DMM-21-02 / Guidelines for Waiver Process per ECL 35-0105(6) and ECL 37-0117(7)	
New York State Department of Environmental Conservation DEC Program Policy	
Issuing Authority: Martin Brand, Deputy Commissioner	Title: Guidelines for Waiver Process per ECL 35-0105(6) and ECL 37-0117(7)
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I. Summary:

This document establishes the process by which manufacturers of household cleansing, personal care, or cosmetic products should apply to the Department of Environmental Conservation (Department) for a waiver of the maximum 1,4-dioxane trace concentrations enacted in ECL 35-0105 and 37-0117. Products that do not exceed the maximum trace concentrations enacted therein need not apply for a waiver as they are already in compliance with the law.

II. Policy:

Manufacturers of household cleansing, personal care, and cosmetic products may apply to the Department for up to two, one-year waivers of the maximum 1,4-dioxane trace concentrations stated in ECL 35-0105 and 37-0117 upon such proof that the manufacturer has taken steps to reduce the concentration of 1,4-dioxane in that product and is unable to comply with the requirements.

III. Purpose and Background:

Sections 35-0105 and 37-0117 of the Environmental Conservation Law enact maximum concentrations of 1,4-dioxane that can be present in household cleansing, personal care, and cosmetic products as of December 31, 2022. Further, ECL 35-0105(6) and 37-0117(7) allow manufacturers of such products to apply for a waiver of such requirements for a year, up to two times. This policy provides clarification on the proof the Department will require to grant such waiver as well as the process for manufacturers to submit and implement the waiver request. While the forthcoming regulations will include provisions for the waiver process, statutory limits will take effect on January 1, 2023, and manufacturers will need know before then what the waiver process entails and whether they will qualify. This Program Policy will assist the

regulated community ahead of the adoption of regulations by enabling them to better plan their compliance schedule.

IV. Responsibility:

The Division of Materials Management Pollution Prevention Unit is responsible for interpreting and implementing this Program Policy.

V. Procedure:

A. Definitions

For the purposes of this policy, the following terms have the following meanings.

"Cosmetic product" means any article (a) intended to be rubbed, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for beautifying, promoting attractiveness, or altering the appearance, and (b) intended for use as a component of any such article. The term "cosmetic product" shall not include any personal care product for which a prescription is required for distribution or dispensation as provided in section two hundred eighty-one of the public health law or section sixty-eight hundred ten of the education law.

"Household cleansing product" means any product, including but not limited to soaps and detergents, containing a surfactant as a wetting or dirt emulsifying agent and used primarily for domestic or commercial cleaning purposes, including but not limited to, the cleansing of fabrics, dishes, food utensils and household and commercial premises. Household cleansing product shall not mean foods, drugs, cosmetics, insecticides, fungicides and rodenticides or cleansing products used primarily in industrial manufacturing, production and assembling processes as provided by the commissioner by rule and regulation.

“Manufacturer” means any person who (1) manufactures a household cleansing product, personal care product or cosmetic product for sale in the state under its own brand name; (2) sells, under its own brand name, a household cleansing product, personal care product or cosmetic product in the state; or (3) owns a brand name that it licenses to another person for use on a household cleansing product, personal care product or cosmetic product sold in the state.

"Personal care product" means any product intended for cleaning or cleansing any part of the body, such as the skin and hair, and including but not limited to, hair shampoo, hair conditioner, soap, bath gels and other bath products. The term "personal care product" shall not include any product for which a prescription is required for distribution or dispensation as provided in section two hundred eighty-one of the public health law or section sixty-eight hundred ten of the education law.

“Responsible official” means a president, vice president, secretary, treasurer, general partner, proprietor, principal executive officer, or any other person who performs policy or decision making functions for and is authorized to legally bind the manufacturer of a household cleansing product, personal care product, or cosmetic product.

B. General Provisions

This document details the process by which manufacturers may obtain a waiver of the requirements of ECL 35-0105(4), 37-0117(3), or 37-0117(4). Manufacturers must submit their waiver applications using the documents published by the Department (Appendices C-E). Applications seeking a waiver pursuant to ECL 35-0105(6) or 37-0117(7) must include a certification by a responsible official. A responsible official must sign the form included in Appendix C to certify that after reasonable inquiry of the person or persons directly responsible for providing the information required to complete the waiver application, the responsible official has concluded that the statements and information in the application are accurate and complete based on the best available information. The responsible official must acknowledge that there are significant penalties for submitting false information. The certification must include the full name, title, signature, date of signature, e-mail address and telephone number of the responsible official.

Each product for which a waiver is sought must be individually named in the application (Appendix D). Products that contain the same formulation other than their fragrance blend can be considered the same product for the purposes of providing the proof required below but each product must be identified. All product-specific information required in Section D may be aggregated into one manufacturer-wide waiver application.

Manufacturers may indicate whether portions of the application contain trade secrets or confidential business information and request that the Department not disclose this information. In accordance with 6 NYCRR part 616, such requests must be in writing and state reasons why the information should be exempted from disclosure. The Department will follow the procedures set forth in part 616 in determining whether to grant access to information that is claimed to be a trade secret or confidential business information. Material presented in waiver applications will be shared publicly by the Department upon notice of approval, with the exception of any information that qualifies as a trade secret or confidential business information subject to the provision of part 616.

C. Establishing the Applicable Product Category

Each product for which a waiver is sought must identify if the product is a household cleansing product, a personal care product, or a cosmetic product. A list of brick codes

that fall within each product category is provided in Appendix A for additional clarification.

If a product is not assigned a category in the application or is assigned a category that the Department deems incorrect, the Department will return the application to the manufacturer. For the former, the manufacturer must assign the product a category. For the latter, the manufacturer may change the product's category or send the Department a justification for why the product falls within the originally identified category. If the manufacturer returns the application within 7 business days with the necessary information, it will retain its spot in the review queue. Otherwise, the application will be treated as new.

If a manufacturer produces a product that is covered under ECL 35-0105 or 37-0117 that does not clearly fit into one of the brick codes in Appendix A, and is unsure which category the product falls within, they can submit a form (Appendix B) to request that the Department make a determination.

D. Proof for Waiver

Manufacturers must provide proof that each product named in the waiver application is not able to meet the applicable maximum 1,4-dioxane trace concentration by the applicable date. Such proof shall include:

1. **A certification of the concentration of 1,4-dioxane that is currently in each product** for which a waiver is sought. The manufacturer must be able to produce documentation of the stated concentration if requested.
    a. If the stated 1,4-dioxane concentration is a result of testing that has been conducted on the product, such documentation must be dated, detail the test method used, and name the lab that conducted the test.
    b. If the stated 1,4-dioxane concentration is a result of a dilution calculation, such documentation must include the name of the ingredient that causes 1,4-dioxane to be present in the final product; a dated test result that shows the concentration of 1,4-dioxane in the ingredient with the test method used and lab that conducted the test or a certification from the supplier stating the amount of 1,4-dioxane present in the ingredient; the percentage of the final product that is made of the ingredient; the dilution calculation that was used to obtain the reported 1,4-dioxane concentration in the product; and an attestation that no other ingredients in the product would contain 1,4-dioxane, based on information available to the manufacturer including testing conducted and knowledge of the product's other ingredients and formulation.
2. **Written explanation (Appendix E) of the efforts that have been or are being conducted** to reduce the concentration of 1,4-dioxane in the product or formulation and why additional time is necessary to comply. Efforts may include, but are not limited to, the success in developing or evaluating alternative

formulations; the ability to source replacement ingredients; or the availability of stripping or other available techniques. Justification for requesting additional time could include an explanation of the efforts to reformulate and why a solution has not been found or an explanation that a solution has been found but the manufacturer is working through product efficacy and safety testing, to scale production, or to deliver the product.

If a manufacturer has identified a compliance option but needs additional time to scale production or deliver to the New York market, such situation should be explained and accompanied by a projected timeline to get the compliant product to market.

If proof for the waiver applies to multiple products for which a waiver is being sought the manufacturer can refer to the proof provided for another product so that it is not submitting the same written justification multiple times. The manufacturer should indicate which distinct explanation applies to each product listed in Appendix D.

E. Filing Process and Timeline

Manufacturers can submit waiver applications electronically (preferred method) or via hard copy. Instructions for each submission method will be posted on the Department's website.

Applications can be submitted as early as October 1, 2021. The Department will review applications on a rolling basis in the order in which they are received. The Department will respond to applications in a timely manner and will take no longer than six months to approve or deny an application.

For household cleansing and personal care products, if a product will comply with the December 31, 2022 maximum trace concentration of 2 ppm, but the manufacturer expects it will not be able to comply with the December 31, 2023 maximum trace concentration of 1 ppm they should not submit a waiver application during the first cycle. A manufacturer may submit an application for a waiver for such products beginning on January 1, 2023.

F. Waiver Renewal

Applications to renew a waiver must update the information required in Section D or include the original information with a statement that it has not changed. Such applications shall indicate that it is a renewal. Applications for waiver renewal may be submitted starting on July 1 of the year in which the original waiver expires.

G. Applicability of Waiver

Waivers granted during the 2021/2022 application cycle exempt a product from compliance with the maximum trace concentration of 2 ppm for household cleansing products or personal care products or the maximum trace concentration of 10 ppm for cosmetic products, whichever is applicable. Waivers granted on or before December 31, 2022 are effective starting December 31, 2022 until December 30, 2023. Waivers, including extensions of a waiver granted in the previous year, granted from January 1, 2023 through December 31, 2023 are effective starting December 31, 2023 until December 30, 2024 and exempt a product from compliance with the maximum trace concentration of 1 ppm for household cleansing products or personal care products or the maximum trace concentration of 10 ppm for cosmetic products, whichever is applicable.

The granting of a waiver allows the manufacturer and retailers to continue the sale of non-compliant product in New York State while such waiver is in effect. Upon the expiration of a waiver, any product that contains 1,4-dioxane in excess of the maximum trace concentrations in the law cannot be sold in the State. Upon the expiration of a waiver, any product offered for sale in the State must comply with the applicable maximum 1,4-dioxane trace concentrations.

VI. Termination of Policy

The foregoing Guidelines for Waiver Process per ECL 35-0105(6) and ECL 37-0117(7) shall be made obsolete and rescinded upon finalization and promulgation of Department regulations in 6 NYCRR Part 352, which will set forth the waiver process.

Appendix A

Scope of Product Categories

Household Cleansing

10000531	Bleach
10000746	Cleaners Other
10000698	Cleaners Variety Pack
10000442	Descalers
10000406	Dish Cleaning/Care – Automatic
10000636	Dish Cleaning/ Care – Hand
10000445	Dish Care/ Protection
10000423	Drain Treatments/ Pipe Unblockers
10006233	Food Treatments
10000443	Stain Removers
10000405	Surface Cleaners
10000426	Toilet Cleaning Products
10000743	Detergent Boosters/ Laundry Bleaches
10000741	Fabric Protectors
10000427	Laundry Color Care
10000424	Laundry Detergents
10000444	Laundry Dry Cleaning
10000747	Laundry Other
10000699	Laundry Variety Packs
10000749	Surface Care Other
10000701	Surface Care Variety Pack
10000434	Surface Care/ Protection
10000694	Cleaning/ Hygiene Products Variety Packs

Personal Care

10000666	Beauty/Personal Care/Hygiene Variety Packs
10000333	Nails- Cleansers/Cosmetic Removers
10000346	Hair- Conditioner/Treatment
10000368	Hair- Shampoo
10000341	Ear/Nasal Care
10000786	General Personal Hygiene Other
10000715	General Personal Hygiene Variety Packs
10000383	Dental Cleansing
10000337	Denture/Orthodontic- Cleansing
10000783	Oral Hygiene Other
10000716	Oral Hygiene Variety Packs
10000328	Bath Additives
10000813	Body Washing Other
10000722	Body Washing Variety Packs
10000330	Cleansing/Washing/Soap- Body
10000573	Wipes-Personal
10000332	Cleansers/ Cosmetic Removers (non powered)
10000505	Baby Hygiene Products

Cosmetic

10000666	Beauty/Personal Care/Hygiene Variety Packs
10000761	Cosmetic Paints/Shimmers/Glitters
10000775	Cosmetic Products Other
10000669	Cosmetic Products Variety Packs
10000532	Cosmetics- Complexion
10000533	Cosmetics- Eyes
10000534	Cosmetics- Lips
10000764	Eyelashes- False
10000486	Skin Lightening
10000672	Cosmetics/Fragrances Variety Packs
10000360	Cosmetics- Nails
10000778	Nail Cosmetic/Care Products Other
10000671	Nail Cosmetic/Care Products Variety Packs
10000359	Nails- False
10000345	Hair- Colour
10000343	Hair- False
10000348	Hair- Perming
10000381	Hair- Sytling (non powered)
10000677	Hair Care Products Variety Packs
10000676	Hair Products Variety Packs
10000329	Bleaching/Lightening Products
10000338	Antiperspirants/ Deodorants
10000340	Depilation/ Epilation (non powered)
10000350	Hair Removal- Care
10000835	Hair Removal/Masking Products Other
10000680	Hair Removal/ Masking Products Variety Packs
10000535	Shaving Preparations
10000536	Breath Fresheners/ Mouth Rinses
10000324	After Shave Care
10006275	After-Sun Moisturisers
10000327	Anti-spot aids (non powered)
10000342	Exfoliants/Masks
10005727	Lip balm
10000812	Skin Care Other
10000721	Skin Care Variety Packs
10000356	Skin Care/Moisturizing Products
10000484	Toners/Astringents
10000814	Skin Tanning Products Other
10000723	Skin Tanning Products Variety Packs
10000388	Sun Tan Accelerator Products
10000731	Sunless Tanning- Oral (non powered)
10000355	Sunless Tanning- Topical (non powered)
1000373	Sun Protectant Products
10000903	Acne treatments

Appendix B

Product Category Determination Application

Product name	
UPC, if applicable	Brick code, if applicable

Does the product contain a surfactant? Yes

Is a prescription required to obtain the product? Yes

Describe the purpose of the product:

Please submit the product's use instructions in the space provided or a copy of the product's label.

Please provide examples of the marketing materials for the product. This can be a link to where the product is listed on the manufacturer's website, a copy of a print or media advertisement, or other marketing such as promotional emails specific to the product.

Appendix C

Certification Form

Company name
Company address

Responsible official name	Title
Email address	Phone number

This waiver application is: ☐ new ☐ renewal

A full and complete application for a waiver of the requirements of ECL 35-0105(4), 37-0117(3) and/or 37-0117(4) must include the following elements:

- ☐ Signed “Certification Form”
- ☐ Complete “Product Identification” information for each requested product
- ☐ Complete “Explanation of Proof” information for each explanation identification included in “Product Identification”

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision. Based on my inquiry of the person or persons directly responsible for gathering the information required to complete this application, I believe the information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.

Responsible official name	Title
Signature	Date

Appendix D

Product Identification

An excel document for the product information can be found to the left of this page as an attachment. Click the paperclip icon to edit the excel document, which will save directly to this PDF.

Appendix E

Explanation of Proof

Explanation Identification (from “Product Identification” column G)

Description of efforts undertaken to decrease the concentration of 1,4-dioxane to date:

Explanation why additional time is needed: