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Monday, August 4, 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 "fluid lecithin" from the general category of "Lecithin – unbleached" from National List

Dear Mr. Pooler:

Please accept the attached petition to remove "fluid lecithin" from the general category of "Lecithin - unbleached" included on the list of non-organically produced agricultural products allowed as ingredients under 7 CFR 205.606. I request review at the earliest opportunity. I respectfully request that this petition be expedited as it is a "petition to remove" a material from the National List.

"Lecithin – unbleached," a category that includes fluid lecithin, was placed on the original National List apparently without a TAP review. It was retained on the National List during a Sunset Review in October 2006 with statements by the NOSB referring to liquid or fluid forms as well as de-oiled forms of lecithin. 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 fluid forms of 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 two copies of the petition to remove "fluid lecithin" from the general category of "Lecithin – unbleached" from the National List. The first copy contains Confidential Business Information (CBI) that is not publicly available and must remain confidential for competitive reasons. The second copy is a facsimile of the first copy, except the CBI has been deleted. Each of the attached documents includes the following:

- A. Petition to remove "fluid lecithin" from the general category of "Lecithin – unbleached" from the National List (7 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 205.606, list and MSDS (1 page)
- 5) Hexane, MSDS (8 pages)
- 6) Acetone MSDS (7 pages)
- 7) Canadian Rule (2 pages)
- 8) The Soil Association Policy (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: Valerie Francis, Executive Director, NOSB
Barbara Robinson, Director, National Organic Program (hard copy by USPS)

**Petition to the USDA National Organic Standards Board to Remove
“Fluid Lecithin” from the general category of
“Lecithin-unbleached” from the National List**

Item A

This is a petition to remove “Fluid Lecithin” from the general category of “Lecithin - unbleached” appearing in Section 205.606 of the National List of non-organically produced agricultural products allowed as ingredients in or on processed products labeled as “organic”.

Item B

- 1) **Substance Name:** Fluid Lecithin
- 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 fluid lecithin and organic lecithin bleached.

- 3) **Current Use of the Substance:** Fluid lecithin is used as an emulsifier, a release agent and an instantizing agent in products ranging from foods to personal care items to supplements. A more complete list of applications is provided in the attached Lecithin Fact Sheet. Please see Attachment 1.
- 4) **Mode of Action:** Organic fluid lecithin is identical in functionality to non-organic fluid lecithin. It is an emulsifier and 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 their oil. “Lecithin – unbleached” as listed in 205.606 is processed from non-organic soybeans, generally using hexane to extract the oil. A second step is used to extract the lecithin from the oil. See Attachment 1, Lecithin Fact Sheet, for diagrams and descriptions of non-organic and organic production systems. To produce de-oiled lecithin, a third step is added during which fluid lecithin is treated with acetone to remove most of the residual oil. That de-oiled lecithin is then physically processed into either powdered or granular forms. See Attachment 4 regarding pesticides used on non-organic soybeans, Attachment 5 regarding hexane used to extract oil and Attachment 6 regarding acetone used to de-oil lecithin.
- 6) **Reviews:** I find no TAP review focused on “lecithin – unbleached.” A 1995 TAP review reference focused on “bleached lecithin.” A 2006 Sunset Review of “bleached lecithin” under 205.605(b) mentioned liquid or fluid lecithin and “bleached lecithin” and “de-oiled” lecithin.

- ❑ **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 non-organic bleached lecithin as a permitted synthetic under 205.605(b). 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 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. Since that time, bleached organic fluid lecithin has become available. Please see Attachment 3.
- 7) **EPA, FDA and State Regulatory Agency Registrations:**
- GRAS Status under 21 CFR 184.1400
 - The California Proposition 65 list does NOT include lecithin
- 8) **CAS Number:** 8002-43-5
- 9) **Physical Properties and Chemical Mode of Action:** Not applicable/Petition to remove from the list
- 10) **Safety Information:** Not applicable/Petition to remove from the list
- 11) **Research Information:** In developing this petition, petitioner has 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 worlds’ leading experts on lecithin and phospholipids. We have attached a Lecithin Fact Sheet compiled by Dr. Szuhaj. 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 information.
 - ❑ Wolf, DiMatteo + Associates as a source of information on organic rules and regulations.
 - ❑ Information as to current world market demand for lecithin – information claimed as confidential business information and presented in paragraph 13 on page 6.
 - ❑ Discussions with processors using organic lecithin in certified organic foods and others using non-organic lecithin in certified organic foods – sometimes in virtually identical products.
 - ❑ Discussions with two other suppliers of organic lecithin, one in France and another in India.

Science notes: All lecithins start their commercial lives as fluid lecithin. Much is used in fluid form. Some is de-oiled to provide either a powdered or granular form. The functionality of de-oiled lecithin is identical to that of fluid lecithin. However, by removing much of the oil, de-oiled lecithin offers a much higher concentration of phospholipids and a “dry” product that is much more convenient for manufacturers to use in certain applications. De-oiled lecithin is not available in organic form at this time but could be made from organic lecithin rather than from

non-organic lecithin with a consequent reduction in the use of non-organic soybeans, synthetic pesticides, synthetic fertilizers and volatile synthetic solvents.

Rule note: Standard fluid lecithin is a processed agricultural product appropriately regulated under NOP §205.606. Since de-oiling makes no chemical change to the lecithin, de-oiled lecithin should also be regulated under 205.606.

Treatment 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. Their organic rules go into effect in December 2008. As drafted, the Canadian rules approve the use of “bleached lecithin” only if essential and then only if made from otherwise organic lecithin. The very same reasoning could apply to de-oiled lecithin – if you have to have it, you have to start with organic lecithin. That policy supports the organic farmer and the organic consumer while addressing the needs of manufacturers seeking de-oiled lecithin. Petitioner requests that the NOSB take a similar policy with respect to de-oiled lecithin. See Attachment 7 for a reference to the Canadian rules.
- ❑ **The Soil Association – effective January 1, 2009:** The Soil Association is the leader in organic certification in the UK and is well respected by other organic associations around the world. The Soil Association has noted the evolution of organic ingredients and the importance of maintaining organic integrity. Starting January 1, 2009, the Soil Association will require all certified organic products using lecithin to use organic lecithin. See Attachment 8 excerpt from the Soil Association’s Certifier Newsletter of June 2008.

12) **Petition Justification Statement** for the Removal of a Non-Organically Produced Agricultural Substance from the National List, §205.606:

Petitioner requests that “fluid lecithin” be removed from the general category of “lecithin – unbleached” on 205.606. It is no longer needed on the National List because certified organic unbleached lecithin is now available in adequate commercial quantities and in the forms and with the functional properties to meet the organic industry’s needs.

The non-organic lecithin still being used in organic products is now made using non-organic soybeans treated with conventional pesticides and processed using hexane. Eliminating the use of non-organic fluid lecithin would eliminate the use of non-organic soybeans, associated toxic pesticides and hexane from the organic supply chain. It would completely support the organic farmer, support the organic consumer and still support the organic manufacturer needing a fluid lecithin. The suggested change would improve the clarity of 205.606 and make it easier for certifiers to apply and enforce. It would also remove much of the incentive for finding ways to continue using non-organic lecithin in organic products.

Organic alternatives to non-organic fluid lecithin

100% organic fluid lecithin is commercially available. Since 2004, process capacity needed to supply organic fluid lecithin has expanded 10 fold. The original food grade lecithin has been joined by a low biological count lecithin for use in personal care products. Customized viscosities have been introduced to meet varying client needs. The production of organic soybeans worldwide has continued to grow to the point that it far exceeds the volume needed to supply the world’s needs for organic lecithin.

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. The 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:** When the National List was drafted, there were no suppliers of organic lecithin and inadequate supplies of organic soybeans from which to make organic lecithin. Since then, the situation has changed significantly as indicated below:
 - **Organic lecithin supplies:** Several companies now 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 yet aware. New suppliers are expected to enter the market as the organic industry matures, organic 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 organic lecithin to produce hundreds of millions of pounds of organic foods and products. Following a major plant expansion in 2007, its plant is operating at 1/10th its production capacity.
 - **Organic soybean supplies – more than adequate:** While lecithin can be extracted from various oilseeds and a few animal sources, soybeans are the primary raw material used in making lecithin. US domestic producers now grow several times more organic soybeans than necessary to meet lecithin demand. International production of organic soybeans far exceeds that of the US and that needed to supply the world's demand for organic lecithin. In case of weather challenges in the US, imports of organic soybeans are available in quantities far larger than needed to meet the entire world demand for organic lecithin. With the growing development of allied organic markets for dairy, poultry, fish and meat products, there is strong demand for everything milled from the organic soybean – meal, oil and fiber. That combination of demand and supply provides a reliable opportunity to extract sufficient organic lecithin with nothing left for disposal.
 - **Regions of production:** Certified organic soybeans are now produced throughout the US, in much of Canada, parts of Mexico, across northern China, in India, Australia, Eastern and Western Europe, Brazil, Paraguay, Bolivia, Uruguay and Argentina.
 - **Numbers of suppliers and amount produced:** Thousands of organic farms and farmers now produce tens of millions of bushels of certified organic soybeans.
 - **Production threats:** Agricultural production is always subject to weather challenges. The scope and geographic diversity of today's production of organic soybeans protect the supply and greatly insulate it from regional or local disasters.
 - **Trade related issues that might temporarily restrict supply:** The production of organic soybeans is geographically diverse and sufficiently small in relation to national food security issues that there have been very few disruptions to international trade. Few if any are expected. Much of the

world's production of organic soybeans is located in countries that lack significant domestic demand for organic soybeans, countries such as Argentina, Paraguay, Bolivia, Brazil and China. Even during Argentina's farmers' strike and internal disputes over tax policy, organic soybeans continued to move into international commerce. The Chinese government actively encourages the development of organic farm production focused on international markets.

CBI Deleted

Petition to remove "fluid lecithin" from 205.606

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Conclusion

Removing non-organic unbleached fluid lecithin from §205.606 and from the organic supply chain will

- Support organic farmers and processors, encouraging the expansion of organic acreage and organic processing capacity.
- Reduce the use of synthetic fertilizers and pesticides in producing soybeans and the use of hexane in processing soybeans thereby protecting the environment, the farmer and the consumer.
- Create a level playing field and remove unfair competition for manufacturers using organic lecithin in processed products certified as organic.
- Help create more uniform certification decisions by NOP accredited certification agencies.
- Encourage expanded use of organic lecithin and the development of other organic ingredients.
- Encourage manufacturers to make their products more “fully” organic by stimulating demand for organic minor ingredients.

Per Federal Register Notice, the following information must be provided for removing "fluid lecithin" from the general category of "Lecithin – unbleached" from the National List:

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

Submitting petitions for §205.606: "... For petitions to remove a non-organic substance from §205.606, the petitioner must state why the substance should be prohibited from use in a non-organic form. Any information acquired since the original petition to add the substance to the National List should be provided."

Petitioner submits that sufficient proof has been presented to meet the standards required to remove non-organic fluid lecithin from the general category of "Lecithin – unbleached" from the National List. Therefore Petitioner respectfully requests that the National Organic Standards Board vote for the removal of "fluid lecithin" from the general category of "Lecithin – unbleached" from the National List.

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"; "**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. Acetone MSDS
7. Canadian Rule
8. 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

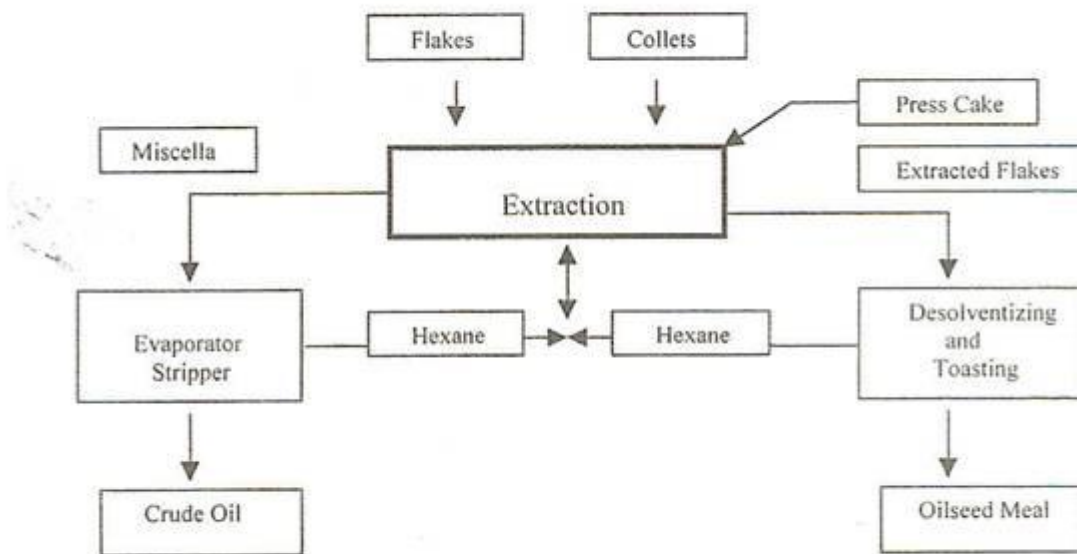


Figure 1

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.

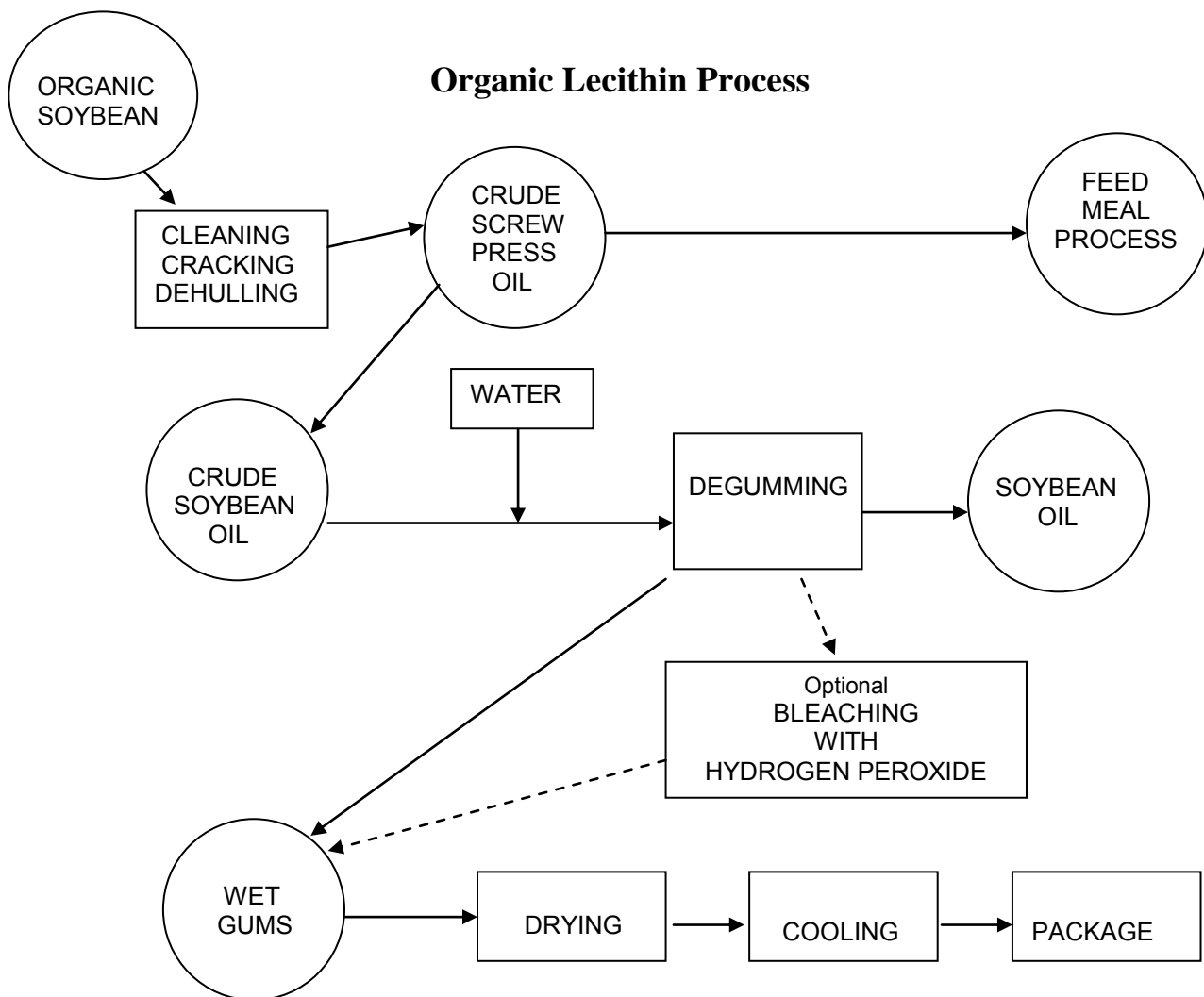


Figure 2

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.

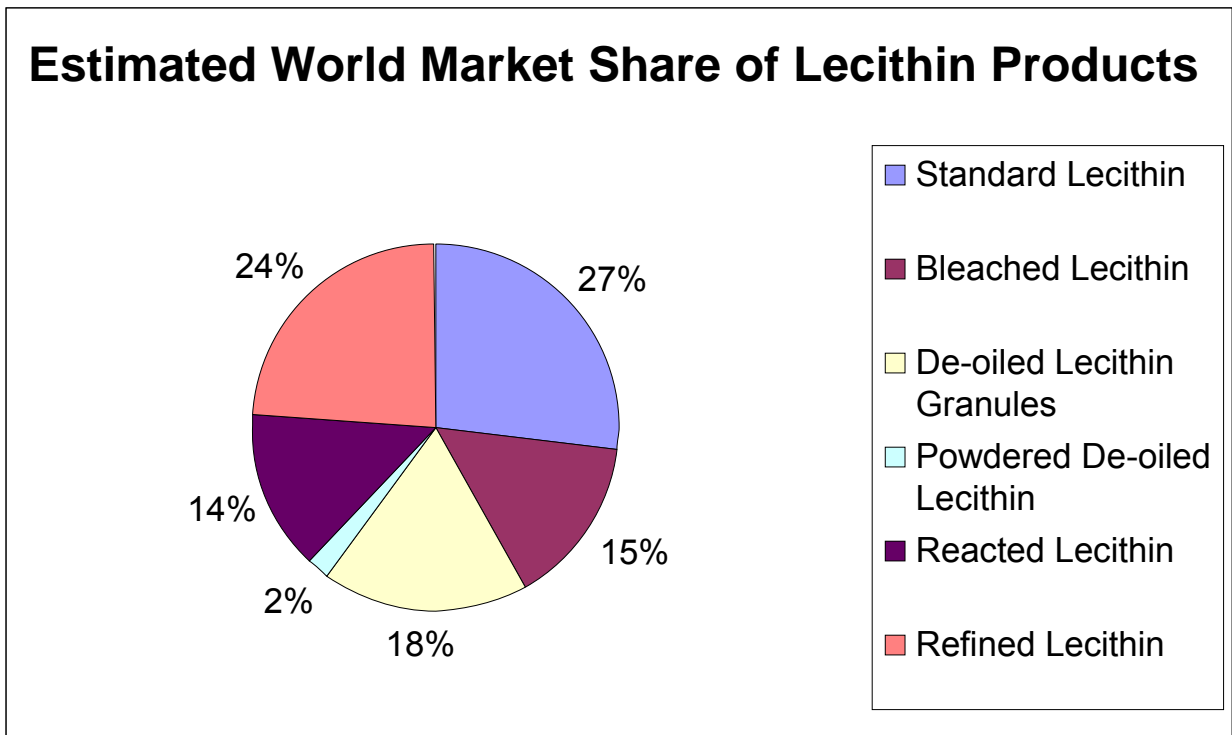


Figure 3

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.

B.F. Szuhaj in Y.H. Hui, ed., *Bailey's Industrial Oil & Fat Products, Fifth Ed.*, John Wiley & Sons, Inc. New York, New York, 1996.

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

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:
AS#: JECFA:
EMA#: JECFA ADI: MG/KG BW/DAY/PERSON
CAS#: JECFA ESTABLISHED: 1991
LAST UPDATE:

V: DENSITY: LOGP:

STRUCTURE CATEGORIES: A06

COMPONENTS: 000141435 ETHANOAMINE

NONYMS:

CHEMICAL FUNCTION: G

TECHNICAL EFFECT: ANTI-OXIDANT
DRYING AGENT

FR 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 “unbleached lecithin” under 205.606. 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:

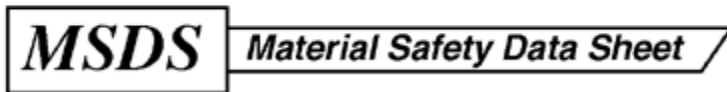
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Prepared by: Environmental Health & Safety
Phone Number: (314) 654-1600 (U.S.A.)

Attachment 6

MSDS Number: **A0446** * * * * * *Effective Date: 02/01/07* * * * * * *Supercedes: 05/20/04*



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.

ACETONE

1. Product Identification

Synonyms: Dimethylketone; 2-propanone; dimethylketal

CAS No.: 67-64-1

Molecular Weight: 58.08

Chemical Formula: (CH₃)₂CO

Product Codes:

J.T. Baker: 5008, 5018, 5356, 5580, 5965, 5975, 9001, 9002, 9003, 9004, 9005, 9006, 9007, 9008, 9009, 9010, 9015, 9024, 9036, 9125, 9254, 9271, A134, V655

Mallinckrodt: 0018, 2432, 2435, 2437, 2438, 2440, 2443, 2850, H451, H580, H981

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Acetone	67-64-1	99 - 100%	Yes

3. Hazards Identification

Emergency Overview

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

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

Health Rating: 2 - Moderate

Flammability Rating: 3 - Severe (Flammable)

Reactivity Rating: 0 - None

Contact Rating: 3 - Severe

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

Storage Color Code: Red (Flammable)

Potential Health Effects

Inhalation:

Inhalation of vapors irritates the respiratory tract. May cause coughing, dizziness, dullness, and headache. Higher concentrations can produce central nervous system depression, narcosis, and unconsciousness.

Ingestion:

Swallowing small amounts is not likely to produce harmful effects. Ingestion of larger amounts may produce abdominal pain, nausea and vomiting. Aspiration into lungs can produce severe lung damage and is a medical emergency. Other symptoms are expected to parallel inhalation.

Skin Contact:

Irritating due to defatting action on skin. Causes redness, pain, drying and cracking of the skin.

Eye Contact:

Vapors are irritating to the eyes. Splashes may cause severe irritation, with stinging, tearing, redness and pain.

Chronic Exposure:

Prolonged or repeated skin contact may produce severe irritation or dermatitis.

Aggravation of Pre-existing Conditions:

Use of alcoholic beverages enhances toxic effects. Exposure may increase the toxic potential of chlorinated hydrocarbons, such as chloroform, trichloroethane.

4. First Aid Measures

Inhalation:

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

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.

Skin Contact:

Immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eye Contact:

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

5. Fire Fighting Measures

Fire:

Flash point: -20C (-4F) CC

Autoignition temperature: 465C (869F)

Flammable limits in air % by volume:

lel: 2.5; uel: 12.8

Extremely Flammable Liquid and Vapor! Vapor may cause flash fire.

Explosion:

Above flash point, vapor-air mixtures are explosive within flammable limits noted above. Vapors can flow along surfaces to distant ignition source and flash back. Contact with strong oxidizers may cause fire. Sealed containers may rupture when heated. This material may produce a floating fire hazard. Sensitive to static discharge.

Fire Extinguishing Media:

Dry chemical, alcohol foam or carbon dioxide. Water may be ineffective. Water spray may be used to keep fire exposed containers cool, dilute spills to nonflammable mixtures, protect personnel attempting to stop leak and disperse vapors.

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.

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 any area where the fire hazard may be acute. Outside or detached storage is preferred. Separate from incompatibles. 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, including explosion proof ventilation. 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:

Acetone:

-OSHA Permissible Exposure Limit (PEL):
1000 ppm (TWA)

-ACGIH Threshold Limit Value (TLV):
500 ppm (TWA), 750 ppm (STEL) A4 - not classifiable as a human carcinogen

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, a half-face organic vapor respirator may be worn for up to ten times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest. A full-face piece organic vapor respirator may be worn up to 50 times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest. For emergencies or instances where the exposure levels are not known, use a full-face piece positive-pressure, air-supplied respirator. **WARNING:** Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

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, volatile liquid.

Odor:

Fragrant, mint-like

Solubility:

Miscible in all proportions in water.

Specific Gravity:

0.79 @ 20C/4C

pH:

No information found.

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

100

Boiling Point:

56.5C (133F) @ 760 mm Hg

Melting Point:

-95C (-139F)

Vapor Density (Air=1):

2.0

Vapor Pressure (mm Hg):

400 @ 39.5C (104F)

Evaporation Rate (BuAc=1):

ca. 7.7

10. Stability and Reactivity

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

Carbon dioxide and carbon monoxide may form when heated to decomposition.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

Concentrated nitric and sulfuric acid mixtures, oxidizing materials, chloroform, alkalis, chlorine compounds, acids, potassium t-butoxide.

Conditions to Avoid:

Heat, flames, ignition sources and incompatibles.

11. Toxicological Information

Oral rat LD50: 5800 mg/kg; Inhalation rat LC50: 50,100mg/m³; Irritation eye rabbit, Standard Draize, 20 mg severe; investigated as a tumorigen, mutagen, reproductive effector.

-----\Cancer Lists\-----			
Ingredient	---NTP Carcinogen---		IARC Category
	Known	Anticipated	
Acetone (67-64-1)	No	No	None

12. Ecological Information

Environmental Fate:

When released into the soil, this material is expected to readily biodegrade. When released into the soil, this material is expected to leach into groundwater. When released into the soil, this material is expected to quickly evaporate. When released into water, this material is expected to readily biodegrade. When released to water, this material is expected to quickly evaporate. This material has a log octanol-water partition coefficient of less than 3.0. This material is not expected to significantly bioaccumulate. When released into the air, this material may be moderately degraded by reaction with photochemically produced hydroxyl radicals. When released into the air, this material may be moderately degraded by photolysis. When released into the air, this material is expected to be readily removed from the atmosphere by wet deposition.

Environmental Toxicity:

This material is not expected to be toxic to aquatic life. The LC50/96-hour values for fish are over 100 mg/l.

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: ACETONE
Hazard Class: 3
UN/NA: UN1090
Packing Group: II
Information reported for product/size: 188L

International (Water, I.M.O.)

Proper Shipping Name: ACETONE
Hazard Class: 3
UN/NA: UN1090
Packing Group: II
Information reported for product/size: 188L

15. Regulatory Information

-----\Chemical Inventory Status - Part 1\-----
Ingredient TSCA EC Japan Australia

Acetone (67-64-1) Yes Yes Yes Yes

-----\Chemical Inventory Status - Part 2\-----
Ingredient Korea DSL NDSL Phil.

Acetone (67-64-1) Yes Yes No Yes

-----\Federal, State & International Regulations - Part 1\-----
Ingredient -SARA 302- -SARA 313-----
RQ TPQ List Chemical Catg.

Acetone (67-64-1) No No Yes No

-----\Federal, State & International Regulations - Part 2\-----
Ingredient CERCLA -RCRA- -TSCA-
261.33 8 (d)

Acetone (67-64-1) 5000 U002 No

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

Australian Hazchem Code: 2[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 IF SWALLOWED OR INHALED. CAUSES IRRITATION TO SKIN, EYES AND RESPIRATORY TRACT. AFFECTS CENTRAL NERVOUS SYSTEM.

Label Precautions:

Keep away from heat, sparks and flame.

Keep container closed.

Use only with adequate ventilation.

Wash thoroughly after handling.

Avoid breathing vapor.

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. Remove contaminated clothing and shoes. Wash clothing before reuse. In all cases, get medical attention.

Product Use:

Laboratory Reagent.

Revision Information:

No Changes.

Disclaimer:

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Prepared by: Environmental Health & Safety

Phone Number: (314) 654-1600 (U.S.A.)

Attachment 7

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.

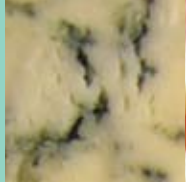
6.3 **Organic Ingredients**

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.