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13 June 2022

CUSTOMS MEMORANDUM CIRCULAR
NO. 86-2022

To: The Assistant Commissioner
All Deputy Commissioners
All Directors and Division Chiefs
All District/ Port Collectors
All Others Concerned

SUBJECT: TARIFF CLASSIFICATION DISPUTE RULING

Pursuant to Commission Order No. 2018-1 (Rules of Procedure on Disputes involving Tariff Classification), attached is the copy of Tariff Classification Circular Dispute Ruling (TCC/DR) No. 22-007 issued on 08 June 2022.

For information and guidance.

For record purposes, please confirm the dissemination of this circular throughout your offices within fifteen (15) days from receipt thereof.

REY LEONARDO B. GUERRERO
Commissioner



cmc no. 80-2022

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BOC-09-31169



REPUBLIC OF THE PHILIPPINES
TARIFF COMMISSION

RE: REQUEST FOR TARIFF CLASSIFICATION
DISPUTE RULING ON "BIBAG® 5008 650G
(BICARBONATE CONCENTRATE FOR
HEMODIALYSIS)" CONSIGNED TO FRESENIUS
MEDICAL CARE PHILIPPINES, INC.

TCC (DR) NO. 22-007

(Import Entry/Customs Reference No. C-44590,
MICP)

Issued on: 08 June 2022

TARIFF CLASSIFICATION DISPUTE RULING

Before this Commission is a request for tariff classification dispute ruling (TCDR), pursuant to Paragraph 2 of Section 1100 of Republic Act No. 10863, otherwise known as the Customs Modernization and Tariff Act (CMTA), on the shipment of bibag® 5008 650g (Bicarbonate Concentrate for Hemodialysis) imported by Fresenius Medical Care Philippines, Inc. (Importer/Consignee) from Germany (country of origin: France). The request of the Importer/Consignee for TCDR, filed by its Authorized Representative, Mr. Rolando I. Fabia of a hartrodtt Philippines, Inc., was accepted by this Commission on 16 March 2022.

The shipment of the said article, declared under ASEAN Harmonized Tariff Nomenclature (AHTN) 2017 subheading 2836.30.00, with a Most Favoured Nation (MFN) rate of duty of zero, was processed under Import Entry/Customs Reference No. C-44590 at the Bureau of Customs (BOC), Manila International Container Port (MICP). The BOC contested the declared heading and reclassified subject article under AHTN 2017 subheading 3004.90.99, with an MFN rate of duty of 5% *ad valorem*.

Hence, this request for tariff classification dispute ruling.

With submitted information deemed sufficient to classify subject article and pursuant to Section 7.3 of Commission Order No. 2018-01, this Commission requested the concerned BOC District Collector on 24 March 2022 for comments on the request for TCDR on bibag® 5008 650g (Bicarbonate Concentrate for Hemodialysis). In a letter dated 7 April 2022 and received by this Commission on 20 April 2022, Mr. Romeo Allan R. Rosales, Acting District Collector of BOC MICP, submitted BOC's comment stating that the subject article was reclassified from the declared AHTN 2017 subheading 2836.30.00 (with MFN rate of duty of zero) to 3004.90.99 (with MFN rate of duty of 5%) based on the submitted documents of the Importer/Consignee and observance of the General Rules of Interpretation under Section 1610 of the CMTA. Furthermore, attached to said letter was a memorandum prepared by Mr. Rosales addressed to Atty. Yasser Ismail A. Abbas, Director III of the BOC Imports Assessment Service (IAS), stating the discussions on the reclassification of the subject article, as follows:

"...5. On February 2, 2022, the assigned Customs Examiner thru the BOC Customer Care Portal System with Ticket No. MICP-01155183 recommended for tariff reclassification/modification on the subject shipment from H.S. Code 2836.30.00-0% MFN rate of duty to 3004.90.99- 5% MFN rate of duty (MFN).

6. The commodity (BIBAG 5008 650g Sodium Bicarbonate USP) is put up in measured dose or in forms or packings for retail sale (bibag 650g) with prophylactic or therapeutic claims. Excluded from Chapter 28 are products suitable for therapeutic or prophylactic uses and put up in measured doses or in forms or packings for retail sale which is classifiable under heading 3004 (except 2844 or 2845). Under Chapter Notes paragraph 2 provides, subject to Note 1 above, goods classifiable in heading 30.04, 30.05, 30.06, 32.12, 33.03, 33.04, 33.05, 33.06, 33.07, 35.06, 37.07 or 38.08 by reason of being put up in measured doses or for retail sale are to be classified in those headings and in no other heading of the Nomenclature.

7. Heading of 3004 covers medicaments consisting of mixed or unmixed products put up in measured doses or in packing for retail sale such as the subject shipment. Explanatory Notes for 3004 states that:

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(b) In packings for retail sale for therapeutic or prophylactic use. This refers to products (for example, **sodium bicarbonate** and tamarind powder) which, because of their packing and, in particular, the presence of appropriate indications (statement of disease or condition for which they are to be used, method of use or application, statement of dose, etc.) are clearly intended for sale directly to users (private persons, hospitals, etc.) without repacking, for the above purpose.

These indications (in any language) may be given by label, literature or otherwise. However, the mere indication of pharmaceutical or other degree of purity is not alone sufficient to justify classification in this heading. On the other hand, even if no indications are given, unmixed products are to be regarded as being put up for retail sale for therapeutic or prophylactic use if they are put up in a form clearly specialised for such use.

8. The importer contends that the shipment would fall under 3004.90.89-0% MFN rate of duty is inapplicable. Heading above HS code 3004.90.89 is "Other medicaments for the treatment of cancer, HIV or other intractable diseases". Intractable diseases refer to rare diseases that have resulted mostly from unidentifiable causes and/or lack of clearly established or curable treatments. BIBAG 5008 650g Sodium Bicarbonate USP is clearly for urine alkalization, acidity in the blood and other medical conditions which shall not fall under 3004.90.89.

9. Pursuant to Section 1610 par. (1) and (6) of the CMTA or RA 10863. **General Rules for the Interpretation (GRI)**. –The classification of goods and its tariff nomenclature as provided pursuant to this Act shall be governed by the following principles:

(1) The titles of sections, chapters and subchapters are provided for easy reference only. For legal purposes, classification shall be determined according to the terms of the headings and any relative section or chapter notes and, provided such headings or notes do not otherwise require, according to the following provisions.

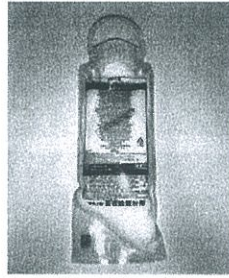
(2) For legal purposes, the classification of goods in the subheadings of a heading shall be determined according to the terms of those subheadings and any related subheading notes and, *mutatis mutandis*, to the above Rules, on the understanding that only subheadings at the same level comparable. For the purposes of the Rule, the relative section and Chapter Notes also apply, unless the context otherwise requires.

10. The commodity (BIBAG 5008 650g Sodium Bicarbonate USP) is a dialysis concentrates that is generally use for urine alkalization, acidity in the blood and other medical conditions. It is packed in lightweight flexible bag and ready to use in hospital or dialysis center. Thus, the applicable H.S. code for the subject shipment is 3004.90.99 with 5% MFN rate of duty..."

In the evaluation of disputes on tariff classification, Section 8 of Commission Order No. 2018-01 provides that this Commission, if it deems necessary, shall conduct a hearing to clarify the facts necessary to resolve the pending disputes in tariff classification. In the present case, however, this Commission found that the submissions of the Importer/Consignee and the BOC are sufficient to make a correct determination on the tariff classification of the subject article. A hearing, therefore, is no longer necessary.

After due examination of the submitted Certificate of Medical Device Registration from the Food and Drug Administration (FDA), safety data sheet, product brochure, package insert, sample, and excerpts from the operations manual of a hemodialysis machine (which uses the product) from the Importer/Consignee, it is established that subject article is a dry bicarbonate concentrate in the form of an odorless white powder intended for bicarbonate hemodialysis (*i.e.*, extracorporeal bicarbonate hemodialysis or bicarbonate hemodiafiltration) treatment of acute and chronic kidney disease. The bibag® is connected/installed to the Fresenius Medical Care 5008 series hemodialysis machines where subject article will be mixed with acid concentrates and diluted with reverse osmosis-treated water to produce the dialysis fluid. Packed in 650-g polyamide-polyethylene (PA/PE) bags, subject article is sufficient for a bicarbonate dialysis session of 6 hours (minimum) at a dialysis flowrate of 500 mL/min and a sodium bicarbonate concentration of 32 mmol/L in the ready-to-use hemodialysis solution.

Below is a photograph of the actual sample submitted by the Importer/Consignee:



The Importer/Consignee declared the product under AHTN 2017 subheading 2836.30.00 while the BOC assessed the product to be appropriately classified under subheading 3004.90.99 based on the justifications provided in their comment. Both Chapters 28 and 30 are part of Section VI of the AHTN 2017.

Note 2 to Section VI of the AHTN 2017 states that subject to Note 1 of the Section, goods classifiable in heading 30.04, 30.05, 30.06, 32.12, 33.03, 33.04, 33.05, 33.06, 33.07, 35.06, 37.07 or 38.08 by reason of being put up in measured doses or for retail sale are to be classified in those headings and in no other heading of the Nomenclature.

Heading 28.36 of the AHTN 2017 covers, among others, carbonates. The Harmonized System (HS) Explanatory Notes (EN) to this heading state that:

"Subject to the exclusions mentioned in the introduction to this sub-Chapter, this heading covers... (A) CARBONATES... (2) Sodium Carbonates... (b) Sodium hydrogencarbonate (acid carbonate, sodium bicarbonate) (NaHCO₃). Usually a crystalline powder or white crystals, soluble in water, especially when hot, and liable to deteriorate in a humid atmosphere. Used in medicine (for treating gravel); for manufacturing digestive tablets and aerated beverages; in the preparation of baking powders; in the porcelain industry, etc."

On the other hand, heading 30.04 of the AHTN 2017 covers medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale. The HS EN to this heading state that:

"This heading covers medicaments consisting of mixed or unmixed products, provided they are:

...(b) In packings for retail sale for therapeutic or prophylactic use. This refers to products (for example, sodium bicarbonate and tamarind powder) which, because of their packing and, in particular, the presence of appropriate indications (statement of disease or condition for which they are to be used, method of use or application, statement of dose, etc.) are clearly intended for sale directly to users (private persons, hospitals, etc.) without repacking, for the above purposes. These indications (in any language) may be given by label, literature or otherwise. However, the mere indication of pharmaceutical or other degree of purity is not alone sufficient to justify classification in this heading."

Based on the foregoing Legal Notes and pertinent HS EN, and even if subject article is in a pure form, this Commission agrees with the BOC that subject article is appropriately covered under heading 30.04 of AHTN 2017 as it is already packed for retail sale and with clear indication on its medical use. However, as a medicament intended for hemodialysis (*i.e.*, due to acute and chronic kidney disease), classification of subject article under AHTN 2017 subheading 3004.90.80 series which covers "Other medicaments for the treatment of cancer, HIV/AIDS or other intractable diseases" should be considered first before the residual subheading, 3004.90.99.

The Supplementary Explanatory Notes (SEN) to AHTN 2017 subheadings 3004.90.81, 3004.90.82, and 3004.90.89 (Other medicaments for the treatment of cancer, HIV/AIDS or other intractable diseases) state that:

"These are medicaments which are solely formulated for patients with cancer, heart ailments, Human Immune-deficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS) or HIV/AIDS, renal failure [emphasis added] or other lingering illnesses and used by the patient as maintenance to suppress the patients' condition at its present level or prevent possible

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complications. These include antineoplastic medicines, dialysis solutions and preparations [emphasis added], chemotherapy solutions, and cardiovascular drugs.”

Subject article, being a dry bicarbonate concentrate in bags intended for connection/installation to hemodialysis machine for use in bicarbonate hemodialysis treatment of acute and chronic kidney disease, falls under AHTN 2017 heading 30.04.

Based on the information received from the Importer/Consignee and the BOC, and the clarifications provided by the foregoing Section Note, HS EN and AHTN 2017 SEN, subject article is properly classified under AHTN 2017 subheading 3004.90.89 by virtue of Rules 1 and 6 of the General Rules for the Interpretation (GRI) of the HS (Section 1610 of the CMTA).

WHEREFORE, premises considered, subject article is hereby classified as follows:

Product	AHTN 2017 Code	2022 MFN Rate
bibag® 5008 650g (Bicarbonate Concentrate for Hemodialysis)	3004.90.89	Zero

This is for compliance by the BOC pursuant to Section 1100 of the CMTA.

So Ordered.

FOR THE COMMISSION

Digitally signed


MARILOU P. MENDOZA
Chairperson

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