

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs

Biopesticides and Pollution Prevention Division (7511P)

1200 Pennsylvania Ave., N.W.

Washington, D.C. 20460

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
81179-3	12/11/2014
Term of Issuance:	
Unconditional	

Name of Pesticide Product:

SolviNix® LC

Name and Address of Registrant (include ZIP Code):

BioProdex, Inc. 8520 NW 2nd Place Gainesville, FL 32607-1423

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

- 1. Submit and/or cite all data required for registration/registration/registration review of your product when the EPA requires all registrants of similar products to submit such data.
- 2. Make the following label change before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 81179-3."

Signature of Approving Official: Thaten In Caulable	Date:
Kimberly Nesci, Chief	12/11/2014
Microbial Pesticides Branch	
Biopesticides and Pollution Prevention Division (7511P)	

EPA Form 8570-6

Page 2 of 2 EPA Reg. No. 81179-3 Decision No. 479507

3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

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 FIFRA and is subject to review by the EPA. 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 the 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 EPA 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.

If these terms are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these terms. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following confidential statement of formula (CSF):

• Basic CSF dated 11/25/2013

If you have any questions, please contact Ms. Jeannine Kausch of my staff at (703) 347-8920 or kausch.jeannine@epa.gov.

Sincerely,

Kimberly Nesci, Chief

Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)

Office of Pesticide Programs

SolviNix® LC

MASTER LABEL

Sub-label A: 1.7-fl oz (50 ml) Vial Containing 1.2 fl oz (35 ml) of SolviNix® LC

Sub-label B: 0.5-fl oz (15 ml) Vial Containing 0.34 fl oz (10 ml) of SolviNix® LC

Active Ingredient:

Tobacco mild green mosaic tobamovirus strain U2 (TMGMV U2)	2.9%	W/V^*
Other Ingredients	97.1%	W/V
Total	100.0%	w/v

^{*} Contains: A minimum of 0.03 ounce of the active ingredient, TMGMV U2, per fluid ounce of SolviNix[®] LC (29 milligrams of TMGMV U2 per ml of SolviNix[®] LC), with an estimated minimum of 1.25 x 10¹⁶ TMGMV U2 virions per fluid ounce of SolviNix[®] LC (4.23 x 10¹⁴ TMGMV U2 virions per gram of SolviNix[®] LC).

KEEP OUT OF REACH OF CHILDREN CAUTION

EPA Reg. No. 81179-G **EPA Est. No.** 081179-FL-001

BioProdex, Inc. 3131 NW 13th Street #54 Gainesville, FL 32609-2183

ACCEPTED

12/11/14

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

PA Reg. No. 81179-3

BioProdex, Inc.

[Sub-label A: 1.7-fl oz (50 ml) Vial Containing 1.2 fl oz (35 ml) of SolviNix[®] LC]

SOLVINIX® LC

A Biological Herbicide for Control of Tropical Soda Apple (Solanum viarum) For post-emergence application to kill tropical soda apple

STOP! Read the entire label before using

Active Ingredient:

Tobacco mild green mosaic tobamovirus strain U2 (TMGMV U2)......2.9% w/v*

Other Ingredients97.1% w/v

Total100.0% w/v

*Contains: A minimum of 0.03 ounce of the active ingredient, TMGMV U2, per fluid ounce of **solvinix*** LC (29 milligrams of TMGMV U2 per ml of **solvinix*** LC), with an estimated minimum of 1.25 x 10¹⁶ TMGMV U2 virions per fluid ounce of **solvinix*** LC (4.23 X 10¹⁴ TMGMV U2 virions per gram of **solvinix*** LC).

Net Contents: 1.2 fluid ounces (35 ml)

For use only in pastures and wooded areas that are fenced to contain grazing animals

KEEP OUT OF REACH OF CHILDREN

CAUTION

[] - Denotes explanatory comments to the reviewer

[Labeling to be folded and enclosed in a plastic bag along with the plastic vial and a transfer pipet]

EPA Reg. No.: 81179-G

EPA Establishment No.: 081179-FL-001

Batch Code: Sell or Use Before:

[Stamped date will be one year from the day of

NOT FOR SALE OR USE AFTER THE
DATE STAMPED ABOVE

FIRST AID

If swallowed:

- Call a poison control center or a doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by the poison control center or the doctor.
- Do not give anything by mouth to an unconscious person.

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 a doctor for treatment advice.

If inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or a doctor for further treatment advice.

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, and then continue rinsing the eye.
- Call a poison control center or a doctor for treatment advice.

Important:

 Have the product container or label with you when calling a poison control center or a doctor, or when going for treatment.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed, absorbed through the skin, or inhaled. Causes moderate eye irritation. Avoid breathing spray mist. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

When handling this product, wear a long-sleeved shirt, long pants, waterproof gloves, shoes, socks, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

ENVIRONMENTAL HAZARDS

Do not apply **SOLVINIX**® **LC** directly to water, 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.

The virus in *SOLVINIX*[®] **LC** has no natural means of spread other than by physical and abrasive contact between infected and healthy plants. A remote possibility is through workers (via contaminated clothes, shoes, hands) and contaminated application equipment. To prevent unwanted virus spread to nontarget plants, avoid contacting skin and clothing with *SOLVINIX*[®] **LC**; thoroughly wash skin with soap and water and clothes with laundry detergent

after handling *SOLVINIX*[®] **LC**; and thoroughly wash application equipment after using *SOLVINIX*[®] **LC**. See the EQUIPMENT CLEANING INSTRUCTIONS section for more details on how to properly wash application equipment.

STOP any pruning or mechanical activities in treated areas, such as mowing or tillage, 48 hours before and after application of **SOLVINIX**® **LC**.

MAY INFECT SOME NON-WOODY FLOWERING PLANTS, INCLUDING SOLANACEOUS CROP PLANTS (EGGPLANT, PEPPER, TOBACCO, AND TOMATILLO).

DIRECTIONS FOR USE

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

For use only in pastures and wooded areas that are fenced to contain grazing animals. For use with a backpack sprayer or a hand-held applicator, the latter dedicated for *SOLVINIX*® LC application only.

USE RESTRICTIONS

APPLY ONLY WHEN TROPICAL SODA APPLE PLANTS ARE ACTIVELY GROWING.

DO NOT APPLY WITHIN 300 FEET OF GREENHOUSE AND GRAFTING OPERATIONS.

SPRAY DIRECTLY AT THE TARGET PLANT - AVOID ANY CROPS AND NONTARGET PLANTS.

DO NOT RE-USE THE SPRAY EQUIPMENT FOR OTHER USES WITHOUT THOROUGH CLEANING AS SPECIFIED.

DO NOT APPLY THIS PRODUCT THROUGH ANY TYPE OF IRRIGATION SYSTEM.

PRODUCT INFORMATION

SOLVINIX LC is a post-emergence bioherbicide to control *Solanum viarum* (common name: tropical soda apple, abbreviated as TSA). It contains a plant virus, *Tobacco mild green mosaic tobamovirus* strain U2 (TMGMV U2), as the active ingredient.

TMGMV U2 kills TSA by triggering a systemic lethal hypersensitive plant response. To initiate this herbicidal action, the virus must enter the plant cells through minute injuries to the plant cell walls. The virus can then replicate and move from cell-to-cell, eliciting the hypersensitive response. To assure virus entry, **SOLVINIX® LC** is applied to TSA foliage with a high-pressure (80 psi), narrow-stream sprayer or a hand-held herbicide applicator as described in the APPLICATION INSTRUCTIONS section.

SOLVINIX LC is sold and shipped in a frozen state. It must be kept frozen in a freezer until ready to be thawed and used. See STORAGE AND DISPOSAL section for further details.

When properly applied using the specified method, **SOLVINIX® LC** will cause treated TSA plants to wilt in about 2-4 weeks after application followed by plant death. Brown leaf spots or flecks may appear on leaves directly exposed to the virus (i.e., inoculated leaves) in 3-5 days after inoculation and before the plants start to wilt. The plants will die in a few days following initial wilting and the entire plant, including roots, will be killed. Rarely, dying plants may sucker, but the new growth will also be killed. Older plants may die more slowly than younger plants.

In order for *SolviNix*® LC to be effective, the TSA plant must be healthy and vigorously growing when inoculated. Therefore, *SolviNix*® LC must be applied only to actively growing TSA plants. Considering this, *SolviNix*® LC will be sold seasonally to coincide with the annual growth cycle of TSA, from spring to late summer.

THE FOLLOWING PLANTS WERE SHOWN TO BE DAMAGED SLIGHTLY OR SEVERELY IF DIRECTLY EXPOSED TO SOLVINIX® LC:

TMGMV U2 is adapted to plants in the Solanaceae family. Of the 435 plant species screened by manual inoculation with TMGMV U2, the following plants developed infection symptoms: Common globe amaranth (*Gomphrena globosa*; family Amaranthaceae); rattlesnake master, eryngo, and plains eryngo (*Eryngium aquaticum*, *Eryngium*

dorae, and Eryngium planum; family Apiaceae); crape jasmine (Tabernaemontana divaricata; family Apocynaceae); African daisy (Osteospermum sp. cv. Sheila; family Asteraceae); balsams (Impatiens sp. cvs. Timor and Toyota; family Balsaminaceae); Paterson's curse (Echium plantagineum; family Boraginaceae); quinoa (Chenopodium quinoa; family Chenopodiaceae); boatlily and inch plant (Tradescantia {=Rhoeo} spathacea and Tradescantia zebrina; family Commelinaceae); plants belonging to the family Gesneriaceae such as African violet (Saintpaulia spp.) and gloxinia (Sinningia spp.); Florida pusley (*Richardia scabra*; family Rubiaceae); wishbone flower (Torenia fournieri; family Scrophulariaceae); and the following species in the family Solanaceae: Jamaican forget-me-not (Browallia petunias americana), trailing (Calibrachoa spp. and Calibrachoa x hybrida), some cultivars of bell pepper (Capsicum annuum), some cultivars of scotch bonnet (Capsicum chinense) including Aji dulce and Indian chilli, jasmine tobacco (Nicotiana alata). Benthamiana tobacco (Nicotiana benthamiana), Cleveland's tobacco (Nicotiana clevelandii), Debney's tobacco (Nicotiana debneyi), Edwardson's tobacco (Nicotiana x edwardsonii), tree tobacco (Nicotiana glauca), glutinosa tobacco (Nicotiana glutinosa), Australian tobacco (Nicotiana hesperis), Native tobacco (Nicotiana occidentalis), Sander's tobacco (Nicotiana x sanderae), woodland tobacco (Nicotiana sylvestris), some cultivars of commercial tobacco (Nicotiana tabacum), petunias (Petunia sp., Petunia sp. cv. Surfinia, Petunia x hybrida), violet-flower petunia (Petunia integrifolia), Chinese lantern (Physalis alkekengi), cutleaf groundcherry (Physalis angulata), Downy groundcherry floridana (Physalis {=Physalis pubescens \}), Mexican husk tomato {=tomatillo} (Physalis philadelphica), hairy groundcherry (Physalis pubescens), Walter's groundcherry (Physalis walteri), Solanum acerifolium (no common soda-apple nightshade (Solanum name), aculeatissimum), Ethiopian nightshade (Solanum aethiopicum), American black nightshade (Solanum americanum). Bahama nightshade (Solanum bahamense), cockroach berry (Solanum capsicoides), pepino Iloron (Solanum caripense), twoleaf nightshade diphyllum), (Solanum Jamaican nightshade (Solanum jamaicense), earleaf nightshade (Solanum mauritianum), black nightshade (Solanum nigrum), hoe nightshade (Solanum physalifolium),

West Indian nightshade (*Solanum ptycanthum*), buffalobur nightshade (*Solanum rostratum*), hairy nightshade (*Solanum sarrachoides*), sticky nightshade (*Solanum sisymbriifolium*), spiny solanum (*Solanum spinosissimum*), fragrant solanum (*Solanum suaveolens*), and hairy nightshade (*Solanum villosum*).

APPLICATION RATE

SOLVINIX® **LC** is packaged as 1.2 fluid ounces (35 ml) in a 1.7-fluid ounce (50 ml) plastic screw-cap vial. Apply **SOLVINIX**® **LC** at the rate of 0.05 fluid ounce (1.5 ml) per gallon of water (~10 micrograms of active ingredient per ml). Each 1.7-fluid ounce (50 ml) vial containing 1.2 fluid ounces (35 ml) of **SOLVINIX**® **LC** should be sufficient to treat approximately 2000 TSA plants with a backpack sprayer set at 80 psi and at a volume of approximately 0.7 to 1.5 fluid ounces of the prepared solution (20 to 40 ml of the prepared solution) per plant.

For hand-held applicators, mix **SOLVINIX® LC** at the rate of 0.05 fluid ounce (1.5 ml) per gallon in the required volume of water to treat the plants at approximately 0.07 to 0.15 fluid ounces of the prepared solution (2 to 4 ml of the prepared solution) per plant.

The amount of **SOLVINIX**® **LC** needed to treat an area and application volume will depend on the density of TSA infestation, distribution pattern, application method, applicator efficiency, height of grass stand, terrain, and other likely factors.

APPLICATION INSTRUCTIONS

Use the following methods to apply **SOLVINIX**® LC: 1) With a high-pressure backpack sprayer delivering a narrow jet of spray at 80 psi at the point of impact on TSA leaves. Ideally, the distance from the nozzle to the leaves should be about 12 to 18 inches. Application with a conventional backpack sprayer having a 3-foot wand and a Quick TeeJet Cap containing a D-1 or D-2 orifice plate and a rubber Oring gasket yields good foliage penetration. 2) With a hand-held herbicide applicator for scattered TSA infestations. Hand-held applicators include commercially available herbicide wipers that typically deliver herbicide through a wick or a tassle

of wicks attached to a plastic re-fillable tube. The hand-held applicator must be dedicated for **SOLVINIX® LC** applications only. Consult the registrant for the appropriate application method for your situation.

About an hour before application, remove the frozen **SOLVINIX**® **LC** vial from the freezer and allow the content to thaw at room temperature. The vial may be thawed by immersion in water at **ROOM** temperature. **The vial MUST NOT BE THAWED by immersion in hot water or by direct heating** as high temperature will destroy or inactivate **SOLVINIX**® **LC**. Wait until the content has fully melted.

Use the required quantity from the vial by transferring at the rate of 0.05 fluid ounce (1.5 ml) of **SOLVINIX**® **LC** per gallon of water (see Table below). Use the plastic liquid dispenser (Transfer Pipet) enclosed in the **SOLVINIX**® **LC** package to transfer when only a fraction of the vial's content is required.

Add the fully melted **SOLVINIX**[®] **LC** to a suitably sized jug, bucket, or tank filled with about half of the final volume of water required for the application. Add water to bring the mix to the desired final volume. Use clean potable water to mix with and apply **SOLVINIX**[®] **LC**.

Promptly re-freeze and store the unused **SOL VINIX**[®] **LC** in the original vial, and the dispenser, for further use within the product's expiration date. Do not melt and re-freeze the product more than three times. When all of the content has been used, triple rinse the empty vial with water and add the rinsate to the mix. Dispose of the vial according to the instructions in the STORAGE AND DISPOSAL section.

Quantity of SolviNix® LC to Add	To Amount of Water
0.05 fluid ounce (1.5 milliliters)	1 Gallon
1.2 fluid ounces (35 milliliters) – entire vial	23 Gallons

For application with a high-pressure sprayer or a hand-held applicator, mix **SOLVINIX**® **LC** at the rate of 0.05 fluid ounce (1.5 ml) per one gallon of water in

a clean, pre-washed spray tank, a clean plastic bucket, or a clean one-gallon water jug*. Mix thoroughly before application. If using a hand-held applicator, carefully transfer and fill the applicator with the diluted **SOLVINIX**® **LC** from the bucket or the jug.

* YOU MUST NOT USE A WASHED MILK JUG BECAUSE ANY MILK RESIDUE PRESENT MAY INACTIVATE THE VIRUS.

After mixing, do not allow *SOLVINIX*[®] LC to remain in the applicator or in the mixing jug, bucket, or tank for more than 24 hours or allow it to reach temperatures above 113°F (45°C). Avoid prolonged exposure of *SOLVINIX*[®] LC to direct sunlight or heat.

Apply **SOLVINIX® LC** to actively growing TSA plants at pre-flowering stage to prevent fruit-set and production of a new crop of seeds. For best results, apply in late spring or early summer in Florida and the Southeast. A single, properly directed application to a few young and healthy leaves per plant is sufficient to allow the virus to infect and kill the entire plant.

SOLVINIX[®] **LC** can be applied in late summer to control late-emerging plants or plants that were missed in earlier applications. The plants must be actively growing when **SOLVINIX**[®] **LC** is applied; dormant or senescent plants may not respond normally to the virus and may not die.

Repeat applications will be necessary to treat plants that are missed in the first application or subsequently emerged plants. For any surviving treated TSA plants, re-apply according to label instructions. If there are still surviving plants after additional treatment, consider other means of control (i.e., mechanical or chemical), consult local extension recommendations, and contact the registrant. The registrant will notify EPA under FIFRA 6(a)(2) for assessment of pesticide resistance in tropical soda apple.

Do not apply **SOLVINIX**® **LC** if leaves are wet from rain or morning dew. Allow the leaves to dry before application.

Do not apply **SOLVINIX**® **LC** to TSA plants that are drought-stressed or dormant (i.e., not actively growing) or occur in waterlogged sites.

Do not apply in late fall when nightly temperatures begin to fall below 55°F (13°C) and if early frost is likely.

SOLVINIX[®] **LC** must be applied only to TSA as it is not effective against other weeds. It is effective only when applied post-emergence; it has no pre-emergence or soil residual activity against TSA. It will not be effective if applied via soil or irrigation water or any other method not specified in this label.

SOLVINIX[®] **LC** does not require the use of any additives or adjuvants. Do not mix it with any other material not mentioned in this label.

EQUIPMENT CLEANING INSTRUCTIONS

The sprayer, namely the tank and the spray wand combined, used for **SOLVINIX**® **LC** application MUST BE CLEANED THOROUGHLY AND IMMEDIATELY AFTER USE by: 1) flushing it twice by running clean water through and discharging the liquid on a TSA plant; 2) then flushing it once with dilute dish-washing soap (2 tablespoons per gallon of water); and 3) finally flushing it twice with water.

Wash the exterior of the hand-held applicator by holding it under clean running water and discharging the liquid on a TSA plant. Do not use the applicator for any use other than to apply **SOLVINIX**® **LC**.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store *SOLVINIX*® LC in a freezer until it is ready to be used. Do not store *SOLVINIX*® LC where food or medicine for human consumption is stored.

Pesticide Disposal: To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry). DO NOT discharge unused SOL VINIX® LC onto the ground, into water, or onto nontarget plants.

Container Handling: Nonrefillable container. Do not reuse or refill the container. Triple rinse the container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into the application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then, offer for recycling if available or puncture and dispose of in a sanitary landfill, by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND DISCLAIMER OF WARRANTIES

BioProdex, Inc. warrants that SOLVINIX® LC conforms to the description and conditions on this label and that it will perform as indicated when used under the directions and conditions of this label. To the extent consistent with applicable law, BioProdex, Inc. and/or the seller makes no other expressed or implied warranty of fitness, merchantability, or otherwise.

LIMITATIONS OF LIABILITY

To the extent consistent with applicable law, it is the manufacturer's intent that the liability of *BioProdex*, *Inc.* and/or of the seller for damages arising from the use of this product is limited to the replacement cost of the product used and shall not include any application costs or consequential damages such as loss of profits or other values.

NO CHANGES AUTHORIZED

No one other than an authorized agent of *BioProdex*, *Inc.* is allowed to make any other warranty or change the conditions, disclaimers, or limitations stated on this label. Any authorization to make changes should be in writing and in specific reference to this label.

RIGHTS AND PRIVILEGES

**Use of TMGMV U2 to control tropical soda apple by eliciting a lethal hypersensitive host response is protected under the Patents US 6,689,718 B2 and US 7,494,955 B2. These patents are licensed to *BioProdex, Inc.*

BioProdex, Inc., 3131 NW 13th Street, # 54, Gainesville, FL 32609-2183, USA TEL: 352-278-1572; FAX: 352-872-5035 Email: info@bioprodex.com; Website: www.bioprodex.com.

See the labeling inside the bag for the Precautionary Statements, First Aid, and Directions for Use

Stop! Read the entire label before using

SOLVINIX® LC

A Biological Herbicide for Control of Tropical Soda Apple (Solanum viarum)

For post-emergence application to kill tropical soda apple

EPA Reg. No.: 81179-G

EPA Establishment No.: 081179-FL-001

Batch Code:

Sell or Use Before:

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Other Ingredients	97.1%	W/V
Total	. 100.0%	W/V

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Net Contents: 1.2 fluid ounces (35 ml)

For use only in pastures and wooded areas that are fenced to contain grazing animals

KEEP OUT OF REACH OF CHILDREN

CAUTION

BioProdex, Inc.

3131 NW 13th Street, # 54, Gainesville, FL 32609-2183, USA

BioProdex, Inc.

[Sub-label B: 0.5-fl oz (15 ml) Vial Containing 0.34 fl oz (10 ml) of SolviNix® LC]

SOLVINIX® LC

A Biological Herbicide for Control of Tropical Soda Apple (Solanum viarum) For post-emergence application to kill tropical soda apple

STOP! Read the entire label before using

Active Ingredient:

SOLVINIX® LC).

Net Contents: 0.34 fluid ounce (10 ml)

For use only in pastures and wooded areas that are fenced to contain grazing animals

KEEP OUT OF REACH OF CHILDREN

CAUTION

[] - Denotes explanatory comments to the reviewer

[Labeling to be folded and enclosed in a plastic bag along with the plastic vial and a transfer pipet]

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Batch Code: Sell or Use Before:

[Stamped date will be one year from the day of the bioherbicide assay and batch certification]

NOT FOR SALE OR USE AFTER THE DATE STAMPED ABOVE

FIRST AID

If swallowed:

- Call a poison control center or a doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by the poison control center or the doctor.
- Do not give anything by mouth to an unconscious person.

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 a doctor for treatment advice.

If inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or a doctor for further treatment advice.

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, and then continue rinsing the eye.
- Call a poison control center or a doctor for treatment advice.

Important:

• Have the product container or label with you when calling a poison control center or a doctor, or when going for treatment.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed, absorbed through the skin, or inhaled. Causes moderate eye irritation. Avoid breathing spray mist. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

When handling this product, wear a long-sleeved shirt, long pants, waterproof gloves, shoes, socks, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

ENVIRONMENTAL HAZARDS

Do not apply **SOLVINIX**® **LC** directly to water, 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.

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wash application equipment after using *SOLVINIX®* **LC**. See the EQUIPMENT CLEANING INSTRUCTIONS section for more details on how to properly wash application equipment.

STOP any pruning or mechanical activities in treated areas, such as mowing or tillage, 48 hours before and after application of **SOLVINIX**® **LC**.

MAY INFECT SOME NON-WOODY FLOWERING PLANTS, INCLUDING SOLANACEOUS CROP PLANTS (EGGPLANT, PEPPER, TOBACCO, AND TOMATILLO).

DIRECTIONS FOR USE

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

For use only in pastures and wooded areas that are fenced to contain grazing animals. For use with a backpack sprayer or a hand-held applicator, the latter dedicated for *SOLVINIX*® LC application only.

USE RESTRICTIONS

APPLY ONLY WHEN TROPICAL SODA APPLE PLANTS ARE ACTIVELY GROWING.

DO NOT APPLY WITHIN 300 FEET OF GREENHOUSE AND GRAFTING OPERATIONS.

SPRAY DIRECTLY AT THE TARGET PLANT - AVOID ANY CROPS AND NONTARGET PLANTS.

DO NOT RE-USE THE SPRAY EQUIPMENT FOR OTHER USES WITHOUT THOROUGH CLEANING AS SPECIFIED.

DO NOT APPLY THIS PRODUCT THROUGH ANY TYPE OF IRRIGATION SYSTEM.

PRODUCT INFORMATION

SOLVINIX LC is a post-emergence bioherbicide to control *Solanum viarum* (common name: tropical soda apple, abbreviated as TSA). It contains a plant virus, *Tobacco mild green mosaic tobamovirus* strain U2 (TMGMV U2), as the active ingredient.

TMGMV U2 kills TSA by triggering a systemic lethal hypersensitive plant response. To initiate this herbicidal action, the virus must enter the plant cells through minute injuries to the plant cell walls. The virus can then replicate and move from cell-to-cell, eliciting the hypersensitive response. To assure virus entry, **SOLVINIX® LC** is applied to TSA foliage with a high-pressure (80 psi), narrow-stream sprayer or a hand-held herbicide applicator as described in the APPLICATION INSTRUCTIONS section.

SOLVINIX LC is sold and shipped in a frozen state. It must be kept frozen in a freezer until ready to be thawed and used. See STORAGE AND DISPOSAL section for further details.

When properly applied using the specified method, **SOLVINIX® LC** will cause treated TSA plants to wilt in about 2-4 weeks after application followed by plant death. Brown leaf spots or flecks may appear on leaves directly exposed to the virus (i.e., inoculated leaves) in 3-5 days after inoculation and before the plants start to wilt. The plants will die in a few days following initial wilting and the entire plant, including roots, will be killed. Rarely, dying plants may sucker, but the new growth will also be killed. Older plants may die more slowly than younger plants.

In order for *SolviNix*® LC to be effective, the TSA plant must be healthy and vigorously growing when inoculated. Therefore, *SolviNix*® LC must be applied only to actively growing TSA plants. Considering this, *SolviNix*® LC will be sold seasonally to coincide with the annual growth cycle of TSA, from spring to late summer.

THE FOLLOWING PLANTS WERE SHOWN TO BE DAMAGED SLIGHTLY OR SEVERELY IF DIRECTLY EXPOSED TO SOLVINIX® LC:

TMGMV U2 is adapted to plants in the Solanaceae family. Of the 435 plant species screened by manual inoculation with TMGMV U2, the following plants developed infection symptoms: Common globe amaranth (*Gomphrena globosa*; family Amaranthaceae); rattlesnake master, eryngo, and plains eryngo (*Eryngium aquaticum*, *Eryngium dorae*, and *Eryngium planum*; family Apiaceae);

crape jasmine (Tabernaemontana divaricata; family Apocynaceae); African daisy (Osteospermum sp. cv. Sheila; family Asteraceae); balsams (Impatiens sp. cvs. Timor and Toyota; family Balsaminaceae); Paterson's curse (Echium plantagineum; family Boraginaceae); quinoa (Chenopodium quinoa; family boatlily Chenopodiaceae); and (*Tradescantia* {=*Rhoeo*} *spathacea* and *Tradescantia* zebrina; family Commelinaceae); plants belonging to the family Gesneriaceae such as African violet (Saintpaulia spp.) and gloxinia (Sinningia spp.); Florida pusley (*Richardia scabra*; family Rubiaceae); wishbone flower (Torenia fournieri; family Scrophulariaceae); and the following species in the family Solanaceae: Jamaican forget-me-not (Browallia americana), trailing petunias (Calibrachoa spp. and Calibrachoa x hybrida), some cultivars of bell pepper (Capsicum annuum), some cultivars of scotch bonnet (Capsicum chinense) including Aji dulce and Indian chilli, jasmine tobacco (Nicotiana Benthamiana tobacco alata). (Nicotiana benthamiana). Cleveland's tobacco (Nicotiana clevelandii), Debney's tobacco (Nicotiana debneyi), Edwardson's tobacco (Nicotiana x edwardsonii), tree tobacco (Nicotiana glauca), glutinosa tobacco (Nicotiana glutinosa), Australian tobacco (Nicotiana hesperis), Native tobacco (Nicotiana occidentalis), Sander's tobacco (Nicotiana x sanderae), woodland tobacco (Nicotiana sylvestris), some cultivars of commercial tobacco (Nicotiana tabacum), petunias (Petunia sp., Petunia sp. cv. Surfinia, Petunia x hybrida), violet-flower petunia (Petunia integrifolia), Chinese lantern (Physalis alkekengi), cutleaf groundcherry (Physalis angulata), Downy groundcherry (Physalis floridana {=Physalis pubescens}), Mexican husk tomato {=tomatillo} (Physalis groundcherry philadelphica), hairy (Physalis pubescens), Walter's groundcherry (Physalis walteri), Solanum acerifolium (no common name), soda-apple nightshade (Solanum aculeatissimum), Ethiopian nightshade (Solanum aethiopicum), American black nightshade (Solanum nightshade americanum), Bahama (Solanum bahamense), cockroach berry (Solanum capsicoides), pepino Iloron (Solanum caripense), twoleaf nightshade (Solanum diphyllum), Jamaican nightshade (Solanum jamaicense), earleaf nightshade (Solanum mauritianum), black nightshade (Solanum nigrum), hoe nightshade (Solanum physalifolium), West Indian nightshade (Solanum ptycanthum),

buffalobur nightshade (*Solanum rostratum*), hairy nightshade (*Solanum sarrachoides*), sticky nightshade (*Solanum sisymbriifolium*), spiny solanum (*Solanum spinosissimum*), fragrant solanum (*Solanum suaveolens*), and hairy nightshade (*Solanum villosum*).

APPLICATION RATE

SOLVINIX® **LC** is packaged as 0.34 fluid ounce (10 ml) in a 0.5-fluid ounce (15 ml) plastic screw-cap vial. Apply **SOLVINIX**® **LC** at the rate of 0.05 fluid ounce (1.5 ml) per gallon of water (~10 micrograms of active ingredient per ml). Each 0.5-fluid ounce (15 ml) vial containing 0.34 fluid ounce (10 ml) of **SOLVINIX**® **LC** should be sufficient to treat approximately 600 TSA plants with a backpack sprayer set at 80 psi and at a volume of approximately 0.7 to 1.35 fluid ounces of the prepared solution (20 to 40 ml of the prepared solution) per plant.

For hand-held applicators, mix **SOLVINIX**® **LC** at the rate of 0.05 fluid ounce (1.5 ml) per gallon in the required volume of water to treat the plants at approximately 0.07 to 0.15 fluid ounces of the prepared solution (2 to 4 ml of the prepared solution) per plant.

The amount of **SOLVINIX**® **LC** needed to treat an area and application volume will depend on the density of TSA infestation, distribution pattern, application method, applicator efficiency, height of grass stand, terrain, and other likely factors.

APPLICATION INSTRUCTIONS

Use the following methods to apply **SOLVINIX**® LC: 1) With a high-pressure backpack sprayer delivering a narrow jet of spray at 80 psi at the point of impact on TSA leaves. Ideally, the distance from the nozzle to the leaves should be about 12 to 18 inches. Application with a conventional backpack sprayer having a 3-foot wand and a Quick TeeJet Cap containing a D-1 or D-2 orifice plate and a rubber Oring gasket yields good foliage penetration. 2) With a hand-held herbicide applicator for scattered TSA Hand-held include infestations. applicators available herbicide wipers that commercially typically deliver herbicide through a wick or a tassle of wicks attached to a plastic re-fillable tube. The hand-held applicator must be dedicated for

SOLVINIX[®] **LC** applications only. Consult the registrant for the appropriate application method for your situation.

About an hour before application, remove the frozen **SOLVINIX**® **LC** vial from the freezer and allow the content to thaw at room temperature. The vial may be thawed by immersion in water at **ROOM** temperature. **The vial MUST NOT BE THAWED** by immersion in hot water or by direct heating as high temperature will destroy or inactivate **SOLVINIX**® **LC**. Wait until the content has fully melted.

Use the required quantity from the vial by transferring at the rate of 0.05 fluid ounce (1.5 ml) of **SOLVINIX**® **LC** per gallon of water (see Table below). Use the plastic liquid dispenser (Transfer Pipet) enclosed in the **SOLVINIX**® **LC** package to transfer when only a fraction of the vial's content is required.

Add the fully melted **SOLVINIX**® **LC** to a suitably sized jug, bucket, or tank filled with about half of the final volume of water required for the application. Add water to bring the mix to the desired final volume. Use clean potable water to mix with and apply **SOLVINIX**® **LC**.

Promptly re-freeze and store the unused **SOL VINIX**® **LC** in the original vial, and the dispenser, for further use within the product's expiration date. Do not melt and re-freeze the product more than three times. When all of the content has been used, triple rinse the empty vial with water and add the rinsate to the mix. Dispose of the vial according to the instructions in the STORAGE AND DISPOSAL section.

Quantity of SolviNix® LC to Add	To Amount of Water
0.05 fluid ounce (1.5 milliliters)	1 Gallon
0.34 fluid ounce (10 milliliters) - entire vial	6.5 Gallons

For application with a high-pressure sprayer or a hand-held applicator, mix **SOLVINIX**® **LC** at the rate of 0.05 fluid ounce (1.5 ml) per one gallon of water in a clean, pre-washed spray tank, a clean plastic bucket, or a clean one-gallon water jug*. Mix thoroughly

before application. If using a hand-held applicator, carefully transfer and fill the applicator with the diluted **SOLVINIX® LC** from the bucket or the jug.

* YOU MUST NOT USE A WASHED MILK JUG BECAUSE ANY MILK RESIDUE PRESENT MAY INACTIVATE THE VIRUS.

After mixing, do not allow **SOLVINIX**® **LC** to remain in applicator or in the mixing jug, bucket, or tank for more than 24 hours or allow it to reach temperatures above 113°F (45°C). Avoid prolonged exposure of **SOLVINIX**® **LC** to direct sunlight or heat.

Apply **SOLVINIX** LC to actively growing TSA plants at pre-flowering stage to prevent fruit-set and production of a new crop of seeds. For best results, apply in late spring or early summer in Florida and the Southeast. A single, properly directed application to a few young and healthy leaves per plant is sufficient to allow the virus to infect and kill the entire plant.

SOLVINIX LC can be applied in late summer to control late-emerging plants or plants that were missed in earlier applications. The plants must be actively growing when **SOLVINIX** LC is applied; dormant or senescent plants may not respond normally to the virus and may not die.

Repeat applications will be necessary to treat plants that are missed in the first application or subsequently emerged plants. For any surviving treated TSA plants, re-apply according to label instructions. If there are still surviving plants after additional treatment, consider other means of control (i.e., mechanical or chemical), consult local extension recommendations, and contact the registrant. The registrant will notify EPA under FIFRA 6(a)(2) for assessment of pesticide resistance in tropical soda apple.

Do not apply **SOLVINIX** LC if leaves are wet from rain or morning dew. Allow the leaves to dry before application.

Do not apply **SOLVINIX® LC** to TSA plants that are drought-stressed or dormant (i.e., not actively growing) or occur in waterlogged sites.

Do not apply in late fall when nightly temperatures begin to fall below 55°F (13°C) and if early frost is likely.

SOLVINIX[®] **LC** must be applied only to TSA as it is not effective against other weeds. It is effective only when applied post-emergence; it has no pre-emergence or soil residual activity against TSA. It will not be effective if applied via soil or irrigation water or any other method not specified in this label.

SOLVINIX[®] **LC** does not require the use of any additives or adjuvants. Do not mix it with any other material not mentioned in this label.

EQUIPMENT CLEANING INSTRUCTIONS

The sprayer, namely the tank and the spray wand combined, used for **SOLVINIX**® **LC** application MUST BE CLEANED THOROUGHLY AND IMMEDIATELY AFTER USE by: 1) flushing it twice by running clean water through and discharging the liquid on a TSA plant; 2) then flushing it once with dilute dish-washing soap (2 tablespoons per gallon of water); and 3) finally flushing it twice with water.

Wash the exterior of the hand-held applicator by holding it under clean running water and discharging the liquid on a TSA plant. Do not use the applicator for any use other than to apply **SOLVINIX**® **LC**.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store **SOLVINIX**® **LC** in a freezer until it is ready to be used. Do not store **SOLVINIX**® **LC** where food or medicine for human consumption is stored.

Pesticide Disposal: To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry). DO NOT discharge unused **SOLVINIX® LC** onto the ground, into water, or onto nontarget plants.

Container Handling: Nonrefillable container. Do not reuse or refill the container. Triple rinse the container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into the application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then, offer for recycling if available or puncture and dispose of in a sanitary landfill, by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND DISCLAIMER OF WARRANTIES

BioProdex, Inc. warrants that SOLVINIX® LC conforms to the description and conditions on this label and that it will perform as indicated when used under the directions and conditions of this label. To the extent consistent with applicable law, BioProdex, Inc. and/or the seller makes no other expressed or implied warranty of fitness, merchantability, or otherwise.

LIMITATIONS OF LIABILITY

To the extent consistent with applicable law, it is the manufacturer's intent that the liability of *BioProdex*, *Inc.* and/or of the seller for damages arising from the use of this product is limited to the replacement cost of the product used and shall not include any application costs or consequential damages such as loss of profits or other values.

NO CHANGES AUTHORIZED

No one other than an authorized agent of *BioProdex*, *Inc.* is allowed to make any other warranty or change the conditions, disclaimers, or limitations stated on this label. Any authorization to make changes should be in writing and in specific reference to this label.

RIGHTS AND PRIVILEGES

**Use of TMGMV U2 to control tropical soda apple by eliciting a lethal hypersensitive host response is protected under the Patents US 6,689,718 B2 and US 7,494,955 B2. These patents are licensed to *BioProdex, Inc.*

BioProdex, Inc., 3131 NW 13th Street, # 54, Gainesville, FL 32609-2183, USA TEL: 352-278-1572; FAX: 352-872-5035 Email: info@bioprodex.com; Website: www.bioprodex.com.

See the labeling inside the bag for the Precautionary Statements, First Aid, and Directions for Use

Stop! Read the entire label before using

SOLVINIX® LC

A Biological Herbicide for Control of Tropical Soda Apple (Solanum viarum)

For post-emergence application to kill tropical soda apple

EPA Reg. No.: 81179-G

EPA Establishment No.: 081179-FL-001

Batch Code:

Sell or Use Before:

[Stamped date will be one year from the day of the bioherbicide assay and batch certification]

NOT FOR SALE OR USE AFTER THE DATE STAMPED ABOVE

Active Ingredient:

Tobacco mild green mosaic tobamovirus strain U2 (TMGMV)	U2)2.9% w/v*
Other Ingredients	97.1% w/v
Total	100.0% w/v

^{*}Contains: A minimum of 0.03 ounce of the active ingredient, TMGMV U2, per fluid ounce of SolviNix® LC (29 milligrams of TMGMV U2 per ml of SolviNix® LC), with an estimated minimum of 1.25 x 10^{16} TMGMV U2 virions per fluid ounce of SolviNix® LC (4.23 X 10^{14} TMGMV U2 virions per gram of SolviNix® LC).

Net Contents: 0.34 fluid ounce (10 ml)

For use only in pastures and wooded areas that are fenced to contain grazing animals

KEEP OUT OF REACH OF CHILDREN

CAUTION

BioProdex, Inc.

3131 NW 13th Street, # 54, Gainesville, FL 32609-2183, USA