

EPA Sanitized

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 (PMN) Number: P-23-0013

Received 11/02/2023

Submission Date: 10/12/22

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

Honeycomb Techno Research USA Inc.

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.

SHARI BARASH

Digitally signed by SHARI
BARASH
Date: 2023.10.10 17:46:28
-04'00'

Shari Z. Barash, Acting Director
New Chemicals Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

10/10/2023

Date

Liu Ping

Name

10/30/2023

Date

Title

HONEYCOMB TECHNO RESEARCH USA INC

Company



Table of Contents

Table of Contents.....	ii
Jurisdiction and General Provisions.....	1
EPA’s Determination under Section 5(a)(3)(B).....	3
Requirements.....	4
I. Terms of Manufacturing.....	4
A. Conditions of Manufacturing for the Company.....	4
B. Limit on Manufacture by Others.....	4
II. Terms of Distribution.....	5
A. Export Notification.....	5
B. Written Agreement.....	5
C. Containers.....	5
D. Recipient Non-Compliance.....	6
E. Termination of Certain Obligations Through Significant New Use Rule (SNUR) and Final SNUR Required Notification.....	7
III. Temporary Transport and Storage.....	7
IV. Release to Water.....	7
V. Hazard Communication Program.....	8
VI. Risk Notification.....	8
VII. Recordkeeping.....	9
VIII. Automatic Sunset of Test Market Exemption (“TME”), Low Volume Exemption (“LVE”), and Low Release and Exposure Exemption (“LoREX”).....	9
IX. Exemptions.....	10
X. Requests for Information.....	10

XI. Successor Liability Upon Transfer of Order	11
XII. Modification and Revocation of the Order	11
XIII. Office of Management and Budget (OMB) Control Number	11
XIV. Reservation of Rights	12
XV. Effective Date	12
XVI. Potentially Useful Information	12
Appendix 1: Definitions.....	14
Appendix 2: Basis for EPA’s Determination	18
I. Health Effects Summary.....	19
II. Environmental Effects.....	19
A. Environmental Fate	19
B. Persistence.....	20
C. Bioaccumulation	20
D. Environmental Effects Summary	21
III. Human Health and Environmental Hazard Statements	21
A. Human Health Hazard	21
IV. Exposure and Risk Summary.....	22
Appendix 3: Termination of Certain Obligations through Significant New Use Rule (SNUR) and SNUR Notification Requirements.....	24
I. Termination of Certain Obligations Through a SNUR.....	24
II. Final SNUR Required Notification	24
Appendix 4: Recordkeeping	25
I. Manufacturing Volume	25
II. Sites of Manufacture.....	25

III. Sales and Transfers	25
IV. Protection in the Workplace.....	25
A. Hazard Communication Program	25
V. Compliance with this Order	26
A. Terms of Manufacturing and Distribution.....	26
B. Water Discharge Limits.....	26
VI. Exemption Records	26
A. Research & Development Exemption	26
Appendix 5: Successor Liability Upon Transfer of Order	27

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-23-0013 submitted by Honeycomb Techno Research USA Inc. (the Company) for Phenol, polymer with 4,4'-bis(chloromethyl)-1,1'-biphenyl; CASRN 208254-04-0 (New Chemical Substance). This Order is issued and entered into under the authority vested in the Administrator of the EPA by Section 5(e)(1) of TSCA, 15 U.S.C. § 2604(e)(1).

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, including both substantive and procedural requirements, such as whether the order was issued

45 days before the end of the PMN Review Period as provided in TSCA § 5(e)(1)(B), 15 U.S.C. § 2604(e)(1)(B).

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. Appendix 1 Definitions shall apply to this Order and its appendices.

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

The following determination constitutes 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)(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, the 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.

The basis for EPA's determination is attached as Appendix 2 to this Order.

Requirements

The Order applies to all commercial manufacturing, processing, distribution in commerce, use and disposal of the New Chemical Substance, P-23-0013, Phenol, polymer with 4,4'-bis(chloromethyl)-1,1'-biphenyl; CASRN 208254-04-0 by the Company, as follows:

I. Terms of Manufacturing

A. Conditions of Manufacturing for the Company

The Company may manufacture the New Chemical Substance only by import into the United States (i.e., no domestic manufacture) at concentrations no higher than ■ % by weight.

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 to the provisions in the Appendix titled Termination of Certain Obligations through Significant New Use Rule (SNUR) and SNUR Notification Requirements.
 - 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 the Appendix titled Termination of Certain Obligations through Significant New Use Rule (SNUR) and SNUR Notification Requirements, and maintain a copy of such notification for 5 years.

II. 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), 15 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 terms and restrictions located in the following Sections and Appendices of this Order:
 - a. The Protection in the Workplace Section and the Protection in the Workplace Appendix,
 - b. The Hazard Communication Program Section and Appendix 2,
 - c. The Terms of Manufacturing Section and the Release to Water Section, and the Recordkeeping Section and Appendix.
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 when fully reacted or cured.

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 of the New Chemical Substance 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 all of the following:

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.

E. Termination of Certain Obligations Through Significant New Use Rule (SNUR) and Final SNUR Required Notification

- a. The requirements of paragraphs B, C, and D of this Terms of Distribution Section and the Temporary Storage and Transport Section will terminate in accordance with the conditions of the Appendix titled Termination of Certain Obligations through Significant New Use Rule (SNUR) and SNUR Notification Requirements.
- b. Whenever the Company distributes the New Chemical Substance to another person, the Company must notify that person in writing of the existence of the final SNUR, according to the conditions outlined in the Appendix titled Termination of Certain Obligations through Significant New Use Rule (SNUR) and SNUR Notification Requirements and maintain a copy of such notification for 5 years.

III. 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 (49 U.S.C. § 5101 *et seq.*) and its implementing regulations issued by the Department of Transportation.

IV. Release to Water

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

If the quotient from the formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = N \text{ ppb}$$

does not exceed 260 ppb, 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.

V. 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.

VI. 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, and
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, within 30 days of receipt of EPA's risk notification, 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 prior to restarting any manufacturing, processing, distribution, use and disposal of the New Chemical Substance.

VII. Recordkeeping

The Company must maintain records pursuant to the requirements in the Recordkeeping Appendix for 5 years (or longer if specified in this Order) after their creation date.

VIII. 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.

IX. Exemptions

The requirements of the Order apply to manufacture, processing, distribution in commerce, use and/or disposal of the New Chemical Substance by the Company at any site under the Company's control. The following exemptions do not apply to the New Chemical substance:

- A. solely for export at 40 C.F.R 720.30(e);
- B. impurity at 720.30(h)(1); and
- C. byproduct at 720.30(h)(2).

The requirements of the Order do not apply to manufacture, processing, distribution in commerce, use, and/or disposal of the New Chemical Substance by the Company at any site under the Company's control for the following:

- A. small quantities manufactured, processed, used or distributed in commerce solely for R&D in accordance with Section 5(h)(3) of TSCA, 15 U.S.C. § 2604(h)(3), as defined at 40 C.F.R. § 720.3(cc), and 40 C.F.R. § 720.36;
- B. when manufactured solely for non-commercial R&D in accordance with 40 C.F.R. § 720.30(i);
- C. when imported as part of an "article" as defined at 40 C.F.R. § 720.3(c) and in compliance with 40 C.F.R. § 720.22(b)(1); or,
- D. when completely reacted or cured.

Regardless of whether the Company meets any exemption expressly permitted by this section, the requirements found in the Recordkeeping Appendix continue to apply.

X. 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.

XI. 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 requirements in the Successor Liability Upon Transfer of Order Appendix.

XII. 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.

XIII. 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.

XIV. 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.

XV. Effective Date

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

XVI. Potentially Useful Information

“Potentially Useful Information” (definition in Appendix 1) would assist in evaluating the potential effects caused by the New Chemical Substance.

Potentially Useful Information	
Information	Effects
Specific Target Organ Toxicity	Human Health

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

NOTE: Any required testing and/or potentially useful information described in this Consent Order was based on EPA’s consideration of available screening-level data, if any, as well as other available information on appropriate testing for the PMN substance. Further, any such

testing/information identified by EPA that includes testing on vertebrates reflects the consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. Pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the potentially useful information.

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 an Appendix to the Order.

“Enclosed Process” means a system of equipment directly connected to the production process that is designed, constructed, and operated in a manner which prevents emissions, or the release of any chemical substance into the facility or environment during the production process. Such emissions, including fugitive emissions, could lead to exposures to workers, the

public, or the environment. For an enclosed process, exposure and release could only occur due to loss of integrity or failure of the manufacturing process equipment or control systems.

“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.”

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

“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.

“Potentially Useful Information” means data, or independent studies that may help EPA better characterize the potential risks associated with the restrictions on manufacturing, processing, use, distribution in commerce, and disposal detailed in this Consent Order. PUI can be submitted to EPA as part of a request to modify or rescind restrictions to this Order and can be submitted using alternative test methods and strategies to generate data to inform risk assessment. EPA encourages dialogue with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h).

“Results in inhalation exposure” means any manufacturing, processing, use or disposal activity/operation that generates a dust, mist, vapor or aerosol to which a worker is reasonably likely to be exposed.

“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

Chemical Name:

Specific: Phenol, polymer with 4,4'-bis(chloromethyl)-1,1'-biphenyl; CASRN 208254-04-0

Conditions of Use (intended, known, or reasonably foreseen)¹:

Intended conditions of use (specific): Import for use as and use as an epoxy molding compound for electronic devices, consistent with the manufacturing, processing, use, distribution, and disposal information described in the PMN.

Known conditions of use: Applying such factors as described in footnote 1, EPA evaluated whether there are known conditions of use and identified use as an epoxy molding compound and use as an additive for electronic formulations.

Reasonably foreseen conditions of use: Applying such factors as described in footnote 1, EPA evaluated whether there are reasonably foreseen conditions of use and identified domestic manufacture based on the submission being import only, use without hazard communication based on policy, use in electric molding based on previous TSCA submissions, and use as a curing agent, resin, coating and in photoresists based on analogous chemicals.

EPA has determined that in the absence of sufficient information to permit the Agency to make a reasoned evaluation of the health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the New Chemical Substance, Phenol, polymer with 4,4'-bis(chloromethyl)-1,1'-biphenyl; CASRN 208254-04-0 (P-23-0013), the New Chemical Substance may present an unreasonable risk of injury to health or the environment without consideration of costs or other non-risk factors, (including an unreasonable risk to a potentially

¹ Under TSCA § 3(4), the term "conditions of use" means "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." In general, EPA considers the intended conditions of use of a new chemical substance to be those identified in the section 5(a) notification. Known conditions of use include activities within the United States that result from manufacture that is exempt from PMN submission requirements. Reasonably foreseen conditions of use are future circumstances, distinct from known or intended conditions of use, under which the chemical substance may be manufactured, processed, distributed, used, or disposed of. EPA expects that the identification of "reasonably foreseen" conditions of use will be made on a fact-specific, case-by-case basis. EPA will apply its professional judgment and experience when considering factors such as evidence of current use of the new chemical substance outside the United States, information about known or intended uses of chemical substances that are structurally analogous to the new chemical substance, and conditions of use identified in an initial PMN submission that the submitter omits in a revised PMN. The sources EPA uses to identify reasonably foreseen conditions of use include searches of internal confidential EPA PMN databases (containing use information on analogue chemicals), other U.S. government public sources, the National Library of Medicine's Hazardous Substances Data Bank (HSDB), the Chemical Abstract Service STN Platform, REACH Dossiers, technical encyclopedias (e.g., Kirk-Othmer and Ullmann), and Internet searches.

exposed or susceptible subpopulation identified as relevant by the Administrator) under the conditions of use, based on the risk assessment summarized below.

I. Health Effects Summary

Human health hazard is relevant to whether a new chemical substance is likely to present an unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance.

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties and by comparing it to structurally analogous chemical substances for which there are information on human health hazard. Absorption of the new chemical substance and low molecular weight fraction < 1000 Da (67.02%) is expected to be nil through the skin, nil through the lungs, and nil through the gastrointestinal (GI) tract based on physical/chemical properties and analogue test data. For the new chemical substance, EPA identified portal-of-entry effects (GI effects) as hazards based on analogue data. Submitted data identified the test substance as not acutely toxic (LD50 > 2000 mg/kg, OECD 423), not irritating to skin or eyes (OECD 404, OECD 405), and not genotoxic (OECD 471). EPA identified a NOAEL of 40 mg/kg/day based on GI effects, which was protective for portal-of-entry effects and was used to derive an exposure route- and population-specific point of departure.

II. Environmental Effects

A. Environmental Fate

Environmental fate is the determination of which environmental compartment(s) a chemical moves to, the expected residence time in the environmental compartment(s) and removal and degradation processes. Environmental fate is an important factor in determining exposure and thus in determining whether a chemical may present an unreasonable risk.

EPA estimated physical/chemical and fate properties of the new chemical substance using data for analogues (polymers). In wastewater treatment, the new chemical substance is expected to be removed with an efficiency of 50% to 90% due to sorption. Removal of the new chemical substance by biodegradation is negligible. Sorption of the new chemical substance to sludge is expected to be moderate to strong and to soil and sediment is expected to be very strong. Migration of the new chemical substance to groundwater is expected to be negligible due to very strong sorption to soil and sediment. Due to low estimated vapor pressure and Henry's law constant, the new chemical substance is expected to undergo negligible volatilization to air. Overall, these estimates indicate that the new chemical substance has low potential to volatilize to air or migrate to groundwater.

B. Persistence

Persistence is relevant to whether a new chemical substance is likely to present an unreasonable risk because chemicals that are not degraded in the environment at rates that prevent substantial buildup in the environment, and thus increase potential for exposure, may present a risk if the substance presents a hazard to human health or the environment.

EPA estimated degradation half-lives of the new chemical substance using data for analogues (polymers). EPA estimated that the new chemical substance's aerobic and anaerobic biodegradation half-lives are > 6 months. These estimates indicate that the new chemical substance may be very persistent in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment).

C. Bioaccumulation

Bioaccumulation is relevant to whether a new chemical substance is likely to present an unreasonable risk because substances that bioaccumulate in aquatic and/or terrestrial species pose the potential for elevated exposures to humans and other organisms via food chains.

EPA estimated the potential for the new chemical substance to bioaccumulate using data for analogues (polymers). EPA estimated that the new chemical substance has low bioaccumulation potential based on bioconcentration or bioaccumulation data reported for polymers (bioconcentration factor = 440 [measured for an analogue]). Although EPA estimated that the new chemical substance could be very persistent, the substance has low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms.

D. Environmental Effects Summary

Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated environmental hazard using predictions based on the negligible water solubility of the new chemical substance. This substance falls within the TSCA New Chemicals Category of Phenols. Acute and chronic toxicity values estimated for fish, aquatic invertebrates, and algae are all no effects at saturation. These toxicity values indicate that the new chemical substance is expected to have low environmental hazard. Because hazards are not expected up to the water solubility limit, acute and chronic concentrations of concern are not identified.

III. Human Health and Environmental Hazard Statements

Hazard and Precautionary Statements.

The following health and environmental hazard and precautionary statements must be included as part of the hazard communication program and appear on each label and SDS, if applicable.

A. Human Health Hazard

Specific Target Organ Toxicity

IV. Exposure and Risk Summary

EPA estimates occupational exposure and environmental release under the intended conditions of use described in the PMN using ChemSTEER (Chemical Screening Tool for Exposures and Environmental Releases; <https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases>). EPA uses EFAST (the Exposure and Fate Assessment Screening Tool; <https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014>) to estimate general population, consumer, and environmental exposures.

For this assessment, EPA assessed worker exposure via inhalation. Exposure via dermal contact was not assessed. Releases to water, air, and landfill were estimated. Exposure to the general population was assessed via drinking water, fish ingestion, and inhalation of stack and fugitive air. Exposure to the general population via ingestion of groundwater impacted by landfill leachate was not assessed because exposures were expected to be negligible (below modeling thresholds). Consumer exposures were not assessed because consumer uses were not identified as intended conditions of use.

Risks to Workers

Risks were not identified for workers for gastrointestinal effects via inhalation of respirable or total particulate based on quantitative hazard data for an analogue ($MOE_{\text{Respirable Particulate}} = 1,792$; $MOE_{\text{Total Particulate}} = 597$; Benchmark $MOE = 100$).

No systemic hazards were identified for the new chemical substance via dermal contact; therefore, risks were not calculated. Based on no identified hazards, risks are not expected for workers via dermal contact.

Risk to General Population

Risks were not identified for the general population for gastrointestinal effects via exposure to drinking water, fish ingestion, or inhalation of stack or fugitive air based on

quantitative hazard data for an analogue ($MOE_{AdultDW} = 2,030$; $MOE_{InfantDW} = 483$; $MOE_{Fish Ingestion} = 444$; $MOE_{Stack Air} > 14$ million; $MOE_{Fugitive Air} = 8,715$; Benchmark $MOE = 100$).

Risks were not evaluated for the general population via groundwater impacted by landfill leachate because landfill exposures are expected to be negligible.

Risk to Consumers

Risks to consumers were not evaluated because consumer uses were not identified as intended conditions of use.

Environmental Risks

Risks from acute and chronic exposures to the environment are not expected at any concentration of the new chemical substance soluble in the water (i.e., no effects at saturation).

Appendix 3: Termination of Certain Obligations through Significant New Use Rule (SNUR) and SNUR Notification Requirements

I. Termination of Certain Obligations Through a SNUR

The Limit on Manufacture by Others, Paragraphs B, C, and D of the Terms of Distribution, and Temporary Storage and Transport Sections of this Order expire 75 days after publication 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 of 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 4: 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 produce them for inspection, copying or as otherwise required under 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. 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 and Distribution

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

B. Water Discharge Limits

Records documenting establishment and implementation of procedures designed to ensure compliance with any applicable water discharge limit, discharge monitoring requirement, or other requirement related to the release to water of the New Chemical Substance. Records may include sampling and laboratory analyses of the discharge, and records related to discharges under the Federal Water Pollution Control Act (commonly known as the Clean Water Act (CWA)) or analogous State law, including location of treatment facility, permit numbers issued under all federal environmental statutes, method of treatment, monitoring and release records (including Discharge Monitoring Reports pursuant to the CWA, and /or additional information in support to demonstrate compliance.

VI. Exemption Records

Records documenting compliance to the requirements of any exemption specifically included in this Order.

A. 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 5: 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 <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

Transferor:

Name of New Chemical Substance:

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	