U.S. Food and Drug Administration

Over-the-Counter (OTC) Monograph M014: Topical Otic Drug Products for Over-the-Counter Human Use (Posted September 20, 2021)[1]

Part A—General Provisions

Part B—Active Ingredients

Part C—Labeling

SOURCE: 51 FR 28656 at 28660, Aug. 8, 1986, unless otherwise noted.

Part A—General Provisions

§ M014.1 Scope

An over-the-counter (OTC) topical otic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this OTC monograph in addition to each of the general conditions established in 21 CFR 330.1.

§ M014.3 Definitions

As used in this OTC monograph:

(a) Anhydrous glycerin. An ingredient that may be prepared by heating glycerin USP at 150 °C for 2 hours to drive off the moisture content.

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[1] Final Administrative Order (OTC000003), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

(b) Earwax removal aid. A drug used in the external ear canal that aids in the removal of excessive earwax.

(c) Water-clogged ears. The retention of water in the external ear canal, thereby causing discomfort and a sensation of fullness or hearing impairment.

(d) Ear drying aid. A drug used in the external ear canal to help dry water-clogged ears.

[51 FR 28656 at 28660, Aug. 8, 1986, as amended by 65 FR 48902 at 48905, Aug. 10, 2000]

Part B—Active Ingredients

§ M014.10 Earwax removal aid active ingredient

The active ingredient of the product consists of carbamide peroxide 6.5 percent formulated in an anhydrous glycerin vehicle.

[51 FR 28656 at 28660, Aug. 8, 1986, as amended by 65 FR 48902 at 48905, Aug. 10, 2000]

§ M014.12 Ear drying aid active ingredient

The active ingredient of the product consists of isopropyl alcohol 95 percent in an anhydrous glycerin 5 percent base.

[65 FR 48902 at 48905, Aug. 10, 2000]

Part C—Labeling

§ M014.50 Labeling of earwax removal aid drug products

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an “earwax removal aid.”

(b) Indication. The labeling of the product states, under the heading “Use,” the following: “For occasional use as an aid to” (which may be followed by: “soften, loosen, and”) “remove excessive earwax.” Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M014.50(b), may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352) relating to misbranding and the prohibition in section 301(d) of the FD&C Act (21 U.S.C. 331(d)) against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the FD&C Act (21 U.S.C. 355(a)).

(c) Warnings. The labeling of the product contains the following warnings under the heading “Warnings”:

(1) “Do not use if you have ear drainage or discharge, ear pain, irritation, or rash in the ear or are dizzy; consult a doctor.”

(2) “Do not use if you have an injury or perforation (hole) of the ear drum or after ear surgery unless directed by a doctor.”

(3) “Do not use for more than 4 days; if excessive earwax remains after use of this product, consult a doctor.”

(4) “Avoid contact with the eyes.”

(d) Directions. The labeling of the product contains the following statement under the heading “Directions”: FOR USE IN THE EAR ONLY. Adults and children over 12 years of age: tilt head sideways and place 5 to 10 drops into ear. Tip of applicator should not enter ear canal. Keep drops in ear for several minutes by keeping head tilted or placing cotton in the ear. Use twice daily for up to 4 days if needed, or as directed by a doctor. Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe. Children under 12 years of age: consult a doctor.

[51 FR 28656 at 28660, Aug. 8, 1986; 52 FR 7830, Mar. 13, 1987; 65 FR 48902 at 48905, Aug. 10, 2000]

§ M014.52 Labeling of ear drying aid drug products

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an “ear drying aid.”

(b) Indications. The labeling of the product states, under the heading “Use,” the following: “dries water in the ears” (optional, which may be followed by: “and relieves water-clogged ears”) (which may be followed by any or all of the following: “after: [bullet][2] swimming [bullet] showering [bullet] bathing [bullet] washing the hair”). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M014.52(b), may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of the FD&C Act relating to misbranding and the prohibition in section 301(d) of the FD&C Act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the FD&C Act.

(c) Warnings. The labeling of the product contains the following warnings under the heading “Warnings”:

(1) “Flammable [in bold type]: Keep away from fire or flame.”

(2) “Do not use [in bold type] in the eyes.”

[2] See 21 CFR 201.66(b)(4).

(3) “Ask a doctor before use if you have [in bold type] [bullet] ear drainage or discharge [bullet] pain, irritation, or rash in the ear [bullet] had ear surgery [bullet] dizziness.”

(4) “Stop use and ask a doctor if [in bold type] irritation (too much burning) or pain occurs.”

(d) Directions. The labeling of the product contains the following statement under the heading “Directions”: [optional, bullet] “apply 4 to 5 drops in each affected ear.”

[65 FR 48902 at 48905, Aug. 10, 2000]