

In this final monograph, products containing the skin protectant ingredients mineral oil or sodium bicarbonate may omit the "For external use only" warning if they also provide labeling for oral use of the product. The agency believes that it could be confusing to consumers if products that contain petrolatum do not have the "For external use only" warning. Therefore, the agency is not exempting petrolatum (except in lip protectant products) from the "For external use only" warning in § 201.66(c)(5)(i) and 347.50(c)(1).

The agency considers the warning about not getting the product into the eye useful to help prevent possible improper use of skin protectant drug products which are often marketed in nonsterile, multiple use containers. The agency believes that the first comment misconstrued the purpose of the "if condition worsens" warning (§ 347.50(c)(3) of this final monograph). The warning is intended to direct consumers to seek medical attention for a condition if it gets worse or has not improved after 7 days of treatment and not to set 7 days as a maximum safe treatment period. The agency has shortened this warning for products containing petrolatum (or white petrolatum) as a single ingredient to state: "See a doctor if condition lasts more than 7 days."

With regard to the suggestion that the warning in § 347.50(c)(4) be revised, after the submission of this comment, the agency published a similar warning for OTC first aid antibiotic drug products (52 FR 47312 at 47324, December 11, 1987) and OTC first aid antiseptic drug products (56 FR 33644 at 33677, July 22, 1991). The agency is revising the warning in § 347.50(c)(4), accordingly, in the new format required by § 201.66.

(Comment 30) One comment considered the two general warnings in § 330.1(g) unnecessary for 100 percent petrolatum. The comment cited two references (Refs. 99 and 100) to support its contention that petrolatum is a uniquely safe OTC drug and presents no risk to the health of children from misuse, overuse, or abuse.

The agency finds the information in the cited references (as well as the information in § 172.880 regarding the regulation of petrolatum as an approved food additive) insufficient to support an exemption for 30 to 100 percent petrolatum from the two general warnings in § 330.1(g). References 99 and 100 list petrolatum concentrations at 0.02 to 5 percent, significantly lower than the concentration range included in the monograph. The agency revised the wording of these warnings in

§ 330.1(g) in the final rule for the new OTC drug product labeling format (64 FR 13254 at 13294).

(Comment 31) One comment stated that the agency's proposed directions for sodium bicarbonate for use as a soak in a tub allow for a topical use concentration of about 0.3 percent, which is less than the dosage range for topical use of 1 to 100 percent (54 FR 40808 at 40818).

The agency has reviewed its calculations and agrees with the comment that the proposed directions for use as a soak in a tub allow for a topical concentration of less than 1 percent, depending on the amount of water in the tub and the size of the cup used. However, these directions are consistent with those suggested in the literature (Refs. 101 through 104). When these measurements are made by consumers, they may not be precise. Accordingly, in this final monograph, the agency recognizes that it is not possible or critical to make a precise determination of the use concentration for this ingredient. Thus, the agency has revised its recommendations.

(Comment 32) The agency has considered topical starch (formerly known as corn starch) in several rulemakings. In the advance notice of proposed rulemaking for OTC skin protectant drug products (43 FR 34628 at 34636), the TFM for OTC skin protectant drug products (48 FR 6820 at 6828), the TFM for OTC skin protectant poison ivy, poison oak, poison sumac, and insect bites drug products (54 FR 40808 at 40811 to 40812), the Miscellaneous External Panel's statement on OTC diaper rash drug products (47 FR 39436 at 39439, September 7, 1982), the TFM for OTC skin protectant diaper rash drug products (55 FR 25204 at 25232), and the TFM (53 FR 30756 at 30782) and final monograph (55 FR 31776 at 31780) for OTC anorectal drug products.

Based on the evaluations of the Topical Analgesic, Miscellaneous External, and Hemorrhoidal Panels, and the subsequent inclusion of topical starch as a protectant in the final monograph for OTC anorectal drug products and in the TFM for OTC diaper rash drug products, the agency is including topical starch at a concentration of 10 to 98 percent as an active ingredient under § 347.10(q) of this final monograph for OTC skin protectant drug products. The agency is including a minor skin irritation indication for the skin protectant uses of topical starch in § 347.50(b)(6). Because topical starch should not be used on broken skin, other conditions (e.g., cuts, scrapes, chapped/cracked skin and lips)

are not included in this final monograph. Warnings applicable to topical starch drug products in a powder dosage form are included in § 347.50(c)(6).

(Comment 33) Two comments from the same company requested that vitamins A and D be added to the list of Category I active ingredients in the skin protectant monograph. The comments stated that shark liver oil, which contains significant quantities of vitamins A and D, is an oleaginous substance that provides lubricity and emolliency. The comments mentioned that vitamins A and D, like cod and shark liver oils, have an emollient nature that provides a physical barrier to an irritant and aids in the temporary relief of minor skin irritations. The comments added that these oleaginous substances can lessen dermal injury caused by friction and lessen itching and dryness caused by water loss from the stratum corneum, thereby providing additional protection for exposed skin. The comments cited the Hemorrhoidal Panel's recommendations on the safety and topical use of vitamins A and D (45 FR 35576 at 35630 and 35634). Another comment stated that a number of the claims recommended by the Hemorrhoidal Panel in the advance notice of proposed rulemaking for OTC skin protectant drug products (43 FR 34628 at 34648) should be listed in the monograph for the ingredients vitamin A and vitamin D.

The Hemorrhoidal Panel did not review vitamin A or vitamin D (cholecalciferol) as single ingredients for use as protectants in OTC anorectal drug products but did consider these ingredients in its review of ingredients used for wound healing (45 FR 35576 at 35655 and 35656). The Hemorrhoidal Panel concluded that the data submitted were insufficient to prove effectiveness of vitamins A and D as wound healing agents and classified these ingredients in Category III for this use (45 FR 35576 at 35655 and 35656). The agency did not include vitamins A or D in the anorectal final monograph because no data were submitted to support the effectiveness of these ingredients for protectant uses. However, the Hemorrhoidal Panel recommended that cod liver and shark liver oils be included in the Category I list of active ingredients for use as protectants in OTC anorectal drug products (45 FR 35576 at 35630 and 35634) and the agency concluded that these oils are monograph ingredients (55 FR 31776 at 31780). The agency pointed out in its proposed rulemaking for OTC diaper rash drug products (55 FR 25204 at 25225) that vitamins A and D have not been classified as skin protectants in