

PRODUCT INFORMATION

KEYWAX FDA Classifications

KEYWAX Rubber/Wax Concentrates are dispersions of butyl or polyisobutylene synthetic rubber in paraffin or microcrystalline wax. They offer the formulator of hot melt adhesives and coatings a convenient means of incorporating rubbery polymers into wax. **KEYWAX Rubber/Wax Concentrates** are supplied at the maximum concentration which can then be blended with additional wax using simple mixing equipment.

The ingredients used in **KEYWAX Rubber/Wax Concentrates** are regulated by code of Federal regulations 21 Food and Drugs. The information provided here is useful for selecting **KEYWAX Rubber/Wax Concentrates** to be used in FDA regulated food packaging applications. The use of **KEYWAX Rubber/Wax Concentrates** is governed by general and specific FDA regulations which pertain to particular end products and additive substances. Some regulations provide a limit on the maximum quantity of an additive, or the quality of an additive. There may also be extraction requirements for some finished materials or articles. The appropriate regulations should be obtained and reviewed in detail prior to use of all products for FDA regulated applications.

It should be noted that the Food and Drug Administration does not actually approve any rubber wax compounds. Rather it publishes lists of permissible ingredients, concentrations and extraction prerequisites. It is the responsibility of the user to ensure that FDA regulated compounds are formulated according to these guidelines, and are processed under conditions of good manufacturing practice.

KEYWAX Rubber/Wax Concentrates are rubber reinforced waxes and all the ingredients used are listed in Federal Regulations 21 Food and Drugs chapter 178.3850 as Reinforced Wax. Noteworthy too, the individual ingredients of **KEYWAX Rubber/Wax Concentrates** are also listed in other Federal Regulations 21 Food and Drugs chapter covering direct and indirect additives for food as follows: Butyl Rubber per 177.1420 – Isobutylene Polymers; Polyisobutylene rubber per 172.615 – Chewing gum base and 177.1420 – Isobutylene Polymers; Microcrystalline and Paraffin Wax per 172.886 and 178.3710 – Petroleum wax; and BHT per 172.115 – BHT, 172.615 – Chewing gum base, 178.2010 – Antioxidants and 178.3710 – Petroleum Wax.

DCO 1575
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KEY POLYMER

CORPORATION

All sales subject to terms &
conditions on reverse side.

SPECIALTY CHEMICAL COMPOUNDS

17 Shepard Street, Lawrence, MA 01843-1023 ■ 978/683-9411 ■ FAX 978/686-7729

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The table shows **KEYWAX Rubber/Wax Concentrates** characterized as a reinforced wax and indirect food additive for packaging cheese and cheese products per 178.3850 and in the context of their application as indirect food additives as adhesives per 175.105 and components of coatings per 175.300 and in their context of application as indirect food additives as components of paper and paperboard per 176.170 and 176.180.

FDA	Scope	21 CFR Section Excerpt GRAS = Generally Recognized As Safe	KEYWAX Rubber / Wax Concentrates	
21 CFR Section 178.3850	Reinforced Wax	Reinforced wax may be safely used as an article or component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food subject to the provisions of this section: It is used as a ... component of packaging materials for cheese and cheese products.	✓	Polyisobutylene & Butyl Rubbers and Paraffin and Microcrystalline Waxes and BHT are listed.
21 CFR Section 175.105	Adhesives	Adhesives may be safely used as components of articles intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions: (1) The adhesive is prepared from one or more of the optional substances in paragraph (C) of this section, subject to any prescribed conditions (2) ...	✓	Polyisobutylene & Butyl Rubbers and Paraffin and Microcrystalline Waxes and BHT are listed in paragraph (C) of this section.
21 CFR Section 175.300	Resinous & Polymeric Coatings	Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.	✓	Polyisobutylene & Butyl Rubbers and BHT are listed. 175.300 b1 b2 lists GRAS thus Microcrystalline and Paraffin Waxes per 172.886.
21 CFR Section 176.170	Paper & Paperboard Components in Contact with Aqueous and Fatty Foods	The substances listed in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packing, processing, preparing, treating, packing, transporting, or holding aqueous or fatty food.	✓	Microcrystalline & Paraffin Waxes & BHT are listed. 176.170 a1 lists GRAS thus Polyisobutylene Rubber per 172.615. 176.170 a2 lists GRAS in packaging thus Butyl Rubber per 177.1420.
21 CFR Section 176.180	Paper & Paperboard Components in Contact with Dry Foods	The substances listed in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding dry food with the surface containing no free fat or oil.	✓	Polyisobutylene & Butyl Rubbers and Paraffin and Microcrystalline Waxes are listed. 176.180 b1 lists 176.170 and 170 to 189 thus BHT.

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CONDITIONS

Seller does not accept any terms or conditions of sale or make any warranties, expressed or implied, other than those contained in this Statement or in any existing written contract between the seller and buyer covering Key Polymer Corporation Products.

ORDER ACCEPTANCE:

Orders are accepted upon the understanding that seller is not obligated to make delivery by any specified date nor liable for damage due to delay or failure in filling order caused by contingencies beyond its control. If delivery dates are specified, they are estimates only and not guaranteed. In the event of unreasonable delay in filling order, buyer may cancel same on written notice to seller, provided said order is not then in process of manufacture.

EXCISE TAXES:

The amount of excise taxes on the production, sale, delivery or transportation of material covered hereby shall be paid by the buyer.

DISCLAIMER OF LIABILITY:

As the conditions or methods of use are beyond our control, we do not assume any responsibility and expressly disclaim any liability for any use of this material. Information contained herein is believed to be true and accurate, but all statements or suggestions are made without warranty, express or implied, regarding accuracy of the information, the hazards connected with the use of the material or the results to be obtained from the use thereof. Compliance with all applicable federal, state and local laws and regulations remains the responsibility of the user.

Buyer shall make an examination both as to quantity and quality of any material delivered hereunder immediately upon receipt and failure of buyer to give notice of any claims within 15 days after receipt of such material shall be an unqualified acceptance of such material and a waiver by buyer of all claims with respect hereto.

USERS RESPONSIBILITY:

Key Polymer product usage suggestions, bulletins and manuals cannot cover all possible situations which the user may experience during processing. Each aspect of your operation should be examined if or where additional precautions or procedures may be necessary. All health and safety information contained in Key Polymer's Material Safety Data Sheets for the products being used should be provided to all employees with exposure to the product. It is the responsibility of the user to provide this information in this manner and to use the information to develop appropriate work practice guidelines and employee instructional programs.

LIABILITY LIMITATION:

Buyer assumes all risk and liability for the results obtained by the use of any material delivered by Key Polymer in the manufacturing processes of buyer or in combination with other substances in manufacturing and repair processes of buyer or in combination with other substances. No claim of any kind, whether as to material delivered or for non-delivery of material, shall be greater in amount than the purchase price of this material in respect of which such claim is made.

**KEY POLYMER CORP.
LAWRENCE, MA 01843**

REV AA
DCO # 0588
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