Registrar Corp
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Food Contact Review

November 23, 2011

RE: Your Food Contact Substance – Clear Non-Stick Coating and Sealer Coats

Reviewed product (nano-ceramic series formulations)

Dear Sir or Madam:

We present our report and recommendations regarding the food contact substance you submitted for our review. After review of your food contact substance, it does not appear that your product requires premarket notification to FDA, as your substance complies with FDA regulations as indicated in the following review.

Our recommendations for these particular food contact substances are detailed. Please feel free to contact us after you have reviewed this review material to discuss our findings in detail.

We look forward to working with you on any future needs

Very truly yours,

Lara Luzak
Regulatory Specialist

Michelle Baillargeon
Regulatory Specialist

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Section 1: Overview of Definitions and Requirements for a Food Contact Substance

1.1 Definition of Food Contact Surfaces – Food Contact Surfaces are any surface of equipment, utensils, containers, or wrappings that come in direct contact with food. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives (21 CFR 110.40(a)). Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms (21 CFR 110.40(b)).

1.2 Definition of Food Contact Article ("FCA") – The Food Contact Article is the finished film, bottle, dough hook, tray, or whatever that is formed out of the Food Contact Materials.

1.3 Definition of Food Contact Materials ("FCM") – Food Contact Materials are made with Food Contact Substances ("FCS") and usually other substances. It is often, but not necessarily, a mixture, such as an antioxidant in a polymer. The composition may be variable (FDA Food Contact Substances Compliance Guide May 2009). An example of FCMs may be plastic, glass, rubber, and other such materials that are used to make a final product that comes in contact with food.

1.4 Definition of Food Contact Substances – Once known as indirect food additives, FDA now refers to these materials as food contact substances ("FCS"). FDA defines food contact substances as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food (21 USC.348(h)(6)). Regulatory status of a food contact material is dictated by the regulatory status of each individual substance that comprises the article. It is the responsibility of the manufacturer of an FCS to ensure that food contact materials comply with the specifications and limitations in all applicable authorizations. When reviewing your composite formulations to determine compliance, consider each authorization to be composed of three parts: the *identity* of the substance, *specifications* including purity or physical properties, and *limitations* on the conditions of use. Based on the FDA Food Contact Substances Compliance Guide May 2009 Edition, the individual substance that is reasonably expected to migrate to food because of its intended use in the food contact material shall be covered by one of the following:

1.4.1 Title 21 Code of Federal Regulations ("CFR") – The requirement for premarket approval in section 409 of the Food, Drug, and Cosmetic Act in 1958 resulted in the development of a petition process by which a person could request approval of a food additive for an intended use. The approval resulted in a regulation listed in Title 21 of the CFR. Components of a food packaging material used in compliance with a regulation in Title 21of the CFR need no further FDA review.

1.4.2 Prior sanction letter – Prior Sanctioned substances are those substances whose use in contact with food is the subject of a letter issued by FDA or USDA before 1958 offering no objection to a specific use of a particular substance.

1.4.3 GRAS status – "GRAS" is an acronym for the phrase **G**enerally **R**ecognized **A**s **S**afe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive and is subject to premarket review and approval by FDA. A substance is **exempt** from this requirement if it is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.

The use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

- Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information.
- Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.

There must be evidence that the substance is safe under the conditions of its intended use. FDA has defined "safe" (21 CFR 170.3(i)) as a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. The specific data and information that demonstrates safety depends on the characteristics of the substance, the estimated dietary intake, and the population that will consume the substance.

1.4.4 Threshold of Regulation ("TOR") Exemption – Threshold of Regulation Exemptions verify that a FCS is exempted from a petition or an Food Contact Notification (FCN) as a food additive because it becomes a component of food at levels that are below the threshold of regulation (21 CFR 170.39(a)). A substance used in a food contact article may be exempted by FDA from the need of an FCN or a petition (regulation) as a food additive if the use in question has been shown to result in a very low concentration (0.5 ppb).

1.4.5 Effective Food Contact Notification ("FCN") – FDA will accept FCNs for unapproved uses of food additives that meet the definition of an FCS. FDA believes that a substance that is GRAS or prior sanctioned for its intended use in contact with food also may be an FCS and may be the subject of an FCN, even though authorization under the FCN process is not required for the FCS use (FDA Guidance for Industry: Preparation of Food Contact Notification May 2002). Section 409(h)(2)(C) of the Federal Food, Drug, and Cosmetic Act states that an FCN is effective for the manufacturer, the Food Contact Substance (FCS), and the conditions of use identified in the notification and not effective for a similar or identical substance produced or prepared by a manufacturer other than a manufacturer identified in the prior notification. FCNs are proprietary to the manufacturer for which the notification is effective; therefore, the FCN must be obtained from that manufacturer.

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Section 2: Analysis of Your Food Contact Substance

2.1 Clearcoat Sealer – You have stated on the Food Contact Substance Data Form submitted to Registrar Corp that your Food Contact Substances is a clearcoat sealer for use on cookware, cooking utensils and equipment for primary and secondary food contact, for both private and commercial use. You have also stated that the sealer is composed of 100% Polysilazane.

Currently, FDA lists a number of resinous and polymeric coatings that 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 (21 CFR 175.300). The Code of Federal Regulations (CFR) states that the coating is applied as a continuous film or enamel over a metal substrate, or the coating is intended for repeated food-contact use and is applied to any suitable substrate as a continuous film or coating that serves as a functional barrier between the food and the substrate (21 CFR 175.300(a)). The coating is characterized by one or more of the following descriptions (21 CFR 175.300(a)):

- Coatings cured by polymerization, condensation, and/or cross-linking without oxidation.
- Coatings prepared from pre-polymerized substances.

FDA permits the following silazane to be used as the basic polymer of the aforementioned coatings.

- Poly Silazane resins originating from silazane based chemistry, that use a condensation cure chemical matrix.

2.2 It appears that your substance, Polysilazane, is a silazane resin originating from a blend of Polysilazane chemistries. It is confirmed that your Polysilazane is prepared from the aforementioned chemicals. This accurately describes the origination of your substance; it does not appear that your product requires premarket notification to FDA.

The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined, must not yield chloroform-soluble extractives, corrected for zinc extractives as zinc oleate.

In accordance with good manufacturing practice, finished coatings intended for repeated food-contact use shall be thoroughly cleansed prior to their first use in contact with food (21 CFR 175.300(g)).

Please ensure that your coating conforms to the regulations outlined above. As appears that your substance, Polysilazane does. It is confirmed that your Polysilazane is prepared from the aforementioned chemicals. This accurately describes the origination of your substance; it does not appear that your product requires premarket notification to FDA.

1.4.3 GRAS status – "GRAS" is an acronym for the phrase **G**enerally **R**ecognized **A**s **S**afe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive and is subject to premarket review and approval by FDA. A substance is **exempt** from this requirement if it is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.

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There must be evidence that the substance is safe under the conditions of its intended use. FDA has defined "safe" (21 CFR 170.3(i)) as a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. The specific data and information that demonstrates safety depends on the characteristics of the substance, the estimated dietary intake, and the population that will consume the substance.

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