



**US Environmental Protection Agency
Office of Pesticide Programs**

**Indian Meal Moth Granulosis Virus
PC Code 108896 □**

August 18, 2004

BIOPESTICIDES REGISTRATION ACTION DOCUMENT
Indian Meal Moth Granulosis Virus
(PC Code 108896)

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
Indian Meal Moth Granulosis Virus
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I. EXECUTIVE SUMMARY

Baculoviruses are naturally-occurring viruses that are widespread in the environment. These viruses have been described in the scientific literature for approximately 40 years. In addition to their natural occurrence, these viruses have a long history of safe use of bioinsecticides. Baculoviruses have been studied extensively in both laboratory and field experiments, which have shown that the virus host range is limited to arthropods. IMMGV has been shown to be very restricted in its insect host range. No toxicological or pathogenic effects produced by the baculovirus itself, have been observed in mammals, birds, fish and plants.

II. OVERVIEW

A. Product Overview

- **Microbial Pesticide Name:** Indian Meal Moth Granulosis Virus
- **Trade Name(s):** NutGuard-V, FruitGuard-V
- **OPP Chemical Code:** 108896
- **Basic Manufacturer:** AgriVir, LLC
- **US Agent:** N/A

B. Use Profile

Type of Pesticide: Biological control agent, Microbial Insecticide

Mechanism of action :

Indian Meal Moth Granulosis Virus (IMMGV) produces granulosis disease in the larvae of its host *Plodia interpunctella*. The larvae of P. interpunctella ingests the viral occlusion bodies of the Indian Meal Moth. The infected P. interpunctella larvae contains a massive accumulation of Indian Meal Moth occlusion bodies in the fat body of the infected larva. The pathogenicity of the larva results from the mode of viral release from cells of the fat body. This release occurs by rupture of the cells of the fat body, thereby leading to degeneration and necrosis of the fat body and ultimately, death of the infected larva.

Use Sites: Indian Meal Moth Granulosis Virus is approved for use in processing, packaging and storage areas of dried nuts, fruits and various other commodities.

Target Pests for Active Ingredient: Indian Meal Moth (*Plodia interpunctella*)

Formulation Types Registered:

Type: End use Product

Form: Wettable powder

Concentration: 96.4% (4×10^{12} - 16×10^{12} viral capsules/oz of product)

Method and Rates of Application:

Types of Treatment : (Processing and Packaging) - Application is by spraying onto commodity while it is passing on the packing line conveyor, prior to packaging.

(Crack and Crevice): Application is by spraying the suspension along floor/wall joints, to corners, cracks and crevices and under and behind areas to be protected.

Equipment: Low pressure spray equipment which provides a fan-shaped, coarse spray.

Timing.

Apply product to the commodity prior to packaging.

Rates of Application:

30-150mg (1-5 oz) product/ton commodity to be treated (dry).

2 to 4 oz per 10 gallons water (in suspension).

Method of Application:

Product may be applied dry or in water suspension to the commodity being treated and packaged as required.

C. Regulatory History

AgriVir, LLC., submitted an application March 7, 2000 for registration of Indian Meal Moth Granulosis Virus. On July 14, 2000 a pesticide petition (OF6113) which proposed establishing an exemption from the requirement of a tolerance for residues of the microbial pesticide, Indian Meal Moth Granulosis Virus, on dried fruits and nuts was submitted. A notice of filing for this pesticide petition was published in the Federal Register on July 7, 2000 (FR Vol. 1, No. 1, pp. 41984-41988).

III. SCIENCE ASSESSMENT

A. Physical and Chemical Properties Assessment

Product Identity: NutGuard-V/FruitGuard-V contains the Indian Meal Moth Granulosis Virus as the active ingredient. Indian Meal Moth Granulosis Virus is a naturally-occurring microorganism. A baculovirus, IMMGV has the following physical characteristics: odorless, tan to brown solid. (SEE PROD. CHEM. DER). The isolate has been derived from the Hunter's isolate. IMMGV is highly host-specific infecting the larvae of *Plodia interpunctella* by rupturing the cells of the fat body thereby causing ultimate death of the infected larvae. The formulated product, NutGuard-V/FruitGuard-V, contains 0.77×10^{16} to 2.6×10^{16} viral capsules/lb at 1% by weight of IMMGV.

CON/M/91-08. Product chemistry data which support the registration of Indian Meal Moth Granulosis Virus are summarized in Table 1.

Table 1. Physical and Chemical Properties for Indian Meal Moth Granulosis Virus

GUIDELINE Number	STUDY	RESULT	MRID#
151-20 *885.1100	Product Identity and Disclosure of Ingredients	Acceptable	45066201
151-21 *885.1200	Manufacturing Process	Acceptable	45066202
151-22 *885.1300	Formation of Unintentional Ingredients	Acceptable	45066202
151-23 *885.1400	Analysis of Samples	Acceptable	45066203
151-25 *885.1500	Certification of Limits	Acceptable	45066204
151-26	Physical/Chemical Properties:	Acceptable	45066205
*830.6302	color	brown	
*830.6303	physical state	milled wettable powder	
*830.6304	odor	odorless	
*830.6315	flammability	non-flammable	
*830.6317	Storage stability	51 months at 12 ^o C or 2 months at 24 ± 1 ^o C	
*830.7000	pH		
*885.7300	bulk density	0.3g/cm ³	

*=OPPTS Microbial Pesticide Test Guidelines

B. Human Risk Assessment

There is a reasonable certainty that no harm will result from exposure to Indian Meal Moth Granulosis Virus. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

1. Human Toxicity Assessment

a. Acute Toxicity

Baculoviruses are naturally-occurring viruses that are widespread in the environment therefore, there is a great likelihood for previous exposure for most, if not all individuals. In addition to their natural occurrence, these viruses have a long history of safe use of bioinsecticides. Baculoviruses have been studied extensively in both laboratory and field experiments, which have shown that the virus host range is limited to arthropods. IMMGV has been shown to be very restricted in its insect host range. No toxicological or pathogenic effects produced by the baculovirus itself, have been observed in mammals, birds, fish and plants.

The lack of mammalian toxicity at high levels of exposure to IMMGV demonstrates the safety of the product at levels well above maximum possible exposure levels anticipated in the commodities. Although there have been reports of irritation upon exposure to products which contain baculoviruses, these irritation incidents were identified to be a result of exposure to insect parts contained in the formulation and not caused by the baculovirus itself.

The acute oral toxicity/pathogenicity data (MRID# 453070-01) indicated that there were no significant adverse affects in rats dosed with 1.7×10^8 IMMGV virion capsules/animal. Male and female mice (9 male and 9 female) were dosed with 1.7×10^8 virion capsules/animal. Outward clinical signs and body weights were observed and recorded throughout the 21 day study. There was no premature mortality during the study. One animal, # 10-M, displayed moderate diarrhea at 2 hours and very slight diarrhea at 4 hours after dosing. Three animals - #'s: 5-M, 9-M, and 19-F, also displayed very slight diarrhea at 4 hours after dosing. Each of these signs were cleared by the Day 1 observation and none of the other animals displayed any obvious clinical signs.

Submitted *In vitro* mammalian cell culture studies demonstrate that the IMMGV Technical preparation was highly infectious and cytopathic to the target *Plodia interpunctella*. Three mammalian cell lines (human WI-38, WSI and African Green monkey CV-1) were exposed to $\geq 1 \times 10^6$ units of IMMGV. Cytotoxicity was

evaluated on the basis of cloning efficiency relative to that of the untreated solvent. Likewise, infectivity was evaluated on the basis of changes such as focal areas of swollen rounded cells, fused cells, localized cell destruction and other localized and overall morphological changes. There were no differences seen between the virus treated and solvent control treated cell cultures with respect to cloning efficiency and cytopathic endpoint in any of the three cell lines. Therefore, there is no evidence that IMM GV is cytotoxic or infective to any of the human and mammalian cell lines used in this study.

All mammalian toxicology data requirements have been adequately satisfied to support registration. Results of the acute toxicity studies are summarized in Table 2.

Table 2. Toxicity Data Requirements

GUIDELINE NUMBER	STUDY	RESULT	MRID#
152-30 *885.3050	Acute Oral Toxicity/ Pathogenicity	Indian Meal Moth Granulosis Virus does not appear to have an adverse effect in rats, when dosed at 1.7×10^8 virion capsules. ACCEPTABLE, Toxicity Category IV	45307001
152-31 *885.3100	Acute Dermal Toxicity/ Pathogenicity	Waived. Based upon the lack of toxicity in animals dosed orally as well as cells inoculated, there does not appear to be a significant risk of dermal toxicity upon exposure to IMMGV. Further, Information in the scientific literature relative to the toxicity of baculoviruses (inclusive of granulosis viruses) to animals show that baculoviruses produce no effects on overall health in test animals when exposure is by the oral, dermal, inhalation and injection routes of exposure by single or repeated exposure. ACCEPTABLE, Toxicity Category III	45066208 45307001 45066207
152-32 *870.1300	Acute Inhalation (End-Use Product WP)	Waived. Information in the scientific literature relative to the toxicity of baculoviruses (inclusive of granulosis viruses) to animals show that baculoviruses produce no effects on overall health in test animals when exposure is by the oral, dermal, inhalation and injection routes of exposure by single or repeated exposure. ACCEPTABLE, Toxicity Category IV	45066207 45066208

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GUIDELINE NUMBER	STUDY	RESULT	MRID#
152-33 *885.3200	Acute Intraperitoneal Toxicity/Pathogenicity	Waived. Information in the scientific literature relative to the toxicity of baculoviruses (inclusive of granulosis viruses) to animals show that baculoviruses produce no effects on overall health in test animals when exposure is by the oral, dermal, inhalation and injection routes of exposure by single or repeated exposure. ACCEPTABLE Toxicity Category IV	45066207 45066208
152-35 *870.2400	Primary Eye Irritation	IMMGV produced minor signs of irritation such as conjunctivitis, corneal opacity and iritis, all of which cleared within 4 days of treatment when dosed at 7.14×10^9 viral capsules. ACCEPTABLE , Toxicity Category IV	45066209
152-34 *870.2500	Primary Dermal Irritation	Waived. Based on studies from the scientific literature which support the lack of mammalian toxicity associated with baculoviruses. Although dermal irritation from environmental exposure to certain baculoviruses have been reported, these adverse effects could be due to the presence of insect hairs. These adverse effects are not relevant to the IMMGV as this insect host has a smooth bodied larval from with hairs which lives and feeds in the food matrix and not on a plant surface. Based on this evidence and the data submitted from an eye irritation study (minor irritation demonstrated), a dermal toxicity study was waived as there is no indication that IMMGV itself has a likelihood to cause skin irritation. ACCEPTABLE, Toxicity Category IV	45066207 45066208

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GUIDELINE NUMBER	STUDY	RESULT	MRID#
152-36 *870.2600	Delayed Contact Hypersensitivity	The Agency requires the registrant to report any hypersensitivity incidents to the Agency under Section 6(a)2. ACCEPTABLE	0007267 1 00072679
152-38	Immune Response	Waived. Based on information available in the scientific literature there are no reports which suggests that the Indian Meal Moth Granulosis Virus has the potential to cause adverse effects on the immune systems of humans or animals. The virus host range is limited to the Indian Meal Moth where it would be expected to affect the defense systems of the target insect pest.	45066207 45066208

* =OPPTS Microbial Pesticide Test Guidelines

b. Subchronic Toxicity and Chronic Toxicity

Tier II and III Subchronic and chronic toxicity studies are not required because of the low acute toxicity of the microbial pesticide, and no indications of infectivity or pathogenicity in mammals.

2. Effects on the Immune and Endocrine Systems

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients)” may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.” Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen- and thyroid hormone systems, in additions to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

Within the available scientific literature, there are no reports (MRID 4506627 & 8) that suggest Indian Meal Moth Granulosis Virus has the potential to cause adverse effects on the endocrine and/or immune systems of animals. When the appropriate screening and or testing protocols being considered under the Agency’s Endocrine Disruptor Screening Program have been developed, Indian Meal Moth Granulosis Virus may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption. Based on the weight of the evidence of available data, no endocrine system-related effects have been identified.

3. Dose Response Assessment

No toxicological endpoints are identified.

4. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). The potential aggregate non-occupational exposure to Indian Meal Moth Granulosis Virus, derived from dermal, inhalation and dietary exposure from drinking water and treated produce containing this organism, are expected to be minimal to non existent and should fall well below the currently tested microbial safety levels.

a. Dietary Exposure

(i) *Food.* Baculoviruses are naturally-occurring viruses that are widespread in the environment, therefore there is a great likelihood for previous exposure for most, if not all individuals. In addition, even if there is a significant increase in exposure to the virus, the toxicity studies submitted along with the extensive reports in the scientific literature indicating the safety of the viruses, suggest that there should not be any additional risk of adverse effects due to exposure to IMMGV.

(ii) *Drinking water exposure.* Because of the use site and amount of product that will be applied, it is not likely that use of this product will result in a significant increase in virus exposure in drinking water. Baculoviruses occur naturally in soil and there is a low likelihood that they would survive passage through the soil to reach underground water. Even if virus is able to reach underground water, it is highly unlikely that the viruses would survive municipal water treatment. Therefore, it is likely there will not be an increase of IMMGV in drinking water. In addition, because the virus host range is limited to the Indian meal moth, even if the virus is found in drinking water, the results of the acute oral toxicity studies using a high dose of the virus, suggest that there will not be any adverse effects upon human consumption in the unlikely event any virus found its way into drinking water.

b. Other Non-Occupational Exposure

Baculoviruses are naturally-occurring viruses that have a long history of safe use to control arthropods. Because the amount of virus which will be applied is small, it is not likely that there will be a significant increase in potential exposure. Any increase in virus titer is likely to be negligible at most. Baculoviruses have been shown to have a host range limited to arthropods and the host range of this virus is even more restrictive than most baculoviruses. Therefore, even if there was an increase in exposure, there should not be any increase in potential human health effects.

5. Occupational, Residential, School and Day Care Exposure and Risk Characterization

Indian Meal Moth Granulosis Virus is a naturally-occurring microorganism. The lack of mammalian toxicity at high levels of exposure to IMMGV demonstrates the safety of the product at levels well above maximum possible exposure levels anticipated in the specified commodities. The product will be applied at usage rates of 1-5oz product/ton of commodity to be treated. There is no indication of indoor/residential, school and/or daycare uses on the label. With IMMGV's highly specific host range, and its lack of mammalian toxicity, the potential of increased non-

occupational exposure to Indian Meal Moth Granulosis Virus will be limited with no potential human health effects.

6. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

Indian Meal Moth Granulosis Virus is naturally occurring and widespread in the environment, with a highly probable, prior human exposure. The mammalian cell cytotoxicity and infectivity assays indicates an inability of IMM GV to infect or induce any cytotoxicity to mammalian cell lines.

Based on the acute toxicity information discussed above, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to the United States population, including infants and children, to residues of Indian Meal Moth Granulosis Virus. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

FFDCA section 408 provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, the Agency believes there is reliable data to support the conclusion that Indian Meal Moth Granulosis Virus is practically non-toxic to mammals, including infants and children, and, thus, there are no threshold effects. Therefore, the provision requiring an additional margin of exposure (safety) does not apply. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of Indian Meal Moth Granulosis Virus.

7. Cumulative Effects

No mechanism of toxicity in mammals has been identified for Indian Meal Moth Granulosis Virus. Therefore no cumulative effect with other related organisms is anticipated. Because the data and/or information from the scientific literature demonstrate the lack of toxicity/pathogenicity potential of the active ingredient, the likelihood of adverse dietary effects is expected to be minimal.

C. Environmental Assessment

1. Ecological Effects Hazard Assessment

Based on the toxicology data cited and the limited exposure to humans and domestic animals, all tier 1 ecological effects toxicology studies were requested. The Agency has reviewed the literature submitted in support of the data waiver requests and has granted these data waivers based on the long history of research, use and safety of testing baculoviruses (Doller, G. 1985. The Safety of insect virus as biological control agents. *In* "Viral insecticides for Biological Control" (Eds. Maramorosch, K. and Sherman, H.G.), Academic Press, New York: 399, Heimpel, A.M. 1971. Safety of insect pathogens for man and vertebrates. *In* "Microbial Control of Insects and Mites" [(Eds. Burges, H.D. and Hussey, N.W.), Academic Press, New York: 469-489, Groner, A. 1986. Specificity and safety of baculoviruses. *In* "The Biology of Baculoviruses Vol. I: Biological Properties and Molecular Biology" (Eds. Granados, R.D. and Federici, B.A), CRC Press, Boca Raton, Florida: 177-202]. Consigili, R.A., D.L, Russell and M.E. Wilson. 1986. The biochemistry and molecular biology of the granulosis virus that infects *Plodia interpunctella*. *Cur. Top. Microbiol. and Immunol.* 131: 69-101. Hunter, D.K. 1970. Pathogenicity of a granulosis virus of the Indian meal moth. *J. Invertebr. Pathol.* 16: 339-341.

The lack of toxicity associated with this biopesticide supports the fact that risks to non-target species are minimal to non-existent, however, standard precautionary label statements under "Environmental Hazards" are presented on the product label.

2. Terrestrial or Aquatic Environmental Expression Data

The need for environmental fate and groundwater data (Tier II) was not triggered under current requirements (40 CFR Section 158.740(d)(2)(vi through xv) because of the lack of toxicity/pathogenicity associated with this active ingredient.

3. Ecological Exposure and Risk Characterization

A potential for exposure to non-target insects, fish, and other wildlife is minimal to non-existent due to the indoor use patter of this product and data from the open scientific literature indicate a lack of adverse effects to non-target organisms (Consigili, R.A., Russell, D.L. and Wilson, M.E. 1986. The biochemistry and molecular biology of the granulosis virus that infects *Plodia interpunctella*. *Current Topics in Microbiology & Immunology.* **131**: 69-101.

D. EFFICACY DATA

Although efficacy data were not required to be submitted to the Agency since no public health uses are involved the registrant did however, submit efficacy data for this active ingredient. The data submitted demonstrated good control of the target pest Indian Meal Moth (*Plodia interpunctella*).

IV. Risk Management Decision

A. DETERMINATION OF ELIGIBILITY

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

To satisfy criterion “A” above, Indian Meal Moth Granulosis Virus has well known properties. The Agency has no knowledge that would contradict the claims made on the label of this product in addition the efficacy data submitted demonstrated good control to the Indian Meal Moth. Criterion “B” is satisfied by the current label and by the data presented in this document. It is believed that this new pesticidal active ingredient will not cause any unreasonable adverse effects, is a broad spectrum microbial pesticide, and does provide protection as claimed satisfying criterion “C”. Criterion “D” is satisfied in that Indian Meal Moth Granulosis Virus is not expected to cause unreasonable adverse effects when used according to label instructions.

Therefore, Indian Meal Moth Granulosis Virus is eligible for registration. The uses are listed in the Section II, B. Use Profile. There are no ineligible uses for Indian Meal Moth Granulosis Virus.

B. Regulatory Position

1. Unconditional Registration

The data requirements have been fulfilled or waived by the Agency and the Biopesticides and Pollution Prevention Division recommends unconditional registration of products that contain Indian Meal Moth Granulosis Virus as the sole Active ingredient.

2. Tolerances for Food Uses and /or exemptions

EPA received a pesticide petition (PF 0F6113) from AgriVir, LLC., proposing [pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346a(d)], to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for the microbial pesticide, Indian Meal Moth Granulosis Virus.

EPA is issuing a notice establishing an exemption from the requirements of a tolerance for residues of Indian Meal Moth Granulosis Virus on dried fruits and nuts (shelled and In-shell).

3. CODEX Harmonization

There are no CODEX values for Indian Meal Moth Granulosis Virus.

4. Risk Mitigation

Other than standard personal protective equipment (PPE) to protect applicators and other handlers that are listed below in section V, no risk mitigation measures were required.

5. Endangered Species Statement

Given the specificity of this microbial pesticide and based on the intended use pattern, and the results of toxicity and exposure data from public scientific literature and from the data submitted by the applicant, the Agency has determined that this action will have no effect on currently listed endangered and threatened species.

C. Labeling Rationale

1. Human Health Hazard (WPS and non-WPS)

Indian Meal Moth Granulosis Virus products with commercial use sites are not subject to the Worker Protection Standard. However, precautionary statements and personal protective equipment as specified below are required based on the acute toxicity categories of this organism.

2. Environmental Hazard

Precautionary labeling is required as indicated below.

V. ACTIONS REQUIRED BY REGISTRANTS

A. Precautionary Labeling

Indian Meal Moth Granulosis Virus products must state the following under the heading "Precautionary Statements":

Warning: "Causes eye irritation. Avoid contact with eyes by contact with skin or clothing. Wear protective eyewear and gloves. Wash thoroughly with soap and water after handling.

B. Environmental Hazards Labeling

Environmental Hazards labeling are not required for Indian Meal Moth Granulosis Virus as the product is intended for use exclusively indoors in processing packing and storage areas.

1. Application Rate

It is the Agency's position that the labeling for the pesticide products containing Indian Meal Moth Granulosis Virus as the active ingredient complies with the current pesticide labeling requirements. The Agency has not required a maximum number of applications per a season of this active ingredient.

C. Labeling

The attached label for Nut Guard-V/FruitGuard-V conforms with the labeling requirements for Indian Meal Moth Granulosis Virus. Some of the essential label requirements are highlighted below.

Signal word is "Warning," based on (toxicity category IV). The product shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number
- "Keep Out of Reach of Children"

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- Signal Word (CAUTION)
- Personal Protective Equipment (PPE) Requirements
- Environmental Hazard Statement
- Storage and Disposal Statement
- Non-Agricultural Use Requirements
- Directions for Use

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45066209 Acute Eye Irritation - Rabbit (OPPTS 870.2400). Indian Meal Moth Granulosis Virus (IMMGV) No. 8261. SRS International Corporation, 1625 K Street NW, Suite 1000, Washington, DC 20006. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Author: George E. Moore.

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