United States Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

TSCA SECTION 5 ORDER FOR A NEW CHEMICAL SUBSTANCE

Premanufacture Notice Number (PMN)
Submission Date
Issuance Date

In accordance with the provisions of Section 5(e) of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2604(e),

[insert Company Name]

is authorized to manufacture, process, distribute in commerce, use, or dispose of the New Chemical Substance in the United States only in accordance with the requirements and conditions described in this Order.

_____ _____
Office of Pollution Prevention and Toxics Date
U.S. Environmental Protection Agency

_____ _____
Name Date

_____
Title

_____
Company

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Jurisdiction and General Provisions

This Order is issued by the United States Environmental Protection Agency ("EPA" or "the Agency") pursuant to Section 5(e) of the Toxic Substances Control Act ("TSCA"), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, 15 U.S.C. § 2604(e), regarding premanufacture notice (PMN) P- [insert PMN number] submitted by [insert Company/Submitter name] (the Company) for [insert chemical name] (New Chemical Substance).

Based upon EPA's assessment of the New Chemical Substance, the administrative record, and determinations made herein, the Company may manufacture, process, distribute in commerce, use, or dispose of the New Chemical Substance in the United States only in accordance with the requirements and conditions described in this Order.

The Company must comply with all provisions of this Order, including but not limited to, all appendices to this Order and all documents incorporated by reference. According to Section 15 of TSCA, 15 U.S.C. § 2614, it is unlawful to fail or refuse to comply with any order issued under Section 5(e) of TSCA, 15 U.S.C. § 2604(e). Any person who violates the terms of this Order may be subject to both criminal and civil liabilities pursuant to Section 16 of TSCA, 15 U.S.C. § 2615, and to specific enforcement and seizures pursuant to Section 17 of TSCA, 15 U.S.C. § 2616. Falsifying information provided to EPA or concealing Information from EPA is a violation of this Order and is subject to penalties pursuant to 18 U.S.C. § 1001.

This Order encompasses the entire agreement between the EPA and the Company with regards to the New Chemical Substance and supersedes all previous agreements between the parties whether oral or written.

The Company waives any rights to challenge the basis or validity of this Order or its terms.

The Company has carefully reviewed this Order and agrees that all information that is claimed as confidential is correctly identified within brackets and that the Company has previously submitted that information to EPA under a claim of confidentiality in accordance with the requirements of TSCA and applicable regulations. Any information that is not bracketed is not claimed as confidential and/or any previous confidentiality claim is withdrawn.

Nothing in this Order substitutes for or supersedes any statutory and regulatory requirements under TSCA or any other statute. The Company must immediately notify EPA if it obtains any information which reasonably supports the conclusion that the New Chemical Substance presents a substantial risk of injury to health or the environment, as required under Section 8(e) of TSCA, 15 U.S.C. § 2607(e). The notice must reference the appropriate PMN identification number for this substance and contain a statement that the New Chemical Substance is subject to this Order.

The terms and conditions not otherwise defined in this Order have the meaning assigned to them in TSCA or in regulations promulgated under TSCA. [HYPERLINK \l "_Appendix_1:_"] Definitions shall apply to this Order and its appendices.

EPA's Determination under Section 5(a)(3)(B)

The following determinations constitute the basis of this Order issued under Section 5(e) of TSCA, 15 U.S.C. § 2604(e):

☐EPA has determined, pursuant to Sections 5(a)(3)(B)(i) and 5(e)(1)(A)(i) of TSCA, 15 U.S.C. §§ 2604(a)(3)(B)(i) and (e)(1)(A)(i), that the information available to the Agency is insufficient to permit a reasoned evaluation of the health and environmental effects of the New Chemical Substance.

OR

☐EPA has determined, pursuant to Sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, 15 U.S.C. §§ 2604(a)(3)(B)(ii)(I) and (e)(1)(A)(ii)(I), that in the absence of sufficient information to permit the Agency to make a reasoned evaluation of the health and environmental effects of the New Chemical Substance, manufacture, processing, distribution in commerce, use, or disposal of the New Chemical Substance may present an unreasonable risk of injury to health or the environment.

OR

☐EPA has determined, pursuant to Sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II) of TSCA, 15 U.S.C. §§ 2604(a)(3)(B)(ii)(II) and (e)(1)(A)(ii)(II), that the New Chemical Substance is or will be produced in substantial quantities and that the New Chemical Substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the New Chemical Substance.

The basis for EPA's determination is attached as [HYPERLINK \l "_Appendix_2:_"] to this Order.

Requirements

The Order applies to all commercial manufacturing, processing, distribution in commerce, processing, use and disposal of the New Chemical Substance, [insert PMN number], [insert chemical name] by the Company, as follows:

I. Testing and Reporting Requirements

The Company has the following testing and/or reporting requirements:

A. Triggered Testing Requirements

The Company is prohibited from manufacturing the New Chemical Substance beyond the cumulative domestic manufacturing volumes ("Manufacturing Limit") or time ("Time Limit") set forth in Table 1 below unless the Company has submitted to EPA the final reports and data for the Required Triggered Testing, in accordance with the Testing Provisions outlined in [HYPERLINK \l "_Appendix_3:_"].

Table 1: Triggered Testing Requirements		
Manufacturing Limit (Kgs) or Time Limit	Study	Test Guideline

B. Cumulative Volume Reporting Requirements

Until the Company submits all final reports and underlying data as specified in Paragraph A above, the Company must report the cumulative manufacturing volume every [frequency of reporting] following submission of the Notice of

Commencement (NOC). These reports must be submitted [reporting conditions……. Ex by January 31st of the year subsequent to the reporting year].

This information must be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.

C. Testing/Reporting Requirements

The Company must report [insert testing and/or reporting requirement] every [frequency and duration] following submission of the Notice of Commencement (NOC).

This information must be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.

II. Terms of Manufacturing

A. Conditions of Manufacturing for the Company

The Company may manufacture the New Chemical Substance only:

☐	In an enclosed process	☐	In the form of a powder
☐	In the form of a liquid	☐	In the form of a solid
☐	Below an annual volume of [volume]	☐	In the form of a gas
☐	Below an aggregate volume of [volume]	☐	By import into the United States (i.e., no domestic manufacture)
☐	Above a Molecular Weight (Mn) of XXXXX]	☐	Other
☐	In a form that is not respirable		

☐	In an application that does NOT generate a vapor, mist, or aerosol

B. Limit on Manufacture by Others

1. The Company must not cause, encourage, or suggest the manufacture of the New Chemical Substance within the United States by any other person.
2. Termination of Certain Obligations Through Significant New Use Rule (SNUR) and Final SNUR Required Notification
   a. The prohibition in the above Paragraph 1 expires according the provisions in [HYPERLINK \l "_Appendix_4:_Termination"].
   b. Whenever the Company causes, encourages, or suggests that person manufacture the New Chemical Substance, the Company must notify that person in writing of the existence of the final SNUR, according to the conditions outlined in [HYPERLINK \l "_Appendix_4:_Termination"], and maintain a copy of such notification for 5 years.

C. Contract Manufacturing

The Contract Manufacturer(s) identified in the PMN may manufacture the New Chemical Substance pursuant to the requirements in the Order for Contract Manufacturers and in [HYPERLINK \l "_Appendix_5:_"].

The Company may petition EPA to include additional Contract Manufacturers pursuant to the Modification and Revocation Section of this Order.

III. Terms of Processing

The Company may process the New Chemical Substance only:

☐ In an enclosed process	☐ In the form of a liquid

☐ Within the site of manufacture	☐ In the form of a solid
☐ In a manner that maintains the Molecular Weight above XXXX	☐ In the form of a gas
☐ In a manner that does not generate respirable particles	☐ Other

IV. Terms of Use

The Company may use the New Chemical Substance only:

☐ In enclosed processes	☐ In the form of a powder
☐ As a site-limited intermediate	☐ In the form of a solid
☐ As an intermediate	☐ In the form of a liquid
☐ In Consumer Applications where the concentration of the New Chemical Substance does not exceed [concentration]	☐ In the form of a gas
☐ As an intermediate where of the concentration of the New Chemical Substance in the product exceeds [concentration]	☐ In an application method that does not generate a vapor, mist, dust or aerosol that results in inhalation to workers
☐ For Commercial Applications	☐ Other

V. Terms of Distribution

The Company may distribute the New Chemical Substance to another person only under the following conditions:

A. Export Notification

The Company must notify, in writing, any person to whom it distributes the New Chemical Substance, that the New Chemical Substance is subject to the notification requirements of TSCA Section 12(b), 5 U.S.C. § 2611(b), and 40 C.F.R. part 707, subpart D.

B. Written Agreement

Prior to distributing the New Chemical Substance to any person, the Company must obtain from that person a written agreement that the person will:

1. Comply with the following terms and restrictions of this Order:
   - a Protection in the Workplace ([HYPERLINK \l "_Protection_in_the"] and [HYPERLINK \l "_Appendix_610:_"]),
   - b Hazard Communication Program ([HYPERLINK \l "_Protection_in_the"]),
   - c Terms of Processing, Use, Disposal and Release to Water ([HYPERLINK \l "_Terms_of_Processing"], [HYPERLINK \l "_Terms_of_Use"], [HYPERLINK \l "_Terms_of_Disposal"] and [HYPERLINK \l "_Release_to_Water"])
2. Not further distribute the New Chemical Substance to any other person except for the purposes of disposal or according to the terms and conditions for temporary transport and storage, or to an end user who will conduct no further processing of the New Chemical Substance.

C. Containers

1. Containers must be labeled according to the requirements in the Occupational Safety and Health Administration (OSHA)'s Hazard Communication Standard set forth at 29 C.F.R. § 1910.1200.

2. Containers must be sealed.
3. Opening sealed containers, removing the New Chemical Substance or cleaning (including rinsing) the transport containers may occur only while the New Chemical Substance is in the possession and control of the Company or those having a written agreement with the Company.

D. Recipient Non-Compliance

If the Company obtains knowledge that a Recipient has failed to comply with any of the Terms of this Order, the Company must immediately cease to supply the substance to that Recipient, unless the Company is able to document that:

1. The Company, within 5 working days of obtaining knowledge of non-compliance, notified the Recipient in writing that the Recipient has failed to comply with any of the Terms of Distribution, or has engaged in a significant new use without submitting a significant new use notice (SNUN) to the EPA.
2. The Company, within 15 working days of notifying the Recipient of the noncompliance, received a written statement of assurance that the Recipient is aware of the Terms of Distribution and will comply with those terms or is aware of the terms of the SNUR and will not engage in a significant new use without submitting a SNUN to EPA.
3. The Company, after obtaining knowledge that the Recipient has failed to comply with any Terms of Distribution requirements or has engaged in a significant new use without submitting a SNUN after receiving a written statement of assurance from the Recipient, immediately ceased to supply the New Chemical Substance to the Recipient and notified EPA.
4. The Company received written notification from EPA that permits its distribution of the New Chemical Substance to the Recipient.

VI. Temporary Transport and Storage

The Company's transport of the New Chemical Substance for temporary storage must be pursuant to the following limitations:

A. Containers containing the New Chemical Substance must be sealed. Containers must be labeled according to the requirements in the OSHA Hazard Communication Standard set forth at 29 C.F.R. § 1910.1200 and should not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. § 1801 *et seq.*) and its implementing regulations issued by the Department of Transportation.

VII. Terms of Disposal

☐	The New Chemical Substance or waste streams containing the New Chemical Substance must be disposed of using the methods(s) described in the PMN.
☐	The New Chemical Substance or waste streams containing the New Chemical Substance must be disposed by:

Disposal Method	**New Chemical Substance**	**Waste Streams From**		
		Manufacturing	Processing	Use
Incineration	☐	☐	☐	☐
Landfill RCRA Subtitle C	☐	☐	☐	☐
Landfill RCRA Subtitle D	☐	☐	☐	☐
Deep Well Injection	☐	☐	☐	☐

Other: [insert]	☐	☐	☐	☐

VIII. Release to Water

☐ The Company is prohibited from any release of the New Chemical Substance, or any waste stream containing the New Chemical Substance, into water.

☐ The Company may release of the New Chemical Substance, or any waste stream containing the New Chemical Substance:

☐	With the application of one of the Treatment Technologies either by the discharger or, in the case of a release through publicly-owned treatment works (POTW), by a combination of treatment by the discharger and the POTW.	
	☐	Chemical Precipitation and settling
	☐	Biological Treatment (activated sludge or equivalent) plus clarification
	☐	Steam Stripping
	☐	Resin or activated carbon absorption
	☐	Chemical Destruction or Conversion
☐	With primary and secondary wastewater treatment as defined in 40 C.F.R. Part 133.	
☐	If the quotient from the formula: number of kilograms/day/site released ---------- x 1000 = N ppb receiving stream flow (million liters/day) does not exceed [limit], when calculated using the methods described in 40 C.F.R. 721.91.	

If for any reason the Company fails to comply with the release limitations applicable to the New Chemical Substance, the Company shall notify EPA, in writing, within 5 days of the release.

The notification must include the location of the release, an explanation and description of the reasons for the release, the amount of the release or deviation, all actions taken or to be taken to prevent or minimize the release and future release, and a schedule for implementation of any measures to be taken to prevent or mitigate effects of the release and any future releases.

IX. Protection in the Workplace

The Company must establish and implement a program to prevent workplace exposure pursuant to the Protection in the Workplace requirements in [HYPERLINK \l "_Protection_in_the"] prior to manufacturing, processing, using and/or distributing the New Chemical Substance.

X. Hazard Communication Program

The Company must establish and implement a hazard communication program consistent with the requirements in 29 C.F.R § 1910.1200 prior to manufacturing, processing, using and/or distributing the New Chemical Substance.

XI. Risk Notification

If EPA finds or determines, that despite the Company's compliance with the terms of this Order, the New Chemical Substance may be contributing to an unreasonable risk or may present an unreasonable risk, or an additional unreasonable risk to human health or the environment:

A. EPA will notify the Company, in writing, of its determination.
B. The Company must cease all manufacturing, processing, distribution, use and disposal of the New Chemical Substance, unless:

1. The Company complies with the specific actions concerning testing, hazard communication and/or limits on manufacturing, processing, distribution, use or disposal of the New Chemical Substance.
2. The Company incorporates any new risk information and information on methods for protecting against such risk, on the label and into the Safety Data Sheet (SDS), within 90 days and provide the updated SDS to all persons who receive or have received the New Chemical Substance within the last 5 years.

The Company may submit a written report refuting EPA's determination and/or the appropriateness of any additional requirements imposed by EPA.

A. The Company's report must be submitted as a support document for the PMN according to the procedures set out in 40 C.F.R. § 720.40.
B. EPA will respond promptly to the Company's report, in writing.
C. The Company, upon receipt of EPA's response, must comply with any requirements imposed by EPA's response or cease all manufacturing, processing, distribution, use and disposal of the New Chemical Substance.

XII. Recordkeeping

The Company must maintain records pursuant to the Recordkeeping Requirements outlined in [HYPERLINK \l "_Appendix_8:_Recordkeeping"] for 5 years (or longer if specified in this Order) after their creation date.

XIII. Automatic Sunset of Test Market Exemption ("TME"), Low Volume Exemption ("LVE"), and Low Release and Exposure Exemption ("LoREX")

The Company is prohibited from the manufacture, processing, distribution in commerce, use, or disposal of the New Chemical Substance pursuant to a TME under 40 C.F.R. § 720.38, or a LVE or LoREX under 40 C.F.R. § 723.50(c)(1) or (2), respectively, as of the effective date of this Order.

XIV. Exemptions

The requirements of the Order do not apply to manufacture, processing, distribution in commerce, use, and/or disposal of the New Chemical Substance in accordance with 40 C.F.R. §§ 720.3, 720.30, 720.36, and 720.38.

The manufactured volume produced under the "Export-Only Exemption", while not itself subject to the terms of this Order, counts towards the manufacturing limit or time limit of the Triggered Testing Section, if applicable in this Order.

XV. Requests for Information

This Order does not affect EPA's ability to seek information regarding TSCA regulated chemicals, including the New Chemical Substance. In order to ensure continuing compliance with the terms of this Order, EPA may issue a request for information to the Company at any time after the effective date of this Order. Failure to respond to such a request shall be a violation of this Order.

XVI. Successor Liability Upon Transfer of Order

The Company may transfer its interest in the New Chemical Substance, including its ability to manufacture the New Chemical Substance conferred by this Order, to a Successor in Interest pursuant to the Successor Liability Upon Transfer of Order requirements in [HYPERLINK \l "_Appendix_10:_"].

XVII. Modification and Revocation of the Order

The Company may request at any time, in writing and based upon new information that EPA modify or revoke provisions of this Order.

EPA may modify or revoke provisions of this Order if EPA determines that specific requirements of this Order are no longer necessary to protect against a previously identified risk, or upon consideration of any information, new or existing, that the New Chemical Substance is not likely to present an unreasonable risk of injury to health or the environment.

EPA may, at any time, upon the receipt or evaluation of any information, new or existing, determine that the New Chemical Substance presents or may present an unreasonable risk of injury to health or the environment, and may issue a rule to regulate the substance or modify this Order to address any risks.

XVIII. Office of Management and Budget (OMB) Control Number

Under the Paperwork Reduction Act and its regulations at 5 C.F.R. part 1320, the Company is not required to respond to this collection of information unless this Order displays a currently valid control number from OMB. The collection of information required in this Order has been approved under the currently valid OMB Control Number 2070-0012.

XIX. Reservation of Rights

Except as specifically provided in this Order, nothing in this Order shall limit EPA's authority to take, direct, or order any action necessary to protect public health, welfare, or the environment. This Order does not prevent EPA from seeking legal or equitable relief to enforce the terms of this Order, from taking other legal or equitable action as it deems appropriate and necessary, or from requiring the Company in the future to perform additional activities pursuant to TSCA or any other applicable law.

EPA may use any information submitted under this Order in an administrative, civil judicial or criminal action.

XX. Effective Date

This Order is effective upon expiration of the applicable review period.

XXI. Potentially Useful Information

"Potentially Useful Information" (Table 2) would assist in evaluating the potential effects caused by the New Chemical Substance.

Table 2: Potential Useful Information		
Information	Effects	Guideline(s)

The Company is not required to submit the "Potentially Useful Information."

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Appendix 1: Definitions

"Chemical protective clothing" means items of clothing that provide a barrier to prevent dermal contact with chemical substances of concern (e.g., clothing that covers the entire body, boots, coveralls, gloves, jackets, and pants).

"Commercial" means the use of a chemical substance or a mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry-cleaning establishment or painting contractor).

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a TSCA regulated chemical. For purposes of this Order, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture the New Chemical Substance under the conditions specified in Appendix 5 of this Order.

"Enclosed Process" means any equipment system (reactor, mixing vessel, storage tank) in which the New Chemical Substance is manufactured, processed, or otherwise used where the New chemical substance is not in direct contact with the workplace air or the environment.

"Equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-reviewed protocols, are inconclusive, internally

inconsistent, or otherwise insufficient to support a reasoned evaluation of the potential risk of injury to human health or the environment of the New Chemical Substance.

"Immediate use" means a use of a chemical substance that is under the control of, and used only by, a person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Intermediate" means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of another chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rates of such chemical reactions.

"Manufacture" means to produce or manufacture in the United States or import into the customs territory of the United States. This definition also applies to related noun and verb forms of "manufacture."

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Open process" is any method of manufacture using equipment (such as a reactor, storage tank, or mixing vessel) causing the new chemical substance to be direct contact with the atmosphere.

"Personal protective equipment" means any protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and respirators. Barrier creams are not included in this definition.

"New Chemical Substance" means the chemical substance described in the premanufacture notice submitted by the Company relevant to this Order.

"Scientifically invalid" means departing in any significant way from the EPA-reviewed protocol or the Good Laboratory Practice Standards at 40 C.F.R. part 792 such that the data do not support a reasoned evaluation of the health or environmental effects of the New Chemical Substance.

"SDS" means safety data sheet, the written listing of data for the chemical substance.

"Sealed" means a closed container that is physically and chemically suitable for long-term containment of the New Chemical Substance, and from which there will be no human exposure to, nor environmental release of, the New Chemical Substance during transport and storage.

"Site-limited intermediate" means an intermediate manufactured, processed, and used only within a site and not distributed in commerce other than as an impurity or for disposal. Imported intermediates cannot be "site-limited."

"Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the New Chemical Substance, including all ownership rights and legal liabilities, through a Transfer Document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the New Chemical Substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the New Chemical Substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 C.F.R. § 720.22(a)(3) and 40 C.F.R. § 720.3(z).

"Transfer Document" means the legal instrument(s) used to convey the interests in the New Chemical Substance, including the right to manufacture the New Chemical Substance, from the Company to the Successor in Interest.

"Work area" means a room or defined space in a workplace where the New Chemical Substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

Appendix 2: Basis for EPA's Determination

The basis for the determination will be provided

Appendix 3: Testing Provisions

I. Notice of Test Scheduling

A. The Company must notify EPA's Monitoring Assistance and Media Programs Division, in writing, the following information within 10 days of scheduling any study or within 15 days after the effective date of this Order, whichever is later:

1. The date when the study is scheduled to commence;
2. The name and address of the laboratory conducting the study;
3. The name and contact information (telephone number, email) of a person at the Company or laboratory whom EPA may contact regarding the study; and,
4. The PMN identification number for each substance and a statement that the substance is subject to this Order.

B. The written notice should be submitted to EPA/OECA as follows:

Postal Mail Address

U.S. Environmental
U.S. Environmental Protection Agency
GLP Section Chief – Pesticides, Water and Toxics Branch
Monitoring Assistance and Media Programs Division (2227A)
Office of Enforcement and Compliance Assurance
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Courier Delivery Address

U.S. Environmental Protection Agency
GLP Section Chief – Pesticides, Water and Toxics Branch
Monitoring Assistance and Media Programs Division (2227A)
Office of Enforcement and Compliance Assurance
Room 7117B
1200 Pennsylvania Avenue, N.W.
Washington, DC 20004

C. Concurrently, the Company must submit a copy of the information as a support document, using the procedures set out in 40 C.F.R. § 720.40.

II. Good Laboratory Practice Standards

Each test performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 C.F.R. part 792.

III. Modified Test Protocols

A. Prior to initiating any test that will use a modified version of a test protocol, the Company must first submit the test protocols to EPA and receive EPA's approval.

B. Test protocols must be submitted as a support document, using the procedures set out in 40 C.F.R. § 720.40.

C. EPA's acceptance of a test protocol does not constitute pre-acceptance of any future test results.

IV. Submission of Test Reports and Underlying Data.

A. The Company must submit the final report (public and Confidential Business Information (CBI) versions, if applicable) and all underlying data, within 90 days of the conclusion of the test.

B. The final report must contain the contents specified in 40 C.F.R. § 792.185.

V. Raw Data

A. EPA may, at its discretion, require the Company to submit raw data, such as slides and laboratory notebooks.

B. The Company must provide raw data to EPA within 30 days of EPA's initial request for such data.

VI. Interim Results

A. EPA may require the Company to submit the results of an interim phase of a test.

B. The Company must provide interim results to EPA within 30 days of EPA's initial request for such results.

VII. Submission of Information

All test information must be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.

VIII. Effect of Equivocal Results

A. If EPA determines the results are scientifically equivocal, the testing requirements, test protocols or Manufacturing Limit may be modified, by an amendment to this Order.

B. The Company may be allowed to continue to manufacture the New Chemical Substance if EPA notifies the Company in writing.

IX. Determination of Invalid Data

A. If the Company finds that data is scientifically invalid, the Company must:

1. Notify EPA, in writing, within 2 weeks of first finding or becoming aware that data generated by a test is scientifically invalid.
2. Explain in detail, the circumstances which have caused, or will cause, development of scientifically invalid data within 2 weeks of providing the notice of invalid data to EPA.
3. Cease manufacture of the New Chemical Substance beyond the Manufacturing or Time Limit. The Company may continue manufacture of the New Chemical Substance beyond the Manufacturing or Time Limit if EPA notifies the Company in writing.

B. If EPA finds that data is scientifically invalid, EPA:

1. Will notify the Company, in writing.
2. May modify the testing requirements, test protocols or Manufacturing or Time Limit, by an amendment to this Order.

3. May require the Company to reconduct the testing and submit the final report and underlying data.
4. May allow the Company to manufacture the New Chemical Substance beyond the Manufacturing Limit or Time Limit if EPA notifies the Company in writing.

C. Refuting EPA's Determination:

1. The Company may refute EPA's determination of invalid data by submitting a written report to EPA.
2. The report must be submitted within 4 weeks of receiving the determination of invalid data from EPA.

Appendix 4: Termination of Certain Obligations through Significant New Use Rule (SNUR) and SNUR Notification Requirements

I. Termination of Certain Obligations Through a SNUR

The requirement in Section II.B.1 in this Order [Limit on Manufacture by Others] expires 75 days after promulgation of a final SNUR corresponding to this Order under Sections 15 U.S.C. §§ 2604(a)(2) and 2604(f)(4) of TSCA, unless the Company is notified by EPA of an action in a Federal Court seeking judicial review of the SNUR. The Prohibition will remain in effect until EPA notifies the Company that all Federal Court Actions have been resolved and the validity of the SNUR has been affirmed.

II. Final SNUR Required Notification

A. Whenever the Company causes, encourages or suggests the manufacture, processing, use or distribution of the New Chemical Substance, the Company must notify that person in writing the existence of the final SNUR.

B. The required notification must be in writing; reference the publication in the Federal Register or Code of Federal Regulations; and must specify all significant new uses under the SNUR that would require significant new use notice to EPA.

C. The written notification must be maintained for 5 years from the date of its creation.

Appendix 5: Contract Manufacturers

I. Contract Manufacturer Limitation

A. The Contract Manufacturer(s) must be identified in the PMN.

B. The Company may request in writing to EPA that the Order be modified to include additional Contract Manufacturers.

II. Manufacture Solely for the Company

A. The Contract Manufacturer must be under contract to manufacture the New Chemical Substance solely for the Company.

B. The contract must specify the identity of the New Chemical Substance, the total quantity to be manufactured, and the basic technology to be used for manufacturing.

C. The Company must submit to EPA, the name, address, and telephone number of the responsible official of the Contract Manufacturer(s).

III. Signed Order

A. EPA will prepare and transmit an Order for each Contract Manufacturer ("Order for Contract Manufacturer") following the terms agreed to by the Company in this Order.

B. The Contract Manufacturer must sign and return the Order for Contract Manufacturer to EPA prior to commencing the manufacture of the New Chemical Substance.

IV. Contract Manufacturer Noncompliance

If the Company learns that a Contract Manufacturer has failed to comply with any provisions in the Order for Contract Manufacturer, the Company must immediately cease the manufacture the New Chemical Substance unless:

A. The Contract Manufacturer is in compliance with a SNUR for the New Chemical Substance, or

B. The Company:

1. Notified the Contract Manufacturer, within 5 working days, in writing that the Contract Manufacturer has failed to comply with the Order for Contract Manufacturer, and
2. Received from the Contract Manufacturer, within 15 working days a statement of assurance that the Contract Manufacturer is aware of the terms of the Order for Contract Manufacturer and will comply with those terms.

C. If, after receiving a statement of assurance, the Company obtains knowledge that the Contract Manufacturer has failed to comply with the provisions in the Order for Contract Manufacturer, the Company must:

1. Immediately cease the manufacturing at the Contract Manufacturer facility,
2. Notify EPA of the noncompliance, and
3. Prevent the manufacture of the New Chemical Substance by the Contract Manufacturer until the Company has received written notification from EPA.

Appendix 6: Protection in the Workplace

The Company is prohibited from manufacturing, processing or using the New Chemical Substance without establishing and implementing the following:

☐	Engineering and Administrative Controls
☐	Dermal Personal Protective Equipment
☐	Respiratory Protection

I. Engineering and Administrative Controls

The Company must implement engineering control measures (e.g., enclosure or confinement of the operation(s), general and local ventilation) or administrative control measures (e.g., workplace policies and procedures), where feasible, to prevent exposure to the New Chemical Substance.

II. Dermal Personal Protective Equipment

A. The Company must ensure that each employee reasonably likely to be dermally exposed through direct handling or contact with equipment or surfaces containing or contaminated with the New Chemical Substance is provided with, and is required to wear, personal protective equipment ("PPE") that provides a barrier to prevent dermal exposure.

B. PPE must be selected and used in accordance with the Occupational Safety and Health Administration (OSHA)'s requirements at 29 C.F.R. §§ 1910.132, 1910.133, and 1910.138.

C. Gloves must be replaced at the end of each work shift during which they are exposed to the New Chemical Substance. If permeation testing was used to establish impermeability, gloves may not be used for longer than for which they were tested.

D. Demonstration of Imperviousness

The Company must demonstrate that the PPE selected provides an impervious barrier to prevent dermal exposure during expected duration and conditions of exposure. The Company may make this demonstration by any one or a combination of the following:

1. Permeation Testing

   PPE must be tested alone and in combination with other chemical substances in the work area under the expected conditions of exposure. Permeation testing should be conducted according to the American Society for Testing and Materials (ASTM) F739 "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact." Results must be reported as the cumulative permeation rate as a function of time and documented in accordance with ASTM F739 using the format specified in ASTM F1194-99 (2010) "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials."

2. Manufacturer Specifications

   Manufacturer specifications may be used to establish that the PPE is impervious to the New Chemical Substance, alone and in combination with other chemical substances in the work area under the expected conditions of exposure.

III. Respiratory Protection

A. Respirators

1. The Company must ensure that each person subject to inhalation is provided with, and is required to wear, a National Institute for Occupational Safety and Health (NIOSH)-certified [Particulate][Gas/Vapor][Combination Particulate and Gas/Vapor] respirator with an Assigned Protection Factor (APF) of [Insert APF].

2. All respirators must be issued, used and maintained according to an appropriate respiratory protection program in accordance with OSHA and NIOSH respiratory protection requirements in 29 C.F.R. § 1910.134 and 42 C.F.R. part 84.

B. New Chemical Exposure Limit (NCEL)

1. As an alternative to the respirator requirements listed in Section III.A of this Appendix, the Company may comply with the requirements of this New Chemical Exposure Limit Section.
2. Before the Company may deviate from the respirator requirements, however, the Company must:
   a. Submit the sampling and analytical method for the New Chemical Substance, verified in accordance with [HYPERLINK \l "_Appendix_115:_Performance-Criteria"], as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.
   b. Obtain exposure monitoring results in accordance with [HYPERLINK \l "_Appendix_126:_Monitoring"].
   c. Select, provide, and ensure use of the appropriate respiratory protection, based on the exposure monitoring results.
   d. Submit the exposure monitoring results and selection criteria for respiratory protection as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.
3. NCEL Determination
   a. The NCEL for the New Chemical Substance is an interim level based on the limited information available to EPA at the time of development of this Order. The NCEL for the New Chemical Substance is as follows:
      i. Time-Weighted Average ("TWA") Limit.
         The Company must ensure that no person is exposed to an airborne concentration of the New Chemical Substance in excess of [insert limit] (the NCEL) as an 8-hour time-weighted average, without using a respirator

in accordance with the NCEL Respiratory Protection Section of this Appendix.

ii. Non-8-Hour Work-shifts.

For non-8-hour work-shifts, the NCEL for that work-shift (NCELn) must be determined by the following equation: NCELn = NCEL x (8/n) x [(24-n)/16], where n = the number of hours in the actual work-shift.

iii. Short-Term Exposure Limit ("STEL").

The Company must ensure that no person is exposed to an airborne concentration of the New Chemical Substance in excess of [insert limit] (the short-term exposure limit) as averaged over any 15-minute period, without using a respirator in accordance with this New Chemical Exposure Limit Section.

b. Automatic Sunset.

If, subsequent to the effective date of this Order, OSHA promulgates, pursuant to Section 6 of the Occupational Safety and Health Act, 29 U.S.C. part 655, a final chemical-specific permissible exposure limit (PEL) applicable to this New Chemical Substance and the OSHA PEL is not challenged in court within 60 days of its promulgation, then any respirator requirements in the Protection in the Workplace section of this Order and any requirements of this New Chemical Exposure Limit section applicable to workers and situations subject to the OSHA PEL will automatically become null and void. The requirements of this Order, however, are not negated by any pre-existing OSHA PEL applicable to the New Chemical Substance.

4. NCEL Respiratory Protection

a. Selection of Appropriate Respiratory Protection

The required respiratory protection is based on the airborne concentration measured during the exposure monitoring.

[The appropriate table will be populated]

b. Reductions in Respiratory Protection

i. Before the Company may make any reduction in any respiratory protection pursuant to this New Chemical Exposure Limit Section, the Company must verify, by 2 consecutive measurements taken at least 7 days apart, that the new respiratory protection is appropriate in accordance with this Appendix.

ii. If the New Chemical Substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements must be taken at least 24 hours apart. The measurements must accurately reflect the highest peak and variability in exposures.

c. Special Situations

i. Measurements Outside Quantitation Limits.

When a value less than the lower quantitation limit (LQL) of the analytical method (as described in [HYPERLINK \l "_Appendix_115:_Performance-Criteria"]) is obtained, the Company must estimate potential exposure using generally established and accepted statistical methods. If the Company obtains an exposure monitoring sample that is more than 10% above the upper quantitation limit (UQL) of the analytical method, the Company must ensure that its workers wear at least a NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece. Any reductions in respiratory protection must comply with the requirements of this Appendix.

ii. Cleanup and Remedial Actions.

During any special cleanup or other remedial actions that may occur before commencing additional exposure monitoring, the Company must ensure that potentially exposed persons use at least the respiratory protection for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

d. NCEL Recordkeeping

Whenever the Company elects to comply with this New Chemical Exposure Limit Section, the Company must maintain the records according to the requirements set forth in [HYPERLINK \l "_Appendix_148:_NCEL"] for 30 years after the date they are created, and the Company must make them available for inspection and copying by EPA in accordance with Section 11 of TSCA, 15 U.S.C. § 2610.

Appendix 7: Recordkeeping

The Company shall maintain the following records for 5 years after the date they are created (or longer if required in this Order) and must make them available for inspection and copying by EPA in accordance with Section 11 of TSCA, 15 U.S.C. § 2610:

I. Manufacturing Volume

Records documenting the manufacturing volume (including import) of the New Chemical Substance and the corresponding dates of manufacture (import).

II. Sites of Manufacture

Records documenting the address of all sites of manufacture, import, processing and use.

III. Sales and Transfers

Records documenting the date of all sales or transfers, the quantity of the New Chemical Substance sold or transferred, and the names and addresses (including shipping address, if different) outside the site of manufacture to whom the Company directly sells or transfers the New Chemical Substance.

IV. Protection in the Workplace

A. Protection in the Workplace Requirements

Records documenting establishment and implementation of a program pursuant to the requirements in Protection in the Workplace Section and Appendix. Records used to demonstrate compliance under 20 C.F.R. § 1910.1200(e) may be used to satisfy this record keeping obligation if such records fulfill the requirements in Protection in the Workplace Section and Appendix.

B. Demonstration of Imperviousness

Records documenting the determinations that chemical protective clothing is impervious to the New Chemical Substance.

C. New Chemical Exposure Limits

Records required by the NCEL Section of this Order must be maintained for 30 years after the date they are created.

D. Hazard Communication Program

1. Records documenting establishment and implementation of a Hazard Communication Program.
2. Copies of labels.
3. Copies of Safety Data Sheets.

V. Compliance with this Order

A. Terms of Manufacturing, Processing, Use, Distribution and Disposal

Records documenting compliance with the applicable manufacturing, processing, use, distribution and disposal requirements in this Order.

B. Disposal Requirements

Records documenting compliance with the applicable disposal requirements including method of disposal, location of disposal sites, dates of disposal and volume of New Chemical Substance. If the estimated disposal volume is not known or reasonable ascertainable by the Company, records must be maintained that demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirement(s).

C. Water Discharge Limits

Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limit including location of treatment facility, permit numbers issued under all federal environmental statutes, method of

treatment, monitoring and release records, and/or additional information in support of compliance.

VI. Exemption Records

Records documenting compliance to the requirements for one or more of the exemptions that satisfy the statutory and regulatory requirements applicable to the exemption.

A. Export-Only Exemption

For any amounts or batches of the New Chemical Substance eligible for the Export-Only Exemption, the Company must maintain, for 5 years from the date of their creation, copies of the export label and export notice to EPA, as required by TSCA Sections 12(a)(1)(B) and 12(b).

B. Research & Development Exemption

For any amounts or batches of the New Chemical Substance eligible for the Research and Development Exemption, the Company must maintain, for 5 years from the date of their creation, the records required by 40 C.F.R. § 720.78(b).

Appendix 8: Successor Liability Upon Transfer of Order

The Company may transfer its interest in the New Chemical Substance, after the New Chemical Substance has been placed on the TSCA Inventory. The terms of this Order apply to a Successor in Interest, pursuant to the following requirements:

1. The Notice of Transfer of Toxic Substances Control Act Section 5(e) Order (Notice of Transfer) must be fully executed before the Successor in Interest manufactures the New Chemical Substance.
2. The Notice of Transfer shall clearly state the effective date of the transfer of interest in the New Chemical Substance and must contain provisions which expressly transfer liability for the New Chemical Substance under the terms of this Order from the Company to the Successor in Interest.
3. Copies of the Notice of Transfer must be maintained by the Successor in Interest at its principal place of business, and at all sites where the New Chemical Substance is manufactured.
4. The Notice of Transfer when fully executed shall be incorporated as, and become an enforceable part, of this Order.
5. The Successor in Interest is liable for compliance with the requirements and obligations of the Order as of the date of the transfer of interest in the New Chemical Substance.
6. The Notice of Transfer shall be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40, within 10 days of the effective date of the transfer.
7. Any new confidentiality claims asserted in the Notice of Transfer must be substantiated at the time of the submission in accordance with TSCA Section 14(c)(3), 15 U.S.C. § 2613(c)(3). Guidance on substantiating CBI claims may be found at [HYPERLINK "https://www.epa.gov/tsca-cbi/substantiating-cbi-claims-under-tsca-time-initial-submission"]. A Notice of Transfer cannot modify a CBI claim made by the PMN Submitter to assert a claim of confidentiality for information which has been released to the public by EPA because (1) PMN Submitter did not assert a CBI claim for that information, or (2)

notwithstanding such a claim, EPA disclosed the information to the public in accordance with its authority under TSCA or applicable regulations.

NOTICE OF TRANSFER OF TOXIC SUBSTANCES CONTROL ACT

SECTION 5(e) ORDER

[Insert Company name] (Transferor)

[Insert name of New Chemical Substance] (New Chemical Substance)

[Insert PMN Number] (PMN Number)

1. Transfer of Interest in New Chemical Substance Pursuant to Terms of the Order. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") its interests in the above-referenced New Chemical Substance, which was the subject of a premanufacture notice ("PMN") and the manufacture of which is governed by an Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of Section 5(e) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. §2604(e).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, it has assumed all obligations conferred under the Order. The Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 C.F.R. § 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby (check one):

___ Reasserts

___ Relinquishes

___ Modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA, 15 U.S.C. § 2613, and 40 C.F.R. part 2, for the New Chemical Substance(s). Where "reasserts" or "relinquishes" is indicated, that designation will be deemed to apply to all such claims. Where "modifies" is indicated, such modification will be explained in detail in an attachment to this Notice of Transfer.

I certify that it is true and accurate that the Successor in Interest has:

(a) Taken reasonable measures to protect the confidentiality of the information;

(b) Determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
(c) A reasonable basis to conclude that the disclosure of the information is likely to cause substantial harm to the competitive position of the Successor in Interest; and
(d) A reasonable basis to believe that the information is not readily discoverable through reverse engineering.

CBI claims for chemical identity must be accompanied by a generic chemical identity, which may be that used for the PMN.

Company (Transferor)	PMN Number
Signature of Authorized Official	Date
Printed name of Authorized Official	
Title of Authorized Official	
Successor in Interest	Date
Signature of Authorized Official	Successor's Technical Contact
Printed Name of Authorized Official	Phone
Title of Authorized Official	Address
Address	City, State, Zip Code
City, State, Zip Code	

Appendix 9: Performance-Criteria for Sampling and Analytical Method

I. Applicability

A. For initial development and validation of the sampling and analytical method for the New Chemical Substance, all the requirements of this Appendix apply.

B. For subsequent exposure monitoring conducted pursuant to Appendix 10 Monitoring Potential Exposure, only the following requirements of this Appendix apply: Sections (IV)(A), (IV)(C)(2), (IV)(D)(2), (VIII), and (IX). Any deviation from the requirements of this Appendix must be approved in writing by EPA.

II. Submission of Verified Method and Certification Statement

A. The Company must submit to EPA a copy of a validated sampling and analytical method for the New Chemical Substance which satisfies the criteria specified in this Appendix.

B. The method description must expressly state how the method compares with each quantitative requirement specified in the Performance-Criteria for Sampling and Analytical Method Section.

C. The submission must include a written statement, signed by authorized officials of both the Company and an independent reference laboratory (the Laboratory), certifying the truth and accuracy of the independent laboratory verification conducted pursuant to the requirements of this Appendix.

D. To assist EPA in identifying the document, it must state in a conspicuous, underlined subject-line at the top of the first page: "NCEL Sampling and Analytical Method for PMN # _____," after which the correct PMN number for the New Chemical Substance must be stated.

E. This information must be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.

III. Verification of Analytical Method by Independent Third-Party Laboratory

A. Verification

1. The Company must have the Laboratory, an independent reference laboratory, verify the validity of the analytical method for the New Chemical Substance, in accordance with the other requirements in this Appendix.
2. It is the Company's responsibility to ensure that the Laboratory complies with all the requirements specified in this Appendix.

B. Independent Reference Laboratory

The Laboratory must be a separate and distinct person (as defined at 40 C.F.R. § 720.3(x)) from the Company and from any other person who may have developed the method for the Company.

C. Accreditation

The Laboratory must be accredited by a formally recognized government or private laboratory accreditation program for chemical testing and/or analysis.

D. Good Laboratory Practice Standards

The analytical method verification by the Laboratory must comply with TSCA Good Laboratory Practice Standards ("GLPS") at 40 C.F.R. part 792. Certain provisions of the TSCA GLPS related to toxicity testing in laboratory animals, 40 C.F.R. § 792.43 "Test system care facilities", 40 C.F.R. § 792.45 "Test system supply facilities" and 40 C.F.R. § 792.90 "Animal and other test system care", are inapplicable to the NCEL requirements. Compliance with TSCA GLPS, however, is not required under this New Chemical Exposure Limit Section where the analytical method is verified by a laboratory accredited by either: the American Industrial Hygiene Association ("AIHA") Industrial Hygiene Laboratory Accreditation Program ("IHLAP") or another comparable program approved in advance in writing by EPA.

E. Analysis of Duplicate Samples

1. The Company must collect six duplicate samples (a total of 12) at the TWA concentration.
2. The samples must be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the New Chemical Substance onto a sample collection device.
3. The duplicate samples must be collected on identical collection media, at the same time, and under the same conditions.
4. One set of six samples must immediately be analyzed by the Company, the other set of six samples must be analyzed by the Laboratory using the method developed by or for the Company.

F. Sample Storage Study

1. If the results of the duplicate samples do not satisfy the requirements in Comparison of Results Section, the Company must perform a sample storage study as follows:
   a. Triplicate Samples
      i. The Company must collect six triplicate samples (a total of 18) at the TWA concentration.
      ii. The samples must be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the New Chemical Substance onto a sample collection device.
      iii. The triplicate samples must be collected on identical collection media, at the same time, and under the same conditions. One set of six samples must immediately be analyzed by the Company.
   b. Analysis After Sample Storage

i. A sample storage evaluation must be performed with the two remaining sets of six samples.

ii. One set of six samples must be analyzed by the Laboratory using the method developed by or for the Company, and the other must be analyzed by the Company on the same day as the Laboratory analyzes its six samples.

iii. The samples must be stored, extracted (if applicable), and analyzed under similar conditions and time frames.

G. Comparison of Results

1. The analytical samples must be evaluated according to the method described in the Statistical Analysis of NCELs Analytical Method Verification Appendix.
2. The samples must be evaluated using a two-sample t-test with unequal variances. The two sides of the critical regions must not exceed a 5% significance level.
3. The average of each set of six samples must be within 10% of the true value.
4. If the average of each set of six samples is not within 10% of the true value, then the sample storage time between collection and analysis must be reduced until the average is within 10%.

H. Submission of Analytical Method Validation

This information must be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.

IV. Accuracy

The sampling and analytical method must clearly demonstrate the following:

A. NCEL Quantitation Limits

1. The sampling and analytical method, and all exposure monitoring data relied on by the Company, must be accurate to within ±25% at a 95% confidence level for

concentrations of the New Chemical Substance ranging from one half the NCEL to twice the NCEL.

2. The analytical method must be capable of reliably quantifying from a lower quantitation limit ("LQL") of one half the NCEL to an upper quantitation limit ("UQL") of at least twice the NCEL.
3. If the Company obtains an exposure monitoring sample that is more than 10% above the actual UQL of the analytical method, the Company must comply with Measurements Outside Quantifications provisions of the NCEL Respiratory Section.

B. Lower Quantitation Limit Signal-To-Noise Ratio

1. The analytical method must be capable of quantifying the PMN to a concentration of one half the NCEL with a signal that is at least five times the baseline noise level.
2. Baseline noise must be amplified to a measurable level when possible, even if the required amplification is beyond that used in routine analysis of samples. (If baseline noise cannot be obtained, another reference must be selected. This may be a peak considered to be noise caused by the reagent matrix.)
3. The sampling preparation method must be specified and the detection limit for the analytical procedure must be reported as mass per injection for chromatographic techniques.

C. Instrument Calibration

1. Initial Calibration
   a. For method development and validation (but not subsequent exposure monitoring), the initial calibration must at a minimum consist of five (5) calibration standards with a linear correlation of 0.95.
   b. The five (5) calibration standards must consist of one standard at each of the following concentrations: one half the NCEL (0.5 x NCEL); between one half and one times the NCEL (>0.5 x NCEL,< 1 x NCEL); one times the NCEL (1

x NCEL); between one and two times the NCEL (>1 x NCEL, < 2 x NCEL), and twice the NCEL (2 x NCEL).

2. Continuing Calibration
   a. During each week of both method development/validation and exposure monitoring, the Company must conduct both an initial instrument calibration and a continuing calibration.
   b. The Company must perform at least one continuing calibration sample at the NCEL concentration, and at least one additional calibration sample per every 10 samples analyzed.
   c. The continuing calibration sample must fall within ± 25% of the initial calibration value. If not, then the initial calibration must be repeated, and any samples associated with that outlying calibration check must be re-analyzed.

D. Calculated Percent Recovery.
   1. Initial Calculation.
      a. For method development and validation, the Company must calculate the percent of the New Chemical Substance recovered by the analytical method from a sample containing a known quantity of the New Chemical Substance.
      b. The sample must be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the New Chemical Substance onto a sample collection device. (Such a sample is referred to as a "matrix spike").
      c. The calculated percent recovery for each matrix spike must be greater than or equal to 75% and less than or equal to 125%.
      d. Spike concentrations for the New Chemical Substance must be included in the sampling and analytical method submitted to EPA.
   2. Subsequent Calculation

During each subsequent exposure monitoring episode or campaign, at least 1 matrix spike, prepared by injecting the New Chemical Substance onto a sample collection device, must be analyzed. (This matrix spike must be prepared at the NCEL concentration.)

E. Sampling Device Capacity

1. The capacity of the sampling device must be tested, and results reported to show under a known and well-defined set of conditions that the device is capable of collecting the new chemical in solid, liquid or vapor phase with minimal loss.
2. The sampling device's capacity (air volume and collected analyte mass) must be specified. For methods that use adsorbent tubes as the collection medium, evidence of the capacity must be provided in the form of breakthrough testing.
3. This testing must be done at a concentration twice the NCEL and under conditions expected in the workplace.
4. Breakthrough is defined to have occurred when the concentration of the New Chemical Substance in the effluent stream is equal to 5% of the concentration of the influent stream, or when 20% of the New Chemical Substance is detected in the backup section of the sampler.

F. Sampling Device Desorption Efficiency

1. Where applicable, the desorption efficiency must be evaluated for the air sampling device.
2. A minimum of six air samples spiked with the New Chemical Substance at least the NCEL concentration must be prepared.
3. A recovery of at least 75% must be obtained for each of the six samples.

V. Precision

The estimate of the coefficient of variation of each set of six samples from the controlled atmosphere test (spiked at 1.0 NCEL, in Analysis of Duplicate Samples or Sample Storage Study must be less than 0.105, including allowance of 0.05 for error due to sampling.

VI. Interpretation of Accuracy and Precision Data

A. If a single matrix spike recovery is less than 75% recovery or greater than 125% or the estimated precision is greater than 0.105, then the Company must re-prepare the matrix spike, re-sample, and re-analyze all samples associated with such matrix spike or triplicate samples.

B. For percent recoveries less than 90% but greater than 75%, correction for low recovery is required. Correct for recovery first by dividing the observed amount by the proportion recovered before determining if measurements fall below the NCEL. For example, if the observed level is 30 mg/m3 and the percent recovery is 75%, use the value 30 mg/m3/(0.75) = 40 mg/m3 when determining whether the levels are below the exposure limit.

VII. Representativeness

All sample conditions used to develop the methodology must mimic the actual workplace environment. Conditions such as the temperature, humidity, lighting, and presence of other chemicals, etc. must mimic the conditions in the workplace.

VIII. Changes Affecting Validity

A. Changes in the workplace environment that may invalidate the verified sampling and analytical method for the New Chemical Substance include but are not limited to:

1. introduction of a new chemical substance
2. changes in the light in the workplace
3. changes in the water or humidity

B. The Company must comply with the Respirator Requirement until the sampling and analytical method has been verified under the new workplace environment.

IX. Comparability

All data and results must be reported in the same units of measurement as the NCEL.

X. Responsibility for Method Validity

The independent Laboratory verification and EPA receipt of the sampling and analytical method does not ensure that the method will produce valid exposure monitoring data. The Company is responsible for ensuring the validity of its exposure monitoring data.

Appendix 10: Monitoring Potential Exposure

I. General

A. Action Level

1. The "action level" is defined as an airborne concentration of the New Chemical Substance, calculated as an 8-hour time-weighted average (TWA), equal to one half the NCEL.
2. For non-8-hour work shifts, the action level is equal to one half the NCELn.
3. The purpose of the action level is to determine the mandatory monitoring frequency.

B. Representative Exposure Groups

1. Whenever exposure monitoring is required by the New Chemical Exposure Limit section, the Company must take representative samples of each person who is reasonably likely to be exposed to the New Chemical Substance.
2. The Company must sample the breathing zone air of at least one person that represents, and does not underestimate, the potential exposure of every person performing the same or substantially similar operations for each work shift, in each job classification, in each work area (hereinafter identified as an "exposure group") where inhalation exposure to the New Chemical Substance is reasonably likely to occur.
3. The exposure of each person need not be itself directly sampled if that exposure is represented by sampling the exposure of another person in the same exposure group.

C. Good Laboratory Practice Standards

Exposure determinations must be performed according to TSCA Good Laboratory Practice Standards at 40 C.F.R. part 792 and the sampling and analytical method developed for the New Chemical Substance.

D. Full Shift Exposure Samples

Representative 8-hour TWA airborne concentrations must be determined using samples representing the full shift exposure for each exposure group.

E. STEL Samples

Determinations of compliance with the STEL must be made from 15-minute breathing zone samples measured at operations where there is maximum short-term exposures, such as during, but not limited to, the following operations: _____. **[Note to Program Managers: Delete this paragraph if there is no STEL.]**

II. Initial Monitoring

The Company must conduct initial exposure monitoring to accurately determine the airborne concentration of the New Chemical Substance for each exposure group before the Company may deviate from the respirator requirements.

III. Periodic Monitoring

A. Samples ≥ Action Level and ≤ TWA

1. If any samples taken during the initial exposure monitoring result in an airborne concentration at or above the action level but at or below the TWA, the Company must repeat the exposure monitoring for that exposure group at least every 6 months.
2. If the New Chemical Substance is not manufactured, processed, or used during a given 6-month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the New Chemical Substance is resumed.
3. Cessation of manufacturing, processing and use of the New Chemical Substance for less than the 6-month period does not constitute grounds for postponement of the 6-month deadline to conduct exposure monitoring.

B. Samples > TWA

1. If any samples taken during the initial exposure monitoring result in an airborne concentration above the TWA, the Company must repeat the exposure monitoring for that exposure group at least every 3 months.
2. If the New Chemical Substance is not manufactured, processed, or used during a given 3-month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the New Chemical Substance is resumed.
3. Cessation of manufacturing, processing, and use of the New Chemical Substance for less than the 3-month period, however, does not constitute grounds for postponement of the 3-month deadline to conduct exposure monitoring.
4. The Company may alter the exposure monitoring schedule from every 3 months to every 6 months for any exposure group for whom two consecutive measurements taken at least 7 days apart result in an airborne concentration at or above the action level but at or below the TWA. Where the New Chemical Substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures.

IV. Termination of Monitoring

A. Initial Exposure Monitoring

1. If representative samples taken during the initial exposure monitoring result in an airborne concentration below the action level, the Company may discontinue monitoring for that exposure group.
2. The Company must still comply with the Additional Monitoring Requirements of this Appendix.

B. Periodic Exposure Monitoring

1. If representative samples taken during the periodic monitoring result in an airborne concentration are below the action level, the Company may discontinue the monitoring for that exposure group.

2. The representative samples must be 2 consecutive measurements taken at least 7 days apart.
3. Where the New Chemical Substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided the measurement reflect the highest peak exposures.
4. The Company must still comply with the Additional Monitoring Requirements of this Appendix.

V. Additional Monitoring

A. For a previously monitored exposure group, the Company must conduct the initial exposure monitoring followed by any periodic exposure monitoring required by this Appendix, within 7 days of:
   1. Any change in the production volume, process, control equipment, personnel or work practices that may cause new or additional exposures to the New Chemical Substance;
   2. Any spills, leaks, ruptures or other breakdowns occur that may cause new or additional exposures to the New Chemical Substance; and
   3. Any process or environmental change that may result in new or additional exposures to the New Chemical Substance.

B. The additional exposure monitoring requirement of this Appendix is not intended to delay implementation of any necessary cleanup or other remedial action. During any cleanup or remedial operations that may occur before commencing additional exposure monitoring, the Company must ensure that potentially exposed persons use at least the respiratory protection specified in Protection in the Workplace Appendix a for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

VI. Notification of Monitoring Results

A. Within 15 working days after receipt of the results of any exposure monitoring required by this Order, the Company must notify each person whose exposure is represented by that monitoring. The notice must identify the NCEL, the exposure monitoring results, and any corresponding respiratory protection required by Appendix 6 Section III a. Affected persons must be notified in writing either individually or by posting the information in an appropriate and accessible location.

B. Whenever the NCEL is exceeded, the written notification must describe the action being taken by the Company to reduce exposure to or below the NCEL or must refer to a document available to the person which states the actions to be taken to reduce exposure.

VII. Exemption based on Objective Data

A. Where the Company has reliable objective data demonstrating that, even under worst-case conditions, employee exposures will not exceed the action level for a specific "exposure group", then that exposure group is exempt from the requirements of the New Chemical Exposure Limit section. Additional monitoring, NCEL recordkeeping and respirator requirements are still applicable.

B. Any such objective data must accurately characterize employee exposures and must be obtained under conditions resembling the types of materials, processes, control methods, work practices, and environmental conditions in workplace operations. Examples of objective data include information on the physical and chemical properties of the New Chemical Substance, industry-wide studies, and/or laboratory test results.

Appendix 11: Statistical Analysis of NCELs Analytical Method Verification Results

This Attachment describes the statistical technique for comparing the analytical results obtained by two laboratories.

STATISTICAL TECHNIQUE

To obtain two-sample t test with unequal variances, perform the following operations:

- Compute means of the data measured by two laboratories.

- Compute mean squares

$$Si^2 = \Sigma(X_{ij} - X_i)^2/(ni - 1),\ i=1, 2$$

- Form the ratio

$$T = (X_1 - X_2)/(W_1 + W_2)^{1/2}$$

- Compute degrees of freedom

$$f = (W_1 + W_2)^2/[W_1^2/(n_1 - 1) + W_2^2/(n_2 - 1)]$$

where,

$$W_1 = S_1^2/n_1,\ i = 1, 2$$

X_1 = Average of the results from the company laboratory

X_2 = Average of the results from the independent laboratory

n_1 = Number of samples analyzed by the company laboratory

n_2 = Number of samples analyzed by the independent laboratory.

Then compare the absolute value of T to the 97.5 percentile point of a t distribution with f degrees of freedom. If the absolute value exceeds the 97.5 percentile point, the results

measured by two laboratories are significantly different at 95% level. Otherwise, they are not significantly different. In general, f may not be an integer. Use interpolation to obtain the 97.5 percentile point of a t distribution with f degrees of freedom.

EXAMPLES -- The following examples (based on simulated data) illustrate the method:

Example 1

Data Set 1	Data Set 2
80.56	97.11
100.01	102.13
86.04	99.83
52.61	97.83
84.85	105.44
95.75	100.04

$X_1 = 83.30$ $n_1 = 6$ $X_2 = 100.40$ $n_2 = 6$

$S_1^1 = 278.72$ $W_1 = 46.25$ $S_2^2 = 9.26$ $W_2 = 1.54$

Absolute value of T = 2.467 f = 5.33

The t table shows that the 97.5 percentile point is 2.571 and 2.447 for 5 and 6 degrees of freedom, respectively. For 5.33 degrees of freedom, the 97.5 percentile point will be approximately 2.530 which is greater than the absolute value of T, 2.467. Hence, the means of two data sets are not significantly different at the 5% level.

However, if this problem had been treated as an ordinary two-sample t test, the means would be significantly different at the 5% level because the absolute of T is greater than 2.228, the 97.5 percentile point for the t distribution with 10 degrees of freedom.

Example 2

Data Set 1	Data Set 2
82.87	108.05
101.85	96.51
87.44	100.04
99.68	104.33
101.15	110.32
99.21	107.00

$X_1 = 95.37$ $n_1 = 6$ $X_2 = 104.37$ $n_2 = 6$

$S_1^1 = 65.59$ $W_1 = 10.93$ $S_2^2 = 27.25$ $W^2 = 4.54$

Absolute value of T = 2.290 f = 8.54

The t table shows that for 8 and 9 degrees of freedom the 97.5 percentile point is 2.306 and 2.262, respectively. For 8.54 degrees of freedom the 97.5 percentile point will be approximately 2.282 which is less than the absolute value of T, 2.290. Hence, the means of two data sets are significantly different at the 5% level.

Appendix 12: NCEL Recordkeeping

Whenever the Company elects to comply with the New Chemical Exposure Limit Section rather than the respirator requirements in the Protection in the Workplace Section of this Order, the Company must maintain the following records until 30 years after the date they are created, and must make them available for inspection and copying by EPA in accordance with Section 11 of TSCA:

1. Records documenting compliance with the analytical method verification requirements of Appendix 9, including copies of the signed certification statement and the verification results obtained by both laboratories;
2. Records documenting either compliance with the Good Laboratory Practice Standards at 40 C.F.R. part 792 or use of a laboratory accredited by the AIHA or another comparable program approved in advance in writing by EPA. Where the Company elects to not comply with TSCA GLPS, such records must include the written accreditation from the AIHA or the written approval from EPA.
3. Records documenting all exposure monitoring dates, duration, and results of each sample taken;
4. Records documenting the name, address, work shift, job classification, and work area of the person monitored and of all other persons whose exposures the monitoring is intended to represent;
5. Records documenting any conditions that might have affected the monitoring results;
6. Records documenting notification of exposure monitoring results required by Appendix 10;
7. Records documenting any changes in the production, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the New Chemical Substance;

8. Records documenting any spills, leaks, ruptures or other breakdowns that may cause new or additional exposure;
9. Records documenting the type of respiratory protective devices worn by the monitored person, if any;
10. Records documenting any actions taken to mitigate exposures to the New Chemical Substance; and
11. Records documenting reliance on the objective data exemption in Appendix 10, including:

    (A) the source of the data,

    (B) protocols and results of any relevant testing or analysis,

    (C) a description of the operation exempted and how the data demonstrate that employee exposures will not exceed the action level,

    (D) other data relevant to the operations, materials and employee exposures covered by the exemption.

Appendix 13: NCELs Respirator Tables

[EMBED Excel.Sheet.12]