

Ref. #1

U. S. Food and Drug Administration
 Center for Food Safety & Applied Nutrition
 Office of Food Additive Safety
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Partial List Of Microorganisms And Microbial-Derived Ingredients That Are Used In Foods

Food ingredients may be "food additives" that are approved by FDA for specific uses or GRAS (generally recognized as safe) substances. A substance may be GRAS only if its general recognition of safety is based on the views of experts qualified to evaluate the safety of the substance. GRAS status may be based either on a history of safe use in food prior to 1958 or on scientific procedures, which require the same quantity and quality of evidence as would be required to obtain a food additive regulation. Because GRAS status may be either affirmed by FDA or determined independently by qualified experts, FDA's regulations do not include all GRAS ingredients and the specific uses described in the GRAS regulations may not be comprehensive for the listed ingredients.

The following list, which derives partially from FDA's regulations in Title 21 of the Code of Federal Regulations (21 CFR), includes approved food additives, substances whose GRAS status has been affirmed by FDA and substances that FDA listed as GRAS based on a history of safe use in food. In addition, microorganisms and microbial-derived ingredients may be the subject of a GRAS notice. For further information, consult the summary listing of GRAS ingredients.

The list below includes some ingredients that are not listed in 21 CFR but have been the subject of opinion letters from FDA to individuals who asked whether FDA would object to the use of the ingredient in food on the basis of an independent GRAS determination. Because the list is not updated on a regular basis, questions about the regulatory status of microorganisms or microbial-derived ingredients that are not on this list may be directed to us via electronic mail at PREMARKT@VM.CFSAN.FDA.GOV.

The following is a compilation of food additives listed in Title 21 of the Code of Federal Regulations (21 CFR) Part 172 and 173, which are derived from microorganisms. This list also includes seaweed sources. Conditions for their use are prescribed in the referent regulations and are predicated on the use of good manufacturing practices.

To access the specific regulations listed below, type in the title number, **21**, and then the section and part numbers, e.g. **172** and **155** at the Government Printing Office web site.

§172.155	Natamycin derived from <i>Streptomyces natalensis</i> and <i>Streptomyces chattanoogensis</i>
§172.325	Bakers yeast protein derived from <i>Saccharomyces cerevisiae</i>
§172.590	Yeast-malt sprout extract, derived from <i>Saccharomyces cerevisiae</i> , <i>Saccharomyces fragilis</i> , <i>Candida utilis</i>
§172.620	Carrageenan, a hydrocolloid extracted from the following members of the families <i>Gigartineae</i> and <i>Soliericeae</i> of the class <i>Rhodophyceae</i> (red seaweed): <i>Chondrus crispus</i> , <i>Chondrus ocellatus</i> , <i>Euचेuma cottonii</i> , <i>Euचेuma spinosum</i> , <i>Gigartina acicularis</i> , <i>Gigartina</i>

	<i>pistillata, Gigartina radula, Gigartina stellata</i>
§172.655	Furcelleran, the refined hydrocolloid extracted from <i>Furcellaria fastigiata</i> of the class <i>Rodophyceae</i> (red seaweed)
§172.695	Xanthan Gum derived from <i>Xanthomonas campestris</i>
§172.725	Gibberellic acid derived by fermentation from <i>Fusarium moniliforme</i>
§172.896	Dried yeasts, <i>Saccharomyces cerevisiae</i> , <i>Saccharomyces fragilis</i> , and dried torula yeast, <i>Candida utilis</i>
§172.898	Bakers yeast glycan from <i>Saccharomyces cerevisiae</i>
§173.110	Amyloglucosidase derived from <i>Rhizopus niveus</i> for use in degrading gelatinized starch into constituent sugars
§173.120	Carbohydrase and cellulase derived from <i>Aspergillus niger</i> for use in clam and shrimp processing
§173.130	Carbohydrase derived from <i>Rhizopus oryzae</i> for use in the production of dextrose from starch
§173.135	Catalase derived from <i>Micrococcus lysodeikticus</i> for use in the manufacture of cheese
§173.140	Esterase-lipase derived from <i>Mucor miehei</i> var. <i>Cooney et Emerson</i> as a flavor enhancer in cheeses, fats and oils, and milk products
§173.145	<i>Alpha</i> -galactosidase derived from <i>Morteirella vinaceae</i> var. <i>raffinoseutilizer</i> for use in the production of sucrose from sugar beets
§173.150	Milk-clotting enzymes, microbial for use in the production of cheese (Milk-clotting enzymes are derived from <i>Endothia parasitica</i> , <i>Bacillus cereus</i> , <i>Mucor pusillus</i> Lindt and <i>Mucor miehei</i> and <i>Aspergillus oryzae</i> modified to contain the gene for aspartic proteinase from <i>Rhizomucor miehei</i> var <i>Cooney et Emerson</i>)
§173.160	<i>Candida guilliermondii</i> as the organism for fermentation production of citric acid
§173.165	<i>Candida lipolytica</i> for fermentation production of citric acid.
§173.280	A solvent extraction process for recovery of citric acid from <i>Aspergillus niger</i> fermentation liquor

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The following is a compilation of GRAS affirmed substances listed in 21 CFR part 184 which are derived from microorganisms. This list also includes seaweed sources. Conditions for their use are prescribed in the referent regulations and are predicated on the use of nonpathogenic and nontoxicogenic strains of the respective organisms and on the use of current good manufacturing practice (184.1(b)). Please be aware that not all GRAS substances have been recorded as such and so this does not represent a complete list of all microbial derived GRAS food ingredients.

§184.1005	Acetic acid may be produced by fermentation

§184.1011	Alginate acid made from certain brown algae
§184.1012	Alpha-amylase enzyme preparation from <i>Bacillus stearothermophilus</i> used to hydrolyze edible starch to produce maltodextrin and nutritive carbohydrate sweeteners.
§184.1027	Mixed carbohydrase and protease enzyme product derived from <i>Bacillus licheniformis</i> for use in hydrolyzing proteins and carbohydrates in the preparation of alcoholic beverages, candy, nutritive sweeteners and protein hydrolysates
§184.1061	Lactic acid may be produced by fermentation
§184.1081	Propionic acid from bacterial fermentation
§184.1115	Agar-agar, extracted from a number of related species of red algae class <i>Rhodophyceae</i>
§184.1120	Brown algae, to be used dried as a flavor enhancer, are seaweeds of the species: <i>Anelopus japonicus</i> , <i>Eisenia bicyclis</i> , <i>Hizikia fusiforme</i> , <i>Kjellmaniella gyrate</i> , <i>Laminaria angustata</i> , <i>Laminaria longiruris</i> , <i>Laminaria longissima</i> , <i>Laminaria ochotensis</i> , <i>Laminaria cloustonia</i> , <i>Laminaria saccharina</i> , <i>Laminaria digitata</i> , <i>Laminaria japonica</i> , <i>Macrocystis pyrifera</i> , <i>Petalonia fascia</i> , <i>Scytosiphon lome</i>
§184.1121	Red algae, to be used dried as a flavor enhancer, are seaweeds of the species: <i>Gloiopeltis furcata</i> , <i>Porphyra crispata</i> , <i>Porphyra deudata</i> , <i>Porphyra perforata</i> , <i>Porphyra suborbiculata</i> , <i>Porphyra tenera</i> , <i>Rhodymenis palmata</i>
§184.1133	Ammonium alginate from certain brown algae
§184.1187	Calcium alginate from certain brown algae
§184.1318	Glucono delta-lactone, by oxidation of D-glucose by microorganisms that are nonpathogenic and nontoxicogenic to man or other animals. These include but are not restricted to <i>Aspergillus niger</i> and <i>Acetobactor suboxydans</i>
§184.1372	Insoluble glucose isomerase enzyme preparations are derived from recognized species of precisely classified, nonpathogenic, and nontoxicogenic microorganisms, including <i>Streptomyces rubiginosus</i> , <i>Actinoplane missouriensis</i> , <i>Streptomyces olivaceus</i> , <i>Streptomyces olivochromogenes</i> , and <i>Bacillus coagulans</i> grown in a pure culture fermentation that produces no antibiotic
§184.1387	Lactase enzyme preparation from <i>Candida pseudotropicalis</i> for use in hydrolyzing lactose to glucose and galactose
§184.1388	Lactase enzyme preparation from <i>Kluyveromyces lactis</i> (previously called <i>Saccharomyces lactis</i>) for use in hydrolyzing lactose in milk
§184.1420	Lipase enzyme preparation from <i>Rhizopus niveus</i> used in the interesterification of fats and oils.
§184.1538	Nisin preparation from <i>Lactococcus lactis</i> Lancefield Group N for use as an antimicrobial agent to inhibit the outgrowth of <i>Clostridium botulinum</i> spores and toxin formation in pasteurized cheese spreads.
§184.1610	Potassium alginate, the potassium salt of alginate acid, derived from certain brown algae
§184.1685	Rennet (animal derived) and chymosin preparation from <i>Escherichia coli</i> K-12, <i>Kluyveromyces marxianus</i> var. <i>lactis</i> or <i>Aspergillus niger</i> var. <i>awamori</i> to coagulate milk in

	cheeses and other dairy products
§184.1695	Riboflavin biosynthesized by <i>Eremothecium ashbyii</i>
§184.1724	Sodium alginate, the sodium salt of alginic acid, derived from certain brown algae
§184.1848	Butter starter distillate from milk cultures of <i>Streptococcus lactis</i> , <i>Streptococcus cremoris</i> , <i>Streptococcus lactis</i> subspecies <i>diacetylactis</i> , <i>Leuconostoc citovororum</i> , <i>Leuconostoc dextranicum</i>
§184.1924	Urease enzyme preparation from <i>Lactobacillus fermentum</i> for use in the production of wine
§184.1945	Vitamin B12 from <i>Streptomyces griseus</i>
§184.1950	Vitamin D, produced by ultraviolet irradiation of ergosterol isolated from yeast and related fungi
§184.1983	Bakers Yeast extract from <i>Saccharomyces cerevisiae</i>
§184.1985	Aminopeptidase enzyme preparation from <i>Lactococcus lactis</i> used as an optional ingredient for flavor development in the manufacture of cheddar cheese.

The following GRAS affirmed substances are listed in 21 CFR Part 186 and are affirmed for use as substances added indirectly to food. Conditions for their use are prescribed in the referent regulations and are predicated on the use of nonpathogenic and nontoxicogenic strains of the respective organisms and on the use of current good manufacturing practice (186.1(b)).

§186.1275	Dextrans, made by fermentation of sucrose by <i>Leuconostoc mesenteroides</i> strain NRRL B-512(F)
§186.1839	Sorbose, made by oxidation of sorbitol by <i>Acetobacter xylinum</i> or by <i>Acetobacter suboxydans</i>

The following is a compilation of microbial derived enzymes which the FDA recognized as GRAS in opinion letters issued in the early 1960's. The opinions are predicated on the use of nonpathogenic and nontoxicogenic strains of the respective organisms and on the use of current good manufacturing practice.

	Carbohydrase, cellulase, glucose oxidase-catalase, pectinase, and lipase from <i>Aspergillus niger</i>
	Carbohydrase and protease from <i>Aspergillus oryzae</i>
	Carbohydrase and protease from <i>Bacillus subtilis</i>
	Invertase from edible baker's yeast or brewer's yeast (<i>Saccharomyces cerevisiae</i>)

The following is a compilation of foods for human consumption listed in 21 CFR Parts 131, 133, 136 and 137 that may contain or be derived from microorganisms.

§131.111	Acidified milk, with or without the addition of characterizing microbial organisms, and aroma - and flavor - producing microbial culture. Conditions for their use are prescribed in the referent regulations
§131.200	Yogurt made by the lactic acid-producing bacteria <i>Lactobacillus bulgaricus</i> and <i>Streptococcus thermophilus</i>
§131.106	Blue cheese, characterized by the presence of the mold <i>Penicillium roquefortii</i>
§133.113	Cheddar cheese, subjected to the action of a lactic acid producing bacterial culture and clotting enzymes of animal, plant or microbial origin used in curing or flavor development
§136.110	Bread, rolls, and buns may contain as optional ingredients lactic-acid producing bacteria
§137.105	Flour may contain alpha-amylase obtained from the fungus <i>Aspergillus oryzae</i>

Prior sanctions were granted for the use of harmless lactic acid producing bacteria, such as *Lactobacillus acidophilus*, as optional ingredients in specified standardized foods. These bacteria are permitted for use in cultured milk (which includes buttermilk) (§ 131.112), sour cream (§ 131.160), cottage cheese (§ 133.128), and yogurt (§ 131.200), provided that the mandatory cultures of *Lactobacillus bulgaricus* and *Streptococcus thermophilus* are also used in the yogurt.

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