

July 01, 2015

**Subject:** PEBA<sup>®</sup> 5533 SA 01 MED

To Whom It May Concern:

Thank you for your interest in the referenced product. The following letter is provided in response to your request for information on the referenced product.

Please note that Arkema does not routinely analyze for additional substances that are not listed in the MSDS. Unless otherwise indicated, the information provided herein is based upon information from raw material suppliers, product composition and Arkema's manufacturing process. Information on any OSHA hazardous components above 1% (by weight) and carcinogens above 0.1% (by weight) is provided in Section 3 of Arkema's Material Safety Data Sheet (MSDS).

#### FDA Food Allergens

The FDA "Food Allergen Labeling and Consumer Protection Act of 2004" has identified eight major foods or food groups--milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans--that account for 90 percent of the food allergens.

None of the eight listed allergens are known to be present in the product or raw materials. Furthermore, there are no allergen containing materials used in or around the manufacturing and transport of this product.

#### Bisphenol A (BPA)

CAS#: 80-05-7 IUPAC name: 4,4'-dihydroxy-2,2-diphenylpropane.

Based on a review of the final product composition and the specifications of the raw materials, this product is not known or expected to contain BPA.

#### Bovine Spongiform or Transmissible Spongiform Encephalopathy (BSE/TSE)

Animal derived materials are primarily a concern with regard to the infectious agent associated with Bovine/Transmissible Spongiform Encephalopathy (BSE/TSE).

Based on a review of the raw materials, there are no animal derived substances used in or around the manufacturing of this product.

#### China RoHS

In 2006 the Chinese Ministry released Administrative Measures on the Control of Pollution Caused by Electronic Information Products (EIP) # 39, also known as China RoHS. The product has been reviewed for the following substances and concentrations: lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE) to a level equal to or less than 0.1% by weight and cadmium to a level equal to or less than 0.01% by weight.

Based on a review of the final product composition and the specifications of the raw materials, this product is not known or expected to contain any of the above listed substances.

CONEG

Model Toxics in Packaging Legislation (also referred to as CONEG) concerns restrictions on the use of certain hazardous substances in packaging or packaging components (including printing inks used in packaging), and restricts the sum of the incidental concentration levels of lead, mercury, cadmium and hexavalent chromium present in the product to a level equal to or less than 100 parts per million by weight.

Based on a review of the final product composition and the specifications of the raw materials, the sum total CONEG substances is not expected to be present above the regulatory limit of 100 ppm.

#### US FDA Food Packaging

Applications of the subject product can be said to fully comply with the US Federal Food, Drug and Cosmetic Act and all applicable food additive regulations subject to the limitations provided herein. It is the responsibility of our customer to determine if the following clearances or cross-references to the clearances are appropriate for the product's intended use.

#### 21 CFR Sec. 177.2600 (c)(4)(i)

Rubber articles intended for repeated use. For use as an elastomer in the preparation of rubber articles intended for repeated use.

Applications are limited to contact with foods of Types I, II, III, IV, V, VI, VII, VIII, and IX identified in table 1 of §176.170(c) of this chapter at temperatures not to exceed 150 °F.

#### Gluten-Free

The term "gluten" is used to collectively refer to proteins that naturally occur in certain grains that may cause adverse health effects in persons with celiac disease. These grains are identified as barley, common wheat, rye, spelt, kamut, triticale, and oats.

Gluten-free labeling generally applies to products used as food ingredients.

Arkema has not labeled the subject product for use as a food ingredient but recognizes the product may be used in food processing facilities where food contact is likely. The subject product is not formulated with ingredients known to contain or be derived from any of the listed grains.

#### Genetically Modified Organisms (GMO)

A Genetically Modified Organism (GMO), for purposes of this review, is considered to be an organism that contains recombinant DNA elements. The genome of these organisms has been altered by insertion of foreign DNA sequences by means of genetic engineering. They are referred to as transgenic or bioengineered organisms.

Determination of the presence of GMOs is currently limited to substances derived from agricultural plants.

Based on a review of the final product composition and the specifications of the raw materials, this product is not known or expected to contain substances identified as GMOs.

#### Material containing HAP(s)

Material containing HAP(s) : Hazardous air pollutants (HAPs) are defined in Section 112(b) of the Clean Air Act Amendments of 1990. Materials that contain HAPs are defined under 40 CFR 63.11180 as materials that contain 0.1 percent or more by mass of any individual HAP that is an OSHA-defined carcinogen as specified in 29 CFR 1920.1200(d) (4), or 1.0 percent or more by mass for any other individual HAP.

Please refer to section 3 of the MSDS for the most current information regarding the presence of any HAP (as defined above) for the listed product.

#### Lactose-Free

Lactose is a sugar derived from dairy products. The concern for the presence of lactose generally applies to substances used as food ingredients. Arkema has not labeled the subject product for use as a food ingredient but recognizes the product may be used in

food processing or packaging facilities where food contact is likely.

Based on the final product composition and the specifications of the raw materials, the subject product is not known to contain or be derived from lactose or lactose containing dairy by-products.

#### Latex Containing Products

21 CFR 801.437 requires labeling of all devices composed of or containing, or having packaging or components that are composed of, or contain, natural rubber that contacts humans. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

Based on a review of the composition of the product and the specifications of the raw materials, this product is not known to contain latex.

#### Ozone Depleting Substances

For the purpose of responding to your inquiry, Arkema defines ozone depleting substances (ODS) in accordance with section 602 of the United States Clean Air Act (40 CFR Part 82).

Based on the final product composition and the specifications of the raw materials, this product is not known or expected to contain substances that are identified as Ozone Depleting Substances

#### California Proposition 65

Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, was enacted as a ballot initiative in November 1986. The Proposition was intended by its authors to protect California citizens and the State's drinking water sources from chemicals known to cause cancer, birth defects or other reproductive harm, and to inform citizens about exposures to such chemicals.

Please refer to the MSDS for the most current information regarding the presence of any Proposition 65 listed chemicals.

#### Polybrominated diphenylethers (PBDEs) flame retardant chemicals

PBDEs (Polybrominated Diphenyl Ethers), also called "brominated flame retardants," are a group of flame retardant chemicals that are added to foam padding, plastics and fabrics. Common PBDEs are pentaBDE (five bromine molecules), octaBDE (eight bromine molecules) and decaBDE (ten bromine molecules).

Based on a review of the final product composition and the specifications of the raw materials, this product is not known or expected to contain any of the above-referenced PBDE chemicals.

#### Phthalates

Substances in this review: Bis(2-ethylhexyl)phthalate (DEHP), Dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), Diisobutyl Phthalate (DINP), Diisodecyl phthalate (DIDP), Di-n-octyl phthalate (DnOP) or Di-n-hexyl phthalate (DnHP).

Based on the final product composition and the specifications of the raw materials, this product is not known or expected to contain substances that are identified as Phthalates.

#### Persistent Organic Pollutants (POP)

The Stockholm Convention on Persistent Organic Pollutants (POPs) concerns restrictions on the release of POPs into the environment. The following response applies to those 12 POPs identified in the original Convention and 9 additional POPs added by amendment in May 2009.

Based on the final product composition and the specifications of the raw materials, this product is not known or expected to contain substances that are identified as Persistent Organic Pollutants.

#### Restriction of Hazardous Substances (RoHS)

RoHS is defined in Directive 2011/65/EU which concerns restrictions on the use of certain hazardous substances in electric and electronic equipment (EEE). RoHS specifically restricts the concentration of the following materials in electric and electronic equipment: lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), other polybrominated compounds present in the product to a level equal to or less than 0.1% by weight. It further restricts the concentration of cadmium present in the product to a level equal to or less than 0.01% by weight.

Based on the final product composition and the specifications of the raw materials, no RoHS substances are known or expected to be present.

#### Substance of Very High Concern (SVHC)

In accordance with Article 59 of the European Regulation 1907/2006 on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), from time to time, the European Chemicals Agency (ECHA) publishes lists identifying substances of very high concern (SVHCs) (as defined in Article 57 of REACH and included in the REACH "Candidate List" for further regulation).

Based on the final product composition and the specifications of the raw materials, this product is not known to contain substances at greater than 0.1% (reporting threshold) which are identified on the June 2015 Candidate list.

#### Material containing TAP(s)

Certain states have Toxic air pollutants (TAPs) lists. Arkema defines Materials containing TAPs as materials that contain 0.1 percent or more by mass of any individual TAP that is an OSHA-defined carcinogen as specified in 29 CFR 1920.1200(d)(4), or 1.0 percent or more by mass for any other individual TAP.

Please refer to section 3 of the MSDS for the most current information regarding the presence of any TAP (as defined above) for the listed product.

#### Volatile Organic Compounds (VOCs)

In the Clean Air Act, 40 Code of Federal Regulations Section 51.100, the Environmental Protection Agency (EPA) defines a VOC as any compound of carbon excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reaction. EPA has excluded many compounds, which have been determined to have negligible photochemical reactivity such as: ethane, methane, methylene chloride, methyl chloroform, perchloroethylene, acetone, and numerous fluorocarbons. Water is not considered a VOC. Arkema Inc. recommends review of State and Federal regulations to determine if a more restrictive requirement exists regarding analytical methods or chemical exclusions during the consideration of VOC content.

Based on the final product composition and the specifications of the raw materials, this product is not known or expected to contain substances identified as VOCs.

The forgoing is subject to the terms and conditions set forth in the invoice or other contract or shipping document issued by Arkema Inc. with respect to the shipment or delivery, including any limitations on liability.

Sincerely,



900 First Avenue  
King of Prussia, PA 19406  
USA

[marisa.hull@arkema.com](mailto:marisa.hull@arkema.com)

PEBAX® is a registered trademark belonging to Arkema.