

KAOLIN PECTIN Livestock

Executive Summary

Kaolin pectin is an adsorbent, anti-diarrheal, and gut protectant used in both humans and livestock. It may be combined with vitamin A to treat bacterial diarrhea in calves.

The subject of the current petition is a request for the approval of kaolin pectin to the National List for medical use in organic livestock. Both kaolin and pectin are considered GRAS as indirect and direct food additives respectively, as consistent with good manufacturing practices. Kaolin has also been approved for use in cosmetics and anorectal drugs, and both kaolin and pectin separately are approved by the EPA as inert additives in pesticides.

Summary of TAP Reviewers' Analyses¹

<i>Synthetic/ Nonsynthetic</i>	<i>Allow without restrictions?</i>	<i>Allow only with restrictions? (See Reviewers' comments for restrictions)</i>
Synthetic (1) Nonsynthetic (2)	Yes (2) No (1)	Yes (1)

Identification

Chemical names:

Kaolin: Hydrated aluminum silicate, $Al_2O_3 \cdot 2SiO_n \cdot 2H_2O$

Pectin: (same name)

Other Names:

Kaolin Pectin: Donnagel-MB; K-P; Kao-Spen; Kaopectate, Kapectolin²

Kaolin: Argilla; Bolus alba; China clay; *Also*: AA Kaolin ASP (mineral); ASP Ultrafine; Acidic white clays; Airflo V 8; Alfaplate; Alphacoat; Alphagloss; Altowhite; Altowhites; Amazon 88; Amazon 90; Amazon Kaolin 855D; Apsilex; Arcilla blanca; Argiflex; Argilla; Argilla alba; Argirec B 22; Argirec KN 15; Astra-Glaze; BOL Blanc; Bentone; Bilt Plate 156; Burgess 10 CB 1 (clay); CB 2 (clay); Century HC; Clay 347; Clays, white, acidic; Comalco; Comalco Kaolin; Electros; Emathlite; Fitrol; Fitrol desiccite 25; Glomax; Hydrite; Kao-gel Kaolin; Kaolin colloidal; Kaopaous; Kaophills-2; Langford; Light kaolin; Mcnamee; Osmo kaolin; Parclay; Porcelain clay; Snow tex; Vanclay; White bole; beta Coat.³

¹ This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator's ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(M) of the OFPA [7 USC 6517(m)]. The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and does not incorporate commercial availability, socio-economic impact, or other factors that the NOSB and the USDA may want to consider in making decisions.

² Found at: <http://www.drugs.com> under brand names for kaolin pectin.

³ Found at: <http://chem.sis.nlm.nih.gov/>

Pectin: Amforol (Veterinary), Citrus pectin, Colyer pectin, Genu Pectin L 200, Marpee NL, Marpee OM, Methoxypectin, Methyl pectin, Methyl pectinate, Mexpectin, Pectinate, Pectinic acid⁴

CAS Number:

Kaolin: 1332-58-7

Pectin: 9000-69-5

Other numbers:

VA Classification: PrimaryGA208⁵

Kaolin: ACX #X1000224-1

EEC Code 559⁶

ICSC #1144

HSDB #630

INS #948

RTECS # GF1670500

Pectin: CCRIS #3935

EEC Code E440⁷

EINECS #232-553-0

HSDB #1917

INS #440

Characterization

Composition:

Kaolin is a natural hydrated aluminum silicate. It is approximately 47% silica, 40% alumina, and 13% water.⁸ There are five principal species within the kaolin (sometimes called kandite) group: kaolinite, dickite, nacrite, halloysite, and metahalloysite. Minerals in the kaolin group are characterized by a 1:1 tetrahedral : octahedral structure. These are dioctahedral minerals.

Pectin is a polyuronic polymer.⁹ It consists of high-molecular-weight polysaccharides, and it consists mainly of the partial methyl esters of polygalacturonic acid and their sodium, potassium, calcium and ammonium salts. Pectin may naturally contain acetate or other ester groups.¹⁰ It is present in the cell walls of all plants, where it serves to cement the cell walls together.¹¹

Properties:

Kaolin:

⁴ Found at: <http://toxnet.nlm.nih.gov/>

⁵ Found at: <http://www.drugs.com/>

⁶ "Acidifiers and Dispersing Agents." http://elfiz2.kee.hu/e_code/acidity.html

⁷ "Specification for Pectins." International Pectin Producers Association.

http://www.ippa.info/specification_for_pectins.htm

⁸ "Kaolinum." British Pharmaceutical Codex, 1911.

<http://www.ibiblio.org/herbmed/eclectic/bpc1911/kaolinum.html>

⁹ "Kaolin and Pectin." Drugs.com.

<http://www.drugs.com/index.cfm?pageID=0&xml=001362&type=pros&bn=Kaolin%20and%20Pectin>

¹⁰ "Specification for Pectins." International Pectin Producers Association.

http://www.ippa.info/specification_for_pectins.htm

¹¹ "Other Inert Pesticide Ingredients: Inerts List 4(A)." Environmental Protection Agency.

<http://www.epa.gov/opprd001/inerts/list4inerts.html> 12 June 2001.

Kaolin is a white, light yellow, light gray, or light brown powder used typically as a gelling agent, thickening agent, or stabilizer. It can be absorbed into the body through inhalation. Evaporation at 20 degrees Celcius is negligible; however airborne concentration may become quickly bothersome during aerosol dispersal of the powder.

Kaolin is insoluble in water and its relative density is 2.6. Its molecular weight is approximately 258. Kaolin is noncombustible.¹²

With the exception of halloysite, which has interlayer water, the composition of the five kaolin species is identical. Kaolinite is the most common soil mineral in many parts of the world. Kaolinite and halloysite generally form through the weathering of primary aluminosilicates under earth surface conditions under moderately acidic to acidic conditions. Nacrite, dickite, and most bed type deposits were formed by the hydrothermal weathering of primary minerals, and thus may differ somewhat in their properties. Consequently, kaolinite is commonly associated with acidic parent materials that have low buffering capacities, such as granitic rock. Alternatively, long term weathering can gradually acidify even relatively basic parent materials. Over time, the base status of these materials declines and the buffering capacity is diminished.¹³

“Kaolinite-type clay” is listed on the EPA’s List of Other Inert Pesticide Ingredients: Inerts List 4(A)¹⁴

Pectin:

Pectins are used as emulsifiers and stabilizers in the food industry. They have been tried for a variety of therapeutic uses including as antidiarrheals, where they are now generally considered ineffective, and in the treatment of hypercholesterolemia. (Reviewer: Contradictory information is present in this TAP report; sources are noted.)

“Pectin” is listed on the EPA’s List of Other Inert Pesticide Ingredients: Inerts List 4(A)

How Made:

Both kaolin and pectin are formed naturally.

Kaolin is a mineral dust formed by weathering of aluminum silicates.¹⁵

Pectin may be obtained for use by extraction into an aqueous medium from appropriate edible plant material, usually citrus fruits or apples. Organic precipitants used are methanol, ethanol and isopropanol. In some types a portion of the methyl esters may have been converted to primary amides by treatment with ammonia under alkaline conditions. The commercial product is normally standardized with sugars, and may be buffered with suitable food grade salts.¹⁶

Pectin consists of a main chain of galacturonic acid interrupted by rhamnose, which causes deviations of the main chain called “pectic elbows.” The main chain is also disrupted by short branches of neutral sugars, called “hairy regions.” Different pectin molecules can have a varying degree of methoxylation (DM), which leads to high methoxyl (HM) pectins with DM>50% or to low methoxyl (LM) pectins with DM<50%. The degree of methoxylation (DM) determines the gelling properties of pectin.

HM pectins form gels through stacking of esterified smooth regions, junctions are stabilized by H-bonds, and gelling occurs only in acidic environments. A high degree of methylation favors gelling. LM pectins form gels through

¹² “Kaolin.” IPCS, CEC. <http://www.inchem.org/documents/icsc/icsc/eics1144.htm>

¹³ http://www.soils.umn.edu/academics/classes/soil5311/LectureNotes/notes/one-to-one_phyllosilicates.html

¹⁴ “Other Inert Pesticide Ingredients: Inerts List 4(A).” Environmental Protection Agency. <http://www.epa.gov/opprd001/inerts/list4inerts.html> 12 June 2001.

¹⁵ Found at: <http://chemfinder.cambridgesoft.com/>

¹⁶ “Specification for Pectins.” International Pectin Producers Association. http://www.ippa.info/specification_for_pectins.htm

complex formation with Ca⁺⁺. The association of non-esterified smooth regions creates hydrophilic cavities for Ca⁺⁺. Low DM and high Ca⁺⁺ favor gelling of LM pectin.

The classical extraction process for pectin consists of the following steps: acidic extraction, filtration, concentration, precipitation, drying and milling. This process leads to HM pectin. HM pectin can be demethoxylated chemically through saponification in order to obtain LM pectin. Saponification generates LM pectin through random demethoxylation, but it also leads to partial hydrolysis of the pectin main chain.

HM pectin can also be demethoxylated enzymatically with an enzyme called Pectin Methyl Esterase (PME). PME can have different origins and different PME have different modes of action. PME from fungi randomly demethoxylates the pectin main chain. PME from higher plants demethoxylate the main chain in a blockwise manner. The use of PME allows generation of very specific pectins without hydrolysis of the pectin main chain, and without the use of an alkaline solution.¹⁷

Specific Uses:

This petition concerns the use of kaolin pectin in the medical treatment of livestock. In both livestock and humans, it may be indicated as an adjunct to rest, fluids, and an appropriate diet in the symptomatic treatment of mild to moderately acute diarrhea. Use is recommended in chronic diarrhea only as a temporary symptomatic treatment until the etiology is determined. A kaolin and pectin combination should not be used if diarrhea is accompanied by fever or if there is blood or mucus in the stool.

IN HUMANS:

General Dosing Information

A 15mg dose produces a serum reduced folate concentration of approximately 1 micromolar (1×10^{-6} Molar).

Usual adult dose

Oral, 60 to 120mL after each loose bowel movement.

Usual pediatric dose

Children up to 3 years of age: Use is not recommended unless directed by a physician.

Children 3 to 6 years of age: Oral, 15 to 30mL after each loose bowel movement.

Children 6 to 12 years of age: Oral, 30 to 60mL after each loose bowel movement.

Children 12 years of age and over: Oral, 45 to 60mL after each loose bowel movement.

Note: In general, dietary treatment of diarrhea in children is preferred whenever possible.

Strength(s) usually available

Kaolin and pectin are combined in various concentrations in commercially available preparations. Some of the most common are:

In the US:

Kao-Spen K-P (OTC): Kaolin, 5.2g; Pectin, 260mg; per 30mL

Kapectolin [Generic] (OTC): Kaolin, 5.85g; Pectin, 130mg, per 30mL

In Canada:

Donnagel-MB alcohol 3.8% (OTC): Kaolin, 6g; Pectin, 143mg; per 30mL¹⁸

Other preparations are:

Ka-Pek for diarrhea (AM Pharmaceutical): Kaolin, 90g; Pectin, 4.5g (per fl.oz.)

Kaogoric antidiarrheal: Paragoric, 5min; Bismuth subgallate, 120mg; Zinc sulfocarbolate, 15mg; Pectin, 15mg; Kaolin, 120mg

Kaopectate: Kaolin, 90g; Pectin, 2g

¹⁷ "Enzymatic Modification of Pectin." Degussa Texturant Systems. 2001. http://www.texturant-systems.com/skw_texturant/html/e/r_d/pectin.htm

¹⁸ "Kaolin and Pectin." Drugs.com.

<http://www.drugs.com/index.cfm?pageID=0&xml=001362&type=pros&bn=Kaolin%20and%20Pectin>

Kaopectate Concentrate: Kaolin, 135g; Pectin, 3g

Kapectin liquid diarrhea preparation: Kaolin, 90g; Pectin 2g

Kapinal antacid and adsorbent (Jenkins): Paregoric, 10mins; Kaolin, 5g; Aluminum hydroxide, 2g; Bismuth subcarbonate, 1g; Pectin, 1g; Aromatics.

Kaolin with Pectin: Kaolin, 20g; Pectin, 1g; Traganth (powdered), 0.5g; Benzoic acid, 0.2g; Saccharin sodium, 0.1g; Glycerin, 2mL; Peppermint oil, 0.15mL; Purified water, to make 100mL

Kaolin without pectin is used in combination with other compounds in medications such as:

Kaocasil (adsorbent for intestinal irritation): Kaolin colloidal, 1g; Calcium carbonate, 1.5g; MG Trisilicate, 1g; Bismuth subgallate, 0.25g; Papain, 1/8g; Atropine sulfate, 1/2000g; Kaola ointment (external analgesic, First Texas Pharmaceutical): Eucalyptol, Guaiacol, Creosote, Methyl salicylate, Glycerin, Kaolin

Kao-lumin tablets (Philips Roxane): Phenobarbitol, 8.1mg; Atropine sulfate, 0.065mg; Kaolin, 325mg; Aluminum hydroxide, 162mg; Kaomagma suspension (Wyeth): Kaolin, Alumina gel; Kapectin with Paregoric: Each oz: Paregoric, 1 fl.dr; Kaolin 90g; Pectin, 2g.¹⁹

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), in a well-closed container, unless otherwise specified by manufacturer. Protect from freezing.

NOTE: The efficacy of any antidiarrheal medication for treatment of most cases of nonspecific diarrhea is questionable, especially in children. Preferred treatment for acute, nonspecific diarrhea consists of fluid and electrolyte replacement, nutritional therapy, and, if possible, elimination of the underlying cause of the diarrhea.²⁰ A patient should check with a physician if diarrhea is not controlled within 48 hours and/or fever develops.²¹

Action:

Kaolin and pectin are administered together to serve as an adsorbent and protectant. Kaolin is a natural hydrated aluminum silicate that is believed to adsorb large numbers of bacteria and toxins and reduce water loss. Pectin is a polyuronic polymer for which the mechanism of action is unknown. Pectin consists of purified carbohydrate extracted from citrus fruit or apple pomace. Studies have shown no decrease in stool frequency or fecal weight and water content with this combination even though stools appeared more formed. Kaolin and pectin are both not absorbed following oral administration (up to 90% of pectin is decomposed in gastrointestinal tract).

Kaolin, due to the aluminum in its composition, may lower the bioavailability of other ingested medications. Taking doses of other oral medications 2 to 3 hours before or after doses of kaolin pectin is not recommended.²² Kaolin (and pectin) preparations may impair the absorption of oral lincomycin by up to 90% when the drugs are

¹⁹ Gosselin, R.E., H.C. Hodge, R.P. Smith, and M.N. Gleason. *Clinical Toxicology of Commercial Products*. 4th ed. Baltimore: Williams and Wilkins, 1976. pp. V-365]

Gosselin, R.E., R.P. Smith, H.C. Hodge. *Clinical Toxicology of Commercial Products*. 5th ed. Baltimore: Williams and Wilkins, 1984. pp.V-333.

McEvoy, G.K. (ed.). *American Hospital Formulary Service--Drug Information 94*. Bethesda, MD: American Society of Hospital Pharmacists, Inc., 1994. (Plus Supplements). pp. 1879.

²⁰ "Kaolin and Pectin." Drugs.com.

<http://www.drugs.com/index.cfm?pageID=0&xml=001362&type=pros&bn=Kaolin%20and%20Pectin>

²¹ "Kaolin." Drugs.com.

<http://www.drugs.com/index.cfm?pageID=1150&int=1&list=1&values=%26drugid%3Dd03078&OpText=kaolin>

²² "Kaolin and Pectin." Drugs.com.

<http://www.drugs.com/index.cfm?pageID=0&xml=001362&type=pros&bn=Kaolin%20and%20Pectin>

administered concomitantly²³, and other studies have found that kaolin impairs absorption of erythromycin and digoxin as well.²⁴ Kaolin also has absorption-related interactions with the following drugs:

Adgan, Allopurinol, Aloprim, Anergan 50, Antinaus 50, Bacramycin, chlorpromazine, Cleocin HCl, Cleocin Pediatric, Cleocin Phosphate, clindamycin, Compazine, Compazine Spansule, ethambutol, fluphenazine, isoniazid, Largon, Levoprome, Lincocin, Lincorex, L-Mycin, Lopurin, Mellaril, Mellaril-S, mesoridazine, methdilazine, methotrimeprazine, Myambutol Nydrasid, Ormazine, Pentazine, Permitil, perphenazine, Phenazine 50, Phenergan, Phenergan Fortis, Phenoject-50, prochlorperazine, Prolixin, Prolixin Decanoate, Prolixin Enanthate, Promacot promazine, Pro-Med, promethazine, Promethegan, propiomazine, Prorex, Serentil, Sparine, Stelazine, Tacaryl, Tamaril, thiethylperazine, thioridazine, Thorazine, Torecan, trifluoperazine, triflupromazine, Trilafon, trimeprazine, Vesprin, V-Gan-25, V-Gan-50, Zylprim.²⁵

IN LIVESTOCK:

The basis of this petition concerns the use of kaolin pectin for livestock medical treatment. It is used in livestock for the same reasons that it is administered to human: as an adsorbent, anti-diarrheal, and gut protectant. It may also be combined with vitamin A to treat bacterial diarrhea in calves.

Status

Historic Use by Organic Farmers:

The use of kaolin pectin for the treatment of diarrhea in livestock is used widely. Formulas are available commercially.

USDA, FDA Final Rule:

The **FDA** has declared kaolin to be GRAS as an indirect food additive, and pectin to be GRAS as a direct food additive, both with the limitation that the levels in food are consistent with good manufacturing practices. Kaolin is also approved for use in ultramarine pigments used in makeup as consistent with good manufacturing practices, and for use as a protectant in anorectal drugs.

Following are pertinent excerpts from the **USDA** Federal Organic Foods Production Act of 1990 regarding acceptable practices in the medical treatment of livestock, and Title 21 of the Federal Code of Regulations detailing the **FDA** status of both kaolin and pectin, summarized above.

FEDERAL ORGANIC FOODS PRODUCTION ACT OF 1990

6509 ANIMAL PRODUCTION PRACTICES AND MATERIALS.

(a) **In General.** Any livestock that is to be slaughtered and sold or labeled as organically produced shall be raised in accordance with this chapter.

²³ *Evaluations of Drug Interactions*. 2nd ed. and supplements. Washington, DC: American Pharmaceutical Assn., 1976, 1978. pp. 136.

McEvoy, G.K. (ed.). *American Hospital Formulary Service--Drug Information 94*. Bethesda, MD: American Society of Hospital Pharmacists, Inc., 1994. (Plus Supplements). pp. 1879.

²⁴ Booth, N.H., L.E. McDonald (eds.). *Veterinary Pharmacology and Therapeutics*. 5th ed. Ames, Iowa: Iowa State University Press, 1982. pp. 21.

²⁵ "Kaolin." Drugs.com.

<http://www.drugs.com/index.cfm?pageID=1150&int=1&list=1&values=%26drugid%3Dd03078&OpText=kaolin>

(d) **Health Care.**

(1) **Prohibited Practices.** For a farm to be certified under this chapter as an organic farm with respect to the livestock produced by such farm, producers on such farm shall not

(A) use subtherapeutic doses of antibiotics;

(B) use synthetic internal paraciticides on a routine basis; or

(C) administer medication, other than vaccinations, in the absence of illness.

(2) **Standards.** The National Organic Standards Board shall recommend to the Secretary standards in addition to those in paragraph (1) for the care of livestock to ensure that such livestock is organically produced.

(e) **Additional Guidelines.**

(1) **Poultry.** With the exception of day old poultry, all poultry from which meat or eggs will be sold or labeled as organically produced shall be raised and handled in accordance with this chapter prior to and during the period in which such meat or eggs are sold.

(2) **Dairy Livestock** A dairy animal from which milk or milk products will be sold or labeled as organically produced shall be raised and handled in accordance with this chapter for not less than the 12-month period immediately prior to the sale of such milk and milk products.

(f) **Livestock Identification.**

(1) **In General.** For a farm to be certified under this chapter as an organic farm with respect to the livestock produced by such farm, producers on such farm shall keep adequate records and maintain a detailed, verifiable audit trail so that each animal (or in the case of poultry, each flock) can be traced back to such farm.

(2) **Records.** In order to carry our paragraph (1), each producer shall keep accurate records on each animal (or in the case of poultry, each flock) including

(A) amounts and sources of all medications administered; and

(B) all feeds and feed supplements bought and fed.

(g) **Notice and Public Comment.** The Secretary shall hold public hearings and shall develop detailed regulations, with notice and public comment, to guide the implementation of the standards for livestock products provided under this section.

CODE OF FEDERAL REGULATIONS

Title 21, Volume 3

Revised as of April 1, 2001

21CFR186.1256

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 186--INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE--Table of Contents

Subpart B--Listing of Specific Substances Affirmed as GRASSec. 186.1256 Clay (kaolin)

(a) Clay (kaolin) $Al_2O_3 \cdot 2SiO_2 \cdot 2H_2O$, Cas Reg. No. 1332-58-7) consists of hydrated aluminum silicate. The commercial products of clay (kaolin) contain varying quantities of alkalis and alkaline earths. Clay (kaolin) is a white to yellowish or grayish fine powder. There are at least three different minerals, kaolinite, dickite, and nacrite, classified as kaolin. Kaolinite or china clay is whiter, less contaminated with extraneous minerals, and less plastic in water.

(b) In accordance with Sec. 186.1(b)(1), the ingredient is used as an indirect human food ingredient with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in the manufacture of paper and paperboard that contact food.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[47 FR 43367, Oct. 1, 1982]

CODE OF FEDERAL REGULATIONS**Title 21, Volume 3**

Revised as of April 1, 1999

21CFR184.1588

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Subpart B--Listing of Specific Substances Affirmed as GRASSec. 184.1588 Pectins

(a) The pectins (CAS Reg. No. 9000-69-5) are a group of complex, high molecular weight polysaccharides found in plants and composed chiefly of partially methylated polygalacturonic acid units. Portions of the carboxyl group occur as methyl esters, and the remaining carboxyl groups exist in the form of the free acid or as its ammonium, potassium, or sodium (CAS Reg. No. 9000-59-8) salts, and in some types as the acid amide. Thus, the pectins regulated in this section are the high-ester pectins, low-ester pectins, amidated pectins, pectinic acids, and pectinates. Pectin is produced commercially by extracting citrus peel, apple pomace, or beet pulp with hot dilute acid (pH 1.0 to

3.5, 70 deg. to 90 deg.C). The extract is filtered, and pectin is then precipitated from the clear extract with ethanol or isopropanol, or as the copper or aluminum salt. The acid extract is sometimes spray- or roller-dried, or it is concentrated to be sold as liquid pectin.

(b) The ingredients meet the specifications of the Food Chemical Codex, 3d Ed. (1981), p. 215, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with Sec. 184.1(b)(1), the ingredients are used in food with no limitation other than current good manufacturing practice. The affirmation of these ingredients as generally recognized as safe (GRAS) as direct human food ingredients is based upon the following current good manufacturing practice conditions of use:

(1) The ingredients are used as emulsifiers as defined in Sec. 170.3(o)(8) of this chapter and as stabilizers and thickeners as defined in Sec. 170.3(o)(28) of this chapter.

(2) The ingredients are used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[48 FR 51149, Nov. 7, 1983]

CODE OF FEDERAL REGULATIONS

Title 21, Volume 1

Revised as of April 1, 2000

21CFR73.2725

TITLE 21--FOOD AND DRUGS

PART 73--LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Subpart C--Cosmetics

Sec. 73.2725 Ultramarines

(a) Identity. The color additives, ultramarines (blue, green, pink, red, and violet) are pigments obtained by calcining at temperatures above 700 deg.C. a mixture of kaolin, sulfur, sodium carbonate, silicious matter, sodium sulfate, and carbonaceous matter, but not necessarily all these substances, to produce a single color. The ultramarines are complex sodium aluminum sulfosilicates having a typical formula Na(AlSiO)S with proportions of each element varying with each color.

(b) Specifications. The ultramarines shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by good manufacturing practice.

Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.

(c) Uses and restrictions. The ultramarine pigments may be safely used for coloring externally applied cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) Labeling requirements. The color additives and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with Sec. 70.25 of this chapter.

(e) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

Sec. 73.50 Ultramarine blue

(a) Identity. The color additive ultramarine blue is a blue pigment obtained by calcining a mixture of kaolin, sulfur, sodium carbonate, and carbon at temperatures above 700 deg.C. Sodium sulfate and silica may also be incorporated in the mixture in order to vary the shade. The pigment is a complex sodium aluminum sulfo-silicate having the approximate formula $\text{Na}_7\text{Al}_6\text{Si}_6\text{O}_{24}\text{S}_3$.

(b) Specifications. Ultramarine blue shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Mercury (as Hg), not more than 1 part per million.

(c) Uses and restrictions. The color additive ultramarine blue may be safely used for coloring salt intended for animal feed subject to the restriction that the quantity of ultramarine blue does not exceed 0.5 percent by weight of the salt.

(d) Labeling requirements. The color additive shall be labeled in accordance with the requirements of Sec. 70.25 of this chapter.

(e) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

CODE OF FEDERAL REGULATIONS

Title 21, Volume 5

Revised as of April 1, 2001

21CFR346.14

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--Continued

PART 346--ANORECTAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart B--Active Ingredients

Sec. 346.14 Protectant active ingredients

(a) The following active ingredients may be used as the sole protectant active ingredient in a product if the ingredient as identified constitutes 50 percent or more by weight of the final product. In addition, the following active ingredients may be used in concentrations of less than 50 percent by weight only when used in combinations in accordance with Sec. 346.22 (a), (b), or (n).

- (1) Aluminum hydroxide gel.
- (2) Cocoa butter.
- (3) Glycerin in a 20- to 45-percent (weight/weight) aqueous solution so that the final product contains not less than 10 and not more than 45 percent glycerin (weight/weight). Any combination product containing glycerin must contain at least this minimum amount of glycerin.
- (4) Hard fat.
- (5) Kaolin.
- (6) Lanolin.
- (7) Mineral oil.
- (8) Petrolatum.
- (9) Topical starch.
- (10) White petrolatum.

(b) The following active ingredients may not be used as a sole protectant ingredient but may be used in combination with one, two, or three other protectant active ingredients in accordance with Sec. 346.22 (a), (b), (n), and (o) and with the following limitations:

- (1) Calamine not to exceed 25 percent by weight per dosage unit (based on the zinc oxide content of calamine).
- (2) Cod liver oil, provided that the product is labeled so that the amount of the product that is used in a 24-hour period represents a quantity that provides 10,000 U.S.P. units of vitamin A and 400 U.S.P. units of cholecalciferol.
- (3) Shark liver oil, provided that the product is labeled so that the amount of the product that is used in a 24-hour period represents a quantity that provides 10,000 U.S.P. units of vitamin A and 400 U.S.P. units of cholecalciferol.
- (4) Zinc oxide not to exceed 25 percent by weight per dosage unit.

CODE OF FEDERAL REGULATIONS
Title 21, Volume 5
Revised as of April 1, 2001

21CFR346.22

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--Continued

PART 346--ANORECTAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE--Table of Contents

Subpart B--Active Ingredients

Sec. 346.22 Permitted combinations of anorectal active ingredients

(a) Any two, three, or four protectants identified in Sec. 346.14(a) may be combined, except aluminum hydroxide gel in Sec. 346.14(a)(1) and kaolin in Sec. 346.14(a)(5) may not be combined with any ingredient in Sec. 346.14(a)(2), (4), (6), (7), (8) and (10), and (b) (2) and (3), provided that the combined percentage by weight of all protectants in the combination is at least 50 percent of the final product (e.g., 1 gram of a 2-gram dosage unit). Any protectant ingredient included in the combination must be present at a level that contributes at least 12.5 percent by weight (e.g., 0.25 gram of a 2-gram dosage unit), except cod liver oil and shark liver oil. If an ingredient in Sec. 346.14(b) is included in the combination, it must not exceed the concentration limit specified in Sec. 346.14(b).

(b) Any single anorectal ingredient identified in Sec. 346.10, 346.12, 346.16, 346.18, or 346.20 may be combined with up to four protectants in accordance with paragraph (a) of this section.

- (c) Any single local anesthetic identified in Sec. 346.10 may be combined with any single vasoconstrictor identified in Sec. 346.12.
- (d) Any single local anesthetic identified in Sec. 346.10 may be combined with any single astringent identified in Sec. 346.18.
- (e) Any single local anesthetic identified in Sec. 346.10 may be combined with any single keratolytic identified in Sec. 346.20.
- (f) Any single vasoconstrictor identified in Sec. 346.12 may be combined with any single astringent identified in Sec. 346.18.
- (g) Any single analgesic, anesthetic, and antipruritic identified in Sec. 346.16 may be combined with any single astringent identified in Sec. 346.18.
- (h) Any single analgesic, anesthetic, and antipruritic identified in Sec. 346.16 may be combined with any single keratolytic identified in Sec. 346.20.
- (i) Any single astringent identified in Sec. 346.18 may be combined with any single keratolytic identified in Sec. 346.20.
- (j) Any single local anesthetic identified in Sec. 346.10 may be combined with any single vasoconstrictor identified in Sec. 346.12 and with any single astringent identified in Sec. 346.18.
- (k) Any single local anesthetic identified in Sec. 346.10 may be combined with any single astringent identified in Sec. 346.18 and with any single keratolytic identified in Sec. 346.20.
- (l) Any single vasoconstrictor identified in Sec. 346.12 may be combined with any single analgesic, anesthetic, and antipruritic identified in Sec. 346.16 and with any single astringent identified in Sec. 346.18.
- (m) Any single analgesic, anesthetic, and antipruritic identified in Sec. 346.16 may be combined with any single astringent identified in Sec. 346.18 and with any single keratolytic identified in Sec. 346.20.
- (n) Any combination of ingredients listed in paragraphs (c) through (m) of this section may be combined with up to four protectants in accordance with paragraph (a) of this section.
- (o) Any product containing calamine for use as a protectant and/or as an astringent and/or containing zinc oxide for use as a protectant and/or as an astringent may not have a total weight of zinc oxide exceeding 25 percent by weight per dosage unit.

NOP:

Kaolin and pectin are both approved (separately) by the NOP for use in organic systems. Below are pertinent excerpts regarding organic livestock production, and the kaolin and pectin entries on the National List, from the 2000 NOP Final Rule.

DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
7 CFR Part 205
[Docket Number: TMD-00-02-FR]
RIN: 0581-AA40

NATIONAL ORGANIC PROGRAM

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final Rule with request for comments.

SUMMARY: This final rule establishes the National Organic Program (NOP or program) under the direction of the Agricultural Marketing Service (AMS), an arm of the United States Department of Agriculture (USDA). This national program will facilitate domestic and international marketing of fresh and processed food that is organically produced and assure consumers that such products meet consistent, uniform standards. This program establishes national standards for the production and handling of organically produced products, including a National List of substances approved for and prohibited from use in organic production and handling. This final rule establishes a national-level accreditation program to be administered by AMS for State officials and private persons who want to be accredited as certifying agents. Under the program, certifying agents will certify production and handling operations in compliance with the requirements of this regulation and initiate compliance actions to enforce program requirements. The final rule includes requirements for labeling products as organic and containing organic ingredients. This final rule also provides for importation of organic agricultural products from foreign programs determined to have equivalent organic program requirements. This program is authorized under the Organic Foods Production Act of 1990, as amended.

Subpart C - Organic Crop, Wild Crop, Livestock, and Handling Requirements

Description of Regulations

General Requirements

This subpart sets forth the requirements with which production and handling operations must comply in order to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." The producer or handler of an organic production or handling operation must comply with all applicable provisions of subpart C. Any production practice implemented in accordance with this subpart must maintain or improve the natural resources, including soil and water quality, of the operation. Production and handling operations which sell, label, or represent agricultural products as organic in any manner and which are exempt or excluded from certification must comply with the requirements of this subpart, except for the development of an organic system plan.

Livestock Production

Any livestock product to be sold, labeled, or represented as organic must be maintained under continuous organic management from the last third of gestation or hatching with three exceptions. Poultry or edible poultry products must be from animals that have been under continuous organic management beginning no later than the second day of life. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of such products, except for the conversion of an entire, distinct herd to organic production. For the first 9 months of the year of conversion, the producer may provide the herd with a minimum of 80-percent feed that is either organic or produced from land included in the organic system plan and managed in compliance with organic crop requirements. During the final 3 months of the year of conversion, the producer must provide the herd feed in compliance with section 205.237. Once the herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation. Livestock used as breeder stock may be brought from a nonorganic operation into an organic operation at any time, provided that, if such livestock are gestating and the offspring are to be organically raised from birth, the breeder stock must be brought into the organic operation prior to the last third of gestation.

Should an animal be brought into an organic operation pursuant to this section and subsequently moved to a nonorganic operation, neither the animal nor any products derived from it may be sold, labeled, or represented as organic. Breeder or dairy stock that has not been under continuous organic management from the last third of gestation may not be sold, labeled, or represented as organic slaughter stock. The producer of an organic livestock

operation must maintain records sufficient to preserve the identity of all organically managed livestock and all edible and nonedible organic livestock products produced on his or her operation.

Except for nonsynthetic substances and synthetic substances included on the National List that may be used as feed supplements and additives, the total feed ration for livestock managed in an organic operation must be composed of agricultural products, including pasture and forage, that are organically produced. Any portion of the feed ration that is handled must comply with organic handling requirements. The producer must not use animal drugs, including hormones, to promote growth in an animal or provide feed supplements or additives in amounts above those needed for adequate growth and health maintenance for the species at its specific stage of life. The producer must not feed animals under organic management plastic pellets for roughage or formulas containing urea or manure. The feeding of mammalian and poultry slaughter by-products to mammals or poultry is prohibited. The producer must not supply animal feed, feed additives, or feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.

The producer of an organic livestock operation must establish and maintain preventive animal health care practices. The producer must select species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites. The producer must provide a feed ration including vitamins, minerals, protein, and/or amino acids, fatty acids, energy sources, and, for ruminants, fiber. The producer must establish appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites. Animals in an organic livestock operation must be maintained under conditions which provide for exercise, freedom of movement, and reduction of stress appropriate to the species. Additionally, all physical alterations performed on animals in an organic livestock operation must be conducted to promote the animals' welfare and in a manner that minimizes stress and pain.

The producer of an organic livestock operation must administer vaccines and other veterinary biologics as needed to protect the well-being of animals in his or her care. When preventive practices and veterinary biologics are inadequate to prevent sickness, the producer may administer medications included on the National List of synthetic substances allowed for use in livestock operations. The producer may not administer synthetic parasiticides to breeder stock during the last third of gestation or during lactation if the progeny is to be sold, labeled, or represented as organically produced. After administering synthetic parasiticides to dairy stock, the producer must observe a 90-day withdrawal period before selling the milk or milk products produced from the treated animal as organically produced. Every use of a synthetic medication or parasiticide must be incorporated into the livestock operation's organic system plan subject to approval by the certifying agent.

The producer of an organic livestock operation must not treat an animal in that operation with antibiotics, any synthetic substance not included on the National List of synthetic substances allowed for use in livestock production, or any substance that contains a nonsynthetic substance included on the National List of nonsynthetic substances prohibited for use in organic livestock production. The producer must not administer any animal drug, other than vaccinations, in the absence of illness. The use of hormones for growth promotion is prohibited in organic livestock production, as is the use of synthetic parasiticides on a routine basis. The producer must not administer synthetic parasiticides to slaughter stock or administer any animal drug in violation of the Federal Food, Drug, and Cosmetic Act. The producer must not withhold medical treatment from a sick animal to maintain its organic status. All appropriate medications and treatments must be used to restore an animal to health when methods acceptable to organic production standards fail. Livestock that are treated with prohibited materials must be clearly identified and shall not be sold, labeled, or represented as organic.

A livestock producer must document in his or her organic system plan the preventative measures he or she has in place to deter illness, the allowed practices he or she will employ if illness occurs, and his or her protocol for determining when a sick animal must receive a prohibited animal drug. These standards will not allow an organic system plan that envisions an acceptable level of chronic illness or proposes to deal with disease by sending infected animals to slaughter. The organic system plan must reflect a proactive approach to health management, drawing upon allowable practices and materials. Animals with conditions that do not respond to this approach must be treated appropriately and diverted to nonorganic markets.

The producer of an organic livestock operation must establish and maintain livestock living conditions for the animals under his or her care which accommodate the health and natural behavior of the livestock. The producer

must provide access to the outdoors, shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment. This requirement includes access to pasture for ruminant animals. The producer must also provide appropriate clean, dry bedding, and, if the bedding is typically consumed by the species, it must comply with applicable organic feed requirements. The producer must provide shelter designed to allow for the natural maintenance, comfort level, and opportunity to exercise appropriate to the species. The shelter must also provide the temperature level, ventilation, and air circulation suitable to the species and reduce the potential for livestock injury. The producer may provide temporary confinement of an animal because of inclement weather; the animal's stage of production; conditions under which the health, safety, or well-being of the animal could be jeopardized; or risk to soil or water quality. The producer of an organic livestock operation is required to manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes nutrient recycling.

Subpart G – Administrative

The National List of Allowed and Prohibited Substances

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

The following nonagricultural substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

(a) Nonsynthetics allowed:

(10) Kaolin

(b) Synthetics allowed:

(21) Pectin (low-methoxy)

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic or made with organic ingredients.

The following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

Any nonorganically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form.

(e) Pectin (high-methoxy)²⁶

NOSB:

The NOSB will be reviewing kaolin pectin for use in livestock medical treatment in September 2002.²⁷

Regulatory: EPA/Other Sources:

OSHA:

Kaolin: Regulations (Standards - 29 CFR)
1910.1000 Table Z-1

²⁶ *Final Rule*, 2002. NOP. <http://www.ams.usda.gov/nop/nop2000/nop2/finalrulepages/entirerule2.htm> 2002.

²⁷ *Materials to Review*. NOSB. <http://www.ams.usda.gov/nop/materialsmay2002.pdf> 2002.

Limits for Air Contaminants
Kaolin...Total Dust: 15 mg/m(3)
...Respirable Fraction: 5 mg/m(3)²⁸

ACGIH:

Kaolin: Occupational Exposure Limits
TLV: 2 mg/m³ (as TWA) (ACGIH 1995-1996).²⁹

NIOSH:

Kaolin:
Recommended Exposure Limit: 10 Hr Time-Weighted Avg: 10 mg/cu m (total).
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 182]

Recommended Exposure Limit: 10 Hr Time-Weighted Avg: 5 mg/cu m (resp).
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 182]³⁰

EPA:

“Kaolinite-type clay” is listed on the EPA’s List of Other Inert Pesticide Ingredients: Inerts List 4(A):
“Pectin” is also listed on the EPA’s List of Other Inert Pesticide Ingredients: Inerts List 4 (A):³¹

The EPA ruled in 1998 that kaolin is exempt from the requirement of a tolerance, noting that kaolin has “no known toxicological effects.” Following is the ruling.

FEDERAL REGISTER
Volume 63, Number 37
February 25, 1998

Rules and Regulations
DOCID: fr25fe98-18

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-300614; FRL-5769-9] RIN 2070-AB78

Kaolin; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA)

ACTION: Final rule

²⁸ Regulations (Standards - 29 CFR) 1910.1000 Table Z-1. OSHA.
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9992&p_text_version=FALSE

²⁹ “Kaolin.” IPCS, CEC. <http://www.inchem.org/documents/icsc/icsc/eics1144.htm>

³⁰ NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C.: Government Printing Office, 1997. pp. 182.

³¹ “Other Inert Pesticide Ingredients: Inerts List 4(A).” Environmental Protection Agency.
<http://www.epa.gov/opprd001/inerts/list4inerts.html> 12 June 2001.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of anhydrous kaolin when used in or on food commodities to aid in the control of insects, fungi, and bacteria (food/feed use). This regulation was requested by Engelhard Corporation.

DATES: This regulation becomes effective February 25, 1998. Objections and requests for hearings must be received by EPA on or before April 27, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300614], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket control number and submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to: Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically to the OPP by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP-300614]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT:

By mail: Driss Benmhend, c/o Product Manager (PM) 90 Biopesticides and Pollution Prevention Division (7511W) Office of Pesticide Programs, Environmental Protection Agency 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 5-W61, CS #1, 2800 Crystal Drive, Arlington, VA 22202, (703) 308-9525; e-mail: benmhend.driss@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

In the Federal Register of November 26, 1997 (62 FR 63168)(FRL-5753-3), EPA issued a notice pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C.346a(d), announcing the filing of a pesticide tolerance petition for the new active ingredient kaolin (PP 7E4908) by Engelhard Corporation, Research Center, 101 Wood Avenue, Iselin, NJ 08830. The notice included a summary of the petition prepared by the petitioner. The summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. The petition requested the establishment of a permanent tolerance exemption for kaolin for all food commodities. Kaolin is a naturally occurring aluminosilicate, used as an indirect food additive for paperboard food contact, adhesives, cellophane, etc. It is also used in pharmaceuticals (tablet diluents poultices), and in toiletries (toothpaste, etc.). Prior to the current petition request, EPA authorized the issuance of an experimental use permit (EUP) to the registrant for the end-use product, M-96-018 Kaolin (70060-EUP-R), containing 98.8% active ingredient. In conjunction with the EUP, EPA approved a petition for a temporary tolerance exemption (PP 7G4793) for the active ingredient when applied to all food commodities. The exemption from a temporary tolerance for kaolin on all food commodities was granted for purposes of the EUP (April 23, 1997, 62 FR 19683) (FRL-5712-8).

There were no comments or requests for referral to an advisory committee, received in response to the notice of filing. The data submitted in the petition and other relevant material have been evaluated and were considered in support of this tolerance.

I. Toxicological Profile

The submitted toxicology studies are acceptable for these new registrations. No additional toxicology data are required. The data reported in the acute oral toxicity studies demonstrated that the acute oral LD₅₀ for kaolin in rats is >5,000 mg/kg of body weight. No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV. The data reported in the acute dermal toxicity study demonstrated that the acute dermal LD₅₀ for kaolin in rats is >5,000 mg/kg of body weight. No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV. The data reported in the primary eye irritation study demonstrate that the test substance was minimally irritating. Kaolin was not corrosive and all eye irritation effects cleared within 72 hours post dosing; Toxicity Category III. The data reported in the primary-skin irritation study demonstrated that the test substance caused no dermal irritation in rabbits treated with 0.5g kaolin for 4 hours. No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV.

Kaolin is used as an indirect food additive for paper/paperboard dry food contact, adhesives, polymeric coatings, rubber articles, and cellophane. Kaolin is used in pharmaceuticals, tablet diluents, poultices, and surgical dusting powders. Kaolin is used as a cosmetic in face powders, face masks, and face packs. Kaolin is used in health products and toiletries, toothpaste, and antiperspirants. Kaolin can be used directly in foods as an anti-caking agent (up to 2.5%). Kaolin has GRAS (Generally Recognized as Safe) status under 21 CFR 186.1256 and is generally recognized as safe "as an indirect human food ingredient with no limitation other than current good manufacturing practice."

II. Aggregate Exposure

1. Dietary exposure and risk characterization. Dietary exposure of kaolin via food or water is difficult to estimate due to the use of kaolin in thousands of products. Kaolin is an inert mineral and has no known toxicological effects
2. Non-dietary exposure, non-occupational exposure. The amount of kaolin currently used in the U.S. pesticide industry as an inert is between 2 million lbs. and 10 million lbs. per year.
3. Aggregate exposure from multiple routes including dermal and inhalation. Risks associated with dermal and inhalation aggregate exposure are measured via the acute toxicity studies submitted to support registration. Because the inhalation toxicity studies for kaolin showed no toxicity (Toxicity Category IV), the risks anticipated for this route of exposure are considered minimal. Results of the acute dermal study indicated low toxicity (Toxicity Category IV), and no significant dermal irritation (Toxicity Category IV). Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via dermal and inhalation exposure are a compilation of two low risk exposure scenarios and are considered negligible.

III. Safety Considerations

The lack of toxicity of kaolin is demonstrated by the above summary. Based on this information, the aggregate exposure to kaolin over a lifetime should not pose appreciable risks to human health. There is a reasonable certainty that no harm will result from aggregate exposure to kaolin residues. Exempting kaolin from the requirement of a tolerance is safe.

Consistent with section 408(b)(2)(c) of the FFDCFA, EPA has assessed the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues and the cumulative effects on infants and children of the residues and other substances with the common mechanism of toxicity. Based on the available information, the Agency concludes that kaolin is ubiquitous in all foods including those consumed by infants and children. Furthermore, kaolin is used as an additive in several food and non food products. Like adults, infants and children are also exposed to kaolin in these products, and there is no evidence that suggests that such exposure may lead to any harm.

IV. Cumulative Effects

Kaolin has no mode of toxicity and therefore no common mechanism of toxicity with other substances.

V. International Tolerances

No international tolerance exemptions are known to exist.

VI. Summary of Findings

Kaolin is considered as GRAS by FDA under 21 CFR 186.1256. EPA has not identified any toxicity or clinical abnormalities. Moreover, the ecological effects studies demonstrated that there were no adverse effects. As a result, the Agency concludes that the exemption from the requirement of a tolerance is safe. Therefore, the tolerance exemption is established as set forth below.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a tolerance regulation issued by EPA under new section 408(e) and (1)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by April 27, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Docket

EPA has established a record for this rulemaking under docket number [OPP-300614] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Electronic comments may be sent directly to EPA at: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

IX. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and Pests, Reporting and recordkeeping requirements.

Dated: February 6, 1998.

Marcia E. Mulkey,
Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180-[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1180 is amended by removing the paragraph heading for paragraph (a), revising paragraph (b), and removing paragraphs (c) and (d) to read as follows:

Sec. 180.1180 Kaolin; exemption from the requirement of a tolerance.

* * * * *

(b) Kaolin is exempted from the requirement of a tolerance for residues when used on or in food commodities to aid in the control of insects, fungi, and bacteria (food/feed use).

[FR Doc. 98-4652 Filed 2-24-98; 8:45 am]
BILLING CODE 6560-50-F³²

Status Among U.S. Certifiers

NOFA, DEC, OMRI:

All approved Surround WP Crop Protectant, a vegetable pesticide with kaolin as its active ingredient, in 2001.³³

OMRI suggests the following annotation to the listing of “Pectin” on the National List:

“Low-methoxy form is synthetic and may only be used when the high-methoxy form is commercially unavailable.”³⁴

State Organic Certifiers:

Minnesota: Follows USDA suggested guidelines.

Oregon: Follows USDA suggested guidelines.

Pennsylvania: Follows OMRI suggested guidelines.

International

IFOAM:

INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS
Basic Standards for Organic Production and Processing
Final Draft 2002

To be voted on at the general assembly
Victoria, August 26-28, 2002

Appendix 4

List of Approved Additives and Processing Aids

Where the substances listed in this annex can be found in nature, natural sources are preferred. Substances of certified organic origin are preferred.

INS 948 Kaolin Processing Aid

Appendix 5

Criteria for the Evaluation of Additives and Processing Aids for Organic Food Products

3. Step by Step Procedure for the use of Additives and Processing Aids

³² Federal Register. *Rules and Regulations*. <http://www.epa.gov/fedrgstr/EPA-PEST/1998/February/Day-25/p4652.htm> 25 February 1998.

³³ *NOFA-NY/OMRI/DEC Approved Vegetable Pest Management Products 2001*.
http://www.nysaes.cornell.edu/recommends/org_app.pdf 2001.

³⁴ *OMRI Comments on the USDA Proposed Rule*. http://www.omri.org/full_comments.pdf 9 June 2000.

1. Instead of using additives or processing aids, the preferred first choice is:
 - Foods grown under organic conditions which are used as a whole product or are processed in accordance with the IFOAM Basic Standards - e.g. flour used as a thickening agent or vegetable oil as a releasing agent
 - Foods or raw materials of plant and animal origin which are produced only by mechanical or simple physical procedures - e.g. salt.
2. The second choice is:
 - substance isolated from food and produced physically or by enzymes - e.g. starch, tartrates, pectin

WHO/JECFA:

Kaolin: ADI Not Specified.

Pectin: The following document is the culmination of years of study concerning the possible toxicity of pectin. The final ruling was that it is also "ADI Not Specified."

**WORLD HEALTH ORGANIZATION
Food Additives, Series 16**

511. PECTINS AND AMIDATED PECTINSExplanation

This substance was evaluated for acceptable daily intake for man (ADI) by the Joint FAO/WHO Expert Committee on Food Additives in 1973 (see Annex, Ref. 33). A toxicological monograph was issued in 1975 (see Annex, Ref. 35).

Since the previous evaluation, additional data have become available and are discussed in the following monograph. The previously published monograph has been expanded and reproduced in its entirety.

BIOLOGICAL DATA**TOXICOLOGICAL STUDIES**

Special studies on reproduction

A three-generation reproduction study of amidated pectin was carried out using groups of eight male and 16 female Charles River CD strain mice. The test groups were fed 2% or 5% amidated pectin. Similar groups of animals fed 2% or 5% non-amidated pectin were utilized as controls. The study design called for two litters to be raised per generation with the second (b) litter utilized to produce the next generation. In general, there were no dose-related effects on mortality, body weight, food consumption, reproductive or survival indices or incidence of gross or histopathologic lesions. Mating of the 2% non-amidated pectin group to produce the F_{2b} litter resulted in only five females becoming pregnant, two died during pregnancy and none of the pups survived to day 21. Since the occurrence was limited to the second litter of one generation and did not occur at a higher dose (5%) the effect is not considered to be related to administration of non-amidated pectin. There was some mortality among the other groups and generations as well, evidently due to respiratory infections (Industrial Biotest, 1979b).*

Groups of one male and five female Wistar rats were utilized in carrying out a two-generation reproduction study of amidated pectin fed at a level of 16.6% in the diet. One set of litters were produced per generation. Five males and

five females per generation were subjected to gross and histopathologic examination. No abnormalities were reported to occur in any of the offspring and the results of the

* This study was validated by an independent audit (see memo of 13 November 1979, International Verband de Pektinproduzenten - submitted to WHO).

gross and histopathologic examination were said to be normal. Data such as reproductive and survival indices, body weight changes, etc. were not presented in the report (Mosinger, 1976).

Special studies on teratology

Groups of 20 or 22 pregnant females Charles River albino rats were fed a diet containing 2 or 5% amidated pectin on gestation days 6 through 15. Similar groups fed diets containing 2 or 5% non-amidated pectin were used as concurrent controls. Dams were sacrificed on day 20 and foetuses were examined externally. Two-thirds of the foetuses were processed for skeletal examination and one-third for soft tissue examination. There was no mortality among the dams during the study and body weights and food consumption were comparable between groups. Data on corpora lutea, implantation sites, resorption sites, foetal viability, foetal weight and sex ratio were comparable between all the groups. No intergroup differences were reported with respect to skeletal or soft tissue anomalies (Industrial Biotest, 1976).*

Short-term studies

Rat

Four groups of 10 male and 10 female rats were fed diets containing 0%, 5%, 10% or 15% pectin (21% amidated) for 90 days. No adverse effects were noted on general condition, behaviour and survival. Growth was slightly decreased at the 15% level and this finding was also noted in a range finding test using 20% pectin in the diet. Some decrease in growth occurred inconsistently also at the 10% dietary level. Food intake and food efficiency were not affected at any level. Haematological parameters showed no significant treatment-related changes. Total serum protein and albumin were reduced at the 15% level but the other clinical biochemical parameters and urinalysis were essentially normal. Caecal weights were increased at all levels but in a dose-related manner. These findings are reminiscent of what is seen when high amounts of starch, modified starch or certain other carbohydrates are fed. Gross histopathology were normal but a slight degree of hyperkeratosis of the forestomach in some males was seen at the 10% and 15% level but is probably not of toxicological significance (Til et al., 1972).

* This study was validated by an independent audit (see memo of 13 November 1979, International Verband de Pektinproduzenten - submitted to WHO).

Long-term studies

Groups of 20 male weanling Wistar rats were fed diets of purina laboratory meal to which was added low molecular pectin (approximately 18% amidated) or non-amidated pectin at 10% of the diet. Control diets contained 10% alphacellulose (alphacel). The rats were fed for two years. The diets were made isocaloric by supplementing the alphacel with dextrose assuming a caloric equivalent for pectin of 0.6187 cal/g. Mortality did not vary significantly between groups. Body weights for the pectin fed groups were similar but significantly less than those of the control animals. A comparison of grams of diet/kg body weight showed a slightly greater food utilization for the pectin fed groups. The controls, however, consumed more food and gained more weight. There was no significant difference in average organ to body weight ratios for adrenal, heart, kidney, liver and spleen. The testes/body-weight ratio of the pectin fed groups did not differ from each other but both were significantly larger than those of the control group. Blood chemistry, SGOT and SPGT done at sacrifice showed no abnormalities in the pectin groups. Gross examination at necropsy showed no unusual findings. Two tumours were noted in the control group and one in the amidated pectin group. All gross lesions and adrenal, heart, kidney, liver, lung, spleen and testes were examined histologically. No compound related effects were observed (Palmer & Jones, 1974; Abdul & Palmer, 1974).

Groups of 50 male and 50 female Charles River strain albino rats were fed amidated pectin at dietary levels of 2% and 5% for two years. Similar groups of rats were fed non-amidated pectin at 2% or 5% of the diet. Initially an untreated control group receiving chow diet only was included in the study, however, this group was sacrificed and discarded at week 36 of the study. The group fed non-amidated pectin served as the control for the amidated pectin groups. An interim sacrifice of 10 animals per group per sex was carried out after three months of testing. Body weight tended to be lower in the males fed 5% of amidated or non-amidated pectin as compared to the males fed 2% amidated or non-amidated pectin. The difference was statistically significant at a number of weeks during the study. The total weight gain at 13 weeks was significantly lower in the males given 5% non-amidated pectin than that of the non-amidated 2% group. No significant changes were noted in food consumption or mortality. Small statistically significant differences between the high dose amidated and non-amidated group occurred with respect to leucocyte and reticulocyte counts at the three-month repeat blood collection, otherwise no significant haematological changes were noted. The 2% amidated pectin females had a large increase (about 3x) in serum glutamin pyruvate levels at the three-month and three-month repeat blood collections. There were other scattered instances of small statistically significant between group differences with respect to other clinical chemistry parameters. No significant changes were noted upon urinalysis. There were scattered instances of small but statistically significant between group differences in absolute organ and relative organ weights.

The absolute and relative adrenal glands weight in the low dose amidated pectin group was high compared to the other groups, although evidently there was not a statistically significant between group difference. The adrenal weights were not increased in the high dose females.

In general, the incidence of neoplastic and non-neoplastic lesions was similar in all the groups. The incidence of chronic inflammation of the liver was 4/37 in the females given 2% non-amidated pectin, 3/40 in the females given 5% non-amidated pectin, 14/39 in the females fed 2% amidated pectin and 13/49 in the females given 5% amidated pectin. Although the incidence of this lesion was increased in the females given amidated pectin, there was no dose response, the incidence being slightly reduced in the 5% amidated pectin group as compared to the 2% group (Industrial Biotest, 1979a).*

A group of 20 male and 20 female Wistar rats were fed a diet containing 16.6% amidated pectin for two years. Growth, final body weight and incidence of neoplastic and non-neoplastic lesions were stated to be comparable to a group of 4000 historical control animals maintained in the performing laboratory. Pathology observations for each animal were provided, but body weight other than at termination, and food consumption data were not reported (Mosinger, 1976).

Wistar rats of the Centre for Investigation and Medical Research at Marseille strain were administered 100 mg/kg bw of 18.4% amidated pectin, daily in the synthetic diet of Lacassagne MABI. Feeding was ad lib. Groups of 20 males and 20 females housed five to a cage were used. Controls consisted of an identical group of rats fed the basic synthetic diet. At this level of pectin in the diet there appeared to be no effects on growth and body weights of fed animals as compared to historic controls. Also, there appeared to be no effects on the serum of fed rats. Since many of the experimental details are lacking it is difficult to reconstruct the complete design of the study. It is clear, however, that tissues from 20 males and 20 females sacrificed at 24 months were studied histologically. Rats dying prior to termination of the study were also said to have been examined microscopically. However, no mention of such animals is made in the detailed pathology. The histopathology revealed no adverse effects on the stomachs or testes of fed males. It should be noted that these

* This study was validated by an independent audit (see memo of 13 November 1979, International Verband de Pektinproduzenten - submitted to WHO).

were very small rats. Only one male reached 640 g, the remainder ranged from 210 to 420 g with seven of the rats weighing 270 g or less. The weight of the females at sacrifice was similar to the males. A first generation produced by mating five animals produced a total of 99 offspring and a second generation produced by mating five animals resulted in only 43 offspring (Mosinger, 1974).

Comments

Non-amidated pectins and their salts as specified are normal constituents of the human diet and have also been administered intravenously at high levels to man without acute toxic effects. The available short-term tests show that even at 5% dietary levels, no adverse effects are seen. The caecal enlargement without any accompanying histological changes is probably related to the presence of large amounts of a polysaccharide in the diet.

Amidated pectins produced mild growth depression at a lower level (10%) than was seen with non-amidated pectins in a 90-day test as well as in a two-year study in rats. The available short-term study in rats revealed caecal enlargement but not associated with any histological abnormality.

A three-generation reproduction study and a teratogenicity study, and a two-year feeding study in rats fed diets containing 2% and 5% amidated pectin or non-amidated pectin showed no significant toxicological differences between animals fed amidated and non-amidated pectin.

EVALUATION

ADI not specified.*

* The statement "ADI not specified" means that, on the basis of the available data (toxicological, biochemical, and other), the total daily intake of the substance, arising from its use or uses at the levels necessary to achieve the desired effect and from its acceptable background in food, does not, in the opinion of the Committee, represent a hazard to health. For this reason, and for the reasons stated in individual evaluations, the establishment of an acceptable daily intake (ADI) in mg/kg bw is not deemed necessary.

REFERENCES

- Abdul, H. & Palmer, G. H. (1974) Two-year pectin feeding study: histopathological studies. Unpublished report from Sunkist Growers, Inc. submitted to the World Health Organization by Sunkist Growers, Inc.
- Industrial Biotest (1976) Teratologic study on amidated pectin. Unpublished report submitted to the International Pectin Producers Association
- Industrial Biotest (1979a) Two-year study on amidated pectin. Unpublished report submitted to the International Pectin Producers Association
- Industrial Biotest (1979b) Three generation reproduction study on amidated pectin. Unpublished report submitted to the International Pectin Producers Association
- Mosinger, M. (1974) Experimentation d'épreuve concernant les effets de l'administration orale prolongée du produit pectine L.H. NST de la Société Unipectine SA. Unpublished report from the "Central d'explorations et de recherches médicales", Marseille, submitted to the World Health Organization by the International Pectin Producers Association
- Mosinger, M. (1976) Two-year chronic feeding study and multi generation reproductive-teratology study with amidated pectin. Unpublished report submitted to the International Pectin Producers Association
- Palmer, G. H. & Jones, T. R. (1974) Two-year pectin feeding study. Unpublished report from Sunkist Growers, Inc. submitted to the World Health Organization by Sunkist Growers, Inc.
- Til, H. P., Seinen, W. & De Groot, A. P. (1972) Sub-chronic (90-day) toxicity study with two samples of pectin (Melange A₂ and C₂) in rats. Unpublished CIVO Report No. 3843 studied August 1972, Submitted to the World Health Organization by the Inst. Eur. Des Ind. de la Pectine

Canadian General Standards:

Kaolin: Under 12. Wine Processing Standards, kaolin is approved for use in Clarification/Fining, although natural settling and racking is preferred.

Under 15.6 Processing and Handling Materials List, kaolin is approved and generally unrestricted.

Pectin: Both low- and high-methoxy pectin are approved as food additives. Modified (citrus) pectin is not allowed (“not a food-grade form of pectin”).³⁵

EEC:

Listed as approved chemicals for use in veterinary medicine, in Article 14 of Council Regulation (EEC) No. 2377/90:

<u>Aluminum silicate (kaolin)</u>	Annex II (E-number 559)	Reg. 2034/96
<u>Pectin</u>	Annex II (E-number 440)	Reg. 2034/96 ³⁶

In organic standards:

ANNEXES I - VIII TO COUNCIL REGULATION (EEC) No 2092/91 of 24 June 1991

on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs.

**ANNEX VI
GENERAL PRINCIPLES**

Sections A, B and C cover the ingredients and processing aids which may be used in the preparation of foodstuffs composed essentially of one or more ingredients of plant origin, referred to in Article 1 (1) (b) of this Regulation, with the exception of wines.

SECTION A –

INGREDIENTS OF NON-AGRICULTURAL ORIGIN (REFERRED TO IN ARTICLE 5 (3) (c) and Article 5 (5a) (d) OF REGULATION (EEC) No 2092/91:

A. 1. Food additives, including carriers

E 440 (i) Pectin

SECTION B –

PROCESSING AIDS AND OTHER PRODUCTS WHICH MAY BE USED FOR PROCESSING OF INGREDIENTS OF AGRICULTURAL ORIGIN FROM ORGANIC PRODUCTION, REFERRED TO IN ARTICLE 5 (3) (d) AND ARTICLE 5 (5a) (e) OF REGULATION (EEC) No 2092/91

D. FEED ADDITIVES, CERTAIN SUBSTANCES USED IN ANIMAL NUTRITION (DIRECTIVE 82/471/EEC) AND PROCESSING AIDS USED IN FEEDINGSTUFFS

1. Feed additives

1.6. Binders, anti-caking agents and coagulants. The following substances are included in this category:

E 559 Kaolinitic clays³⁷

CODEX:

³⁵ “Certified Organic Management Standards.” Certified Organic Associations of British Columbia. http://www.certifiedorganic.bc.ca/Standards/Bk2_COABC_Organic_Management_Standards_Version4-03-02.pdf March 2002.

³⁶ “Status of MRL Procedures.” EEC. <http://www.emea.eu.int/pdfs/vet/srwp/076599en.pdf> 19 March 2002.

³⁷ “Annexes I-VIII to Council Regulation (EEC) No 2092/91 of 24 June 1991.” European Union. February 2002. <http://www.defra.gov.uk/farm/organic/reg2092annex.pdf>

GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING, AND MARKETING OF ORGANICALLY PRODUCED FOOD**Annex 2: Permitted Substances for the Production of Organic Foods****Table 3**

Ingredients of Non-Agricultural Origin

For plant products:

Pectin**Table 4**

Processing Aids Which May Be Used for the Preparation of Agricultural Products

For plant products:

Kaolin

For livestock and bee products:

Kaolin³⁸**Japan Agricultural Standards for Organic Agricultural Products and Their Processed Foods:**Kaolin: Approved as a processing aid and a food additive.Pectin: Approved as a food additive.³⁹**SCF:**Kaolin: ADI Not Specified**Section 2119 OFPA U.S.C. 6518(m)(1-7) Criteria**

1. *The potential of the substance for detrimental interactions with other materials used in organic farming systems.*

As mentioned earlier, both kaolin and pectin have been approved for use in organic systems. For the purpose which this petition addresses, eg: for the use of kaolin pectin as medicine in livestock, there is no evidence that together the two ingredients would cause harmful interactions in an organic system.

2. *The toxicity and mode of action of the substance and of its break down products or any contaminants, and their persistence and areas of concentration in the environment.*

Kaolin is a naturally occurring clay, and can pollute even in its natural environment through erosion. Occupational limits have been set on the amount of exposure workers can have to inhaled kaolin dust, as short-term exposure can cause lung irritation and long-term exposure can cause fibrosis (kaolinosi) and impaired function in the lungs.^{40, 41} Animal studies confirm that prolonged inhalation of kaolin may be harmful, resulting detrimental effects in the lungs and blood cells.

Kaolin is generally considered to be “practically non-toxic” when orally consumed by humans, and is FDA approved as a food additive. Harmful levels occur only if massive amounts are consumed. The probable oral lethal

³⁸ “Guidelines for the Production, Processing, Labelling, and Marketing of Organically Produced Food: Proposed Draft Amendments.” Codex Alimentarius Commission. http://www.hc-sc.gc.ca/food-aliment/frtia-raaii/ip-pi/codex/pdf/e_cl01_48e.pdf December 2001.

³⁹ Japanese Agricultural Standards. <http://www.fas.usda.gov/gainfiles/200004/25647377.pdf>

⁴⁰ *International Chemical Safety Cards: Kaolin*. NIOSH, CEC. <http://www.cdc.gov/niosh/ipcsneng/neng1144.html>

⁴¹ Rom, W.N. (ed.). *Environmental and Occupational Medicine*. 2nd ed. Boston: Little, Brown and Company, 1992. pp. 483

dose for humans (based on animal data) is calculated as "more than 2.2 lbs" or greater than 15 g/kg.⁴² In studies, mice have been successfully fed diets of 80% kaolin.⁴³

Pectin has also been FDA approved as a food additive and safe by the EPA through many animal studies. (Refer to EPA ruling.) There are some studies that do suggest some toxic effects, but some are due to massive doses. In one study, massive IV injections led to temporary splenomegaly in rabbits and parenchymatous lesions in the livers and kidneys of mice.⁴⁴ In another study, a dietary level of 2% pectin depressed the growth of chickens and quail significantly; also the digestibility of the diet was depressed in chickens and quail, but not in rats.⁴⁵

In laboratory animals (rats, fowl, and dogs), as well as humans, pectin is seen to have antihypercholesterolemic effects, with the high molecular weight and high-methoxy pectins being the most active.⁴⁶

3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*

In the manner in which kaolin is to be used, in kaolin pectin, there is unlikely chance of environmental contamination. However, if workers are to be exposed to kaolin dust during manufacture, they must take appropriate precautions.

4. *The effects of the substance on human health.*

(See 2. Toxicity)

Problems in humans during pregnancy and breast-feeding have not been documented, as the kaolin and pectin combination is poorly absorbed after oral administration.⁴⁷

As mentioned earlier, kaolin pectin, due to the aluminum in kaolin, decreases the absorption of drugs taken concurrently. Taking doses of other oral medications 2 to 3 hours before or after doses of kaolin pectin is not recommended.⁴⁸

5. *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops, and livestock.*

There is no evidence of detrimental effects in the agroecosystem.

6. *The alternatives to using the substance in terms of practices or other available materials.*

⁴² American Conference of Governmental Industrial Hygienists, Inc. *Documentation of the Threshold Limit Values and Biological Exposure Indices*. 6th ed., vol. I,II, III. Cincinnati: ACGIH, 1991. pp. 839-40.

⁴³ Gosselin, R.E., R.P. Smith, H.C. Hodge. *Clinical Toxicology of Commercial Products*. 5th ed. Baltimore: Williams and Wilkins, 1984. pp. II-95.

⁴⁴ Rossoff, I.S. *Handbook of Veterinary Drugs*. New York: Springer Publishing Company, 1974. pp. 416.

⁴⁵ Vohra, P., Et. al; Nutr Rep Int 19(4) 463. 1979.

⁴⁶ Aiello, S.E. (ed). *The Merck Veterinary Manual*. 8th ed. Merck & Co., Inc., Philadelphia: National Publishing Inc., 1998. pp. 414.

⁴⁷ "Kaolin." Drugs.com.

<http://www.drugs.com/index.cfm?pageID=1150&int=1&list=1&values=%26drugid%3Dd03078&OpText=kaolin>

⁴⁸ "Kaolin and Pectin." Drugs.com.

<http://www.drugs.com/index.cfm?pageID=0&xml=001362&type=pros&bn=Kaolin%20and%20Pectin>

An alternative medication for diarrhea in livestock is bismuth subsalicylate (Pepto-Bismol), which is also scheduled for review by the NOSB in September 2002. Antibiotics to perhaps treat the cause of intestinal problems is not allowed in organic practice.

7. *Its compatibility with a system of sustainable agriculture.*

There is no evidence to suggest that the use of kaolin pectin as a medication would be incompatible with a system of sustainable agriculture.

TAP Reviewers' Discussion

Reviewer 1 [*Ph.D. in Mammalian/Avian Physiology; Nutrition/Physiology research for USDA-ARS. Central U.S.*]

OFPA Criteria Evaluation

(1) The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

As the substances are naturally present and relatively abundant, fecal excretion of kaolin should not be a problem, nor that of pectin as most will be degraded in the intestine. Thus, no harmful potential is evident.

(2) The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

Substances in question have no known toxicological effects. None apparent in the literature.

(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
No evidence that kaolin and pectin will contaminate environment.

(4) the effect of the substance on human health;

Indirect effects via livestock and the food chain to humans are not possible. Direct and prolonged consumption by humans could result in decreased bioavailability of some key nutrients (ie. trace minerals and vitamins), but only in very prolonged feeding. Proper medical use of this substance poses no danger.

(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

None.

(6) the alternatives to using the substance in terms of practices or other available materials; and
Not applicable.

(7) its compatibility with a system of sustainable agriculture.

Compatible.

Reviewer 1 Conclusions

Kaolin pectin should be approved for treating bacterial diarrhea in livestock.

Reviewer 1 Recommendations Advised to the NOSB

The substance is natural, nonsynthetic. For Livestock, the substance should be Added to the National List.

Reviewer 2 [PhD, Animal Science; Professor of Animal Science, Central U.S.]

Observations

Identification

The information provided is accurate.

Characterization

The information on kaolin and pectin composition is accurate. The information on pectin properties should indicate that it is perhaps the best known of the soluble dietary fibers used in human and animal nutrition. It is readily fermentable in the fermentative compartments of the gut (i.e., reticulorumen, cecum/ceca, large bowel). Fed at too high a concentration, it can result in osmotic diarrhea. As regards specific uses, livestock must be defined. Certainly kaolin pectin would be of little use in ruminant livestock (not to include calves, which are non-ruminants until 8 weeks of age). Does livestock include poultry? Why is information on humans provided if this petition has to do with livestock? All other information in this section appears accurate.

Status

The information provided is accurate.

Code of Federal Regulations information

The material presented speaks to the safety and efficacy of kaolin and pectin when used properly.

National Organic Program information

Both kaolin and pectin are approved separately for use in organic systems. No reason exists that they should not be approved for use together in organic systems.

National List of Allowed and Prohibited Substances

Both of the substances in question are currently on the list of allowed substances.

Environmental Protection Agency information

The material presented speaks to the safety and efficacy of kaolin and pectin when used properly.

World Health Organization information

The material presented shows the safety of pectin, even at high (unphysiological) levels of administration.

CODEX information

In item #2, the negative effect of pectin on growth of chickens and quail was referred to. This is because pectin is hygroscopic and when present in the feed makes the diet somewhat hygroscopic. The birds have a beak and diet collects and builds up on the beak, preventing adequate feed consumption. So the negative response is not due to the pectin itself but rather to the reduced feed intake by the bird resulting from the hygroscopic nature of the diet and the inability to eat at maximal capacity.

Reviewer 2 Conclusions/Recommendations to the NOSB

Kaolin pectin contains a nonsynthetic and a synthetic moiety that, in combination, is effective as an adsorbent, an anti-diarrheal agent, and a gut protectant for livestock. Properties of each moiety have been well defined separately and in combination. It should be allowed to be placed on the National List without restrictions.

Reviewer 3 [BS, Food Science, Education director for a not-for-profit organization, Past Member of the NCR SARE Technical Committee, Chairman of state organic program, CEO of a USDA accredited agency, Central US]

Summary

“Kaolin pectin is an adsorbent, anti-diarrheal, and gut protectant used in both humans and livestock. It may be combined with vitamin A to treat bacterial diarrhea in calves.

The subject of the current petition is a request for the approval of kaolin pectin to the National List for medical use in organic livestock. Both kaolin and pectin are considered GRAS as indirect and direct food additives respectively, as consistent with good manufacturing practices.

Specific Uses:

Kaolin pectin has been petitioned for use in the medical treatment of livestock. It may be indicated as an adjunct to rest, fluids, and an appropriate diet in the treatment of mild to moderately acute diarrhea.

Kaolin and pectin are administered together to serve as an adsorbent and protectant. Kaolin is a natural hydrated aluminum silicate that is believed to adsorb large numbers of bacteria and toxins and reduce water loss. Pectin is a polyuronic polymer for which the mechanism of action is unknown. Pectin consists of purified carbohydrate extracted from citrus fruit or apple pomace.

The basis of this petition concerns the use of kaolin pectin for livestock medical treatment. It is used in livestock for the same reasons that it is administered to human: as an adsorbent, anti-diarrheal, and gut protectant. It may also be combined with vitamin A to treat bacterial diarrhea in calves.

How Made:

Both kaolin and pectin are formed naturally.

Kaolin is a mineral dust formed by weathering of aluminum silicates.⁴⁹

Pectin may be obtained for use by extraction into an aqueous medium from appropriate edible plant material, usually citrus fruits or apples. No organic precipitants are used other than methanol, ethanol and isopropanol. In some types a portion of the methyl esters may have been converted to primary amides by treatment with ammonia under alkaline conditions. The commercial product is normally standardized with sugars, and may be buffered with suitable food grade salts.⁵⁰

Status:

Impact on Human Health and the Environment:

The **FDA** has declared kaolin to be GRAS as an indirect food additive, and pectin to be GRAS as a direct food additive, both with the limitation that the levels in food are consistent with good manufacturing practices.

Under 40 CFR Part 180:[OPP-300614; FRL-5769-9] RIN 2070-AB78

Kaolin; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA)

ACTION: Final rule

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of anhydrous kaolin when used in or on food commodities to aid in the control of insects, fungi, and bacteria (food/feed use).

From the Scientific Review: I. Toxicological Profile

⁴⁹ Found at: <http://chemfinder.cambridgesoft.com/>

⁵⁰ “Specification for Pectins.” International Pectin Producers Association.
http://www.ippa.info/specification_for_pectins.htm

“ No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV. The data reported in the primary eye irritation study demonstrate that the test substance was minimally irritating. Kaolin was not corrosive and all eye irritation effects cleared within 72 hours post dosing; Toxicity Category III. The data reported in the primary-skin irritation study demonstrated that the test substance caused no dermal irritation in rabbits treated with 0.5g kaolin for 4 hours. No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV.”

“... Kaolin has GRAS (Generally Recognized as Safe) status under 21 CFR 186.1256 and is generally recognized as safe ``as an indirect human food ingredient with no limitation other than current good manufacturing practice.””

“... Kaolin is an inert mineral and has no known toxicological effects...”

“Non-dietary exposure, non-occupational exposure. The amount of kaolin currently used in the U.S. pesticide industry as an inert is between 2 million lbs. and 10 million lbs. per year.”

“Kaolin has no mode of toxicity and therefore no common mechanism of toxicity with other substances.”

***NOP:**

Kaolin and pectin are both approved (separately) by the NOP for use in organic systems. Below are pertinent excerpts regarding organic livestock production, and the kaolin and pectin entries on the National List, from the 2000 NOP Final Rule.

The National List of Allowed and Prohibited Substances

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

The following nonagricultural substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

(a) Nonsynthetics allowed:

(10) Kaolin

(b) Synthetics allowed:

(21) Pectin (low-methoxy)

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic or made with organic ingredients.

The following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

Any nonorganically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form.

(e) Pectin (high-methoxy)⁵¹

Status Among Certifiers, etc.

NOFA, DEC, OMRI:

⁵¹ *Final Rule, 2002.* NOP. <http://www.ams.usda.gov/nop/nop2000/nop2/finalrulepages/entirerule2.htm> 2002.

All approved Surround WP Crop Protectant, a vegetable pesticide with kaolin as its active ingredient, in 2001.⁵² OMRI suggests the following annotation to the listing of “Pectin” on the National List: “Low-methoxy form is synthetic and may only be used when the high-methoxy form is commercially unavailable.”⁵³

State Organic Certifiers:

Minnesota: Follows USDA suggested guidelines.

Oregon: Follows USDA suggested guidelines.

Pennsylvania: Follows OMRI suggested guidelines.

IFOAM: (To be voted on at the general assembly Victoria, August 26-28, 2002)

List of Approved Additives and Processing Aids

Where the substances listed in this annex can be found in nature, natural sources are preferred. Substances of certified organic origin are preferred.

INS 948 Kaolin Processing Aid

Criteria for the Evaluation of Additives and Processing Aids for Organic Food Products

3. Step by Step Procedure for the use of Additives and Processing Aids

1. Instead of using additives or processing aids, the preferred first choice is:

- Foods grown under organic conditions which are used as a whole product or are processed in accordance with the IFOAM Basic Standards - e.g. flour used as a thickening agent or vegetable oil as a releasing agent
- Foods or raw materials of plant and animal origin which are produced only by mechanical or simple physical procedures - e.g. salt.

2. The second choice is:

- substance isolated from food and produced physically or by enzymes - e.g. starch, tartrates, pectin

Pectin: The following statement is from a document concerning years of study concerning the possible toxicity of pectin. The final ruling was that it is also “ADI Not Specified.”

WHO EVALUATION:

“...on the basis of the available data (toxicological, biochemical, and other), the total daily intake of the substance, arising from its use or uses at the levels necessary to achieve the desired effect and from its acceptable background in food, does not, in the opinion of the Committee, represent a hazard to health. For this reason, and for the reasons stated in individual evaluations, the establishment of an acceptable daily intake (ADI) in mg/kg bw is not deemed necessary.”

Canadian General Standards:

Kaolin: Under 12. Wine Processing Standards, kaolin is approved for use in Clarification/Fining, although natural settling and racking is preferred.

Under 15.6 Processing and Handling Materials List, kaolin is approved and generally unrestricted.

Pectin: Both low- and high-methoxy pectin are approved as food additives. Modified (citrus) pectin is not allowed (“not a food-grade form of pectin”).⁵⁴

EEC:

Listed as approved chemicals for use in veterinary medicine, in Article 14 of Council Regulation (EEC) No. 2377/90:

Aluminum silicate (kaolin) Annex II (E-number 559) Reg. 2034/96

⁵² *NOFA-NY/OMRI/DEC Approved Vegetable Pest Management Products 2001.*

http://www.nysaes.cornell.edu/recommends/org_app.pdf 2001.

⁵³ *OMRI Comments on the USDA Proposed Rule.* http://www.omri.org/full_comments.pdf 9 June 2000.

⁵⁴ “Certified Organic Management Standards.” Certified Organic Associations of British Columbia.

http://www.certifiedorganic.bc.ca/Standards/Bk2_COABC_Organic_Management_Standards_Version4-03-02.pdf March 2002.

PectinAnnex II (E-number 440) Reg. 2034/96⁵⁵**CODEX:**

GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING, AND MARKETING OF ORGANICALLY PRODUCED FOOD

Annex 2: Permitted Substances for the Production of Organic Foods

Table 3

Ingredients of Non-Agricultural Origin

For plant products:

PectinTable 4

Processing Aids Which May Be Used for the Preparation of Agricultural Products

For plant products:

Kaolin

For livestock and bee products:

Kaolin⁵⁶**Japan Agricultural Standards** for Organic Agricultural Products and Their Processed Foods:Kaolin: Approved as a processing aid and a food additive.Pectin: Approved as a food additive.⁵⁷**Section 2119 OFPA:**

- The potential of the substance for detrimental interactions with other materials used in organic farming systems. From the Scientific Review: “Both kaolin and pectin have been separately approved for use in organic systems. There is no evidence that together the two ingredients would cause harmful interactions in an organic system.”

- The toxicity and mode of action of the substance and of its break down products or any contaminants, and their persistence and areas of concentration in the environment.

From the Scientific Review: “Kaolin is generally considered to be “practically non-toxic” when orally consumed by humans, and is FDA approved as a food additive. Harmful levels occur only if massive amounts are consumed....”

- The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance. From the Scientific Review: “In the manner in which kaolin is to be used, in kaolin pectin, there is unlikely chance of environmental contamination. However, if workers are to be exposed to kaolin dust during manufacture, they must take appropriate precautions.”

- The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops, and livestock.

From the Scientific Review: “There is no evidence of detrimental effects in the agroecosystem.”

- The alternatives to using the substance in terms of practices or other available materials.

From the Scientific Review: “An alternative medication for diarrhea in livestock is bismuth subsalicylate (Pepto-Bismol), which is also scheduled for review by the NOSB in September 2002.” (See review of Bismuth Subsalicylate.)

- Its compatibility with a system of sustainable agriculture.

From the Scientific Review: “There is no evidence to suggest that the use of kaolin pectin as a medication would be incompatible with a system of sustainable agriculture.”

⁵⁵ “Status of MRL Procedures.” EEC. <http://www.emea.eu.int/pdfs/vet/srwp/076599en.pdf> 19 March 2002.

⁵⁶ “Guidelines for the Production, Processing, Labelling, and Marketing of Organically Produced Food: Proposed Draft Amendments.” Codex Alimentarius Commission. http://www.hc-sc.gc.ca/food-aliment/friia-raaii/ip-pi/codex/pdf/e_cl01_48e.pdf December 2001.

⁵⁷ Japanese Agricultural Standards. <http://www.fas.usda.gov/gainfiles/200004/25647377.pdf>

Reviewer 3 Conclusion and Recommendation

Kaolin pectin is nonsynthetic and should be allowed with restrictions*.

***Suggested Restrictions: language should be consistent with NOP Section 205.605(b) 21 regarding Pectin.**

TAP Conclusion

Two of the reviewers asserted that kaolin pectin is nonsynthetic while the third reviewer believed that it has both synthetic and nonsynthetic elements. Two of the reviewers recommended that kaolin pectin be added to the National List without restrictions, while the third reviewer suggested that it be allowed with specific restrictions.