

6th April 2023

The Chief Manager, Business Intelligence & Analysis

Kenya Revenue Authority

Times Towers

Nairobi, Kenya

Dear Sir,

REF: Objection to Proposed Classification of Mouthwash D

We refer to SAD, number xxxxxx. The declaration is for the importation of Mouthwash D. We have classified the product under subheading 3004.90.00, but the KRA officers at the release point have proposed classification under subheading 3306.90.00. We are writing to object to KRA's proposed classification as well as support our classification.

The structure of the objection is sectionalised as follows:

- 1) Analysis of the ingredients in the mouthwash and their purpose in the product
- 2) Illustration that chlorhexidine is a pharmacologically active ingredient from different public sources.
- 3) Illustration that chlorhexidine is considered an essential medicine by several Health authorities.
- 4) Types of Mouthwashes, illustration of differences from public sources
- 5) Analysis of the relevant Legal Notes and Text, that support our Classification.
- 6) Analysis of WCO Rulings
- 7) Conclusion

Our commentary on each section is highlighted in blue.

Description and properties of the Ingredients in Mouthwash D

The ingredients of the product are chlorhexidine gluconate, 0.12m/v, sorbitol solution 9% v/v, aniseed flavour, polyoxyl 40 hydrogenated castor oil, peppermint oil, purified water, quinoline yellow colour, sunset yellow colour.

Chlorhexidine is a broad-spectrum antimicrobial biguanide used as a topical antiseptic and in dental practice for the treatment of inflammatory dental conditions caused by microorganisms. It is one of the most common skin and mucous membrane antiseptic agents in use today. The molecule itself is a cationic bis-guanide consisting of two 4-chlorophenyl rings and two biguanide groups joined by a central hexamethylene chain. Topical chlorhexidine for disinfection, as well as oral rinses for dental use, carries activity against a broad range of pathogens including bacteria, yeasts, and viruses.

Sorbitol, less commonly known as glucitol, is a sugar alcohol with a sweet taste which the human body metabolizes slowly.

Aniseed has a licorice flavour that is sweet, mildly spicy, and very aromatic. This flavour is produced by anethole, an organic compound related to estragole, which produces flavours in tarragon and basil. One key characteristic of anethole is that it is very soluble in alcohol but only slightly soluble in water.

Polyoxyl castor oil and polyoxyl hydrogenated castor oil are non-ionic surfactants, which are used as emulsifying and solubilising agents in pharmaceutical preparations and cosmetics.

Peppermint oil is commonly used as flavouring in foods and beverages and as a fragrance in soaps and cosmetics.

Purified water is intended for use in formulation of medicines that are not intended to be sterile and apyrogenic. Purified water is widely used for oral and topical products and in granulation processes for tablets and capsules.

Quinoline yellow can be used to colour cosmetics, drugs, and food, including dietary supplements, sauces, soups and broths, bakery, dairy fats and oil, seafood, seasonings, breath fresheners, desserts, and convenient foods, and beverages.

Sunset yellow can be used to provide an orange colour to foods, drugs, and cosmetics, including dietary supplements,

The analysis above shows that the only active ingredient in the Mouthwash D is chlorhexidine gluconate. It is used as a topical antiseptic and in dental practice for the treatment of inflammatory dental conditions caused by microorganisms.

In depth analysis of chlorhexidine gluconate(Major Component of the Mouthwash D) **The descriptions 1,2,3 are to illustrate the pharmacological activity of chlorhexidine**

Description 1 (Uses of chlorhexidine)

Chlorhexidine (commonly known by the salt forms chlorhexidine gluconate and chlorhexidine Di gluconate (CHG) or chlorhexidine acetate) is a disinfectant and antiseptic with the molecular formula $C_{22}H_{30}Cl_2N_{10}$, which is used for skin disinfection before surgery and to sterilize surgical instruments. It may be used both to disinfect the skin of the patient and the hands of the healthcare providers. It is also used for cleaning wounds, preventing dental plaque, treating yeast infections of the mouth, and to keep urinary catheters from blocking. It is used as a liquid or powder.

Side effects may include skin irritation, teeth discoloration, and allergic reactions, although the risk appears to be the same as other topical antiseptics. It may cause eye problems if direct contact occurs. Use in pregnancy appears to be safe. Chlorhexidine may come mixed in alcohol, water, or surfactant solution. It is effective against a range of microorganisms but does not inactivate spores.

Chlorhexidine came into medical use in the 1950s. Chlorhexidine is available over the counter in the United States. It is on the World Health Organization's List of Essential Medicines. In 2020, it was the 273rd most commonly prescribed medication in the United States, with more than 1 million prescriptions.

Uses

Chlorhexidine is used in disinfectants (disinfection of the skin and hands), cosmetics (additive to creams, toothpaste, deodorants, and antiperspirants), and pharmaceutical products (preservative in eye drops, active substance in wound dressings and antiseptic mouthwashes).

In endodontics, chlorhexidine has been used for root canal irrigation and as an intracanal dressing but has been replaced by the use of sodium hypochlorite bleach in much of the developed world.

Antiseptic

CHG is active against Gram-positive and Gram-negative organisms, facultative anaerobes, aerobes, and yeasts. It is particularly effective against Gram-positive bacteria (in concentrations $\geq 1 \mu\text{g/L}$). Some medical tests report results in micrograms per litre (mcg/L). A microgram is one-millionth of a gram. Significantly higher concentrations (10 to more than $73 \mu\text{g/mL}$) are required for Gram-negative bacteria and fungi. Chlorhexidine is ineffective against polioviruses and adenoviruses. The effectiveness against herpes viruses has not yet been established unequivocally.

There is strong evidence that chlorhexidine is more effective than povidone-iodine for clean surgery. Evidence shows that it is the most effective antiseptic for upper limb surgery, and there is no data to suggest that alcoholic chlorhexidine increases the risk of tourniquet-related burns, ignition fires or allergic episodes during surgery.

Meta-data spanning several decades shows that the efficacy of chlorhexidine (against organisms that cause surgical site infection) has not changed, dispelling concerns over emerging resistance.

Chlorhexidine, like other cation-active compounds, remains on the skin. It is frequently combined with alcohols (ethanol and isopropyl alcohol).

Note that Chlorhexidine is a cationic surfactant. This is important because it influences the classification.

Dental use

Use of a CHG-based mouthwash in combination with normal tooth care can help reduce the build-up of plaque and improve mild gingivitis. About 20 mL twice a day of concentrations of 0.1% to 0.2% is recommended for mouth-rinse solutions with a duration of at least 30 seconds. Such mouthwash also has a number of adverse effects including damage to the mouth lining, tooth discoloration, tartar build-up, and impaired taste. Extrinsic tooth staining occurs when chlorhexidine rinse has been used for 4 weeks or longer.

Mouthwashes containing chlorhexidine which stain teeth less than the classic solution have been developed, many of which contain chelated zinc.

Using chlorhexidine as a supplement to everyday mechanical oral hygiene procedures for 4 to 6 weeks and 6 months leads to a moderate reduction in gingivitis compared to placebo, control or mechanical oral hygiene alone.

Chlorhexidine is a cation which interacts with anionic components of toothpaste, such as sodium lauryl sulfate and sodium monofluorophosphate, and forms salts of low solubility and reduced antibacterial activity. Hence, to enhance the antiplaque effect of chlorhexidine, "it seems best that the interval between toothbrushing and rinsing with CHX [chlorhexidine] be more than 30 minutes, cautiously close to 2 hours after brushing".

Topical

Chlorhexidine gluconate is used as a skin cleanser for surgical scrubs, as a cleanser for skin wounds, for preoperative skin preparation, and for germicidal hand rinses. Chlorhexidine eye drops have been used as a treatment for eyes affected by *Acanthamoeba* keratitis.

Chlorhexidine is very effective for poor countries like Nepal and its use is growing in the world for treating the umbilical cord. A 2015 Cochrane review has yielded high-quality evidence that within the community setting, chlorhexidine skin or cord care can reduce the incidence of omphalitis (inflammation of the umbilical cord) by 50% and neonatal mortality by 12%.

In the U.S., between 2007 and 2009, Hunter Holmes McGuire Veterans Administration Medical Centre conducted a cluster-randomized trial and concluded that daily bathing of patients in intensive care units with washcloths saturated with chlorhexidine gluconate reduced the risk of hospital-acquired infections.

Mechanism of action

At physiologic pH, chlorhexidine salts dissociate and release the positively charged chlorhexidine cation. The bactericidal effect is a result of the binding of this cationic molecule to negatively charged bacterial cell walls. At low concentrations of chlorhexidine, this results in a bacteriostatic effect, at high concentrations, membrane disruption results in cell death.

Chemistry

It is a cationic polybiguanide (bisbiguanide). It is used primarily as its salts (e.g., the dihydrochloride, diacetate, and digluconate).

Veterinary medicine

In animals, chlorhexidine is used for topical disinfection of wounds, and to manage skin infections. Chlorhexidine-based disinfectant products are used in the dairy farming industry.

Description 2(Uses of Chlorhexidine)

Chlorhexidine (CHX) is one of the most commonly prescribed antiseptic agents in the dental field. It has a long-lasting antibacterial activity with a broad-spectrum of action and it has been shown to reduce plaque, gingival inflammation, and bleeding. Its use is considered a powerful adjuvant to mechanical oral hygiene (brushing and flossing), especially in those cases in which it cannot be performed correctly. Available as mouthwash, gel, aerosol, spray, and disks, CHX is considered a safe compound, with minimal and transitory local and systemic side effects. Data support its periodic use as an adjuvant to normal brushing and flossing in subjects unable to maintain proper oral hygiene due to physical and/or mental impairment, or lack of motivation, or decreased salivary rate. CHX is also a useful alternative to mechanical oral

hygiene procedures in those cases in which they are contraindicated, e.g., after a surgical procedure, or as a preoperative rinse before procedures in which use of a dental dam is not possible.

Description 3(Uses of Chlorhexidine)

Chlorhexidine gluconate is mainly available in over the over-the-counter products to clean and prepare the skin before surgery and before injections in order to help reduce bacteria that potentially can cause skin infections. These products are available as solutions, washes, sponges, and swabs and under many different brand names and as generics. Chlorhexidine gluconate is also available as a prescription mouthwash to treat gingivitis and as a prescription oral chip to treat periodontal disease.

Prescription chlorhexidine gluconate mouthwashes and oral chips used for gum disease already contain a warning about the possibility of serious allergic reactions in their labels.

In 1998, FDA issued a Public Health Notice to warn health care professionals about the risk of serious allergic reactions with medical devices such as dressings and intravenous lines that contain chlorhexidine gluconate.

The descriptions 1,2,3 above, all indicate that the active ingredient in Mouthwash D, chlorhexidine is used for therapeutic purposes.

WCO/WHO HS Classification of Chlorhexidine

Google Search Terms: WCO Chlorhexidine

The Link is:

https://www.wcoomd.org/-/media/wco/public/global/pdf/topics/nomenclature/covid_19/prioritization-medicines-list-during-covid_19-v9_wco_en.pdf?la=en

Antiemetic	metoclopramide (14)(6)	2924.29; 3004.90*	17.2 Antiemetic medicines
	ondansetron (62)(29)	2933.29; 3004.90*	17.2 Antiemetic medicines
Antiseptic	chlorhexidine (6)(3)	2925.29; 3004.90*	15.1 Antiseptics
	alcohol-based hand rub	3808.94	15.1 Antiseptics
	povidone (74)(36)-iodine	3905.99; 3004.90*	15.1 Antiseptics
Bronchodilators	salbutamol (20)(9)	2922.50; 3004.90*	25.1 Antiasthmatic and medicines for chronic obstructive pulmonary disease
	ipratropium bromide (31)(14)	2939.79; 3004.49*	25.1 Antiasthmatic and medicines for chronic obstructive pulmonary disease
Cough suppressants	Codeine	2939.11; 3004.49*	2.2 Opioid analgesics

WHO Essential Medicines listing

Google Search Terms: who list of essential medicines pdf

The Link is:

<https://apps.who.int/iris/rest/bitstreams/1237479/retrieve>

15. DISINFECTANTS AND ANTISEPTICS	
15.1 Antiseptics	
<input type="checkbox"/> chlorhexidine	Solution: 5% (digluconate).
<input type="checkbox"/> ethanol	Solution: 70% (denatured).
<input type="checkbox"/> povidone iodine	Solution: 10% (equivalent to 1% available iodine).

WHO Model List of Essential Medicines

21st edition

chlorhexidine [c]	Solution or gel: 7.1% (digluconate) delivering 4% chlorhexidine (for umbilical cord care).
Complementary List	
<input type="checkbox"/> ibuprofen [c]	Solution for injection: 5 mg/ mL.
<input type="checkbox"/> prostaglandin E [c]	Solution for injection: <i>Prostaglandin E1:</i> 0.5 mg/ mL in alcohol. <i>Prostaglandin E 2:</i> 1 mg/ mL.
surfactant [c]	Suspension for intratracheal instillation: 25 mg/ mL or 80 mg/ mL.

Ministry of Health Kenya, Essential Medicines listing

Google Search Terms: Moh kenya list of essential medicines pdf

The Link is:

<https://www.health.go.ke/wp-content/uploads/2020/07/Kenya-Essential-Medicines-List-2019.pdf>

17. DISINFECTANTS and ANTISEPTICS				
17.1 Antiseptics				
17.1.1	Chlorhexidine	Solution for dilution	5% (as gluconate/digluconate)	2
17.1.2	Ethanol	Solution	70% (denatured)	2
17.1.3	Povidone iodine	Solution	10% (equiv. to Iodine 1%)	2

#	Item Added	Indication/Notes
27.3.1	Chlorhexidine solution (mouthwash) 0.2% (as gluconate/digluconate)	New section. Medicines for the Throat and Mouth. For supportive care for immunocompromised patients (e.g. with cancer)

U.S. Food and Drug Administration Approval of Chlorhexidine as a Medicament

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/21669s000TOC.cfm



NDA 21-669

Sage Products, Inc.
Attention: Ajay Chawla
Product Development Compliance Manager
3909 Three Oaks Road
Cary, Illinois 60013

Dear Mr. Chawla:

Please refer to your new drug application (NDA) dated August 29, 2003, received September 4, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for 2% Chlorhexidine Gluconate* Cloth *(equivalent to 500 mg chlorhexidine gluconate per cloth).

We acknowledge receipt of your submission(s) dated October 21, and December 10, 2004; and February 25, April 4, 6, and 20, 2005.

The October 21, 2004 submission, received October 25, 2004, constituted a complete response to our July 1, 2004 action letter.

This new drug application provides for the use of 2% Chlorhexidine Gluconate* Cloth, *(equivalent to 500 mg chlorhexidine gluconate per cloth) as a patient preoperative skin preparation.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the labeling (immediate container label and outer container and carton labels) submitted April 20, 2005, and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "FPL for approved NDA 21-669." Approval of this submission by FDA is not required before the labeling is used.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

The active ingredient in Mouthwash d, chlorhexidine is categorised as an essential medicine by the following Public Health Authorities (1) World Customs Organisation by classifying it under subheading 3004.90 (2) World Health Organisation (3) Ministry of Health Kenya (4) US Food and Drug Administration.

Types of Mouthwash/Rinse by the American Dental Association

The Link is:

<https://www.ada.org/resources/research/science-and-research-institute/oral-health-topics/mouthrinse-mouthwash>

Broadly speaking, there are two types of mouth rinse: cosmetic and therapeutic. Cosmetic mouth rinses may temporarily control bad breath and leave behind a pleasant taste but have no chemical or biological application beyond their temporary benefit. For example, if a product doesn't kill bacteria associated with bad breath, then its benefit is considered to be solely cosmetic. Therapeutic mouth rinses, by contrast, have active ingredients intended to help control or reduce conditions like bad breath, gingivitis, plaque, and tooth decay.

Active ingredients that may be used in therapeutic mouth rinse include:

- ✓ cetylpyridinium chloride.
- ✓ chlorhexidine.
- ✓ essential oils.
- ✓ fluoride.
- ✓ peroxide.

Cetylpyridinium chloride may be added to reduce bad breath. Both chlorhexidine and essential oils can be used to help control plaque and gingivitis. Fluoride is a proven agent in helping to prevent decay.

Peroxide is present in several whitening mouth rinses. Therapeutic mouth rinse is available both over the counter and by prescription, depending on the formulation. For example, mouth rinses containing essential oils are available in stores, while those containing chlorhexidine are available only by prescription.

Clinical Considerations

Some of the conditions mouth rinses are designed to address are discussed in the following sections.

Alveolar Osteitis (Dry Socket)

Alveolar osteitis (AO), also known as dry socket, is a common postoperative condition following dental extraction procedures, particularly those of the third molar. AO occurs when the fibrin clots that normally form following extraction is dislodged. AO usually results in intense pain in and around the extraction site 2 to 3 days after the procedure. A recent systematic review and meta-analysis of 18 trials has shown chlorhexidine, without the use of antibiotics, to be effective for lowering the risk of AO following third molar extractions. A moderate, but statistically not significant, increase in efficacy was seen in the gel formulation compared with the rinse formulation; however, the review could not recommend a specific dosing regimen. Studies included in the review reported minor, nonclinical reactions to chlorhexidine, including staining of teeth, dentures, and tongue, and altered taste.

Oral Malodour (Bad Breath)

Volatile sulphur compounds (VSCs) are the major contributing factor to oral malodour or bad breath. They arise from a variety of sources (e.g., breakdown of food, dental plaque and bacteria associated with oral disease). Cosmetic mouth rinses can temporarily mask bad breath and provide a pleasing flavour, but do not have an effect on bacteria or VSCs. Mouth rinses with therapeutic agents like antimicrobials, however, may be effective for more long-term control of bad breath. Antimicrobials in mouth rinse formulations include chlorhexidine, chlorine dioxide, cetylpyridinium chloride, and essential oils (e.g., eucalyptol, menthol, thymol, and methyl salicylate). Other agents used in mouth rinses to inhibit odour-causing compounds include zinc salts, ketone, terpene, and ionone. Although the combination of chlorhexidine and cetylpyridinium chloride plus zinc lactate has been shown to significantly reduce bad breath, it also may significantly contribute to tooth staining.

Plaque and Gingivitis

When used in mouth rinses, antimicrobial ingredients like cetylpyridinium chloride, chlorhexidine, and essential oils have been shown to help reduce plaque and gingivitis when combined with daily brushing and flossing. While some studies have found that chlorhexidine achieved better plaque control than essential oils, no difference was observed with respect to gingivitis control. Cetylpyridinium chloride and chlorhexidine may cause brown staining of teeth, tongue, and/or restorations.

Preprocedural Mouth Rinse

Some dental equipment and procedures, including ultrasonic scalers, air polishing, air-water syringe and tooth polishing with air turbine handpieces or air abrasion, generate aerosols, a mix of liquid and solid particles. Aerosols can remain airborne for up to four hours before settling on surrounding surfaces. In addition to settling on environmental surfaces, aerosols containing microorganisms can be inhaled by dental care providers, posing a risk for disease transmission.¹¹ Respiratory diseases associated with aerosols include influenza, and tuberculosis, as well as COVID-19 SARS-CoV-2.¹¹⁰

Research suggests that having a patient use a mouth rinse prior to treatment may reduce the number of aerosolized microorganisms. However, there is no evidence that preprocedural mouth rinse protects against clinical disease among dental staff.

Bactericidal effect of preprocedural mouth rinses. The evidence suggests that preprocedural mouth rinse is effective at reducing bacterial contamination in dental aerosols. Certain antimicrobial rinse solutions used from 30 seconds to 2 minutes versus water or no rinse effectively reduced aerosol contamination produced during periodontal prophylaxis. For example, chlorhexidine (either 0.12 or 0.2%) is an effective antimicrobial solution for this purpose. One drawback, however, is that chlorhexidine can cause tooth staining, supragingival calculus formation, and a change in taste sensation. Researchers also, though, have found comparable performance between chlorhexidine and cetylpyridinium chloride as a preprocedural rinse in reducing bacterial load in aerosols.

Virucidal effect of preprocedural mouth rinses. Although little clinical data have been collected, one small study found that preprocedural rinses, including normal saline, reduced SARS-CoV-2 viral load in saliva.

One review of four in vitro studies, however, found that a preprocedural rinse with chlorhexidine was effective at reducing viral load. Essential oils also were shown to have antiviral properties against enveloped viruses.

Types of Mouthwash/Rinse by the Listerine

The Link is:

<https://www.listerine-me.com/mouth-coach/types-of-mouthwash-and-their-uses>

TYPES OF MOUTHWASH & THEIR USES

A dental care routine that includes brushing only does not eliminate all germs that can accumulate on the surface of the teeth, gums and other non-dental surfaces and therefore will not guarantee giving your mouth the required hygiene. Food debris can also get stuck between the teeth and cause many problems and would not be removed by a brush.

You need to follow a routine of daily cleaning of three steps to maintain the health of your teeth and avoid problems and diseases that can affect the gums and teeth such as gingivitis, plaque and other problems that cause weak teeth and bad breath. The three steps a proper daily routine consists of are: brushing, flossing, and mouth washing.

You might know that not all types of mouthwash are the same, there are many types of mouthwash that can have different effects according to the active ingredients they contain. This article will walk you through the types of mouthwash available, their benefits and their uses, so you can choose the one that suits you the best.

Uses of Mouthwash

Some types of mouthwash are used to help eliminate issues that affect the mouth and teeth such as reducing plaque, gingivitis, tooth decay and bad breath. These types of mouthwash are considered to be therapeutic, and they help solve these problems with the active ingredients they contain. While other mouthwashes are made to merely give you fresh breath without having any anti-bacterial or properties.

Most therapeutic mouthwashes can be obtained without a prescription, but some require a prescription according to the ingredients they contain.

Active ingredients used in mouthwashes.

There are many active ingredients used in various types of mouthwash, each with its own effects and benefits. They include:

- ✓ Cetylpyridinium chloride: It is added to mouthwash to reduce bad breath.
- ✓ Chlorhexidine: It can be used to help control plaque and gingivitis and generally can't be bought without a prescription.
- ✓ Essential oils: Helps control plaque and gingivitis.
- ✓ Fluoride: It is used to help prevent tooth decay
- ✓ Peroxide: Helps teeth whitening
- ✓ Sodium Fluoride: used for preventing tooth decay and helping decrease teeth sensitivity.
- ✓ Eucalyptus: help prevent plaque and gingivitis
- ✓ Hydrogen peroxide: used for teeth whitening and is highly effective in penetrating the hard tissues of the teeth.

Types of mouthwash

There are various types of mouthwash available in the market that can be considered cosmetic or therapeutic according to their ingredients. A mouthwash may be considered cosmetic if it does not contain germ-killing ingredients.

Cosmetic mouthwash:

As the name indicates, cosmetic mouthwashes aim to temporarily control the smell of the breath and leave a pleasant taste in the mouth without eliminating germs, as a mouthwash with germ-killing ingredients can do. Therefore, their refreshing effect does not last for an extended period.

Fluoride Mouthwash

Fluoride mouthwash helps rebuild weakened tooth enamel in a process called remineralization, making teeth more resistant to decay and tooth erosion. When you use fluoride mouthwash, you help reverse the early signs of tooth decay and keep your teeth healthy.

Fluoride can be obtained from many natural sources such as some foods and most water sources such as rivers, lakes, and wells, but the concentration of fluoride in these sources is less than the level you need to provide the necessary protection for your teeth. Using a fluoride mouthwash such as Listerine® Fluoride Defence ensures that you get the necessary amount of fluoride to help prevent cavities. It contains added fluoride, essential oils, and green tea extract which strengthens the enamel of the teeth and helps prevent tooth decay.

Antiseptic mouthwash

Antiseptic mouthwash helps eliminate the bacteria that cause bad breath because it contains bacteria-killing substances. Eucalyptus oil is an effective antibacterial agent that is used in some Antiseptic mouthwash products to help kill bacteria and fight against plaque. It is extracted from the eucalyptus tree (*Eucalyptus globulus*) which has been long used as an antiseptic to kill germs by traditional aboriginal of Australia, the native home of the eucalyptus tree.⁶ Try using Listerine® Cool Mint Mouthwash antiseptic mouthwash that helps fight plaque effectively and provides fresh breath protection.

Natural mouthwash

For people who prefer using non-alcoholic products for whatever reason, a natural mouthwash is the choice for you! Natural mouthwashes offer the same benefits as other mouthwashes, except that they are gentle with a milder taste and are alcohol-free.

Whitening mouthwash

Dental care has become more than dental and oral health, as having bright white teeth and an attractive smile is a must have too. People have become greatly keen on getting dental care products that have whitening properties. A whitening mouthwash can be the perfect complement to your home teeth whitening program that helps remove stains and brighten dull teeth.

Protecting your teeth and keeping them healthy and free of cavities requires constant care. Using a proper mouthwash effective in killing germs and microbes that survive after brushing makes your efforts more effective and helps you keep your mouth fresh for longer.

Summary of Observations from the Description

1. Chlorhexidine is recognised worldwide as a pharmacologically active agent.
2. The WCO, WHO, Ministry of Health Kenya recognise it as an essential Medicine.
3. There are two types of Mouthwashes, a) Cosmetic b) Therapeutic. Those with pharmacologically active ingredients are to be classified under heading 3004, those for cosmetic purpose, are to be classified under heading 3306.
4. Chlorhexidine has a wide variety of antiseptic and therapeutic purposes (listed above in detail)
5. Chlorhexidine is a cationic solution which can be used during treatment.
6. The WCO indicates that products containing chlorhexidine are to be classified under subheading 3004.90.

Analysis of Legal Notes and Text Relevant to the HS Classification of Mouthwash D

The structure of the analysis consists of extracts from the relevant legal notes, followed by our analysis, highlighted in blue.

Section VI Explanatory Notes

PRODUCTS OF THE CHEMICAL OR ALLIED INDUSTRIES

2.- Subject to Note 1 above, goods classifiable in heading 30.04, 30.05, 30.06, 32.12, 33.03, 33.04, 33.05, 33.06, 33.07, 35.06, 37.07 or 38.08 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 the Nomenclature.

GENERAL

Note 2.

Section Note 2 provides that goods (other than those described in heading 28.43 to 28.46 or 28.52) which are covered by heading 30.04, 30.05, 30.06, 32.12, 33.03, 33.04, 33.05, 33.06, 33.07, 35.06, 37.07 or 38.08 by reason of being put up in measured doses or for retail sale, are to be classified in those headings notwithstanding that they could also fall in some other heading of the Nomenclature. For example, sulphur put up for retail sale for therapeutic purposes is classified in heading 30.04 and not in heading 25.03 or 28.02, and dextrin put up for retail sale as a glue is classified in heading 35.06 and not in heading 35.05.

The product Mouthwash D is for therapeutic purpose. The therapeutic property is provided by chlorhexidine which is a pharmacological active ingredient. WCO, WHO, MOH Kenya have all indicated that it is an essential medicine. WCO has told us that chlorhexidine is to be classified under subheading 3004.90,

therefore the instant product cannot then be classified under subheading 3306 due to the instructions by Section VI Note 2

Chapter 29 Explanatory Notes

(2) Certain other separate chemically defined organic products, which would otherwise have been classified in Chapter 29, may be excluded when put up in certain forms, or if they have been subjected to certain treatments which leave their chemical composition unchanged. Examples are :

(a) Products for therapeutic or prophylactic uses, put up in measured doses or in forms or in packings for retail sale (heading 30.04).

(d) Perfumery, cosmetic or toilet preparations (e.g., acetone), put up in packings for retail sale for such use (headings 33.03 to 33.07).

Chlorhexidine is classifiable under subheading 2925.90 as per the WCO as a chemically defined organic product. The product in the current scenario has undergone treatment by combination with other products for therapeutic uses. Therefore, as per chapter 29 Note 2(a) above, the resultant product is to be classified under heading 3004.

Chapter 30 Explanatory Notes

Pharmaceutical products

1.- This Chapter does not cover :

(e) Preparations of headings 33.03 to 33.07, even if they have therapeutic or prophylactic properties.

3.- For the purposes of headings 30.03 and 30.04 and of Note 4 (d) to this Chapter, the following are to be treated :

(a) As unmixed products :

(1) Unmixed products dissolved in water.

(2) All goods of Chapter 28 or 29; and

(3) Simple vegetable extracts of heading 13.02, merely standardised or dissolved in any solvent.

(b) As products which have been mixed :

(1) Colloidal solutions and suspensions (other than colloidal sulphur).

(2) Vegetable extracts obtained by the treatment of mixtures of vegetable materials; and

(3) Salts and concentrates obtained by evaporating natural mineral waters.

Chapter 30, Note 1(e) refers to products of headings 33.03 to 33.07 which have only subsidiary therapeutic properties as will be illustrated by the WCO rulings for subheading 3306.90. In the instant case the presence of chlorhexidine in the product eliminates the subsidiary nature for classification in heading 3306. We have illustrated the uses of chlorhexidine and types of mouthwashes in the writeups above. Those that have recognised active ingredients are to be classified under 3004, while those for cosmetic purposes are to be classified under heading 3306.

Heading 30.04 Explanatory Notes

30.04 - 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.

3004.10 - Containing penicillins or derivatives thereof, with a penicillanic acid structure, or streptomycin's or their derivatives

3004.20 - Other, containing antibiotics

- Other, containing hormones or other products of heading 29.37 :

3004.31 - - Containing insulin

3004.32 - - Containing corticosteroid hormones, their derivatives, or structural analogues

3004.39 - - Other

- Other, containing alkaloids or derivatives thereof :

3004.41 - - Containing ephedrine or its salts

3004.42 - - Containing pseudoephedrine (INN) or its salts

3004.43 - - Containing norephedrine or its salts

3004.49 - - Other

3004.50 - Other, containing vitamins or other products of heading 29.36

3004.60 - Other, containing antimalarial active principles described in Subheading Note 2 to this Chapter

3004.90 - Other

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 injectable 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 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.

On the other hand, even if no indications are given, unmixed products are to be regarded as being put up for retail sale for therapeutic or prophylactic use if they are put up in a form clearly specialised for such use. Medicaments consisting of mixed products for therapeutic or prophylactic uses and not put up in measured doses or in forms or packings for retail sale are classified in heading 30.03 (see the corresponding Explanatory Note).

Under the terms of Chapter Note 3, the following are also regarded as unmixed products :

(1) Unmixed products dissolved in water.

(2) All goods of Chapter 28 or 29. Such products include colloidal sulphur and stabilised solutions of hydrogen peroxide.

This heading includes pastilles, tablets, drops, etc., of a kind suitable only for medicinal purposes, such as those based on sulphur, charcoal, sodium tetraborate, sodium benzoate, potassium chlorate or magnesia.

However, preparations put up as throat pastilles or cough drops, consisting essentially of sugars (whether or not with other foodstuffs such as gelatin, starch or flour) and flavouring agents (including substances having medicinal properties, such as benzyl alcohol, menthol, eucalyptol and tolu balsam) fall in heading 17.04. Throat pastilles or cough drops containing substances having medicinal properties, other than flavouring agents, remain classified in this heading when put up in measured doses or in forms or packings for retail sale, provided that the proportion of those substances in each pastille or drop is such that they are thereby given therapeutic or prophylactic uses.

The heading also covers the following products, provided they are put up as prescribed in paragraph (a) or (b) above :

(1) Organic surface-active products and preparations, with active cation (e.g., quaternary ammonium salts), having antiseptic, disinfectant, bactericidal or germicidal properties.

The heading also excludes :

(c) Aqueous distillates or aqueous solutions of essential oils and preparations of headings 33.03 to 33.07, even if they have therapeutic or prophylactic properties (Chapter 33).

1)The product is packaged for retail sale at volumes of 100ml/200ml therefore requirement (a) of heading 30.04 is satisfied.

2)The requirements of heading 30.04 (b) is satisfied by the specific indications of the use, "antiseptic to kill or inhibit the growth of bacteria, viruses, and fungi". The daily dosage is indicated.

Description

Mouthwash D, 200ml kills and inhibits the growth of bacteria, viruses and fungi, protecting teeth from plaque build-up and preventing gum disease.

Mouthwash D is used for Gingivitis, Pain and inflammation of mouth and throat, Skin cleansing, Dental plaque and bacteria, Keratitis, Infection before any surgical procedure and other conditions.

How to use

Adults 15 ml for 30 seconds, every 1.5 – 3 hours

Children 5 – 15 ml, every 3 hours

3) Chlorhexidine is a cationic surfactant. Heading 30.04 explanatory notes indicates that surface active products and preparations with antiseptic, disinfectant, bactericidal or germicidal properties are to be classified under heading 30.04. Chlorhexidine has all those properties. It follows that the instant product will be classified in heading 30.04.

4) Note that as per the heading 30.04 explanatory notes, products of chapter 29 are to be regarded as unmixed. Chlorhexidine is a product of chapter 29. Therefore, it satisfies the conditions of Terms of Heading 30.04

5) Note that the chlorhexidine imparts the essential character to the product in question, its pharmacological activity is not subsidiary. Therefore, by deduction from the examples provided in heading 30.04 explanatory Notes the Mouthwash D will be classified under heading 30.04.

6) The following statement in heading 30.04 explanatory notes is important in the determination of the classification of products which might be classifiable in two headings:

“However, preparations put up as throat pastilles or cough drops, consisting essentially of sugars (whether or not with other foodstuffs such as gelatin, starch or flour) and flavouring agents (including substances having medicinal properties, such as benzyl alcohol, menthol, eucalyptol and tolu balsam) fall in heading 17.04. Throat pastilles or cough drops containing substances having medicinal properties, other than flavouring agents, remain classified in this heading when put up in measured doses or in forms or packings for retail sale, provided that the proportion of those substances in each pastille or drop is such that they are thereby given therapeutic or prophylactic uses.”

Implication of this statement: If the product under consideration has recognised pharmacologically active ingredients, in proportions which have a therapeutic or prophylactic uses, then the product remains classified in heading 30.04. This statement clarifies between mouthwashes classifiable under heading 30.04 and those of 33.06. The instant product, Mouthwash D has significant medicinal properties as we have demonstrated in the preceding sections and is therefore classified under 30.04.

Chapter 33 Explanatory Notes

Essential oils and resinoids; perfumery, cosmetic or toilet preparations
Notes.

1.- This Chapter does not cover :

. b) Medicinal preparations having a subsidiary use as perfumery, cosmetic or toilet preparations (heading 30.03 or 30.04).

3.- Headings 33.03 to 33.07 apply, inter alia, to products, whether or not mixed (other than aqueous distillates and aqueous solutions of essential oils), suitable for use as goods of these headings and put up in packings of a kind sold by retail for such use.

GENERAL

Headings 33.03 to 33.07 include products, whether or not mixed (other than aqueous distillates and aqueous solutions of essential oils), suitable for use as goods of these headings and put up in packings of a kind sold by retail for such use (see Note 3 to this Chapter).

The products of headings 33.03 to 33.07 remain in these headings whether or not they contain subsidiary pharmaceutical or disinfectant constituents or are held out as having subsidiary therapeutic or prophylactic value (see Note 1 (e) to Chapter 30). However, prepared room deodorisers remain classified in heading 33.07 even if they have disinfectant properties of more than a subsidiary nature.

This Chapter does not cover :

(b) Medicinal preparations having a subsidiary use as perfumery, cosmetic or toilet preparations (heading 30.03 or 30.04).

1) Detailed explanatory notes to chapter 33 make it clear that products with essential character imparted by substances with pharmacological properties are not to be classified in this chapter. That is, if the active ingredient in a substance is of more than a subsidiary nature, then the product is not classifiable in chapter 33. Chlorhexidine provides more than subsidiary activity. Therefore, Mouthwash D, is not classifiable in chapter 33

2)Chapter 33, General Note (b) confirms that a medical preparation whose major purpose is medicinal, with subsidiary cosmetic application, is not covered by chapter 33. We have demonstrated that chlorhexidine is a medical preparation, with minor cosmetic application. Mouthwashes classifiable under chapter 33 only provide cosmetic solutions to dental/oral hygiene. Refer to the types of mouthwashes earlier discussed

Cosmetic means "relating to treatment intended to restore or improve a person's appearance" "affecting only the appearance of something rather than its substance" "a preparation applied to the body, especially the face, to improve its appearance".

Heading 33.06 Explanatory Notes

33.06 - Preparations for oral or dental hygiene, including denture fixative pastes and powders; yarn used to clean between the teeth (dental floss), in individual retail packages.

3306.10 - Dentifrices

3306.20 - Yarn used to clean between the teeth (dental floss)

3306.90 - Other

This heading covers preparations for oral or dental hygiene such as :

(I) Dentifrices of all types :

(1) Toothpastes and other preparations for teeth. These are substances or preparations used with a toothbrush, whether for cleaning or polishing the accessible surfaces of teeth or for other purposes such as anticaries prophylactic treatment.

Toothpastes and other preparations for teeth remain classified in this heading, whether or not they contain abrasives and whether or not they are used by dentists.

(2) Denture cleaners, i.e., preparations for cleaning or polishing dentures, whether or not they contain agents with abrasive properties.

(II) Mouth washes and oral perfumes.

(III) Denture fixative pastes, powders, and tablets.

The heading also covers yarn used to clean between the teeth, in individual retail packages (dental floss).

1)What does oral/dental hygiene in the terms of heading 33.06 mean: Oral hygiene is the practice of keeping your mouth clean and disease-free. It involves brushing and flossing your teeth as well as visiting your dentist regularly for dental X-rays, exams, and cleanings. Oral hygiene is the practice of keeping one's mouth clean and free of disease and other problems (e.g., bad breath) by regular brushing of the teeth (dental hygiene) and cleaning between the teeth. It is important that oral hygiene be carried out on a regular basis to enable prevention of dental disease and bad breath. The most common types of dental disease are tooth decay (cavities, dental caries) and gum diseases, including gingivitis, and periodontitis.

2)What does hygiene mean: Hygiene is a series of practices performed to preserve health. According to the World Health Organization (WHO), "Hygiene refers to conditions and practices that help to maintain health and prevent the spread of diseases." Personal hygiene refers to maintaining the body's cleanliness.

3)From the definition above it is clear that oral/dental hygiene is not referring to treatment of oral or dental diseases. Maintenance of oral/dental hygiene does not require pharmacologically active ingredients in mouthwash/rinse unless there is a medical issue to be resolved. Refer to types of mouthwashes/rinses earlier discussed. Note that chlorhexidine has side effects, if not utilised as instructed, similar to all medications. Refer to earlier discussion as well as FDA website under chlorhexidine.

4)Mouthwashes are an oral hygiene element and there are plenty of individual products. There are two main types of mouthwash applications: preventive and therapeutic. A single product may possess a double function: antiplaque substances prevent as well as support the treatment of periodontal diseases, among others. It is not strictly associated with the concentration of active substances seen in mouthwashes, but with the duration of usage and of course with current health status. In prevention, long-term use is required, whereas in therapy, short-time use is usually sufficient. Another function is to provide relief in some conditions, in preoperative or postoperative management as well as in aesthetic dentistry (anti-stain and whitening effects).

5) Mouthwash D is for the treatment of oral/dental diseases, it is not for the maintenance of hygiene or for aesthetic purposes . Therefore, classification of Mouthwash D, in heading 33.06 contradicts the Terms of Heading.

WCO Rulings Subheading 3306.90

Ruling 1. Antiseptic solution consisting, inter alia, of boric acid, thymol, eucalyptol, and benzoic acid, intended to aid dental and oral hygiene, to prevent bad breath and plaque formation, but having only subsidiary therapeutic or prophylactic properties.

Adoption : 1990

Ruling 2. Anti-plaque preparation in the form of a liquid, intended to remove plaque and give lustre to the teeth; it is used by rinsing, before the teeth are brushed with a toothbrush and a dentifrice.

Adoption : 1993

Table 3: WCO/WHO HS Classification of Chlorhexidine

Google Search Terms: WCO Chlorhexidine

The Link is:

https://www.wcoomd.org/-/media/wco/public/global/pdf/topics/nomenclature/covid_19/prioritization-medicines-list-during-covid-19-v9_wco_en.pdf?la=en

Antiemetic	metoclopramide (14)(6)	2924.29; 3004.90*	17.2 Antiemetic medicines
	ondansetron (62)(29)	2933.29; 3004.90*	17.2 Antiemetic medicines
Antiseptic	chlorhexidine (6)(3)	2925.29; 3004.90*	15.1 Antiseptics
	alcohol-based hand rub	3808.94	15.1 Antiseptics
	povidone (74)(36)-iodine	3905.99; 3004.90*	15.1 Antiseptics
Bronchodilators	salbutamol (20)(9)	2922.50; 3004.90*	25.1 Antiasthmatic and medicines for chronic obstructive pulmonary disease
	ipratropium bromide (31)(14)	2939.79; 3004.49*	25.1 Antiasthmatic and medicines for chronic obstructive pulmonary disease
Cough suppressants	Codeine	2939.11; 3004.49*	2.2 Opioid analgesics

Analysis of WCO Decisions

- 1) During the Covid Pandemic the WCO and WHO listed a number of essential medicines and their HS Classification in a document Titled " List of priority medicines for customs during COVID-19 pandemic: WHO Secretariats of INN Programme and EML" (Table 3 above). In this document the essential component/active ingredient in the Mouthwash D, chlorhexidine is classified as a chemically defined product under subheading 2925.29, while preparations with chlorhexidine are classified under 3004.90 which is in conformity with our classification. This confirms our assertion that it is a pharmacologically active ingredient, and its use in the product under consideration is not subsidiary.
- 2) Note that in ruling 1 by the WCO, the product does not have any internationally recognised pharmacologically active ingredient and the product has only subsidiary therapeutic purpose. It is put up to aid dental and oral hygiene, to prevent bad breath and plaque formation. Therefore, it is for cosmetic purpose and has little therapeutic value. This ruling is very important in the classification of our product. It tells us that if the major use of a product is therapeutic, then heading 33.06 does not apply.
- 3) In ruling 2 the cosmetic nature of products classifiable in heading 3306 is further emphasized. It is an anti-plaque preparation, intended to remove plaque and give lustre to the teeth; There is no therapeutic component at all, its functions are all cosmetic. This ruling provides a further guide as to the nature of products expected to be classified under heading 33.06.

Conclusions

- 1) Chlorhexidine gluconate is an essential medicine recognised worldwide. It imparts the essential character to the product. Refer to the analysis of the ingredients in Mouthwash D.
- 2) There are two major types of mouthwash. 1) for cosmetic purpose, classifiable in heading 33.06 2) for therapeutic purpose, with active ingredients, classifiable in heading 30.04

- 3) Chlorhexidine is a cationic surfactant, it has antiseptic, disinfectant, bactericidal or germicidal properties. Cationic surfactant with these properties is to be classified in heading 30.04.
- 4) The WCO, has classified preparations with chlorhexidine under 3004.90.
- 5) The WCO Rulings indicate that not all mouth washes are to be classified under heading 33.06. The determinant is the pharmacological activity of the product.
- 6) The packaging and literature on the product satisfy all the requirements for pharmaceutical products as per the chapter 30 explanatory notes.
- 7) Mouthwash D contains Chlorhexidine gluconate 0.12% m/v and is indicated for Post periodontal surgery to prevent bacterial infection, reduce biofilm formation and gingival inflammation after surgery (attached is an abstract on Efficacy of Chlorhexidine rinses after periodontal or implant surgery for your ease of reference).

An abstract on the effect of chlorhexidine in reducing oral colonization in geriatric patients: a randomized controlled trial was carried out with Thymol an ingredient contained in Listerine. The risk of oral bacterial colonization is nearly three times higher in thymol group compared to the chlorhexidine group. Attached for your ease of reference.

Chlorhexidine gluconate also controls dental plaque, prevents gum disease, and eliminates halitosis and is generally prescribed by a dentist or pharmacist upon diagnosis of the above-mentioned medical conditions.

This product is therefore a medicament as opposed to other products which may be purely for oral or dental hygiene.

We hereby enclose copies of the following documents for your reference.

- Product sample
- Listing certificate from Pharmacy & Poisons Board

From our assessment, this product should be classified under heading: 30.04 {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} Tariff Code 3004.90.00{other}

Our Technical experts will be readily available for any clarification required.

In light of the above, we kindly request you to guide us on the suitable tariff classification for above-mentioned product.

Thanking you for your valued consideration.

Yours faithfully,

Janron Consult

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