

**THE AUTHORITY FOR ADVANCE RULINGS
IN KARNATAKA
GOODS AND SERVICES TAX
VANIJYA THERIGE KARYALAYA, KALIDASA ROAD
GANDHINAGAR, BENGALURU - 560 009**

Advance Ruling No. KAR ADRG 07 / 2021

Date : 26-02-2021

Present:

1. Dr. Ravi Prasad M.P.
Additional Commissioner of Commercial Taxes Member (State Tax)
2. Sri. Mashhood Ur Rehman Farooqui,
Joint Commissioner of Central Tax, Member (Central Tax)

1.	Name and address of the applicant	M/s. Ce Chem Pharmaceuticals Pvt Ltd, 9 th Cross, 4 th Phase, Peenya Industrial Area, Bengaluru, - 560058
2.	GSTIN or User ID	29AAACI3514N1ZE
3.	Date of filing of Form GST ARA-01	13.10.2020
4.	Represented by	Sri. Ajayan T.V, Advocate & CA Authorised Representative
5.	Jurisdictional Authority - Centre	The Commissioner of Central Tax, Bengaluru North West Commissionerate (BNWD1)
6.	Jurisdictional Authority - State	LGSTO-75, Bengaluru
7.	Whether the payment of fees discharged and if yes, the amount and CIN	Yes, discharged fee of Rs.5,000/- under CGST Act and Rs 5,000/- under KGST Act through debit from cash ledger vide reference number DC2910200114059 dated 13.10.2020

**ORDER UNDER SECTION 98(4) OF CGST ACT, 2017
& UNDER SECTION 98(4) OF KGST ACT, 2017**

M/s Ce-Chem Pharmaceuticals Pvt Ltd., 9th Cross, 4th Phase, Peenya Industrial Area, Bengaluru, - 560058 (called as the 'Applicant' hereinafter), having GSTIN number 29AAACI3514N1ZE, have filed an application for Advance Ruling under Section 97 of the CGST Act, 2017 & KGST Act, 2017 read with Rule 104 of CGST Rules 2017 & KGST Rules 2017, in FORM GST ARA-01, discharging the fee of Rs.4,800/- each under the CGST Act and the KGST Act.

2. The applicant is a private limited company manufacturing and selling different pharmaceutical formulations and proposes to manufacture Isopropyl rubbing alcohol IP and Chlorhexidine Gluconate & Isopropyl Alcohol solution, as detailed below, and classify the same under Chapter Heading 3004 attracting 12 % GST



Sl.No.	Name of Product	Composition
1	Isopropyl Rubbing Alcohol IP	Isopropyl Alcohol IP 70% v/v Excipients: Purified water IP QS
2	Chlorhexidine Gluconate and Isopropyl Alcohol solution	Chlorhexidine Gluconate solution IP 2.5% v/v Equivalent to 0.5% w/v of Chlorhexidine Gluconate Isopropyl Alcohol IP 70% v/v Purified water IP QS

In view of the above, the applicant sought advance ruling in respect of the following question:

Whether Isopropyl rubbing alcohol IP and Chlorhexidine Gluconate and Isopropyl Alcohol solution are to be classified under Chapter Heading 3004 attracting 12 % GST, and if not, what would be the appropriate classification and justification for such classification

3. BRIEF FACTS OF THE CASE:

3.1 The Applicant is a private limited company manufacturing and selling different pharmaceutical formulations comprising of Tablets, Capsules, Oral Liquids and Dry Syrups in India and also exporting to various countries across the globe. The Applicant ensures that all its products meet the quality standards as specified by WHO-GMP and ISO certifications. The Applicant is also functioning under licenses issued by the Office of the Drugs Controller for the State of Karnataka which are valid up to 31-03-2023. They enclosed the copy of letter **No.DCD/MFG/SR-1467/17-18 dated 22 Feb 2019**, issued in this regard by the Additional Drugs Controller & Licensing Authority.

3.2 The applicant obtained the permission to manufacture the products mentioned at para 2 supra, as there is considerable requirement for hand sanitizers due to the present pandemic of covid-19. The **letter No.DCD/MFG/CR-760/19-20 dated 18 May 2020 issued in this regard by the Additional Drugs Controller & Licensing Authority is attached**. The Applicant is proposing to manufacture and supply the products at Sl.No.1 and 2, across India. **A flowchart of the manufacturing process is attached**. All the ingredients of the products are listed under the Indian Pharmacopoeia. The products of the aforesaid composition as given in the table above, proposed to be manufactured and supplied by the Applicant, are known in common parlance as Hand Sanitizers.

3.3 The applicant furnished the copy of letter F.No.Z 25023/09/2018-2020-DCC(AYUSH) dated 2nd April, 2020, issued by the Advisor (Ay.) and Head, Drugs Policy Section, of the Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH), on the subject of expediting the process for grant of approval/license/renewal of license for manufacturing of ASU immunity boosting healthcare products and sanitizers, addressed to all State/Union Territory Licensing Authorities and Drug Controllers of AYUSH, after stating that Regulatory and Quality Control provisions for the manufacturing of Ayurvedic, Siddha and Unani drugs/medicines under the Drugs and Cosmetics Act, 1940 and Rules thereunder are



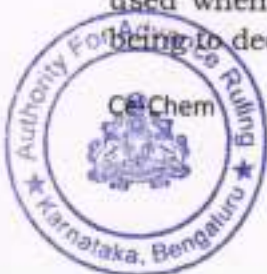
enforced by the State/Union Territory Licensing Authorities and Drug Controllers appointed by the State/UT Government; and after further stating that due to COVID 19 outbreak the need for public use of ASU based immunity boosting products for healthy people and hand sanitizers has been significantly emphasized and their demand has increased manifold, it was directed, inter-alia, that all the State AYUSH Licensing Authorities and Drug Controllers are to complete the licensing/approval/renewal process expeditiously.

3.4 Further, the Central Drugs Standard Control Organization, under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, (CDSCO in short), has, vide its letter dated 17.03.2020 issued in File No.DCGI/Misc/2020 (96), on the subject of "Monitoring of the quality standards of hand sanitizer as per Drugs and Cosmetics Act, 1940 and Rules made thereunder and expediting the licensing of manufacturers of such products", stated, among other things, that hand sanitizers are licensed under Drugs and Cosmetic Rules, 1945 and the standard of such products shall be as prescribed under the Second Schedule of the Drugs and Cosmetics Act, 1940 and rules made thereunder. **The applicant furnished the copy of the said letter dated 17.03.2020 of the Central Drugs Standard Control Organization.** The CDSCO has again, vide letter dated 18.03.2020 issued in File No.DCGI/Misc/2020 (96), addressed to all State and Union Territory Drug Controllers, directed that in view of present situation due to outbreak of COVID-19, and to meet the growing demand of hand sanitizer, all applications for grant of manufacturing license under the Drugs and Cosmetics Act, 1940 and rules made thereunder, for manufacturing of such products, are to be processed within three working days. **The copy of said letter dated 18.03.2020 of the Central Drugs Standard Control Organization is furnished.** Further, by the Gazette Notification No.S.O.2451(E) published on 27th July 2020, the Central Government has in exercise of the powers conferred under Section 26B of the Drugs and Cosmetics Act, 1940, directed, inter-alia, that the drug, namely, hand sanitizer shall be exempted from the requirement of sale licence for its stocking or sale under the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. **The copy of the said Gazette Notification No.S.O.2451(E) published on 27th July 2020 is furnished by the applicant.**

3.5 The copies of the certificates issued by a technical expert, Shri. V.L. Hambar, M. Pharm, former Deputy Drugs Controller, Drugs Control Department, Government of Karnataka certifying that Isopropyl rubbing Alcohol I.P is used as a Hand Sanitizer and that it has a number of uses such as, as a skin disinfectant, as natural bactericidal treatment, to kill fungus and viruses and to reduce skin infection risks and also certifying that Chlorhexidine Gluconate and Isopropyl Alcohol solution is used as a Hand Sanitizer and has antimicrobial activity; are also furnished.

4. Applicant's Interpretation of the Law:

4.1 Hand Sanitizers can be both alcohol based or alcohol free and are generally used when soap and water are readily unavailable, the principal purpose of their use being to decrease infectious disease causing microorganisms on hands.



4.2 The rate schedule published under CGST Notification No. 1/2017 Central Tax (Rate) dated 28-06-2017 as amended by Notification No.41/2017-Central Tax (Rate) dated 14-11-2017, and 6/2018-Central Tax (Rate) dated 25th January 2018, in Schedule II, with the notified rate of central tax of 6%, at Sl.No.63 provides as under:

Sl. No.	Chapter/Heading/ Sub-heading/ Tariff item	Description of Goods
63	3004	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, including Ayurvedic, Unani, homoeopathic siddha or Bio-chemic systems medicaments, put up for retail sale.

4.3 Explanation 3 to the Notification No.1/2017-CT (Rate) ibid states that "Tariff item", "sub-heading" "heading" and "Chapter" shall mean respectively a tariff item, sub-heading, heading and chapter as specified in the First Schedule to the Customs Tariff Act, 1975 (51 of 1975).

4.4 It can be seen that in the notification 1/2017- CT (Rate) ibid, the description of goods stated against Chapter Heading 3004 under Schedule II at Sl.No.63 contain "*Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, in forms or packings for retail sale.*"

4.5 While the GST Rate Schedule has given only the Chapter Heading, it is found in the Customs Tariff Act, 1985 under Chapter 30, tariff heading 3004 90 is a sub-classification "other", which has under it, a sub-classification against tariff item 3004 90 87, the description of which states "*Antibacterial formulations, not elsewhere specified or included*".

4.6 It can be seen that in the letter F.No.Z 25023/09/2018-2020-DCC(AYUSH) dated 2nd April, 2020, issued by the Advisor (Ay.) and Head, Drugs Policy Section, of the Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH), on the subject of expediting the process for grant of approval/license/renewal of license for manufacturing of ASU immunity boosting healthcare products and sanitizers, addressed to all State/Union Territory Licensing Authorities and Drug Controllers of AYUSH, after stating that Regulatory and Quality Control provisions for the manufacturing of Ayurvedic, Siddha and Unani drugs/medicines under the Drugs and Cosmetics Act, 1940 and Rules thereunder are enforced by the State/Union Territory Licensing Authorities and Drug Controllers appointed by the State/UT Government; and after further stating that due to COVID 19 outbreak the need for public use of ASU based immunity boosting products for healthy people and hand sanitizers has been significantly emphasized and their demand has increased manifold, it was directed,



inter-alia, that all the State AYUSH Licensing Authorities and Drug Controllers are to complete the licensing/approval/renewal process expeditiously.

4.7 It can also be seen that the Central Drugs Standard Control Organization, under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, (CDSCO in short), has, vide its letter dated 17.03.2020 issued in File No.DCGI/Misc/2020 (96), on the subject of "*Monitoring of the quality standards of hand sanitizer as per Drugs and Cosmetics Act, 1940 and Rules made thereunder and expediting the licensing of manufacturers of such products*", stated, among other things, that hand sanitizers are licensed under Drugs and Cosmetic Rules, 1945 and the standard of such products shall be as prescribed under the Second Schedule of the Drugs and Cosmetics Act, 1940 and rules made thereunder. The CDSCO has again, vide letter dated 18.03.2020 issued in File No.DCGI/Misc/2020 (96), addressed to all State and Union Territory Drug Controllers, directed that in view of present situation due to outbreak of COVID-19, and to meet the growing demand of hand sanitizer, all applications for grant of manufacturing license under the Drugs and Cosmetics Act, 1940 and rules made thereunder, for manufacturing of such products, are to be processed within three working days. Further it is pertinent to note that the Applicant is manufacturing hand sanitizers of various combinations under Form 25 licence. Form 25, is a licence issued in accordance with Rule 69 of the Drugs and Cosmetic Rules, 1945, consequent to the application preferred in Form 24 for the grant of licence to manufacture for sale or for distribution of drugs other than those specified in Schedule C, C (1) and X.

4.8 It can also be seen that the Central Government, by the Gazette Notification No.S.O.2451(E) published on 27th July 2020, has in exercise of the powers conferred under Section 26B of the Drugs and Cosmetics Act, 1940, directed, inter-alia, that the drug, namely, hand sanitizer shall be exempted from the requirement of sale licence for its stocking or sale under the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945.

4.9 The Applicant submits that the definition of "drug" given under the Drugs and Cosmetic Act, 1940 in Section 3(b)(i), stipulates inter alia that:

"drug" includes—

5(f) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;"(emphasis supplied)

4.10 The fact that such a broad classification of "drug" cannot be ignored while considering the character of the product in question has been laid down in the decision in **BPL Pharmaceuticals Ltd v. CCE, Vadodara, 2002-TIOL-63-SC-CX**. In the said decision, while deciding upon the classification of a product called "Selsun Shampoo", in para 29 the Supreme Court observed thus:

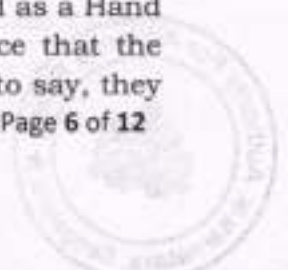


"29. We cannot ignore the above broad classification while considering the character of the product in question. Certainly, the product in question is not intended for cleansing, beautifying, promoting attractiveness or altering appearance. On the other hand it is intended to cure certain diseases as mentioned supra."

4.11 Thus, the letter F.No.Z 25023/09/2018-2020-DCC(AYUSH) dated 2nd April, 2020, issued by the Advisor (Ay.) and Head, Drugs Policy Section, of the Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH), on the subject of expediting the process for grant of approval/license/renewal of license for manufacturing of ASU immunity boosting healthcare products and sanitizers, addressed to all State/Union Territory Licensing Authorities and Drug Controllers of AYUSH as well as the Letter dated 17.03.2020 issued in File No.DCGI/Misc/2020 (96), by the Central Drugs Standard Control Organization, under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, on the subject of Monitoring of the quality standards of hand sanitizer as per Drugs and Cosmetics Act, 1940 and Rules made thereunder and expediting the licensing of manufacturers of such products, irrefutably establish not only that for the manufacturing of Ayurvedic, Siddha and Unani hand sanitizers as well as Allopathic hand sanitizers, licenses under the Drugs and Cosmetics Act, 1940 and under Drugs and Cosmetic Rules, 1945 are necessary but also that the Regulatory and Quality Control provisions are enforced by the State/Union Territory Licensing Authorities and Drug Controllers appointed by the State/UT Government. This contention of the Appellant is also bolstered by the exemption issued by the Central Government by the Gazette Notification No.S.O.2451(E) published on 27th July 2020, by which the Central Government, has categorically stated that the drug, hand sanitizer, shall be exempted from the requirement of sale licence for its stocking or sale under the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. Therefore it can indisputably be seen that hand sanitizers are understood and recognized by the Government of India as that which requires license to manufacture as drugs under the prevalent Drugs and Cosmetic Act, 1940 and the rules made thereunder, and but for the exemption issued under the Gazette Notification No.S.O.2451(E) published on 27th July 2020 as stated supra, would also have required a sale licence for its stocking or sale.

4.12 It is also a pertinent fact that Section Note 2 of Section VI of the Customs Tariff Act, 1975, stipulates that, "Subject to Note 1 above, **goods classifiable in heading 3004, 3005, 3006, 3212, 3303, 3304, 3305, 3306, 3307, 3506, 3707 or 3808 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 this Schedule.**" (*Emphasis supplied*).

4.13 Further, the certificates issued by a technical expert, Shri. V.L. Hambar, M. Pharm, former Deputy Drugs Controller, Drugs Control Department, Government of Karnataka certifying that Isopropyl rubbing Alcohol I.P is used as a Hand Sanitizer and that it has a number of uses such as, as a skin disinfectant, as natural bactericidal treatment, to kill fungus and viruses and to reduce skin infection risks and also certifying that Chlorhexidine Gluconate and Isopropyl Alcohol solution is used as a Hand Sanitizer and has antimicrobial activity; which are attached clearly evidence that the hand sanitizers perform a recognized function of being antimicrobial, that is to say, they



are intended to remove disease causing microorganisms and to prevent the onset of a disease.

4.14 Therefore, given that the subject products are understood in common parlance as Hand Sanitizers which perform a recognized function of being antimicrobial in that they are to be used to prevent the onset of diseases that are caused by viruses such as COVID-19 and other germs and bacteria, the trade also recognizes these Hand Sanitizers in commercial parlance as a product intended to remove disease causing microorganisms and to prevent the onset of a disease. Thus these Hand Sanitizers are nothing but a remedy in a specified formulation to remove disease causing bacteria or microorganisms **as also certified by the technical expert.**

4.15 The Applicant submits that a medicine, or a course of action to prevent disease, is termed Prophylactic. The fact that these Hand Sanitizers are considered by the Government of India to also qualify as Drugs which are to be manufactured under a license issued by the Drug Controller, would also underscore the fact that they are qualified to be termed as medicaments. Thus the Applicant is of the view that the Hand Sanitizers, which are being manufactured by the Applicant under the licence Form 25, would definitely qualify as a medicament for prophylactic use.

4.16 The Applicant's aforesaid view is also bolstered by the decision of the Apex Court in **CCE v. M/s. Wockhardt Life Sciences Ltd, 2012-TIOL-24-SC-CX**, wherein the meaning of the word prophylactic was noted by the Apex Court in para 16 thus:

"16. It is also relevant to explore the meaning of the word 'prophylactic' in medical parlance as well, in order to resolve the controversy before us. The word 'prophylactic' derives from Greek word 'prophylaktikos' which means 'to take precautions against' or 'to keep guard before'. Dorland's Medical Dictionary 1364 (28th ed. 1994) defines 'prophylactic' as 'an agent that tends to ward off disease'. Merriam-Webster's Medical Desk Dictionary 579 (1993) defines it as 'guarding from or preventing the spread or occurrence of disease or infection'; Mosby's Dictionary 1284 (4th ed. 1994) defines it as a biologic, chemical, or mechanical agent that prevents the spread of disease."

4.17 It is further pertinent to note that the Apex Court has, in its decision in **CCE, Calcutta v. Sharma Chemical Works, 2003-TIOL-33-SC-CX**, held that merely because a product is sold over the counter without prescription does not take away its status of being a medicament. In **Megdhoot Gram Udyog SewaSansthan v. CCE, Lucknow, 2004-TIOL-103-SC-CX**, it has been held that a product may be medicinal without having been prescribed by a medical practitioner.

4.18 The Apex Court in **M/s.O.K. Play (India) Ltd v CCE, Delhi III, Gurgaon, 2005-TIOL-18-SC-CX-LB**, has held that it is important to bear in mind that functional utility, design, shape and predominant usage have also got to be taken into account while determining the classification of an item.

4.19 In **Natural Health Products (P) Ltd v. CCE, Hyderabad, 2003-TIOL-19-SC-CX**, it has been held by the Apex Court that when there is no definition of any kind in



the relevant taxing statute, the articles enumerated in the tariff schedules must be construed as far as possible in their ordinary or popular sense, that is, how the common man and persons dealing with it understand it.

4.20 As discussed supra, the Hand Sanitizers, whether alcohol based or alcohol free, are recognized commercially as a preventive medicament or substance intended to remove disease causing microorganisms/bacteria and to prevent the onset of a disease. The Applicants are therefore of the view that the Hand Sanitizers being manufactured by the Applicant, would attract the description against tariff item 3004 90 87 which states "*Antibacterial formulations, not elsewhere specified or included*" specified in Chapter 30 of the Customs Tariff Act, 1985.

4.21 On the basis of the foregoing submissions, the Applicant submits that the Hand Sanitizers intended to be manufactured by the Applicant, would thus qualify to be termed as *Medicaments consisting of mixed products for prophylactic uses, in forms or packings for retail sale*", and are classifiable under tariff item 3004 90 87 specified in Chapter 30 of the Customs Tariff Act, 1975 and would therefore attract applicability of the notified rate of central tax of 6%, under tariff item 3004 at Sl.No.63 of Schedule II of the CGST Notification No. 1/2017 Central Tax (Rate) dated 28-06-2017 as amended and the corresponding notified rate of state tax of 6% under tariff item 3004 at Sl.No.63 of Schedule II of the relevant SGST Notification (01/2017) No. FD 48 CSL 2017, Bengaluru, dated 29.06.2017 as amended.

5. **PERSONAL HEARING: / PROCEEDINGS HELD ON 16.12.2020**

Sri. Ajayan T V, Advocate, Chartered Accountant & duly authorised representative of the applicant appeared for virtual personal hearing proceedings held on 16.12.2020 & reiterated the facts narrated in their application and furnished additional written submissions.

6. **FINDINGS & DISCUSSION**

6.1. At the outset we would like to make it clear that the provisions of CGST, Act 2017 and SGST, Act 2017 are in *parimateria* and have the same provisions in like matter and differ from each other only on a few specific provisions. Therefore, unless a mention is particularly made to such dissimilar provisions, a reference to the CGST Act would also mean reference to the corresponding similar provisions in the KGST Act.

6.2. We have considered the submissions made by the applicant in their application for advance ruling as well as the submissions made by Sri. Ajayan T.V, Authorized Representative during the virtual personal hearing. We also considered the issue involved, on which advance ruling is sought by the applicant, relevant facts & the applicant's interpretation of law.

6.3 On verification of the nature of the activity carried out by the applicant it was observed that the applicant is a private limited company manufacturing and selling different pharmaceutical formulations comprising of tablets, capsules, oral liquids and dry syrups in India and also exporting to various countries.



6.4 We find that the applicant has emphasized the licenses issued by the office of Drugs Controller for the state of Karnataka, letter dated 02.04.2020 issued by Ministry of AYUSH (directing licensing authorities to issue licenses expeditiously) , a letter dated 18.03.2020 of Central Drugs Standard Control Organisation (directing to dispose the licensing applications within 3 working days) and a notification dated 27.07.2020 which exempted hand sanitizers from the requirement of sale license for stocking or sale under the provisions of Chapter IV of the Drugs and Cosmetic Act, 1940 and the Drugs and Cosmetic Rules, 1945. We find that the above information is not relevant to decide the issue of classification of hand sanitizers as per discussion which follows.

6.5 For the purpose of classification of Hand Sanitizer for the purpose of GST and the applicable rate of GST, it is to be noted that hand sanitizers are used to disinfect the skin surfaces from microbes and viruses. Disinfectants are frequently used in hospitals, dental surgeries, kitchens, and bathrooms to kill infectious organisms. Drug is defined in Section 3 (b) of the Drugs and Cosmetic Act, 1940 as

"drug" includes—

[(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;]

[(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of 10[vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;]

[(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

[(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;

Thus, we find that drugs not only include medicines but also substances. So, obtaining a license for manufacturing of hand sanitizers, which is a disinfectant is actually a compliance of Drugs and Cosmetic Act, 1940. However, to decide the issue whether the disinfectant/ hand sanitizer should fall under HSN 3004 or 3808, we need to revert to HSN explanatory notes, case laws and common understanding of the product in the market.

6.6 The HSN Code 3808 94 00 clearly covers all disinfectants. When there is a specific entry covering disinfectants, the same needs to be classified under the same head. But the Chapter Note 1 to the Chapter 38 clearly states that this Chapter does not cover medicaments (Heading 3003 or 3004). Hence, it is be decided whether the



product in question is covered under HSN 3003 or 3004 or not. HSN 3004 reads as under:

"Medicaments (excluding goods of heading 3002, 3005 or 3006) 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 the forms of packings for retail sale, including Ayurvedic, Unani, Siddha, homoeopathic or bio-chemical systems medicaments, put up in retail sale".

6.7 It is clear from the above, for a goods to be covered under HSN 3004, the goods so supplied should be for "therapeutic use" or for "prophylactic use". It is seen that the agent would be called a therapeutic agent only if it has a curative effect against a disease. Since the product in question is not used for treatment of an already prevalent disease in a patient, the same cannot be said to have a therapeutic use.

6.8 Further, according to Oxford Dictionary, the term "prophylactic" has the following meaning: "Protecting against or tending to prevent a disease". The term prophylaxis has the meaning "Treatment intended to prevent disease". The good in question, no doubt is used as an alternative to soap, it cannot be said to have a prophylactic use in COVID Infection as the goods are not specific to COVID-19 infection. The same cannot be compared with Polio drops or covaxin, wherein the Polio drops have a prophylactic use in preventing Polio myelitis disease or covaxin helps in preventing COVID -19 infection. Such a thing cannot be said of the goods in question as it is not specific to any disease. Hence the goods in question cannot be covered under HSN 3004.

6.9. Further, as per explanatory notes to HSN of WCO, Heading 3004 is given as below:

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

(a) Put up in measured doses or in forms such as tablets, ampoules (for example, re-distilled water, in ampoules of 1.25 to 10 cm³, for use either for the direct treatment of certain diseases, e.g., alcoholism, diabetic coma or as a solvent for the preparation of injectible medicinal solutions), capsules, cachets, drops or pastilles, medicaments in the form of transdermal administration systems, or small quantities of powder, ready for taking as single doses for therapeutic or prophylactic use.

The heading also includes measured doses in the form of transdermal administration systems which are generally put up in the form of self-adhesive patches (usually rectangular or round) and which are applied directly to the skin of patients. The active substance is contained in a reservoir which is closed by a porous membrane on the side entering into contact with the skin. The active substance released from the reservoir is absorbed by passive molecular diffusion through the skin and passes directly into the bloodstream. These systems should not be confused with medical adhesive plasters of heading 30.05.

The heading applies to such single doses whether in bulk, in packings for retail sale, etc., or



(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.

From the above also, it is clear that sanitizers are not available as measured doses or in forms of tablets, ampoules etc. Therefore, it is not classifiable under Heading 3004.

6.10. HSN 3003 reads as under:

"Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic use, not put up in measured doses or in forms or packings for retail sale, including Ayurvedic, Unani, Siddha, homoeopathic or bio-chemical systems medicaments".

Even here, the same logic which is applicable to HSN 3004 applies here and it cannot be said to be for therapeutic or prophylactic use and hence cannot be included in HSN 3003.

6.11 Coming to the meaning of Disinfectants, Disinfectants are those goods used for disinfection. The disinfect has the meaning "to get rid of infection" or "cleanse by destroying infecting micro-organisms especially by chemical means. Disinfectant is any substances that is used to kill germs, such as viruses, bacteria, and other microorganisms that can cause infection and disease. Further as per the common parlance also, the Alcohol based hand sanitizers are never classified as Medicaments.

6.12 The applicant has taken support of the *CCE Calutta vs Sharma Chemical Works[2003 (154) ELT 328]* to state that mere fact of product being sold across the counters and not under Doctor's prescription, does not by itself lead to a conclusion that it is not a medicament. We have not adopted such a reasoning in this Ruling.

6.13 Further, we rely on the Supreme Court judgment in the case of *Ciens Laboratories, Mumbai* that the goods are classifiable are not therapeutic or prophylitic in nature . The Apex Court had ruled that if a product's primary function is care and not cure then its not a medicament. In the present case, sanitizers are primarily used as care rather than as cure for COVID-19.

6.14 The applicant has taken the support of the judgement of the Hon'ble Supreme Court in the case of *Wockhardt Life Sciences Ltd*, in support of his contention that the goods are classifiable under Heading 3004. The Apex Court relied upon common




parlance test to decide the issue. Similarly, the Hon'ble Supreme Court in the case of State of Goa and Another v. M/s Colfax Laboratories Ltd has clearly stated that the intention of the user should be given importance while classifying the product. Same findings are given by the Apex Court in the case of M/s. O.K.Play and Naturalle Health Products. The applicant is of the understanding that as per common parlance, hand sanitizers are bought as drugs. We do not accept this contention. We observe that, people buy hand sanitizers as an alternative to soap and for disinfecting purpose. In the present case, it is seen that the alcohol-based hand sanitizers, as the name itself suggests is to sanitize the hands and disinfect them and hence cannot be covered under Medicaments.

6.15 The goods covered under heading 3808 are covered entry no. 87 of Schedule III of Notification No.01/2017 – Central Tax (Rate) dated 28.06.2017 and are taxable at the rate of 9% under the CGST Act. Similarly, the goods are taxable at the rate of 9% under the KGST Act.

7. In view of the foregoing, we pass the following

RULING

Isopropyl rubbing alcohol IP and Chlorhexidine Gluconate & Isopropyl Alcohol solution merit classification under Chapter Heading 3808 & attract 18 % GST, in terms of entry no. 87 of Schedule III of Notification No.01/2017 – Central Tax (Rate) dated 28.06.2017


(Dr.M.P.Ravi Prasad)
Member

Karnataka Advance Ruling Authority
Place : Bengaluru - 560 009

Date : 26-02-2021

To,

The Applicant

Copy to :


The Principal Chief Commissioner of Central Tax, Bangalore Zone, Karnataka.

The Commissioner of Commercial Taxes, Karnataka, Bengaluru.

The Commissioner of Central Tax, Bangalore North West Commissionerate, Bengaluru.

The Asst. Commissioner, LGSTO-75, Bengaluru.

Office Folder.


(Mashhood Ur Rehman Farooqui)
Member

Karnataka Advance Ruling Authority
Bengaluru - 560 009

