



HARMONIZED SYSTEM
COMMITTEE

-
28th Session
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O. Eng.

Brussels, 20 September 2001.

POSSIBLE AMENDMENT OF THE EXPLANATORY NOTES TO CLARIFY
THE CLASSIFICATION OF VITAMIN PREPARATIONS IN THE HARMONIZED SYSTEM

(Item VIII.4 on Agenda)

I. BACKGROUND

1. The Secretariat receives numerous enquiries concerning the classification of “vitamin preparations” every year. Similar questions are routinely received at HS seminars, which the Secretariat organizes in different parts of the world. In order to ensure the correct and uniform classification of such products, the Secretariat believes that an improvement of the Explanatory Notes could be a step in the right direction.

II. SECRETARIAT COMMENTS

2. As a first move, the Secretariat is of the opinion that the classification of a specific vitamin preparation by the HS Committee would be an appropriate first step in this process. From there, based on the Committee’s decision and instructions, the Secretariat could prepare draft amendments to the Explanatory Notes (in addition to a possible Classification Opinion) to be examined at the Committee’s next session.
3. The Secretariat has selected the following product to be considered by the Committee. This product is, in the Secretariat’s view, a typical product for this category of vitamin preparations :
4. “Nature Made® Vitamin C 500 mg Supplement with Rose Hips” (tablets).

According to the label on the container, one tablet contains 500 mg of ascorbic acid, corn starch, croscarmellose sodium, cellulose, rose hips, stearic acid, lemon bioflavonoid complex, magnesium stearate and acerola. It is further printed on the label that Vitamin C is a powerful antioxidant that may keep you healthy by neutralizing free radicals and boosting the immune system. The tablets are put up in containers (130 tablets). The recommended dose is one tablet daily with a meal. The following text is also printed on the label :

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"These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat cure or prevent any disease."

Classification of vitamins/vitamin preparations

5. The classification of vitamins and vitamin preparations can, in the Secretariat's view, be summarized as follows :
6. Vitamins/vitamin preparations can be classified in heading 21.06, 29.36 or 30.03/30.04, depending on the composition, use, presentation, etc.
7. Heading 29.36 covers vitamins and intermixtures thereof. The scope of the heading is governed by Notes 1 (c) to (g) of Chapter 29, which stipulate that the heading is restricted to pure vitamins or intermixtures thereof and such products (i) "dissolved in water", (ii) "dissolved in other solvents ...", (iii) "stabilised for the purposes of preservation or transport by adding anti-oxidants, anti-caking agents, etc..." (see also the Explanatory Note to heading 29.36, Item (d) on page 423), and (iv) "with an added anti-dusting agent or a colouring matter or a odoriferous substance ...".
8. Consequently, preparations containing ingredients (other than vitamins) which are not allowed according to the provisions of Note 1 to Chapter 29, e.g., minerals are excluded from heading 29.36.
9. Since vitamin preparations are usually put up in measured doses and in packings for retail sale, the question to be considered is whether they should be classified in **heading 30.04** by virtue of Note 2 to Section VI.
10. While it can be argued that vitamin preparations have prophylactic value, they are not normally medicaments used for the prevention of a specific disease or ailment (based on the inquiries the Secretariat has received lately). The Secretariat has examined the classification of several vitamin/mineral preparations in the past. Such preparations basically contain the recommended daily dietary allowances of vitamins/minerals and are therefore, in the Secretariat's view, food preparations which are put up and consumed, for the purpose of maintaining general health or well-being. Vitamin preparations used in the prevention or treatment of a specific disease or ailment would normally contain a much higher dose of an active ingredient than the normal dietary allowance.
11. Furthermore, the HS Committee at its 21st Session (March 1998) (Doc. 42.100, Annex F/4) agreed that the scope of headings 30.03 (and 30.04) should be limited to products used in medicine which contain, per dose, a sufficient quantity of an active substance with a curative or prophylactic effect against a particular ailment or disease. The determination of active substances could be based on details made available at the time of importation by laboratory analysis.
12. Consequently, the Secretariat would be inclined to classify most vitamin preparations in **heading 21.06**, by application of Note 1 (a) to Chapter 30. This would be supported by the Explanatory Note to heading 30.04 (page 470, second paragraph) which excludes "food supplements containing vitamins or mineral salts which are put up for the purpose of maintaining health or well being ..." from that heading.

Classification of the product in question

13. The product at issue (“Vitamin C 500 mg Supplement with Rose Hips”) does not contain minerals. However, in addition to binders, mould release agents, etc, it also contains rose hips and acerola which are fruits known as natural sources of vitamin C for nutritional supplements. Accordingly this product can not be classified in heading 29.36 (see Note 1 to Chapter 29).
14. The printing on the label (“These products are not intended to diagnose, treat cure or prevent any disease”) clearly indicates that this product does not contain, per dose, a sufficient quantity of an active substance with a curative or prophylactic effect against a particular ailment or disease. Consequently, this product is excluded from headings 30.03 and 30.04 (see paragraphs 11 and 12 above).
15. Accordingly, the Secretariat is of the opinion that “Nature Made® Vitamin C 500 mg Supplement with Rose Hips” should be classified in heading 21.06, by application of Note 1 (a) to Chapter 30.

III. CONCLUSION

16. The Committee is invited to rule on the classification of a vitamin preparation referred to as “Nature Made® Vitamin C 500 mg Supplement with Rose Hips”, on the basis of the Secretariat’s comments set out in paragraphs 3 to 15 above.
17. The Committee is also invited to instruct the Secretariat as to what further action (e.g., further clarification of the Explanatory Notes) should be taken in this regard (see paragraph 2 above).

Vitamin C preparation (500 mg) in the form of tablets containing ascorbic acid, corn starch, croscarmellose sodium, cellulose, rose hips, stearic acid, lemon bioflavonoid complex, magnesium stearate and acerola. The tablets are put up in containers (130 tablets).
