



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-1118]

Additions to Listing of Exempt Chemical Mixtures

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Direct final rule.

SUMMARY: Under this direct final rule, the Drug Enforcement Administration (DEA) is updating the Table of Exempt Chemical Mixtures to include the listing of nine additional preparations. This action is in response to DEA's review of new applications for exemption. Having reviewed applications and relevant information, DEA has found that these preparations meet the applicable exemption criteria. Therefore, this rule amends the regulations to codify that these products are exempted from the application of certain provisions of the Controlled Substances Act.

DATES: This direct final rule is effective [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] without further action, unless DEA receives adverse comment by DEA no later than [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which this rule is based, the Administrator will withdraw this direct final rule and will issue a new rule, after she has reconsidered the issues in light of the comments and objections filed.

Written comments must be postmarked and electronic comments must be submitted on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management

System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-1118” on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION: Any interested person may file comments or objections to this order, on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. If any such comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the rule is based, the

the Administrator will withdraw this direct final rule. The Administrator may reconsider the application in light of the comments and objections filed and reinstate, terminate, or amend the original order as deemed appropriate.

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on <http://www.regulations.gov>. Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's (DEA) public docket file. Please note that the Freedom of Information Act applies to all comments received.

New Exempt Chemical Mixtures

The manufacturers of nine chemical mixtures listed below have applied for an exemption pursuant to 21 CFR 1310.13. DEA has reviewed the applications, as well as any additional information submitted by the respective manufacturers. DEA has found that: (1) each of these chemical mixtures is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and (2) the listed chemical(s) contained in these chemical mixtures cannot be readily recovered. Therefore, DEA has determined that each of the applications should be granted, and previously issued a letter to this effect. This regulatory action conforms DEA regulations to the exemptions previously issued.

Background

Under 21 CFR 1310.13(a), the Administrator may, by publication of a final rule in the *Federal Register*, exempt from the application of all or any part of the Controlled Substances Act (CSA) a chemical mixture consisting of two or more chemical components, at least one of which is not a list I or list II chemical. Each manufacturer must apply for such an exemption (21 CFR 1310.13) to ensure that each manufacturer's product warrants an exemption by demonstrating that:

(1) The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(2) The listed chemical or chemicals contained in the chemical mixture cannot be readily recovered.

Any manufacturer seeking an exemption for a chemical mixture, not automatically exempt under 21 CFR 1310.12, may apply to the Administrator by submitting an application for exemption which contains the information required by 21 CFR 1310.13(c):

(1) The name, address, and registration number, if any, of the applicant;

(2) The date of the application;

(3) The exact trade name(s) of the applicant's chemical mixture;

(4) The complete qualitative and quantitative composition of the chemical mixture (including all listed and all non-listed chemicals); or if a group of mixtures, the concentration range for the listed chemical and a listing of all non-listed chemicals with respective concentration ranges;

(5) The chemical and physical properties of the mixture and how they differ from the properties of the listed chemical or chemicals; and if a group of mixtures, how the group's properties differ from the properties of the listed chemical;

(6) A statement that the applicant believes justifies an exemption for the chemical mixture or group of mixtures. The statement must explain how the chemical mixture(s) meets the exemption criteria;

(7) A statement that the applicant accepts the right of the Administrator to terminate exemption from regulation for the chemical mixture(s) granted exemption under 21 CFR 1310.13; and

(8) The identification of any information on the application that is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information.

The Administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application that he deems necessary for determining if the application should be granted.

21 CFR 1310.13 further specifies that within a reasonable period of time after the receipt of an application for an exemption, the Administrator will notify the applicant of acceptance or rejection of the application for filing. If the application is not accepted for filing, an explanation will be provided. The Administrator is not required to accept an application if any information required pursuant to 21 CFR 1310.13 is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of this section.

If the exemption is granted, the applicant shall be notified in writing and the Administrator shall issue, and publish in the *Federal Register*, an order on the application. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the Administrator may suspend the effectiveness of the order until he has reconsidered the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as deemed appropriate.

A formulation granted exemption by publication in the Federal Register will not be exempted for all manufacturers. The current Table of Exempt Chemical Mixtures lists those products that have been granted exempt status prior to this update. That table can be viewed online at: http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_list.htm.

Findings

Having considered the information provided in each of the below listed applications, I find that each of the referenced chemical mixtures meets the requirements for exemption under 21 CFR 1310.13(a). Therefore, each of these mixtures is exempt from the application of sections 302, 303, 310, 1007, and 1008 of the CSA (21 U.S.C. 822, 823, 830, 957 and 958).

DEA is updating the table in 21 CFR 1310.13(i) to include each of these exempt chemical mixtures.

Regulatory Analyses

Administrative Procedure Act

An agency may find good cause to exempt a rule from prior public notice provisions of the Administrative Procedure Act (5 U.S.C. 553(b)(B)), if it is determined to be unnecessary, impracticable, or contrary to the public interest. DEA finds that it is unnecessary to engage in notice and comment procedures because this rulemaking grants exemptions for the below listed products in accordance with standards set by existing DEA regulations. Each of these manufacturers has previously received a letter from DEA granting exempted status for the specific products. This regulatory action hereby conforms DEA regulations to the exemptions previously considered and issued.

Executive Orders 12866 and 13563, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This direct final rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients

thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. DEA has determined that this direct final rule is not a "significant regulatory action" under E.O. 12866, section 3(f).

Executive Order 12988, Civil Justice Reform

The Administrator further certifies that this rulemaking meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612), and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities. This regulation will not have a significant impact upon firms who distribute these products. In fact, the approval of Exempt Chemical Mixture status for these products reduces the regulatory requirements for distribution of these materials.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, the DEA has determined that this action will not result in any Federal mandate that may result “in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action does not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this direct final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 16, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

List of Subjects in 21 CFR Part 1310

Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

Scott Brinks

Federal Register Liaison Officer,
Drug Enforcement Administration

Under the authority vested in the Attorney General by section 102(39)(A)(vi) of the Act (21 U.S.C. 802(39)(A)(vi)) and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR 0.100), the Administrator hereby amends 21 CFR part 1310 as set forth below.

PART 1310--RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 827(h), 830, 871(b), 890.

2. In § 1310.13, table 1 to paragraph (i) is amended by adding the following entries in alphabetical order by Manufacturer to read as follows:

§ 1310.13 Exemption of chemical mixtures; application.

* * * * *

(i) * * *

Table 1 to Paragraph (i)—Exempt Chemical Mixtures			
Manufacturer	Product name¹	Form	Approval Date
* *	* *	* *	*
Dr. Haces, L.L.C.	PodoPhylis, Podiatric Insole	Polyurethane Iodine Insole	12/15/2021
* *	* *	* *	*
Mitsubishi Chemical Corporation	Aquamicon AKX	Liquid	04/08/2021
Mitsubishi Chemical Corporation	Aquamicon AS	Liquid	04/08/2021
Mitsubishi Chemical Corporation	Aquamicon Titrant SS 1 mg	Liquid	04/08/2021
Mitsubishi Chemical Corporation	Aquamicon Titrant SS 3 mg	Liquid	04/08/2021
Mitsubishi Chemical Corporation	Aquamicon Titrant SS 10 mg	Liquid	04/08/2021
Mitsubishi Chemical Corporation	Aquamicon Titrant SS-Z 1 mg	Liquid	09/01/2020
Mitsubishi Chemical Corporation	Aquamicon Titrant SS-Z 3 mg	Liquid	09/01/2020

Mitsubishi Chemical Corporation	Aquamicon Titrant SS-Z 5 mg	Liquid	04/08/2021
* *	* *	* *	*

¹ Designate product line if a group.

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