DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

December 8, 2014

This is in reply to your inquiry concerning the regulatory status under U.S. law of the use of toluene diisocyanate based polyurethane binders (TDI PU) for agglomerated cork stoppers for wine. Below are your questions and our responses to each.

1. *Is the TDI PU used in agglomerated wine corks without a functional barrier covered under 21 CFR Part 175?*

   No. FDA does not consider the listing of a material under 21 CFR 175.105 to permit its use in the manufacture of agglomerated cork stoppers. Concerning 21 CFR 175.105 (Adhesives), the use of a substance as a binder for cork granules in the manufacture of agglomerated cork stoppers for wine and other beverages would not meet the following limitation, listed at 21 CFR 175.105(a)(2)(ii), "The quantity of adhesive which contacts fatty or aqueous food 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." Thus, authorization of a substance for use under 21 CFR 175.105, including the polyurethanes listed under 21 CFR 175.105(c)(5), does not authorize its use as a binder for cork wine stoppers.

2. *If not, is there any other US regulation that permits the use of TDI PU in agglomerated wine corks without a functional barrier?*

   No.

3. *If not, what is the legal basis for the sale of agglomerated wine corks containing TDI PU for direct contact with wine/spirits in the US?*

   If there is a reasonable expectation that components of the TDI PU binder will migrate to, or otherwise affect, the wine under the intended conditions of use, then the TDI PU would be a unapproved food additive, unless there were a) a prior sanction (a letter issued from FDA prior to September 6, 1958 on this usage of TDI PU) or b) an independent determination that the usage of TDI PU is generally recognized as safe (GRAS). FDA does not believe a prior sanction exists for this use, nor is aware of published or otherwise generally available data that would allow a GRAS determination for such use. Therefore, if there is a reasonable expectation that components of the

TDI PU binder will migrate to, or otherwise affect, the wine under the intended conditions of use, we believe there is no legal basis for the sale of agglomerated wine corks containing TDI PU for use in the United States. If migration of components of the TDI PU to wine is determined *not* to be expected, either based on the existence of a barrier or that there are no component substances in the binder that are expected to migrate to the wine, then authorization for this use under FDA regulations would not be required for the legal marketing of the corks. However, for a given usage of TDI PU binder in agglomerated wine corks, FDA would call into question a claim of no migration in the absence of data and information that support that a functional barrier exists or that there are no component substances in the binder that are expected to migrate to wine.

4. *Some of our members have been presented with third party risk assessments concluding that the use of TDI PU in agglomerated corks does not present any risk as far as food safety is concerned. Based on what we understand of US food contact substance laws, while these safety assessments may provide some comfort for purchasers of the corks with regard to potential private lawsuits, they do not provide a regulatory legal basis for the use of TDI PU in agglomerated corks. Therefore, food producers who use the corks as a closure in a food product would still be using an "unapproved food additive." Would you please confirm whether our understanding of the US laws is correct?"*

   As mentioned above, assuming migration to the wine is reasonably expected, in terms of a non-FDA risk assessment or safety determination, only a valid determination that TDI PU is GRAS under the intended conditions of use would represent a legal basis for this use, and FDA is not aware of published or otherwise generally available data that would allow a GRAS determination for such use. Other than a valid GRAS determination, only a determination of safety conducted by FDA on a submission for premarket review, such as a food contact notification, that results in an authorization under FDA regulations (such as an effective food contact notification) for such use would provide a legal basis for this use of PU binder (if the corks are marketed in the U.S.), and this has not occurred to date.

Sincerely,

Kenneth A. Mcadams -S

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