SCIENTIFIC SUB-COMMITTEE 40.361 E

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CLASSIFICATION OF CERTAIN VITAMIN-BASED PREPARATIONS

(Item II.15 on Agenda)

Reference documents :

36.372 (SSC/4)
36.828 (HSC/8)
37.100, Annex F/7 (HSC/8 - Report)
37.765 (SSC/6)
37.900, Annex A/14 (SSC/6 - Report)
38.100, Annex D, paragraph 48 (HSC/11 - Report)
38.905 (HSC/14)
38.998 (HSC/14)
39.400, Annex IJ/7 (HSC/15 - Report)
39.438 (SSC/9)
39.480 Annex A/4 (SSC/9 - Report)
39.654 (HSC/16)
40.184 (HSC/17)
40.260, Annex H/2 (HSC/17 - Report)

I. BACKGROUND

Previous decision to classify "Rovimix AD_3" in heading 29.36

1 At its 6th Session (October 1990), the Harmonized System Committee examined the classification of "Rovimix AD_3, Type 500/100", consisting of vitamins A and D_3 (in a 5:1 ratio) dispersed in a matrix of gelatin and carbohydrates; the vitamins were stabilized with ethoxyquin. The product was used for animal nutrition and was intended to be added to composite feedstuffs and milk substitutes (e.g., premixes,

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compound feeds and milk replacers). After some discussion, the Committee agreed to seek the views of the Scientific Sub-Committee concerning, *inter alia*, whether the matrix in "Rovimix AD_3" could be regarded as a stabiliser in the sense of Note 1 (f) to Chapter 29.

2 At its 4th Session (February 1991), the Scientific Sub-Committee concluded that the matrix in "Rovimix AD_3" could be considered as a stabilizer in the sense of Note 1 (f) to Chapter 29.

3 On the basis of the Sub-Committee's conclusion above, the Harmonized System Committee (7th Session, April 1991) classified "Rovimix AD_3" in heading 29.36 (Doc. 36.600, Annex D, paragraph 28). In this connection, the Committee, at its 8th Session (October 1991), adopted amendments to the Explanatory Note to heading 29.36 (Doc. 37.100, Annex L/3) to clarify that products of the heading could be stabilised for the purposes of preservation or transport :

"-by adding anti-oxidants,
-by adding anti-caking agents (e.g., carbohydrates),
-by coating with appropriate substances (e.g., gelatin, waxes or fats), whether or not plasticised, or
-by adsorbing on appropriate substances (e.g., silicic acid),

provided that the quantity added or the processing in no case exceeds that necessary for their preservation or transport and that the addition or processing does not alter the character of the basic product and render it particularly suitable for specific use rather than for general use."

Classification of "Rovimix A-500, Type P", "Rovimix E-50 SD" and "Lutavit E-50"

4 In January 1993, the Secretariat received a request from the South African Administration for advice on the classification of "Rovimix A-500, Type P", "Rovimix E-50 SD" and "Lutavit E-50". Since their compositions (see Doc. 38.905, paragraph 1) were similar to that of "Rovimix AD_3", the Secretariat gave the opinion that, like "Rovimix AD_3", these three products were classifiable in heading 29.36. However, in view of certain arguments raised by the South African Administration in a subsequent response to the Secretariat, this question was sent to the Harmonized System Committee for consideration (see Doc. 38.905).

5 In this connection, the Secretariat had also received from the Philippine Administration a request for advice concerning the classification of several similar preparations, described in Doc. 38.998.

6 At its 15th Session (April 1995), the Harmonized System Committee decided that the points referred to in paragraph 14 of Doc. 38.905

should be referred to the next session of the Scientific Sub-Committee for advice. It was understood that the classification of "Rovimix AD_3" and the Explanatory Note to heading 29.36 might have to be reviewed, depending on the advice received. The questions thus referred to the Scientific Sub-Committee were as follows :

(1)Whether additives in the form of a matrix or coating (e.g., matrix of gelatin, carbohydrates and glycerol) or as an adsorbent (e.g., silicic acid) act as stabilisers for vitamins within the meaning of Note 1 (f) to Chapter 29 or as a solvent in the context of heading 29.36 (see heading text and Item (d) of the Explanatory Note on page 423);

(2)Whether the additive (i.e., 35% silicon dioxide and 15% moisture) in a 50% choline chloride preparation also acts as a stabiliser within the meaning of Note 1 (f) to Chapter 29;

(3)If the answer to (2) is in the negative, what are the differences, in terms of functions, between the additives used in "Rovimix AD_3", "Rovimix A-500, Type P", "Rovimix E-50 SD" and "Lutavit E-50" and the additive used in the choline chloride preparation.

7 At its 9th Session (June 1995), the Scientific Sub-Committee addressed the questions referred to in paragraph 6 above. The Sub-Committee's conclusions are summarized as follows :

(a)In "Rovimix A-500, Type P", "Rovimix E-50 SD" and "Lutavit E-50", the additives in the form of a matrix, a coating or an adsorbent effectively made these products specific preparations for animal feeding and, therefore, the additives could not be permitted under Note 1 (f) to Chapter 29. The additives could be regarded as acting as standardising agents or carriers for vitamines in order to facilitate their use as premixes in animal feeding. Certain additives (e.g., a matrix of gelatin and carbohydrates) could protect sensitive vitamins from air or light, but the quantities present in the products under consideration went far beyond that requirement. Silicic acid was generally known to be used in animal feeding, and vitamins adsorbed on silicic acid could not be regarded as being for general use. On this basis, these and similar products cited by the Philippine Administration were classifiable in heading 23.09.

(b)The additives used in the product in question could not be regarded as solvents for vitamins in terms of heading 29.36.

(c)Since choline chloride was a stable chemical compound, the additives (e.g., silicon dioxide) did not have a stabilising effect, but were in the nature of standardising agents to facilitate the product's use in animal feeding in specified dosages.

(d)The additives in all the products considered had the same function, i.e., as standardising agents or carriers. However, additives such as a matrix of gelatin and carbohydrates could also have a stabilising effect on vitamins sensitive to air or light.

(e)The Sub-Committee was generally of the view that the Harmonized System Committee should reconsider its earlier decision concerning the classification of "Rovimix AD_3" in heading 29.36.

(f)The Explanatory Note to heading 29.36 (page 423, Item (d), second paragraph) could be retained since (i) some additives specified therein could have a stabilising effect on sensitive vitamins and (ii) the proviso regarding limits on the quantity added provided a good basis for distinguishing vitamins of heading 29.36 from vitamin-based preparations of other headings. However, the expression "by a[d]sorbing on appropriate substances (e.g., silicic acid)" should be deleted, since such substances were usually added to preparations intended for animal feeding.

8 At its 17th Session (May 1996), the Harmonized System Committee considered the conclusions summarized in paragraph 7 above, taking into account further comments submitted by the Swiss Administration (see Doc. 40.184). During the discussion, the Delegate of the EC drew the Committee's attention to the recent EC submission to the Secretariat of a compilation of technical information, prepared by the European Chemical Industry Council (CEFIC), concerning vitamins; he felt that this information should be reviewed by the Scientific Sub-Committee. In addition, some delegates expressed disagreement with the Scientific Sub-Committee's conclusions (paragraph 7 above), while others supported them (see Doc. 40.260, Annex H/2). The Delegate of the United States, in particular, felt that the Sub-Committee should give its views concerning the normal quantities of additives used in vitamin products of heading 29.36 and the functions of each additive.

9 Finally, the Committee agreed to ask the Scientific Sub-Committee to review the conclusions in this regard from its 9th Session, taking into account the new information submitted by the EC, the comments submitted by the Swiss Administration and the questions posed by the US Delegate.

II. SECRETARIAT COMMENTS

10 The descriptions of the products under consideration are given in Annexes A and B to this document. An excerpt of Doc. 40.184 (Swiss comments) is reproduced in Annex C to this document for ease of reference.

11 Owing to its large volume, the additional information submitted by the EC on behalf of CEFIC is not reproduced in this document. However, one copy was given to each Delegation at the Harmonized System Committee's 17th Session, with a request to forward it to the Delegate who would be attending the 11th session of the Scientific Sub-Committee. English and French versions will also be available in the meeting room during the Sub-Committee's 11th Session.

12 Owing to a lack of time, the Secretariat is not providing an analysis or summary of the CEFIC submission in this working document. However, the Sub-Committee's attention is drawn, in particular, to Parts 4 and 5 of the CEFIC submission, where CEFIC addresses the conclusions of the Scientific Sub-Committee's 10th Session in this regard and discusses certain vitamin-based products individually.

II. CONCLUSION

13 The Sub-Committee is requested to review its 10th Session conclusions (paragraph 7 above) concerning vitamin-based products, taking account of the additional comments submitted by the Swiss Administration (Doc. 40.184), the information provided by CEFIC and the various arguments made at the 17th Session of the Harmonized System Committee. In particular, the Sub-Committee is asked to express its views on the following :

(a) The functions of each additive present in "Rovimix A-500, Type P" (ethoxyquin and a matrix of gelatin, glycerine and carbohydrates), "Rovimix E-50 SD" (Silicic acid and a matrix of gelatin and sucrose) and "Lutavit E-50" (amorphous silica and moisture).

(b) Whether the additives in "Rovimix A-500, Type P", "Rovimix E-50 SD" and "Lutavit E-50" are present in excess of the amount necessary for preservation or transport of the vitamins, under the terms of Note 1 (f) to Chapter 29; in this connection, the Sub-Committee is also requested to indicate how to draw a line of demarcation between the amount of such additives necessary for preservation or transport and an amount that would be considered excessive for that purpose;

(c) Whether "Rovimix A-500, Type P", "Rovimix E-50 SD" and "Lutavit E-50" are preparations rendered particularly

suitable for specific use rather than general use (i.e., whether these products can be used not only for making premixes for animal feeds, but also for making human foodstuffs and medicaments for humans or animals or whether similar vitamin-based preparations with differing compositions are used for making human foodstuffs or medicaments (for humans or animals)).

14 Finally, after consideration of the points in paragraphs 12 and 13 above, the Sub-Committee is requested to summarize its position concerning :

(i)the classification of "Rovimix AD_3" (see Annex A);

(ii)the classification of "Rovimix A-500, Type P", "Rovimix E-50 SD" and "Lutavit E-50" (see Annex A);

(iii)the classification of "Rovimix A, Type 500 W", "Lutavit A-500", "Microvit AD_3 SUPRA 500-100", "Microvit B_{12} PROMIX 10000" and "Microvit H PROMIX 2000" (see Annex B);

(iv)the need for amending the Explanatory Note to heading 29.36 (page 423, Item (d)).

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DESCRIPTION OF "ROVIMIX AD_3", EXAMINED BY THE SCIENTIFIC SUB-COMMITTEE AND THE HARMONIZED SYSTEM COMMITTEE

"Rovimix AD_3"

"Rovimix AD_3" has the following approximate compostion :

Vitamins A and D_3 (5:1 ratio)	15%
Gelatin	40%
Carbohydrates	30%
Glycerol	10%
Ethoxyquin	5%

The chemical stabilizer in the product is ethoxyquin (anti-oxidant). The other additives (gelatin, carbohydrates and glycerol) form a matrix in which the vitamins are dispersed, making the product free-flowing.

DESCRIPTIONS OF THE PRODUCTS SUBMITTED BY THE SOUTH AFRICAN ADMINISTRATION

"Rovimix A-500, Type P" : Brown to dark-brown fine granular powder composed of vitamin A (min. 500.000 I.U./g) finely dispersed in a matrix of gelatin, glycerine and carbohydrates; the vitamin is stabilized with ethoxyquin. It is used for animal nutrition (premixes, compound feeds).

"Rovimix E-50 SD" : Yellowish powder composed of Vitamin E acetate (minimum 50%) finely dispersed in a matrix of gelatin and sucrose. The individual particles are coated with a small amount of silicic acid. It is used for animal nutrition (milk replacers, premixes and mineral feeds).

"Lutavit E-50" : White powder composed of vitamin E acetate (51.4%), amorphous silica and moisture. It is used as a supplement in animal feed.

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EXTRACT OF DATA SHEETS PROVIDED BY THE PHILIPPINES

Name of product	Manufacturer	Appearance	Composition	Uses
1. ROVIMIX A Type 500 W	ROCHE	Yellowish to brownish powder	-Vitamin A : min. 500.000 I.U./g -Vitamin A is finely dispersed in a matrix of gelatin and dextrin -Vitamin A is stabi-lized with ethoxyquin	For animal nutri-tion (stress preparations, liquid diets)
2. LUTAVIT A 500	BASF	Yellow to brownish, free-flowing powder (at least 97 % < 0.63 mm)	Vitamin A (acetate) : min. 500,000 I.U./g. Vitamin A is "stabilized" by : -esterification with acetic acid -combination of antioxidant -embedding the vitamin droplets in a gelatin/carbohydrate composition -coating particles with a release agent -adding complexing agents	Animal feed additive
3. MICROVIT AD_3 SUPRA 500-100	RHONE-POULENC	Orange-beige, free-flowing powder	-Vitamin A (acetate) : Min. 50,000 I.U./g	Animal feed additive

Name of product	Manufacturer	Appearance	Composition	Uses
			-Vitamin D_3 : Min. 100,000 I.U./g -Digestible coating (gelatin, carbohydrate) -Antioxidant (BHT)	
4. MICROVIT B_{12} PROMIX 10000	RHONE-POULENC	Pink beige to reddish brown, fine free-flowing powder	-Vitamin B_{12} : 9,000 to 11,000 mg/kg -Carrier (calcium carbonate, silica)	Animal feed additive
5. MICROVIT H PROMIX 2000	RHONE-POULENC	Cream white, fine free-flowing powder	-D-Biotin : Min. 20,000 mg/kg -Diluent (starch, defatted soyabean meal)	Animal feed additive

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EXCERPT FROM DOC. 40.184 (SWISS COMMENTS)

"Do additives in the form of a matrix, coating or adsorbent act as stabilizers for vitamins within the meaning of Note 1 (f) to Chapter 29 ?

(a) The addition of additives does not make them specific preparations for animal feed, since similar vitamin A and E preparations based on the same additives are used in the food and pharmaceutical sectors. Indeed, the majority of industries now market vitamins with this type of formulation in various areas of vitamin use (food for human consumption, animal feed, pharmaceutical uses).

(b) None of the additives mentioned in the Explanatory Note (anti-oxidants, gelatin, carbohydrates, fats, anti-caking agents) can be regarded as mere standardizing agents or carriers. These additives have been selected after lengthy research by the vitamin industry. They ensure optimum stability for preservation and transport. In this connection, it should be noted that the legislation of many countries stipulates a minimum preservation period. Without adequate protection, the majority of vitamins would not meet those conditions.

1. Anti-oxidants (ethoxyquin, BHA, BHT) alone do not give vitamins sufficient stability. A complex formulation of gelatin, carbohydrate and fat is necessary to protect vitamin A against humidity, light and oxygen, the vitamin being extremely unstable. These additives, used in certain specific proportions, allow the formation of a microporous matrix consisting of a coating agent and gelatin cross-linked transversally, in which droplets of vitamin A are accommodated. Both the amounts and the proportions of these additives are important for stabilizing the products. It is important to note that the additives do not in any way alter the original character of the products and do not render them suitable for a specific use.

2. Though less sensitive than vitamin A, vitamin E in the form of tocopherol acetate also has to be protected against oxidation, light and humidity, particularly when stored for lengthy periods or in an aggressive environment (heat, copper, iron, manganese, etc.) in containers or other packaging. Consequently, appropriate matrices (gelatin, silicic acid, etc.) have been developed to protect and stabilize that vitamin for preservation and transport purposes. The adsorption on silicic acid reduces the surface that can be attacked by reactive substances and, moreover, acts as an anti-caking agent. Thus, the silicic acid very clearly performs a stabilizing function and increases the suitability for transport or ensures a longer

preservation period. Many countries' legislation prohibits the use of vitamin E in oil form in animal feed. The vitamins concerned (A500, E50, etc.) cannot be regarded as premixes, but constitute base materials for the production of premixes. The reason is that the above-mentioned formulations are highly concentrated forms and require an additional physical process (dilution) before entering the composition of the final product.

(c) In no case do the amounts of additives used as stabilizers exceed the quantities necessary for preservation and transport purposes. As mentioned above, the formulations used are the result of lengthy research and provide optimum stability for preservation and transport. They should be regarded as a technical feasibility compromise between the need for stability and the demand for maximum product purity. It is not in the interest of any vitamin manufacturer to dilute his products unnecessarily, since any dilution adds to the costs. It is no coïncidence that several manufacturers use very similar formulations : this reflects the best solution for the need for stability in respect of vitamins A and E.

(d) Silicic acid as an anti-caking agent or as an adsorbent is employed in various sectors (e.g. animal feed, food for human consumption, pharmaceutical applications). Its use in a variety of fields makes it a general-purpose substance and not a substance for a specific application in animal feed. In general, a fluidity adjunct such as SiO_2 is added in proportions of 3 to 4 %; in the cases at issue, the high proportions show that the function is more than that of a mere adjunct added to vest the products with a certain fluidity."