

Office of Land and Emergency Management

National Oil and Hazardous Substances Pollution Contingency Plan (NCP)

Subpart J – Use of Dispersants, and Other Chemical and Biological Agents

Guidance for Listing Products on the NCP Product Schedule or NCP Sorbent Product List

Disclaimer

This guidance does not create any rights—substantive or procedural—enforceable by any party in litigation with the United States of America. It does not substitute for the Clean Water Act, Oil Pollution Act of 1990, or EPA's regulations; nor is it a regulation itself. Mention or depiction of products or devices in this guidance does not imply EPA endorsement.

Preface

Transitioning Listed Products to the New NCP Product Schedule or Sorbent Product List [§ 300.955(f)]

The regulatory amendments published on June 12, 2023 (88 FR 38280) provide a process to transition listed products from the current NCP Product Schedule to the new NCP Product Schedule, as well as for listing sorbent products previously certified by EPA on the new Sorbent Product List. From December 11, 2023, Subpart J product submitters will have two years to retest their product and resubmit an application for listing as provided in the NCP. The 24-month transition period provides time to prepare and submit new packages according to amended testing and listing requirements and for EPA to review and make listing determinations. The transition period also allows for the continued availability of listed products to be accessible for planning and response activities.

NCP Product Schedule Transitioning

All products listed on the NCP Product Schedule as of December 11, 2023, will remain conditionally listed until December 12, 2025, at which time all products that have not been submitted and listed on the NCP Product Schedule based on the amended testing and listing criteria will be removed. Products will be transitioned from the current NCP Product Schedule to the new NCP Product Schedule prior to December 12, 2025, provided a new complete package is submitted in accordance with § 300.955(b), and EPA makes a determination to list the product on the new NCP Product Schedule.

Products listed on the NCP Product Schedule prior to December 11, 2023, for which a new submission is not received or that do not meet the revised listing criteria, will not be transitioned to the new NCP Subpart J Product Schedule at the end of the 24-month transition period on December 12, 2025.

Sorbent Product Transitioning

All products previously identified as sorbents that received written certifications confirming their status as a sorbent from EPA will remain available for use until December 12, 2025, at which time all sorbent products must have submitted revised information as applicable under § 300.955(a) and (b) and meet any relevant listing requirements to be listed on the new Sorbent Product List. EPA will no longer issue written certifications for sorbent products after December 11, 2023. Sorbents products meeting the 2023 Subpart J requirements will be listed on the publicly available <u>Sorbent Product List</u>. No technical data are required to be submitted for sorbent products consisting <u>solely</u> of a material, or any combination of the materials, identified in the definition of sorbent under §300.915(g)(1); these materials are automatically included on the Sorbent Products List as generic sorbents, and no further action is necessary. Refer to <u>Chapter 5 Sorbents and the Sorbent Product List</u> of this guidance for more information.

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List of Abbreviations

Abs Accredited Bodies

AKA Also Known As

BFT Baffled Flask Test

CFR Code of Federal Regulations

CWA Clean Water Act

DE Dispersant Effectiveness

DfE Design for the Environment

EPA Environmental Protection Agency

FR Federal Register

LC₅₀ Lethal Concentration of 50 percent of the test species

I.U.B. International Union of Biochemistry

IC₅₀ Inhibition concentration for 50 percent of the test species

ILAP International Laboratory Accreditation Cooperation

ISO International Organization for Standardization

NCP National Oil and Hazardous Substances Pollution Contingency Plan

NELAC National Environmental Laboratory Accreditation Conference

NELAP National Environmental Laboratory Accreditation Program

NOEC No Observed Effect Concentration

OPA Oil Pollution Act of 1990

PAH Polycyclic aromatic hydrocarbons

PCB Polychlorinated biphenyls

SPR Strategic Petroleum Reserve

TNI The NELAC Institute

UCL₉₅ Ninety-fifth (95th) percentile Upper Confidence Limit

USC United States Code

Chapter 1: NCP Subpart J Product Schedule and Sorbent Product List

1.1 Introduction

The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) is the federal government's blueprint for responding to both oil spills and hazardous substance releases. Subpart J of the NCP governs the use of dispersants, other chemicals and other spill mitigating substances when responding to oil discharges into jurisdictional waters and adjoining shorelines of the United States.¹

The Environmental Protection Agency (EPA or the Agency) proposed revisions to Subpart J of the NCP in the Federal Register (FR) on January 22, 2015 (80 FR 3383), including amended testing, listing, and authorization of use provisions, and new monitoring requirements for agent products. Dispersant monitoring requirements were published in the FR on July 27, 2021 (86 FR 40234) and became effective on January 24, 2022. Final testing, listing, and authorization of use regulatory amendments were published in the Federal Register on June 12, 2023 (88 FR 38280) and became effective December 11, 2023.²

The purpose of this document is to provide guidance on the data, information, and submission requirements for listing chemical and biological agent products on the NCP Product Schedule and listing sorbent products on the Sorbent Product List.

1.2 Subpart J Regulatory Background

Sections 311(d) and 311(j) of the Clean Water Act (CWA), as amended by section 4201 of the Oil Pollution Act of 1990 (OPA), Public Law 101-380, direct the President to prepare and publish the National Oil and Hazardous Substances Pollution Contingency Plan (National Contingency Plan, or NCP) for removal of oil and hazardous substances. CWA 311(d)(2)(G) provides that the President establish a schedule that identifies 1) spill mitigating substances that may be used in carrying out the NCP, if any, 2) the waters in which such substances may be used, and 3) the quantities of such substances which can be used safely in such waters. Executive Order 12777, Section 8(b), delegates CWA 311(d)(2)(G) to the EPA Administrator.

Subpart J of the NCP establishes the framework for the use of dispersants and any other spill mitigating substances in response to oil discharges (40 Code of Federal Regulations (CFR) part 300 series 900). Subpart J implements the statutory schedule required by CWA section 311(d)(2)(G), which includes the NCP Product Schedule, the Sorbent Product List, and the Subpart J authorization of use procedures that, when taken together, identify the waters and quantities in which such spill mitigating substances may be used safely when responding to oil discharges into waters of the United States and adjoining shorelines.

¹ See 33 United States Code (U.S.C.) § 1321(b) for full jurisdictional scope of CWA section 311.

² Corresponding corrections were published in the Federal Register on June 28, 2023 (88 FR 41834).

1.3 Data, Information, and Submission Requirements for the NCP Product Schedule or Sorbent Product List

This document offers guidance on the requirements established under Subpart J of the NCP for listing chemical and biological agent products on the NCP Product Schedule or listing sorbent products on the Sorbent Product List. Product testing protocols, along with additional requirements for data and information, serve as the basis for a national level screening of these spill mitigating products. The data, information, and submission requirements, as well as associated regulatory provisions, include:

- § 300.5 NCP Definitions,
- § 300.915 Data and information requirements for listing on the NCP Product Schedule or Sorbent Product List,
 - § 300.915(a) General Information for any Product Category
 - o § 300.915(b) Dispersant Testing and Listing Requirements
 - § 300.915(c) Surface Washing Agent Testing and Listing Requirements
 - § 300.915(d) Bioremediation Agent Testing and Listing Requirements
 - § 300.915(e) Solidifier Testing and Listing Requirements
 - o § 300.915(f) Herding Agent Testing and Listing Requirements
 - § 300.915(g) Sorbent Requirements
- §300.950 Submission of Proprietary Business Information (PBI),
- § 300.955 Addition of a Product to the NCP Product Schedule or Sorbent Product List,
 - § 300.955(a) Submission
 - o § 300.955(b) Package Contents
 - § 300.955(c) EPA Review
 - § 300.955(d) Request for Review of Decision
 - § 300.955(e) Changes to a Product Listing
 - § 300.955(f) Transitioning Listed Products to the New NCP Product Schedule or Sorbent Product List
- § 300.965 Mandatory Product Disclaimer,
- § 300.970 Removal of a Product from the NCP Product Schedule or Sorbent Product List,
 and
- Appendix C to Part 300 Requirements for Product Testing Protocols and Summary Test Data
 - Dispersant Baffled Flask Efficacy and Toxicity Tests
 - Standard Acute Toxicity Test for Bioremediation Agents, Surface Washing Agents, Herding Agents, and Solidifiers
 - Bioremediation Agent Efficacy Test

Subpart J provisions for authorization of use and for atypical dispersant monitoring are not addressed in this guidance. Additional background information on the atypical dispersant monitoring requirements can be found in the Federal Register published on July 27, 2021 (86 FR 40234); information on the authorization of use requirements, as well as further information on

the listing requirements, can be found in the Federal Register published on June 12, 2023 (<u>88 FR</u> <u>38280</u>).

1.4 Using This Guidance

This guidance is intended to assist those interested in listing an agent product on the NCP Product Schedule, or a sorbent product on the Sorbent Product List, in understanding the data, information and submission requirements. A list of acronyms used throughout the guidance is provided at the beginning of this document.

The guidance is divided into ten chapters and eight attachments as follows:

- Chapter 1: NCP Subpart J Product Schedule and Sorbent Product List
- Chapter 2: § 300.5 Definitions Applicable to NCP Product Schedule and Sorbent Product List
- Chapter 3: Subpart J Data and Information Requirements for Listing on the NCP Product Schedule
- Chapter 4: Subpart J Testing Requirements and Listing Thresholds by Product Category for Listing on the NCP Product Schedule
- Chapter 5: Sorbents and the Sorbent Product List
- Chapter 6: Proprietary Business Information (PBI) [§ 300.950]
- Chapter 7: Addition of a Product to the NCP Product Schedule or Sorbent Product List [§ 300.955]
- Chapter 8: Submitter Responsibilities for Listed Products
- Chapter 9: NCP Product Schedule and NCP Product Schedule Technical Notebook
- Chapter 10: Removal of a Product from the NCP Product Schedule or Sorbent Product List [§ 300.970]
- Attachment A: Product Listing Checklist
- Attachment B: Quick Links to the Electronic Code of Federal Regulations (eCFR)
- Attachment C: Dispersant Data Submission Sample Template
- Attachment D: Surface Washing Agent Data Submission Sample Template
- Attachment E: Bioremediation Agent Data Submission Sample Template
- Attachment F: Solidifier Data Submission Sample Template
- Attachment G: Herding Agent Data Submission Sample Template
- Attachment H: Sorbent Data Submission Sample Template
- Attachment I: Proprietary Business Information (PBI) Submission Sample Template

1.5 NCP Subpart J Information Line and Website

In addition to this guidance, EPA has established the NCP Subpart J Information Line as a resource for answering questions submitters may have with the submission of data and information for listing on the NCP Product Schedule and Sorbent Product List.



NCP Subpart J Information Line: (202) 260-2342

The NCP Subpart J Information Line is not a staffed hotline, but a voice messaging service maintained by EPA and checked daily by contractor staff. Calls are returned within 24 hours. Callers should leave their full name, company name, phone number, email address, and reason for the call (e.g., application materials, clarifications for listing a product).

The NCP Subpart J Information Line and the EPA's OEM NCP Subpart J Website were created to assist manufacturers with submitting products for listing. The website includes information on listing a product on the NCP Product Schedule and links to the NCP Product Schedule and the Technical Notebook. The Technical Notebook includes the relevant data manufacturers submitted for their product for listing on the NCP Product Schedule. This information provides useful information to On-Scene Coordinators, Regional Response Teams, and responders on products listed on the NCP Product Schedule.

Chapter 2: § 300.5 Definitions Applicable to NCP Product Schedule and Sorbent Product List

2.1 Introduction

Chapter 2 highlights the regulatory definitions of the five NCP Product Schedule agent categories, as well as of the sorbent category. These definitions clarify and provide information on the relevant listing categories and allow submitters to identify the listing and testing requirements applicable to each category. The regulatory definitions are established under Part 300 of the NCP at 40 CFR § 300.5. Additional background information on these definitions can be found in the Federal Register published on June 12, 2023 (88 FR 38280).

2.2 NCP Product Schedule Product Category Definitions

2.2.1 Dispersants

Substances that emulsify, disperse, or solubilize oil by promoting the formation of small droplets or particles of oil in the water column.

2.2.2 Surface Washing Agents

Substances that separate oil from solid surfaces, such as beaches, rocks, metals, or concrete, through a detergency mechanism that lifts and floats oil. Product and oil are generally to be collected and recovered from the environment with minimal dissolution, dispersion, or transfer of oil into the water column.

2.2.3 Bioremediation Agent

Biological agents and/or nutrient additives deliberately introduced into a contaminated environment to increase the rate of biodegradation and mitigate any deleterious effects caused by the contaminant constituents. Bioremediation agents include microorganisms, enzymes, and nutrient additives such as fertilizers containing bioavailable forms of nitrogen, phosphorus, and potassium.

2.2.4 Solidifiers

Substances that through a chemical reaction cause oil to become a cohesive mass, preventing oil from dissolving or dispersing into the water column. Solidifiers are generally collected and recovered from the environment.

2.2.5 Herding Agents

Substances that form a film on the water surface to control the spreading of the oil to allow for oil removal.

2.3 Sorbent Product Category Definition

Section 300.5 defines sorbents as inert and insoluble substances that readily absorb and/or adsorb oil or hazardous substances, and that are not combined with or act as a chemical agent,

biological agent, or sinking agent³. Sorbents may be used in their natural bulk form or as manufactured products in particulate form, sheets, rolls, pillows, or booms. Sorbents are generally collected and recovered from the environment. Sorbents consist of:

- (1) Natural organic substances (e.g., feathers, cork, peat moss, and cellulose fibers such as bagasse, corncobs, and straw);
- (2) Inorganic/mineral compounds (e.g., volcanic ash, perlite, vermiculite, zeolite, clay); and
- (3) Synthetic compounds (e.g., polypropylene, polyethylene, polyurethane, polyester).

³ Under § 300.910(e)(1), a sinking agent, or any other chemical agent, biological agent, or any substance that is used to directly sink oil to the bottom of the water body is considered a prohibited agent or substance.

Chapter 3: Subpart J Data and Information Requirements for Listing on the NCP Product Schedule

3.1 Introduction

Chapter 3 will help submitters and testing laboratories to identify and meet the data and information requirements for all chemical and biological agent product categories covered under Subpart J for listing on the NCP Products Schedule. Laboratory accreditation requirements are also discussed in this chapter. Data and information requirements, including testing protocols, are established under Part 300 of the NCP at 40 CFR § 300.915 and in Appendix C to Part 300. Additional data requirements for the following specific chemical and biological agent product categories are mentioned later in this chapter:

- Dispersants (§ 300.915(b));
- Surface Washing Agents (§ 300.915(c));
- Bioremediation Agents (§ 300.915(d));
- Solidifiers (§ 300.915(e)); and
- Herding Agents (§ 300.915(f)).

3.2 Section 300.915(a) General Information for Any Product Category

Paragraph (a) of § 300.915 includes the general submission requirements that are applicable to all types of chemical or biological agents that may be listed on the NCP Product Schedule, as well as to sorbent products that may be listed on the Sorbent Product List. The sections below detail the general information and data requirements.

3.2.1 Submitter Information

Under § 300.915(a)(1), submitters are required to provide their name, physical address, email, and telephone number.

3.2.2 Submitter Identity and Documentation of that Identity

The requirements under § 300.915 are addressed to the submitter of an application for listing a product to the NCP Product Schedule or Sorbent Product List. Under § 300.915(a)(2), the submitter must provide its identity, and document that identity, as the manufacturer of the product, vendor, importer, distributor of the product, and/or a designated agent acting on behalf of the manufacturer. The final rule requires there be an entity serving as a single point of contact responsible for the product submission. This helps avoid any conflicts or claims from unauthorized entities on products listed or submitted for listing consideration. The phrase "and/or a designated agent acting on behalf of the manufacturer" in Subpart J provides flexibility relative to the single, authorized entity that is representing the manufacturer and submitting a product package for listing consideration. For example, this flexibility may be applied, as appropriate, to parties that acquire the legal rights to intellectual property for an existing product such that they would have the legal authority to manufacture the product.

3.2.3 Product Name(s), Brand(s), and/or Trademark(s)

Under § 300.915(a)(3), submitters are required to provide all name(s), brand(s), and/or trademark(s) under which the product is to be sold.

3.2.4 Supplier Information

Under § 300.915(a)(4), submitters are required to provide names, physical addresses, emails, and telephone numbers of the primary distributors, vendors, importers and/or designated agents acting on behalf of the manufacturer.

3.2.5 Safety Data Sheet (SDS)

Under § 300.915(a)(5), submitters are required to provide the Safety Data Sheet (SDS) for the product.

3.2.6 Product Storage Information

Under § 300.915(a)(6), submitters are required to provide the maximum, minimum, and optimum temperature, humidity, and other relevant conditions for product storage and a brief description of the consequences to performance if the product is not stored within these limits.

3.2.7 Shelf-life Information

Under § 300.915(a)(7), submitters are required to provide the anticipated shelf life of the product at the storage conditions noted in paragraph (a)(6) of this section and documentation for this determination.

3.2.8 Product Label(s)

Under § 300.915(a)(8), submitters are required to provide a sample product label for all name(s), brand(s), and/or trademark(s) under which the product is to be sold that includes manufacture and expiration dates, and conditions for storage. You may use an existing label provided it already contains the required dates and storage information.

3.2.9 Chemical or Biological Agent Category

Under § 300.915(a)(9), submitters are required to provide the chemical or biological agent category under which you want the product to be considered for listing on the NCP Product Schedule, including detailed information on the specific process(es) through which the product affects the oil, and the specific environment(s) on which it is intended to be used (e.g., waters and/or adjoining shorelines). If your product meets the definition of more than one chemical or biological agent category, you must identify all applicable categories and provide the test data to meet the listing criteria appropriate to each.

3.2.10 Product Use Procedures

Under § 300.915(a)(10), submitters are required to provide product concentrations, use ratios, types of application equipment, conditions for use, any application restrictions; and, as applicable, procedures for product and oil containment, collection, recovery, and disposal.

These procedures must address, as appropriate, variables such as weather, water salinity, water temperature, types and weathering states of oils or other pollutants. The procedures must include supporting documentation and current appliable standard methods used to determine them.

3.2.11 Environmental Fate Information

Under § 300.915(a)(11), submitters are required to provide available information on environmental fate, including any known measured data, methodologies, and supporting documentation, on the persistence, bioconcentration factor, bioaccumulation factor, and biodegradability of the product and all of its components in the environment.

3.2.12 Physical and Chemical Properties

Under § 300.915(a)(12), submitters are required to provide physical and chemical property information of the product, as appropriate, including a citation of the current applicable standard methods used to determine these properties. Submitters are required to use an accredited laboratory to conduct these tests (§ 300.915(a)(17)). The complete list of physical and chemical data requirements include:

- Physical State and Appearance;
- Vapor Pressure;
- Flash Point;
- Pour Point;
- Viscosity;
- Specific Gravity;
- Particle Size for Solid Components; and
- pH.

This information, in combination with the other general product information requirements, provides added context to the evaluation of product behavior and the process through which it would affect the oil when used in the intended water and/or shoreline environment.

3.2.13 Product Components Information

Under § 300.915(a)(13), submitters are required to provide the identity and concentration of all components of the product, including each specific component name; corresponding Chemical Abstract Service (CAS) Registry Number; the maximum, minimum, and average weight percent of each component in the product; and the intended function of each component (e.g., solvent, surfactant). For more information on what submitted information will be available for public disclosure upon submission, see Chapter 6: Proprietary Business Information.

3.2.14 Microorganism, Enzyme, and/or Nutrient Testing [§ 300.915(a)(14)]

Under § 300.915(a)(14), submitters with products that also contain microorganisms, enzymes, and/or nutrients, are required to provide the following along with a citation or a description of the methodology used to determine:

- The name of all microorganisms by current genus and species, including any reclassifications, and any physical, chemical, or biological manipulation of the genetic composition and the weight percent of each genus in the product;
- The name of all enzymes and their International Union of Biochemistry (I.U.B.) number(s);
 Enzyme Classification (EC) code numbers; the source of each enzyme; units; and specific oil-degrading activity;
- The name(s), maximum, minimum, and average weight percent of the nutrients contained in the product; and
- Data, methodology, and supporting documentation, for the levels of bacterial, fungal, or viral pathogens or opportunistic pathogens including, but not limited to: enteric bacteria such as *Salmonella*, fecal coliforms, *Shigella*, coagulase positive *Staphylococci*, and beta hemolytic *Streptococci* and enterococci.

Reporting may be provided, for example, as the most probable number of the number of colony-forming units per unit volume. As the regulation does not specify analytical pathogen testing methods, the submitter may choose from current applicable standard methods for the purposes of product submission. The methodology for obtaining these values as well as the supporting documentation must be included with the reported values.

3.2.15 Metals, Cyanide, Chlorinated Hydrocarbons, Pesticides, Polychlorinated Biphenyls and Polynuclear Aromatic Hydrocarbons Testing [§ 300.915(a)(15)]

Under § 300.915(a)(15), submitters are required to provide data, methodology, and supporting documentation for the levels of the following:

- Arsenic, cadmium, chromium, copper, lead, mercury, nickel, vanadium, zinc, and any other heavy metal reasonably expected to be in the product;
- Cyanide;
- Chlorinated hydrocarbons;
- Pesticides;
- Polychlorinated biphenyls (PCBs); and
- Polycyclic aromatic hydrocarbons (PAHs).

As the regulation does not specify analytical contaminant testing methods, the submitter may choose from current applicable standard methods for the purposes of product submission. The methodology for obtaining these values as well as the supporting documentation must be included with the reported values.

3.2.16 Prohibited Agents Certification

Under § 300.915(a)(16), submitters are required to provide certification, including data, methodology, and supporting documentation, indicating that the product does not contain any of the prohibited agents or substances identified in § 300.910(e).

3.2.17 Laboratory Accreditation Information

Under § 300.915(a)(17) submitters are required to provide information about the accredited laboratory that conducted the required tests, including the name of the laboratory, address, contact name, email, and phone number; and the national and/or international accreditations held by the laboratory that are applicable to the test(s) performed.

Submitters are required to use accredited laboratories to conduct the testing to support product submissions for listing consideration on the NCP Product Schedule. Options for laboratory accreditations include, but are not limited to, the National Environmental Laboratory Accreditation Program (NELAP); International Organization for Standardization (ISO); and state accredited bodies.

The National Environmental Laboratory Accreditation Program (NELAP) is an accreditation system operated by The National Environmental Laboratory Accreditation Conference (NELAC) Institute (known as The NELAC Institute (TNI). TNI's website is located at: https://www.nelac-institute.org/index.php.

TNI establishes the standards of NELAP and state governmental agencies recognized by TNI to serve as Accreditation Bodies (ABs) for labs. Accreditation resources including NELAP recognized ABs and Non-Governmental ABs can be found under the "Laboratory Accreditation" tab on the TNI website.

If a state has not adopted NELAP, the state may develop its own accreditation program with its own requirements, which can be verified through the appropriate state agency website.

U.S. labs can also be accredited by the International Laboratory Accreditation Cooperation (ILAC) recognized ABs in accordance with ISO/IEC 17025:2005. International laboratories are assessed against the standard ISO/IEC 17025:2005 "General Requirements for the Competence of Testing and Calibration Laboratories." In most major countries, ISO/IEC 17025 is the standard for which most labs must hold accreditation to be deemed technically competent. Accreditation can be verified via the applicable AB website (e.g., https://search.anab.org/search-accredited-companies.aspx or https://www.a2la.org/dirsearchnew/newsearch.cfm).

3.2.18 Test Data and Calculations

Under § 300.915(a)(18), submitters are required to provide as part of the submission package to the agency, all test data and calculations, specifically including the following information:

- Raw data and replicates, including positive controls.
- Notes and observations collected during tests.

- Calculated mean values and standard deviations.
- Reports, including a summary of stock solution preparation.
- Source and preparation of test organisms.
- Test conditions.
- Chain of custody forms.

3.2.19 Production Volume Information

Under § 300.915(a)(19), submitters are required to provide an estimate of the annual product production volume, the average and maximum amount that could be produced per day, and the time frame needed to reach that maximum production rate in days.

3.2.20 Environmental Certifications

Under § 300.915(a)(20), submitters are required to provide any recognition received from EPA's Design for the Environment (DfE) or Safer Choice programs, as applicable.

3.2.21 International Product Information

Under § 300.915(a)(21), submitters are required to provide international product testing or use data or certifications, if available, informing the performance capabilities or environmental impacts of the product.

3.3 Specific Product Category Data Requirements for Products Listed on the NCP Product Schedule

As per § 300.915(a)(9), submitters must provide product specific category data and information requirements for all product categories for which the product meets the category definitions found in § 300.5. If your product meets the definition of more than one chemical or biological agent category, you must identify all applicable categories and provide the test data to meet the listing criteria appropriate to each. The specific product categories and their rule references consist of the following:

- Dispersants (§ 300.915(b));
- Surface Washing Agents (§ 300.915(c)).
- Bioremediation Agents (§ 300.915(d));
- Solidifiers (§ 300.915(e)); and
- Herding Agents (§ 300.915(f)).

More information on these data requirements, which include testing protocols, are found in Chapter 4: Subpart J Testing Requirements and Listing Thresholds by Product Category for Listing on the NCP Product Schedule.

3.3.1 Data Submission Sample Templates for NCP Product Schedule Categories

Attachments C through H include sample templates. These sample templates are provided as examples for compiling data and information in the order of general and product-specific category requirements for listing a product on the NCP Product Schedule or the Sorbent

Product List. Sample templates for each product category, with directions and references to the Subpart J testing and data requirements are included in Attachments C through G of this guidance. The sorbent product sample template is also included in Attachment H of this guidance. Subpart J sorbent data and information application requirements are detailed in Chapter 5 of this guidance. These sample templates may be, but are not required to be, used when submitting a product for listing. When all the data and information have been compiled, refer to Chapter 7: Addition of a Product the NCP Product Schedule of Sorbent Product List for next steps in the listing process.

Table 3-1: Subpart J Data Submission Sample Templates Quick Locator

Attachment C: Dispersant Data Submission Sample Template
Attachment D: Surface Washing Agent Data Submission Sample TemplateD-1
Attachment E: Bioremediation Agent Data Submission Sample TemplateE-1
Attachment F: Solidifier Data Submission Sample Template
Attachment G: Herding Agent Data Submission Sample TemplateF-1
Attachment H Sorbent Data Submission Sample TemplateH-1
Attachment I: Proprietary Business Information (PBI) Submission Sample TemplateI-1

3.3.2 Appendix C to Part 300 Testing Protocols

Appendix C to Part 300 establishes laboratory protocols required under Subpart J to make determinations for listing a product on the NCP Product Schedule. The protocols apply, based on product type, to dispersants, bioremediation agents, surface washing agents, herding agents, and solidifiers as defined in § 300.5 of the NCP. Applicable product testing protocols include the following:

- Appendix C to Part 300, Section 2.0 Baffled Flask Dispersant Efficacy Test (BFT) This
 laboratory protocol establishes procedures to evaluate the degree to which a product
 effectively disperses oil spilled on the surface of seawater. The test uses Strategic
 Petroleum Reserve Bryan Mound as the reference oil.
- Appendix C to Part 300, Section 3.0 Dispersant Toxicity Testing This laboratory protocol
 includes testing for 1) dispersant standard static acute toxicity tests; 2) dispersant-oil
 mixture static acute toxicity tests; 3) dispersant developmental assay; and 4) dispersant 7day static subchronic tests.
- Appendix C to Part 300, Section 4.0 Standard Acute Toxicity Testing for Surface Washing Agents, Bioremediation Agents, Herding Agents, and Solidifiers – This protocol includes testing for 1) saltwater standard acute toxicity tests; and 2) freshwater standard acute toxicity tests.

• Appendix C to Part 300, Section 5.0 Bioremediation Agent Efficacy Test Protocol – This protocol quantifies changes in Alaska North Slope (ANS) 521 weathered crude oil composition of alkanes and aromatics resulting from the use of a bioremediation agent in either artificial seawater or freshwater.

Chapter 4: Subpart J Testing Requirements and Listing Thresholds by Product Category for Listing on the NCP Product Schedule

4.1 Dispersant Testing and Listing Requirements [§ 300.915(b)]

Dispersants are substances that emulsify, disperse, or solubilize oil by promoting the formation of small droplets or particles of oil in the water column. Manufacturers submitting a product under the dispersant category are required to test the product for efficacy and toxicity for use in saltwater environments only. Subpart J requires accredited laboratories to follow the efficacy and toxicity testing protocols established for dispersant products in Appendix C to Part 300. The dispersant agent product must meet established thresholds for product listing (See Table 4-1).

4.1.1 Dispersant Efficacy Test and Listing Criteria [§ 300.915(b)(1)]

Efficacy testing of dispersant products using the Baffled Flask Dispersant Efficacy Test is designed to be representative of moderately turbulent sea conditions where dispersants are more likely to be successful when used. The test is to determine the product's ability to disperse the SPR Bryan Mound reference crude oil in saltwater at both 5°C and 25°C. In addition, the test methodology incorporates baffles in the wall of the testing flask and adds a stopcock at the bottom (Figure 1), improving reproducibility and repeatability in the hands of different laboratory technicians. The Baffled Flask specifications can be found in section 2.0 of Appendix C to Part 300.

4.1.2 Dispersant Toxicity Tests and Listing Criteria [§ 300.915(b)(2)]

Dispersant toxicity testing, only for saltwater environments, include the following:



Figure 1: Modified Baffled Trypsinizing Flask

- **Dispersant Standard Static Acute Toxicity Tests** this test is for dispersant alone. It determines the product's toxicity for saltwater species *Americamysis bahia* (48-hr duration) and *Menidia beryllina* (96-hr duration). The test method uses standardized artificial saltwater to allow for better reproducibility. Information on specific requirements can be found in section 3.5 of Appendix C to Part 300.
- Dispersant-Oil-Mixture Static Acute Toxicity Tests The test uses Strategic Petroleum
 Reserve Bryan Mound as reference oil for Americamysis bahia (48-hr duration) and Menidia

- beryllina (96-hr duration). Testing the oil and dispersant mixture is intended to provide data on the relative toxicity of the oil and the potential hazards associated with dispersant use. Information on specific requirements can be found in section 3.5 of Appendix C to Part 300.
- **Dispersant Developmental Assay** The test uses dispersant alone and Strongylocentrotus purpuratus or Arbacia punctulate (72-hour duration). The developmental assay serves as a sensitive surrogate test for early life stages. Information on specific requirements can be found in section 3.6 of Appendix C to Part 300.
- **Dispersant 7-day Static Subchronic Tests** The test uses *Americamysis bahia* and *Menidia beryllina*. The subchronic testing provides additional screening information given dispersants transfer oil into the water column and are not intended to be recovered from the environment. Information on specific requirements can be found in section 3.7 of Appendix C to Part 300.

Separate toxicity tests must be performed with a reference toxicant for each species tested. Information on acceptable reference toxicants and procedures to conduct reference toxicant tests with the species can be found in the specific EPA methods cited in sections 3.3.3, 3.5.1, 3.6.1, and 3.7.1 of Appendix C to Part 300.

4.1.3 Dispersant Testing and Threshold Summary

Testing requirements and thresholds are summarized in Table 4-1. To be listed on the NCP Product Schedule, dispersants must meet the established thresholds. Refer to Chapter 3 and the data submission sample template in <u>Attachment C</u> of this guidance.

Table 4-1: Dispersants – Subpart J Required Tests and Thresholds

Subpart J Testing Requirements and Thresholds – Dispersants			
Required Dispersant Tests	Dispersant Testing Thresholds		
Dispersant Baffled Flask Effectiveness Test (test method found in section 2.0 of Appendix C to Part 300).	§ 300.915(b)(1): The dispersant must demonstrate for each temperature a Dispersant Effectiveness (DE) at the 95% lower confidence level (LCL ₉₅) greater than or equal to: • ≥ 70% for SPR Bryan Mound Oil at 5°C and • ≥ 75% for SPR at Bryan Mound Oil at 25°C.		
Dispersant Alone 48-hr and 96-hr Standard Static Acute Toxicity Test (test method found in section 3.5 of Appendix C to Part 300).	§ 300.915(b)(2)(i): The dispersant alone must demonstrate a lethal concentration of 50 percent of the test species (LC ₅₀) at the lower 95% confidence interval of greater than 10 ppm in saltwater for all tested species.		
Dispersant Mixed with Oil 48-hr and 96-hr Static Acute Toxicity Test (test method found in section 3.5 of Appendix C to Part 300).	§ 300.915(b)(2)(i): The dispersant must demonstrate an LC ₅₀ at the lower 95% confidence interval of greater than 10 ppm saltwater only for all tested species.		

Subpart J Testing Requirements and Thresholds – Dispersants			
Required Dispersant Tests	Dispersant Testing Thresholds		
Dispersant Sea Urchin Developmental	§ 300.915(b)(2)(ii): The inhibition		
Toxicity Test Assay (test method found in 3.6	concentration for 50% of the test species		
of Appendix C to Part 300).	(IC ₅₀) at the lower 95% confidence interval		
	must be greater than 1 ppm saltwater only for		
	all tested species.		
Dispersant 7-day Sub-chronic Toxicity Test	§ 300.915(b)(2)(iii): The dispersant sub-		
(test method found in section 3.7 Appendix C	chronic No Observed Effect Concentration		
to Part 300).	(NOEC) must be or greater than 1 ppm		
	saltwater only for all tested species.		

4.2 Surface Washing Agent Testing and Listing Requirements [§ 300.915(c)]

Surface washing agents are substances that separate oil from solid surfaces, such as beaches, rocks, metals, or concrete, through a detergency mechanism that lifts and floats oil. The product and oil are generally to be collected and recovered from the environment with minimal dissolution, dispersion, or transfer into the water column. Manufacturers submitting a product under the surface washing agent category are required to test for efficacy and toxicity to determine listing eligibility on the NCP Product Schedule.

4.2.1 Surface Washing Agent Efficacy Test and Listing Criteria [§ 300.915(c)(1)]

Under § 300.915(c)(1), the Agency has established a surface washing agent efficacy testing requirement. Accredited laboratories are required to use an applicable standard recognized efficacy testing methodology for surface washing agents. Using an applicable standard methodology, surface washing agents must meet an efficacy of greater than or equal to 30% in either freshwater or saltwater or both. Examples of such methodologies include the American Society for Testing and Materials (ASTM) Standard Test Method for Evaluating the Effectiveness of Cleaning Agents⁴ and the Environment Canada's Test Method⁵. The capability of a particular surface washing agent depends upon the application procedures and the characteristics of the surface being cleaned, such as size, shape, and material.

4.2.2 Surface Washing Agent Toxicity Test and Listing Criteria [§ 300.915(c)(2)]

Accredited laboratories are required to use the toxicity methodology specified in section 4.0 of Appendix C to Part 300 depending on the product's intended use:

⁴ ASTM Standard Test Method for Evaluating the Effectiveness of Cleaning Agents. Designation: G122—96 (Reapproved 2008). ASTM International, 100 Barr Harbour Dr., P.O. Box C–700 West Conshohocken, Pennsylvania 19428–2959, United States.

⁵ Fingas, Merv and Fieldhouse, Ben; "Surface Washing Agents or Beach Cleaners" (2010). Chapter 21 Surface-Washing Agents or Beach Cleaners. In Oil Spill Science and Technology (p716). London: Gulf Professional Publishing.

- Freshwater testing for acute toxicity for the product alone using *Ceriodaphnia dubia* and *Pimephales promelas*,
- Saltwater testing for acute toxicity for the product alone using *Americamysis bahia* and *Menidia bery*llina, or
- Both of the above if product is intended for both freshwater and saltwater applications.

Required data and thresholds are summarized in Table 4-2. To be listed on the NCP Product Schedule, surface washing agents must meet the established thresholds. Refer to Chapter 3 and data submission sample template in <u>Attachment D</u> of this guidance.

Table 4-2: Surface Washing Agents: Subpart J Required Tests and Thresholds

Subpart J Testing Requirements and Thresholds Table			
Surface Washing Agents			
Surface Washing Agents Required Tests	Surface Washing Agents Testing		
	Thresholds		
Surface Washing Agent Effectiveness Test for Freshwater, Saltwater or Both depending on product intended use. (Use applicable standard method and cite method e.g., ASTM Standard Test Method for Evaluating the Effectiveness of Cleaning Agents (G122—96) and Environment Canada's Test Method).	§ 300.915(c)(1): Using an applicable standard methodology, surface washing agents must meet an efficacy of greater than or equal to 30% in either freshwater or saltwater or both.		
Surface Washing Agents – Conduct fresh or saltwater toxicity tests or both depending on use			
Saltwater 96-hr Static Acute Toxicity Test and Saltwater 48-hr Static Acute Toxicity Test (test methods found in section 4.0 of Appendix C to Part 300).	§ 300.915(c)(2): The surface washing agents must demonstrate an LC ₅₀ at the lower 95% confidence interval of greater than 10 ppm saltwater for all tested species.		
Freshwater 96-hr Static Acute Freshwater Toxicity Test and Freshwater 48-hr Static Acute Freshwater Toxicity Test (test methods found in section 4.0 of Appendix C to Part 300).	§ 300.915(c)(2): The surface washing agents must demonstrate an LC ₅₀ at the lower 95% confidence interval of greater than 10 ppm in freshwater for all tested species.		

4.3 Bioremediation Agent Testing and Listing Requirements [§ 300.915(d)]

Bioremediation agents include microorganisms, enzymes, and nutrient additives, such as fertilizers, containing bioavailable forms for nitrogen, phosphorus, and potassium. Manufacturers submitting a product under the bioremediation agent category are required to test the product for efficacy and toxicity. Submitters have the option to test products for use in saltwater environments only, for use in freshwater environments only, or for use in both. The

bioremediation agent product must meet established thresholds for product listing (See Table 4-3).

Nonproprietary commercially available formulations of nutrients are not specifically listed on the NCP Product Schedule, even though as nutrient additives they are subject to Subpart J requirements. Section 4.3.3 of this chapter describes the provisions at § 300.915(d)(4) for generically listed nonproprietary nutrients.

4.3.1 Bioremediation Agent Efficacy Test and Listing Criteria [§ 300.915(d)(1)]

Efficacy testing is to determine the product's ability to biodegrade weathered ANS crude oil in freshwater or saltwater, or both, depending on the intended product use. The test method, specified in section 5.0 of Appendix C to Part 300, quantifies changes in the oil composition, specifically the degradation of both alkanes and aromatics as determined by gas chromatography/mass spectrophotometry.

4.3.2 Bioremediation Agent Toxicity Test and Listing Criteria [§ 300.915(d)(2)]

Accredited laboratories are required to use the toxicity methodology specified in section 4.0 of Appendix C to Part 300 depending on the product's intended use:

- Freshwater testing for acute toxicity for the product alone using *Ceriodaphnia dubia* and *Pimephales promelas*,
- Saltwater testing for acute toxicity for the product alone using *Americamysis bahia* and *Menidia bery*llina, or
- Both of the above if product is intended for both freshwater and saltwater applications.

Required data and thresholds are summarized in Table 4-3. To be listed on the NCP Product Schedule, surface washing agents must meet the established thresholds. Refer to Chapter 3 and data submission sample template in <u>Attachment E</u> of this guidance.

Table 4-3: Bioremediation Agents – Subpart J Required Tests and Thresholds

Subpart J Testing Requirements and Thresholds Bioremediation Agents		
Required Bioremediation Agent	Bioremediation Agent Testing Thresholds	
Tests		
Bioremediation 28-Day Effectiveness Test (test method found in section 5.0 of Appendix C to Part 300) This test uses weathered ANS test oil.	§ 300.915(d)(1): The percentage reduction of total alkanes (aliphatic fraction) from the GC/MS analysis must be greater than or equal to 85% at day 28, based on the ninety-fifth (95th) percentile Upper Confidence Limit (UCL ₉₅) for both freshwater and saltwater. The percentage reduction of total aromatics (aromatic fraction) must be greater than or equal to 35% at day 28 for both saltwater and freshwater based on the UCL ₉₅ .	

Subpart J Testing Requirements and Thresholds Bioremediation Agents			
Required Bioremediation Agent Bioremediation Agent Testing Thresholds			
Tests			
Bioremediation Agents – Conduct fresh or saltwater toxicity tests or both depending on use			
Saltwater 96-hr Static Acute Toxicity	§ 300.915(d)(2): The bioremediation agent must		
Test and Saltwater 48-hr Static Acute	demonstrate an LC ₅₀ at the lower 95% confidence		
Toxicity Test (test methods found in	interval of greater than 10 ppm saltwater for all		
section 4.0 of Appendix C to Part	tested species.		
300).			
Freshwater 96-hr Static Acute	§ 300.915(d)(2): The bioremediation agent must		
Freshwater Toxicity Test and	demonstrate an LC ₅₀ at the lower 95% confidence		
Freshwater 48-hr Static Acute	interval of greater than 10 ppm in freshwater for all		
Freshwater Toxicity Test (test	tested species.		
methods found in section 4.0 of			
Appendix C to Part 300).			

4.3.3 Generic Listing [§ 300.915(d)(4)].

If the product consists solely of ammonium nitrate, ammonium phosphate, ammonium sulfate, calcium ammonium nitrate, sodium nitrate, potassium nitrate, synthetically derived urea, sodium triphosphate (or tripolyphosphate), sodium phosphate, potassium phosphate (mono- or dibasic), triple super phosphate, potassium sulphate, or any combination thereof, no technical product data are required. The product will be generically listed as non-proprietary nutrients on the NCP Product Schedule, and no further action is necessary. For products that may contain components not specifically identified in § 300.915(d)(4), the requirements under § 300.955: Addition of a Product to the NCP Product Schedule or Sorbent Product List, apply, including the bioremediation agents testing and listing provisions under § 300.915(d).

Please refer to Chapter 3: Subpart J Data and Information Requirements for Listing on the NCP Product Schedule and the bioremediation data submission sample template in <u>Attachment E</u> of this guidance for further information.

4.4 Solidifier Agent Testing Requirements [§ 300.915(e)]

Solidifiers are substances that through a chemical reaction cause oil to become a cohesive mass, preventing oil from dissolving or dispersing into the water column, and which are generally collected and recovered from the environment. Manufacturers submitting a product under the solidifier agent category are required to test for toxicity to determine listing eligibility on the NCP Product Schedule. There are no efficacy testing requirements in the NCP Subpart J for solidifiers.

Accredited laboratories are required to use toxicity testing methods specified in section 4.0 of Appendix C to Part 300 of Subpart J for the following depending on the product's intended use:

- Freshwater testing for acute toxicity for the product alone using *Ceriodaphnia dubia* and *Pimephales promelas*,
- Saltwater testing for acute toxicity for the product alone using *Americamysis bahia* and *Menidia bery*llina, or
- Both if product is intended for both freshwater and saltwater applications.

Required data points and thresholds are summarized in Table 4-4. To be listed on the NCP Product Schedule, solidifier agents must meet the established thresholds. Refer to Chapter 3 Subpart J Data and Information Requirements for Listing on the NCP Product Schedule and data submission sample template in Attachment F of this guidance.

Table 4-4: Solidifiers – Subpart J Required Tests and Thresholds

Subpart J Testing Requirements and Thresholds - Solidifiers			
Solidifier Required Tests	Solidifier Testing Thresholds		
Solidifiers – Conduct fresh or saltwater toxicity tests or both depending on use			
Saltwater 96-hr Static Acute Toxicity Test	§ 300.915(e)(1): The solidifier must demonstrate		
and	an LC ₅₀ at the lower 95% confidence interval of		
Saltwater 48-hr Static Acute Toxicity Test	greater than 10 ppm saltwater for all tested		
(test methods found in section 4.0 of	species.		
Appendix C to Part 300).			
Freshwater 96-hr Static Acute Freshwater	§ 300.915(e)(1): The solidifier must demonstrate		
Toxicity Test and Freshwater 48-hr Static	an LC ₅₀ at the lower 95% confidence interval of		
Acute Freshwater Toxicity Test (test	greater than 10 ppm in freshwater for all tested		
methods found in section 4.0 of Appendix C	species.		
to Part 300).			

4.5 Herding Agent Testing Requirements [§ 300.915(f)]

Herding agents or herders are substances that form a film on the water surface to control the spreading of the oil to allow for oil removal. Manufacturers submitting a product under the herding agent category are required to test for toxicity to determine listing eligibility on the NCP Product Schedule. There are no efficacy testing requirements in the NCP Subpart J for herders.

Accredited laboratories are required to use toxicity testing methods specified in section 4.0 Appendix C to Part 300 for the following depending on the product's intended use:

- Freshwater testing for acute toxicity for the product alone using *Ceriodaphnia dubia* and *Pimephales promelas*,
- Saltwater testing for acute toxicity for the product alone using *Americamysis bahia* and *Menidia beryllina*, or
- Both if product is intended for both freshwater and saltwater applications.

Required data and thresholds are summarized in Table 4-5. To be listed on the NCP Product Schedule, herding agents must meet the established thresholds. Refer to Chapter 3 Subpart J

Data and Information Requirements for Listing on the NCP Product Schedule and the data submission sample template in <u>Attachment G</u> of this guidance.

Table 4-5: Herding Agents – Subpart J Required Tests and Thresholds

Subpart J Testing Requirements and Thresholds Table Herding Agents		
Herding Agent Required Tests	Herding Agent Testing Thresholds	
Herding Agents – Conduct fresh or saltwater toxicity tests or both depending on use		
Saltwater 96-hr Static Acute Toxicity	§ 300.915(f)(1): The herding agent must	
Test and	demonstrate an LC ₅₀ at the lower 95% confidence	
Saltwater 48-hr Static Acute Toxicity	interval of greater than 10 ppm saltwater for all	
Test (test methods found in section 4.0 of	tested species.	
Appendix C to Part 300).		
Freshwater 96-hr Static Acute	§ 300.915(f)(1): The herding agent must	
Freshwater Toxicity Test and Freshwater	demonstrate an LC ₅₀ at the lower 95% confidence	
48-hr Static Acute Freshwater Toxicity	interval of greater than 10 ppm in freshwater for	
Test (test methods found in section 4.0 of	all tested species.	
Appendix C to Part 300.		

4.6 Providing a Neat (Undiluted) Sample to Laboratory for Testing

The neat product sample along with a chain of custody should be provided to the laboratory conducting testing to aid in product comparison. The test methods described in Appendix C to Part 300 are intended to provide a basic set of test procedures that will provide baseline data for comparison of products on a national basis. The testing protocols were not developed with the intent of replicating possible real-world situations. The dispersant toxicity testing protocol was developed using conservative estimates. In using the data currently available on the NCP Product Schedule, On-Scene Coordinators (OSC) and Regional Response Teams (RRT) understand these data are intended for use for relative comparisons and rankings of products.

4.7 EPA Reference Test Oil Procurement

EPA secured the reference test oils for the specific purpose of establishing nationally consistent testing that would serve as a baseline comparison of products considered for listing on the NCP Product Schedule. EPA is providing reference test oils specifically to test products for listing on the NCP Product Schedule, as well as to test representative samples when an expired product is being considered for authorization for use by an On-Scene Coordinator to demonstrate the product

Subpart J Reference Test Oils – For Accredited Laboratories Subpart J Testing Only

Environmental Data Services, Ltd (EDS) 5 Brilliant Avenue

Pittsburgh, PA 15215 Phone: (412) 408-3288

Email: dwaldschmidt@eds-us.net

For additional information:

Contact the NCP Subpart J Information Line at

202-260-2342.

still meets the applicable efficacy and toxicity listing requirements under § 300.915.

EPA, through its contractor Environmental Data Services, Ltd (EDS), will be distributing reference test oils in volumes limited to those required for testing dispersants and bioremediation agents for the purposes of listing on the NCP Product Schedule or for demonstrating whether expired products meet applicable efficacy and toxicity requirements under § 300.915. EDS is only able to ship reference oils to a laboratory or facility that is equipped to receive it. There is no charge for the test oils from EDS, but shipping must be paid for by the recipient laboratory. The two oils available for testing include:

- Strategic Petroleum Reserve (SPR) Bryan Mound Test Oil: For Baffled Flask Dispersant Efficacy Test and Dispersant Toxicity Testing.
- Alaska North Slope (ANS) 521 Weathered Test Oil: For Bioremediation Agent Efficacy Test Protocol.

For surface washing agents, EPA reference test oils are not needed as the applicable standard efficacy methodology selected by the submitter will specify what test oil to use. Likewise, EPA reference test oils are not needed for the acute toxicity test of surface washing agents, solidifiers, or herding agents.

Table 4-6 includes the volume that will be distributed, upon request, to the testing laboratories. These volumes provide sufficient quantities of EPA reference oil needed to conduct the required tests for dispersant products or for bioremediation agent products following the protocols in Appendix C to Part 300.

Table 4-6: Appendix C to Part 300 Reference Test Oil Distribution Quantities for Subpart J Testing Labs

Distribution Quantities to Meet Appendix C Product Testing Volume Requirements			
Product Tests	Oil	Quantity	
DISPERSANT –	Strategic Petroleum Reserve	1 X 500 ml	
 Efficacy Test 	(SPR) Bryan Mound		
 Product-Oil Mixture Acute Toxicity Test 			
BIOREMEDIATION AGENT –	Alaska North Slope 521	1 X 2 oz jar	
 Efficacy Test – Freshwater 	Weathered Oil		
BIOREMEDIATION AGENT –	Alaska North Slope 521	1 X 2 oz jar	
 Efficacy Test –Saltwater 	Weathered Oil		
BIOREMEDIATION AGENT –	Alaska North Slope 521	2 X 2 oz jars	
 Efficacy Test – Both Freshwater and 	Weathered Oil		
Saltwater			

Chapter 5: Sorbents and the Sorbent Product List

5.1 Introduction

Sorbents as defined in § 300.5, are inert and insoluble substances that readily absorb and/or adsorb oil or hazardous substances, and that are not combined with or act as a chemical agent, biological agent, or sinking agent. Sorbents may be used in their natural bulk form or as manufactured products in particulate form, sheets, rolls, pillows, or booms. Sorbents are generally collected and recovered from the environment. The list of sorbent materials provided in the definition includes:

- Natural organic substances (e.g., feathers, cork, peat moss, and cellulose fibers, such as bagasse, corncobs, and straw);
- Inorganic/mineral compounds (e.g., volcanic ash perlite, vermiculite, zeolite, clay); and
- Synthetic compounds (e.g., polypropylene, polyethylene, polyurethane, polyester).

Sorbents are **not** listed on the NCP Product Schedule. Known sorbent materials and products will be identified on a publicly available <u>Sorbent Product List</u> for the use of such products when responding to an oil discharge. NOTE: Response actions, including the use of sorbents, are subject to OSC oversight under the NCP.

5.2 Sorbent Product List

Known sorbent materials and products will be identified on a publicly available <u>Sorbent Product List</u> and will serve as reference for the use of such products when responding to an oil discharge. The Sorbent Product List is comprised of two parts: 1) sorbents covered by § 300.915(g)(1) and 2) sorbents covered by § 300.915(g)(2). Please review the sorbent provisions under § 300.915(g)(1) and § 300.915(g)(2).

Under § 300.915(g)(1), the Sorbent Product List covers sorbent products that consist solely of the materials, or any combination thereof, identified in § 300.915(g)(1)(i)-(iii). No technical data are required to be submitted to EPA. A sorbent product covered by § 300.915(g)(1) is considered generically listed on the Sorbent Product List whether or not the sorbent product is also specifically identified on the Sorbent Product List using a name, brand, or trademark. OSCs should be aware that a sorbent product that consist solely of the materials, or any combination thereof, listed in § 300.915(g)(1)(i)-(iii), but not specifically identified by a trademark, are generically listed on the Sorbent Product List. Specific listing of sorbent products with a name, brand, or trademark under § 300.915(g)(1) are based solely on the sorbent product representation, and do NOT represent a determination made by EPA. Any sorbent manufacturer who has determined its sorbent product is covered by § 300.915(g)(1) may ask EPA to specifically include their name, brand, or trademarked sorbent product by sending EPA (see address below) the following information:

1) The sorbent product manufacturer's name, physical address, email, and telephone number, and

2) The name(s), brand(s), and/or trademark(s) of the sorbent product to EPA's Product Schedule Manager.

U.S. Environmental Protection Agency

1200 Pennsylvania Ave, NW

Mail Code: 5104A, Room 1448, William J. Clinton North Building

Washington, DC 20460

Attention: Product Schedule Manager

Under § 300.915(g)(2), EPA will consider listing sorbent products on the Sorbent Product List. consisting of one or more natural organic substances, inorganic/mineral compounds, and/or synthetic compounds not specifically identified in § 300.915(g)(1)(i)-(iii). EPA will review the submitted product data and information described in § 300.915(g)(2)(i)-(iii) to determine if the product meets the regulatory definition of a sorbent. EPA may request clarification or additional information, as necessary, consistent with the NCP.

Under § 300.955(f), products previously identified as sorbents by EPA will remain available for use until December 12, 2025, at which time all sorbent products must have submitted information as applicable under § 300.955(a) and (b) and be listed in the new Sorbent Product List. The transitions period provides time for products manufacturers to understand the new provisions.

Section 300.915(g) of Subpart J provides the requirements for sorbent materials and products to be identified on the publicly available Sorbent Product List for the use of such products when responding to an oil discharge as follows:

- § 300.915(g)(1), For sorbent products that consist solely of the following materials, or any combination thereof, <u>no technical data are required</u>, and <u>no further action is necessary</u> for use as a sorbent:
 - (i) Feathers, cork, peat moss, and cellulose fibers such as bagasse, corncobs, and straw;
 - (ii) Volcanic ash, perlite, vermiculite, zeolite, and clay; and
 - (iii) Polypropylene, polyethylene, polyurethane, and polyester.
- § 300.915(g)(2), If the product consists of one or more natural organic substances, inorganic/mineral compounds, and/or synthetic compounds not specifically identified in [§ 300.915(g)(1)], but you believe the product meets the definition of a sorbent then, as applicable under § 300.955(a) and (b), you must submit the following information for consideration for listing it as a sorbent on the Sorbent Product List:
 - (i) The information required under paragraphs (a)(1) through (a)(8), and paragraph (a)(13) through (a)(15) of [§ 300.915];
 - (ii) The certification required under paragraph (a)(16) of [§ 300.915]; and
 - (iii) Information, including data, to support the claim your product meets the sorbent definition under § 300.5.

A sample template for new sorbent data requirements can be found in <u>Attachment H</u> of this guidance.

Chapter 6: Proprietary Business Information [§ 300.950]

6.1 Introduction

Subpart J specifies what information submitters are allowed to claim as Proprietary Business Information or PBI (formerly known as Confidential Business Information or CBI). The aim is to balance public access to information with proprietary business needs.

When submitting a product for listing on the NCP Product Schedule or the Sorbent Product List, only certain information may be claimed as PBI in accordance with § 300.950. Specifically, submitters may only claim as PBI the concentration; the maximum, minimum, and average weight percent; and the units of each component as identified in § 300.915(a)(13) and (14), and as applicable. EPA will handle such claims in accordance with 40 CFR part 2, subpart B Confidentiality of Business Information. All other information submitted to EPA for listing on the NCP Product Schedule as required under § 300.915 and § 300.955 cannot be claimed as PBI and will be available for public disclosure upon submission without further notice to the submitter. PBI claims must be made at the time the submitter submits the product listing request to EPA.

<u>Attachment I</u> of this guidance includes a Proprietary Business Information Submission Sample Template available for use to make PBI claims.

6.2 Proprietary Business Information Sample Format for Chemical and Biological Agents and Sorbents [§ 300.915(a)(13)]

The submitter may use the following sample format, or similar, when submitting PBI for chemical and biological agents and sorbents to EPA (refer to <u>Attachment I</u> of this guidance).

Table 6-1 Sample Format for Submitting PBI for Chemical and Biological Agents and Sorbents

Chemical Name	CAS#	Concentration Percentage by Weight (PBI)	Intended Function
Sodium stearate	822-16-2	MAX/MIN/AVG%	Surfactant

When submitting as PBI the associated concentrations, weight percentages and units for the components of a chemical or biological agent product, please note the following:

- **Chemical Name:** Use the proper chemical name for each product component and not the commercial name, chemical families, classes or group names. **The chemical name of product components cannot be claimed PBI.**
- Chemical Abstract Service (CAS) Registry Number: Include CAS Registry Number for each chemical. The CAS Registry Number of product components cannot be claimed CBI.
- **Concentration, Percentage by Weight:** Include the concentration, the maximum, minimum, and average weight percent, and the units as applicable for each component of the total

formulation (*This is the only information submitters may claim as PBI*). Concentrations are often expressed in terms of either mass or volume percentages. *Generally, the total average weight percent for chemical components combined should equal or approximate 100% (microorganisms and enzymes are to be reported in their respective units).*

- Category: Identify the intended function of each component (e.g., surfactant, solvent). The intended function of product components cannot be claimed PBI.
- 6.3 Proprietary Business Information Sample Format for Chemical and Biological Agents and Sorbent Products Containing Microorganisms, Enzymes, and/or Nutrients [§ 300.915(a)(14)]

The submitter may use the following sample formats, or similar, when submitting PBI for chemical and biological agents and sorbents that have components containing microorganisms, enzymes, and/or nutrients to EPA (refer to <u>Attachment I</u> of this guidance).

6-2: Sample Format for Submitting PBI for Products Containing Microorganisms:

Microorganism Name	Reclassifications	Any Physical, Chemical, or Biological Manipulation of the Genetic Composition	Weight Percent of Each Genus in the Product (PBI)
Microorganism (current genus, species)			MAX/MIN/AVG%

- *Microorganisms:* Provide the name of all microorganisms by current genus and species.
- Reclassification and Manipulation of Genetic Composition: Include any reclassifications and any physical, chemical, or biological manipulation of the genetic composition.
- The genus and species, reclassifications, and the physical, chemical or biological manipulation of the genetic composition of the product components cannot be claimed as PBI.
- Weight Percent: Include weight percent of each genus in the product. This is the only information submitters may claim as PBI.

6-3: Sample Format for Submitting PBI for Products Containing Enzymes

Enzyme Name	International Union of Biochemistry (I.U.B.) Number(s)	Enzyme Classification (EC) Code Numbers	Source of Each Enzyme	Units (PBI)	Specific Oil- Degrading Activity
Enzyme					

• Enzymes: Include the name of all enzymes and their International Union of Biochemistry (I.U.B.) number(s); Enzyme Classification (EC) code numbers; the source of each enzyme;

- units; and specific oil-degrading activity. *The name, I.U.B. and EC, enzyme source and specific oil-degrading activity of product components cannot be claimed PBI.*
- Units are expressed in terms of either mass or volume percentages. Enzymes are to be reported in their respective units; the units may be claimed as PBI.

6-4: Sample Format for Submitting PBI for Products Containing Nutrients

Nutrient Name	CAS#	Weight Percent	Intended Function
Ammonium nitrate	6454-52-2	MAX/MIN/AVG%	Nutrient additive

- Nutrient Name: Use the proper nutrient names and not the commercial names, chemical families, classes or group names. The nutrient names of product components cannot be claimed PBI.
- Chemical Abstract Service (CAS) Registry Number: Include CAS Registry Number for each nutrient. The CAS Registry Number of product components cannot be claimed CBI.
- Concentration, Percentage by Weight: Include the concentration, the maximum, minimum, and average weight percent, and the units as applicable for each component of the total formulation. This is the only information that may be claimed as PBI. Concentrations are often expressed in terms of either mass or volume.
- Category: Identify the intended function of each component. The intended function of nutrient components cannot be claimed as PBI.

6.4 Submitting Proprietary Business Information

REMINDER: <u>PBI information should not be submitted to EPA electronically.</u> Any PBI submitted electronically to EPA will immediately be deleted in accordance with EPA policy.

When mailing a submission package to EPA for listing a product under the NCP Product Schedule or the Sorbent Product List, all information claimed as PBI must be enclosed separately within the submission package and marked "Proprietary Business Information." Include all PBI separately from the rest of your submission package, mark it as "Proprietary Business Information" and place it in a separate inner envelope labeled with "PROPRIETARY BUSINESS INFORMATION—TO BE OPENED BY THE PRODUCT SCHEDULE MANAGER ONLY."

EPA will handle PBI claims in accordance with 40 CFR part 2, subpart B *Confidentiality of Business Information*. Shipping Subpart J product submission packages via secure courier (i.e., Fed Ex, UPS), as well as sharing the tracking number with EPA, will assist EPA in securing those packages. When product submission packages arrive at EPA, they are stored in a locked secure location, with access only to personnel that have been authorized to handle PBI.

Chapter 7: Addition of a Product to the NCP Product Schedule or Sorbent Product List [§ 300.955]

7.1 Introduction

To ensure you are submitting a complete package, follow these steps and refer to the product listing checklist in Attachment A of this guidance when preparing the submission package. Proper preparation assists EPA in conducting their review. **EPA will not review incomplete packages.**

7.2 Package Contents and Cover Letter

Section 300.955(b) specifies that the submitters package shall include, as applicable, in this order:

- (1) A cover letter on company letterhead signed and dated by the submitter certifying that:
 - (i) All testing was conducted on representative product samples;
 - (ii) Testing was conducted at a nationally or internationally accredited laboratory in accordance with the methods specified in Appendix C to Part 300, and other applicable methods as appropriate; and
 - (iii) All test results and product technical data and information are true and accurate.
- (2) A page numbered Table of Contents showing the information and data submitted under § 300.915(a) through (g), as applicable (*Please note: Adding page numbers to each page will assist EPA in the review of the submission package*);
- (3) All required data and information arranged in the same order as specified in § 300.915(a) through (g); and
- (4) A separate envelope containing and labeled Proprietary Business Information as specified in § 300.950(b), if applicable (see Chapter 6 for detailed information on submitting PBI).

7.3 Submission Address

Submit your completed package to:

Attn: NCP Product Schedule Manager U.S. Environmental Protection Agency 1200 Pennsylvania Ave. NW Mail Code: 5104A, Room 1448 William J. Clinton North Building Washington, DC 20460



If you have questions on submitting a product package, contact the NCP Subpart J Information Line at: (202) 260-2342

7.4 EPA Review and Product Listing Determination

7.4.1 Review Timeline

As provided in § 300.955(c), EPA will within 90 days of receiving a product application package:

- (1) Review the package for completeness and compliance with all data and information requirements in § 300.915, § 300.950, and § 300.955; verify information; and request clarification or additional information, including testing, as necessary;
- (2) Make a product listing determination based on a technical evaluation of all data and information submitted in accordance with the requirements for each product category, relevant information on impacts or potential impacts of the product or any of its components on human health or the environment, and the intended use of the product; and
- (3) Notify the submitter in writing of its decision to list the product on the NCP Product Schedule or the Sorbent Product List, or of its decision and supporting rationale to reject the submission. If the submission is rejected:
 - (i) The submitter may revise and resubmit a complete package to address test results, data, or information deficiencies.
 - (ii) For resubmissions, EPA's 90-day review will not start until a complete package is resubmitted.

7.4.2 Request for Review of Decision

If your product is rejected for listing on the NCP Product Schedule or the Sorbent Product List, under § 300.955(d) the submitter may request that the EPA Administrator or designee review the determination. The request must be in writing within 30 days of receipt of notification of EPA's decision not to list the product on the NCP Product Schedule or the Sorbent Product List. The request must contain a clear and concise statement with supporting facts and technical analysis demonstrating why the product meets the listing requirements.

- (1) The EPA Administrator or designee may request additional information from the submitter and may offer an opportunity for a meeting with EPA.
- (2) The EPA Administrator or designee will notify the submitter in writing of the decision within 60 days of receipt of the review request, or within 60 days of receipt of requested additional information.

Chapter 8. Submitter Responsibilities for Listed Products

8.1 Introduction

After products are listed on the NCP Product Schedule, there are responsibilities that submitters must meet. These responsibilities include displaying the mandatory product disclaimer as provided under § 300.965, notifying EPA of any administrative changes within 30 days, and retesting and submitting new product application packages for product reformulations. This chapter highlights product listing and submitter responsibilities.

8.2 Notification for Listing

EPA will notify the submitter in writing of its decision to list the product on the NCP Product Schedule or the Sorbent Product List. In addition to notification in writing of EPA's decision to list the product on the NCP Product Schedule or Sorbent Product list, products will be posted to the NCP Product Schedule and Sorbent Product List on EPA's website.

8.3 Mandatory Product Disclaimer [§ 300.965]

The listing of a product on the NCP Product Schedule does not constitute approval or recommendation of the product for use in response to an oil discharge. To avoid possible misinterpretation or misrepresentation, any label, advertisement, or technical literature for the product must display in its entirety the disclaimer shown below. The disclaimer must be conspicuous and must be fully reproduced on all product literature, labels, and electronic media including webpages.

DISCLAIMER

[PRODUCT NAME] is listed on the National Contingency Plan (NCP) Product Schedule. This listing does NOT mean that EPA approves, recommends, licenses, or certifies the use of [PRODUCT NAME] on an oil discharge. This listing means only that data have been submitted to EPA as required by Subpart J of the NCP. Only a Federal On-Scene Coordinator (OSC) may authorize use of this product in accordance with Subpart J of the NCP in response to an oil discharge.

8.4 Making Administrative Changes to a Product Listing [§ 300.955(e)]

Submitters must notify EPA in writing within 30 days of any changes to information submitted under § 300.915(a)(1) through (8) and § 300.915(a)(19) through (21) for a product on the NCP Product Schedule. Specifically, notifications are required for changes to the following information:

- Submitter's name, physical address, email, and telephone number (§ 300.915(a)(1));
- Submitter's identity and documentation of that identity, as the manufacturer of the product, vendor, importer, distributor of the product, and/or a designated agent acting on behalf of the manufacturer (§ 300.915(a)(2));

- All name(s), brand(s), and/or trademark(s) under which the product is to be sold (§ 300.915(a)(3));
- Names, physical addresses, emails, and telephone numbers of the product suppliers, such
 as primary distributors, vendors, importers and/or designated agent acting on behalf of the
 manufacturer (§ 300.915(a)(4));
- The Safety Data Sheet (SDS) for the product (§ 300.915(a)(5));
- The maximum, minimum, and optimum temperature, humidity, and other relevant conditions for product storage and brief description of the consequences to performance if the product is not stored within these limits (§ 300.915(a)(6));
- The anticipated shelf life of the product at the storage conditions noted in (§ 300.915(a)(6)) and documentation for this determination (§ 300.915(a)(7));
- A sample product label for all name(s), brand(s), and/or trademark(s) under which the
 product is to be sold that includes the manufacture and expiration dates, and conditions for
 storage. You may use an existing label provided in already contains the required dates and
 storage information ((§ 300.915(a)(8));
- An estimate of the annual product production volume, the average and maximum amount that could be produced per day, and the time frame needed to reach that maximum production rate in days (§ 300.915(a)(19));
- Recognitions received from EPA's Design for the Environment (DfE) or Safer Choice programs, as applicable (§ 300.915(a)(20)); and
- International product testing or use data or certifications, if available, informing the performance capabilities or environmental impacts of the product ((§ 300.915(a)(21)).

The notification must detail the specific changes, the reasons for such changes, and include supporting data and information. EPA may request additional information and clarification regarding these changes.

8.5 Product Reformulation [§ 300.955(e)(2)]

Changes in the components and/or concentrations of a product require that the reformulated product be retested according to the requirements for the product category and that a new complete package be submitted under a new, distinct name in accordance with § 300.955(b) for review and consideration for listing on the NCP Product Schedule or Sorbent Product List by EPA.

Chapter 9: NCP Product Schedule and NCP Product Schedule Technical Notebook

9.1 Introduction

EPA will make a product listing determination based on the technical evaluation of all data and information submitted in accordance with the requirements for each product category, relevant information known to the Agency on impacts or potential impacts of the product or any of its components on human health or the environment, and the intended use of the product. Products listings will be added to the NCP Product Schedule. The product specific data provided by submitters is made available through the NCP Product Schedule Technical Notebook. The listing of a product on the NCP Product Schedule does not constitute approval or recommendation of the product, it means only that the regulatory data submission and testing and listing requirements have been satisfied. Sorbent products are not listed on the NCP Product Schedule. Instead, sorbents are listed in the Sorbent Product List. For sorbent listing information, refer to Chapter 5 Sorbents and the Sorbent Product List.

9.2 NCP Product Schedule

The NCP Product Schedule presents products (including all name(s), brand(s), and/or trademark(s) under which the product is to be sold) in an alphabetical table of contents, with navigation to the listing information, and by category type (i.e., bioremediation agents, dispersants, herding agents, solidifiers, and surface washing agents). The NCP Product Schedule is updated as needed to include, for example, new listings, product removals, and administrative changes (for more information please refer to Section 8.4: Making Administrative Changes to a Product Listing, in Chapter 8 of this guidance). The NCP Product Schedule document is made available for public disclosure on EPA's website. In addition, users can navigate to the online NCP Product Schedule Technical Notebook Product Data and Information Summaries by clicking on the product names (and aka's) under the category type. EPA will assign numbers to the products as they are listed for tracking purposes.

9.3 NCP Product Schedule Technical Notebook

As a companion to the NCP Product Schedule, the <u>NCP Product Schedule Technical Notebook</u> contains the Subpart J required data, information, and testing results of listed products as provided by product submitters. The product data and information in the NCP Product Schedule Technical Notebook will assist On-Scene Coordinators in further understanding countermeasures that may be considered in their planning for and responding to oil spills.

The NCP Product Schedule Technical Notebook is updated as needed to include, for example, new listings, product removals, and administrative changes (for more information, please refer to Section 8.4: Making Administrative Changes to a Product Listing, in Chapter 8 of this guidance); and made available for public disclosure on EPA's website. NCP Product Schedule Technical Notebook users can navigate to all product data and information summaries, including all product's name(s), brand(s), and/or trademark(s), by category type, alphabetically, or categorically by product.

Chapter 10: Removal of a Product from the NCP Product Schedule or Sorbent Product List [§ 300.970]

10.1 Introduction

EPA may determine there is a need to remove products from the NCP Product Schedule or the Sorbent Product List. The Agency will notify the submitter of a determination to remove a listed product and will provide an opportunity for the submitter to appeal that decision prior to removal of the listed product from the NCP Product Schedule or the Sorbent Product List.

Additionally, Subpart J does not prohibit submitters from, at any time, requesting their products be removed from the NCP Product Schedule or Sorbent Product List. The Agency will make final determinations regarding any such request. The NCP Product Schedule and Sorbent Product List will identify products that have been removed, including those removed at the request of the submitter.

10.2 Removal of a Product by EPA

In accordance with § 300.970, the EPA Administrator or designee may remove a listed product from the NCP Product Schedule or Sorbent Product List for reasons including, but not limited to:

- (1) Misleading, inaccurate, outdated, or incorrect statements and information regarding the composition or use of the product to remove or control oil discharges made to any person, or private or public entity, including on labels, advertisements, technical literature, or electronic media, or within the product submission to EPA; or
- (2) Alterations to the components, concentrations, or use conditions of the product without proper notification to EPA as required by § 300.955(e); or
- (3) Failure to print the disclaimer provided in § 300.965 on all labels, advertisements, technical literature, or electronic media for products listed on the NCP Product Schedule; or
- (4) New or previously unknown relevant information concerning the impacts or potential impacts of the product to human health or the environment.

EPA will notify the submitter in writing, at their address of record, of its reasons for deciding to remove the product. If EPA receives no appeal from the submitter in 30 days, the product will be removed from the NCP Product Schedule or Sorbent Product List without further notice to the submitter.

Submitters have the option to appeal the decision to remove their product within 30 days of receipt of EPA's notification. The appeal must contain a clear and concise statement with supporting facts and technical analysis demonstrating why the product should not be removed. The EPA Administrator or designee will notify the submitter in writing of the decision within 60 days of the appeal, or within 60 days of receipt of any requested additional information.

10.3 Removal of a Product by a Submitter

Submitters may request that their listed product be removed from the NCP Product Schedule or the Sorbent Product List. This may occur, for example, if a product is no longer being manufactured or if a company is going out of business. Submitters should send a formal letter to EPA requesting their product be removed from the NCP Product Schedule or the Sorbent Product List including the reason for removal. EPA will make the final determination on delisting under any such request.

Attachment A: Product Listing Checklist

Ge	eneral Checklist for Listing a Product on the NCP Product Schedule
Completed	Activity
	1. Read the regulatory requirements under Subpart J of the NCP in their entirety (including Appendix C to Part 300).
	2. Read the product definitions and determine product category (under § 300.5 of the NCP. Subpart J Product Categories: Dispersant, Surface Washing Agent, Bioremediation Agent, Herding Agent, Solidifiers, and Sorbents (see Chapter 2 of this guidance)).
	3. Review the specific listing data requirements for your product category (under § 300.915 and Appendix C to Part 300, see sample templates in Attachments C – H of this guidance)
	 4. Review testing requirements for your product category (under § 300.915 and including Appendix C to Part 300) a. Physical and Chemical Properties; b. Pathogens and Contaminants; c. Toxicity for all products (choose fresh water, salt water or both as appropriate); and d. Efficacy for Dispersants, Surface Washing Agents, and Bioremediation Agents.
	 5. Select an accredited lab and/or labs to conduct the testing required for your product category. a. Send neat (undiluted) product and chain of custody to lab(s) for analysis. 6. Complete application for your product category (see Chapters 3 – 5 and sample
	templates in Attachments C – I of this guidance).
	7. Follow Proprietary Business Information (PBI) instructions under § 300.950 (see Chapter 6 and Attachment I of this guidance). Note: Submitters may claim as PBI only the concentrations of components in their product; the maximum, minimum, and average weight percent of each component; and the units of each component as identified in § 300.915(a)(13) and (14) and as applicable.
If you have que	 8. Submit your product package to EPA as required under § 300.955: a. Cover letter; b. Page numbered Table of Contents; c. All required data and information arranged in the same order as specified in § 300.915(a) through (g); and d. A separate envelope containing and labeled Proprietary Business Information as specified in § 300.950(b), if applicable.

Attachment B: Quick Links to the <u>Electronic Code of</u> <u>Federal Regulations</u> (eCFR)⁶

NCP Definitions – § 300.5

Full list of NCP definitions including those applicable to Subpart J: https://www.ecfr.gov/current/title-40/chapter-l/subchapter-J/part-300/subpart-A/section-300.5 (eCFR)

Subpart J Regulation

Subpart J — Use of Dispersants, and Other Chemical and Biological Agents:

https://www.ecfr.gov/current/title-40/chapterl/subchapter-J/part-300/subpart-J(eCFR)

Appendix C to Part 300

Access to Appendix C to Part 300 —Requirements for Product Testing Protocols and Summary Test Data:

https://www.ecfr.gov/current/title-40/chapter-I/subchapter-J/part-300#Appendix-C-to-Part-300 (eCFR)

⁶ The *Code of Federal Regulations* (CFR) is the official legal print publication containing the codification of the general and permanent rules published in the *Federal Register* by the departments and agencies of the Federal Government. The Electronic Code of Federal Regulations (eCFR) is a continuously updated online version of the CFR. It is not an official legal edition of the CFR.

Attachment C: Dispersant Data Submission Sample Template

DISPERSANT DATA SUBMISSION SAMPLE TEMPLATE FOR § 300.915 DATA AND INFORMATION REQUIREMENTS

PRODUCT NAME:

CATEGORY: DISPERSANT

GENERAL PRODUCT INFORMATION [§ 300.915(a)]

(1) NAME, ADDRESS, EMAIL, AND TELEPHONE NUMBER OF SUBMITTER [§ 300.915(a)(1)]

Your name, physical address, email, and telephone number.

Company Name

Physical Address

City, State Zip Code

Phone: (###) ###-####

E-mail

(Point of Contact)

(2) SUBMITTER IDENTIFICATION [§ 300.915(a)(2)]

Your identity and documentation of that identity, as the manufacturer of the product; vendor, importer, or distributor of the product; and/or designated agent acting on behalf of the manufacturer.

(3) PRODUCT NAME, BRAND, OR TRADEMARK [§ 300.915(a)(3)]

All name(s), brand(s), and/or trademark(s) under which the product is to be sold.

(4) NAME, ADDRESS, EMAIL, AND TELEPHONE NUMBER OF SUPPLIERS [§ 300.915(a)(4)]

Names, physical addresses, emails, and telephone numbers of the primary distributors, vendors, importers, and/or designated agent acting on behalf of the manufacturer.

Company Name

Physical Address

City, State Zip Code

Phone: (###) ###-###

E-mail:

(Point of Contact)

(5) SAFETY DATA SHEET (SDS) [§ 300.915(a)(5)]

The Safety Data Sheet for the product.

(6) PRODUCT STORAGE [§ 300.915(a)(6)]

- 1. Maximum storage temperature (e.g., °F and/or °C):
- 2. Minimum storage temperature (e.g., °F and/or °C):
- 3. Optimum storage temperature (e.g., °F and/or °C):
- 4. Humidity (e.g., g/kg):
- 5. Other relevant conditions for product storage:
- 6. Description of the consequences to performance if product is not stored within these limits:

(7) SHELF LIFE STORAGE CONDITIONS [§ 300.915(a)(7)]

The anticipated shelf life of the product at the storage conditions noted in paragraph(a)(6) of this section and documentation for this determination.

(8) PRODUCT LABEL [§ 300.915(a)(8)]

A sample product label for all name(s), brand(s), and/or trademark(s) under which the product is to be sold that includes manufacture and expiration dates, and conditions for storage. You may use an existing label provided it already contains the required dates and storage information.

(9) PRODUCT CATEGORY AND PROCESSES [300.915(a)(9)]

The chemical or biological agent category under which you want the product to be considered for listing on the NCP Product Schedule including detailed information on the specific process(es) through which the product affects the oil, in the specific environment(s) on which it is intended to be used (e.g., waters and/or adjoining shoreline). If your product meets the definition of more than one chemical or biological agent category, you must identify all applicable categories and provide the test data to meet the listing criteria appropriate to each.

(10) RECOMMENDED PRODUCT USE PROCEDURES [§ 300.915(a)(10)]

Recommended product use procedures, including product concentrations, use ratios, types of application equipment, conditions for use, any application restrictions; and, as applicable, procedures for product and oil containment, collection, recovery, and disposal. These procedures must address, as appropriate, variables such as weather, water salinity, water temperature, types and weathering states of oils or other pollutants. The procedures must include supporting documentation and current applicable standard methods used to determine them.

(11) ENVIRONMENTAL FATE OF COMPONENTS [§ 300.915(a)(11)]

Available information on environmental fate, including any known measured data, methodologies, and supporting documentation, on the persistence, bioconcentration factor, bioaccumulation factor, and biodegradability of the product and all of its components in the environment.

(12) PHYSICAL/CHEMICAL PROPERTIES [§ 300.915(a)(12)]

Physical and chemical properties of the product, as appropriate, and a citation for the current applicable standard methods used to determine them including:

- (i)Physical State and Appearance:
- (ii) Vapor Pressure:
- (iii)Flash Point:
- (iv)Pour Point:
- (v)Viscosity:
- (vi)Specific Gravity:
- (vii)Particle Size for Solid Components:
- (viii)pH:

(13) IDENTIFICATION AND CONCENTRATION OF PRODUCT COMPONENTS [§ 300.915(a)(13)]

The identity and concentration of all components in the product, including each specific component name; corresponding Chemical Abstract Service (CAS) Registry Number; the maximum, minimum, and average weight percent of each component in the product; and the intended function of each component (e.g., solvent, surfactant).

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

Note 1: Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter.

Note 2: You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule and **include any PBI information in a separate sealed envelope**.

(14) MICROORGANISMS, ENZYMES AND/OR NUTRIENTS [§ 300.915(a)(14)]

For products that contain microorganisms, enzymes, and/or nutrients, provide the component information as follows, including a citation and description of the methodology used to determine:

1. Microorganisms [§ 300.915(a)(14)(i)]

- a. Name of all microorganisms by current genus and species:
- b. Any reclassifications:
- c. Any physical, chemical, or biological manipulation of the genetic composition:
- d. Weight percent of each genus in the product:

See Chapter 6 and the sample template in Attachment I of this guidance.

2. Enzymes [§ 300.915(a)(14)(ii)]

- a. Name of all enzyme(s):
- b. International Union of Biochemistry (I.U.B.) Number(s),
- c. Enzyme Classification (EC) Code Number:
- d. Source of Enzymes:
- e. Units:
- f. Specific Oil-Degrading Activity:

See Chapter 6 and the sample template in Attachment I of this guidance.

3. Nutrients [§ 300.915(a)(14)(iii)]

- a. Name(s) of all Nutrients:
- b. Maximum Weight Percent of Nutrients:
- c. Minimum Weight Percent of Nutrients:
- d. Average Weight Percent of Nutrients:

See Chapter 6 and the sample template in Attachment I of this guidance.

4. Data, methodology, and supporting documentation for levels of bacterial, fungal, or viral pathogens, or opportunistic pathogens, including but not limited to [§ 300.915(a)(14)(iv): Enteric bacteria, suchs as *Salmonella*, fecal coliforms, Shigella, coagulase postive *Staphylococci*, and beta hemolytic *Streptococci* and enterococci.

NOTE – Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter. You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule and include any PBI information in a separate sealed envelope (See Chapter 6 of this guidance).

(15) DATA, METHODOLOGY AND SUPPORTING DOCUMENTATION FOR LEVELS OF THE FOLLOWING [§ 300.915(a)(15)]:

Data, methodology, and supporting documentation for the levels of the following:

- 1. Arsenic, cadmium, chromium, copper, lead, mercury, nickel, vanadium, zinc, and any other heavy metal reasonably expected to be in the product;
- 2. Cyanide;
- 3. Chlorinated hydrocarbons;
- 4. Pesticides;
- 5. Polychlorinated biphenyls (PCBs); and
- 6. Polycyclic aromatic hydrocarbons (PAHs).

(16) PROHIBITED AGENT CERTIFICATION [§ 300.915(a)(16)]

Certification including data, methodology and supporting documentation indicating that product does not contain any prohibited agents identified in § 300.910(e).

(17) LABORATORY INFORMATION [§ 300.915(a)(17)]

Information about the accredited laboratory that conducted the required tests, including: (i)Name of the laboratory, address, contact, name, email, and phone number; and (ii) the national and/or international accreditations held by the laboratory that are applicable to test(s) performed.

(18) LABORATORY TEST DATA AND REPORTS [§ 300.915(a)(18)]

All test data and calculations, including:

- 1. Raw data and replicates, including positive controls;
- 2. Notes and observations collected during tests;
- 3. Calculated mean values and standard deviations;
- 4. Reports, including a summary of stock solution preparation;
- 5. Source and preparation of test organisms;
- 6. Test conditions; and
- 7. Chain of custody forms.

(19) PRODUCTION VOLUMES [§ 300.915(a)(19)]

An estimate of the annual production volume, the average and maximum amount that could be produced in a day, and the time frame needed to reach that maximum production rate in days.

(20) DESIGN FOR THE ENVIRONMENT (now Safer Choice) [§ 300.915(a)(20)]

Recognition received from EPA's Design for the Environment (DfE) or Safer Choice programs, as applicable.

(21) INTERNATIONAL PRODUCT TESTING, DATA, AND/OR CERTIFICATIONS [§ 300.915(a)(21)] International product testing or use data or certifications, if available, informing the performance capabilities or environmental impacts of the product.

PRODUCT CATEGORY TESTING AND LISTING REQUIREMENTS [§ 300.915(b)]

DISPERSANT EFFICACY TEST AND LISTING CRITERIA [§ 300.915(b)(1)]

<u>Efficacy Test:</u> Dispersant must be tested using the Baffled Flask Dispersant Efficacy Test in Appendix C to Part 300, Section 2.0.

<u>Listing Criteria:</u> Dispersant must demonstrate for each temperature a Dispersant Effectiveness (DE) at the 95% lower confidence level (LCL95) greater than or equal to:

- ≥70% for Strategic Petroleum Reserve Bryan Mound test oil at 5°C; and
- ≥75% for Strategic Petroleum Reserve Bryan Mound test oil at 25°C.

Test Oil	Dispersant Effectiveness	Dispersant Effectiveness
	Temperature at 5°C	Temperature at 25°C
SPR Bryan Mound	[Percent] DE _{LCL95}	[Percent] DE _{LCL95}

DISPERSANT TOXICITY TESTS AND LISTING CRITERIA [§ 300.915(b)(2)]

<u>Toxicity Tests:</u> Dispersant must be tested, using the methods in Section 3.0 of Appendix C to Part 300, for:

- Dispersant alone and the dispersant mixed with Strategic Petroleum Reserve Bryan Mound for acute toxicity, using *Americamysis bahia* and *Menidia beryllina*;
- Dispersant alone for developmental toxicity using Strongylocentrotus purpuratus or Arbacia punctulata; and
- Dispersant alone for subchronic effects using Americamysis bahia and Menidia beryllina.

<u>Listing Criteria:</u> Dispersant tested alone must demonstrate:

- For acute toxicity a median lethal concentration for 50% of the test species (LC50) at the lower 95% confidence interval greater than 10 ppm.
- For developmental toxicity the inhibition concentration for 50% of the test species (LC50) at the lower 95% confidence interval greater than 1 ppm; and
- For sub-chronic toxicity the No Observed Effect Concentration (NOEC) greater than 1 ppm.

Note: Reference Toxicants. Separate toxicity tests must be performed with a reference toxicant for each species tested (Section 3.3.3 of Appendix C to part 300). Submitters should provide results in format shown below.

		PROCE	DURES		
Material Tested	96-hr Static Acute <i>Menidia</i> beryllina	48-hr Static Acute Americamysis bahia	72-hr Sea Urchin Developmental Assay Strongylocentrotus purpuratus/Arbacia punctulata		7-day Subchronic <i>M. beryllina</i> & <i>A. bahia</i>
Dispersant Only	Yes	Yes	Yes		Yes
Dispersant/Reference Oil Mixture	Yes	Yes	No		No
Material Tested		icity Test Data Summ		LCEO ()	
Material Tested	Saltwater Specie			LC50 (ppm)	0.01
Dispersant Only	Menidia beryllin			[Conc]	96-hr
	Americamysis bo			[Conc]	48-hr
Dispersant/Reference Oil Mixture	Menidia beryllina			[Conc]	96-hr
	Americamysis bahia			[Conc]	48-hr
SDS Reference Toxicant (AKA DSS or SLS)	Menidia beryllina			[Conc]	96-hr
	Americamysis bo	ahia		[Conc]	48-hr
	Developme	ental Test Data Sumn	nary		
Material Tested	Sea Urchin Spec	cies		LC50 (ppm)	
Dispersant	Strongylocentro	tus purpuratus / Arbo	acia	[Conc]	72-hr
Copper Sulfate Reference Toxicant	Strongylocentrotus purpuratus / Arbacia punctulata			[Conc]	72-hr
	Subchror	nic Test Data Summa	ry		
Material Tested	Saltwater Specie	es		LC50 (ppm)	
Dispersant	Menidia beryllin	а		[Conc]	7-day
	Americamysis bo	ahia		[Conc]	7-day

Attachment D: Surface Washing Agent Data Submission Sample Template

SURFACE WASHING AGENT DATA SUBMISSION SAMPLE TEMPLATE FOR § 300.915 DATA AND INFORMATION REQUIREMENTS

PRODUCT NAME:

CATEGORY: SURFACE WASHING AGENT

GENERAL PRODUCT INFORMATION [§ 300.915(a)]

(1) NAME, ADDRESS, EMAIL, AND TELEPHONE NUMBER OF SUBMITTER [§ 300.915(a)(1)]

Your name, physical address, email, and telephone number.

Company Name

Physical Address

City, State Zip Code

Phone: (###) ###-####

E-mail

(Point of Contact)

(2) SUBMITTER IDENTIFICATION [§ 300.915(a)(2)]

Your identity and documentation of that identity, as the manufacturer of the product; vendor, importer, or distributor of the product; and/or designated agent acting on behalf of the manufacturer.

(3) PRODUCT NAME, BRAND, OR TRADEMARK [§ 300.915(a)(3)]

All name(s), brand(s), and/or trademark(s) under which the product is to be sold.

(4) NAME, ADDRESS, EMAIL, AND TELEPHONE NUMBER OF SUPPLIERS [§ 300.915(a)(4)]

Names, physical addresses, emails, and telephone numbers of the primary distributors, vendors, importers, and/or designated agent acting on behalf of the manufacturer.

Company Name

Physical Address

City, State Zip Code

Phone: (###) ###-###

E-mail:

(Point of Contact)

(5) SAFETY DATA SHEET (SDS) [§ 300.915(a)(5)]

The Safety Data Sheet for the product.

(6) PRODUCT STORAGE [§ 300.915(a)(6)]

- 1. Maximum storage temperature (e.g., °F and/or °C):
- 2. Minimum storage temperature (e.g., °F and/or °C):
- 3. Optimum storage temperature (e.g., °F and/or °C):
- 4. Humidity (e.g., g/kg):
- 5. Other relevant conditions for product storage:

6. Description of the consequences to performance if product is not stored within these limits:

(7) SHELF LIFE STORAGE CONDITIONS [§ 300.915(a)(7)]

The anticipated shelf life of the product at the storage conditions noted in paragraph(a)(6) of this section and documentation for this determination.

(8) PRODUCT LABEL [§ 300.915(a)(8)]

A sample product label for all name(s), brand(s), and/or trademark(s) under which the product is to be sold that includes manufacture and expiration dates, and conditions for storage. You may use an existing label provided it already contains the required dates and storage information.

(9) PRODUCT CATEGORY AND PROCESSES [300.915(a)(9)]

The chemical or biological agent category under which you want the product to be considered for listing on the NCP Product Schedule including detailed information on the specific process(es) through which the product affects the oil, in the specific environment(s) on which it is intended to be used (e.g., waters and/or adjoining shoreline). If your product meets the definition of more than one chemical or biological agent category, you must identify all applicable categories and provide the test data to meet the listing criteria appropriate to each.

(10) RECOMMENDED PRODUCT USE PROCEDURES [§ 300.915(a)(10)]

Recommended product use procedures, including product concentrations, use ratios, types of application equipment, conditions for use, any application restrictions; and, as applicable, procedures for product and oil containment, collection, recovery, and disposal. These procedures must address, as appropriate, variables such as weather, water salinity, water temperature, types and weathering states of oils or other pollutants. The procedures must include supporting documentation and current applicable standard methods used to determine them.

(11) ENVIRONMENTAL FATE OF COMPONENTS [§ 300.915(a)(11)]

Available information on environmental fate, including any known measured data, methodologies, and supporting documentation, on the persistence, bioconcentration factor, bioaccumulation factor, and biodegradability of the product and all its components in the environment.

(12) PHYSICAL/CHEMICAL PROPERTIES [§ 300.915(a)(12)]

Physical and chemical properties of the product, as appropriate, and a citation for the current applicable standard methods used to determine them including:

- (i)Physical State and Appearance:
- (ii) Vapor Pressure:
- (iii)Flash Point:
- (iv)Pour Point:
- (v)Viscosity:
- (vi)Specific Gravity:
- (vii)Particle Size for Solid Components:
- (viii)pH:

(13) IDENTIFICATION AND CONCENTRATION OF PRODUCT COMPONENTS [§ 300.915(a)(13)]

The identity and concentration of all components in the product, including each specific component name; corresponding Chemical Abstract Service (CAS) Registry Number; the maximum, minimum, and

average weight percent of each component in the product; and the intended function of each component (e.g., solvent, surfactant).

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

Note 1: Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter.

Note 2: You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule and **include any PBI information in a separate sealed envelope**.

(14) MICROORGANISMS, ENZYMES AND/OR NUTRIENTS [§ 300.915(a)(14)]

For products that contain microorganisms, enzymes, and/or nutrients, provide the component information as follows, including a citation and description of the methodology used to determine:

1. Microorganisms [§ 300.915(a)(14)(i)]

- a. Name of all microorganisms by current genus and species:
- b. Any reclassifications:
- c. Any physical, chemical, or biological manipulation of the genetic composition:
- d. Weight percent of each genus in the product:

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

2. Enzymes [§ 300.915(a)(14)(ii)]

- a. Name of all enzyme(s):
- b. International Union of Biochemistry (I.U.B.) Number(s):
- c. Enzyme Classification (EC) Code Number:
- d. Source of Enzymes:
- e. Units:
- f. Specific Oil-Degrading Activity:

See Chapter 6 and the sample template in Attachment I of this guidance.

3. Nutrients [§ 300.915(a)(14)(iii)]

- a. Name(s) of all Nutrients:
- b. Maximum Weight Percent of Nutrients:
- c. Minimum Weight Percent of Nutrients:
- d. Average Weight Percent of Nutrients:

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

4. Data, methodology, and supporting documentation for levels of bacterial, fungal, or viral pathogens, or opportunistic pathogens, including but not limited to [§ 300.915(a)(14)(iv):

Enteric bacteria, suchs as *Salmonella*, fecal coliforms, Shigella, coagulase postive *Staphylococci*, and beta hemolytic *Streptococci* and enterococci.

NOTE – Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter. You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule and include any PBI information in a separate sealed envelope (See Chapter 6 of this quidance).

(15) DATA, METHODOLOGY AND SUPPORTING DOCUMENTATION FOR LEVELS OF THE FOLLOWING [§ 300.915(a)(15)]:

Data, methodology, and supporting documentation for the levels of the following:

- 1. Arsenic, cadmium, chromium, copper, lead, mercury, nickel, vanadium, zinc, and any other heavy metal reasonably expected to be in the product;
- 2. Cvanide:
- 3. Chlorinated hydrocarbons;
- 4. Pesticides;
- 5. Polychlorinated biphenyls (PCBs); and
- 6. Polycyclic aromatic hydrocarbons (PAHs).

(16) PROHIBITED AGENT CERTIFICATION [§ 300.915(a)(16)]

Certification including data, methodology and supporting documentation indicating that product does not contain prohibited agents identified in § 300.910(e).

(17) LABORATORY INFORMATION [§ 300.915(a)(17)]

Information about the accredited laboratory that conducted the required tests, including:

(i)Name of the laboratory, address, contact, name, email, and phone number; and (ii) the national and/or international accreditations held by the laboratory that are applicable to test(s) performed.

(18) LABORATORY TEST DATA AND REPORTS [§ 300.915(a)(18)]

All test data and calculations, including:

- 1. Raw data and replicates, including positive controls;
- 2. Notes and observations collected during tests;
- 3. Calculated mean values and standard deviations;
- 4. Reports, including a summary of stock solution preparation;
- 5. Source and preparation of test organisms;
- 6. Test conditions; and
- 7. Chain of custody forms.

(19) PRODUCTION VOLUMES [§ 300.915(a)(19)]

An estimate of the annual production volume, the average and maximum amount that could be produced in a day, and the time frame needed to reach that maximum production rate in days.

20) DESIGN FOR THE ENVIRONMENT (now Safer Choice) [§ 300.915(a)(20)]

Recognition received from EPA's Design for the Environment (DfE) or Safer Choice programs, as applicable.

(21) INTERNATIONAL PRODUCT TESTING, DATA, AND/OR CERTIFICATIONS [§ 300.915(a)(21)] International product testing or use data or certifications, if available, informing the performance capabilities or environmental impacts of the product.

PRODUCT CATEGORY TESTING AND LISTING REQUIREMENTS [§ 300.915(c)]

SURFACE WASHING AGENT EFFICACY TEST AND LISTING CRITERIA [§ 300.915(c)(1)]

- <u>Efficacy Test:</u> Surface washing agents must be tested using an applicable standard methodology [e.g., Environment Canada's Test Method or ASTM Standard Test Method for Evaluating the Effectiveness of Cleaning Agents (ASTM G122—96)].
- <u>Listing Criteria</u>: Surface washing agent must meet an efficacy of ≥30% in either freshwater or saltwater, or both, depending on the intended product use.

Use Environment	Effectiveness (%)
Saltwater use	[Conc] or N/A
Freshwater use	[Conc] or N/A

STANDARD ACUTE TOXICITY TEST AND LISTING CRITERIA [§ 300.915(c)(2)]:

- <u>Toxicity Test:</u> Surface washing agents must be tested for acute toxicity in freshwater, saltwater, or both, depending on the intended product use per the method in Appendix C to Part 300, section 4.0.
- <u>Listing Criteria:</u> Surface washing agent must demonstrate an LC50 at the lower 95% confidence interval of greater than 10 ppm in either freshwater or saltwater for all tested species.

Note: Reference Toxicants. Separate toxicity tests must be performed with a reference toxicant for each species tested (Section 3.3.3 of Appendix C to part 300). Submitters should provide results in format shown below.

	PROCEDURE					
	96-hr Static		48-hr Static	96-hr Static		48-hr Static
Use Environment	Acute Menid	lia	Acute	Acute		Acute
	beryllina		Americamysis	Pimep	hales	Ceriodaphnia
			bahia	promo	elas	dubia
Saltwater use	Yes		Yes	No		No
Freshwater use	No		No	Yes		Yes
Freshwater and saltwater	Yes		Yes	Yes		Yes
use						
Saltv	vater Static Ac	ute	Toxicity Test Data	Summ	ary:	
Material Tested		Saltwater Species LC5		LC50 (pp	0 (ppm)	
Surface Washing Agent		M	enidia beryllina		[Conc]	96-hr
		An	nericamysis bahia		[Conc]	48-hr
SDS Reference Toxicant (AKA	DSS or SLS)	M	enidia beryllina		[Conc]	96-hr
		Americamysis bahia [0		[Conc]	48-hr	
Fresh	water Static A	cute	e Toxicity Test Dat	a Sumr	nary:	
Material Tested		Fr	eshwater Species		LC50 (ppm)	
Surface Washing Agent		Pir	mephales promela	S	[Conc]	96-hr
			riodaphnia dubia		[Conc]	48-hr
SDS Reference Toxicant (AKA DSS or SLS)		Pimephales promelas		S	[Conc]	96-hr
		Се	riodaphnia dubia		[Conc]	48-hr

Attachment E: Bioremediation Agent Data Submission Sample Template

BIOREMEDIATION AGENT DATA SUBMISSION SAMPLE TEMPLATE FOR § 300.915 DATA AND INFORMATION REQUIREMENTS

PRODUCT NAME:

CATEGORY: BIOREMEDIATION AGENT

GENERIC LISTING § 300.915(d)(4)

If your product consists solely of ammonium nitrate, ammonium phosphate, ammonium sulfate, calcium ammonium nitrate, sodium nitrate, potassium nitrate, synthetically derived urea, sodium triphosphate (or tripolyphosphate), sodium phosphate, potassium phosphate (mono- or dibasic), triple super phosphate, potassium sulphate, or any combination thereof, no technical product data are required. These types of products are generically listed as non-proprietary nutrients on the NCP Product Schedule, and **no further action is necessary.**

GENERAL PRODUCT INFORMATION [§ 300.915(a)]

(1) NAME, ADDRESS, EMAIL, AND TELEPHONE NUMBER OF SUBMITTER [§ 300.915(a)(1)]

Your name, physical address, email, and telephone number.

Company Name

Physical Address

City, State Zip Code

Phone: (###) ###-####

E-mail

(Point of Contact)

(2) SUBMITTER IDENTIFICATION [§ 300.915(a)(2)]

Your identity and documentation of that identity, as the manufacturer of the product; vendor, importer, or distributor of the product; and/or designated agent acting on behalf of the manufacturer.

(3) PRODUCT NAME, BRAND, OR TRADEMARK [§ 300.915(a)(3)]

All name(s), brand(s), and/or trademark(s) under which the product is to be sold.

(4) NAME, ADDRESS, EMAIL, AND TELEPHONE NUMBER OF SUPPLIERS [§ 300.915(a)(4)]

Names, physical addresses, emails, and telephone numbers of the primary distributors, vendors, importers, and/or designated agent acting on behalf of the manufacturer.

Company Name

Physical Address

City, State Zip Code

Phone: (###) ###-###

E-mail

(Point of Contact)

(5) SAFETY DATA SHEET (SDS) [§ 300.915(a)(5)]

The Safety Data Sheet for the product.

(6) STORAGE TEMPERATURES [§ 300.915(a)(6)]

- 1. Maximum storage temperature (e.g., °F and/or °C):
- 2. Minimum storage temperature (e.g., °F and/or °C):
- 3. Optimum storage temperature (e.g., °F and/or °C):
- 4. Humidity (e.g., g/kg):
- 5. Other relevant conditions for product storage:
- 6. Description of the consequences to performance if product is not stored within these limits:

(7) SHELF LIFE STORAGE CONDITIONS [§ 300.915(a)(7)]

The anticipated shelf life of the product at the storage conditions noted in paragraph(a)(6) of this section and documentation for this determination.

(8) PRODUCT LABEL [§ 300.915(a)(8)]

A sample product label for all name(s), brand(s), and/or trademark(s) under which the product is to be sold that includes manufacture and expiration dates, and conditions for storage. You may use an existing label provided it already contains the required dates and storage information.

(9) PRODUCT CATEGORY AND PROCESSES [300.915(a)(9)]

The chemical or biological agent category under which you want the product to be considered for listing on the NCP Product Schedule including detailed information on the specific process(es) through which the product affects the oil, in the specific environment(s) on which it is intended to be used (e.g., waters and/or adjoining shoreline). If your product meets the definition of more than one chemical or biological agent category, you must identify all applicable categories and provide the test data to meet the listing criteria appropriate to each.

(10) RECOMMENDED PRODUCT USE PROCEDURES [§ 300.915(a)(10)]

Recommended product use procedures, including product concentrations, use ratios, types of application equipment, conditions for use, any application restrictions; and, as applicable, procedures for product and oil containment, collection, recovery, and disposal. These procedures must address, as appropriate, variables such as weather, water salinity, water temperature, types and weathering states of oils or other pollutants. The procedures must include supporting documentation and current applicable standard methods used to determine them.

(11) ENVIRONMENTAL FATE OF COMPONENTS [§ 300.915(a)(11)]

Available information on environmental fate, including any known measured data, methodologies, and supporting documentation, on the persistence, bioconcentration factor, bioaccumulation factor, and biodegradability of the product and all of its components in the environment.

(12) PHYSICAL/CHEMICAL PROPERTIES [§ 300.915(a)(12)]

Physical and chemical properties of the product, as appropriate, and a citation for the current applicable standard methods used to determine them including:

(i)Physical State and Appearance:
(ii)Vapor Pressure:
(iii)Flash Point:
(iv)Pour Point:
(v)Viscosity:
(vi)Specific Gravity:
(vii)Particle Size for Solid Components:
(viii)pH:

(13) IDENTIFICATION AND CONCENTRATION OF PRODUCT COMPONENTS [§ 300.915(a)(13)]

The identity and concentration of all components in the product, including each specific component name; corresponding Chemical Abstract Service (CAS) Registry Number; the maximum, minimum, and average weight percent of each component in the product; and the intended function of each component (e.g., solvent, surfactant).

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

Note 1: Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter.

Note 2: You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule and **include any PBI information in a separate sealed envelope**.

(14) MICROORGANISMS, ENZYMES AND/OR NUTRIENTS [§ 300.915(a)(14)]

For products that contain microorganisms, enzymes, and/or nutrients, provide the component information as follows, including a citation and description of the methodology used to determine:

1. Microorganisms [§ 300.915(a)(14)(i)]

- a. Name of all microorganisms by current genus and species:
- b. Any reclassifications:
- c. Any physical, chemical, or biological manipulation of the genetic composition:
- d. Weight percent of each genus in the product:

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

2. Enzymes [§ 300.915(a)(14)(ii)]

- a. Name of all enzyme(s):
- b. International Union of Biochemistry (I.U.B.) Number(s):
- c. Enzyme Classification (EC) Code Number:
- d. Source of Enzymes:
- e. Units:

f. Specific Oil-Degrading Activity:

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

- 3. Nutrients [§ 300.915(a)(14)(iii)]
- a. Name(s) of all Nutrients:
- b. Maximum Weight Percent of Nutrients:
- c. Minimum Weight Percent of Nutrients:
- d. Average Weight Percent of Nutrients:

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

4. Data, methodology, and supporting documentation for levels of bacterial, fungal, or viral pathogens, or opportunistic pathogens, including but not limited to [§ 300.915(a)(14)(iv):

Enteric bacteria, suchs as *Salmonella*, fecal coliforms, Shigella, coagulase postive *Staphylococci*, and beta hemolytic *Streptococci* and enterococci.

NOTE – Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter. You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule and include any PBI information in a separate sealed envelope (See Chapter 6 of this guidance).

(15) DATA, METHODOLOGY AND SUPPORTING DOCUMENTATION FOR LEVELS OF THE FOLLOWING [§ 300.915(a)(15)]:

Data, methodology, and supporting documentation for the levels of the following:

- 1. Arsenic, cadmium, chromium, copper, lead, mercury, nickel, vanadium, zinc, and any other heavy metal reasonably expected to be in the product;
- 2. Cyanide;
- 3. Chlorinated hydrocarbons;
- 4. Pesticides;
- 5. Polychlorinated biphenyls (PCBs); and
- 6. Polycyclic aromatic hydrocarbons (PAHs).

(16) PROHIBITED AGENT CERTIFICATION [§ 300.915(a)(16)]

Certification including data, methodology and supporting documentation indicating that product does not contain prohibited agents identified in § 300.910(e).

(17) LABORATORY INFORMATION [§ 300.915(a)(17)]

Information about the accredited laboratory that conducted the required tests, including:

(i)Name of the laboratory, address, contact, name, email, and phone number; and (ii) the national and/or international accreditations held by the laboratory that are applicable to test(s) performed.

(18) LABORATORY TEST DATA AND REPORTS [§ 300.915(a)(18)]

All test data and calculations, including:

- 1. Raw data and replicates, including positive controls;
- 2. Notes and observations collected during tests;
- 3. Calculated mean values and standard deviations;
- 4. Reports, including a summary of stock solution preparation;
- 5. Source and preparation of test organisms;
- 6. Test conditions; and
- 7. Chain of custody forms.

(19) PRODUCTION VOLUMES [§ 300.915(a)(19)]

An estimate of the annual production volume, the average and maximum amount that could be produced in a day, and the time frame needed to reach that maximum production rate in days.

(20) DESIGN FOR THE ENVIRONMENT (now Safer Choice) [§ 300.915(a)(20)]

Recognition received from EPA's Design for the Environment (DfE) or Safer Choice programs, as applicable.

(21) INTERNATIONAL PRODUCT TESTING, DATA, AND/OR CERTIFICATIONS [§ 300.915(a)(21)]

International product testing or use data or certifications, if available, informing the performance capabilities or environmental impacts of the product.

PRODUCT CATEGORY TESTING AND LISTING REQUIREMENTS [§ 300.915(d)]

BIOREMEDIATION AGENT EFFICACY TEST AND LISTING CRITERIA [§ 300.915(d)(1)]

• Efficacy Test:

- Bioremediation agent must successfully degrade both alkanes and aromatics as determined by gas chromatography/mass spectrometry (GC/MS) in freshwater or saltwater, or both, depending on the intended product use, following the test method specified in Appendix C to Part 300, Section 5.0.
- Appendix C specifies three types of tests that are applicable to the type of product: Type 1 for products containing living microorganisms; Type 2 for products containing proprietary nutrients but no live microorganism; or Type 3 for products (such as an enzyme) containing no live microorganisms and no nutrients.

• Listing Criteria:

- The percentage reduction of total alkanes (aliphatic fraction) from the GC/MS analysis must be greater than or equal to 85% at day 28, based on the ninety-fifth (95th) percentile Upper Confidence Limit (UCL₉₅) for both freshwater and saltwater.
- The percentage reduction of total aromatics (aromatic fraction) must be greater than or equal to 35% at day 28 for saltwater and freshwater based on the UCL₉₅.
- The benchmark reduction ranges in aliphatic and aromatic fractions for the positive control are the same as for the products specified above.
- The day 28 GC/MS results from the killed control must not be less than 90% of the day 0 results.

		Saltwate	r Data Summary	Table:			
	TOTAL A	LKANES (PP	M)	TOTAL A	TOTAL AROMATICS (PPM)		
	Day 0	Day 28	% Reduction	Day 0	Day 28	% Reduction	
PRODUCT							
Positive Control							
Negative Control							
		Freshwat	er Data Summar	y Table			
	TOTAL A	LKANES (PP	M)	TOTAL A	ROMATICS (I	PPM)	
	Day 0	Day 28		Day 0	Day 28		
PRODUCT							
Positive Control							
Negative Control							

STANDARD ACUTE TOXICITY TEST AND LISTING CRITERIA [§ 300.915(c)(2)]:

- <u>Toxicity Test:</u> Bioremdiation agents must be tested for acute toxcity in freshwater or saltwater, or both, depending on the intended product use per methods in Appendix C to Part 300, Section 4.0.
- <u>Listing Criteria:</u> Bioremediation agents must demonstrate an LC50 at the lower 95% confidence interval of greater than 10 ppm in either freshwater or saltwater for all tested species.

Note: Reference Toxicants. Separate toxicity tests must be performed with a reference toxicant for each species tested (Section 3.3.3 of Appendix C to part 300). Submitters should provide results in format shown below.

shown below.								
	Procedure							
Material Tested	96-hr Static Acute <i>Menidia</i> <i>beryllina</i>	48-hr Static Acute Americamysis bahia	96-hr Static Acute Pimephales promelas	48-hr Static Acute Ceriodaphnia dubia				
Saltwater only	Yes	Yes	No	No				
Freshwater only	No	No	Yes	Yes				
Freshwater and saltwater use	Yes	Yes	Yes	Yes				
Saltwater Static Acute Toxicity Test Data Summary:								
Material Tested		Saltwater Species LC50 (p		om)				
Product	Λ	1enidia beryllina	[Conc]	96-hr				

Saltwater Static Acute Toxicity Test Data Summary:							
Material Tested Saltwater Species LC50 (ppm)							
Product	Menidia beryllina	[Conc]	96-hr				
	Americamysis bahia	[Conc]	48-hr				
SDS Reference Toxicant (AKA DSS or SLS)	Menidia beryllina	[Conc]	96-hr				
	Americamysis bahia	[Conc]	48-hr				
Freshwater Statio	Acute Toxicity Test Data S	Summary:					
Material Tested	Freshwater Species	LC50 (p)	om)				
Product	Pimephales promelas	[Conc]	96-hr				
	Ceriodaphnia dubia	[Conc]	48-hr				
SDS Reference Toxicant (AKA DSS or SLS)	Pimephales promelas	[Conc]	96-hr				
	Ceriodaphnia dubia	[Conc]	48-hr				

Attachment F: Solidifier Product Data Submission Sample Template

SOLIDIFIER DATA SUBMISSION SAMPLE TEMPLATE FOR § 300.915 DATA AND INFORMATION REQUIREMENTS

PRODUCT NAME: CATEGORY: SOLIDIFIER

GENERAL PRODUCT INFORMATION [300.915(a)]

(1) NAME, ADDRESS, EMAIL, AND TELEPHONE NUMBER OF SUBMITTER [§ 300.915(a)(1)]

Your name, physical address, email, and telephone number.

Company Name

Physical Address

City, State Zip Code

Phone: (###) ###-####

E-mail

(Point of Contact)

(2) SUBMITTER IDENTIFICATION [§ 300.915(a)(2)]

Your identity and documentation of that identity, as the manufacturer of the product; vendor, importer, or distributor of the product; and/or designated agent acting on behalf of the manufacturer.

(3) PRODUCT NAME, BRAND, OR TRADEMARK [§ 300.915(a)(3)]

All name(s), brand(s), and/or trademark(s) under which the product is to be sold.

(4) NAME, ADDRESS, EMAIL, AND TELEPHONE NUMBER OF SUPPLIERS [§ 300.915(a)(4)]

Names, physical addresses, emails, and telephone numbers of the primary distributors, vendors, importers, and/or designated agent acting on behalf of the manufacturer.

Company Name

Physical Address

City, State Zip Code

Phone: (###) ###-####

E-mail

(Point of Contact)

(5) SAFETY DATA SHEET (SDS) [§ 300.915(a)(5)]

The Safety Data Sheet for the product.

(6) PRODUCT STORAGE [§ 300.915(a)(6)]

- 1. Maximum storage temperature (e.g., °F and/or °C):
- 2. Minimum storage temperature (e.g., °F and/or °C):
- 3. Optimum storage temperature range (e.g., °F and/or °C):
- 4. Humidity (e.g., g/kg):

- 5. Other relevant conditions for product storage:
- 6. Description of the consequences to performance if the product is not stored within these limits:

(7) SHELF LIFE STORAGE CONDITIONS [§ 300.915(a)(7)]

The anticipated shelf life of the product at the storage conditions noted in paragraph(a)(6) of this section and documentation for this determination.

(8) PRODUCT LABEL [§ 300.915(a)(8)]

A sample product label for all name(s), brand(s), and/or trademark(s) under which the product is to be sold that includes manufacture and expiration dates, and conditions for storage. You may use an existing label provided it already contains the required dates and storage information.

(9) PRODUCT CATEGORY AND PROCESSES [300.915(a)(9)]

The chemical or biological agent category under which you want the product to be considered for listing on the NCP Product Schedule including detailed information on the specific process(es) through which the product affects the oil, in the specific environment(s) on which it is intended to be used (e.g., waters and/or adjoining shoreline). If your product meets the definition of more than one chemical or biological agent category, you must identify all applicable categories and provide the test data to meet the listing criteria appropriate to each.

(10) RECOMMENDED PRODUCT USE PROCEDURES [§ 300.915(a)(10)]

Recommended product use procedures, including product concentrations, use ratios, types of application equipment, conditions for use, any application restrictions; and, as applicable, procedures for product and oil containment, collection, recovery, and disposal. These procedures must address, as appropriate, variables such as weather, water salinity, water temperature, types and weathering states of oils or other pollutants. The procedures must include supporting documentation and current applicable standard methods used to determine them.

(11) ENVIRONMENTAL FATE OF COMPONENTS [§ 300.915(a)(11)]

Available information on environmental fate, including any known measured data, methodologies, and supporting documentation, on the persistence, bioconcentration factor, bioaccumulation factor, and biodegradability of the product and all of its components in the environment.

(12) PHYSICAL/CHEMICAL PROPERTIES [§ 300.915(a)(12)]

Physical and chemical properties of the product, as appropriate, and a citation for the current applicable standard methods used to determine them including:

(i)Physical State and Appearance:

(ii) Vapor Pressure:

(iii)Flash Point:

(iv)Pour Point:

(v) Viscosity:

(vi)Specific Gravity:

(vii)Particle Size for Solid Components:

(viii)pH:

(13) IDENTIFICATION AND CONCENTRATION OF PRODUCT COMPONENTS [§ 300.915(a)(13)]

The identity and concentration of all components in the product, including each specific component

name; corresponding Chemical Abstract Service (CAS) Registry Number; the maximum, minimum, and average weight percent of each component in the product; and the intended function of each component (e.g., solvent, surfactant).

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

Note 1: Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter.

Note 2: You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule and **include any PBI information in a separate sealed envelope**.

(14) MICROORGANISMS, ENZYMES AND/OR NUTRIENTS [§ 300.915(a)(14)]

For products that contain microorganisms, enzymes, and/or nutrients, provide the component information as follows, including a citation and description of the methodology used to determine:

1. Microorganisms [§ 300.915(a)(14)(i)]

- a. Name of all microorganisms by current genus and species:
- b. Any reclassifications:
- c. Any physical, chemical, or biological manipulation of the genetic composition:
- d. Weight percent of each genus in the product:

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

2. Enzymes [§ 300.915(a)(14)(ii)]

- a. Name of all enzyme(s):
- b. International Union of Biochemistry (I.U.B.) Number(s):
- c. Enzyme Classification (EC) Code Number:
- d. Source of Enzymes:
- e. Units:
- f. Specific Oil-Degrading Activity:

See Chapter 6 and the sample template in Attachment I of this guidance.

3. Nutrients [§ 300.915(a)(14)(iii)]

- a. Name(s) of all Nutrients:
- b. Maximum Weight Percent of Nutrients:
- c. Minimum Weight Percent of Nutrients:
- d. Average Weight Percent of Nutrients:

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

4. Data, methodology, and supporting documentation for levels of bacterial, fungal, or viral pathogens, or opportunistic pathogens, including but not limited to [§ 300.915(a)(14)(iv):

Enteric bacteria, suchs as *Salmonella*, fecal coliforms, Shigella, coagulase postive *Staphylococci*, and beta hemolytic *Streptococci* and enterococci.

NOTE – Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter. You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule and include any PBI information in a separate sealed envelope (See <u>Chapter 6</u> of this quidance).

(15) DATA, METHODOLOGY AND SUPPORTING DOCUMENTATION FOR LEVELS OF THE FOLLOWING [§ 300.915(a)(15)]:

Data, methodology, and supporting documentation for the levels of the following:

- 1. Arsenic, cadmium, chromium, copper, lead, mercury, nickel, vanadium, zinc, and any other heavy metal reasonably expected to be in the product;
- 2. Cyanide;
- 3. Chlorinated hydrocarbons;
- 4. Pesticides;
- 5. Polychlorinated biphenyls (PCBs); and
- 6. Polycyclic aromatic hydrocarbons (PAHs).

(16) PROHIBITED AGENT CERTIFICATION [§ 300.915(a)(16)]

Certification including data, methodology and supporting documentation indicating that product does not contain prohibited agents identified in § 300.910(e).

(17) LABORATORY INFORMATION [§ 300.915(a)(17)]

Information about the accredited laboratory that conducted the required tests, including:

(i)Name of the laboratory, address, contact, name, email, and phone number; and (ii) the national and/or international accreditations held by the laboratory that are applicable to test(s) performed.

(18) LABORATORY TEST DATA AND REPORTS [§ 300.915(a)(18)]

All test data and calculations, including:

- 1. Raw data and replicates, including positive controls;
- 2. Notes and observations collected during tests;
- 3. Calculated mean values and standard deviations;
- 4. Reports, including a summary of stock solution preparation;
- 5. Source and preparation of test organisms;
- 6. Test conditions; and
- 7. Chain of custody forms.

(19) PRODUCTION VOLUMES [§ 300.915(a)(19)]

An estimate of the annual production volume, the average and maximum amount that could be produced in a day, and the time frame needed to reach that maximum production rate in days.

(20) DESIGN FOR THE ENVIRONMENT (now Safer Choice) [§ 300.915(a)(20)]

Recognition received from EPA's Design for the Environment (DfE) or Safer Choice programs, as applicable.

(21) INTERNATIONAL PRODUCT TESTING, DATA, AND/OR CERTIFICATIONS [§ 300.915(a)(21)]

International product testing or use data or certifications, if available, informing the performance capabilities or environmental impacts of the product.

PRODUCT CATEGORY TESTING AND LISTING REQUIREMENTS [§ 300.915(e)]

STANDARD ACUTE TOXICITY TEST [300.915(e)(1)]:

- <u>Toxicity Test:</u> Solidifier must be tested for acute toxicity in saltwater, fresh water, or both environments, depending on the intended product use per the methods in Appendix C to Part 300, Section 4.0.
- <u>Listing Criteria:</u> Solidifier must demonstrate an LC50 at the lower 95% confidence interval of greater than 10 ppm in either freshwater, saltwater or both for all tested species.

Note: Reference Toxicants. Separate toxicity tests must be performed with a reference toxicant for each species tested (Section 3.3.3 of Appendix C to part 300). Submitters should provide results in format shown below.

	Procedure					
	96-hr Static	48-hr Static	96-hr Static	48-hr Static		
Use Environment	Acute Menidia	Acute	Acute	Acute		
	beryllina	Americamysis	Pimephales	Ceriodaphnia		
		bahia	promelas	dubia		
Saltwater use	Yes	Yes	No	No		
Freshwater use	No	No	Yes	Yes		
Freshwater and saltwater	Yes	Yes	Yes	Yes		
use						

Saltwater Static Acute Toxicity Test Data Summary:						
Material Tested	Saltwater Species LC50 (ppm)					
Solidifier	Menidia beryllina	[Conc]	96-hr			
	Americamysis bahia	[Conc]	48-hr			
Reference Toxicant (SDS, DSS, SLS)	Menidia beryllina	[Conc]	96-hr			
	Americamysis bahia	[Conc]	48-hr			
Freshwater Static	Acute Toxicity Test Data Sun	nmary:				
Material Tested	Species		LC50 (ppm)			
Solidifier	Pimephales promelas	[Conc]	96-hr			
	Ceriodaphnia dubia	[Conc]	48-hr			
Reference Toxicant (SDS, DSS, SLS)	Pimephales promelas	[Conc]	96-hr			
	Ceriodaphnia dubia	[Conc]	48-hr			

Attachment G: Herding Agent Data Submission Sample Template

HERDING AGENT DATA SUBMISSION SAMPLE TEMPLATE FOR § 300.915 DATA AND INFORMATION REQUIREMENTS

PRODUCT NAME:

CATEGORY: HERDING AGENT

GENERAL PRODUCT INFORMATION [300.915(a)]

(1) NAME, ADDRESS, EMAIL, AND TELEPHONE NUMBER OF SUBMITTER [§ 300.915(a)(1)]

Your name, physical address, email, and telephone number.

Company Name

Physical Address

City, State Zip Code

Phone: (###) ###-####

E-mail

(Point of Contact)

(2) SUBMITTER IDENTIFICATION [§ 300.915(a)(2)]

Your identity and documentation of that identity, as the manufacturer of the product; vendor, importer, or distributor of the product; and/or designated agent acting on behalf of the manufacturer.

(3) PRODUCT NAME, BRAND, OR TRADEMARK [§ 300.915(a)(3)]

All name(s), brand(s), and/or trademark(s) under which the product is to be sold.

(4) NAME, ADDRESS, EMAIL, AND TELEPHONE NUMBER OF SUPPLIERS [§ 300.915(a)(4)]

Names, physical addresses, emails, and telephone numbers of the primary distributors, vendors, importers, and/or designated agent acting on behalf of the manufacturer.

Company Name

Physical Address

City, State Zip Code

Phone: (###) ###-####

E-mail

(Point of Contact)

(5) SAFETY DATA SHEET (SDS) [§ 300.915(a)(5)]

The Safety Data Sheet for the product.

(6) PRODUCT STORAGE [§ 300.915(a)(6)]

- 1. Maximum storage temperature (e.g., °F and/or °C):
- 2. Minimum storage temperature (e.g., °F and/or °C):
- 3. Optimum storage temperature range (e.g., °F and/or °C):
- 4. Humidity (e.g., g/kg):

- 5. Other relevant conditions for product storage:
- 6. Description of the consequences to performance if the product is not stored within these limits:

(7) SHELF LIFE STORAGE CONDITIONS [§ 300.915(a)(7)]

The anticipated shelf life of the product at the storage conditions noted in paragraph(a)(6) of this section and documentation for this determination.

(8) PRODUCT LABEL [§ 300.915(a)(8)]

A sample product label for all name(s), brand(s), and/or trademark(s) under which the product is to be sold that includes manufacture and expiration dates, and conditions for storage. You may use an existing label provided it already contains the required dates and storage information.

(9) PRODUCT CATEGORY AND PROCESSES [300.915(a)(9)]

The chemical or biological agent category under which you want the product to be considered for listing on the NCP Product Schedule including detailed information on the specific process(es) through which the product affects the oil, in the specific environment(s) on which it is intended to be used (e.g., waters and/or adjoining shoreline). If your product meets the definition of more than one chemical or biological agent category, you must identify all applicable categories and provide the test data to meet the listing criteria appropriate to each.

(10) RECOMMENDED PRODUCT USE PROCEDURES [§ 300.915(a)(10)]

Recommended product use procedures, including product concentrations, use ratios, types of application equipment, conditions for use, any application restrictions; and, as applicable, procedures for product and oil containment, collection, recovery, and disposal. These procedures must address, as appropriate, variables such as weather, water salinity, water temperature, types and weathering states of oils or other pollutants. The procedures must include supporting documentation and current applicable standard methods used to determine them.

(11) ENVIRONMENTAL FATE OF COMPONENTS [§ 300.915(a)(11)]

Available information on environmental fate, including any known measured data, methodologies, and supporting documentation, on the persistence, bioconcentration factor, bioaccumulation factor, and biodegradability of the product and all of its components in the environment.

(12) PHYSICAL/CHEMICAL PROPERTIES [§ 300.915(a)(12)]

Physical and chemical properties of the product, as appropriate, and a citation for the current applicable standard methods used to determine them including:

(i)Physical State and Appearance:

(ii) Vapor Pressure:

(iii)Flash Point:

(iv)Pour Point:

(v) Viscosity:

(vi)Specific Gravity:

(vii)Particle Size for Solid Components:

(viii)pH:

(13) IDENTIFICATION AND CONCENTRATION OF PRODUCT COMPONENTS [§ 300.915(a)(13)]

The identity and concentration of all components in the product, including each specific component

name; corresponding Chemical Abstract Service (CAS) Registry Number; the maximum, minimum, and average weight percent of each component in the product; and the intended function of each component (e.g., solvent, surfactant).

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

Note 1: Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter.

Note 2: You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule and **include any PBI information in a separate sealed envelope**.

(14) MICROORGANISMS, ENZYMES AND/OR NUTRIENTS [§ 300.915(a)(14)]

For products that contain microorganisms, enzymes, and/or nutrients, provide the component information as follows, including a citation and description of the methodology used to determine:

1. Microorganisms [§ 300.915(a)(14)(i)]

- a. Name of all microorganisms by current genus and species:
- b. Any reclassifications:
- c. Any physical, chemical, or biological manipulation of the genetic composition:
- d. Weight percent of each genus in the product:

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

2. Enzymes [§ 300.915(a)(14)(ii)]

- a. Name of all enzyme(s):
- b. International Union of Biochemistry (I.U.B.) Number(s):
- c. Enzyme Classification (EC) Code Number:
- d. Source of Enzymes:
- e. Units:
- f. Specific Oil-Degrading Activity:

See Chapter 6 and the sample template in Attachment I of this guidance.

3. Nutrients [§ 300.915(a)(14)(iii)]

- a. Name(s) of all Nutrients:
- b. Maximum Weight Percent of Nutrients:
- c. Minimum Weight Percent of Nutrients:
- d. Average Weight Percent of Nutrients:

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

4. Data, methodology, and supporting documentation for levels of bacterial, fungal, or viral pathogens, or opportunistic pathogens, including but not limited to [§ 300.915(a)(14)(iv):

Enteric bacteria, suchs as *Salmonella*, fecal coliforms, Shigella, coagulase postive *Staphylococci*, and beta hemolytic *Streptococci* and enterococci.

NOTE – Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter. You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule and include any PBI information in a separate sealed envelope (See Chapter 6 of this quidance).

(15) DATA, METHODOLOGY AND SUPPORTING DOCUMENTATION FOR LEVELS OF THE FOLLOWING [§ 300.915(a)(15)]:

Data, methodology, and supporting documentation for the levels of the following:

- 1. Arsenic, cadmium, chromium, copper, lead, mercury, nickel, vanadium, zinc, and any other heavy metal reasonably expected to be in the product;
- 2. Cyanide;
- 3. Chlorinated hydrocarbons;
- 4. Pesticides;
- 5. Polychlorinated biphenyls (PCBs); and
- 6. Polycyclic aromatic hydrocarbons (PAHs).

(16) PROHIBITED AGENT CERTIFICATION [§ 300.915(a)(16)]

Certification including data, methodology and supporting documentation indicating that product does not contain prohibited agents identified in § 300.910(e).

(17) LABORATORY INFORMATION [§ 300.915(a)(17)]

Information about the accredited laboratory that conducted the required tests, including:

(i)Name of the laboratory, address, contact, name, email, and phone number; and (ii) the national and/or international accreditations held by the laboratory that are applicable to test(s) performed.

(18) LABORATORY TEST DATA AND REPORTS [§ 300.915(a)(18)]

All test data and calculations, including:

- 1. Raw data and replicates, including positive controls;
- 2. Notes and observations collected during tests;
- 3. Calculated mean values and standard deviations;
- 4. Reports, including a summary of stock solution preparation;
- 5. Source and preparation of test organisms;
- 6. Test conditions; and
- 7. Chain of custody forms.

(19) PRODUCTION VOLUMES [§ 300.915(a)(19)]

An estimate of the annual production volume, the average and maximum amount that could be produced in a day, and the time frame needed to reach that maximum production rate in days.

(20) DESIGN FOR THE ENVIRONMENT (now Safer Choice) [§ 300.915(a)(20)]

Recognition received from EPA's Design for the Environment (DfE) or Safer Choice programs, as applicable.

(21) INTERNATIONAL PRODUCT TESTING, DATA, AND/OR CERTIFICATIONS [§ 300.915(a)(21)]

International product testing or use data or certifications, if available, informing the performance capabilities or environmental impacts of the product.

PRODUCT CATEGORY TESTING AND LISTING REQUIREMENTS [§ 300.915(f)]

STANDARD ACUTE TOXICITY TEST [300.915(f)(1)]:

- <u>Toxicity Test:</u> Herding agent must be tested for acute toxicity in saltwater, fresh water, or both, depending on the intended product use per the methods in Appendix C to Part 300, Section 4.0.
- <u>Listing Criteria:</u> Herding agent must demonstrate an LC50 at the lower 95% confidence interval of greater than 10 ppm in either freshwater or saltwater for all tested species.

Note: Reference Toxicants. Separate toxicity tests must be performed with a reference toxicant for each species tested (Section 3.3.3 of Appendix C to part 300). Submitters should provide results in format shown below.

	Procedure					
	96-hr Static	48-hr Static	96-hr Static	48-hr Static		
Use Environment	Acute Menidia	Acute	Acute	Acute		
	beryllina	Americamysis	Pimephales	Ceriodaphnia		
		bahia	promelas	dubia		
Saltwater use	Yes	Yes	No	No		
Freshwater use	No	No	Yes	Yes		
Freshwater and saltwater	Yes	Yes	Yes	Yes		
use						

Saltwater Static Acute Toxicity Test Data Summary:					
Material Tested	Saltwater Species		LC50 (ppm)		
Herding Agent	Menidia beryllina	[Conc]	96-hr		
	Americamysis bahia	[Conc]	48-hr		
Reference Toxicant (SDS, DSS, SLS)	Menidia beryllina	[Conc]	96-hr		
	Americamysis bahia	[Conc]	48-hr		
Freshwater Static Acute Toxicity Test Data Summary:					
Material Tested	Species	LC50 (ppm)			
Herding Agent	Pimephales promelas	[Conc]	96-hr		
	Ceriodaphnia dubia	[Conc]	48-hr		
Reference Toxicant (SDS, DSS, SLS)	Pimephales promelas	[Conc]	96-hr		
	Ceriodaphnia dubia	[Conc]	48-hr		

Attachment H: Sorbent Data Submission Sample Template

SORBENT DATA SUBMISSION SAMPLE TEMPLATE FOR § 300.915(g)(2) DATA AND INFORMATION REQUIREMENTS

(Sorbents under § 300.915(g)(2) follow § 300.915(a)(1) through (a)(8); (a)(13) through (a)(15); and certifications under (a)(16))

PRODUCT NAME: CATEGORY: SORBENT

Under § 300.915(g)(2): If the product consists of one or more natural organic substances, inorganic/mineral compounds, and/or synthetic compounds not specifically identified in paragraph (g)(1) of this section, but you believe the product meets the definition of a sorbent then, as applicable under § 300.955(a) and (b), you must submit the following information for consideration for listing it as a sorbent on the Sorbent Product List:

- (i) The information required under paragraphs (a)(1) through (a)(8), and paragraph (a)(13) through (a)(15) of [§ 300.915];
- (ii) The certification required under paragraph (a)(16) of [§ 300.915]; and
- (iii) Information, including data, to support the claim your product meets the sorbent definition under § 300.5.

For more information on listing a sorbent, refer to <u>Chapter 5 Sorbents and the Sorbent Product List</u> of this guidance.

GENERAL PRODUCT INFORMATION [§ 300.915(a)]

(1) NAME, ADDRESS, EMAIL, AND TELEPHONE NUMBER OF SUBMITTER [§ 300.915(a)(1)]

Your name, physical address, email, and telephone number.

Company Name

Physical Address

City, State Zip Code

Phone: (###) ###-####

E-mail

(Point of Contact)

(2) SUBMITTER IDENTIFICATION [§ 300.915(a)(2)]

Your identity and documentation of that identity, as the manufacturer of the product; vendor, importer, or distributor of the product; and/or designated agent acting on behalf of the manufacturer.

(3) PRODUCT NAME, BRAND, OR TRADEMARK [§ 300.915(a)(3)]

All name(s), brand(s), and/or trademark(s) under which the product is to be sold.

(4) NAME, ADDRESS, EMAIL, AND TELEPHONE NUMBER OF SUPPLIER [§ 300.915(a)(4)]

Names, physical addresses, emails, and telephone numbers of the primary distributors, vendors,

importers, and/or designated agent acting on behalf of the manufacturer.

Company Name

Physical Address

City, State Zip Code

Phone: (###) ###-####

E-mail

(Point of Contact)

(5) SAFETY DATA SHEET (SDS) [§ 300.915(a)(5)]

The Safety Data Sheet for the product.

(6) PRODUCT STORAGE [§ 300.915(a)(6)]

- 1. Maximum storage temperature (e.g., °F and/or °C):
- 2. Minimum storage temperature (e.g., °F and/or °C):
- 3. Optimum storage temperature range (e.g., °F and/or °C):
- 4. Humidity (e.g., g/kg):
- 5. Other relevant conditions for product storage:
- 6. Description of the consequences to performance if product is not stored within these limits:

(7) SHELF LIFE STORAGE CONDITIONS [§ 300.915(a)(7)]

The anticipated shelf life of the product at the storage conditions noted in paragraph(a)(6) of this section and documentation for this determination.

(8) PRODUCT LABEL [§ 300.915(a)(8)]

A sample product label for all name(s), brand(s), and/or trademark(s) under which the product is to be sold that includes manufacture and expiration dates, and conditions for storage. You may use an existing label provided it already contains the required dates and storage information.

Requirements (9) through (12) Not Applicable to Sorbents

(13) IDENTIFICATION AND CONCENTRATION OF PRODUCT COMPONENTS [§ 300.915(a)(13)]

The identity and concentration of all components in the product, including each specific component name; corresponding Chemical Abstract Service (CAS) Registry Number; the maximum, minimum, and average weight percent of each component in the product; and the intended function of each component (e.g., solvent, surfactant).

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

Note 1: Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter.

Note 2: You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule and **include any PBI information in a separate sealed envelope**.

(14) MICROORGANISMS, ENZYMES AND/OR NUTRIENTS [§ 300.915(a)(14)]

For products that contain microorganisms, enzymes, and/or nutrients, provide the component information as follows, including a citation and description of the methodology used to determine:

1. Microorganisms [§ 300.915(a)(14)(i)]

- a. Name of all microorganisms by current genus and species:
- b. Any reclassifications:
- c. Any physical, chemical, or biological manipulation of the genetic composition:
- d. Weight percent of each genus in the product:

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

2. Enzymes [§ 300.915(a)(14)(ii)]

- a. Name of all enzyme(s):
- b. International Union of Biochemistry (I.U.B.) Number(s):
- c. Enzyme Classification (EC) Code Number:
- d. Source of Enzymes:
- e. Units:
- f. Specific Oil-Degrading Activity:

See Chapter 6 and the sample template in Attachment I of this guidance.

- **3.** Nutrients [§ 300.915(a)(14)(iii)]
- a. Name(s) of all Nutrients:
- b. Maximum Weight Percent of Nutrients:
- c. Minimum Weight Percent of Nutrients:
- d. Average Weight Percent of Nutrients:

See <u>Chapter 6</u> and the sample template in <u>Attachment I</u> of this guidance.

4. Data, methodology, and supporting documentation for levels of bacterial, fungal, or viral pathogens, or opportunistic pathogens, including but not limited to [§ 300.915(a)(14)(iv):

Enteric bacteria, suchs as *Salmonella*, fecal coliforms, Shigella, coagulase postive *Staphylococci*, and beta hemolytic *Streptococci* and enterococci.

NOTE – Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter. You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule and include any PBI information in a separate sealed envelope (See Chapter 6 of this quidance).

(15) DATA, METHODOLOGY, AND SUPPORTING DOCUMENTATION FOR LEVELS OF THE FOLLOWING [§ 300.915(a)(15)]:

Data, methodology, and supporting documentation for the levels of the following:

- 1. Arsenic, cadmium, chromium, copper, lead, mercury, nickel, vanadium, zinc, and any other heavy metal reasonably expected to be in the product;
- 2. Cyanide;
- 3. Chlorinated hydrocarbons;
- 4. Pesticides;
- 5. Polychlorinated biphenyls (PCBs); and
- 6. Polycyclic aromatic hydrocarbons (PAHs).

(16) PROHIBITED AGENT CERTIFICATION [§ 300.915(a)(16)]

Certification including data, methodology and supporting documentation indicating that product does not contain prohibited agents identified in § 300.910(e).

Requirements (17)-(21) Not Applicable to Sorbents

Attachment I: Proprietary Business Information (PBI) Submission Sample Template

PROPRIETARY BUSINESS INFORMATION (PBI) SUBMISSION SAMPLE TEMPLATE FOR § 300.915(a)(13) and (14) DATA AND INFORMATION REQUIREMENTS

PRODUCT NAME: [include product name] **CATEGORY:** [include product category]

(13) IDENTIFICATION AND CONCENTRATION OF PRODUCT COMPONENTS [§ 300.915(a)(13)]

The identity and concentration of all components in the product, including each specific component name; corresponding Chemical Abstract Service (CAS) Registry Number; the maximum, minimum, and average weight percent of each component in the product; and the intended function of each component (e.g., solvent, surfactant).

SAMPLE FORMAT:

Chemical Name	CAS#	Concentration Percentage by Weight (PBI)	Intended Function
Sodium stearate	822-16-2	MAX/MIN/AVG%	Surfactant

Note 1: The total of the average components in the product should equal 100% weight.

Note 2: Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter.

Note 3: You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule **and include any PBI information in a separate sealed envelope** (See <u>Chapter 6</u> of this quidance).

(14) MICROORGANISMS, ENZYMES AND/OR NUTRIENTS [§ 300.915(a)(14)]

For products that contain microorganisms, enzymes, and/or nutrients, provide the component information as follows, including a citation and description of the methodology used to determine:

1. Microorganisms [§ 300.915(a)(14)(i)]

- a. Name of all microorganisms by current genus and species:
- b. Any reclassifications:
- c. Any physical, chemical, or biological manipulation of the genetic composition:
- d. Weight percent of each genus in the product:

SAMPLE FORMAT:				
Microorganism Name	Reclassifications	Any Physical, Chemical, or Biological Manipulation of the Genetic Composition	Weight Percent of Each Genus in the Product (PBI)	
Microorganism (current genus, species)			MAX/MIN/AVG%	

2. Enzymes [§ 300.915(a)(14)(ii)]

- a. Name of all enzyme(s):
- b. International Union of Biochemistry (I.U.B.) Number(s),
- c. Enzyme Classification (EC) Code Number:
- d. Source of Enzymes:
- e. Units:
- f. Specific Oil-Degrading Activity:

SAMPLE FORMAT:

Enzyme Name	International Union of Biochemistry (I.U.B.) Number(s)	Enzyme Classification (EC) Code Numbers	Source of Each Enzyme	Units (PBI)	Specific Oil- Degrading Activity
Enzyme					

3. Nutrients [§ 300.915(a)(14)(iii)]

- a. Name(s) of all Nutrients:
- b. Maximum Weight Percent of Nutrients:
- c. Minimum Weight Percent of Nutrients:
- d. Average Weight Percent of Nutrients:

SAMPLE FORMAT:

Nutrient Name	CAS#	Weight Percent	Intended Function
Ammonium nitrate	6454-52-2	MAX/MIN/AVG%	Ammonium nitrate

4. Data, methodology, and supporting documentation for levels of bacterial, fungal, or viral pathogens, or opportunistic pathogens, including but not limited to [§ 300.915(a)(14)(iv):

Enteric bacteria, such as Salmonella, fecal coliforms, Shigella, coagulase positive Staphylococci, and beta hemolytic Streptococci and enterococci.

NOTE – Under § 300.950, you may only claim as Proprietary Business Information (PBI) the concentration, the maximum, minimum, and average weight percent; and the units of each component of the total formulation as identified in § 300.915(a)(13) and (14) and as applicable. All other product information submitted to EPA as required under § 300.915 and § 300.955 will be available for public disclosure upon submission, without further notice to the submitter. You must make your PBI claim at the time you submit your information to EPA to be listed on the NCP Product Schedule and include any PBI information in a separate sealed envelope (See Chapter 6 of this guidance).