- 1 ITEM: "Sugar spheres" with a diameter of 0.5 to 0.8 mm, consisting of a minimum of 80%
- 2 sugar, a minimum of 8.5% corn starch, and a maximum of 1.5% purified water. These
- 3 products are intended to be used by pharmaceutical companies as a carrier for active
- 4 substances.

5

# 6 Tariff Classification Suggestion

#### 7 Phase 1

## 8 Top 3 Candidate Chapters

## Chapter Justification

- 17 By GRI 1, classification follows headings/notes; heading 17.04 covers sugar confectionery, which fits sugar spheres shaped from ≥80% sugar. As a sugar–starch mix, GRI 2(b)/3(b) point to the essential character (sugar). Chapter 17 excludes only Chapter 30 medicaments, which these are not.
- 19 Chapter 19 covers preparations of cereals/starch, but 19.01 is residual (not elsewhere specified or included), so 17.04 is more specific per GRI 3(a). Also, 19.05 refers to wafers/empty cachets in sheets, not sugar spheres.
- **30** Excluded: these are not medicaments of 30.03/30.04 and are not among the specific goods listed in Note 4 to 30.06 (e.g., placebos for clinical trials, dental cements, ostomy appliances).

## 9 Phase 2

12

13

14 15

16 17

18 19

## 10 TARIFF CLASSIFICATION OPINION

- 11 I. Applicable Regulatory Framework
  - General Rules for the Interpretation of the Harmonized System (GRI) GRI 1: "The titles of Sections, Chapters or Sub-Chapters are provided for ease of reference only; for legal purposes, classification shall be determined according to the terms of the headings and any relative Section or Chapter Notes..." GRI 2(b): "Any reference in a heading to a material or substance shall be taken to include a reference to mixtures or combinations of that material or substance with other materials or substances...

    The classification of goods consisting of more than one material or substance shall be according to the principles of Rule 3." Explanatory Note to GRI 2(b): "However,

this Rule does not extend the scope of headings... to the point where... the addition of other materials... results in the article losing the character of goods of those headings." • GRI 3(a): "The heading which provides the most specific description shall be preferred to headings providing a more general description." • GRI 3(b): "Mixtures... which cannot be classified by reference to Rule 3(a), shall be classified as if they consisted of the material or component which gives them their essential character..." • GRI 6: "For legal purposes, the classification of goods in the subheadings of a heading shall be determined according to the terms of those subheadings... provided that only subheadings at the same level are comparable."

- Chapter 17 (Sugars and sugar confectionery) Note 1: "This Chapter does not cover... medicaments and other products of Chapter 30." Relevant headings: 17.01: "Cane or beet sugar and chemically pure sucrose, in solid form." Subheadings: 1701.91 "Containing added flavoring or coloring matter" and 1701.99 "Other." National Note (Chap. 17): "With flavoring(s)... means: with the addition of flavor." 17.02: "Other sugars, including lactose, maltose, glucose and fructose...; sugar syrups...; caramelized sugar and molasses." 17.03: "Molasses resulting from the extraction or refining of sugar." 17.04: "Sugar confectionery (including white chocolate), not containing cocoa."
- Chapter 19 (Preparations of cereals, flour, starch or milk; pastrycooks' products) Notes: exclusion of "medicaments and other products of Chapter 30." Relevant headings: 19.01: "Malt extract; food preparations of flour... starch... not elsewhere specified or included..." 19.02: "Pasta..." 19.03: "Tapioca and substitutes prepared from starch, in the form of flakes, grains, pearls..." 19.04: "Prepared foods obtained by the swelling or roasting of cereals...; cereals... otherwise prepared, not elsewhere specified or included." 19.05: "Bread, pastry, cakes, biscuits... wafers, empty cachets of a kind suitable for pharmaceutical use..."
- II. Legal-Technical Analysis Product description: "Sugar spheres" of 0.5 to 0.8 mm diameter, composed of at least 80% sugar, at least 8.5% corn starch, and at most 1.5% purified water; intended to be used as a core/carrier for pharmaceutical active substances.
  - 1) Applicable Chapter Under GRI 1, classification is determined by the legal text of headings and Notes. The product is a solid preparation based on sugar formed into spheres. Within Chapter 17 there are headings for "sugar" (17.01) and for "sugar confectionery" (17.04). The nature of formed "sugar spheres" ready to serve as a carrier corresponds to a manufactured sugar article. Heading 17.04 covers "Sugar confectionery, not containing cocoa," which is more specific than the raw material

- "sugar... in solid form" of heading 17.01. Under GRI 3(a), the more specificdescription should be preferred.
- Additionally, as a mixed product (sugar and starch), GRI 2(b) and, if necessary, GRI 3(b) apply. The essential character is imparted by sugar (≥80% by weight), so classification remains within Chapter 17; between 17.01 (sugar as a material) and 17.04 (sugar confectionery articles), the more specific for a formed article is 17.04 (GRI 3(a) and 3(b)).
- 61 2) Heading and subheading
- Heading 17.04: "Sugar confectionery (including white chocolate), not containing
   cocoa."
- Subheading (GRI 6): within 17.04, options are: 1704.10 "Chewing gum, whether or not sugar-coated" (not applicable). 1704.90 "Other" (applicable to confectionery other than chewing gum).
- 67 Accordingly, by GRI 6, 1704.90 applies.
- 68 III. Exclusion of Alternative Headings or Chapters (Chapters 17 and 19)
- 69 1701 (including 1701.99 "Other"): 1701 covers "Cane or beet sugar and chemically 70 pure sucrose, in solid form." Although GRI 2(b) allows consideration of mixtures, its 71 Explanatory Note clarifies that it does not extend to include articles that, by the 72 addition of substances, lose the character of the goods of that heading. "Sugar 73 spheres" with about 8.5% starch, formed as an article, cease to be the sugar of 74 17.01 and become a sugar confectionery (a sugar preparation). Moreover, 75 subheading 1701.91 is limited to sugar "containing added flavoring or coloring 76 matter" (and the National Note defines "with flavoring(s)" as the addition of flavor), 77 a situation different from the present case (addition of starch as binder/structure). Under GRI 1 and 3(a), 17.04 more specifically describes a formed sugar article than 78 79 17.01. Subheading 1701.99 is excluded.
- 1702: "Other sugars... lactose, maltose, glucose and fructose..." The product is primarily sucrose formed, not sugars of 17.02 nor syrups; excluded.
- 1703: "Molasses..."; not molasses; excluded.
- 19.01: "Food preparations of flour... starch... not elsewhere specified or included."
   The product is expressly covered in Chapter 17 as a sugar article (17.04). Under GRI
   1 and the "not elsewhere specified or included" clause of 19.01, 19.01 is excluded.
- 19.02: "Pasta..."; not pasta; excluded.

- 19.03: "Tapioca and substitutes prepared from starch, in... pearls..." Although the physical form is granular, this heading requires products "prepared from starch" as the base; here the essential constituent is sugar (≥80%). Under GRI 3(b), the essential character (sugar) and the specific description of 17.04 prevail; 19.03 is excluded.
- 19.04: "Products based on cereals..."; not a cereal-based product nor a prepared cereal; excluded.
- 19.05: "Bakery products... wafers, empty cachets..." Sugar spheres are not wafers/hosts nor bakery products; excluded.
- 96 IMPORTANT NOTE exclusion of 1701.99 As reasoned, the addition of starch (≈8.5%) and 97 the formation into "spheres" confer on the product the nature of a sugar article
- 98 (confectionery) rather than the sugar of 17.01. GRI 2(b) cannot be used to keep it in 17.01
- 99 when the addition of other materials deprives the article of the character of "cane or beet
- sugar... in solid form" of 17.01. Applying GRI 3(a), the description "Sugar confectionery, not
- 101 containing cocoa" (17.04) is more specific than the generic "sugar... in solid form" (17.01)
- for a manufactured/formed sugar-based product; therefore, 1701.99 is excluded in favor of
- 103 1704.90.
- 104 IV. Documentary Requirements To support classification at clearance:
- Technical data sheet and specification sheet with weight percentages of sugar,
   starch, and water.
- Description of the manufacturing process showing formation into spheres and the
   excipient/carrier function.
- Batch certificate of analysis (composition, moisture).
- Product photographs (size 0.5–0.8 mm) and packaging.
- Declaration that it contains no cocoa and no flavoring/coloring (to exclude 1701.91).
- Intended use (as a raw material/excipient; not a finished medicament), consistent
   with Note 1 to Chap. 17 (excludes Chapter 30 medicaments).
- 114 V. Conclusion Based on GRI 1, 2(b), 3(a), 3(b), and 6; the legal texts of headings 17.01 and
- 17.04; and the reasoned exclusion of headings in Chapters 17 and 19 analyzed, the
- 116 described "sugar spheres" are classified as sugar confectionery not containing cocoa
- 117 under subheading 1704.90.
- 118 Classification table:

- Chapter: 17 (Sugars and sugar confectionery)
- Heading: 17.04 (Sugar confectionery, not containing cocoa)
- Subheading (HS at 6 digits): 1704.90 (Other)
- Tariff line (8 digits LIGIE): Not determined in this opinion, as it is limited to the subheading level.
- NICO: Not applicable in this opinion.
- 125 Final determination: Subheading 1704.90.