

CLASSIFICATION OF ALCOHOL BASED HAND SANITIZER

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Issues in classification – Pharma Products

1. Chapter 30 of the Customs Tariff Act covers classification of pharmaceutical products. The most essential characteristic of any medicine is its curative effect i.e. **therapeutic use**. Curative effect means its ability to cure the disease or mitigate the disease. Another important characteristic is medicines should have the ability to prevent any disease i.e., **prophylactic use**. The therapeutic or the prophylactic values are the basic factors to be considered in classification of a product as medicines.
2. However, it must be noted that mere having some therapeutic or prophylactic properties alone cannot make any product as medicines. The product must be used mainly to cure or prevent diseases and contains curative/preventive ingredients even in small quantities to classify as medicines.
3. For instance, there have been many disputes as to whether a product is a cosmetic product or medicines. Certain cosmetics may also have some curative or preventive effect. However, the primary intention of using cosmetics is to enhance the appearance. Ancillary property of curing or preventing the disease shall not make cosmetic as medicines.
4. Similar classification dispute existed as to whether a product is food supplement or medicine. The food supplements are also known as health tonics or nutraceuticals. Food supplements generally contains vitamins or proteins. It may have some element of therapeutic or prophylactic values. However, the primary intention is the general well-being and not to treat any disease.

Hand Sanitizer – Classification

5. From the common parlance, hand sanitizer is used for handwash. Technically the same may be disinfectant (CH 3808), skin washing liquid (CH 3401), cleaning preparation (CH 3402) or medicine (CH 3003). The ingredient shall differ, manufacturing process shall differ, but the end use is to clean the hand. The classification in such cases shall be made based on its ingredients and application.

6. There are a number of judicial precedents which have held that a product would be classified as medicament under Chapter 30 since its ingredients were found to be in Ayurvedic texts, for cure or prevention of a particular disease. Hence one of the essential tests of classification of this product would be based on the ingredients and its end use (reference to common parlance)
7. **Currently**, we understand that there are two tariff entries which are under deliberation. They are
HSN 3003
Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale
HSN 3402
Organic surface-active agents (other than soap); surface-active preparations, washing preparations (including auxiliary washing preparations) and cleaning preparations, whether or not containing soap, other than those of heading 3401
8. Before evaluating the appropriate classification, one may also have to evaluate the classification adopted for the said goods, prior to the COVID-19 pandemic. Earlier, a general hand sanitizer was used as a product to clean the hands and was merely used as an alternative to soap (liquid form or in bar form).

Jurisprudence

9. **Ciens Laboratories¹ - Importance of Pharmaceutical Ingredients**

The Hon'ble Supreme Court held that the following guiding principles emerge from the discussion;

- (a) when a product contains **pharmaceutical ingredients** that have therapeutic or prophylactic or curative properties, the proportion of such ingredients is not invariably decisive. What is of importance is the **curative attributes of such ingredients** that render the product a medicament and not a cosmetic.
- (b) though a product is sold without a prescription of a medical practitioner, it does not lead to the immediate conclusion that all products that are sold over/across the

¹ 2013 (295) E.L.T. 3(S.C.)

counter are cosmetics. There are several products that are sold over-the-counter and are yet, medicaments.

- (c) prior to adjudicating upon whether a product is a medicament or not, Courts have to see what the people who actually use the product understand the product to be. **If a product's primary function is "care" and not "cure", it is not a medicament.** Cosmetic products are used in enhancing or improving a person's appearance or beauty, whereas medicinal products are used to treat or cure some medical condition. A product that is used mainly in curing or treating ailments or diseases and contains curative ingredients even in small quantities, is to be branded as a medicament.

10. **IPCA Health products (P) Ltd² - Prophylactic use Vs. General Use**

The Hon'ble Supreme Court has held that products hexiprep, hexiscrup and hexiaque used for cleaning of wounds and abrasions and minor cuts and disinfecting the skin prior to surgery are classifiable under CET sub-heading 3003.10 and not under chapter heading 38.08 since these products have therapeutic properties and prophylactic use.

11. **Sarvotham Care Ltd³ - Limited Use Vs. Regular Use**

The Hon'ble Supreme Court in this case held that suggestion that shampoo should be used once a week and on other days, normal shampoos may be used, showed it was to be used like medicine, unlike other normal Shampoos. It was more so as it was not used for cleaning hair. Hence, shampoo was classifiable as medicine under sub-heading 3003.10 of Central Excise Tariff and not under sub-heading 3305.99 ibid as 'preparation for use on hair'.

12. **Shree Baidyanath Ayurved Bhavan Ltd⁴ - Limited Use Vs. Regular Use**

Merely because there is some difference in the tariff entries, the product will not change its character. **Something more is required for changing the classification especially when the product remains the same.**

The Hon Supreme Court in this case held that medicine is ordinarily prescribed by a medical practitioner and it is used for a limited time and not taken every day unless it is so prescribed to deal with a specific disease like diabetes. Scientific and technical

² 2004-TIOL-39-SC-CX

³ 2015 (322) E.L.T. 575 (S.C.)

⁴ 1996 (83) E.L.T. 492 (S.C.) and 2009-TIOL-53-SC-CX

meaning of the terms and expressions used in the tax laws like Excise Act not to be resorted. The goods to be classified according to the popular meaning attached to them by those using the product.

13. **Marico Industries Ltd⁵ - Medicinal Purpose Vs. Cleansing Purpose**

The Hon'ble Supreme Court in the case held that Mediker used for anti-lice treatment is drug because of its **medicinal affect**. Once it is drug, it cannot be shampoo.

14. **Muller & Phipps (India) Ltd⁶ - Medicinal Purpose Vs. General Purpose**

It was a case of Johnson Prickly Heat Powder. This powder was again held to be a medicament because it was **not an ordinary talcum powder but a powder to be used to get rid of the problem of prickly heat**.

15. **Hindusthan Lever Ltd⁷ - Cure Vs. Care**

The Hon'ble Supreme Court in this case held that if a particular product is substantially for the care of skin and simply because it contains subsidiary pharmaceutical or antiseptic constituents or is having subsidiary curative or prophylactic value, it would not become medicament and would still qualify as the product for the care of the skin. There would be certain products which would be purely for the care of skin and certain other products would be clearly medicament and such cases may not pose any problem. The issue of determination as to whether a particular product falls in Chapter 33 or Chapter 30 would arise in those cases where certain products have the shades or qualities of both, namely, skin care as well as cure of skin diseases. In such cases, the necessary exercise requires to be undertaken.

16. **Colfax Laboratories Ltd⁸ - Intention of Use for Prevention of Disease**

The Hon'ble Supreme Court in this case held that intended use of an article must be for treatment, mitigation or prevention of disease to come within definition of 'medicinal preparations' under Section 2(g) of Drugs and Cosmetics Act, 1940.

⁵ 2016 (338) E.L.T. 335 (S.C.)

⁶ 2004 (167) ELT 374 = 2004-TIOL-48-SC-CX

⁷ 2015 (323) E.L.T. 209 (S.C.)

⁸ 2003 (148) E.L.T. 18 (S.C.)

17. **Sanmar Electronics Corporation Ltd⁹ - Popular Meaning and Commercial Sense**

The High Court of Madras in this case held that interpretation regarding classification of goods to be construed in the sense in which persons who deal in such goods understand it normally. The goods must also be classified according to their popular meaning and commercial sense as well. The Court to select meaning relevant to context in which it has to interpret the word. The functional test also a relevant factor.

Summary Comments

18. From the above settled legal principles, it may be summarized that while classifying the pharmaceutical products following factors are to be considered;

- (a) Curative effect of the product (therapeutic use)
- (b) Preventive effect of the product (prophylactic use)
- (c) Period of usage i.e, to be used for limited period or regularly
- (d) Product contains curative/preventive ingredients even in small quantities
- (e) License to manufacture, store and sell by FDA
- (f) Reference to Pharmacopoeia or authoritative books
- (g) Trade parlance, i.e, how it is known in the market
- (h) Certificate by the technical experts or authorities.

19. As per World Health Organisation Guidelines on **Hand Hygiene** in Health Care issued in April 2010¹⁰ provides the following two separate formulation for alcohol-based hand-rub

FORMULATION 1 - Final concentrations	FORMULATION 2 - Final concentrations
Ethanol 80% (v/v), Glycerol 1.45% (v/v), Hydrogen peroxide 0.125% (v/v)	Isopropyl alcohol 75% (v/v), Glycerol 1.45% (v/v), Hydrogen peroxide 0.125% (v/v)

The said formulation was recommended by WHO much before the spread of COVID pandemic and was for the purpose of general hand hygiene and not specifically for any curative and preventive purpose against a particular disease.

⁹ 2010 (252) E.L.T. 332 (Mad.)

¹⁰ https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf

20. Also, with reference to a document released by the US FDA & Drug Administration¹¹ a specific question on whether hand sanitizer is effective against COVID-19. The response provided against the said question is as under

The best way to prevent the spread of infections and decrease the risk of getting sick is by washing your hands with plain soap and water, advises the Centers for Disease Control and Prevention (CDC). Washing hands often with soap and water for at least 20 seconds is essential, especially after going to the bathroom; before eating; and after coughing, sneezing, or blowing one's nose. If soap and water are not available, CDC recommends consumers use an alcohol-based hand sanitizer that contains at least 60% alcohol.

21. One can draw reference to the fact that even a normal soap would help in controlling the spread of infections/COVID. However, this aspect is not sufficient to classify a soap as a medicament.
22. Similarly, general alcohol-based hand sanitizer without any curative or preventive ingredients may not be considered as a medicament and hence it would be risky to classify the same under HSN 3003. The fact is that a general sanitizer is used as an alternative to wash hands (to maintain hygiene) with normal soap. Further, the test of trade parlance and the period of usage could be a ground to be considered before classifying the said product under HSN 3003. Certificate from a technical expert may be obtained in such cases.
23. However, if the product is different from the standard hand sanitizer which is used for general hand hygiene and contains certain curative and preventive ingredients, then a view can be taken to classify it under HSN 3003, subject to satisfaction of other factors.

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Note: Certain excerpts of this note have been referred from the upcoming book on Practical Guide to GST on Healthcare and Pharmaceutical Sector, authored by the same writers

¹¹ <https://www.fda.gov/drugs/information-drug-class/qa-consumers-hand-sanitizers-and-covid-19>