DEPARTMENT OF HOMELAND SECURITY

U.S. CUSTOMS AND BORDER PROTECTION

Notice of Issuance of Final Determination Concerning

Certain Analytical-Grade Acetonitrile

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection ("CBP") has issued a final determination concerning the country of origin of certain analytical-grade acetonitrile. Based upon the facts presented, CBP has concluded that the country of origin of the analytical-grade acetonitrile is the country of origin of the crude acetonitrile for purposes of U.S. Government procurement.

DATES: The final determination was issued on September 18, 2015. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within [insert 30 days from date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Ross Cunningham, Valuation and Special Programs Branch, Regulations and Rulings, Office of International Trade (202) 325-0034.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on September 18, 2015 pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued a final determination concerning the country of origin of certain analytical-grade acetonitrile, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ H265712, was

issued under procedures set forth at 19 CFR Part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511-18). In the final determination, CBP concluded that the processing in the United States does not result in a substantial transformation. Therefore, the country of origin of the analytical-grade acetonitrile is the country of origin of the crude acetonitrile for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: September 18, 2015

Harold Singer
Acting Executive Director
Regulations and Rulings
Office of International Trade

HQ H265712

September 18, 2015

OT:RR:CTF:VS H265712 RMC

CATEGORY: Country of Origin

David R. Stepp
Bryan Cave LLP
120 Broadway
Suite 300
Santa Monica, CA 90401-2386

Re: U.S. Government Procurement; Country of Origin of Acetonitrile; Substantial Transformation

Dear Mr. Stepp:

This is in response to your letter dated April 1, 2015, requesting a country-of-origin determination on behalf of the Sigma-Aldrich Corporation ("Sigma-Aldrich"). You state that Sigma-Aldrich wishes to sell "analytical-grade acetonitrile" to the U.S. Government and thus seeks a determination that the country of origin of its product will be the United States. We note that Sigma-Aldrich is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination. A meeting was held by teleconference on August 15, 2015.

FACTS:

Analytical-grade acetonitrile is a purified chemical that Sigma-Aldrich plans to manufacture in the United States from crude, commercial-grade acetonitrile imported from China and other countries. You state that commercial-grade acetonitrile is most useful as an industrial-grade solvent. Because it is produced as a byproduct of other industrial processes, you state that it contains a relatively low level of "pure acetonitrile." You state that commercial-grade acetonitrile "can be less than 95%" and that it contains contaminants such as water.

As its name suggests, purified analytical-grade acetonitrile contains fewer contaminants and may be up to 99.5% pure. In its purified, analytical grades, acetonitrile is suitable for use in chemical testing instruments such as Liquid Chromatography-Mass Spectrometry and Ultra-Performance Liquid Chromatography. These instruments are used for analyzing chemicals for pharmaceutical drug development and production, food safety, medical clinical testing, and environmental testing. You state that commercial-grade acetonitrile is unsuitable for these applications because its impurities would cause false readings and damage the testing equipment.

Sigma-Aldrich produces several analytical grades of purified acetonitrile, including CHROMASOLV® Plus for HPLC; MC-MS CHROMASOLV®; LC-MS Ultra CHROMASOLV®, tested for UHPLC-MS; and CHROMASOLV® Plus, for HPLC. Sigma-Aldrich will purify the imported commercial-grade acetonitrile using the following processes. The steps are set forth in general terms in accordance with your request to exclude confidential information:

1. Freezing the crude product;
2. Extracting the pure acetonitrile from the frozen mass;
3. Analyzing the purified acetonitrile output product and the correct purity level for the grade being produced;
4. Packaging the purified acetonitrile, which requires:
    a. Special glass bottles
    b. Rinsing the bottles

c. Filling the bottles

You state that the process is lengthy and requires sophisticated, expensive equipment and highly educated personnel. The steps described above take about four days for a "typical batch" of 20,000 liters. Scientists, all of whom possess at least a Bachelor of Science degree, perform or oversee the production process which uses a specialized unit and precision testing equipment.

ISSUE:

Whether the purification process described above will "substantially transform" the product such that the country of origin of the finished analytical-grade acetonitrile will be the United States for U.S. Government procurement purposes.

LAW AND ANALYSIS:

Pursuant to Subpart B of Part 177, 19 CFR § 177.21 *et seq*., which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq*.), CBP issues country-of-origin advisory rulings and final determinations as to whether an article is a product of a designated country for the purpose of granting waivers of certain "Buy American" restrictions on U.S. Government procurement.

In rendering final determinations for purposes of U.S. Government procurement, CBP applies the provisions of Subpart B of Part 177 consistent with the Federal Procurement Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the Trade Agreements Act. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define "U.S.-made end product" as "an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with name, character, or use distinct from that of the article or articles from which it was transformed." *See* 48 C.F.R § 25.003.

You argue that the imported commercial-grade acetonitrile will be substantially transformed when Sigma-Aldrich purifies it into analytical-grade acetonitrile. Therefore, in your view, the finished product will be eligible for U.S. Government procurement because its country of origin will be the United States.

A substantial transformation occurs when an article is used in a manufacturing process that results in a new article that has a new name, character or use different from that of the original imported article. In previous rulings, "CBP has consistently held that refining or purification of a crude substance does not generally effect a substantial transformation that results in a different article of commerce with a new name, character, or use". Headquarters Ruling Letter ("HQ") H113256, dated December 27, 2010. For example, CBP has held that refining linseed oil, in H554664, dated October 29, 1987, and Octamine (an aviation lubricant), in HQ 556143, dated March 2, 1992, did not result in an article with a new name, use, or character.

You argue that the acetonitrile purification processes will result in a substantial transformation because the finished product will have a new name, character, and use. Although a change in a product's name is the weakest evidence of a substantial transformation, as noted in *Uniroyal, Inc. v. United States*, 3 CIT 220 (1982), *aff'd* 702 F.2d 1022 (Fed. Cir. 1983), you point that "[t]he imported product is referred to as 'crude' or 'commercial grade,' whereas the processed product is referred to as 'purified' and 'analytical grade.'" In both cases, however, the name of the product remains acetonitrile. The adjectives "crude," "commercial grade," "purified," and "analytical" qualify the noun "acetonitrile." As we have previously noted, the addition of an adjective in front of a product name is generally not persuasive. *See* HQ 731731, dated February 23, 1989. We therefore find that the purification process does not result in an article with a new name.

You also argue that the processed acetonitrile has a new character compared to the crude acetonitrile. You state that the imported crude acetonitrile has the character of an industrial manufacturing byproduct, whereas the purified product has the character of a laboratory reagent. CBP's examination of character, however, focuses on the chemical and physical properties of the product itself. *See* HQ 571975, dated April 3, 2002. CBP's Laboratories and Scientific Services Directorate informed us that no chemical reactions or physical changes occur in Sigma-Aldrich's processing. Instead, the processing only removes impurities in the acetonitrile. We therefore find that the purification process does not result in an article with a different character.

While the finished product will not have a different name or character, it will have a different use. The imported crude product can be used as a solvent for industrial processes but not in precision testing applications because impurities can damage the testing equipment or produce measurement errors. Although the finished product could also be used as a solvent, you state that this is unlikely because it would be "cost prohibitive." Therefore, you state that its likely use is confined to analytical testing.

In support of your argument that a substantial transformation will take place when the crude acetonitrile is purified into analytical-grade acetonitrile, you analogize to rulings HQ 563301, dated August 26, 2005 and HQ 731731, dated February 23, 1989. In HQ 731731, we found that a substantial transformation occurred when raw powdered vancomycin hydrochloride was processed into a finished antibiotic drug capable of intravenous use. As imported, the raw chemical was unfit for medical use. Applying the three substantial transformation factors, we found that the name changed to "sterile" vancomycin hydrochloride, the use changed to an injectable antibiotic, and the character changed to a purified solution of uniform potency levels. Accordingly, we found that the chemical was substantially transformed. Similarly, in HQ 563301 we found that a substantial transformation occurred when bulk parathormone was processed into finished parathormone cartridges. We held that the "extensive processing transforms the raw parathormone from an unstable, non-sterile, frozen material unsuitable for human use into a pharmaceutical agent ready for human use."

A common theme in HQ 563301 and HQ 731731 is the production of a medicine from chemicals that were previously unfit for human consumption. In both cases, we found that—along with the required change in name and character—this conversion from raw chemicals to medication represented a significant change in use. Here, aside from the fact that no change in name or character will occur, the production of analytical-grade acetonitrile results in a less significant change in use, namely, from one type of industrial use to another.

We believe that this case is more analogous to cases involving the refining and purification of chemicals than to those involving the production of medicine. As noted above, CBP has consistently held that refining or purification of a crude substance does not generally effect a substantial transformation. You attempt to distinguish one of these cases, H566143, dated March 2, 1992, by pointing out that there was no substantial transformation because "both the precursor and purified substances had the same essential character as aviation lubricants of merely different grades and were therefore not different articles of commerce, and both substances had the same chemical structures." Yet here too the crude and purified acetonitrile will have the same essential character as acetonitrile and you have provided no evidence that the substances will have a different chemical structure. Therefore, we are "bound to follow the well-settled principle of Customs law that the mere refining of a chemical does not result in a substantial transformation of the imported chemicals into a new and different article of commerce with a new name, character, and use." HQ 556143, dated March 2, 1992.

HOLDING:

The purification process described above will not substantially transform the acetonitrile, and the country of origin of the finished analytical-grade acetonitrile will not be the United States for U.S. Government procurement purposes.

Sincerely,

Harold Singer, Acting Executive Director
Regulations & Rulings
Office of International Trade

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