Express Terms

6 NYCRR Part 352 Product Chemical Restrictions and Disclosure.

Subpart 352-1, 1,4-Dioxane Limits for Household Cleansing, Personal Care, and Cosmetic Products

(Statutory Authority: ECL sections 1-0101, 3-0301, 35-0105, and 37-0117)

6 NYCRR Part 352 Product Chemical Restrictions and Disclosure is being added as follows:

Subpart 352-1, 1,4-Dioxane Limits for Household Cleansing, Personal Care, and Cosmetic Products

352-1.1 Purpose and Applicability

(a) Purpose

The purpose of this Subpart is to implement the maximum allowable concentrations of 1,4-dioxane in household cleansing products as set forth in article 35 of the Environmental Conservation Law (ECL) and for personal care and cosmetic products as set forth in Title 1 of article 37 of the ECL. This regulation includes procedures to apply for waivers as provided in articles 35 and 37, requirements for compliance evaluations of regulated products and method performance criteria for laboratory testing.

(b) Applicability

This Subpart applies to any household cleansing product that is distributed, sold, offered or exposed for sale, and to any personal care or cosmetic product that is sold or offered for sale in the State of New York.

352-1.2 Definitions

(a) ‘Continuing Calibration Verification’ means an assessment of an analytical instrument’s calibration drift and memory effects over the course of an analytical sequence.

(b) ‘Correlation Coefficient’ means the statistical relationship between two variables.

(c) ‘Cosmetic product’ means any article (1) 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 (2) intended for use as a component of any such article. The term ‘cosmetic product’ shall not include any personal care product as defined in this section for which a prescription is required for distribution or dispensation as provided in section 281 of the Public Health Law or section 6810 of the Education Law.

(d) ‘Household cleansing product’ means any product, including but not limited to, soaps, detergents, and other similar products that include an antimicrobial agent, which contain a surfactant as a wetting or dirt emulsifying agent and are used primarily for domestic or commercial cleaning purposes, including but not limited to, the cleansing of fabrics, dishes, food utensils, automobiles, and household and commercial premises. Household cleansing product shall not mean:

(1) foods, drugs and cosmetics, including personal care items such as toothpaste, shampoo and hand soap;

(2) products labeled, advertised, marketed, and distributed for use primarily as pesticides, as defined in article 33 of the Environmental Conservation Law; or

(3) cleansing products used primarily in industrial manufacturing, production and assembling processes.

(e) ‘Initial Calibration’ means a plot of instrument responses to an analyte versus known concentrations of analyte from certified reference materials. The initial calibration must cover a range containing the applicable limitation set forth in section 352-1.3 of this Part.

(f) ‘Initial Calibration Verification’ means an assessment of the reference materials used to calibrate an analytical instrument by analyzing certified reference materials obtained from a second source.

(g) ‘Internal Standard’ means a chemical substance that is similar, but not identical to, the analyte or analytes of interest that are added to a sample at a known concentration. An internal standard is used

for quantitation of 1,4-dioxane and to account for matrix effects or variability in instrument response by normalizing the response of 1,4-dioxane, or both, thereby decreasing measurement bias to the extent that their behavior mimics that of 1,4-dioxane.

(h) 'Laboratory Control Sample or Laboratory Control Sample Duplicate' means a clean matrix prepared and analyzed in the same analytical batch and in exactly the same manner as the other routine samples. The laboratory control sample or laboratory control sample duplicate is used to assess general method performance based on the ability of the laboratory to successfully recover 1,4-dioxane from the matrix.

(i) 'Limit of Detection' means the minimum concentration of an analyte that can be reliably detected with a signal to noise ratio of 3:1 or greater.

(j) 'Limit of Quantitation' means the minimum concentration of an analyte that can be reliably quantitated with defined accuracy and precision, and a signal to noise ratio of 10:1 or greater.

(k) 'Manufacturer' means any person who (1) manufactures, produces or substantially produces any covered household cleansing product, personal care product or cosmetic product for sale in the State under its own brand name or under any other brand name for sale in the State; (2) sells in the State, under its own brand name, any covered household cleansing product, personal care product or cosmetic product; (3) owns a brand name that it licenses to another person for use on any covered household cleansing product, personal care product or cosmetic product sold in the State; (4) imports any covered household cleansing product, personal care product or cosmetic product for sale in the State; or (5) manufactures any covered household cleansing product for sale in the State without affixing a brand name.

(l) 'Matrix Spike or Matrix Spike Duplicate' means samples to which known concentrations of 1,4-dioxane have been added before extraction and analysis.

(m) ‘Method Blank’ means a clean matrix containing only the internal standard. The method blank is used to assess background interference or contamination that exists in the analytical system that might lead to the reporting of elevated concentration levels or false positive data. Results from tests of the method blank should be below the limit of quantitation.

(n) ‘Multiple Reaction Monitoring’ means a mass spectrometry scanning mode whereby a particular ion mass-to-charge is selected in the first stage, fragmented in a second stage, and specific product ions resulting from the fragmentation are detected in the third stage. Multiple reaction monitoring typically results in increased sensitivity of the instrumentation.

(o) ‘Percent Recovery’ means the amount of 1,4-dioxane analyzed relative to the known amount spiked, converted to percentage.

(p) ‘Percent Relative Standard Deviation’ means a statistical analysis that determines how measurements in a data set are scattered around the average. Percent relative standard deviation is defined as the standard deviation of the measurements in the data set divided by their average, converted to percentage.

(q) ‘Person’ means any individual, partnership, firm or corporation, or unincorporated association

(r) ‘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 281 of the Public Health Law or section 6810 of the Education Law.

(s) ‘Relative Percent Difference’ means a statistical analysis between two measurements defined as the absolute difference between the two measurements, divided by their average, then converted to percentage.

(t) ‘Selected Ion Monitoring’ means a mass spectrometry scanning mode in which only a limited mass-to-charge ratio range is transmitted/detected by the instrument. Select ion monitoring typically results in increased sensitivity of the instrumentation.

(u) ‘Signal to Noise Ratio’ means a measure that compares the level of a desired signal to the level of background noise.

(v) ‘State’ means the State of New York.

352-1.3 Prohibitions.

(a) No person shall distribute, sell, offer for sale, or expose for sale in the State any household cleansing product or personal care product which contains 1,4-dioxane in excess of two parts per million on or after December 31, 2022.

(b) No person shall distribute, sell, offer for sale, or expose for sale in the State any household cleansing product or personal care product which contains 1,4-dioxane in excess of one part per million on or after December 31, 2023.

(c) No person shall distribute, sell, offer for sale, or expose for sale in the State any cosmetic product which contains 1,4-dioxane in excess of ten parts per million on or after December 31, 2022.

(d) If a manufacturer is uncertain whether a product is a household cleansing, personal care, or cosmetic product for purposes of determining which 1,4-dioxane limit applies, the manufacturer may request that the department determine the applicable product category. Such request must be submitted on a form approved by the department. The department will notify the manufacturer which product category is applicable.

352-1.4 Waiver Application.

(a) General Provisions

(1) A manufacturer of any household cleansing, personal care, or cosmetic product may apply to the department for a one-year waiver from the applicable requirements of section 352-1.3 of this Part for a specific household cleansing, personal care, or cosmetic product upon proof that the manufacturer has taken steps to reduce the presence of 1,4-dioxane in that product and is unable to comply with the applicable requirements of section 352-1.3 of this Part. Thereafter, a manufacturer may apply for one additional one-year waiver for that product, upon the submission of similar proof. Waivers will be granted in the department's sole discretion, based upon the department's evaluation of the application and the efforts undertaken by the manufacturer to comply with the 1,4-dioxane limits set forth in section 352-1.3 of this Part.

(2) A manufacturer must submit its waiver application in a format approved by the department. Each application must contain a certification signed by an authorized representative of the manufacturer. Such application with a certifying signature shall be considered a written instrument that could subject the signatory to liability under article 175 of the New York State Penal Law for filing a false statement or false information.

(3) Each household cleansing, personal care, or cosmetic product for which a waiver is sought must be individually named in the application and identified by product type, i.e., household cleansing, personal care or cosmetic product.

(4) Each household cleansing, personal care, or cosmetic product that contains the same formulation, but different fragrance blends, must be identified as a separate product, although the manufacturer can rely on the same proof for the purpose of requesting a waiver if the proof is the same. All information required in subdivision (b) of this section must be provided for each product but may be aggregated into one manufacturer-wide waiver application.

(5) At the time of submission of a waiver application, a manufacturer may request in writing that certain information in its application be deemed confidential business information by the department in accordance with the provisions of Part 616 of this Title. The department will evaluate such a request in accordance with and subject to the criteria set forth in Part 616. The name of the product, whether the product is a household cleansing, personal care or cosmetic product, and the current level of 1,4-dioxane in such product may not be claimed as confidential.

(b) Proof for Waiver

(1) A manufacturer must provide proof that it has taken steps to reduce the concentration of 1,4-dioxane for each household cleansing, personal care, or cosmetic product identified in its waiver application, but is not able to meet the 1,4-dioxane limits set forth in section 352-1.3 of this Part by the applicable statutory deadline. The waiver application must include:

(i) Certification of the concentration of 1,4-dioxane that is currently in each product for which a waiver is sought. The reported concentration must be the highest of any variation that exists on the market at the time the waiver is submitted.

(ii) A written explanation of the efforts conducted, or those that are being conducted, to reduce the concentration of 1,4-dioxane in a product or formulation, and why additional time is necessary to comply with the limits set forth in section 352-1.3 of this Part.

(iii) If a manufacturer is seeking waivers for multiple products based on the same explanation for not meeting the limitations set forth in section 352-1.3 of this Part, the manufacturer may provide a detailed explanation once and create a shorthand for such explanation to identify the products to which that explanation is applicable.

(2) While a waiver is in effect, the manufacturer must be able to produce documentation of the stated concentration of 1,4-dioxane upon request by the department. Documentation must include the information specified below.

(i) 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(s) used, show that the criteria detailed in section 352-1.6 of this Part were met, and name the lab that conducted the test(s).

(ii) If the stated 1,4-dioxane concentration is a result of a dilution calculation, such documentation must include:

('a') the name of the ingredient(s) that cause(s) 1,4-dioxane to be present in the final product;

('b') a dated test result that shows the concentration of 1,4-dioxane in the ingredient(s);

('c') documentation of the test method(s) used and that the criteria detailed in section 352-1.6 of this Part were met, and the name of the lab that conducted the test(s);

('d') the percentage of the final product that consists of each ingredient identified as containing 1,4-dioxane;

('e') the dilution calculation that was used to obtain the reported 1,4-dioxane concentration in the product; and

('f') an attestation that no other ingredients in the product contain 1,4-dioxane.

(c) Filing Process and Timeline.

A manufacturer may submit its waiver application via e-mail or regular mail following directions published by the department. The department may set a date for the submission of applications.

(d) Additional One-Year Waiver

(1) A manufacturer of any household cleansing, personal care, or cosmetic product may apply to the department for one additional one-year waiver from the applicable requirements of section 352-1.3 of this Part, in accordance with subdivisions (a)-(c) of this section upon the submission of similar proof.

(2) An application for an additional one-year waiver must update all the information required in subdivision (b) of this section that was included in the original application, in addition to updating information on the efforts undertaken towards meeting the statutory limits.

(3) An application for waiver renewal must be submitted in the third quarter of the effective timeframe of the initial waiver.

(4) Applications for an additional one-year waiver must state that more time is needed to comply with the 1,4-dioxane limitations set forth in section 352-1.3(b) or (c) of this Part. Additional one-year waivers will not be granted to allow more time to comply with the 1,4-dioxane limitations set forth in section 352-1.3(a) of this Part.

(e) Applicability of Waiver

(1) A waiver of the limitations set forth in section 352-1.3(a) or (c) of this Part will be valid through December 30, 2023. A waiver of the limitations set forth in section 352-1.3(b) of this Part will be valid until December 30, 2024.

(2) If the department grants an additional one-year waiver of the limitation set forth in section 352-1.3(b) of this Part, the waiver will be valid until December 30, 2025.

(3) A household cleansing, personal care, or cosmetic product that has been granted a waiver may be sold in the State while the waiver is in effect notwithstanding that it contains 1,4-dioxane in excess of the limits set forth in section 352-1.3 of this Part. In no case shall a waiver issued by the department be effective after December 30, 2025.

352-1.5 Compliance Evaluation.

(a) A manufacturer must conduct a compliance evaluation to demonstrate compliance with the limitations set forth in section 352-1.3 of this Part for any household cleansing, personal care, or cosmetic product that is distributed, sold, offered or exposed for sale in the State. The compliance evaluation must include one or more of the following analyses:

(1) A reasonable inquiry and documentation by the manufacturer of its raw material suppliers regarding the chemical composition of the raw materials in the household cleansing, personal care, or cosmetic product(s);

(2) A reasonable assessment by the manufacturer of the sum of the concentrations of 1,4-dioxane contributed by each raw material in the finished product formulation; and

(3) Analytical testing conducted in accordance with the criteria in section 352-1.6 of this Part, for the household cleansing, personal care, or cosmetic product(s) or raw material(s) that contribute 1,4-dioxane to the final product formulation.

(i) If a manufacturer is aware or anticipates that variation may exist between formulations of a household cleansing, personal care, or cosmetic product which may affect the concentration of 1,4-dioxane in the product, such that it would alter compliance with the applicable threshold stated in section 352.1-3 of this Part, the manufacturer must conduct the product's compliance evaluation actions for the formulation that the manufacturer expects to result in the highest 1,4-dioxane concentration and which may be distributed, sold or offered for sale in the State.

(ii) A manufacturer must retain records demonstrating that a compliance evaluation was conducted for as long as a product is distributed, sold, offered, or exposed for sale in the State, including any records demonstrating that laboratory testing was performed in accordance with section 352-1.6 of this Part.

(iii) A manufacturer must submit the compliance evaluation to the department upon request within 15 days.

352-1.6 Guidelines for Laboratory Tests

(a) The following method performance criteria ensure that analytical testing conducted to determine the concentration of 1,4-dioxane in a product or raw material is reliable and accurate. Provided all

criteria set forth in this subdivision are met, a manufacturer may utilize any analytical method to assess compliance.

(1) Sample preparation criteria.

(i) Different sample preparation techniques may be used, including but not limited to those needed for headspace, solid phase microextraction, and direct inject, provided that all other performance criteria are met.

(ii) The product should be mixed or shaken prior to sampling, as needed, to ensure the sample is representative of the product contents.

(2) Method criteria.

(i) The method must use isotope dilution with 1,4-dioxane-d_8 as an internal standard. It is recommended that the concentration of the internal standard in the sample be within the calibration range of 1,4-dioxane.

(ii) A signal to noise ratio of 3:1 must be met for all 1,4-dioxane ions in all samples, including calibration solutions.

(iii) The Limit of Detection should be at or below one tenth of the applicable limitation set forth in section 352-1.3 of this Part. For example, for products with a limit of one part per million, the limit of detection must be less than or equal to 0.1 part per million.

(iv) The Limit of Quantitation should be at or below the applicable limitation set forth in section 352-1.3 of this Part.

(v) Methods may use full scan, selected ion monitoring, or multiple reaction monitoring scanning modes to meet the limit of quantitation, depending on available instrumentation.

(vi) Methods must incorporate, at a minimum, one quantitation and one qualifier ion for 1,4-dioxane and internal standard identification.

('a') 1,4-Dioxane

(‘1’) Quantitation Ion:

(‘i’) For scan and select ion monitoring: 88

(‘ii’) For multiple reaction monitoring: 88 in the first stage; 57 in the second stage

(‘2’) Qualifier Ion:

(‘i’) For scan and select ion monitoring: 57, 58

(‘ii’) For multiple reaction monitoring: 88 in the first stage; 58 in the second stage

(‘b’) 1,4-Dioxane-d_8

(‘1’) Quantitation Ion:

(‘i’) For scan and select ion monitoring: 96

(‘ii’) For multiple reaction monitoring: 96 in the first stage; 62 in the second stage

(‘2’) Qualifier Ion:

(‘i’) For scan and select ion monitoring: 62, 64

(‘ii’) For multiple reaction monitoring: 96 in the first stage; 64 in the second stage

(3) Instrument criteria.

(i) All study samples must be analyzed on a properly calibrated instrument and meet the instrument manufacturer’s specifications. If the instrument calibrations, or other instrument check requirements (i.e., mass spectrometer tune, mass calibration check, or qualitative identification criteria), are outside the acceptable criteria, standard measures to correct the problem must be performed prior to analyzing any sample.

(ii) The use of a gas chromatograph/mass spectrometer is recommended for the chromatographic separation and fragmentation of analytes for identification. The ratios of qualifier ions should be established during calibration and must be maintained throughout sample analysis to verify the identity of 1,4-dioxane and ensure that there are no interfering peaks.

(4) Calibration.

(i) The instrument tune check must be done prior to calibration. The use of 4-bromofluorobenzene tune for full scan, and check tune for select ion monitoring and multiple reaction monitoring, is recommended.

(ii) Retention time and relative retention time requirements:

('a') the internal standard retention time must be within 0.33 minutes to mid-point of initial calibration; and

('b') the analyte retention time must be less than 0.17 minutes to mid-point of initial calibration or first Continuing Calibration Verification.

(iii) The initial calibration must utilize at least five non-zero calibration concentrations. The fitted line of the calibration curve must have a relative standard deviation of less than or equal to 20 percent of the average response factor or must be linear with a correlation coefficient greater than 0.99. The lowest calibration level must be within 50 percent of its true value.

('a') An initial calibration verification standard solution, with a concentration at or near the mid-point of the calibration curve, must be analyzed immediately following the initial calibration and be within 30 percent of its true value.

('b') A continuing calibration verification standard solution must be analyzed before sample analysis, after every tenth analytical run, and at the end of analysis. The determined concentration must be within 20 percent of the true value. If the calibration verification does not meet the acceptance criteria, perform any necessary instrument maintenance, and inject another aliquot of the continuing calibration verification solution. If the response of the analyte is still not within 20 percent of the true value, then a new initial calibration curve is recommended as described in subparagraph 352-1.6(a)(4)(iii) of this Part.

(iv) Solvent blanks should be inserted between samples with high concentration analytes to verify no carryover or cross contamination of 1,4-dioxane from one sample to the next.

(5) Quality control.

(i) All data must adhere to a quality control protocol and include a duplicate sample preparation and analysis for each product analyzed. Quality control protocols are acceptable if they incorporate steps to ensure that method blanks, analytical accuracy, and precision are maintained for each run and the protocol can demonstrate a relative percent difference less than or equal to 20 percent and an extraction recovery between 70 and 130 percent of the expected analyte concentrations. An acceptable quality control protocol must include the following:

('a') A method blank is run with every batch of up to 20 samples. The concentration of 1,4-dioxane in all method blanks must be less than the limit of quantitation.

('b') A laboratory control sample and laboratory control sample duplicate preparation are analyzed with every batch of 20 samples and must be within 30 percent of the true value and relative percent difference less than or equal to 20 percent.

('c') A matrix spike and matrix spike duplicate are analyzed with every batch of 20 samples with a recovery value within 70 and 130 percent and relative percent difference less than or equal to 20 percent. The laboratory may establish internal control limits but must not exceed the 70 to 130 percent recovery range.

('d') The retention time of the analyte of interest in the sample is less than ten seconds to the mid-point of the initial calibration or the first continuing calibration verification.

('e') The limit of quantitation must be within 50 percent recovery of the spiked reference concentration and relative standard deviation less than or equal to 20 percent of four to seven replicates.

352-1.7 Severability.

If any provision of this Part, or its application to any person or circumstance is held to be invalid, the remainder of this Part, and the application of that provision to other persons or circumstances, will not be affected.