

US FDA Compliance Statement

3 November 2023

1. Based on interpretation of the FDA regulations, PAC Bond 400 meets the ingredient requirements of the following sections of 21 CFR when used according to the following regulations and any limitations that may apply:
 - a. CFR - Code of Federal Regulations Title 21
 - b. Title 21 - Food and Drugs
 - c. Chapter I - Food and Drug Administration
 - d. Department of Health and Human Services
 - e. Subchapter B - Food for Human Consumption (Continued)
 - f. Part 175 - Indirect Food Additives: Adhesives and Components of Coatings
 - g. Subpart B—Substances for Use Only as Components of Adhesives
 - h. §175.105 - Adhesives.
2. This states:

“(a) 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 named in paragraph (c) of this section, subject to any prescribed limitations.
 - (2) The adhesive is either separated from the food by a functional barrier or used subject to the following additional limitations:
 - (i) *In dry foods.* The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.
 - (ii) *In fatty and aqueous foods:*
 - (a) The quantity of adhesive that contacts packaged fatty and aqueous foods shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.
 - (b) Under normal conditions of use the packaging seams or laminates will remain firmly bonded without visible separation.

(b) To assure safe usage of adhesives, the label of the finished adhesive container shall bear the statement “food-packaging adhesive”.

3. Based on interpretation of the FDA regulations, PAC Bond 400 meets the ingredient requirements of the following sections of 21 CFR when used according to the following regulations and any limitations that may apply:
 - a. CFR - Code of Federal Regulations Title 21
 - b. Title 21 - Food and Drugs
 - c. Chapter I - Food and Drug Administration
 - d. Department of Health and Human Services
 - e. Subchapter B - Food for Human Consumption (Continued)
 - f. Part 176 - Indirect Food Additives: Paper and Paperboard Components
 - g. Subpart B—Substances for Use Only as Components of Paper and Paperboard
 - h. §176.170 - Components of paper and paperboard in contact with aqueous and fatty foods.
4. This states:

“Substances identified 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, packaging, processing, preparing, treating, packing, transporting, or holding aqueous and fatty foods, subject to the provisions of this section. Components of paper and paperboard in contact with dry food of the type identified under Type VIII of table 1 in paragraph (c) of this section are subject to the provisions of §176.180.

(a) Substances identified in paragraph (a) (1) through (5) of this section may be used as components of the food-contact surface of paper and paperboard. Paper and paperboard products shall be exempted from compliance with the extractives limitations prescribed in paragraph (c) of this section: *Provided*, That the components of the food-contact surface consist entirely of one or more of the substances identified in this paragraph: *And provided further*, That if the paper or paperboard when extracted under the conditions prescribed in paragraph (c) of this section exceeds the limitations on extractives contained in paragraph (c) of this section, information shall be available from manufacturing records from which it is possible to determine that only substances identified in this paragraph (a) are present in the food-contact surface of such paper or paperboard.

(1) Substances generally recognized as safe in food.

(2) Substances generally recognized as safe for their intended use in paper and paperboard products used in food packaging.

(3) Substances used in accordance with a prior sanction or approval.

(4) Substances that by regulation in parts 170 through 189 of this chapter may be safely used without extractives limitations as components of the uncoated or coated food-contact surface of paper and paperboard in contact with aqueous or fatty food, subject to the provisions of such regulation.”

5. Based on interpretation of the FDA regulations, PAC Bond 400 meets the ingredient requirements of the following sections of 21 CFR when used according to the following regulations and any limitations that may apply:
 - a. CFR - Code of Federal Regulations Title 21
 - b. Title 21 - Food and Drugs
 - c. Chapter I - Food and Drug Administration
 - d. Department of Health and Human Services
 - e. Subchapter B - Food for Human Consumption (Continued)
 - f. Part 176 - Indirect Food Additives: Paper and Paperboard Components
 - g. Subpart B—Substances for Use Only as Components of Paper and Paperboard
 - h. §176.180 - Components of paper and paperboard in contact with dry food.
6. This states:

“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 of the type identified in §176.170(c), table 1, under Type VIII, subject to the provisions of this section.

 - (a) The substances are used in amounts not to exceed that required to accomplish their intended physical or technical effect, and are so used as to accomplish no effect in food other than that ordinarily accomplished by packaging.
 - (b) The substances permitted to be used include the following:
 - (1) Substances that by §176.170 and other applicable regulations in parts 170 through 189 of this chapter may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard, subject to the provisions of such regulation.”

We trust that this meets your requirements. If you have any questions or require additional information, please feel free to contact me directly by telephone at +61 7 3352 3909.

Yours Sincerely,



Norman Clarke
Director

Packaging Adhesive Equipment Consultants & Solutions Pty Ltd