

Non Amidated Low Methoxyl Pectin

Handling

Executive Summary

In order to understand non amidated low methoxyl pectin, one has to understand pectins in general. Pectins are complex polysaccharides, basically polymers of α -D-(1-4)- linked galacturonic acid that act as cellular binders in the peel of many different fruits and vegetables. Pectins have been divided into two groups in the market; those containing more than 50 percent (%) esterification (high methoxyl pectin, HMP) and those containing less than 50 % esterification (Low Methoxyl Pectin, LMP). LMP are highly reactive with cations. The petitioned purpose is for use as a non-organically produced Agricultural product. However, non amidated low-methoxyl pectin has a number of food and beverage applications as well as applications in pharmaceutical products.

Pectins are mainly used as gelling agents, but can also act as thickeners, water binder and stabilizer. Low methoxyl pectins (< 50 % esterified) form thermoreversible gels in the presence of calcium ions at low pH (pH 3-4.5). The lower the methoxyl content, the slower the gel set. The degree of esterification can be (incompletely reduced using commercial pectin methylesterase, leading to a higher viscosity and firmer gelling in the presence of Ca^{2+} ions. The term degree of esterification is intended to mean the extent to which free carboxylic acid groups contained in the poly-galacturonic acid chain of the pectin have been esterified (e.g., by methylation) or in other ways rendered non acidic (e.g., by amidation). The main sources of non amidated low methyl pectins is high methoxyl pectin such as citrus peel and apple pomace by chemical demethylation.

Demethylation is a chemical process. There are four methods of demethylation according to agents used. The agents used are acids, alkalis, enzymes, and ammonia in alcohol. Acid demethylation is commonly used to manufacture LMP. Depolymerization is the main disadvantage of the acid treatment which hydrolyzes glycosidic bonds. Researchers have shown that using higher concentrations of acid at low temperatures gave less depolymerization during demethylation than when lower concentrations and higher temperatures were used.

Identification of Petitioned Substance

Identification

Chemical Name:

Non-Amidated
Low Methoxyl Pectin

Other Names:

Pectin
Apple Pomace
Citrus Pomace
Citrus Peels
Modified Citrus Pectin
Pectinic Powder

Trade Names:

Pectin
CAS Number: 9000-69-5

Other Codes:

INS No. 440

Characterization of Petitioned Substance**Composition of the Substance:**

Apple Pomace: 10 - 15%
sugar beet chips: 10 - 20%
sunflower infructescence: 15 - 25%
Citrus peels: 20 - 35%

Molecular Weight 20,000-400,000 Polysaccharide substance present in the Cells walls of all plant tissues which acts as an intercellular cementing material. One of the richest sources of pectin is lemon or orange rind (peel) which contains about 30% of this polysaccharide. It occurs naturally as the partial methyl ester of α -(1-4) linked D-polygalacturonate

Properties of the Substance:

Pectin is described as being a white, yellowish, light grayish or light brownish powder. It is produced/processed by a number of different companies which includes:

Herbstreith & Fox, Neuenburg/Württ, Germany
Cargill Texturizing Solutions, Mechelen, Belgium
CP Kelso, Denmark
Danisco Ingredients USA Inc., Kansas
Obipektin AG, Switzerland
Yantai Andre Pectin Co., Ltd, Yantai, P.R. China

Pectin is regulated under the Food and Drug Administration's regulations; 21 CFR, Part 184, Subpart B, Section 184.1588 are 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, at temperatures that range from 70 °C to 90 °C). The extract is then filtered, and pectin is precipitated from the clear extract with ethanol or isopropanol, or as the copper or aluminum salt. The acid extract is sometimes sprayed or roller dried or it is concentrated to be sold as liquid pectin.

Specific Uses of the Substance:

Pectins are one of the most versatile stabilizers available. Pectins are used as emulsifiers, gelling agents, thickeners, and stabilizers which has made them essential additives in the production of many food products. Traditionally pectin was used in the production of jams and fruit jellies industrially and domestically. They were used in low as well as high sugar products. It seems that pectin secured the desired texture and limited the creation of water/juice on top of the surface as well as helped achieved even distribution of the fruit in certain products. With changes that have taken place in our lifestyles over the years pectin is primarily for industrial use.

In today's market, product and application development by major food processors and pectin producers have over the years resulted in a huge expansion of the application and use of pectins. Pectin is a key stabilizer in many food products. The following are some listed applications of pectin:

1. The preparation of jellies, jams, and deserts in fruit applications.
2. Bakery fillings and toppings of fruit preparations for dairy applications.
3. Dairy applications such as acidized milk proteins drinks and yogurts (thickening agent).
4. Confectionary applications such as fruit jellies, jam, Fruit butter, marmalade, and neutral jellies.
5. Beverage applications.
6. The production and manufacturing of Nutritional and health products.
7. Pharmaceutical and medical applications.

Over the years, positive public acceptance of pectin has proven helpful in the widespread use of pectin. As a result, there is growing interest in investigating direct health benefits from pectins and their application in the regulated non-food segment as well as in functional foods and nutraceuticals. Pectins also find medical and pharmaceutical applications such as in Veterinary Therapeutic category pectin is listed as an anti-diarrheal agent.

The wide range of applications explains the need for many different types of commercial pectins, which are sold according to their application, for example:

- Rapid set pectin is traditionally used for jams and marmalades.
- Slow set pectin is used for jellies and for some jams and preserves, especially using vacuum cooking at lower temperatures. This type of pectin is also important for use with higher sugar products like bakery and biscuit jams, sugar and confectionery items.
- Stabilizing Pectins are used for stabilizing acidic protein products such as yogurts, whey and soy drinks against the effects of heat processing.
- Low methoxyl esters and amidated pectins are used in a wide variety of low sugar products, reduced sugar preserves, fruit preparations for yogurts, dessert gels and toppings, and savory applications such as sauces and marinades. These types of pectins can also be used in low acid high sugar products such as preserves containing low acid fruits such as figs, and bananas and other confectionary products.

Approved Legal Uses of the Substance:

The ingredient must be of purity suitable for its intended used. Under U. S. FDA code of Federal Regulations, pectin (non-amidated low methoxyl pectin) is recognized as generally recognized as Safe (GRAS) ingredient in food. The affirmation of these ingredients as GRAS as direct human food ingredients, is based upon the following good manufacturing practice conditions of use:

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.

The ingredients are used in food at levels not to exceed current good manufacturing.

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Summary of Legal References: Food Product	Application	ASC Solution	
21 CFR Section 184.1588 and 170.3 (o) (8)	Can be used as emulsifiers and emulsifier salts	used in food at levels not to exceed current good Manufacturing practice	
21 CFR Section 170.3 (o) (28)	Also as Stabilizers and thickeners		

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134 In The Food and Agriculture (FAO)/World Health Organization (WHO)-Codex Alimentarius references
 135 Pectins have been given an acceptable daily intake (ADI) of “not specified by the FAO/WHO Joint Expert
 136 Committee on Food Additives (JECFA), and are listed on that basis in the Code General Standard for Food
 137 Additives.

138 The European Union states that Pectins (E440 (i)) and Amidated Pectin (E440 (ii)) have both been given and
 139 ADI “not specified” by the Scientific Committee for Food. Specifications are listed in Commission
 140 Directive 98/86/EC of the 11th November 1998, Published in Volume 41, Issue L334 of the Official Journal.
 141 Pectins may be used under “Quantum Satis” conditions in most foods, except those specifically restricted
 142 under Directive 95/2/EC of the 20th February 1995 on Food Additives other than Colors and Sweeteners.
 143 Quantum Satis means use as much as necessary to achieve the desired effect and no more. Essentially
 144 limited to what is considered to be Good Manufacturing Practice.

145 As natural polymers and chemically modified natural polymers, pectins are exempt from REACH
 146 registration for EU. REACH is a new European Community Regulation on chemicals and their safe use
 147 ([EC 1907/2006](#)). It deals with the Registration, Evaluation, Authorization and Restriction of Chemical
 148 substances. The new law entered into force on 1 June 2007.

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150 **Action of the Substance:**

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152 Pectins of low methyl-ester content are widely used in the food industry because they can form gels in the
 153 presence of calcium ions. These pectins are generally prepared by controlled acid de-esterification of high
 154 methoxyl pectins, although three other methods can be used, namely by means of alkali, enzyme, and
 155 ammonia. Treatment of pectin with acid, alkali, or microbial pectin methyl-esterase are thought to give low
 156 methoxyl pectins with a random distribution of free carboxyl groups, whereas the action of plant pectin
 157 methyl-esterase leads to low methoxyl pectins where the free carboxyl groups are block wise distributed.
 158 The calcium binding of these pectins has been extensively studied; results showed that calcium ions cross-
 159 link the pectin chains in an “egg-box” like leading to gelation. The fourth method uses ammonia generally
 160 in alcoholic systems and produces a different type of low methoxyl pectins (amidated pectins) have some
 161 advantages compared to the non-amidated ones: they need less calcium to gel, they are less sensitive to
 162 precipitation by high amounts of calcium, and their gels are claimed to be perfectly thermo irreversible.

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Status

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169 **International:**

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171 There is a Monograph that was prepared at the 71st JECFA (2009) and published in FAO JECFA
 172 monographs 7 (2009), superseding in FAO JECFA monographs 4 (2007). A group ADI “not specified was
 173 established for pectins and amidated pectins, singularly or in combination at the 25th JECFA in 1981.

THE MONOGRAPH IS ALSO IN THE REPORT OF THE JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX ALIMENTARIUS COMMISSION, TENTH SESSION, ROME, 1-12 JULY, 1974, REPORT OF THE NINTH SESSION OF THE, CODEX COMMITTEE ON FOOD ADDITIVES, WAGENINGEN, 10-14 DECEMBER 1973. The Committee noted that the Expert Committee had given an acceptable daily intake (ADI) only to "amidated" pectin and had considered that "non-amidated" pectin did not require limitation by an ADI. The representative of the International Federation of Pectin Producers explained that in products with a minimum solids requirement of above 55% non-amidated pectin would be used, whereas the amidated pectin was more likely to be used in "low calorie" products. The Committee decided that the provision should be amended in order to make it clear that the endorsement referred to "non-amidated" pectin.

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Is the petitioned substance formulated or manufactured by a chemical process? (From 7 U.S.C. § 6502 (21)).

The main sources of non amidated low methyl pectins (LMP) are high methoxyl pectin such as citrus peel and apple pomace by chemical demethylation. Demethylation is a chemical process. There are four methods of demethylation according to the agents used: acids, alkalis, enzymes and ammonia in alcohol. Acid demethylation is commonly used to manufacture LMP. Depolymerization is the main disadvantage of the acid treatment which hydrolyzes glycosidic bonds (Kertesz, 1951). Kim *et al.* (1978) showed that using higher concentration of acid at low temperatures gave less depolymerization during demethylation than when lower concentration and higher temperatures were used.

Evaluation Question #2: Is the petitioned substance formulated or manufactured by a process that chemically changes the substance extracted from naturally occurring plant, animal, or mineral sources? (From 7 U.S.C. § 6502 (21)).

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Evaluation Question #3: Is the petitioned substance created by naturally occurring biological processes? (From 7 U.S.C. § 6502 (21)).

One of the richest sources of pectin is lemon or orange rind (peel) which contains about 30% of this polysaccharide. It occurs naturally as the partial methyl ester of α -(1-4) linked D-polygalacturonate. Pectins are present in many fruits and vegetables in varying amounts and qualities. The major sources of pectin are citrus peel, the residue from the extraction of citrus juice and oil, and apple pomace, the dried residue from the extraction of apple juice.

Evaluation Question #4: Is there a natural source of the petitioned substance? (From 7 CFR § 205.600 (b) (1)).

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Evaluation Question #5: Is there an organic agricultural product that could be substituted for the petitioned substance? (From 7 CFR § 205.600 (b) (1).)

There are no known sources for non amidated low methoxyl pectin. The main sources of non amidated low methyl pectins are high methoxyl pectin such as citrus peel and apple pomace by chemical demethylation. As such it is reasoned that any organically grown fruit and/or vegetable could be a source for the petitioned substance. In that the juice industry which is the source of citrus peel and apple pomace, is also one of the primary sources of pectins, one concern would be the production volume needed to produce an organically grown source of the petitioned substance.

Evaluation Question #6: Are there adverse effects on the environment from the petitioned substance's manufacture, use, or disposal? (From 7 CFR § 205.600 (b) (2).)

Manufacture

Substantial safety and toxicology data exists based on the reviews that have been done of pectins (non amidated low methoxyl pectins included) by the FAO/WHO JECFA and the U.S. FDA that suggest that the petitioned substance is not harmful to human health or the environment. Since the manufacture of pectin is a by-product of the fruit juice industry, its production therefore serves to reduce the waste streams generated from the making of fruit juices.

Use

Citrus pectin is categorized as "generally regarded as safe" by the U.S. Food and Drug Administration, When MCP is used as intended, side effects rarely occur. However, some people may experience stomach discomfort after taking MCP. There have been a few case reports in which asthma developed in people after exposure to powdered pectin. Modified citrus pectin may cause serious allergic reactions in those who are allergic to citrus fruits, and the intake of large quantities may cause temporary flatulence or intestinal discomfort.

Disposal

For accidental releases of Non Amidated Low Methoxyl Pectin, the MSDS indicate that environmental precautions are "Not Applicable". Pectins are believed not to be dangerous to the environment with respect to mobility, persistency and degradability, bio-accumulative potential, aquatic toxicity and other data relating to ecotoxicity. Small quantities of waste are disposed of as domestic refuse. Greater quantities are disposed of in accordance with the local regulations.

Evaluation Question #7: Does the petitioned substance have an adverse effect on human health as defined by applicable Federal regulations? (From 7 CFR § 205.600 (b) (3).)

Kaolin-pectin formulations are popular for symptomatic therapy of diarrhea. Kaolin is a form of aluminum silicate and pectin (a carbohydrate extracted from the rind of citrus fruits). Although kaolin-pectin is

claimed to act as a demulcent and adsorbent in the treatment of diarrhea (related to the binding of bacterial toxins [endotoxins and enterotoxins] in the GI tract), clinical studies have not demonstrated any benefit from its administration. It may change the consistency of the feces but neither decreases the fluid or electrolyte loss, nor shortens the duration of the illness. Nevertheless, it is often administered to small animals, foals, calves, lambs, and kids. Kaolin-pectin products may adsorb or bind other drugs administered PO and reduces bioavailability.

The Journal Allergy Asthma Immunology reported on a clinical case of pectin anaphylaxis and possible association with Cashew allergy. Doctors at Children's Hospital, Los Angeles were able to identify a child with pectin-induced food anaphylaxis after ingesting pectin containing fruit smoothie. The child had an adverse reaction to ingesting grapefruit. The pectin source in fruit smoothie was confirmed to be of citrus origin. The anaphylaxis to pectin and cashews were confirmed by skin tests or radioallergosorbent tests (RASTs)

Doctors reported in the Journal of Allergy and Clinical Immunology a case of anaphylaxis caused by pectin component of barium sulphate suspension. They reported the first case of IgE-mediated anaphylaxis by pectin contained in a barium suspension. Cross-reactivity was demonstrated with cashew, pistachio and other nuts. Physicians should be aware of allergy to pectin in barium examinations, mainly in patients allergic to vegetables and nuts.

Evaluation Question #8: Is the nutritional quality of the food maintained when the petitioned substance is used? (From 7 CFR § 205.600 (b) (3).)

A high degree of esterification, or many bonded methanol groups, produces high methoxyl (HM) pectin, while a low degree of esterification gives low methoxyl (LM) pectin.

The ratio of esterified to non-esterified galacturonic acid units plays a central role in determining the properties and behaviour of the pectin, and determines which food applications it can be used in.

The growing consumer demand for low sugar jams due to weight management issues, coupled with regulation changes in the EU that allow for a product with a lower solid content to still be called a jam, has seen an increase in the use LM pectin.

"These products of lower sugar content tend to be slightly less acidic and require pectin that will gel effectively under these conditions," explains Apple. "This is where the LM pectin's and specifically the LMA pectin's (Amidated Low Methoxyl pectin) are appropriate. These pectins rely on the presence of bivalent cat ions typically calcium to build a gel."

Amidated pectin is a chemically modified form whereby some galacturonic acid is converted to carboxylic acid amide by reaction with ammonia.

"Thus the rise in consumer demand for reduced sugar and sugar-free jams is driving the market for LMA pectins, rather than inherent health benefits," he said.

Evaluation Question #9: Is the petitioned substance to be used primarily as a preservative? (From 7 CFR § 205.600 (b) (4).)

Based upon the information in the petition for the non amidated low methoxyl pectin as a non organically produced agricultural product that can be used as an emulsifier, stabilizer, and a thickener under FDA, 21 CFR Section 184.1588 and 21 CFR 170.3 (o) (8), and 21 CFR Section 170.3 (o) (28). However because of the structure of Pectin, non amidated low methoxyl pectin, there are other applications for the product. Some of these include the use of the petition product in low carbohydrate jellies and jams. The petitioned substance can also be used in other aspects of food processing such dairy, confection and baking industry. The product can also be used in the pharmaceutical, nutraceutical and medical industry.

Evaluation Question #10: Is the petitioned substance to be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? (From 7 CFR § 205.600 (b) (4).)

Based upon the petition, the non amidated low methoxyl pectin is being petitioned for use as a non-organically produced agricultural product allowed as an ingredient in or on processed products labeled as organic or made with organic ingredients. However non amidated low methoxyl pectin is derived primarily from High methoxyl pectin which may be extracted from a variety of fruits and vegetables both conventional and organically grown. The primary source of pectins is from citrus peel and apple pomace as a result of juice industry

Evaluation Question #11: Is the petitioned substance generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices? (From 7 CFR § 205.600 (b) (5).)

Non amidated Low methoxyl pectin is considered Generally y Recognized As Safe (GRAS) when used as an emulsifier and emulsifier salt, and as a stabilizer and thickener under FDA, 21 CFR Section 184.1588 and 21 CFR 170.3 (o) (8), and 21 CFR Section 170.3 (o) (28). when used in accordance with current Good Manufacturing Practices.

In 1995-1996, new potential uses of pectates in food products stimulated interest in re-evaluating the information available concerning the safety of pectins and pectates as food ingredients. Data relevant to the re-evaluation was obtained in rats in 14-day and 13-week subchronic feeding studies with sodium pectate. The Ames tests and other mutagenicity tests were conducted with sodium acetate, bleached sodium pectate and mixed sodium/calcium pectate salts. These toxicological studies with pectates provided further evidence of their safety, and supported the continued GRAS status of pectins and pectate salts.

Evaluation Question #12: Does the petitioned substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? (From 7 CFR § 205.600 (b) (5).)47

Pectin is a polysaccharide derived from the cell wall of plants. Pectins are variable in their chain lengths; complexity; and the order of each of the monosaccharide units.

Under acidic conditions, pectin forms a gel, and it can be used as an edible thickening agent in processed foods. This effect is used for making jam s and jellies.

Biosynthesis

They are synthesized in the plant Golgi apparatus and form a matrix in which the hemicellulose polysaccharides of the plant cell are embedded. An important part of fruit walls, pectin is broken down to pectinic acid and finally pectic acid. During this chemical breakdown process, the fruit gets softer as the cell walls degenerate!

Chemical composition

Pectin is composed of three main polysaccharide types:

- polygalacturonan, which is composed of repeated D-galacturonic acid monosaccharide subunits
 - rhamnogalacturonan I which is composed of alternating L-rhamnose and D-galacturonic acid subunits
 - rhamnogalacturonan II which is a complex, highly branched polysaccharide
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Sources

Apples, plums and oranges contain much pectin, and pectin is sometimes found in yogurt, while soft fruits like cherries and strawberries contain little pectin. For commercial utilization, pectin is extracted from shredded fruit peel or pulp by adding hot water. The pectin dissolves into the hot water, and may then be precipitated as a gel by adding ethanol

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