DRAFT

[DATE] __ 2020

[ADDRESSEE]
[ADDRESS]

Re: TSCA Inspection

Dear **[ADDRESSEE]**:

The U.S. Environmental Protection Agency (EPA) will inspect **[YOUR COMPANY]** at the office located at **[ADDRESS]** under the authority of Section 11 of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2610 at 9:30 am on **[DATE]**.

The purpose of the inspection is to determine compliance with the requirements of TSCA Sections 4, 5, 8, 12, and 13, as applicable to the chemical substances or mixtures manufactured, produced, imported, processed, or stored in your establishments, facilities, or other premises. The inspection team will (1) review files, data, and correspondence that are either required to be maintained by TSCA, or applicable to the chemical substances or mixtures within your establishments, facilities, or other premises, and (2) interview personnel.

Please prepare the requested Documents and Lists below as separate documents on electronic media (CD/DVD/USB flash drive) using an Adobe portable document file (.pdf) that is searchable using optical character recognition (OCR) for the inspector to examine. For each **List** requested, please also include a separate Microsoft Excel Workbook. If the company is not engaged in the activities for which information is requested, please state that and confirm that it is not applicable to the company. The following information is requested for the last five years from the date of this inspection letter, unless otherwise specified.

- **Document 0. General Company Information.** Provide details on the following:
    - Brief company history of ownership and business.
    - Corporate structure (including foreign and domestic parent companies).
    - Listing of all U.S. facilities owned by the company, including subsidiaries, and their locations as well as a listing of all U.S. facilities leased by the company, including their locations.
    - Number of employees at each facility operated by the company.
    - Gross annual sales at the corporate level for the last two complete years or accounting cycles (note the fiscal cycle) rounded to at least three significant figures.
    - Identifying information for each facility and U.S. parent company, including data universal numbering system (DUNS) number.
    - Importer of Record ID for all sites that import into the U.S. that are owned by the U.S. parent company.

- Scope of business, main North American Industry Classification System (NAICS) codes under which the site operates, and main industries that the company and site supply.

- **Document 1. Process Flow Diagrams**. Manufacturing and process flow diagrams listing each raw material input and the resulting products (by Chemical Abstracts Service Registry Number (CASRN)) for each step between the particular raw material and the commercial product, including intermediates, byproducts, and catalysts, that are part of the commercial production but are not intended for sale or distribution. For each facility operated by the company indicate all steps including on-site use, marketing, transfer, recycling, and waste disposal. Provide the certificate of analysis from a representative lot for each manufactured product that is used in commerce.

- **Document 2. TSCA Section 4 Documentation.** Letters of intent to conduct testing and proof of data submittal, or requests for exemption from testing, for chemicals manufactured or used by the company that are subject to an active TSCA Section 4 final test rule.

- **Document 3. TSCA Section 5(a)(1) and 5(a)(2) Documentation.** Any Bonafide Intents. Premanufacture Notices (PMNs) submitted by your company, or requests for exemption from the PMN review process, including Low Volume, Test Marketing, and Polymer Exemptions, and any EPA responses to these submittals or requests. Similarly, Significant New Use Rule Notices submitted by your company and any EPA responses to these submittals or requests. Also include Notices of Commencement submitted by your company, where applicable.

- **Document 4. TSCA Section 5(e) and 5(f) Documentation.** A list of TSCA Section 5(e)/(f) Consent Orders to which your company is subject.

- **Document 5. TSCA Section 5(h) Documentation.** Research and development activities and procedures in effect at the company, specifically as related to compliance with the requirements of a TSCA Research and Development (R&D) Exemption. Provide documentation of prudent laboratory practices and of the notification and evaluation of risks, where appropriate. Also include operating manuals or written procedures that are used by laboratory personnel to manage chemicals with unknown hazards.

- **Document 6. TSCA Section 8(a) and 8(b) Documentation.** Recordkeeping and reporting under the Preliminary Assessment Information Rule (PAIR) and Chemical Data Reporting Rule (CDR). For CDR, provide a Copy of Record of the 2016 Chemical Data Reporting submittal filed by or on behalf of each facility operated by the company and a sample calculation of the volumes reported to 2016 CDR, including sources used for each facility.

- **Document 7. TSCA Section 8(c), 8(d), and 8(e) Documentation.** Documentation of allegations of adverse reactions that may be subject to TSCA Section 8(c) reporting. A list of 8(d) health and safety studies submitted to EPA and copies of any known health and

safety studies that were not submitted to EPA. Also provide TSCA Section 8(e) substantial risk information not known to EPA.

- **Document 8. Corporate Policies and Procedures.** Company policies developed by the company or individual facilities to ensure compliance with TSCA Sections 5, 8, 12, and 13.

List 1:
Prepare a list of chemical substances that were imported or manufactured between January l, 2012, and December 31, 2018, in tabular format. The list should include the following information for each chemical substance on an annual basis (i.e., 2012, 2013, 2014, 2015, 2016, 2017, and 2018):

1. Accepted chemical name;
2. CASRN or the EPA Accession Number;
3. Brand name or product identifier;
4. Indicate the physical form and any product specification changes that have occurred;
5. If the substance is a mixture, indicate the CASRN or the EPA Accession Number and percentage of each component;
6. Indicate if the chemical is a byproduct, is an impurity, or is an intermediate. If you identify a chemical as a byproduct or an intermediate, indicate in the process diagrams (Document 6) how it is produced;
7. Volume in pounds or kilograms produced (a) annually if by continuous process, or (b) per batch and batch number, or (c) quantity imported per shipment and shipment number, as applicable to the chemical substance or mixture;
8. For imports, also list the name of the supplier, the country of origin for the chemical, the U.S. port of entry(ies), the Harmonized Tariff Schedule (HTS) code, and representative import certification(s) submitted for each chemical or group of chemicals; and
9. For manufactured chemicals, also note if the chemical is toll manufactured or co-manufactured (if so, include the name of the party for whom the chemical is manufactured), whether the manufacturing process is continuous or batch, and how many employees are directly involved with the manufacturing process for each chemical (including engineers, foremen, packagers and handlers).

List 2:
Prepare a list of all R&D chemicals manufactured or imported by the company and an indication of whether or not the R&D chemical is transferred off-site or outside the control of the company for the purposes of manufacture, processing, use, transport, storage and disposal related to the R&D activities. For those chemical substances transferred off-site, also provide:

1. Names and addresses of those who received the R&D chemical;
2. The amount distributed to each addressee; and
3. Safety Data Sheet (SDS) and/or other documentation to indicate that written notification has been provided to the recipient of the R&D chemical that the chemical

substance is for R&D purposes only and if applicable, a notification of potential risks identified by the facility.

For all chemical substances for which the company has concluded that the exemption applies and the amount manufactured is greater than 100 kilograms per calendar year (kg/yr), also provide the amount manufactured and the disposition of those chemicals.

List 3:
Prepare a list of all health and safety studies relating to any chemical substance that the company manufactured under the R&D exemption (not just chemical substances that have a potential for commercialization).

List 4:
Prepare a list of all the chemical substances (including mixtures) that were purchased from domestic suppliers (U.S. distributors) and used at individual facilities operated by the company in manufacturing and processing activities. The list should include the following information for each chemical component:

1. Brand or product name;
2. Accepted chemical name(s) of each component;
3. CASRN or the EPA Accession Number of each component. If a CASRN is proprietary, provide an SDS from the supplier.
4. Indicate the physical form and any product specification changes that have occurred; and
5. The supplier and location.

List 5:
Prepare a list of chemical substances (along with mixtures and the components of each) by CASRN and the total volume (in pounds) of each of the chemicals or mixtures that were exported to foreign countries. The list should include the following information for each component:

1. Accepted chemical name of each component;
2. CASRN or the EPA accession number of each component;
3. Indicate the physical form and any product specification changes that have occurred;
4. The percentage of each component;
5. The destination country; and
6. A copy of any export notification(s) required under TSCA 12(b).

Terms used in this document are defined in the Code of Federal Regulations, Chapter 40, Sections 704.3, 704.25, 704.33, 707.63, 710.3, 710.43, 711.3, 712.3, 716.1, 717.3, 720.3, and 721.3, (40 C.F.R. §704.3, 704.25, 704.33, 707.63, 710.3, 710.43, 711.3, 712.3, 716.1, 717.3, 720.3, and 721.3).

If you are unable to provide the identity of the chemical substances or mixtures because your suppliers or customers have a Confidential Business Information (CBI) claim on the products that were purchased domestically, imported or exported, please identify those products along with the suppliers and their respective SDS's and have the information available during the inspection.

Pursuant to regulations appearing at Title 40 of the Code of Federal Regulations (40 CFR) Part 2, Subpart B, and specifically Section 2.306, you are entitled to claim information provided to or collected by the EPA during the inspection as confidential business information (CBI). If you do not assert a confidentiality claim at the time the information is provided to the EPA, it could be made available to the public without further notice. The EPA can only disclose information claimed as CBI in accordance with the procedures set forth in 40 CFR Part 2, Subpart B (see 40 CFR§ 2.203(b)).

If you have any questions concerning this request, please contact me at **[(xxx) xxx-xxxx]** or **[_____]**@epa.gov. Thank you for your cooperation in this matter.

Sincerely,

[SIGNATORY]
Waste and Chemical Section
Enforcement Division