Government of Canada / Gouvernement du Canada

# NEW SUBSTANCES NOTIFICATION FORM
## for chemicals and polymers

This form is to be used for fulfilling the information requirements prescribed in the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations) of the *Canadian Environmental Protection Act, 1999* (the Act).

Notifications must be submitted to:

**Single Window Information Manager: https://ec.ss.ec.gc.ca**

**Email: substances@ec.gc.ca**

Executive Director, Substance Prioritization, Assessment and Coordination Division
Department of Environment and Climate Change Canada
351 St-Joseph Boulevard
Place Vincent Massey
Gatineau QC K1A 0H3
If you are using a courier, please use J8Y 3Z5.

| Department Use Only |
|---|
| NSN Reference No. |
| FP No. |
| Date Received (YYYY/MM/DD): |
| Total number of pages: |

You may reproduce this form, or portions thereof, for notification purposes. The form is available electronically on the New Substances program website.

Detailed instructions for completing this notification form are included in section 6 of the *Guidance document for the* New Substances Notification Regulations (Chemicals and Polymers) (Guidance Document).

Part A — Administrative and substance identity information requirements

Part B — Technical information requirements

Part C — Additional information required for biochemicals or biopolymers

Part D — Additional information requirements

Part E — Human and environmental exposure information (known and anticipated)

Appendix I: New Substances Fees Payment Form

Appendix II: Substance Functional Use Codes

Appendix III: Application Codes

Appendix IV: Data Codes, Attachments and Confidential Information

Ce formulaire est disponible en français, sur demande, en communiquant avec la Ligne d'information de la gestion des substances au 1-800-567-1999 (sans frais au Canada) ou au (819) 938-3232 (de l'étranger). Le formulaire est disponible en ligne sur le site Web du Programme des substances nouvelles.

## Part A - Administrative and substance identity information requirements

(refer to section 6.2 of the Guidance Document)

### A.1 Signature page, confidentiality requests and agreements

**A.1.1 Representative of the resident manufacturer or importer of the substance identified in block A.2 or A.3 (notifier)**

**Certification statement:**
I hereby certify on the basis of the information in my possession and to the best of my knowledge and belief that, all information provided in this form, as well as any attachments to the form, is accurate and complete; and I will be required to keep the information and any supporting data for a period of five years as per section 13 of the Regulations.

| Name of the Person | Title | Date (YYYY/MM/DD) |
|---|---|---|
| Signature: | | |

**A.1.2 Agent of the non-resident importer of the substance identified in block A.4 (Canadian Agent)**

**Certification statement:**
I hereby certify on the basis of the information in my possession and to the best of my knowledge and belief that, all information provided in this form, as well as any attachment to the form by the notifier (the person listed in block A.3.), is accurate and complete; I understand that all notices and correspondence from the New Substances (NS) program will be sent to my attention as the "Canadian Agent" and I will be required to keep the information and any supporting data for a period of five years as per section 13 of the Regulations.

| Name of the Person | Title | Date (YYYY/MM/DD) |
|---|---|---|
| Signature: | | |

**A.1.3 Toll manufacturer statement of responsibilities identified in block A.7:**

I hereby accept all compliance responsibilities with respect to the manufacture of the notified substance and any accidental release of the notified substance.

| Name of the Person | Title | Date (YYYY/MM/DD) |
|---|---|---|
| Signature: | | |

**A.1.4 Fees provided (if applicable): $** _____ (complete Appendix I – New Substances Fees Payment Form**)**

**A.1.5 Confidentiality requests:**

| | | | | | |
|---|---|---|---|---|---|
| Name of manufacturer or importer (blocks A1.1-A1.3 and A.2-A.6) | ☐ | Quantity of substance (blocks A.10-A.11) | ☐ | Activity with the substance (blocks A.12 and A.7-A.8) | ☐ |
| Anticipated uses of the substance (blocks A.15.1-A15.6) | ☐ | Substance identity (blocks A.16-A.17 and A.19-A.28) If checked, complete block A.18 | | | ☐ |

**Justification for confidentiality request** (select all that apply)**:**

Pursuant to section 313 of the Act, any person who provides information may request that the information or part of it be treated as confidential. If you have requested confidentiality in relation to this substance, indicate the rationale for the confidentiality request.

| | | |
|---|---|---|
| 1. | It is a trade secret | ☐ |
| 2. | It is information of a financial, commercial, scientific or technical nature that is treated consistently in a confidential manner | ☐ |
| 3. | Its disclosure could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position | ☐ |
| 4. | Its disclosure could reasonably be expected to interfere with contractual or other negotiations | ☐ |

**A.1.6 Limited disclosure agreement** (optional)**:**

The person manufacturing or importing the substance hereby gives permission to the Minister of the Environment and Climate Change to disclose information, regarding the substance, including information for which a confidentiality request is made, with the new chemical regimes of the United States Environmental Protection Agency (US EPA) and/or the European Chemicals Agency (ECHA) and/or the Australian Industrial Chemicals Introduction Scheme (AICIS). The person makes this limited authorization for disclosure with the understanding and belief that the US EPA, ECHA, AICIS and the NS program will give the information all the protection it is entitled under applicable laws.

Agreeing to disclose to the following agencies: US EPA ☐ ECHA ☐ AICIS ☐

Not agreeing to disclose ☐

**A.1.7 Information sharing agreement** (optional)**:**

☐ I hereby grant the Minister of the Environment permission to release the name, address and phone number of the technical contact indicated in block A.6 of this form to any person who has provided the Minister with: (1) documentation of intent to manufacture or import the substance described in block A.17 of this form; and, (2) a statement granting the Minister permission to release the name, address and phone number of their technical contact.

## Part A - Administrative and substance identity information requirements

(refer to section 6.2 of the Guidance Document)

| **A.2 Corporate headquarters of the resident manufacturer or resident importer (principal place of business in Canada):** (if the importer or manufacturer is not located in Canada, skip to block A.3) | | |
|---|---|---|
| Contact name and title: | | Canadian Federal Business Number: |
| Company name: | | Street: |
| City: | Province: | Postal code: |
| Telephone No: | Email: | |
| Preferred Language of Correspondence: | English □ | French □ |

| **A.3 Corporate headquarters of the non-resident importer** (if applicable, also complete block A.4)**:** | | |
|---|---|---|
| Contact name and title: | | |
| Company name: | | Street: |
| City: | State / Country: | Zip / Postal Code: |
| Telephone No: | Email: | |
| Preferred Language of Correspondence: | English □ | French □ |

| **A.4 Canadian Agent of the non-resident importer** (needed if block A.3 has been completed)**:** | | |
|---|---|---|
| Contact name and title: | | Canadian Federal Business Number: |
| Company name: | | Street: |
| City: | Province: | Postal code: |
| Telephone No: | Email: | |
| Preferred language of correspondence: | English □ | French □ |

| **A.5 Third party information supplier** (only needed if any information is provided to the NS program directly by a third party)**:** | | |
|---|---|---|
| Contact name and title: | | Canadian Federal Business Number (if applicable): |
| Company name: | | Street: |
| City: | State / Country: | Zip / Postal code: |
| Telephone No: | Email: | |
| Preferred language of correspondence: | English □ | French □ |

| **A.6 Technical contact** (name of a person who can answer technical questions pertaining to the information provided)**:** | | |
|---|---|---|
| Contact name and title: | | Canadian Federal Business Number (if applicable): |
| Company name: | | Street: |
| City: | State / Country: | Zip / Postal code: |
| Telephone No: | Email: | |
| Preferred language of correspondence: | English □ | French □ |

## Part A - Administrative and substance identity information requirements

(refer to section 6.2 of the Guidance Document)

**A.7 Proposed sites of manufacture in Canada, including toll manufacturing:**

| | | |
|---|---|---|
| Contact name and title: | Canadian Federal Business Number (if applicable): | |
| Manufacturing company name : | Street: | |
| City: | Province: | Postal Code: |
| Telephone No: | Alternative telephone No: | Email: |

This substance is manufactured on toll (If checked, complete block A.1.3) ☐

**A.8 Proposed port of entry into Canada:**

| | |
|---|---|
| Port of entry: | |
| City: | Province: |

If A.8 information provided as an attachment, provide attachment number:____

**A.9 Previous New Substances Notification number, Pre-notification Consultation number or other consultative process** (Check below if none)**:**

None ☐

| Process | Number | Date (YYYY/MM/DD) |
|---|---|---|
| | | |
| | | |

**A.10 Quantity** (quantity in kg/yr that triggered the requirement to notify)**:**

100 kg ☐ 1 000 kg ☐ 10 000 kg ☐ 50 000 kg ☐

**A.11 Date when the amount in block A.10 is expected to be exceeded (YYYY/MM/DD):**

**A.12 Activity:** Manufacture ☐ Import ☐ Manufacture and Import ☐

**A.13 Substance type:** (check all that apply)

Chemical ☐ Polymer ☐ → All reactants specified on the DSL or NDSL[1] ☐

Biochemical ☐ Biopolymer ☐ → Meets the RRR[2] polymer criteria ☐

Research & Development ☐ Contained Export Only ☐ Contained Site Limited Intermediate ☐

Nanomaterial[3] ☐ UVCB[4] ☐

Present on the NDSL or Confidential NDSL[1] ☐ NDSL Confidential Substance Identity Number:_____

**A.14 Schedule number:**

Special category: 1 ☐ 3 ☐

Chemical/Biochemical: 4 ☐ 5 ☐ 6 ☐

Polymer/Biopolymer: 9 ☐ 10 ☐ 11 ☐

Biochemical /Biopolymer[5]: 2 ☐

[1] DSL is the acronym for Domestic Substances List and NDSL is the acronym of the Non-domestic Substances List.
[2] RRR is the acronym for Reduced Regulatory Requirement polymer criteria.
[3] Refer to section 3.3.1.4 and Appendix 10 of the Guidance document.
[4] Substances of Unknown or Variable composition Complex reaction products or Biological materials.
[5] NSN for notified substances that are biochemicals or biopolymers must also contain specific items from Schedule 2 of the Regulations. Schedule 2 is not a stand-alone schedule.

## Part A - Administrative and substance identity information requirements

(refer to section 6.2 of the Guidance Document)

**A.15.1 Anticipated uses of the substance** (this is required for all Schedules of the Regulations)**:**

| | |
|---|---|
| **A.15.2 If known, specify the functional use code for this substance** (refer to Appendix II) | |
| **A.15.3 If known, specify the application code for this substance** (refer to Appendix III) | |
| **A.15.4 If known, specify the North American Industry Classification System Code (NAICS) for this substance** | |

**A.15.5 Select one of the following:**

This substance is intended to be manufactured or imported solely for use in products regulated by the *Food and Drugs Act* (F&DA)[6] ☐

This substance is intended to be manufactured or imported for an industrial, commercial, and/or consumer use other than for use in products regulated by the F&DA[7] ☐

This substance is intended to be manufactured or imported for use in products regulated by the F&DA and in industrial, commercial, and/or consumer products (dual use)[7] ☐

**A.15.6 Is the substance intended to be a substitute for another substance or group of substances? (optional)** Yes ☐ No ☐

If yes, provide the following (if available):

Chemical name of substituted substance(s):_____

Chemical Abstracts Service (CAS) Registry number(s) of substituted substance(s): _____

Benefit(s) or reason(s) for substitution (e.g., replaces a toxic substance, reduces impact of climate change, replaces ozone-depleting substance):

**A.16 CAS Registry Number** (this is required for all Schedules of the Regulations)**:**

**A.17 Explicit chemical name of the substance[8]** (this is required for all Schedules of the Regulations)**:**

Nomenclature: CAS ☐ IUPAC ☐

**A.18 Proposed masked name[9]** (if provided, check the box "Substance Identity" in block A.1.5)**:**

Multiple masking ☐ Justification enclosed ☐ Attachment number:____

[6] There are no fees to be submitted for this NSN.
[7] Fees are required for this NSN.
[8] UVCB substance names may include a description of the synthesis (e.g., acetylation, alkaline hydrolysis)
[9] For information requirements concerning masked name requests, refer to section 7.2.2 of the Guidance Document. Note that justification as outlined in section 7.2.2-3 is required for each masked name request. For multiple masking, notifiers are required to provide additional justification as described in Appendix 5.4 of the Guidance Document.

## Part A - Administrative and substance identity information requirements

(refer to section 6.2 of the Guidance Document)

**A.19 Known trade name(s) or synonym(s) of the explicit chemical name of the substance, including internal codes and test substance identifiers** (provide information in block A.25) (this is required for all Schedules of the Regulations)**:**

| Name or identifier | % by weight of the notified substance | Confidential information[10] |
|---|---|---|
| | | Yes □ No □ |
| | | Yes □ No □ |
| | | Yes □ No □ |
| | | Yes □ No □ |

If A.19 information provided as an attachment, provide attachment number:____

**A.20 UVCB composition (immediate precursors and major or key constituents as anticipated)**
(provide if UVCB is checked in block A.13)**:**

| Substance name | CAS Registry Number | Range of possible composition expressed in % |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

If A.20 information provided as an attachment, provide attachment number:____

**A.21 The structural formula of the substance, if possible, or a partial structural formula**
(this is required for Schedules 1, 3, 5, 6 9, 10 and 11 of the Regulations)**:**

If A.21 information provided as an attachment, provide attachment number:____
RRR Polymer: Reaction scheme enclosed □ Attachment number: :____

**A.22 Molecular formula** (this is required for Schedules 1, 3, 5, 6, 9, 10 and 11 of the Regulations)**:**

**A.23 Gram molecular weight** (this is required for Schedules 1, 5 and 6 of the Regulations)**:**

**A.24 Monomers and reactants** (this is required for Schedules 3, 9, 10 and 11 of the Regulations)**:**

| Substance name | CAS Registry Number | % by weight |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | **100%** |

If A.24 information provided as an attachment, provide attachment number:____

[10] Trade name(s) or name(s) commonly used are not expected to be confidential. Refer to section 7.2.1.1 of the Guidance Document.

## Part A - Administrative and substance identity information requirements

(refer to section 6.2 of the Guidance Document)

**A.25 Additives, stabilizers and solvents present when the substance is tested for each name or identifier listed in block A.19** (this is required for Schedules 1, 3, 5, 6, 9, 10 and 11 of the Regulations)**:**

| Name or identifier of test substance in block A.19 | Additives, stabilizers and solvents | | |
|---|---|---|---|
| | Substance name | CAS Registry Number | % by weight |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

If A.25 information provided as an attachment, provide attachment number:____

**A.26 Degree of purity in its technical grade composition** (this is required for Schedules 1, 5 and 6 of the Regulations)**:**

**A.27 Impurities and their concentration by weight** (this is required for Schedules 1, 3, 5, 6, 9, 10 and 11 of the Regulations)**:**

| Substance name | CAS Registry Number | % by weight |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

If A.27 information provided as an attachment, provide attachment number:____

**A.28 Safety Data Sheet** (this is required for all Schedules of the Regulations, if available)**:** Attachment number:____

## Part B - Technical information requirements

(refer to section 6.3 of the Guidance Document and to Appendix IV for explanation on the use of each column)

| **If you request confidentiality in relation to the information requirements under Part B, indicate the rationale for the confidentiality request by selecting one or more from the four criteria listed in block A.1.5** | 1.□ 2.□ 3.□ 4.□ |
|---|---|

| **B.1 Physical and chemical information** | **Required for Schedule** | **Data code[11]** | **Value & conditions** | **Attachment number** | **Confidential information** |
|---|---|---|---|---|---|
| Melting point | 5, 6 | | °C | | Yes □ No □ |
| Boiling point | 5, 6 | | °C | | Yes □ No □ |
| Water solubility[12] | 5, 6 | | g/L @ °C | | Yes □ No □ |
| Water extractability | 10, 11 | | % 100% water-available □ | | Yes □ No □ |
| Vapour pressure | 5, 6 | | @ °C | | Yes □ No □ |
| Density | 5, 6 | | g/cm$^3$ @ °C | | Yes □ No □ |
| Octanol/water partition coefficient | 5, 6, 10, 11 | | | | Yes □ No □ |
| Hydrolysis as a function of pH[13] | 6, 10, 11 | | | | Yes □ No □ |
| Ready biodegradation | 5, 6, 11 | | | | Yes □ No □ |
| Adsorption-desorption[13] | 6 | | | | Yes □ No □ |
| Spectroscopy IR □ UV □ NMR □ Mass □ | 6 | | | | Yes □ No □ |
| Formulated for dispersal in water | 3, 10, 11 | | Yes □ No □ | | Yes □ No □ |
| Physical state | 3, 10, 11 | | | | Yes □ No □ |
| Number average molecular weight ($M_n$)[14] | 3, 9, 10, 11 | | | | Yes □ No □ |
| Weight percent < 1,000 Daltons[15] | 3, 9, 10, 11 | | | | Yes □ No □ |
| Weight percent < 500 Daltons[15] | 3, 9, 10, 11 | | | | Yes □ No □ |

| **B.2 Ecotoxicity information[16]** | **Required for Schedule** | **Data code[11]** | **Value & conditions** | **Attachment number** | **Confidential information** |
|---|---|---|---|---|---|
| Acute aquatic toxicity<br>Fish □ Daphnia □ Algae □ | 5, 10, 11 | | | | Yes □ No □ |
| Second acute aquatic toxicity<br>Fish □ Daphnia □ Algae □ | 6, 11 | | | | Yes □ No □ |
| Third acute aquatic toxicity<br>Fish □ Daphnia □ Algae □ | 6 | | | | Yes □ No □ |

11 For information on waiver requests, refer to section 8.7 and Appendix 6 of the Guidance Document.
12 For nanomaterial, review section 6.3.1.3 of the Guidance Document.
13 Review subsections 7(2), 7(3), 11(2) and 11(3) of the Regulations to determine if these test data are required prior to exceeding 50 000 kg/yr.
14 For information requirements when providing Gel Permeation Chromatography (GPC) data and frequently encountered difficulties, refer to Appendix 7 of the Guidance Document.
15 Not required for Schedule 3 that is for Research and Development substances.
16 Review section 6.3.2.1 of the Guidance Document to determine the most appropriate test to provide at each Schedule of the Regulations.

## Part B - Technical information requirements

(refer to section 6.3 of the Guidance Document and to Appendix IV for explanation on the use of each column)

| B.3 Health toxicity information | Required for Schedule | Data code[11] | Value & conditions | Attachment number | Confidential information |
|---|---|---|---|---|---|
| Acute mammalian toxicity<br>Oral □ Dermal □ Inhalation □ | 5, 6, 10, 11 | | | | Yes □ No □ |
| Second acute mammalian toxicity<br>Oral □ Dermal □ Inhalation □ | 6 | | | | Yes □ No □ |
| Skin irritation | 6, 11 | | | | Yes □ No □ |
| Skin sensitization | 6, 11 | | | | Yes □ No □ |
| Repeated dose mammalian toxicity[13]<br>Oral □ Dermal □ Inhalation □ | 6, 11 | | | | Yes □ No □ |
| *In vitro* test for gene mutations[13] [17] | 5, 6, 11 | | | | Yes □ No □ |
| *In vitro* test for chromosomal aberrations[13] | 6, 11 | | | | Yes □ No □ |
| *In vivo* mammalian mutagenicity test for chromosomal aberration **OR** gene mutation | 6, 11 | | | | Yes □ No □ |

## Part C - Additional information required for biochemicals or biopolymers

(refer to section 6.4 of the Guidance Document and to Appendix IV for explanation on the use of each column)

| | |
|---|---|
| **If you request confidentiality in relation to the information requirements under Part C, indicate the rationale for the confidentiality request by selecting one or more from the four criteria listed in block A.1.5** | 1.□ 2.□ 3.□ 4.□ |

| C.1 Information required for the production organism | Required for Schedule | Data code[11] | Attachment number | Confidential information |
|---|---|---|---|---|
| Identification of the production organism | 1, 3, 4, 5, 6, 9, 10, 11 | | | Yes □ No □ |
| Source and history of the production organism | 1, 3, 4, 5, 6, 9, 10, 11 | | | Yes □ No □ |
| Adverse environmental or human health effects of the production organism | 1, 3, 4, 5, 6, 9, 10, 11 | | | Yes □ No □ |
| Concentration of viable production organism (including in end-use products)[18] | 1, 3, 4, 5, 6, 9, 10, 11 | | | Yes □ No □ |
| Method of separation of the production organism from the biochemical or biopolymer[19] | 1, 3, 5, 6, 10, 11 | | | Yes □ No □ |

| C.2 Information required for biochemicals or biopolymers[20] | Required for Schedule | Data code[11] | Attachment number | Confidential information |
|---|---|---|---|---|
| Encoded products | 1, 3, 5, 6, 10, 11 | | | Yes □ No □ |
| Biological activity | 1, 3, 5, 6, 10, 11 | | | Yes □ No □ |
| Catalytic function | 1, 3, 5, 6 | | | Yes □ No □ |
| Enzyme Commission number and name | 1, 5, 6 | | | Yes □ No □ |
| Substrate specificity | 1, 3, 5, 6 | | | Yes □ No □ |
| Optimum pH and temperature | 1, 3, 5, 6 | | | Yes □ No □ |
| Catalytic constants $K_M$ and $K_{cat}$ | 1, 3, 5, 6 | | | Yes □ No □ |
| Cofactors | 1, 3, 5, 6 | | | Yes □ No □ |
| Enzymatic activity | 1, 3, 5, 6 | | | Yes □ No □ |

17 For nanomaterial, review section 6.3.3.5 of the Guidance Document.

18 This information is only required for Schedule 1 or 3 that are for a substance that is a contained site-limited intermediate substance that is not manufactured and consumed at the site of manufacture; or a contained export-only substance.

19 This information is not required for Schedule 1 or 3 that are for research and development substances.

20 This information is not required for Schedule 1 or 3 that are for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture.

## Part D — Additional information requirements

(refer to section 6.5 of the Guidance Document)

| If you request confidentiality in relation to the information requirements under Part D, indicate the rationale for the confidentiality request by selecting one or more from the four criteria listed in block A.1.5 | 1.□ 2.□ 3.□ 4.□ |
|---|---|

| D.1 Other agencies | Required for Schedule | Agency name, file number and the outcome | Attachment number | Confidential information |
|---|---|---|---|---|
| Other government agencies, either outside or within Canada, the agency's file number, the outcome of the assessment and any risk management actions imposed. | 1, 3, 4, 5, 6, 9, 10, 11 | | | Yes □ No □ |

| D.2 Other requirements | Required for Schedule | Information or test data | Attachment number | Confidential information |
|---|---|---|---|---|
| Other information and test data in the person's possession, including those listed in the Regulations but not required for the Schedule submitted. | 1, 3, 4, 5, 6, 9, 10, 11 | | | Yes □ No □ |

| D.3 Other requirements for nanomaterials | Recommended for Schedule | Data code[11] | Attachment number | Confidential information |
|---|---|---|---|---|
| Primary particle size and particle size distribution | 1, 3, 4, 5, 6, 9, 10, 11 | | | Yes □ No □ |
| Agglomeration and/or aggregation state, shape surface area, surface functionalization, surface coating and surface charge | 1, 3, 4, 5, 6, 9, 10, 11 | | | Yes □ No □ |
| Water solubility[21] | 5, 6 | | | Yes □ No □ |
| *In vitro* test for gene mutations in mammalian cells[21] | 5, 6, 11 | | | Yes □ No □ |

| D.4 Additional information and attachments | | |
|---|---|---|
| **Attachment name** | **Attachment number** | **Confidential information** |
| | | Yes □ No □ |
| | | Yes □ No □ |
| | | Yes □ No □ |
| | | Yes □ No □ |
| | | Yes □ No □ |
| | | Yes □ No □ |
| | | Yes □ No □ |
| | | Yes □ No □ |
| | | Yes □ No □ |
| | | Yes □ No □ |
| | | Yes □ No □ |
| | | Yes □ No □ |
| | | Yes □ No □ |

[21] Review sections 6.3.1.3 and 6.3.3.5 of the Guidance Document for alternative protocols for nanomaterial.

| D.4 Additional information and attachments (continued) | | |
|---|---|---|
| **Attachment name** | **Attachment number** | **Confidential information** |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |
| | | Yes ☐ No ☐ |

## Part E — Human and environmental exposure information (known and anticipated)

(refer to section 6.6 of the Guidance Document)

| | |
|---|---|
| **If you request confidentiality in relation to the information requirements under Part E, indicate the rationale for the confidentiality request by selecting one or more from the four criteria listed in block A.1.5** | 1.☐ 2.☐ 3.☐ 4.☐ |

### E.1 Anticipated annual manufacture, import and export quantities of notified substance

**E.1.1 Quantity of the substance manufactured, imported and exported** **Confidential? Yes ☐ No ☐**

Estimate the quantity of substance to be manufactured, imported, and/or exported for the first 12 months. Also estimate the maximum anticipated quantity for any future 12-month period. Report the amount of pure substance, not including solvents or other components if the substance is in a mixture. For consolidated notifications, report quantities for each substance (this information is required for substances subject to any of the Schedules prescribed in the Regulations).

| | Quantity during first 12 months (kg/yr) | Maximum quantity in any 12-month period (kg/yr) |
|---|---|---|
| **Quantity manufactured within Canada** | | |
| **Quantity imported into Canada** | | |
| **Quantity for export (if applicable)** | | |

**E.1.2 Canadian sites of greatest quantity** **Confidential? Yes ☐ No ☐**

List the three sites in Canada where the greatest quantity of the substance to be manufactured or imported by the notifier is anticipated to be used or processed, if known (this information is required for chemicals subject to Schedule 5 or 6 and non-RRR polymers subject to Schedule 9, 10 or 11 of the Regulations. For contained site-limited intermediate substances subject to Schedule 1 or 3 of the Regulations, the single location of use is required).

| Site | Quantity (kg/yr) |
|---|---|
| **Site 1 Company name and site address:** | |
| **Site 2 Company name and site address:** | |
| **Site 3 Company name and site address:**<br><br>If E.1.2 information provided as an attachment, provide attachment number:____ | |

## E.2 Uses involving the substance

**E.2.1 Description of activities in Canada** **Confidential? Yes ☐ No ☐**

Describe all industrial, commercial, and consumer activities involving the substance in Canada (e.g., manufacture, import and distribution, industrial formulation, reformulation of a concentrate, commercial activity). The purpose of this section is to identify the major steps in the chemical life cycle which will be used to evaluate the potential for exposure to humans and the environment. Provide all information requested to the extent to which it is known or reasonably ascertainable (this information is required for substances subject to any of the Schedules prescribed in the Regulations).

**Describe each of the notifier's industrial, commercial, or consumer activities in Canada:**

**Describe any expected industrial, commercial, or consumer activities by downstream processors or users of the substance in Canada:**

**If the substance is imported into Canada, describe <u>the imported product(s)</u> containing the notified substance (e.g., pure notified substance, intermediate product, end-use product):**

If E.2.1 information provided as an attachment, provide attachment number:____

**E.2.2 Anticipated end-uses, functions and concentrations of the substance** **Confidential? Yes ☐ No ☐**

**Provide the concentration (or range of concentrations) of the notified substance in the product(s) <u>as imported or manufactured in Canada</u>** (this information is required for chemicals subject to Schedule 1, 4, 5, or 6, and non-RRR polymers subject to Schedule 3, 9, 10 or 11 of the Regulations)**:**

Identify and describe each anticipated end-use products containing the new substance (e.g., architectural paint, hair shampoo, automotive lubricant). "Function" is related to the inherent physical and chemical properties of the substance (e.g., degreaser, catalyst, plasticizer, ultraviolet absorber, fragrance). "Percent of annual quantity" is the percentage of total annual quantity imported or manufactured for each end-use (this information is required for substances subject to any of the Schedules prescribed in the Regulations).

| End-use products containing the substance | Function of substance | Identify end-use as industrial, commercial and/or consumer | Concentration of substance, if known[22] | Percent of annual quantity |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**E.2.3 Historical and other likely end-uses, functions and concentrations of the substance** **Confidential? Yes ☐ No ☐**

Identify each historical or other likely end-uses and functions of the new substance. These uses and functions are not envisioned to be pursued by the notifier, but are known historically or to exist in other jurisdictions or in the patent literature, or understood based on knowledge of the substance properties (this information is required for NDSL chemicals subject to Schedule 5, chemicals subject to Schedule 6, and polymers subject to Schedule 10 or 11 of the Regulations).

| End-use products containing the substance | Function of substance | Identify end-use as industrial, commercial and/or consumer | Concentration of substance, if known |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

[22] This information is required for substances subject to Schedule 1, 3, 4, 5, or 6, and non-RRR polymers subject to Schedule 9, 10 or 11 of the Regulations.

## E.3 Human exposure

**E.3.1 Direct human exposure** **Confidential? Yes ☐ No ☐**

If the notifier does not have specific information about the potential for human exposure, including from the use of consumer products, then descriptions can be based on information from downstream processors and users of the substance or on experience with similar substances. Provide all information requested, to the extent to which it is known or reasonably ascertainable. Where only limited information is provided, exposure evaluations will be based on conservative estimates (this information is required for chemicals subject to Schedule 5 or 6 and non-RRR polymers subject to Schedule 9, 10 or 11 of the Regulations).

**Describe the anticipated circumstances and degree of direct human exposure to the substance, including the concentration of the substance, the duration and frequency of exposure and the route of exposure (dermal, oral, inhalation):**

**Is the substance anticipated to be used in products intended for use by or for children? Yes ☐ No ☐**
**If yes, describe the types of products (e.g., shampoo, markers):**

**Describe any conditions of use or factors that may limit direct human exposure to the substance:**

If E.3.1 information provided as an attachment, provide attachment number:____

**E.3.2 Significant public exposure** **Confidential? Yes ☐ No ☐**

Indicate whether the public is anticipated to be significantly exposed to the substance in a product, taking into account factors including concentration of the substance, duration, frequency and circumstances of exposure (e.g., route of exposure) and factors that may limit direct human exposure. If not, provide information substantiating that the public is not anticipated to be significantly exposed (this information is required for substances subject to Schedule 1, 3 or 10 and NDSL chemicals subject to Schedule 5 of the Regulations. Additional test data may be required prior to importing or manufacturing more than 50 000 kg/yr depending on the assessment of this information (review subsections 7(2), 7(3), 11(2) and 11(3) of the Regulations).

**Is the public anticipated to be significantly exposed to the substance in a product?: Yes ☐ No ☐**

**If no, provide information substantiating that the public is not anticipated to be significantly exposed:**

If E.3.2 information provided as an attachment, provide attachment number:____

## E.4 Environmental exposure

### E.4.1 Description of operations (industrial, commercial, and consumer)

Complete Sections E.4.1A, E.4.1B and E.4.1C for the substance as applicable.

In most cases, notifiers will only have specific information relating to operations under their control. Where specific information is not available, for example, in the case where operations are controlled by downstream processors or users of the substance, descriptions can be based on available information and experience with similar substances. Provide all information requested to the extent to which it is known or reasonably ascertainable. Where only limited information is provided, exposure evaluations will be based on conservative estimates.

**E.4.1A Manufacture and/or processing of the notified substance in Canada** **Confidential? Yes ☐ No ☐**

Processing the notified substance can include, for example, formulation or blending the substance.

For the description of operation and/or flow diagram, identify the major steps, focusing on waste streams and potential points of release of the substance during the operation and equipment cleaning.

If the same operation occurs at multiple sites and the processes differ significantly, or if there are multiple operations, the information can be reported by replicating the table (this information is required for manufacture and/or processing of notified substances in Canada that are subject to any of the Schedules prescribed in the Regulations).

**Number of sites:**

| | | | |
|---|---|---|---|
| **Batch operations** | **Maximum quantity (kg/batch)** | **Maximum batches/day** | **Maximum batches/month** |
| | | | |

| | | |
|---|---|---|
| **Continuous operations** | **Maximum quantity (kg/day)** | **Maximum number of days/month** |
| | | |

**Provide description of operation and/or flow diagram:**

**Provide a brief description of the methods used for cleaning the equipment, transportation lines, and vessels (e.g., vacuumed, washed with water, washed with organic solvents) and the maximum cleaning frequency (e.g., per month, after each batch):**

If E.4.1A information provided as an attachment, provide attachment number:____

**E.4.1B Industrial and commercial uses** **Confidential? Yes ☐ No ☐**

| Describe the industrial and/or commercial uses for the substance. Industrial uses include, for example, painting automotive parts, applying interior pipe coatings, lubricating equipment. Commercial uses include, for example, dry cleaning, car washes, automotive servicing (this information is required for substances with industrial and/or commercial uses that are subject to any of the Schedules prescribed in the Regulations). | **Maximum quantity (kg/day)** |
|---|---|
| | |
| | |

**Provide a brief description of the methods used for cleaning the equipment, transportation lines, and vessels (e.g., vacuumed, washed with water, washed with organic solvents) and the maximum cleaning frequency (e.g., per month, per batch):**

If E.4.1B information provided as an attachment, provide attachment number:____

**E.4.1C Consumer uses** **Confidential? Yes ☐ No ☐**

| **Describe the consumer uses for the substance. Consumer uses include, for example, dishwashing, do-it-yourself automotive oil changing** (this information is required for substances with consumer uses that are subject to any of the Schedules prescribed in the Regulations). | **Maximum quantity (kg/person/day)** |
|---|---|
| If E.4.1C information provided as an attachment, provide attachment number:____ | |

**E.4.2 Description of the transportation and storage operations** **Confidential? Yes ☐ No ☐**

| In most cases, specific information relating to operations under the notifier's control will be available. Where specific information is not available, for example, in the case where operations are controlled by downstream processors or users of the substance, descriptions can be based on available information and experience with similar substances. Provide all information requested to the extent to which it is known or reasonably ascertainable. Where only limited information is provided, exposure evaluations will be based on conservative estimates (this information is required for chemicals subject to Schedule 1, 5 or 6, and polymers subject to Schedule 3, 10 or 11 of the Regulations). |
|---|
| **Provide the expected mode(s) of transportation and storage of the notified substance (e.g., air, rail, truck):** |
| **Describe the size and type of container(s) used to transport and/or store the notified substance (e.g., tank truck, tote, drum):** |
| **Specify the percentage of the annual quantity transported and/or stored in each type of container:** |
| **Provide the quantity or percent of substance remaining as residue in each type of container after use:** |
| **Are transportations and/or storage containers cleaned in Canada? Yes ☐ No ☐**<br>**If yes, describe the methods used for cleaning (e.g., vacuumed, washed with water, washed with organic solvents) and the cleaning frequency (e.g., 10 drums per day) for each container type:**<br>If E.4.2 information provided as an attachment, provide attachment number:____ |

**E.4.3 Limiting environmental exposure** **Confidential? Yes ☐ No ☐**

| **Describe any factors that may limit environmental exposure to the substance (e.g., incineration, chemical treatment, pollution prevention practices, recycling, existing regulatory requirements) including on-site treatment** (this information is required for NDSL chemicals subject to Schedule 5, chemicals subject to Schedule 6, and polymers subject to Schedule 10 or 11 of the Regulations)**:** |
|---|
| **Describe the methods recommended for destruction or disposal of the substance** (this information is required for chemicals subject to Schedule 1, 5 or 6, and polymers subject to Schedule 3, 10 or 11 of the Regulations)**:**<br>If E.4.3 information provided as an attachment, provide attachment number:____ |

**E.4.4 Handling waste containing the substance** **Confidential? Yes ☐ No ☐**

Provide the following information on the releases of the substance from activities in Canada. Releases generated from operational processes and from cleaning equipment, transport and storage vessels should be included.

**Is there production of waste containing the substance?** (this information is required for chemicals subject to Schedule 1, 5 or 6, and polymers subject to Schedule 3, 10 or 11 of the Regulations)

**No ☐ Solid ☐ Liquid ☐ Gaseous ☐**

**If no, provide explanation why there is no production of waste containing the substance:**

| | | |
|---|---|---|
| **Is there direct release of waste containing the substance to the environment?** (this information is required for chemicals subject to Schedule 1, 5 or 6 and polymers subject to Schedule 3 or 11 of the Regulations)<br><br>**Yes ☐ No ☐ If yes, provide:** | **The component(s) of the environment into which the substance is anticipated to be released (e.g., receiving body of water, agricultural land, air)** | |
| | **The maximum rate of release of the substance (e.g., kg/day) and maximum frequency of release (e.g., days/month)** | |
| **Is the waste containing the substance anticipated to be released to a municipal wastewater treatment plant?** (this information is required for chemicals subject to Schedule 1, 5 or 6 and polymers subject to Schedule 3 or 11 of the Regulations)<br><br>**Yes ☐ No ☐ If yes, provide:** | **The identification of the receiving body of water** | |
| | **The rate (e.g., kg/day) and maximum frequency (e.g., days/month) of release of the substance** | |
| **Are alternative treatment or disposal methods applied to the substance in Canada (e.g., deep-well injection)?** (this information is required for chemicals subject to Schedule 1, 5 or 6 and polymers subject to Schedule 3 or 11 of the Regulations)<br><br>**Yes ☐ No ☐ If yes, provide:** | **A brief description of the treatment or disposal method** | |

**E.4.5 High release to the aquatic environment** **Confidential? Yes ☐ No ☐**

Indicate whether the substance is anticipated to be released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after waste water treatment (High Release). If the release is less than or equal to 3 kg per day, per site, provide the data substantiating the quantity released (this information is required for NDSL chemicals subject to Schedule 5 and polymers subject to Schedule 10 of the Regulations. Additional test data may be required prior to importing or manufacturing more than 50 000 kg/yr depending on the assessment of this information (review subsections 7(2), 7(3), 11(2) and 11(3) of the Regulations).

**Does the substance meet the definition of High Release?: Yes ☐ No ☐**

**If no, provide information substantiating the quantity released.**

If E.4.5 information provided as an attachment, provide attachment number:____