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Thursday, June 26, 2008

Robert Pooler, Agricultural Marketing Service
Program Manager, USDA/AMS/TM/NOP
Room 4008-So., Ag Stop 0268
1400 Independence Ave., SW
Washington, DC 20250
Tel: 202 720-3252
Fax: 202 205-7808

Re: Petition to Remove "Lecithin - Bleached" from National List

Dear Mr. Pooler:

Please accept the attached petition to remove "bleached lecithin" from the list of synthetic substances allowed as ingredients under 7 CFR 205.605(b). I request review at the earliest opportunity. I further respectfully request that this petition be expedited as it is a "petition to remove" a material from the National List.

"Lecithin - Bleached" was placed on the National List after an original TAP review completed in 1995. It was retained on the National List during a Sunset Review in October 2006 with the following statement by the NOSB:

The Board strongly hopes that a petition will be presented in short order to restrict the use of bleached lecithin to dry forms only.

Since then, the supply of organic lecithin has evolved to the point that there are now certified organic lecithins available to replace the need for non-organic bleached lecithin.

In preparing this petition, I have sought examples of prior "petitions to remove" and found few to follow. I have made every effort to comply with the requirements in 7 CFR Part 205 and the 2007 Federal Register Notice outlining National List petition requirements. I have adjusted them as best I can for removal rather than inclusion.

Attached please find the following:

- A) Petition to remove Lecithin - Bleached from the National List (6 pages)
- B) Attachments:
 1. Lecithin Fact Sheet by Dr. Bernard Szuhaj, an expert on lecithin (4 pages)
 2. The original 1995 TAP review on bleached lecithin (7 pages)
 3. The 2006 Sunset Review on bleached lecithin (2 pages)
 4. Pesticides involved with soy production under 205.605(b), list and MSDS (1 page)
 5. Hexane MSDS (8 pages)

6. Canadian draft rule on bleached lecithin, reference citation and relevant excerpt (2 pages)
7. The Soil Association, new policy on bleached and unbleached lecithin, reference citation and relevant excerpt (1 page)

Thank you for your assistance in putting this petition before the NOSB. If you need any additional information, please contact me.

Respectfully,

Lynn Clarkson

Lynn Clarkson
Managing Director, Clarkson Soy Products, LLC
e-mail lynn.clarkson@clarksongrain.com

CC: Barbara Robinson, Acting Director National Organic Program
Valerie Francis, Executive Director, NOSB

Petition to the USDA National Organic Standards Board to Remove “Lecithin – Bleached” from the National List

Item A

This is a petition to remove **Lecithin - Bleached** from Section 205.605(b) of the National List of Synthetic Non-Agricultural Products Allowed as Ingredients in or on Processed Products Labeled as “Organic” or “Made with Organic.”

Item B

- 1) **Substance Name:** Lecithin - Bleached
- 2) **Petitioner’s Name:** Clarkson Soy Products, LLC
Address: 320 East South Street PO Box 80
Cerro Gordo, IL 61818-0080
Contact person – Lynn Clarkson
Title – Managing Director
Telephone number: 217 763-2861
E-mail lynn.clarkson@clarksongrain.com

Petitioner is a Manufacturer of Organic Lecithin and Organic Lecithin – Bleached.

- 3) **Current Use of the Substance:** Bleached lecithin is used as an emulsifier, a release agent and an instantizing agent in products ranging from foods to personal care items to supplements. Foods using bleached lecithin as an ingredient include instant beverages, chocolates, baked goods, margarine and ice cream. Other applications are listed in the attached Lecithin Fact Sheet (Attachment 1).
- 4) **Mode of Action:** Bleached lecithin is functionally identical to unbleached lecithin. It differs only in color. Bleached lecithin is used in food applications where a lighter color is deemed important. As an emulsifier, it functions as a natural surfactant between oil and water systems. With chocolates, it modifies their functionality for better enrobing and reduced crystallization. In release applications, it modifies cooking surfaces to permit products to be more easily removed. In instantizing applications, it reduces the hydration properties of powders that would otherwise clump during dispersion in liquid products. In baking applications, it serves multiple functions by emulsifying fats with water and inhibiting starch retrogradation and staling.
- 5) **Substance Source and Manufacturing Description:** Lecithin can be extracted from various vegetable seed sources and some animal sources. It is most commonly extracted from soybeans. In the first step, soybeans are selected and then processed to extract the oil. Bleached lecithin, as listed in 205.605(b) is processed from non-organic soybeans, using hexane to extract the oil. During step two, hydrogen peroxide is conventionally used to bleach the lecithin. At that point, the product is a beached fluid lecithin. To produce bleached de-oiled lecithin, the solvent acetone is used to de-oil bleached lecithin, producing the granular or powdered form of bleached lecithin. There are very limited applications for bleached de-oiled lecithin in a granular or powdered form. See Attachment 1, Lecithin Fact Sheet, for diagrams and descriptions of conventional and organic production systems.

6) **Reviews:**

- ❑ **1995 TAP review:** At the time of the original TAP review in 1995, there was no organic lecithin. The quality of organic vegetable oil itself was regarded by one of the reviewers as questionable. Without commenting on the use of hydrogen peroxide as a bleaching agent, one of the two reviewers mentioned the risk of hexane carryover but recommended the acceptance of conventional bleached lecithin as a permitted synthetic. Please see Attachment 2.
- ❑ **2006 Sunset Review and Recommendation:** During Sunset Review in October 2006, the NOSB recommended renewing “bleached lecithin” under 205.605(b). In its comments, the board further recognized that there are “plentiful non-synthetic and organic alternatives to synthetic bleached lecithin in liquid form” but that there is no such alternative for “bleached lecithin” in de-oiled form. Because the Sunset Review provided no opportunities to add annotations, the board saw no alternative but to recommend renewal of bleached lecithin. In closing its final recommendation, the board invited a petition to restrict the use of bleached lecithin to dry forms only. Please see Attachment 3. Since that time, bleached organic lecithin has become available.

7) **EPA, FDA and State Regulatory Agency Registrations:**

- FDA GRAS Status under 21 CFR 184.1400
- The California Proposition 65 list does NOT include bleached lecithin

8) **CAS Number:** Lecithin CAS# 8002-43-5

9) **Physical Properties and Chemical Mode of Action:** Not Applicable/Petition to Remove from the List

Please note that the current allowance of Bleached Lecithin under 205.605(b) permits the introduction of conventional soybeans, associated pesticides and hexane into certified organic production. See Attachment 4 regarding pesticides used on soybeans and Attachment 5 for an MSDS for hexane.

10) **Safety Information:** Not Applicable/Petition to Remove from the List

11) **Research Information:** In developing this petition, I have used several sources of information including:

- ❑ Petitioners’ own experience as a certified processor and supplier of organic lecithin. Petitioner has commercially supplied organic lecithin under NOP certification since January 2004.
- ❑ Scientific advice and review by Dr. Bernard Szuhaj, one of the world’s leading experts on lecithin and phospholipids. I have attached a Lecithin Fact Sheet compiled by Dr. Szuhaj. Please see Attachment 1. Given the complexity and importance of scientific points made in this petition, petitioner offers Dr. Szuhaj’s services to the NOSB and its Handling Committee should they wish more technical information.
- ❑ Wolf, DiMatteo + Associates as a source of information on organic rules in the US, Canada and the UK.
- ❑ Published information and commercial industry estimates of the world and US market size and segmentation for conventional lecithin. See the attached Lecithin Fact Sheet, Attachment 1.

- ❑ Discussions with manufacturers using organic lecithin in certified organic foods and others using conventional lecithin in certified organic foods – sometimes in virtually identical products.
- ❑ Discussions with two other processors/suppliers of organic lecithin, one in France and another in India.

Rule note: Standard lecithin is a processed agricultural product regulated under NOP §205.606. While bleaching makes no chemical change to the functional properties of lecithin, it does make a change to some pigments that influence color. That appears to have been sufficient to classify it as a synthetic under 205.605(b). De-oiled lecithin is sometimes mistakenly included under the “bleached lecithin” Category. There are two forms of de-oiled lecithin, bleached and un-bleached. Bleached de-oiled lecithin is rarely used. Regardless, neither de-oiled lecithin nor acetone treatment have ever been petitioned or reviewed for consideration on the National List.

Treatment of “bleached lecithin” under other organic rules:

- ❑ **The Canadian Rules – effective December 14, 2008:** The Canadian organic community has had several years to develop organic rules and practices. They took the opportunity to investigate the US experience and consider what has worked, what has not worked and what has evolved. The Canada Organic Standards go into effect on December 14, 2008. As drafted, these regulations allow for the use of “bleached lecithin” in organic products only if made from otherwise organic lecithin. By requiring that “bleached lecithin” start with organic lecithin, Canada supports the organic farmer and protects the organic consumer while addressing the needs of manufacturers seeking bleached lecithin. See Attachment 6 for a reference to the Canadian rules and excerpted portion.
- ❑ **The Soil Association – effective January 1, 2009:** The Soil Association is the leader in organic certification in the UK and is well respected by agencies around the world. The Soil Association has noted the evolution of organic ingredients and the importance of maintaining organic integrity and promoting organic preference. The Soil Association has announced that it is closing the door to synthetic substances entering the organic food chain through the use of conventional lecithin. Starting January 1, 2009, the Soil Association will require all certified organic products using lecithin to use organic lecithin. The use of bleached conventional lecithin as currently approved under the NOP would disqualify a product as organic according to the Soil Association. See Attachment 7 for an excerpt from the Soil Association’s Certifier Newsletter of June 2008.

12) **Petition Justification Statement** for the Removal of a Synthetic from the National List:

Petitioner is requesting that “bleached lecithin” be removed from 205.605(b) because it is no longer necessary or appropriate for the handling of organic products. There are non-synthetic and organic substances available and in use to fully replace the current use of non-organic bleached lecithin in organic and “made with” organic products, including certified organic forms of bleached lecithin, in adequate commercial quantities and in the forms and with the functional properties to meet the organic industry’s needs.

Organic Alternatives to Non-Organic Bleached Lecithin

In contrast to the situation in 1995 during the original TAP review, today there are thousands of farmers producing organic soybeans on five continents, at least a dozen crushers extracting high quality organic oil and several processors offering organic lecithin. The single difference between

bleached and unbleached lecithin is color. The world of organic ingredients has evolved to address the color issue with certified organic solutions.

- ❑ Organic light-colored fluid lecithin: By reducing color pigments through selection of lighter colored raw materials and reducing processing temperatures, organic processors can offer 100% organic light-colored lecithin that matches the industry color definition of “bleached lecithin.” In addition, color pigments can now be reduced by using filter media allowed in organic production. Either way, manufacturers can now find the same functionality and similar color from an organic lecithin that is not bleached.
- ❑ Organic fluid bleached lecithin: Using hydrogen peroxide allowed under 205.605(b) to treat organic fluid lecithin, organic processors now offer a bleached “organic” lecithin identical in functional properties and color to the synthetic non-organic bleached lecithin currently allowed.
- ❑ Organic egg yolks: Organic egg yolks, which contain lecithin, are an effective emulsifier now being used in organic products. These include organic ice creams, frozen yogurts, mayonnaise and salad dressing products.

Commercial Availability

- ❑ **Quality:** Petitioner supplies certified organic lecithin from a state-of-the-art processing plant in Iowa. It has supplied organic lecithin from that plant since January 2004. Its lecithin products are regularly used in organic baby foods, chocolates, baked goods, vegetable oil sprays, supplements and personal care items. It offers a standard fluid lecithin and customized formulations of fluid lecithin varying in viscosity. It has commercialized a 100% organic light colored lecithin and an organic bleached lecithin and is prepared to fulfill orders pending removal of bleached lecithin from 205.605(b). The processing plant is certified organic, Kosher and Halal. It has passed quality control inspections by some of the world’s leading food and cosmetic companies.
- ❑ **Quantity:**
 - ❑ Organic Lecithin Supplies: Several companies offer organic lecithin including one in France, one in India and the petitioner in the US. There may be others of which petitioner is not aware. New suppliers are expected to enter the market as the organic industry matures, demand increases, and organic preference is enforced. .
 - ❑ Process Capacity: There is sufficient processing capacity to meet current and future market requirements for USDA certified organic lecithin. Petitioner has never turned down an order for organic lecithin. Its plant has sufficient raw material and process capacity to supply the organic lecithin component of hundreds of millions of pounds of organic foods and products. Following a major plant expansion in August 2007, its plant is operating at 1/10th its production capacity.
 - ❑ Organic Soybean Supplies are more than adequate: Soybeans are the primary raw material used for making lecithin, although other oil seeds may be used as well. Domestic organic farmers grow several times more soybeans than necessary to supply the world’s need for organic lecithin. In case of weather challenges in the US, imports of organic soybeans are available in quantities far larger than needed to cover the entire world demand for organic lecithin. Current global organic soy production is now more than 2 billion pounds per year. Organic lecithin supply derived from this quantity of organic soy beans would be in the range of 9 million pounds, many times in excess of current usage of all lecithin products in organic and “made with organic” products. With

the development of allied organic markets for dairy, egg and meat products, there is strong demand for other components produced from the organic soybean in making lecithin – meal, oil and fiber. That combination of demand and supply provides a reliable opportunity to extract organic lecithin with nothing left for disposal.

A Review By Today's Standards

If a petition to add bleached lecithin to 205.605(b) was being considered today, the petitioner would need to prove the following, per 205.600:

1. *That "bleached lecithin" can not be produced from a natural source and that there are no organic substitutes:*
Today there are certified organic forms of light colored lecithin as well as a "bleached lecithin."
2. *That the manufacture, use and disposal of "bleached lecithin" do not have an adverse effect on the environment and are done in a manner compatible with organic handling:*
The current listing of non-organic bleached lecithin as an allowed ingredient in organic and "made with" organic products permits and condones conventionally produced soybeans grown and treated with toxic and synthetic pesticides (seed treatments, fungicides, insecticides and herbicides) and further processed using hexane. Hexane is itself a neurotoxicant which threatens worker safety. Several of the pesticides used on conventional soybeans are so hazardous that application requires licensing, and specialized application and handling training. Disposal of these pesticides and extraction agents are restricted in an attempt to minimize environmental damage.
3. *"That the substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures or nutritive value lost during processing, except when the replacement of nutrients is required by law:"*
The primary reason for bleaching lecithin is only to alter the color of an otherwise agricultural product.
4. *That the substance is essential for the handling of organically produced agricultural products:*
"Bleached lecithin" is NOT essential to handling organically produced agricultural products. Bleaching adds no functional improvements over unbleached lecithin. It just lightens the color. That can now be done with bleached organic lecithin, 100% organic light-colored lecithin, or organic egg yolks.

An application to add synthetic bleached lecithin to the National List would not be accepted today as an approved synthetic under 205.605(b) because such a petition could not meet the requirements of the regulations under today's market conditions.

Continuation of the allowed use of bleached non-organic lecithin leaves the organic food chain open to the use of conventional soybeans and associated pesticides as well as the use of hexane in making organic products. Hexane is a known neurotoxicant.

Confusion in the Marketplace

- A. Labeling Confusion: Non-organic bleached lecithin is being identified only as "lecithin" on organic product labels. This appears to comply with FDA labeling requirements but does not properly inform the consumer that bleached lecithin is in the organic product.
- B. Ingredient Approval Confusion: In some cases, de-oiled lecithin is being allowed under the current bleached lecithin listing. The original 1995 TAP Review and NOSB decisions did not

evaluate the use of acetone or de-oiled lecithin and it is questionable whether de-oiled lecithin is included in the Lecithin – Bleached listing.

- C. 2006 Sunset Review: Sunset renewal occurred because of the misconception that there is widespread use or need for bleached de-oiled lecithin. Such products are not commonly used because of potential problems with oxidative flavors.

Conclusion

In conclusion, removing non-organic bleached lecithin from 205.605(b) and from the supplychain will:

- ✓ Support organic farmers and processors and encourage expansion of organic acreage and processing capacity;
- ✓ Protect organic consumers and reduce ingredient panel labeling confusion;
- ✓ Help create more uniform certification decisions by USDA NOP Accredited Certification Agencies;
- ✓ Encourage the expanded use of organic lecithin products and other organic substitutes;
- ✓ Help manufacturers to make their products more organic by stimulating market demand for organic minor ingredients.

Per Federal Register Notice, the following information must be provided for removing Lecithin – Bleached:

Federal Register / Vol. 72, No. 11 / Thursday, January 18, 2007 / Rules and Regulations **2169**

(12)B. Removal of a Synthetic From the National List, §§ 205.601, 205.603, 205.605(b)

- Explain why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product.
- Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.

Petitioner submits that sufficient and overwhelming proof that these petition requirements have been met. Therefore Petitioner respectfully requests that the National Organic Standards Board vote for the removal of “Lecithin – Bleached” from the National List and that the Secretary of Agriculture accept the NOSB’s recommendation and promptly amend the National List in the Federal Register.

Attachments

1. Lecithin Fact Sheet and References
2. 1995 TAP Review
3. 2006 Sunset Review
4. Pesticides (fungicides, insecticides and herbicides) available for use on soybeans compiled from the “Illinois Agriculture Handbook, 2008”; The “**2008 Illinois Agricultural Pest Management Handbook**” is available on-line. School IPM Implementation in Illinois: Final Grant Report (Adobe PDF, www.ipm.uiuc.edu/)
5. Hexane MSDS
6. Canadian Rule
7. Soil Association Policy

Lecithin Fact Sheet

- **What is lecithin?**

Most commercial lecithin is made from soybeans. It can also be made from vegetable crops such as corn, canola and sunflower. Animal-based lecithin can be obtained from egg yoke and animal organs.

Commercial lecithin is primarily made up of phospholipids and vegetable oils. Soybean lecithin contains approximately 65% phospholipids as acetone insoluble (AI) compounds and soybean oil. The major phospholipids in lecithin are in phosphatidylcholine, phosphatidylethanolamine and phosphatidylinositol.

- **How is lecithin made?**

Conventional Solvent Extraction Process

Solvent Extraction

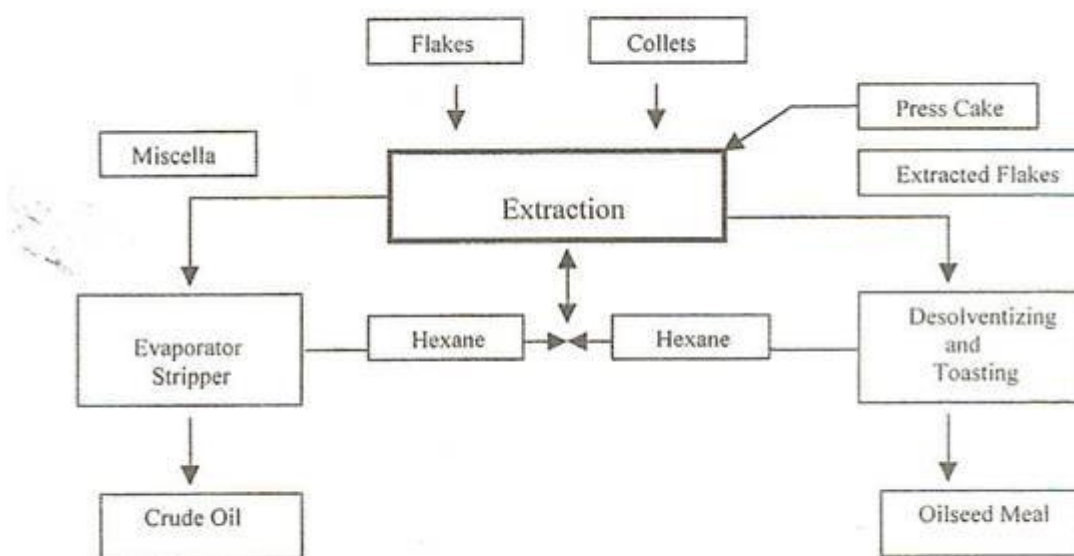


Figure 1

As seen in Figure 1, commercial lecithin is made from crude soybean oil extracted from soybean flakes with hexane. The crude soybean oil is treated with water or steam to precipitate the lecithin as gums. These wet gums are centrifuged and dried. Soybean oil and fatty acids are added to standardize the products.

Commercial lecithin has an acetone insoluble (AI) content of 64-68%, an acid value (AV) of 24 -28 and a moisture content of less than 1%. The AI is the amount of phospholipids in the lecithin product determined by acetone insoluble gravimetric analysis. The AV is the titratable acidity from the phospholipids and added fatty acids.

The hexane used in commercial soybean processing is a neurotoxicant. In powdered and granular lecithin, acetone is used to precipitate the phospholipids from the oil and the acetone is removed by filtration and evaporation. Oxidized acetone may result in the acetone recovery process producing toxic compounds such as mesityl oxide and isophenone.

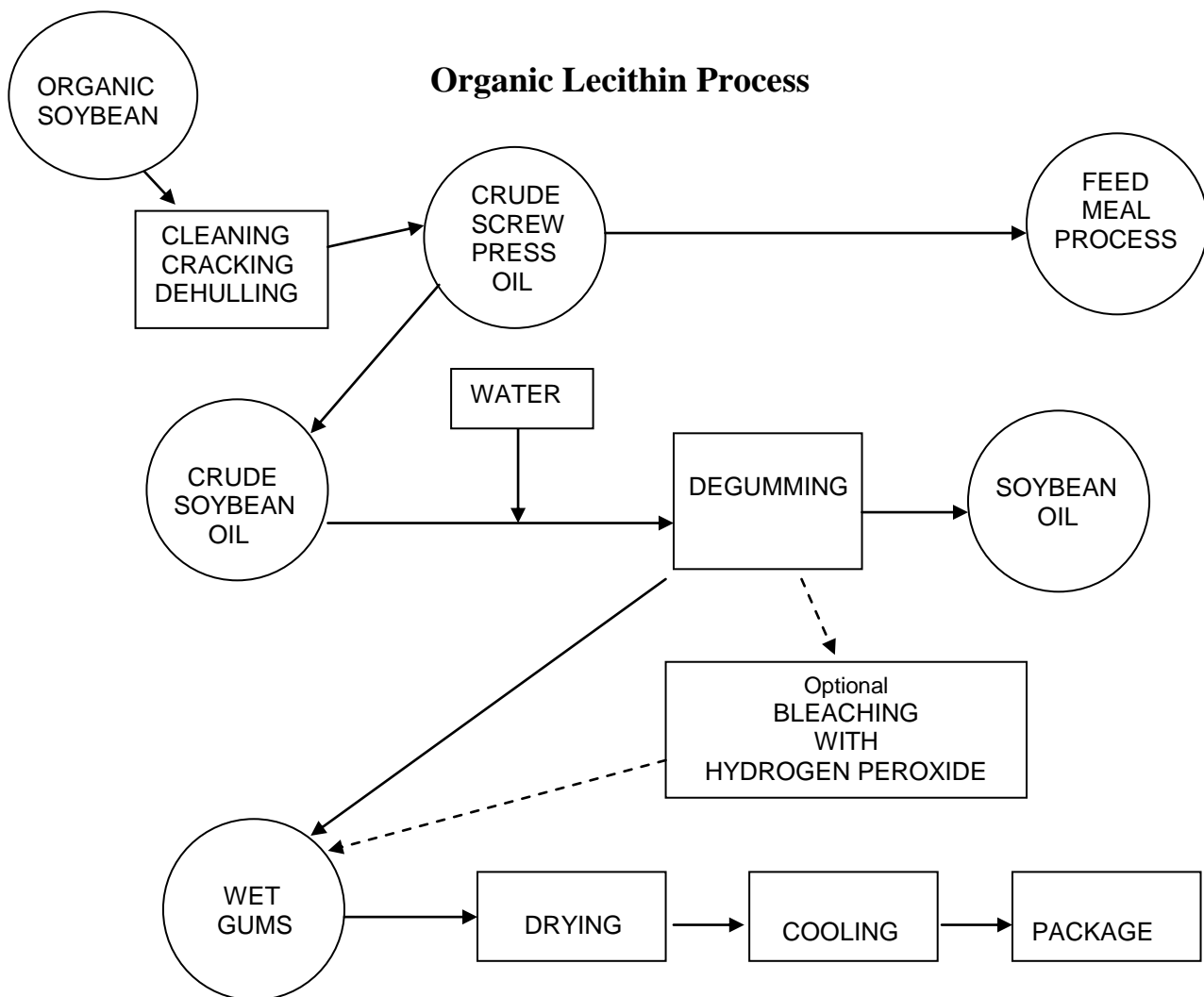


Figure 2

The organic lecithin process as seen in Figure 2 above, follows NOP rules and uses expeller soybean oil. The crude expeller soybean oil is hydrated with water or steam and the lecithin gums are removed by centrifugation and dried. Organic soybean oil or fatty acids may be added to adjust the composition to standardize the product for acetone insolubles (AI) and acid value (AV).

Organic lecithin does not use organic prohibited solvents like hexane and acetone. It is made from organic soybeans using the expeller press process to remove the crude soybean oil.

- **What are the major types of lecithin?**

The pie chart in Figure 3 below estimates the market share of the lecithin products produced worldwide in 5 categories:

1. standard lecithin
2. bleached lecithin
3. de-oiled lecithin
4. reacted lecithin
5. refined lecithin

Crude or standard lecithins are the major category at 42% of the market. This category includes unbleached and bleached lecithin products. Approximately 64% of the crude lecithin category is standard lecithin and 36% is bleached lecithin. These lecithins are used primarily in food applications.

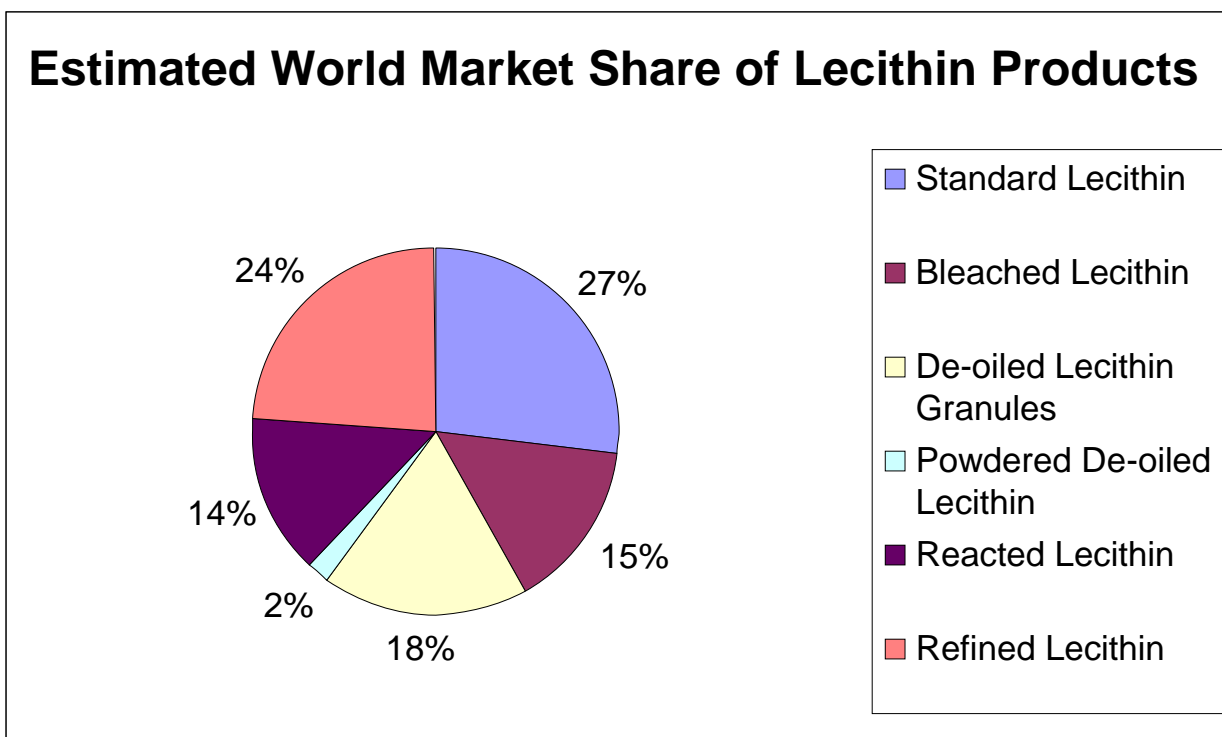


Figure 3

De-oiled lecithins are approximately 20% of the total lecithin category in both powdered and granular form. The granular form is the most prevalent de-oiled product with over 95% of this market segment. These products are made by acetone precipitation of standard crude lecithin with a minimum AI of 95%. The granular lecithin is primarily used in the nutrition market and the powdered de-oiled lecithin is used in baking and anti-sticking of confections.

Reacted lecithins are lecithins that are chemically modified to enhance dispersability in water. Hydroxylation and acylation are used to make these reacted lecithin products. They are used primarily in instantizing and water-based food systems because of their dispersing properties. Enzyme modification is also done in the reacted lecithin category and is used in baking and animal feed applications.

Refined lecithins are made by the addition of special products such as mono and diglycerides and other vegetable oils to enhance handling properties. The primary area of use would be in release, instantizing and baking applications.

- **How is lecithin used?**

Lecithins have a wide range of food applications which include emulsification, release properties, wetting, dispersing and texturization.

The major applications for lecithin include margarine, chocolates, instantizing powders, release sprays and baked goods.

Lecithin is used as a natural surfactant between oil and water systems as seen in margarine products. Lecithin also helps modify chocolates for better enrobing and reduces crystallization of cocoa fat.

In release applications, lecithins modify the cooking surface to allow for products to be more easily removed.

As in instantizing agent, lecithin reduces the hydration properties of powders that would otherwise clump during dispersion in water and milk products.

In baking, the lecithin provides a multifunction application by emulsifying the fat and water and as an anti-staling agent by inhibiting starch retrogradation.

Powdered lecithins are used in commercial applications of food systems where liquid lecithin is more difficult to handle and the powdered lecithin is more easily incorporated.

- **Regulatory status**

Lecithins are considered as generally recognized as safe (GRAS). They are GRAS under 21 CFR 184.1400. They are also listed in the Food Chemicals Codex, (FCC) the international Codex Alimentarius and the US Pharmacopeia. Lecithin is not on the California Proposition 65 List. Analytical methods are available through the American Oil Chemists Society (AOCS) and can be referred to through the International Lecithin and Phospholipid Society at the ILPS.org website.

Genetically modified soybeans (GMO) are not regulated except through the NOP. Less than 10% of all soybeans are non-GMO today.

- **References**

B.F. Szuhaj, ed., *Lecithins: Sources, Manufacture and Uses*, (AOCS monograph), American Oil Chemists Society, Champaign, IL, 1989.

B.F. Szuhaj and G.R. List, eds., *Lecithins*, (AOCS monograph), American Oil Chemists Society, Champaign, IL, 1985.

B.F. Szuhaj and E.F. Sipos, in G. Charalambous and G. Doxastakis, ed., *Food Emulsifiers – Chemistry, Technology, Functional Properties and Applications*, Elsevier, Amsterdam, 1989.

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H. Wittcoff, ed., *The Phosphatides*, American Chemical Society Monograph Series, Reinhold Publishing Corp., New York, 1951.

Code of Federal Regulations, Title 21:172.814 (Food and Drugs), U.S. Government Printing Office, Washington, D.C., 1977.

National Soybean Processors' Association (NSPA), *Yearbook and Trading Rules (1976-1977)*, The Association, Washington, D.C., 1977.

un bleached Non

allowed

Attachment 2

NOSB NATIONAL LIST FILE CHECKLIST

bleached Syn

allowed 9
No 4

PROCESSING

MATERIAL NAME: Lecithin, Soy, Vegetable

CATEGORY: unknown

Complete?: 3/16

NOSB Database Form

References

MSDS (or equivalent)

FASP (FDA)

Date file mailed out: 2/14/95

TAP Reviews from: _____

Richard Thauer

Steve Harper

Supplemental Information:

un bleached

MISSING INFORMATION: no MSDS available

NOSB/NATIONAL LIST COMMENT FORM/BALLOT

Use this page to write down comments and questions regarding the data presented in the file of this National List material. Also record your planned opinion/vote to save time at the meeting on the National List.

Name of Material Lecithin, Soy

Type of Use: Crops; Livestock; Processing

TAP Review by:

1. Richard Theuer
2. Steve Harper
3. _____

Comments/Questions:

My Opinion/Vote is:

Signature _____ Date _____

USDA/TAP REVIEWER COMMENT FORM

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Attach additional sheets if you wish.

This file is due back to us within 30 days of: Feb 14

Name of Material: Lecithin (Vegetable)

Reviewer Name: Steven Harper

Is this substance Natural or Synthetic? Explain (if appropriate)

Naturally derived substance.

Please comment on the accuracy of the information in the file:

Accurate

This material should be added to the National List as:

Synthetic Allowed Prohibited Natural

or, This material does not belong on the National List because: Lecithin is a naturally derived substance found in soybean oil.

Are there any restrictions or limitations that should be placed on this material by use or application on the National List?

Chemically modified lecithins are synthetic substances and should not be allowed under this classifications. However, they fit in the synthetic allowed category.

Any additional comments or references?

There is certainly a chance that trace amounts of hexane can be found in lecithin. Optimally lecithin from cold pressed oils would be a preference in the organic industry. However, the quality of these lecithins has been very poor.

Signature Steven Harper

Date 3/10/95

2.

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date: 14 Feb 1995.

Material: Lecithin
Reviewer: Richard C. Theuer

NATURAL Lecithin is the substance isolated as a gum following hydration of solvent-extracted soy, safflower or corn oils. No chemical modification or structural alteration occurs in this process, so unbleached lecithin is natural.

SYNTHETIC Most commercial lecithins are bleached with hydrogen peroxide or benzoyl peroxide to improve color. In this reviewer's judgment, bleached lecithin is thus synthetic.

The remainder of this review will focus entirely on natural, unbleached lecithin.

COMMENTS RE SECTION 2119(m) CRITERIA:

1. Lecithin is removed from vegetable oils in a "degumming" step. Having end uses for his by-product of vegetable oil refining keeps this substance out of the waste stream and so supports sustainable agricultural production and processing.
2. Lecithin is Generally Recognized As Safe (GRAS) [21CFR184.1400].
3. Lecithin acts as an emulsifier; there are no limitations on its use other than good manufacturing practice.

The following natural substance should be allowed as an ingredient in organic foods. It should not be added to the National List of natural substances prohibited for use as ingredients or processing aids in Organic Food:

lecithin (natural, unbleached).

12 Mar 1995

Identification

Common Name	Lecithin, Soy	Chemical Name	
Other Names			
Code #: CAS		Code #: Other	
N. L. Category	unknown	MSDS	<input type="radio"/> yes <input type="radio"/> no

Chemistry

Family

Composition Complex mixture of alcohol-insoluble phosphatides. Found in all living organisms.

Properties Plastic to fluid consistency. Light yellow to brown with no odor or slightly nut-like odor and bland taste. Partially soluble in water but readily hydrates to form emulsions. Soluble in fatty acids but practically insoluble in fixed oils. Partially soluble in alcohol and practically insoluble in acetone.

How Made Extracted from soybeans and other plant sources. Soybeans are dried, flaked and the crude soybean oil is extracted almost universally with the use of hexane. Some expeller pressed oil is processed. The crude oil is filtered, hydrated, centrifuged, dried and cooled. Standardized lecithin is the fraction centrifuged. Some chemically modified lecithins are produced but are typically labeled as such. Most commercial lecithins are bleached with hydrogen peroxide or benzoyl peroxide to improve color.

Use/Action

Type of Use Processing

Specific Use(s) Emulsifier, Surface active agent, antioxidant, wetting agent, viscosity agent.

Action Lecithin owes its specific functional qualities to its amphiphilic chemical composition. The surface-active phospholipic molecules, which form the major constituent of lecithin, have both a hydrophobic (water repelling) and hydrophilic (water attracting) portion.

Combinations

Status

OFPA

N. L. Restriction

EPA, FDA, etc

Directions

Safety Guidelines

State Differences

Historical status

International status Allowed by IFOAM, EU and Codex.

NOSB Materials Database

4.

OFPA Criteria

2119(m)1: chemical interactions **Not Applicable**

2119(m)2: toxicity & persistence **Not Applicable**

2119(m)3: manufacture & disposal consequences

Lecithin is a by-product of making vegetable oils and as such is creating an end use which will keep this substance out of the waste stream.

2119(m)4: effect on human health

None that have been detected.

2119(m)5: agroecosystem biology **Not Applicable**

2119(m)6: alternatives to substance

Egg yolks, and other synthetic emulsifiers such as mono-di glycerides. None perform the same functions as well.

2119(m)7: Is it compatible?

It is compatible because of historic acceptance and the fact that it is a naturally derived substance. (SH).

References

AU: Claughton,-S.M.; Pearce,-R.J.

TI: Protein enrichment of sugar-snap cookies with sunflower protein isolate.

SO: J-Food-Sci-Off-Publ-Inst-Food-Technol. Chicago, Ill. : The Institute. Mar/Apr 1989. v. 54 (2)p. 354-356

CN: DNAL 389.8-F7322

AU: Bell,-J.M.; Slotkin,-T.A.

TI: Perinatal dietary supplementation with a commercial soy lecithin preparation: effects on behavior and brain biochemistry in the developing rat.

SO: Dev-Psychobiol. New York, N.Y. : John Wiley & Sons. Sept 1985. v. 18 (5) p. 383-394. ill.

CN: DNAL QP351.D4

AU: Bell,-J.M.; Lundberg,-P.K.

TI: Effects of a commercial soy lecithin preparation on development of sensorimotor behavior and brain biochemistry in the rat.

SO: Dev-Psychobiol. New York, N.Y. : John Wiley & Sons. Jan 1985. v. 18 (1) p. 59-66. ill.

CN: DNAL QP351.D4

AU: Hirotsuka,-M.; Taniguchi,-H.; Narita,-H.; Kito,-M.

TI: Increase in emulsification activity of soy lecithin-soy protein complex by ethanol and heat treatments.

SO: J-Food-Sci. Chicago, Ill. : Institute of Food Technologists. July/Aug 1984. v. 49 (4) p. 1105-1110. ill.

CN: DNAL 389.8-F7322

AU: Beane,-M

TI: Vitamin Q in soy lecithin

SO: Prevention, Apr 1974, 26 (4): 59-66.

CN: DNAL 449.8-P92

Boyd Foster, 1994, written communication. Arrowhead Mills, Texas

U.S. FOOD AND DRUG ADMINISTRATION
FOOD ADDITIVE SAFETY PROFILE

LECITHIN (VEGETABLE)

AS#: 977092242 HUMAN CONSUMPTION: MG/KG BW/DAY/PERSON
ASP#: 2285 MARKET DISAPPEARANCE: LBS/YR
TPE: NUL MARKET SURVEY: MG/KG BW/DAY/PERSON
AS#: JECFA: JECFA ADI: 1991
EMA#: JECFA ESTABLISHED: 1991
CAS#: LAST UPDATE:

V: DENSITY: LOGP:

STRUCTURE CATEGORIES: A06

COMPONENTS: 000141435 ETHANOAMINE

SYNONYMS:

CHEMICAL FUNCTION: G

TECHNICAL EFFECT: ANTI-OXIDANT
DRYING AGENT

FOR REG NUMBERS: 184.1400

MINIMUM TESTING LEVEL:

COMMENTS:

Attachment 3

FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)

Date: 11-11-06

Subject: **Sunset Renewal Vote for Lecithin, bleached under 205.605b synthetics allowed.**

Chair: **Kevin O'Rell**

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: XXX

Guidance Statement: _____

Other: _____

Statement of the Recommendation (including Recount of Vote):

The Board recommends renewing **Lecithin, bleached** 205.605b synthetics allowed.

NOSB Vote: **Motion:** Andrea Caroe **Second:** Bea James

Board vote: Yes - 11 No- 3 Abstain- 0 Absent - 0

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

Sunset Material Vote

Response by the NOP:

National Organic Standards Board

Final Recommendation for Lecithin, bleached

October 19, 2006

I. List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups.”

(b) Synthetics allowed

II. Committee Summary:

On April 20, 2006, as part of the Sunset Review process, the Board voted not to re-list bleached lecithin, based on public comment from the industry which indicated that the organic and non-synthetic forms of lecithin, bleached and unbleached could fulfill the same functions in an organic system. New detailed information was received during the last comment period from several manufacturers that use this as an ingredient. It has become clear that although there are plentiful non-synthetic and organic alternatives to synthetic bleached lecithin in liquid form, there is currently no such alternative for bleached lecithin in dry, de-oiled form,

It is the goal of this Board to encourage the development of new organic alternatives to conventional materials. The emergence in the last four years, of a variety of organic alternatives to bleached liquid lecithin is a clear example that the National List process is working as it was intended: to promote and not inhibit the development organic alternatives to conventional materials. It is the hope of the Board that in the coming years, we will be asked to consider increasing petitions for the removal from the National List of conventional materials for which organic alternatives have been made commercially available. Nevertheless, it is now clear that there is neither a non-synthetic, nor an organic alternative to dry, de-oiled synthetic lecithin.

It is not possible to re-new the dry form and not re-new the liquid form, because annotations cannot be entertained as part of the Sunset Review. Therefore, at this time we see no choice but to recommend that renewal of lecithin, bleached.

The Board strongly hopes that a petition will be presented in short order to restrict the use of bleached lecithin to dry forms, only.

III. Board Recommendation

The Board recommends renewing the following substance(s) in this use category:

Lecithin, bleached

Moved: Andrea Caroe

Seconded: Bea James

Board vote: Yes - 11

No- 3

Abstain- 0

Absent- 0

Attachment 4

Pesticides, List and MSDS references

The application of any pesticide approved for use on conventional soybeans is implicitly accepted in the organic supply chain with the approval of conventional “bleached lecithin” under 205.605. Since in making choices, it is good to consider the implicit consequences, petitioner has included a list of pesticides approved for use on soybeans in the “2008 Illinois Agricultural Pest Management Handbook.” The overall category of pesticides includes the subcategories of fungicides, insecticides and herbicides. The Handbook can be accessed on the web: **2008 Illinois Agricultural Pest Management Handbook**. School IPM Implementation in Illinois: www.ipm.uiuc.edu/

Listed fungicides include:

Apron - http://www.syngenta.ca/pdf/msds/Apron_XL_LS_25585_en_msds.pdf
Allegiance FL - <http://www.bayercropscience.ca/Products/Seed-Treatments/Allegiance/Labels-and-MSDS/MSDS.aspx>
Bravo - <http://www.cdms.net/LDat/mp26L002.pdf>
Contans WG - http://www.prophyta.de/englisch/pdf/Contans_Safty_Data_Sheet_English.pdf
Captan - [http://www.agrian.com/pdfs/Captan_400-C_Seed_Protectant_Aagricultural_Fungicide_\(04132006_Version_20\)_MSDS.pdf](http://www.agrian.com/pdfs/Captan_400-C_Seed_Protectant_Aagricultural_Fungicide_(04132006_Version_20)_MSDS.pdf)
Domark - <http://www.cdms.net/LDat/mp71J001.pdf>
Dynasty - <http://www.fluoridealert.org/pesticides/msds/fludioxonil.dynasty.pdf>
Headline - <http://www.cdms.net/LDat/mp62L043.pdf>
Maxim - <http://www.fluoridealert.org/pesticides/msds/fludioxonil.maxim.nz.pdf>
PCNB - http://www.american-vanguard.com/media/pdf/products/msds/pcnb_10g.pdf
Quadris - <http://www.cdms.net/LDat/mp5QN003.pdf>
Quilt - <http://www.cdms.net/LDat/mp6FR064.pdf>
SoyGard - [http://www.agrian.com/pdfs/Soygard_Fungicide_Containing_Protege_And_Allegiance_\(04072006_Version_20\)_MSDS.pdf](http://www.agrian.com/pdfs/Soygard_Fungicide_Containing_Protege_And_Allegiance_(04072006_Version_20)_MSDS.pdf)
Stratego - [http://www.agrian.com/pdfs/Stratego_Fungicide_\(03062003\)_MSDS.pdf](http://www.agrian.com/pdfs/Stratego_Fungicide_(03062003)_MSDS.pdf)
Trilex - <http://www.fluoridealert.org/pesticides/msds/Trifloxystrobin.trilex.pdf>
Tilt - <http://www.cdms.net/LDat/mp423011.pdf>
Topsin-M - <http://www.cdms.net/LDat/mp7CK006.pdf>
Tetraconazole - <http://www.fluoridealert.org/pesticides/tetraconazole.epa.2005.facts.pdf>
Topsin - <http://www.cdms.net/LDat/mp7CJ002.pdf>
Vitavax - [http://www.agrian.com/pdfs/Vitavax-34_\(05102006\)_MSDS.pdf](http://www.agrian.com/pdfs/Vitavax-34_(05102006)_MSDS.pdf)
Yield Shield - [http://www.bayercropscience.com/BAYER/CropScience/BCSUS.nsf/files/Gustafson%20Labels/\\$file/yield_shield.pdf](http://www.bayercropscience.com/BAYER/CropScience/BCSUS.nsf/files/Gustafson%20Labels/$file/yield_shield.pdf)

Listed insecticides include:

Ambush - <http://www.american-vanguard.com/media/pdf/products/msds/ambush25w.pdf>
Asana - <http://www.cdms.net/LDat/mp184021.pdf>
Baythroid - <http://www.cdms.net/LDat/mp7JO001.pdf>
Cobalt - <http://www.greenbook.net/Docs/Msds/M88661.pdf>
Lorsban 4E - <http://www.cdms.net/LDat/mp02A087.pdf>
Mustang Max - <http://www.cdms.net/LDat/mp67J001.pdf>
Pounce - <http://www.cdms.net/LDat/mp5KH001.pdf>
Proaxis - http://www.tenkoz.com/pdf/msds/Tenkoz_Proaxis_MSDS_051104.pdf
Warrior - <http://www.cdms.net/LDat/mp5JH037.pdf>

Listed herbicides include:

Authority First - http://msds.fmc.com/msds/100000014597-MSDS_US-E.pdf
Authority MTZ - http://msds.fmc.com/msds/100000014778-MSDS_US-E.pdf
Boundary - <http://www.fluoridealert.org/pesticides/msds/norflurazon.boundary.pdf>
Canopy EX - <http://www.cdms.net/LDat/mp6RG006.pdf>
Canopy - <http://www.cdms.net/LDat/mp803002.pdf>
Extreme - <http://www.cdms.net/LDat/mp3GR011.pdf>
Fusion - http://www.syngentacropprotection.com/pdf/msds/03_482310312005.pdf
Gangster V - <http://www.fluoridealert.org/pesticides/msds/flumioxazin.gangster.v.pdf>
Prefix - <http://www.cdms.net/LDat/mp8CB001.pdf>
Pursuit Plus - <http://www.cdms.net/LDat/mp859018.pdf>
Synchrony - <http://www.cdms.net/LDat/mp76U002.pdf>

Attachment 5

MSDS Number: **H2381** * * * * * *Effective Date: 07/05/07* * * * * * *Supersedes: 05/07/07*

MSDS

Material Safety Data Sheet

From: Mallinckrodt Baker, Inc.
222 Red School Lane
Phillipsburg, NJ 08865



24 Hour Emergency Telephone: 908-859-2151
CHEMTREC: 1-800-424-9300

National Response in Canada
CANUTEC: 613-996-6666

Outside U.S. and Canada
Chemtrec: 703-527-3887

NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals.

All non-emergency questions should be directed to Customer Service (1-800-582-2537) for assistance.

HEXANE

1. Product Identification

Synonyms: Hexanes, Normal Hexane; Hexyl Hydride; Hexane 95%

CAS No.: 110-54-3 (n-hexane)

Molecular Weight: 86.18

Chemical Formula: CH₃(CH₂)₄CH₃ n-hexane

Product Codes:

J.T. Baker: 9262, 9304, 9308, N168

Mallinckrodt: 5186

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Hexane	110-54-3	85 - 100%	Yes
Methylcyclopentane	96-37-7	1 - 2%	Yes
Trace amount of Benzene (10 ppm)	071-43-2	*	No

3. Hazards Identification

Emergency Overview

DANGER! EXTREMELY FLAMMABLE LIQUID AND VAPOR. VAPOR MAY CAUSE FLASH FIRE. HARMFUL OR FATAL IF SWALLOWED. HARMFUL IF INHALED. CAUSES IRRITATION TO SKIN, EYES AND RESPIRATORY TRACT. AFFECTS THE CENTRAL AND PERIPHERAL NERVOUS SYSTEMS.

SAF-T-DATA^(tm) Ratings (Provided here for your convenience)

Health Rating: 3 - Severe (Life)

Flammability Rating: 3 - Severe (Flammable)

Reactivity Rating: 1 - Slight

Contact Rating: 2 - Moderate

Lab Protective Equip: GOGGLES & SHIELD; LAB COAT & APRON; VENT HOOD; PROPER GLOVES;
CLASS B EXTINGUISHER

Storage Color Code: Red (Flammable)

Potential Health Effects

The health hazards addressed are for the major component: n-hexane.

Inhalation:

Inhalation of vapors irritates the respiratory tract. Overexposure may cause lightheadedness, nausea, headache, and blurred vision. Greater exposure may cause muscle weakness, numbness of the extremities, unconsciousness and death.

Ingestion:

May produce abdominal pain, nausea. Aspiration into lungs can produce severe lung damage and is a medical emergency. Other symptoms expected to parallel inhalation.

Skin Contact:

May cause redness, irritation, with dryness, cracking.

Eye Contact:

Vapors may cause irritation. Splashes may cause redness and pain.

Chronic Exposure:

Repeated or prolonged skin contact may defat the skin and produce irritation and dermatitis. Chronic inhalation may cause peripheral nerve disorders and central nervous system effects.

Aggravation of Pre-existing Conditions:

Persons with pre-existing skin disorders or eye problems or impaired respiratory function may be more susceptible to the effects of the substance. May affect the developing fetus.

4. First Aid Measures

Inhalation:

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

Ingestion:

Aspiration hazard. If swallowed, DO NOT INDUCE VOMITING. Give large quantities of water. Never give anything by mouth to an unconscious person. Get medical attention immediately.

Skin Contact:

Remove any contaminated clothing. Wipe off excess from skin. Wash skin with soap and water for at least 15 minutes. Get medical attention if irritation develops or persists.

Eye Contact:

Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.

Note to Physician:

BEI=2,5-hexadione in urine, sample at end of shift at workweeks end, 5 mg/g creatine. Also, measure n-hexane in expired air. Analgesics may be necessary for pain management, there is no specific antidote. Monitor arterial blood gases in cases of severe aspiration.

5. Fire Fighting Measures

Fire:

Flash point: -23C (-9F) CC

Autoignition temperature: 224C (435F)

Flammable limits in air % by volume:

l_{el}: 1.2; u_{el}: 7.7

Extremely Flammable Liquid and Vapor! Vapor may cause flash fire. Dangerous fire hazard when exposed to heat or flame.

Explosion:

Above flash point, vapor-air mixtures are explosive within flammable limits noted above. Contact with oxidizing materials may cause extremely violent combustion. Explodes when mixed @ 28C with dinitrogen tetraoxide. Sensitive to static discharge.

Fire Extinguishing Media:

Dry chemical, foam or carbon dioxide. Water may be ineffective.

Special Information:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode. Water spray may be used to keep fire exposed containers cool. Vapors can flow along surfaces to distant ignition source and flash back. Vapor explosion hazard exists indoors, outdoors, or in sewers.

6. Accidental Release Measures

Ventilate area of leak or spill. Remove all sources of ignition. Wear appropriate personal protective equipment as specified in Section 8. Isolate hazard area. Keep unnecessary and unprotected personnel from entering. Contain and recover liquid when possible. Use non-sparking tools and equipment. Collect liquid in an appropriate container or absorb with an inert material (e. g., vermiculite, dry sand, earth), and place in a chemical waste container. Do not use combustible materials, such as saw dust. Do not flush to sewer! If a leak or spill has not ignited, use water spray to disperse the vapors, to protect personnel attempting to stop leak, and to flush spills away from exposures. US Regulations (CERCLA) require reporting spills and releases to soil, water and air in excess of reportable quantities. The toll free number for the US Coast Guard National Response Center is (800) 424-8802.

J. T. Baker SOLUSORB® solvent adsorbent is recommended for spills of this product.

7. Handling and Storage

Protect against physical damage. Store in a cool, dry well-ventilated location, away from direct sunlight and any area where the fire hazard may be acute. Store in tightly closed containers (preferably under nitrogen atmosphere). Outside or detached storage is preferred. Inside storage should be in a standard flammable liquids storage room or cabinet. Separate from oxidizing materials. Containers should be bonded and grounded for

transfers to avoid static sparks. Storage and use areas should be No Smoking areas. Use non-sparking type tools and equipment. Containers of this material may be hazardous when empty since they retain product residues (vapors, liquid); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:

N-Hexane [110-54-3]:

-OSHA Permissible Exposure Limit (PEL): 500 ppm (TWA)

-ACGIH Threshold Limit Value (TLV): 50 ppm (TWA), Skin

other isomers of hexane

-ACGIH Threshold Limit Value (TLV): 500 ppm (TWA), 1000 ppm (STEL)

Ventilation System:

A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.

Personal Respirators (NIOSH Approved):

If the exposure limit is exceeded and engineering controls are not feasible, wear a supplied air, full-facepiece respirator, airlined hood, or full-facepiece self-contained breathing apparatus. Breathing air quality must meet the requirements of the OSHA respiratory protection standard (29CFR1910.134).

Skin Protection:

Wear impervious protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact.

Eye Protection:

Use chemical safety goggles and/or a full face shield where splashing is possible. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:

Clear, colorless liquid.

Odor:

Light odor.

Solubility:

Insoluble in water.

Specific Gravity:

0.66

pH:

No information found.

% Volatiles by volume @ 21C (70F):

100

Boiling Point:

ca. 68C (ca. 154F)

Melting Point:

ca. -95C (ca. -139F)

Vapor Density (Air=1):

3.0

Vapor Pressure (mm Hg):

130 @ 20C (68F)

Evaporation Rate (BuAc=1):

9

10. Stability and Reactivity

Stability:

Stable under ordinary conditions of use and storage. Heat will contribute to instability.

Hazardous Decomposition Products:

May produce acrid smoke and irritating fumes when heated to decomposition.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

Strong oxidizers.

Conditions to Avoid:

Heat, flames, ignition sources and incompatibles.

11. Toxicological Information

N-Hexane: Oral rat LD50: 28710 mg/kg. Irritation eye rabbit: 10 mg mild. Investigated as a tumorigen, mutagen and reproductive effector.

-----\Cancer Lists\-----

Ingredient	---NTP Carcinogen---		IARC Category
	Known	Anticipated	
Hexane (110-54-3)	No	No	None
Methylcyclopentane (96-37-7)	No	No	None
Trace amount of Benzene (10 ppm) (071-43-2)	Yes	No	1

12. Ecological Information

Environmental Fate:

When released into the soil, this material may biodegrade to a moderate extent. When released into the soil, this material is not expected to leach into groundwater. When released into the soil, this material is expected to quickly evaporate. When released into water, this material may biodegrade to a moderate extent. When released to water, this material is expected to quickly evaporate. When released into the water, this material is expected to have a half-life between 1 and 10 days. This material has an estimated bioconcentration factor (BCF) of less than 100. This material has a log octanol-water partition coefficient of greater than 3.0. This material is not expected to significantly bioaccumulate. When released into the air, this material is expected to be readily degraded by reaction with photochemically produced hydroxyl radicals. When released into the air, this material is expected to have a half-life between 1 and 10 days.

Environmental Toxicity:

No information found.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be handled as hazardous waste and sent to a RCRA approved incinerator or disposed in a RCRA approved waste facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Domestic (Land, D.O.T.)

Proper Shipping Name: HEXANES
Hazard Class: 3
UN/NA: UN1208
Packing Group: II
Information reported for product/size: 215L

International (Water, I.M.O.)

Proper Shipping Name: HEXANES
Hazard Class: 3
UN/NA: UN1208
Packing Group: II
Information reported for product/size: 215L

15. Regulatory Information

-----\Chemical Inventory Status - Part 1\-----

Ingredient	TSCA	EC	Japan	Australia
Hexane (110-54-3)	Yes	Yes	Yes	Yes
Methylcyclopentane (96-37-7)	Yes	Yes	No	Yes
Trace amount of Benzene (10 ppm) (071-43-2)	Yes	Yes	Yes	Yes

-----\Chemical Inventory Status - Part 2\-----

Ingredient	Korea	--Canada--		
		DSL	NDSL	Phil.
Hexane (110-54-3)	Yes	Yes	No	Yes
Methylcyclopentane (96-37-7)	Yes	Yes	No	Yes
Trace amount of Benzene (10 ppm) (071-43-2)	Yes	Yes	No	Yes

-----\Federal, State & International Regulations - Part 1\-----

Ingredient	-SARA 302-		-----SARA 313-----	
	RQ	TPQ	List	Chemical Catg.
Hexane (110-54-3)	No	No	Yes	No
Methylcyclopentane (96-37-7)	No	No	No	No
Trace amount of Benzene (10 ppm) (071-43-2)	No	No	Yes	No

-----\Federal, State & International Regulations - Part 2\-----

Ingredient	CERCLA	-RCRA-	-TSCA-
		261.33	8 (d)

Hexane (110-54-3)	5000	No	No
Methylcyclopentane (96-37-7)	No	No	No
Trace amount of Benzene (10 ppm) (071-43-2)	10	U019	No

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
 SARA 311/312: Acute: Yes Chronic: Yes Fire: Yes Pressure: No
 Reactivity: No (Mixture / Liquid)

WARNING:
 THIS PRODUCT CONTAINS A CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER.

Australian Hazchem Code: 3[Y]E

Poison Schedule: None allocated.

WHMIS:

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings: Health: 1 Flammability: 3 Reactivity: 0

Label Hazard Warning:

DANGER! EXTREMELY FLAMMABLE LIQUID AND VAPOR. VAPOR MAY CAUSE FLASH FIRE. HARMFUL OR FATAL IF SWALLOWED. HARMFUL IF INHALED. CAUSES IRRITATION TO SKIN, EYES AND RESPIRATORY TRACT. AFFECTS THE CENTRAL AND PERIPHERAL NERVOUS SYSTEMS.

Label Precautions:

- Keep away from heat, sparks and flame.
- Keep container closed.
- Use only with adequate ventilation.
- Wash thoroughly after handling.
- Avoid breathing vapor or mist.
- Avoid contact with eyes, skin and clothing.

Label First Aid:

Aspiration hazard. If swallowed, vomiting may occur spontaneously, but DO NOT INDUCE. If vomiting occurs, keep head below hips to prevent aspiration into lungs. Never give anything by mouth to an unconscious person. Call a physician immediately. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. In all cases call a physician.

Product Use:

Laboratory Reagent.

Revision Information:

MSDS Section(s) changed since last revision of document include: 3.

Disclaimer:

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Prepared by: Environmental Health & Safety
Phone Number: (314) 654-1600 (U.S.A.)

Attachment 6

Canadian Draft Rule on “Bleached Lecithin”

The Canadian Organic Regime – “bleached lecithin”: The Canadian Rule as drafted states that “bleached lecithin” can be used if it is made from otherwise organic lecithin. Copies of the standards (general production standards and permitted substances list) and the "Organic Products Regulations" are all available on the OTA website at: <http://www.ota.com/standards/canadian.html> and the permitted substances list, which is where lecithin is found, can be downloaded directly at: http://www.pwgsc.gc.ca/cgsb/on_the_net/organic/032_0311_2006-e.pdf

Please see next page, highlight by petitioner.

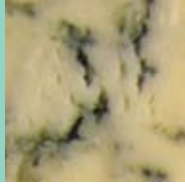
6.3 **Organic Ingredients**

Common Name(s)	Origin and Usage
Alcohol, ethyl (ethanol)	Alcohol used as an ingredient shall be from an organic source.
Vegetable extracts	Shall be obtained from organic sources without the use of synthetic solvents.

6.4 **Non-organic Ingredients**

6.4.1 *Food Additives*

Common Name(s)	Origin and Usage
Acids	Including a) alginic, b) citric — produced by microbial fermentation of carbohydrate substances, and c) lactic.
Agar	Water extracts only, for livestock and bee products.
Alginates (alginic acid, sodium alginate, potassium alginate)	
Ammonium bicarbonate	For use as a leavening agent only.
Ammonium carbonate	For use as a leavening agent only.
Ascorbic acid, non-synthetic	
Ascorbic acid, synthetic	Synthetic form is allowed in fruits and vegetables only if the natural form is not available.
Calcium carbonate	For milk products. Prohibited as a colouring or anti-caking agent.
Calcium chloride	Not allowed as a food additive in any (standardized) milk products.
Calcium citrate	
Calcium phosphates (monobasic, dibasic, and tribasic forms)	
Carageenan	
Carbon dioxide	For controlled atmosphere storage.
Citric acid	From fruit and vegetable products.
Ferrous sulphate	For iron enrichment or fortification of products when recommended or required by regulation. Sulphates produced using sulphuric acid are prohibited.
Glycerides (mono and diglycerides)	For use only in drum drying of products. Organisms from genetic engineering are excluded. Documentation is required. Shall be produced from organic sources unless not commercially available.
Glycerine	Shall be produced by hydrolysis of natural (vegetable or animal) fats and oils.
Gums	Water-extracted only (includes arabic, guar, karaya, tragacanth, locust bean and carob bean). For milk products: fat, confectionery, canned meat and egg products. For canned meat: gelatine, agar and carrageen.
Kelp and kelp products	For use only as a thickener and dietary supplement.
Lactic acid	For fermented vegetable products or in sausage casings.
Lecithin	Bleached form is allowed when unbleached form is not suitable. From organic sources only.
Magnesium chloride (nigari)	Derived from seawater, for soybean products.



Excerpt from Soil Association Certification Limited Certification News Spring 2008

Organic food additives, including carriers

We understand that consumers expect organic products to contain the highest proportion of organic ingredients possible and believe that organic ingredients should always be used if available. Following a review of the list of approved additives in the Soil Association organic standards, our internal standards development team decided that additives from natural sources must be organic by 2009 or 2013 (these are listed below):

2009

- E410 Locust bean gum
- E412 Guar gum
- E414 Arabic gum
- E422 Glycerol
- E440a Pectin
- E300 Ascorbic acid
- E301 Sodium ascorbate
- E322 Lecithins
- E325 Sodium lactate
- E330 Citric acid
- E331 Sodium citrate
- E333 Calcium citrates
- E407 Carrageenan

2013

- E415 Xanthan gum
- E334 Tartaric acid (L(+)-)
- E306 Tocopherol rich extract (Vitamin E)
- E270 Lactic acid

To develop the markets for these products, we urge users, manufacturers and suppliers of any of the ingredients listed to contact James Kightley in our business development team. James is working hard to build links between suppliers and end users in order to resolve as many supply issues as possible. So please do get in contact at jkightley@soilassociation.org or 0117 914 2432.