claus process and refined to very high levels of purity suitable for sulfuric acid production (El-Bishtawi and Haimour, 2004; Elsner et al., 2003).

Properties of the Substance:

Under normal conditions, sulfur atoms form cyclic octa-atomic molecules with chemical formula S₈ (Fig 1). Elemental sulfur is a bright yellow crystalline solid at room temperature. Sulfur is an odorless,



Fig 1. 3-dimensional depiction of cyclooctasulfur (NCBI, 2017)

Table 1. Physical Properties of Cyclooctasulfur*

Chemical formula	S ₈
Molar mass	256.48 g mol ⁻¹
Appearance	Vivid, yellow, translucent crystals
Odor	Odorless, or faint odor of rotten eggs if not 100% pure
Density	2.07 g cm ⁻³
Melting point	246°F (119°C; 392 K)
Boiling point	832°F (444°C)
Flash Point	405°F (207.2°C)
log P (Partition coefficient)	6.117
Specific Gravity	2.07@70°F
*NCBI, 2017; Georgia Gulf Sulfur Corporation, 2000	

34 tasteless solid usually sold in blocks or pellets. It is easily crushed into a powder. Sulfur is a reactive
 35 element that given favorable circumstances combines with all other elements except gases, gold, and
 36 platinum. Sulfur from all sources is available at a purity level of 90-100%, although synthetically produced
 37 elemental sulfur purity exceeds 99.9%. Arsenic, selenium, lead, tellurium, cadmium and mercury are found
 38 analytically in synthetically produced sulfur at 0.1% or less (Georgia Gulf Sulfur Corporation, 2000).

39 **Specific Uses of the Substance:**

40 Elemental sulfur is granulated to a fine powder (325 mesh) for use as a pesticide (control for mites, insects,
 41 fungi and rodents) in livestock production. The particle size for this powder is 44 microns (0.0017 inches) or
 42 less. Livestock species include chickens, turkeys, ducks, geese, game birds, pigeons, equine species, cattle,
 43 swine, sheep, and goats. Sulfur dusting and or spraying is used for both the animals and their respective
 44 accommodations.

45 **Approved Legal Uses of the Substance:**

46 Pesticides are regulated by the US Environmental Protection Agency (EPA). Element sulfur is a ubiquitous,
 47 natural component of the environment, but is still required to be registered by the EPA for use as a
 48 pesticide. Registration includes evaluation of ingredients, crop or animal, site, frequency, amount, storage
 49 and disposal with respect to human health and the environment. The EPA also requires pesticide
 50 reregistration at timed intervals to ensure that new potential pesticide issues can be appropriately
 51 addressed. EPA has registered sulfur for use as an insecticide, fungicide and rodenticide on several

52 hundred food and feed crops, ornamental, turf and residential sites. Sulfur is applied in dust, granular or
53 liquid form, and is an active ingredient in nearly 300 EPA registered pesticide products. While most of
54 these registrations are for use in crops, the EPA currently considers all registered uses of sulfur to be
55 eligible for reregistration including the use of sulfur as an insecticide for control of mites, insects, fungi and
56 rodents of indoor food animals including sheep, goats, beef/range/feeder cattle, hogs/pigs/swine, poultry
57 and birds (EPA, 1991a).

58 Sulfur has been known and used as a pesticide since very early times in history, and has been registered for
59 use as a pesticide in the United States since the 1920s. EPA issued a Registration Standard for sulfur in
60 December 1982. The only data requirement imposed at that time was a proposal for crop and facility
61 reentry intervals. No additional generic data have been required since then (EPA, 1991a). Sulfur is exempt
62 from the EPA tolerance establishment requirement (40 CFR §180.1236).

63 The USDA organic regulations (7 CFR Part 205) currently permit the use of elemental sulfur in organic crop
64 production as an insecticide (including acaricide or mite control), §205.601(e), as plant disease control,
65 §205.601(i) and as a plant or soil amendment, §205.601(j).

66 **Action of the Substance:**

67 Sulfur with a purity of 99.5% or better is recognized as a pharmaceutical product. It has both an antiseptic
68 and a parasitocidal action in lotions, ointments, dusting and dips (Windholz et al., 1983). It has long been
69 known that certain insects are killed to some extent by dry sulfur. The insecticidal properties of sulfur have
70 been shown to be the result of: (1) Its ability to react with oxygen; (2) its ability to soften newly secreted
71 wax on the exoskeletons of insects; and (3) the amount of H₂S formed in its decomposition (Shafer, 1915).
72 More specifically, arthropod respiration is through spiracles that actively open and close to permit air to
73 flow into and out of trachea where oxygen and CO₂ exchange with the arthropod hemolymph: a blood like
74 fluid (Lighton, 1996). Both oxygen and carbon dioxide toxicity can result from defective spiracle function
75 (Kobayashi et al., 1984; Hetz and Bradley, 2005). Spiracles also prevent water loss. Excessive water loss as a
76 result of spiracle dysfunction can also kill arthropods (Lighton, 1996; Chandrashekhara et al., 1993). Sulfur
77 appears to interact with this mechanism, preventing opening and closing of spiracles, and reducing or
78 preventing airflow and increasing water loss.

79 **Combinations of the Substance:**

80 Sulfur is often used with lime (Windholz et al., 1983). Sulfur can be mixed 1:1 with lard and used as an
81 ointment for the prevention of scaly leg in poultry (Bedford, 1924). Diatomaceous earth or kaolin earth can
82 be combined with elemental sulfur powder in preparations for housing and dustbathing treatments for
83 ectoparasites (Martin and Mullens, 2012).

84 Status

85 **Historic Use:**

86 Sulfur is already permitted for use as an insecticide (including acaricide or mite control) in organic crop
87 production if requirements of 205.206(e) are met. Producers are also required to use preventative,
88 mechanical, physical and other pest, weed and disease management practice. Sulfur has historically been
89 used for the prevention and treatment of lice, fleas, ticks and mites which cause or carry pathogens for a
90 number of diseases in horses, pigs, cattle and poultry (MRCVS, 1914). Early American farmers burned
91 native sulfur with charcoal to minimize caterpillar infestations (McWilliams, 2010).

92 **Organic Foods Production Act, USDA Final Rule:**

93 Sulfur is currently permitted for several uses in organic crop production. In §205.601(e) sulfur and the
94 sulfur derivative lime sulfur (including calcium polysulfide) are allowed for use as insecticides (including
95 acaricides or mite control). In §205.601(i) sulfur and its derivative lime sulfur are allowed for use in plant
96 disease control. In §205.601(j) sulfur and its derivative sulfuric acid are allowed as soil amendments. In
97 the case of sulfuric acid, sulfur purity of 99% is required. Sulfur is not found on the National List for use
98 in livestock.

99 Elemental sulfur is a sulfur compound falling into a category defined by §6517 of the Organic Foods
100 Production Act (National List) for sulfur compounds where an exemption can be made so that the National
101 List may provide for its use in an organic farming or handling operation.

102 International**103 Canada - Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015)**

104 Sulfur is permitted by Canada organic standards in livestock production for control of external parasites.
105 Additionally, non-synthetic elemental sulfur and calcium polysulfide (lime sulfur) are listed for crop
106 production for use as a soil amendment where more buffered sources of sulfur are not appropriate, and as
107 a foliar application. Calcium polysulphide is also listed for use on plants as a fungicide, an insecticide and
108 an acaricide for mite control. Sulfur smoke bombs are also listed for use in rodent control when a full pest
109 control program is maintained but temporarily overwhelmed.

**110 CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing
111 of Organically Produced Foods (GL 32-2013)**

112 Codex Alimentarius guidelines (GL 32-2013) permit the use of sulfur for livestock and livestock products in
113 bee husbandry for pest and disease control. With recognition by the certification body or authority, GL 32-
114 2103 permits the use of sulfur in soil fertilizing and conditioning, and plant pest disease control,

115 European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

116 Commission Regulation (EC) No 889/2008 permits the use of elemental sulfur (98% pure) as a fertilizer or
117 soil amendment and as a fungicide, acaricide and repellent in organic farming. Sulfur is not permitted for
118 use as an insecticide in livestock.

119 Japan Agricultural Standard (JAS) for Organic Production

120 The Japan Agriculture Standard for Organic Production permits the use of sulfur as a fertilizer or soil
121 improvement. Sulfur is not permitted for use as an insecticide in livestock.

122 International Federation of Organic Agriculture Movements (IFOAM)

123 The iFOAM norms allow the use of sulfur as a fertilizer and soil conditioner and as a crop protectant in
124 organic crop production. iFOAM allows the use of sulfur for pest and disease control in beekeeping. Sulfur
125 is not permitted for use as an insecticide in livestock.

126

127 Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

128

129 **Evaluation Question #1: Indicate which category in OFPA that the substance falls under:** (A) Does the
130 substance contain an active ingredient in any of the following categories: copper and sulfur
131 compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated
132 seed, vitamins and minerals; livestock parasiticides and medicines and production aids including
133 netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is
134 the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological
135 concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert
136 ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part
137 180?

138 Elemental sulfur is a sulfur compound – S₈ (Fig 1). Its use in this petition is a livestock parasiticide. Sulfur is
139 exempt from a residual tolerance (40 CFR 180.1236) and listed as a stabilizer for food use in 40 CFR 180.930.

140 **Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the
141 petitioned substance. Further, describe any chemical change that may occur during manufacture or
142 formulation of the petitioned substance when this substance is extracted from naturally occurring plant,
143 animal, or mineral sources (7 U.S.C. § 6502 (21)).**

144 Sulfur is an abundant element on the earth. Elemental sulfur is found in volcanic sites and salt domes.
145 Sulfur was classically mined using the Frasch process in the US as late as the 1920s. In the Frasch process
146 superheated water is pumped into a sulfur deposit to melt the sulfur, which is then brought to the surface
147 with compressed air. Sulfur produced by the Frasch process was 99.5% pure and required no further
148 purification. In some locations sulfur is found near the earth's surface in sulfur craters. Here sulfur from

149 the deposits is broken up and harvested with various kinds of mining equipment ranging from hand
150 carried baskets to modern conveyor systems.

151 Sulfur is also found in petroleum, natural gas and fossil products from which it must be removed as a legal
152 mandate to avoid the production of sulfur dioxide, a contaminant of the air. Hydrogen sulfide from
153 petroleum refining and fossil fuels is converted to pure sulfur by the Claus process. The Claus process is
154 used to produce the majority of sulfur available today. In a heating and cooling cycle, hydrogen sulfide
155 recovered from fossil products is combusted to form water and elemental sulfur:

156



158

159 The addition of an aluminum or titanium catalyst permits the reaction of SO_2 formed during combustion
160 with additional molecules of H_2S to yield sulfur and water:

161



163 In 2015, recovered elemental sulfur and its byproduct sulfuric acid were produced at 103 operations in 27
164 States. Total shipments were valued at about \$933 million. Elemental sulfur production was 8.7 million
165 tons; Louisiana and Texas accounted for about 52% of domestic production. Elemental sulfur was
166 recovered, in descending order of tonnage, at petroleum refineries, natural-gas-processing plants, and
167 coking plants by 39 companies at 96 plants in 26 States. Domestic elemental sulfur provided 64% of
168 domestic consumption. About 11 million tons of sulfur were used in the US in 2015 (USGS, 2016).

169 **Evaluation Question #3: Discuss whether the petitioned substance is formulated or manufactured by a
170 chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).**

171 Elemental sulfur is both a mined mineral and a synthetic product. Although, available commercially the
172 purity of the mined product is not as high as the synthetic form. Sulfur is primarily recovered synthetically
173 by a thermal catalytic process from sulfite and hydrogen sulfide produced during refining and use of fossil
174 products.

175 **Evaluation Question #4: Describe the persistence or concentration of the petitioned substance and/or its
176 by-products in the environment (7 U.S.C. § 6518 (m) (2)).**

177 Sulfur has been used as a pesticide in the United States since the 1920s, and is currently registered for use
178 as an insecticide and fungicide on a wide range of field and greenhouse-grown food and feed crops,
179 livestock (and livestock quarters), and indoor and outdoor residential sites. Although sulfur has
180 insecticidal and fungicidal properties when used as directed, it is also an abundant and ubiquitous element
181 in the natural environment (Brown, 1982, EPA, 2013b).

182 Elemental sulfur is combusted at volcanic sites, and metabolized by sulfur bacteria to produce hydrogen
183 sulfide that enters the atmosphere. Hydrogen sulfide in the atmosphere makes clouds more reflective
184 producing a cooling effect on the earth. Sulfur in the atmosphere is involved in the prevention of global
185 warming (Blake, 2007, Wingenter et al., 2007). Elemental sulfur is required for the existence of animal and
186 plant life. Available evidence indicates that elemental sulfur is rapidly and extensively incorporated into
187 the natural sulfur cycle via oxidation to sulfate and/or reduction to sulfide with subsequent volatilization
188 (Lovelock, 1974; EPA, 2013b). The sulfur cycle can be simplified to four basic step: 1) mineralization of
189 organic sulfur (e.g. methionine, cysteine) to an inorganic form (H_2S), 2) oxidation of sulfide, elemental
190 sulfur and related compounds to sulfate, SO_4^{2-} , 3) reduction of sulfate to sulfide, 4) microbial
191 immobilization of sulfur compounds and subsequent incorporation into an organic form of sulfur (Shaver,
192 2014; la Riviere, 1966). A simplified diagram of the natural sulfur cycle is shown in Fig 2.

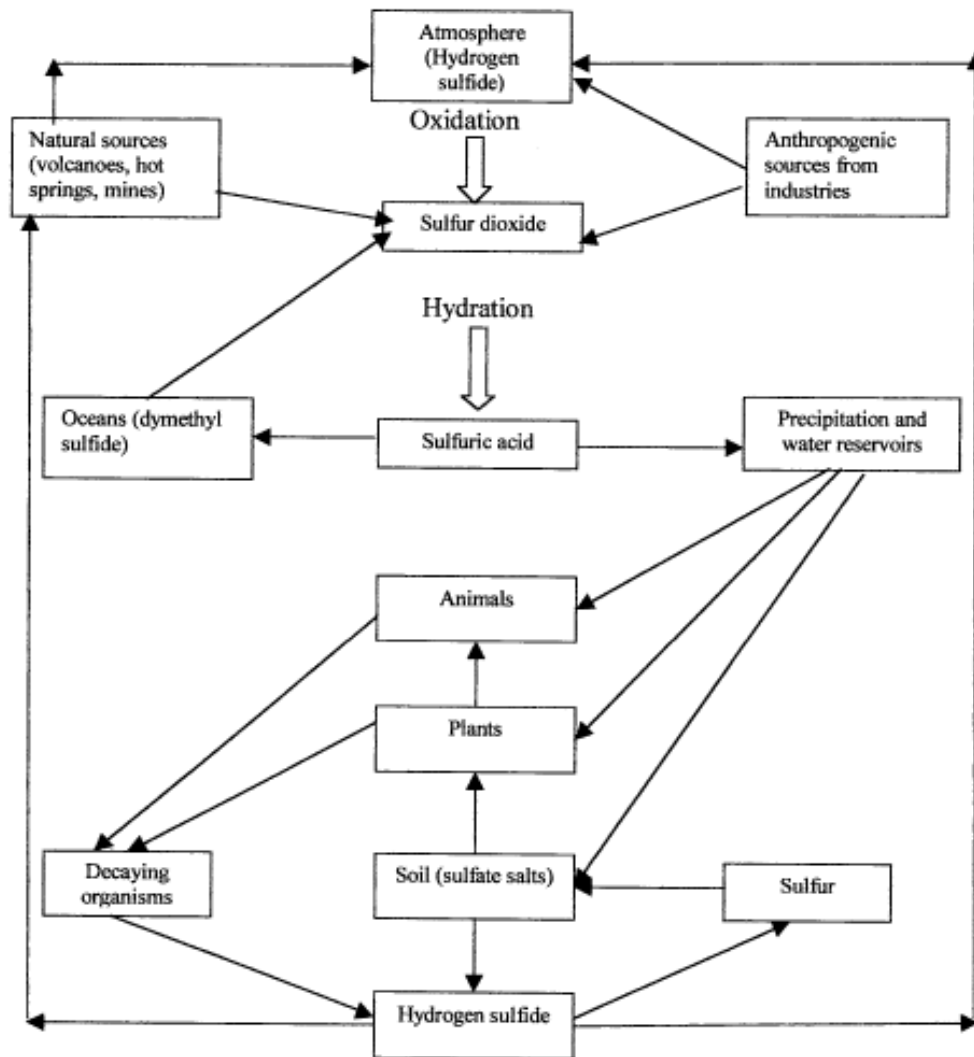
193 Hydrogen sulfide entering the atmosphere reacts with oxygen to form sulfur dioxide. In water, sulfur
194 dioxide forms hydrogen sulfite which in excess is responsible for generating acid rain, i.e. fossil fuels
195 containing sulfur that are burned in the presence of air form sulfur dioxide that is subsequently absorbed
196 into rain water. The pH range for acid rain is 4.2-4.4. Acidification of lakes, rivers and streams resulting
197 from acid rain has led to the devastation of ecological communities and has put many on the brink of
198 destruction. Industrial nations recognizing the environmental problems caused by acid rain have reacted

199 by developing processes to remove sulfur from fossil fuels. Recovered sulfur is usually very pure (EPA,
 200 2016).
 201

Table 2 Occurrence of Sulfur in Nature			
Sources			
Natural			
	Volcanic deposits		Mixed with gypsum and pumice stone
			Realgar or ruby sulfur (arsenic sulfide)
Subterranean deposits			
		Elemental	Sulfur Ore
		Metallic Sulfides	Acanthite, arsenopyrite, bismuthinite, chalcopyrite, cinnabar, cobaltite, copper pyrite, digenite, galena, iron, pyrite, molybdenite, pentlandite, sphalerite
		Non-metallic sulfides	Angelite, anglesite, barite or heavy spar, celestite, gypsum, thenardite
		Hot Springs	Sulfurous water
		Fossil Fuels	Coal, petroleum, natural gas
Dietary			
		Food	Onion, cabbage, cauliflower, broccoli, oil of garlic, mustard, eggs
		Vitamins	Thiamine, pyridoxine (vitamin B6), biotin
		Amino Acids	Methionine, keto-methionine, cysteine, cystine, homocysteine, cystathionine, taurine, cysteic acid
		Preservatives	Sulfur dioxide
Biological			
		Biochemicals	Proteins, lipoic acid, coenzyme A, glutathione, chondroitin sulfate, heparin, fibrinogen, ergothionine, estrogens, ferredoxin
		Microorganisms	Aerobic heterotrophic (most fungi and aerobic bacteria), <i>Desulfo vibrio</i> and <i>Desulfo tomaculum</i> , chemoautotrophic (e.g., thiobacillus), photoautotrophic (Chlorobium and Chromatium)
Industrial			
	Fertilizers		Phosphates and Ammonium sulfate
	Anthropogenic	Combustion of fossil fuels	SO ₂ , H ₂ S
from Komarnisky et al., 2003			

202 **Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its**
 203 **breakdown products and any contaminants. Describe the persistence and areas of concentration in the**
 204 **environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).**

205 Elemental sulfur is found naturally and combined with iron and base metals and sulfide minerals. In
 206 petroleum, sulfur occurs in a variety of complex molecules. In natural gas sulfur is present as hydrogen
 207 sulfide. Sulfur is present in plants, animals and humans in a number of biological molecules. Recovered
 208 sulfur is the primary source of sulfur used for industrial applications. It is recovered from sulfur ores,
 209 during the refining of oil, and through the purification of natural gas (Komarnisky et al., 2003). Table 2
 210 provides the sources of sulfur in the environment.



211 Fig 2. A simplified diagram of the natural sulfur cycle (Komarniskey et al., 2003)
 212
 213

214 Sulfur is essential for life in a range of concentrations as a part of or in combinations with other molecules.
 215 However, sulfur is known to cause polio encephalomalacia in ruminants and may inhibit arachidonic acid
 216 metabolism and platelet plasma membrane function in rabbits (Komarniskey et al., 2003). Consumption by
 217 ruminants of a high dietary percentage (>0.3%) of sulfur as elemental sulfur or sulfate can cause toxic
 218 effects. Sulfur bacteria in the rumen produce the poisonous gases, hydrogen sulfide and sulfur dioxide that
 219 eructate from the rumen and are absorbed through the lungs. Diets rich in sulfate can depress feeding. In
 220 spite of the liver’s capability for detoxifying sulfide in the blood, extreme cases of sulfur toxicity can lead to
 221 death (Kandyliis, 1984).

222 Elemental sulfur is insoluble in water. However, its solubility in organic solvents, such as methanol, is
223 greater. Tests with zebrafish larvae showed sulfur toxicity at concentrations as low as 1%. A sulfur
224 concentration that high may be achieved by dilution with methanol (Svenson et al., 1997).

225 **Evaluation Question #6: Describe any environmental contamination that could result from the**
226 **petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).**

227 Elemental sulfur is transported from mining, manufacturing and transshipping sites in pipelines and in
228 tank cars in molten form. Molten sulfur has the potential to emit hydrogen sulfide gas, which 1) presents a
229 safety hazard to those working in the vicinity and 2) an environmental hazard, since H₂S is very toxic
230 (Sulphur Institute, 2013).

231 Pollution of the soils can take place where elemental sulfur is stored in the open. Wind eroding fine dust
232 from sulfur blocks or grains stored in the open is deposited downwind of the manufacturing or storage
233 facility. Over several years surrounding soils can become acidified with pH as low as 1. Acidification is the
234 result of soil bacteria converting the sulfur to sulfuric acid. (Nyborg, 1978).

235 **Evaluation Question #7: Describe any known chemical interactions between the petitioned substance**
236 **and other substances used in organic crop or livestock production or handling. Describe any**
237 **environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).**

238 Diatomaceous earth, kaolin and lard are natural substances that may be used for organic production. They
239 are used with sulfur for dustbathing poultry to prevent lice and mite infestations. For example, equal parts
240 lard and sulfur can be used to treat birds for the scaly-leg mite. Another treatment for depluming mites
241 uses a combination of ¾ oz. sodium fluoride (not on the National List), 2 oz. sulfur, ½ oz. of household
242 soap and 1 gallon of water. For lice, a dust bath containing sulfur and lime is effective (Rumball, 1927). In
243 the treatment of the hen house for mites, lice and fleas, it is recommended to not only clean and coat
244 surfaces, but to dust with a 3:1 combination of powdered slacked lime and sulfur (Herrick, 1915). When
245 sulfur is used to treat honeybee colonies for mites, no changes in the hedonic performance of the honey is
246 observed in comparison to a water spray control (Hosamani et al., 2007). Sulfur is not toxic to the honey
247 bee (Kuan and Chi, 2007)..

248 Windblown elemental sulfur from storage piles can result in heavy local deposits: 1 to 100 metric
249 tons/hectare or more. These soils become completely barren with pH 1 to 2. Reclamation is possible by
250 adding large amounts lime, CaCO₃ (Nyborg, 1978).

251 Sulfur as an element is not particularly flammable. However, combining sulfur with potassium chlorate
252 can produce a very unstable, even explosive mixture (Tanner, 1959). Strong oxidizers such as perchlorates,
253 peroxides, permanganates, chlorates can react with sulfur spontaneously cause a fire or explosion (NJ
254 Health, 2011).

255 **Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical**
256 **interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt**
257 **index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).**

258 Elemental sulfur is generally used for livestock insecticide applications in granular or finely powdered
259 form. Liquids and mixtures are also in use. Small amounts of dusting sulfur or liquids find their way into
260 soils or water, either as part of the manufacturing process, transport and storage or application to animals.
261 None of these applications is recognized as an environmental problem (EPA, 1991b). In soils, sulfur is
262 oxidized to sulfuric acid (H₂SO₄) by soil bacteria mostly of the genus *Thiobacillus*. Important factors for the
263 rate of oxidation include 1) the fineness of the sulfur particles, 2) the resident population of *Thiobacillus*
264 spp., 3) soil temperature and 4) soil moisture content. Powdered sulfur is quickly oxidized (Nyborg, 1978).
265 In general there is very little effect on the vegetation, soil or the invertebrate population of the soil from
266 small amounts of sulfur dust. Too much sulfur, e.g. from a sulfur storage or manufacturing facility will
267 cause the pH of the soil to drop as low as pH 2.5 or lower. Although, H₂SO₄ in the soil can generally diffuse
268 in the soil as a sulfate ion leachate, the introduction of high levels of sulfur can cause the loss of vegetative
269 ground cover and affect a number of insect taxa (Carcamo et al., 1998). High sulfur contamination and
270 subsequent acidification has a clear negative effect on earthworms, snails, and several ground beetle
271 species. Among the beetles, ecological specialists are those most vulnerable to acidification, whereas
272 ecological generalists are more resistant (Carcamo and Parkinson, 2001). Earthworms have an important

273 influence on the sulfur turnover in the soil caused by their burrowing, feeding, digestion and egestion
274 (Grethe et al., 1996).

275 Many species of sulfur reducing bacteria produce and metabolize elemental sulfur in a number of chemical
276 transformations, both in soils and water. Quite a few of these have not yet been identified or characterized.
277 In some cases, particularly in the absence of sufficient nitrate, hydrogen sulfide is produced in the
278 metabolism of elemental sulfur. Hydrogen sulfide is responsible for a serious sulfur odor (Liang, 2016).
279 Livestock operations frequently produce significant levels of hydrogen sulfide, notwithstanding from
280 general practice rather than prevention or treatment for parasites using elemental sulfur (Guarrasi et al.,
281 2015).

282 **Evaluation Question #9: Discuss and summarize findings on whether the use of the petitioned**
283 **substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A)**
284 **(i)).**

285 Sulfur is an abundant element and a significant part of the earth's geochemical equilibrium: gaseous,
286 aqueous and solid. Sulfur products in the environment include elemental sulfur, thiosulfates, sulfites,
287 sulfates, polythionates and polysulfides (Nriagu and Hem, 1978). Natural and industrial activities, such as
288 volcanic action, burning fossil fuels, agriculture, etc. change the geochemical equilibrium, such that the
289 environment becomes polluted, e.g. acid rain, bad smelling air. However, the potential for pollution by
290 elemental sulfur is mostly found in its effect on soils. In soils, the oxidation and reduction of sulfur, the
291 mineralization-immobilization of biologically bound soil sulfur, i.e. amino acids, enzymes, etc., the
292 sorption of SO₂, the formation H₂SO₄ and SO₂ emission by some sulfur fertilizers and the retention and
293 leaching of sulfates play a role in sulfur pollution (Nyborg, 1978). As a fertilizer or amendment, elemental
294 sulfur is oxidized to sulfuric acid in aerobic soils by soil bacteria. Too much can lead to soil acidification.
295 Windblown elemental sulfur from storage piles can result in heavy local deposits (1 to 100 metric tons or
296 more). Soils become completely barren with pH values of 1 to 2. Liming can help to return these soils to a
297 proper pH (Nyborg, 1974).

298 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of**
299 **the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (ii) and 7 U.S.C. § 6518**
300 **(m) (4)).**

301 Current available US Environmental Protection Agency toxicity studies and literature searches for
302 elemental sulfur do not indicate any systemic toxicity associated with elemental sulfur exposure and no
303 endpoints of toxicological concern have been identified. The acute toxicity of sulfur is low. Acute oral
304 toxicity is a category IV hazard, i.e. fifty percent lethal dose (LD₅₀) is greater than 5000 milligrams (mg) per
305 kilogram (kg) of body weight. Only the word caution or no signal word is required on the label for
306 elemental sulfur for acute toxicity. Elemental sulfur is considered a category III hazard for dermal exposure
307 and inhalation. For dermal exposure, LD₅₀ > 2000 mg/kg ≤ 5000 mg/kg. Only the signal word caution is
308 required. For inhalation, LC₅₀ > 0.5 mg/L < 2.0 mg/L and the signal word caution must be on the label.
309 Sulfur is an eye and skin irritant (category III, moderate irritation (erythema) at 72 hours), but is not a skin
310 sensitizer. The EPA is satisfied that in most cases labels contain sufficient information about personal
311 protective equipment and reentry and this information is generally followed by applicators (EPA, 2013a).
312 The EPA's review of incident data indicates that both the relative number of reported incidents and the
313 severity of reported health effects are low.

314 In livestock production, H₂S is a hazard to human health. This colorless toxic gas with a rotten egg odor is
315 produced during the degradation of liquid manure stored in anaerobic conditions within agricultural
316 livestock operations. In spite of regulatory limits for H₂S exposure of 1 ppm, levels as high as 9, 22 and 97
317 ppm have been reported for poultry, beef/dairy and swine production, respectively (Guarrasi et al., 2015).
318 The contribution of elemental sulfur to the H₂S livestock production hazard for workers is negligible (EPA,
319 2013a).

320 **Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be**
321 **used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed**
322 **substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).**

323 Extracts of neem seeds diluted with water or soap have been shown to be effective treatments for mites,
324 ticks, fleas, flies and some insects for livestock (Schmahl et al., 2010). Pest control in poultry production

325 depends upon the production system. In cage free production, where chickens can partake in dustbathing
326 behaviors, both kaolin and diatomaceous earth in the dust bath can serve as a good treatment for mites and
327 lice (Martin and Mullens, 2012). Several essential oils have been shown to be effective against lice and ticks
328 (Rossini et al., 2008; Jaenson et al., 2005)).

329
330 **Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned**
331 **substance unnecessary (7 U.S.C. § 6518 (m) (6)).**

332 In livestock production, control of parasites living on the outside of animals (ectoparasites, e.g. mites) and
333 in their housing should focus on excluding vectors such as wild animals and rodents from the production
334 system. Pens and housing should be kept clean. In addition, caretakers should ensure that they do not
335 transfer mites, ticks or lice from an infected population a non-infected one. This can include placing baits
336 and traps near the production facility for both the ectoparasites and their vectors, removing spilled feed,
337 and monitoring rodent and wild bird activity. Buildings should be painted and sealed. Wood buildings
338 must be treated to prevent infestation. In addition, livestock should be monitored regularly for infestations.
339 Wild animal populations in fields, pastures, activity areas and forage should be monitored and potentially
340 infested animals should be sequestered from un-infested herds. Forage and pasture conditions should be
341 monitored, since ectoparasite load is often affected by the extent of grass cutting. Livestock lines that are
342 generally resistant to ectoparasite infestation should be chosen for breeding (Yakout and Wells, 2013).

343 Biological control of ectoparasites with pathogens such as nematodes, bacteria, fungi and viruses and
344 predators that naturally prey on ectoparasites of livestock are potentially useful in ectoparasite
345 management. For example, both parasitic wasps and the common bacterium, *Bacillus thuringiensis* may be
346 useful to protect sheep from various infesting flies, where the bacteria is also effective against lice. Some
347 pathogenic fungi also selectively attack flies, lice and ticks (Wall, 2007).

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APPENDIX C
EPA Sulfur RED Facts May 1991



R.E.D. FACTS

Sulfur

Pesticide Reregistration

All pesticides sold or used in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains from pesticide producers and reviews a complete set of studies showing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for sulfur.

Sulfur

The element sulfur is a ubiquitous, natural component of the environment. Currently, sulfur is registered by EPA for use as an insecticide, fungicide and rodenticide on several hundred food and feed crop, ornamental, turf and residential sites. It is also used as a fertilizer or soil amendment for reclaiming alkaline soils. Sulfur is applied in dust, granular or liquid form, and is an active ingredient in nearly 300 registered pesticide products. All registered uses of sulfur are eligible for reregistration.

Regulatory History

Sulfur has been known and used as a pesticide since very early times, and has been registered for pesticidal use in the United States since the 1920s. EPA issued a Registration Standard for sulfur in December 1982. The only data requirement imposed at that time was a proposal for crop reentry intervals. No additional generic data have been required since then.

US EPA ARCHIVE DOCUMENT

Health Effects

All of EPA's toxicology data requirements for sulfur have been satisfied for a number of years. Sulfur is known to be of low toxicity, and poses very little if any risk to human health.

Acute Effects

Short-term studies show that sulfur is of very low acute oral toxicity and does not irritate the skin (it has been placed in Toxicity Category IV, the least toxic category, for these effects). Sulfur also is not a skin sensitizer. However, sulfur can cause some eye irritation, dermal toxicity and inhalation hazards (it has been placed in Toxicity Category III for these effects).

Chronic Effects

Chronic exposure to elemental sulfur at low levels is generally recognized as safe. Epidemiological studies show that mine workers exposed to sulfur dust and sulfur dioxide throughout their lives often had eye and respiratory disturbances, chronic bronchitis and chronic sinus effects. However, no known risks of oncogenic, teratogenic, or reproductive effects are associated with the use of sulfur. Also, sulfur has been shown to be non-mutagenic in microorganisms.

Routes Of Exposure

We are all exposed to sulfur, since this element is ubiquitous in the environment. Sulfur in its various forms represents about 1.9 percent of the total weight of the earth. Most terrestrial and aquatic environments contain high levels of sulfur.

Through the Diet

People may be exposed to small amounts of sulfur through the food supply. However, since sulfur does not pose any relevant toxic effects, no dietary risk assessment was performed. Sulfur is generally recognized as safe, as noted in 40 CFR 180.2(a), so no tolerances (or residue limits) need be established for residues of sulfur in or on food or feed commodities.

During Application

People can be exposed to sulfur while mixing, loading or applying the pesticide, and while working among treated crops. Based on incidents of skin and eye irritation reported among field workers in California, EPA has determined that a hazard exists for workers reentering fields following foliar application of sulfur dust. Therefore, a 24-hour reentry interval and protective clothing requirements must be added to the labeling of all outdoor use sulfur products.

Environmental Hazards

All the environmental fate and ecological effects data requirements are satisfied for sulfur. This ubiquitous substance does not cause unreasonable adverse effects in the environment when used according to approved labeling, and poses little or no hazard to non-target organisms.

Environmental Fate

In the 1982 Registration Standard, all environmental fate data requirements were waived for sulfur based on the fact that it is a natural component of the environment. The use of elemental sulfur as a pesticide or a soil amendment is not an environmental concern because it becomes incorporated into the natural sulfur cycle.

Ecological Effects

In six studies on ecological effects (involving bobwhite quail, two fish species, daphnia, mysid shrimp and honey bees), sulfur has been shown to be practically non-toxic to the species tested. Thus, although there is potential for non-target organisms to be exposed to sulfur, little hazard to these species is expected to result.

Additional Data Required

The generic data base supporting the reregistration of products containing sulfur has been reviewed and determined to be complete. No further generic data are required to support reregistration. Some product-specific data are being required, as described in Appendix D to the Reregistration Eligibility Document.

Product Labeling Changes Required

All end-use outdoor sulfur product labels must bear an updated water contamination warning, and a 24-hour reentry statement and protective clothing requirements to protect handlers and field workers from adverse skin and eye effects. Please see the Reregistration Eligibility Document for the exact wording of these required label statements.

Regulatory Conclusion

* The studies available to EPA indicate that the element sulfur is of low toxicity, and its use as a pesticide poses very little known hazard to people and nontarget species.

* Sulfur dust can cause eye and skin irritation to people who handle the pesticide or come into contact with treated foliage during field work. Therefore, a 24-hour reentry interval and protective clothing requirements

**For More
Information**

must be included on all outdoor sulfur product labels.

* The pesticide sulfur can be used without causing unreasonable adverse effects in people or the environment. Therefore, all pesticide products containing sulfur as the sole active ingredient are eligible for reregistration.

* EPA will reregister individual products containing sulfur once product specific data and revised product labeling are submitted to and accepted by the Agency.

EPA is requesting public comments on the Reregistration Eligibility Document for sulfur during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED, or to submit written comments, please contact the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, U.S. EPA, Washington, D.C. 20460, telephone 703-557-4436, or Fax #703-557-1884. Please note that after the comment period closes, the RED will be available from NTIS, at the address and telephone number below.

To obtain a copy of the December 1982 Registration Standard for sulfur, please contact the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA. 22161, telephone 703-487-4650. Request document #PB86-102043.

For more information about sulfur or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (7508W), Office of Pesticide Programs, U.S. EPA, Washington, D.C. 20460, telephone 703-808-8000, or Fax #703-308-8005.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, 24 hours a day, seven days a week, or Fax your inquiry to 806-743-3094.

APPENDIX D

ORCAL BioSul Efficacy Trial Report, Webco R&D, 2012

OR-CAL AG SLUG & SNAIL BAIT HYDRANGEA FIELD TRIAL, Webco R&D, 2012

ORCAL BioSul Efficacy Trial Report

TRIAL ID: 8: 11-30-12

TRIAL DATES: 11/30/12 – 12/10/12

Introduction:

ORCAL consigned Webco R&D to produce laboratory variations of the base formula mix and complete efficacy trials using ORCAL, Inc. SOP FG-403.8. Data were recorded over the 10 day trial period including the 1 hour attraction observation for each bait formula tested. Trial formulae included BIO-SUL, Iron Fist, Sluggo, Ferramol and Worry Free. Palatability was observed one hour after animals were introduced to bait. Room temperature and mortality were recorded daily.

Materials and Methods:

Trial Site - The trial was conducted indoors onsite at Webco R&D in Creswell, OR. [Coordinates: 43.913671, - 122.048179].

Apparatus Description – Ventilated lidded plastic trays sized 7.5 in. x 12 in. with well water dampened paper toweling.

Tray Treatments – All trays were baited at 40 lb/acre with bait broadcast over the wet toweling. Each bait formulation tray trial was run in triplicate. An untreated control was run during the comparative trial to confirm health of the collected population.

Test Specimen – The comparative study used (110) *Deroceros reticulatum* collected from un-baited Salem, OR fields on 26 November 2012.

Result assessment - The count of feeding animals was recorded one hour after animals were induced to the baited trays. Daily efficacy was recorded for all trays.

Discussion of Results:

The one hour attraction response observation showed all the bait formulations to have feeding response. This response observation is qualitative only and no statistical comparisons are completed with the collected data. The comparison of formulation one hour feeding attraction ranged from 16.67% to 56.67% of population.

The 10 day trial ambient temperature range was 55-59°F.

Results:

1. Molluscicidal Activity

Each tray was charged with (10) *D. reticulatum* immediately after baiting the trays. The cumulative number of dead slugs & % mortality recorded each day during the course of the trial are charted and graphed as follow:

Table 1. Individual Tray Efficacy & 1 hour feed response data:

Animals	Bait Type	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	1 Hr Response
10	BIO-SUL	0	0	7	9	9	9	10	10	10	10	10	2
10	BIO-SUL	0	0	4	8	9	10	10	10	10	10	10	2
10	BIO-SUL	0	0	5	7	8	10	10	10	10	10	10	1
10	Ferramol	0	0	2	3	5	8	8	9	10	10	10	1
10	Ferramol	0	0	2	5	8	8	9	10	10	10	10	3
10	Ferramol	0	0	2	3	8	9	10	10	10	10	10	3
10	Ferroxx	0	0	8	9	9	9	10	10	10	10	10	3
10	Ferroxx	0	0	4	5	9	9	9	10	10	10	10	7
10	Ferroxx	0	0	5	8	9	10	10	10	10	10	10	4
10	Iron Fist	0	0	1	7	7	9	10	10	10	10	10	6
10	Iron Fist	0	0	5	8	10	10	10	10	10	10	10	3
10	Iron Fist	0	0	5	9	10	10	10	10	10	10	10	7
10	Sluggo	0	0	1	3	6	9	10	10	10	10	10	5
10	Sluggo	0	0	0	2	6	9	10	10	10	10	10	2
10	Sluggo	0	0	2	4	9	10	10	10	10	10	10	3
10	Worry Free	0	0	3	5	8	10	10	10	10	10	10	5
10	Worry Free	0	0	0	1	7	10	10	10	10	10	10	7
10	Worry Free	0	0	1	3	8	10	10	10	10	10	10	5
10	Control	0	0	0	0	0	0	0	0	0	0	0	N/A
	Average Daily Temperature		56F	56F	56F	56F	55F	56F	59F	58F	58F	58F	

Table 2. Average Tray Efficacy & 1 hour feed response data:

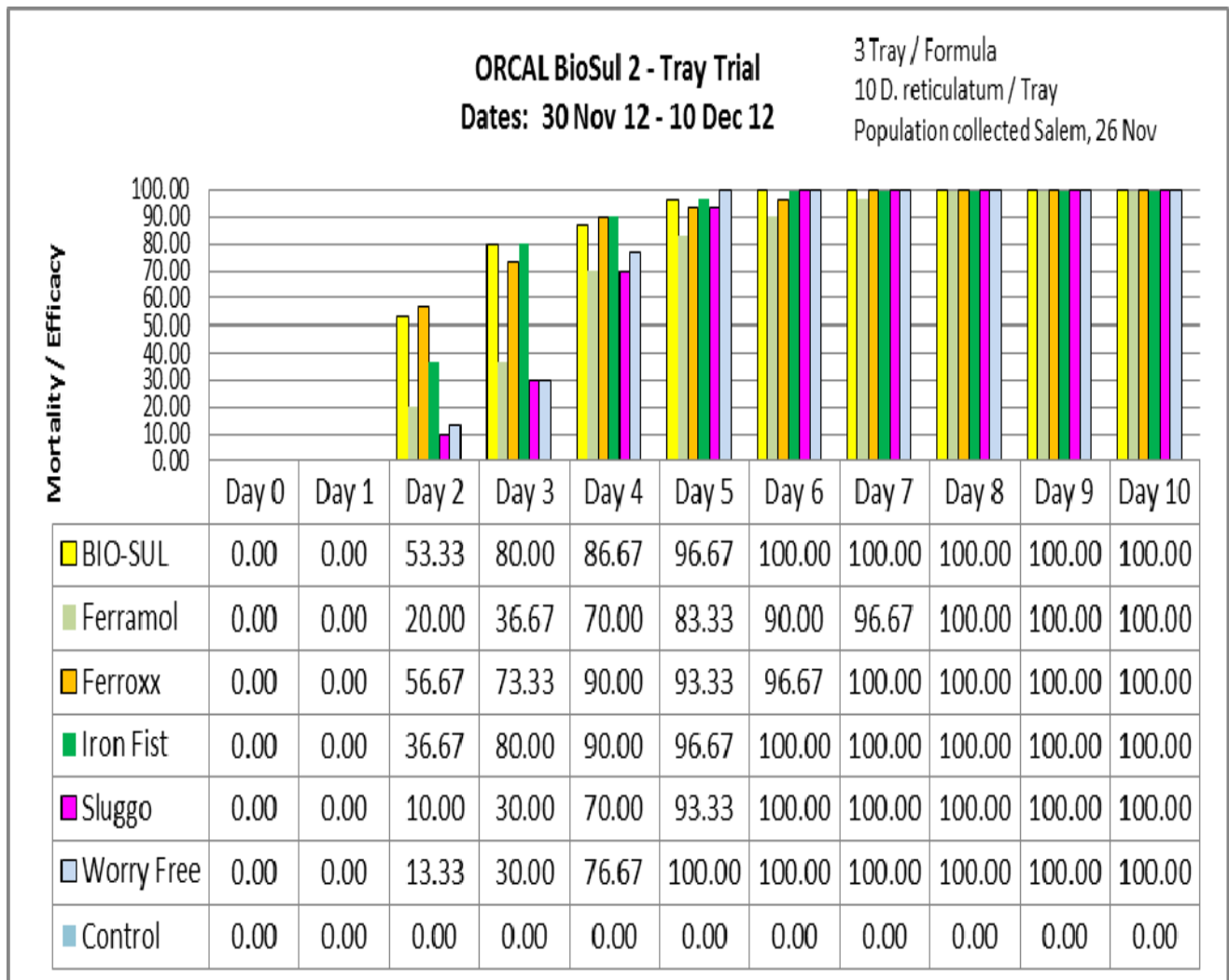
% MORTALITY / EFFICACY	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	% 1 hr Response
	DATA AVE											
BIO-SUL	0	0	53.33	80	86.67	96.67	100	100	100	100	100	16.67
Ferramol	0	0	20	36.67	70	83.33	90	96.67	100	100	100	23.33
Ferroxx	0	0	56.67	73.33	90	93.33	96.67	100	100	100	100	46.67
Iron Fist	0	0	36.67	80	90	96.67	100	100	100	100	100	53.33
Sluggo	0	0	10	30	70	93.33	100	100	100	100	100	33.33
Worry Free	0	0	13.33	30	76.67	100	100	100	100	100	100	56.67
Control	0	0	0	0	0	0	0	0	0	0	0	N/A

Table 3. Statistical analyses as cumulative number of dead slugs per tray using one-way Anova:

BAIT TYPE:	DAT 1	DAT 2	DAT 3	DAT 4	DAT 5	DAT 6	DAT 10
BIO-SUL	0 a	16 c	24 d	26 c	29 c	30 b	30 b
Ferramol	0 a	6 b	11 bc	21 bc	25 b	27 b	30 b
Ferroxx	0 a	17 c	22 cd	27 c	28 bc	29 b	30 b
Iron Fist	0 a	11 c	24 d	27 c	29 c	30 b	30 b
Sluggo	0 a	3 a	9 bc	21 bc	28 bc	30 b	30 b
Worry Free	0 a	4 a	9 bc	23 c	30 c	30 b	30 b
Control	0 a	0 a	0 a	0 a	0 a	0 a	0 a

Cumulative count followed by same letter do not significantly differ (P = 0.10)

The cumulative % mortality recorded in the trays during the course of the trial is graphed below:




DISCUSSION AND CONCLUSIONS:

The objective of this trial was to confirm the efficacy of BIO-SUL and monitor same in a comparison trial with other market products. This final formulation of BIO-SUL provides an early response bait well meeting the industry standards. The only formulation with better early response in the trial was Ferroxx with (5) times active ingredient over other metal active based baits.

It is the conclusion from this test that ORCAL BIO-SUL is the recommended formulation for good early response and consistent efficacy.

Respectfully Submitted:

 / 17 July 2013

Sheryl Webb / Date



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**ORCAL AG SLUG & SNAIL BAIT HYDRANGEA FIELD TRIAL
BROOKINGS, OR AUGUST 2012**

TRIAL ID: 8:8-20-12

TRIAL DATES: 20 - 23 August, 2012

Objective:

The objective of this field trial was to re-evaluate several ORCAL production Ag slug & snail bait formulations for efficacy at the Oregon Hydrangea Company production fields. Un-baited field was limited for the May 2012 trial and the plots chosen for this re-trial were chosen for dense population and hydrangea species vulnerable to slug damage.



Severe Hydrangea Slug Damage



Hydrangea Crop Slug Damage

Crops are maintained for approximately 30 years with ~200,000 cuttings per year per row. Crops can be completely destroyed without use of slug control.

Methodology:

Trial Site - The trial was conducted at Oregon Hydrangea Company, 15696 Hwy 101 S, Brookings, OR. [Coordinates: 42 Deg 1' 58.89" N / 124 Deg 14' 35.97" W as depicted below:



Test Plants – Oregon Hydrangea Company *Hydrangea Macrophylla Oregon Pride* row field plants were used for trial.

Plot Description – Two trial plots were used. Plot #1 was a total test area of 348 feet x 90 feet with each bait type replicated (6) times. Plot #2 was a total test area of 290 feet x 90 feet with each bait type replicated 5 times. Broadcast application for a total bait area of 3,828 square feet per bait condition.

Test Baits – (7) Ag Slug & Snail Bait conditions were included in the study & compared to unbaited control plots:

(#1) 4% Metaldehyde ORCAL Coated Blue Ag Pellet w/ Mint Attractant.

(#2) 4% Metaldehyde ORCAL Wheat Pellet w/ Experimental Attractant.

(#3) 50:50 Blend of #1 + #2 Pellets.

(#4) 50:50 Blend of 4% Metaldehyde ORCAL Coated Blue Ag Pellet w/ Experimental Attractant + #2.

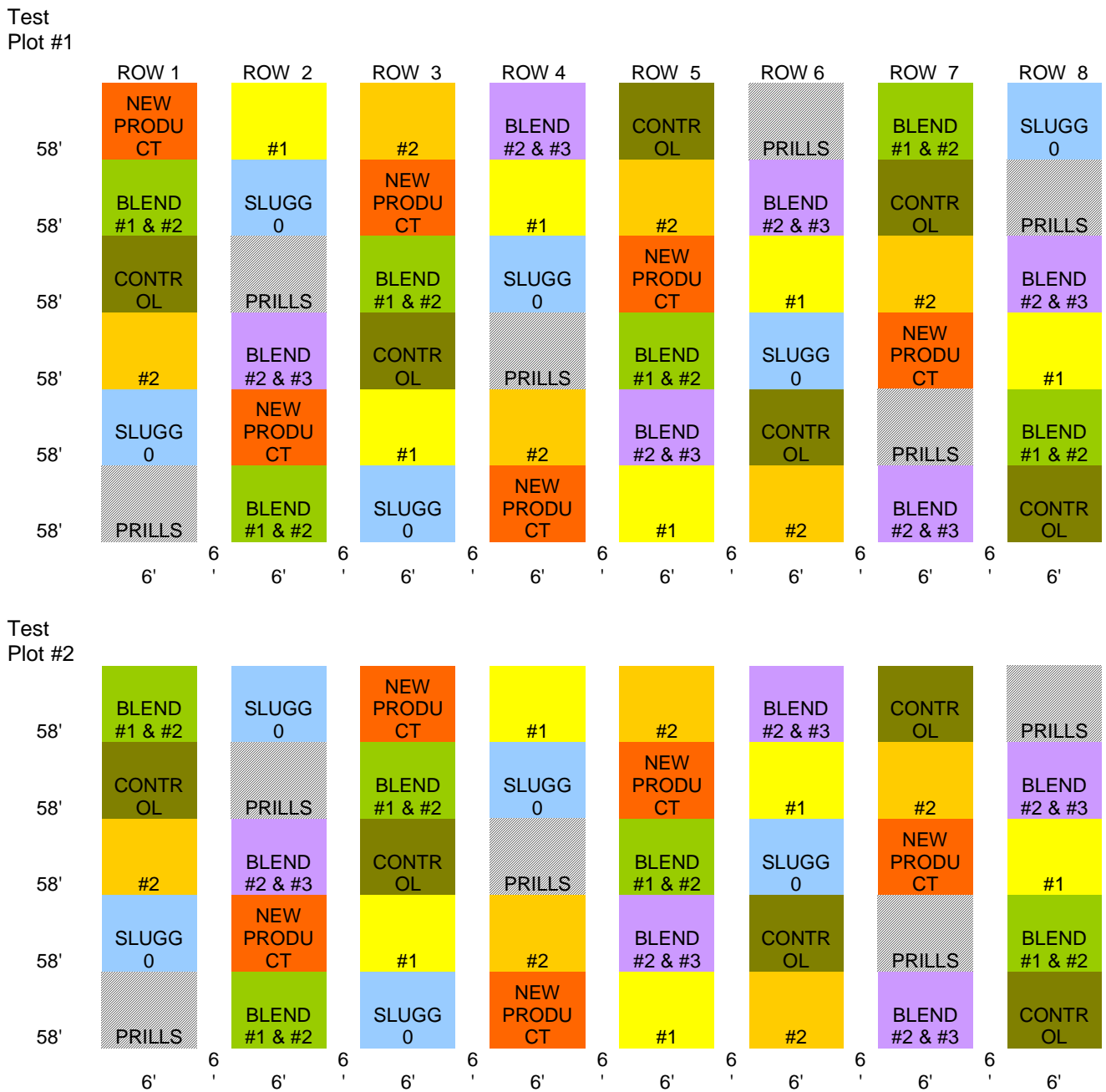
(#5) Sluggo 1% Iron Phosphate Pellets

(#6) 4% Metaldehyde Coated Prills

(#7) BioSul.

OREGON HYDRANGEA COMPANY TRIAL SLUG BAIT ACTUAL PLOT PLAN:

08/20/2012 SLUG BAIT TRIALS



Richard Yock, Owner, irrigated the field plots on 19 August and baited the test plots on 20 August 2012. On 22 August 2012 beer traps were placed in the baited rows at even intervals throughout the test plot with (1) open plastic beer traps per bait plot.

On 23 August 2012 Steve Horn, Tim Baker, Pam Baker, Richard Yock and writer collected field data to account for efficacy activity. Parameters recorded were evidence of slime, count of slugs in the beer traps, and count of slugs both alive & dead in the baited & control rows.



PLOT 1 / 8.23.12



PLOT 2 / 8.23.12

The prominent slug noted was Arion ater. Derocerus reticulatum were included in the animal populations, but the target species for the crop is mainly Arion ater (shown below).



The 23 August 2012 data was recorded as follows:

Bait Type	Description	Beer Count	Live Count	Slime Evidence	Dead Count
Sluggo	1% Iron Phosphate	4	9	1	4
Bait #1	4% Blue Ag Coated Mint Attractant	15	13	15	13
Bait #2	4% Meta Flour Exp Attractant	0	10	43	53
Bait #1 & #2 Blend		3	16	32	44
Bait #2 & #3 Blend	4% Flour & 4% Blue Exp Attractant	13	12	51	36
Prills	4% Coated Exp Attractant	49	17	1	4
BioSul	Sulfur	2	9	3	14
Control	Un-Baited	76	36	2	0

In order to discuss the results, the population control (denoted by the animals in the beer traps) and also the dead animal counts for each plot were analyzed using one-way Anova with results below. Means followed by the same letter do not significantly differ (P=0.10).

Efficacy significant difference based on total dead animal count:

<i>Treatment</i>	<i>Count</i>	<i>Sum</i>	<i>Average</i>
Sluggo	11	4	0.36 b
Bait #1	11	13	1.18 c
Bait #2	11	53	4.81 d
Bait #1 & #2	11	44	4.00 d
Bait #2 & #3	11	36	3.27 d
Prills	11	4	0.36 b
BioSul	11	14	1.27 c
Control	11	0	0.00 a

One-Way ANOVA Group Data:	
<i>SS</i>	28.905
<i>df</i>	6
<i>MS</i>	4.817
<i>F</i>	5.1094
<i>P-value</i>	0.001
<i>F crit</i>	1.9496

Population control significant difference based on total beer trap animal count:

<i>Treatment</i>	<i>Count</i>	<i>Sum</i>	<i>Average</i>
Sluggo	11	4	0.36 bd
Bait #1	11	15	1.36 c
Bait #2	11	0	0.00 d
Bait #1 & #2	11	3	0.27 b
Bait #2 & #3	11	13	1.18 bc
Prills	11	49	4.45 a
BioSul	11	2	0.18 bd
Control	11	76	6.91 a

One-Way ANOVA Group Data:


<i>SS</i>	483.5909
<i>df</i>	7
<i>MS</i>	69.0844
<i>F</i>	13.4085
<i>P-value</i>	2.51E-11
<i>F crit</i>	1.7933

DISCUSSION:

Results for the test plots show significant positive efficacy difference between the flour based Bait #2 and blends with Bait #2 from all other baits. There was no significant difference between Bait #1 (4% Metaldehyde ORCAL Coated Blue Ag Pellet w/ Mint Attractant) and BioSul. All treatments were significantly different than the control as calculated by mortality.

Population control was checked by the count of animals in the beer traps for each plot. The significant differences analyzed by ANOVA show no population control using the 4% Prill bait with the results same as untreated plots. All baits excluding the 4% Prill show positive population control in the trial. However, Undyed Flour 4% Meta, BioSul, and Sluggo were the top control tested with no significant differences between them.

Respectfully Submitted:

 / 27 August 2012

Sheryl Webb / Date