California Department of Public Health

MEMORANDUM

DATE: June 25, 2008

TO: Clerk of the Board
California Air Resources Board
Headquarters Building
1001 "I" Street
P.O. Box 2815

FROM: Rufus Howell
Deputy Director
Center for Environmental Health
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SUBJECT: Comments on reduction of Toners/Astringents

Attached is a position paper developed by the Department of Public Health (DPH) with regard to toners/astringents and a reinstatement of DPH's position on rubbing alcohol.

DPH acknowledges that the Air Resources Board proposal is 35 percent by weight volatile organic carbon.

Attachment

cc: Robert Schlag, M.Sc
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Food and Drug Branch
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Health Benefits Products

FDB Comments

The California Air Resources Board (CARB) has asked the Food, Drug and Radiation Safety Division to comment on the public health impact of reducing the amount of alcohol [volatile organic carbon (VOC)] in Astringents/Toners to 10% and Rubbing Alcohol to 70%.

Non-Medicated Astringents/Toners

Food and Drug Branch (FDB) personnel met with representatives of the cosmetic and medical industries who are concerned with the reduction of alcohol in non-medicated astringents/toners as currently considered by CARB. Non-medicated astringents/toners are classified as cosmetics. Cosmetics are articles applied to the human body for the purpose of cleansing, beautifying, promoting attractiveness or altering appearance; they are not products used for the mitigation of diseases. However, physicians frequently advise patients with severe acne to use "non-medicated astringents/toners" because of the perceived therapeutic value of the high (>90%) alcohol content in treating cases of severe acne. A review of the Over the Counter (OTC) acne monograph (21 CFR Part 333) indicates that alcohol is not an approved active ingredient for the treatment of acne. This however, does not preclude a physician from prescribing a course of treatment for acne with a product not covered by the monograph.

Lowering the alcohol content in non-medicated astringents/toners to 10%, will likely lead to the discontinuation of the medical community using this category of products as a treatment for acne. Modifying the existing acne monograph to include alcohol as an active ingredient could be done, but will take many years.

FDB has no legal basis to support the cosmetic and medical industries' opinions for non-medicated astringents/toners, which are classified as cosmetics, being used as drugs, when there is an established procedure for the US Food and Drug Administration (FDA) to amend the monograph to include isopropyl alcohol. Cosmetics are not allowed to claim therapeutic/medicinal affects; therefore the argument that these products should be used in the treatment of severe acne vulgaris cannot be supported. In conclusion, because these products are classified as cosmetics, **FDB cannot oppose the reduction of alcohol to 10% in non-medicated astringents/toners.**

As shown in the background below, medicated astringents are not intended for acne vulgaris treatment and neither drug product classification (medicated astringent or acne) identifies alcohol as an active ingredient. If in fact alcohol has a therapeutic effect on acne vulgaris, as the medical industry contends, FDB would urge them to petition FDA to change the acne monograph (21 CFR Part 333 Subpart D) for the allowance of alcohol as an active ingredient.

Medicated Astringents

A final monograph (21 CFR Part 347) has been issued for OTC skin protectant products that are used as astringents by FDA on August 16, 1991. The final monograph defines an astringent drug product as a drug product that is applied to the skin or mucous membranes for a local and limited protein coagulant effect. Three ingredients, aluminum acetate, aluminum sulfate, and witch hazel (Hamamelis water), were granted monograph status. After January 1, 1995, the ingredient "Hamamelis water" must be referred to as "witch hazel," as the result of an amendment to the final monograph that reflects an official name change in the United States Pharmacopeia. Aluminum acetate may be used for temporary relief of minor skin irritations due to poison ivy; poison oak; poison sumac; insect bites; athlete's foot; or rashes caused by soaps, detergents, cosmetics, or jewelry. Products containing aluminum sulfate are used to stop bleeding caused by minor surface cuts and abrasions as may occur during shaving. Products containing witch hazel (Hamamelis water) may be used for the relief of minor skin irritations due to insect bites, minor cuts, or minor scrapes.

FDB cannot comment on whether a 10% alcohol limit on medicated astringents would prevent the proper formulation of these regulated products because FDB is not aware of all the ingredient ramifications when formulating these products. Alcohol concentrations >10% may be necessary as a solvent to dissolve already approved active ingredients.

Acne

A final monograph (21 CFR Part 333 Subpart D) has been issued for OTC acne vulgaris products. Acne vulgaris is a chronic disease of sebaceous follicles that is multifactorial in etiology and varies in severity as evidenced by lesion type, size, numbers, scarring, and post-inflammatory pigmentary changes. There are two major types of acne lesions: noninflammatory and inflammatory. Although most drug products for acne are intended for the broad indication of acne vulgaris, some products have been developed that only target one of these two specific subsets of acne vulgaris lesions. Noninflammatory lesions of acne are the open (blackheads) or closed (whiteheads) comedones. Inflammatory lesions are divided into papules, pustules, and nodules/nodulocystic lesions, depending on the severity and location of the inflammation within the dermis.

The active ingredients of the acne product category consist of any of the following: resorcinol – 2%, resorcinol monoacetate – 3%, salicylic acid - 0.5% to 2%, and sulfur – 3% to 10%. Benzoyl peroxide is also allowed with certain label warnings.

The following ingredients were submitted to the FDA as inactive ingredients in topical acne products: alcohol, allantoin, aluminum oxide, bentonite,

benzalkonium chloride, benzethonium chloride, calcium phosphate, carbomer 940, carboxyvinyl polymer, cetyl alcohol, cholesterol, citric acid, colloidal alumina, cosmetic colors, dioctyl sodium sulfosuccinate, edetate disodium, glycerin, glycerol monostearate, glyceryl monostearate, hexachlorophene, hydrocarbon hydrotropes, isopropyl alcohol (isopropyl), isopropyl palmitate, laureth-4 (polyoxyethylene lauryl ether), menthol, methylbenzethonium chloride, methylparaben (methyl parasept), methyl salicylate, polyethylene, polyethylene glycol monostearate, polyethylene glycol 1000 monostearate, propylene glycol, propylparaben (propyl parasept), purified water, soapless cleansers, sodium hydroxide, sodium lauryl sulfate, stearic acid, sulfated surfactants, and sulfonated alkyl benzenes.

Industry explained that a 2% salicyclic acid solution requires at least 20% alcohol for dissolution.

It is FDB's opinion that a 10% alcohol limit for acne products would adversely affect their health benefit.

Rubbing Alcohol

The May 21, 1982 Federal Registrar (Vol. 47. No. 99) describes the proposed rules for a monograph entitled "Alcohol Drug Products for Topical Antimicrobial OTC Human Use". The Panel reviewed isopropyl alcohol concentrations of 12.5%, 20%, 24%, 31%, 35%, 50%, 70%, 90% and 91%. It was determined that water has to be present for any anti-microbial effect. Various microorganisms were tested against these strengths of alcohol. Based on available data, the Panel concluded that isopropyl alcohol is safe and effective for use as an OTC topical antimicrobial agent in aqueous solutions ranging from 50% to 91.5% by volume. This proposed monograph indicates that 70% isopropyl alcohol is the best blend of alcohol and water to cause the quickest kill of the majority of organisms tested. No further activity on this monograph has occurred since 1982.

It is FDB's opinion that a 70% isopropyl alcohol limit for the "rubbing alcohol" category would not adversely affect the health benefit of rubbing alcohol.