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Guidance for completing the Statement of Product Specification Form (Form 6003)

PMRA Guidance Document



*Protecting the health and
environment of Canadians*



*Protéger la santé des Canadiens
et l'environnement*

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For further information, please contact:

Publications

Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9
E-mail: pmra.publications-arla@canada.ca
Facsimile: 613-736-3758

Pest Management Information Service

1-800-267-6315 or 613-736-3799
E-mail: pmra.info-arla@canada.ca

Internet: canada.ca/pesticides

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Disclaimer

This document does not constitute part of the *Pest Control Products Act* or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations, and the applicable administrative policies.

Note: This document supersedes all prior documents related to the completion of an SPSF.

Table of contents

1.0	Purpose	1
1.1	Introduction	1
2.0	Electronic SPSF features	1
2.1	Guidance checkboxes	1
2.2	Form modification options.....	1
2.3	Field restrictions and automatic calculations.....	2
3.0	PDF requirements for electronic SPSFs	3
4.0	Form overview	3
5.0	Required composition information.....	3
5.1	Requirements for a technical grade active ingredient	3
5.2	Requirements for an integrated system product (ISP)	4
5.3	Requirements for an end-use product.....	5
5.3.1	Completing the components section for formulants in an end-use product	6
5.4	Requirements for a manufacturing concentrate (MA)	6
5.5	Requirements for a repack end-use product (Repack).....	7
5.6	Requirements specific to microbial pest control agents (MPCA) and products	7
6.0	Minimum vs. nominal requirements.....	9
6.1	How to determine if a registered source of an active ingredient is nominal or minimum.....	9
6.2	Guarantee when using nominal and minimum sources of the same active ingredient.....	10
6.3	Required fields summary.....	10
7.0	Summary of the field requirements for different product components.....	10
8.0	Certification of approving official	11
9.0	Completing the alternate suppliers/formulators page	11
10.0	Standard certified limits	12
11.0	Formula for the calculation of a guarantee as percent or in g/L.....	12
	List of document abbreviations	13
	Reference documents	14
Appendix A	Field definitions for boxes A to N	15
Appendix B	Product component definitions	17
Appendix C	Definitions and codes for formulation types.....	19
Appendix D	Scientific unit abbreviations.....	21

1.0 Purpose

The Statement of Product Specification Form (SPSF) allows for the reporting of specific product information that includes a detailed list of the pest control product's components (in other words, formulation) for submission and approval. Pest control products include technical grade active ingredients, integrated system products (ISPs), manufacturing concentrates (MAs) and end-use products. A separate SPSF must be completed for each individual pest control product.

1.1 Introduction

This document contains guidance instructions for completing an SPSF. Typically, a technical grade active ingredient contains an active ingredient and impurities; an ISP contains an active ingredient, impurities, and a stabilizer; an MA contains both a technical grade active ingredient and a diluent; and, an end-use product contains a technical grade active ingredient, diluent, and other formulators.

2.0 Electronic SPSF features

The electronic Statement of Product Specification SMART Form contains several embedded features to assist users in the completion of the SPSF with the Adobe Acrobat Standard Edition 5.0 or greater.

2.1 Guidance checkboxes

There are 3 available checkboxes to the left of the main form for each type of component in the pest control product. These checkboxes are labelled A (Active ingredient), F (Formulant) and I (Impurity). Refer to these definitions under Section 2 of the *Pest Control Products Act*.

The selection of a checkbox greys out the fields of the form not applicable to the selected component type. Select the appropriate checkbox to add an additional product component(s).

2.2 Form modification options

Print: Click this button to print the SPSF. The greyed out fields are automatically deselected next to the guidance checkboxes and enables printing of the SPSF form.

Add Sites: Click this button to add a new page with which to identify alternate formulant suppliers and alternate formulating sites (Refer to Section 9).

Add Components: Click this button to append five (5) additional component rows and include more product components.

Delete Page: Click this button to delete a selected page or range of pages.

Row Functions

Every row has four different functions available: Insert, Delete, Copy, and Paste. For the first row of the components section, and the first row of every additional page, the functions are visible to the left of the row. For other rows, click the "Row number field", then the functions will appear on the left. First, click the "Row number field", and then select the function button to use any of the functions:

- **Insert Row:** Click this button to add 1 additional component row. Click the "Row number field"; then, select the "Insert" button. A pop-up prompts you to affirm the action. A new row is added above the currently selected row.
- **Delete Row:** Click this button to delete one component row. Click the "Row number field"; then, select the "Delete" button. A pop-up prompts you to affirm the action. Data in the selected row is deleted.

- **Copy and Paste Row:** Click these buttons to copy the data from one row to another row. Click the “Row number field” of the row to be copied; then select the “Copy” button. Click the “Row number field” of the row to which the data will be pasted; then, select the “Paste” button. If there is any data in the row being pasted to, a pop-up prompts you as to whether the data in that row should be overwritten. If the row is empty, the paste executes without a prompt. Rows do not have to be full to be copy-pasted.

2.3 Field restrictions and automatic calculations

Number of Decimal Places

Numerical fields (for example, the Value in box 14B) require the use of scientific notation for very small and very large numbers. For example, the number 0.00004 is entered as 4e-5, and the number 12 000 000 = 1.2×10^7 is entered as 1.2e7.

The “Number of Decimal Places” drop down list at the beginning of the components section is a global selector that changes the number of decimal places for decimal and scientific notation values generated by the auto-calculation. For any number entered that is less than 0.0001 (regardless of auto-calculation), it will be converted to scientific notation.

When a component type (A, F, or I) is selected, a “Number of Decimal Places” selector will appear next to that row. If this value needs to be changed later, it can be viewed again at any time by unchecking the A, F, or I that is currently checked for the row, and then re-checking it. Note that the global selector changes the value for every row in the SPSF. Therefore, set the global selector at the start of the form filling process without later changes, unless you want to override the specific selector for every row.

Automatic Calculations

Every row in the components section has a checkbox with the text “Auto-calculation on” next to it. When this box is checked, and depending on certain conditions, it allows for the automatic calculation of % Nominal (Box 12), the Lower and Upper Certified Limits (Box 11 and Box 13); the Guarantee Value (Box 14B), and the Lower, and Upper Certified Limits (Box 14D and 14E). The calculations are listed below (Refer to Sections 10 and 11):

For Technical Grade Active Ingredients:

Product Type technical grade active ingredient

- If Box 6 is empty:
 - Box 12 and 14B are equal to Box 9
 - Standard limits in Box 11, 13, 14D and 14E
- If Box 6 has a value:
 - Box 12 is equal to Box 9
 - Standard limits in Box 11 and 13
 - Box 14B is equal to (Box 6 multiplied by Box 9)
 - Standard limits in Box 14D and 14E

Product Type ISP

- No calculations of Box 14 Values

For Product Types end-use product or MA

Active ingredients

- Box 12 and 14B are equal to (Box 6 multiplied by Box 9)
- Standard limits for Box 11, 13, 14D and 14E

For Formulants:

- Box 11 and Box 13 limits are calculated based on the value in Box 9, and no value for Box 12

Note: Auto-calculation is not an option for Impurities.

Any of the auto-calculated values can be overridden while the auto-calculation box is still checked. Simply click on a calculated field to override the data, and enter any new number. This step can be useful for adding or removing leading and trailing zeroes; making slight modifications to calculations; or, adding and removing decimal places of precision. If at any point you want to go back to auto-calculating all values and undo any overrides, uncheck the auto-calculation box, and then check it again; afterward, all relevant values can be re-calculated.

Summation of %w/w

The summation of all %w/w values (Box 9) automatically appears in the “Sum of the %w/w” box at the bottom of each component page. The sum value for end-use products and MA products must exactly equal 100%. The sum value must be in the range of 98.5–101.5% for technical grade active ingredient and ISP products. If the sum is above or below these values, the text appears red and a warning is displayed on the first page until the sum value is acceptable (the text turns green).

3.0 PDF requirements for electronic SPSFs

The submission of an SPSF in PDF format requires that all security features be disabled. The disabling of security features ensures there are no editing restrictions within the document. In addition, it allows internal annotations and further review by the PMRA. Access the “Help” function in Adobe Acrobat for information about disabling the security features in an Adobe Acrobat PDF file.

4.0 Form overview

The form has three (3) main sections further subdivided into fields/boxes for information:

Product Information Section - Page 1 (Boxes A–O): All fields in this section must be completed. Appendix A contains more details about completing each field in this section.

Components Section: All applicable fields in this section must be completed for each individual component of the product. Refer to Appendix B for details about completing each field, and to Section 5 for component definitions.

Alternate Formulating Sites / Alternate Formulant Suppliers Section: This section is only required if alternate sites or suppliers are applicable to the product. Refer to Section 9 for details about alternate sites or suppliers.

Note: A summary of the field requirements for different product components are listed in Section 7.

5.0 Required composition information

5.1 Requirements for a technical grade active ingredient

An active ingredient is the main active component of the pest control product. The technical grade active ingredient must be listed in Row 1. Impurities of the Manufacturing concentrate (MA) are listed in subsequent rows. These specifications must be in accordance with the *Guidance for developing datasets for conventional pest control product applications*.

These fields are **required** to be completed for a technical grade active ingredient:

- Common name (box 2) — the ISO common name is required, if it is known
- Chemical name (box 3) — the IUPAC or CAS name of the active ingredient is required
- CAS# (box 7)
- % w/w (box 9)
- Purpose (box 10) — “active ingredient”
- % LCL (box 11) — Refer to Section 6 for nominal vs. minimum requirements
- % Nominal (box 12) — The typical amount of the product, expressed as a percent; it is not required if the technical grade active ingredient is registered with a minimum guarantee
- % UCL (box 13) — This value is not required if the source of the active ingredient is registered with a minimum guarantee
- Label Guarantee (box 14A)
- Value (box 14B)
- Units (box 14C)
- LCL and UCL (boxes 14D and 14E) — These values are not required for a minimum guarantee (refer to Section 6 for information about nominal and minimum guarantees)

Completing the product components section for impurities (as applicable)

Usually, impurities are by-products or residual chemicals that occur only in the manufacture of technical grade products. Therefore, these impurities are listed only in technical grade active ingredients and ISP products.

These **fields** are required to be completed for impurities:

- Common name (box 2) — if an established name or a code name¹ has been assigned
- Chemical name (box 3)
- CAS# (box 7) — if this number has been assigned
- % w/w (box 9) — The typical level of impurities in the product, expressed in w/w percent
- Purpose (box 10) — "impurity"
- % UCL (box 13) — In accordance with the manufacturing specification, or highest level that is expected in production

5.2 Requirements for an integrated system product (ISP)

The active ingredient in the ISP must be listed on Row 1. This entry must be followed by any added formulants (for example, preservative, or stabilizer), and then by the listing of any impurities on the following rows.

These fields are **required** for the active ingredient and any added formulants in an ISP:

- Common name (box 2) — The ISO common name is required, if it is established
- Chemical name (box 3)
- CAS# (box 7)
- % w/w (box 9)
- Purpose (box 10)
- % LCL (box 11) — Refer to Section 6 for nominal vs. minimum requirements
- % Nominal (box 12) — The typical level in the product, expressed as a percent; it is not required if the technical grade active ingredient is registered with a minimum guarantee
- % UCL (box 13) — This value is not required if the source of the active ingredient is registered with a minimum guarantee
- Label Guarantee (box 14A)
- Value (box 14B)
- Units (box 14C)
- LCL and UCL (boxes 14D and 14E) — These values are not required for a minimum guarantee. (Refer to Section 6 for information about nominal vs. minimum guarantees)

Formulation preservative requirements

A formulation preservative is defined as a formulated pest control product added to protect a formulation from degradation or denaturation by pests. It is considered an active ingredient if it is used for a pesticidal purpose. However, usually formulation preservatives do not contribute to the intended effect of the pest control product to which they are added. Formulation preservatives are listed in the SPSF with the same requirements and format as active ingredients.

Completing the product components section for impurities (when applicable)

Impurities are by-products or residual chemicals that occur only in the manufacture of technical grade products. Usually, they are solely listed in technical grade active ingredients and in ISP products.

¹ If the applicant has assigned code names to the impurities, these names should be entered in box 2 to allow cross-referencing within the supporting data.

These boxes contain the **required fields** for impurities:

- Common name (box 2) — required if known or code name¹ assigned
- Chemical name (box 3)
- CAS# (box 7)
- % w/w (box 9)
- Purpose (box 10)
- % UCL (box 13)

5.3 Requirements for an end-use product

The active ingredient(s) in an end-use product must be listed first. These ingredients are followed by any safeners and formulation preservatives. Subsequently, these substances are followed by other formulants (Refer to subsection 2(b) of the *Pest Control Products Regulations*).

If an end-use product is formulated with multiple active ingredients, each active ingredient must be listed in a separate row on the SPSF, before any other component types.

These fields are **required** to be completed for each active ingredient in an end-use product:

- Trade name (box 1) — the brand name for the product that contains the active ingredient
- Common name (box 2) — the ISO common name is required, if it is established
- Chemical name (box 3) — the IUPAC or CAS name of the active ingredient is required
- Supplier name and address (box 4)
- Reg # (box 5) — include the registration number of the registered product for the source of active ingredient in the formulation. If the product is pending registration, enter the submission number, if it is known, or enter “pending”.
- Purity (box 6)
- CAS# (box 7)
- % w/w (box 9)
- Purpose (box 10) — active ingredient
- % LCL (box 11) — refer to Section 6 for nominal vs. minimum requirements
- % Nominal (box 12) — this field represents the percent calculated nominal concentration; it is not required if the source of the active ingredient is registered with a minimum guarantee
- % UCL (box 13) — not required if the source of the active ingredient is registered with a minimum guarantee
- Label Guarantee (box 14A)
- Value (box 14B) — the numerical value of the guarantee as it appears on the label of the product
- Units (box 14C) — the abbreviated units that describe the numerical guarantee (Refer to Appendix D for the common units of scientific abbreviation)
- LCL and UCL (boxes 14D and 14E)— not required for ingredients with a minimum guarantee

5.3.1 Completing the components section for formulants in an end-use product

Formulants are components other than the active ingredients that are added to a formulation. Each formulant and its associated information should be listed in a separate row. If a formulant is an alternate in the same amount, it is listed on a separate row directly below the formulant, and the % w/w and certified limits for the alternate formulant are left blank.

There can be multiple suppliers for a particular formulant (in other words, a chemically identical formulant supplied by a different company); this formulant can have the same name). Therefore, the names and addresses of the alternate suppliers are to be listed on the Alternate Formulating Site / Alternate Formulator Supplier Page.

These fields are **required** for each formulant:

- Supplier's name and address (box 4)
- CAS# (box 7) — not required for trade name formulants
- % w/w (box 9)
- Purpose (box 10)
- % LCL (box 11)
- % UCL (box 13)

Only **one** of these fields is required:

- Trade name (box 1) — required if a formulant has a trade name
- Chemical/common name (boxes 2 and 3) — if a formulant does not have a trade name, provide the chemical or common name

5.4 Requirements for a manufacturing concentrate (MA)

The active ingredient of the MA must be listed first, followed by any formulation preservatives. Afterward, formulants and any impurities are listed in accordance with the *Guidance for developing datasets for conventional pest control product applications*.

If an MA is formulated with multiple active ingredients, each active ingredient must be listed in a separate row on the SPSF, before any other component types.

These fields are **required** for each active ingredient in an MA:

- Trade name (box 1) — the brand name for the product that contains the active ingredient in the MA, if one exists
- Common name (box 2)
- Chemical name (box 3)
- Supplier name and address (box 4)
- Reg# (box 5) — include the registration number of the registered product source of the active ingredient in the formulation. If it is known, enter the submission number of the product pending registration, or enter "pending"
- Purity (box 6)
- CAS# (box 7)
- % w/w (box 9)
- Purpose (box 10)
- % LCL (box 11) — refer to Section 6 for nominal vs. minimum requirements
- % Nominal (box 12) — this field represents the percent calculated nominal concentration; this value is not required if the source of the active ingredient (MA) is registered with a minimum guarantee
- % UCL (box 13) — this value is not required if the source of the active ingredient is registered with a minimum guarantee
- Label Guarantee (box 14A)
- Value (box 14B) — enter the numerical value of the guarantee as it appears on the label of the product
- Units (box 14C) — enter the abbreviated units that describe the numerical guarantee (Refer to Appendix D for common scientific abbreviations)
- LCL and UCL (boxes 14D and 14E) — these values are not required for MA components with a minimum guarantee

Completing the components section for formulants in an MA

A formulant is a component of a pest control product that is added intentionally to the product, and is not an active ingredient. Each formulant and its associated information are listed in a separate row. If a formulant is an alternate in the same amount, it is listed on a separate row directly below the formulant. The % w/w and certified limits for the alternate formulant are left blank.

If there are multiple suppliers for a particular formulant (in other words, a chemically identical formulant by a different supplier with the same formulant name), the names and addresses of the alternate suppliers are to be listed on the Alternate Formulating Site / Alternate Formulator Supplier Page.

These fields are **required** for each formulant within an MA concentrate preparation:

- Supplier's name and address (box 4)
- CAS# (box 7) — not required for trade name formulants
- % w/w (box 9)
- Purpose (box 10)
- % LCL (box 11)
- % UCL (box 13)

Only **one** of these fields is required:

- Trade name (box 1) — required if a formulant has a trade name
- Chemical/common name (box 2 and 3) — if a formulant does not have a trade name, provide the chemical or common name

5.5 Requirements for a repack end-use product (Repack)

When a product consists of 100% of an existing product **registered with the PMRA**, it is considered to be a repackaged product. Therefore, the detailed formulation does not have to be listed. Instead, the name of the product (as registered with the PMRA) must be listed, with the registration number and the guarantee as presented on the label. The % w/w is represented as 100% of the repackaged product.

These fields are **required** in the representation of a Repack:

- Trade name (box 1)
- Supplier's name and address (box 4)
- Reg # (box 5)
- %w/w (box 9) — "100"
- Purpose (box 10) — "Active ingredient"
- Label Guarantee (box 14A) — name of the active ingredient as it appears on the label of the source product
- Value (box 14B) — as listed on the label of the source product
- Units (box 14C) — as listed on the label of the source product
- Other Info. (box 15) — Enter "Repack" in this box

If there is a formulation preservative present, these fields are **required** on a separate row:

- Purpose (box 10) — "Preservative"
- Label Guarantee (box 14A) — preservative statement on the label of the source product
- Value (box 14B) — as listed on the label of the source product
- Units (box 14C) — as listed on the label of the source product

5.6 Requirements specific to microbial pest control agents (MPCA) and products

Microbial pest control agents (MPCA) are active ingredients: These micro-organisms include types of bacterium, alga, fungus, protozoan, virus, mycoplasma or rickettsia, and related organisms, and, any associated metabolites. All of these micro-organisms and metabolites contribute their effects to pest control. Consequently, MPCAs can be contained in the formulation of end-use products.

Requirements for an MPCA (technical grade active ingredient application)

The technical grade active ingredient is considered to be the material that contains the MPCA. Additionally, this ingredient contains no other component other than for the purposes of MPCA growth, replication, or typical purification.

Typically, the technical grade active ingredient is assumed to be the purest preparation that results from a production process.

The MPCA must be listed on Row 1 followed by any impurities on the subsequent rows.

These fields are **required** for an MPCA active ingredient:

- Common name (box 2) — taxonomic name
- % w/w (box 9)
- Purpose (box 10)
- %LCL (box 11) — must represent the %w/w range for manufacture of the product. If the technical grade active ingredient has only one ingredient, enter 100 for the LCL and leave box 13 blank*
- % Nominal (box 12)
- %UCL (box 13) — must represent the %w/w range for manufacture of the product. Leave blank if LCL value is 100*
- Label Guarantee (box 14A)
- Value (box 14B)
- Units (box 14C)
- LCL and UCL (boxes 14D and 14E)

Completing the product components section for impurities (as applicable)

Impurities are by-products (for example, genotoxins) that can occur in the manufacture of an MPCA.

These **fields** are to be completed for impurities:

- Common name (box 2) — only required if the common name is known, or has a code name² assigned
- Chemical name (box 3) — if applicable
- CAS# (box 7)
- % w/w (box 9)
- Purpose (box 10)
- % UCL (box 13)

Requirements specific to an end-use product containing an MPCA Technical Component

The active ingredient must be listed first, followed by any formulation preservatives, formulants, and any impurities.

If an end-use product is formulated with multiple active ingredients, each active ingredient must be listed in a separate row on the SPSF, and before any other component types.

These **fields** are required for each active ingredient within an end-use product:

- Trade name (box 1) — the brand name for the product that contains the active ingredient, if a trade name exists
- Common name (box 2) — taxonomic name
- Supplier name and address (box 4)
- Reg# (box 5) — include the registration number of the registered product source for the active ingredient in the formulation. If it is known, enter the submission number of an active ingredient pending registration, or enter "pending"
- Purity (box 6)
- % w/w (box 9)

² If the applicant has assigned code names to the impurities, these code names must be entered in box 2 to allow cross referencing within the supporting data.

- Purpose (box 10)
- % LCL (box 11) — must represent the % w/w range for formulating the product. If the end-use product has only one ingredient, enter 100 for the LCL, and leave box 13 blank
- % Nominal (box 12)
- % UCL (box 13) — must represent the % w/w range for manufacture of the product. Leave this box blank, if the LCL value is 100
- Label Guarantee (box 14A)
- Value (box 14B) — the numerical value of the guarantee as it appears on the label of the product
- Units (box 14C) — the abbreviated units that describe the numerical guarantee (Refer to Appendix D for common scientific abbreviations)
- LCL and UCL (boxes 14D and 14E) — not required for a minimum guarantee

Completing the components section for formulants in an end-use product containing an MPCA

Formulants are components other than the active ingredients that are added to a formulation. Each formulant and its associated information should be listed in a separate row. If a formulant is an alternate in the same quantity, it is listed on a separate row directly below the formulant. The % w/w and certified limits for the alternate formulant are left blank.

There can be multiple suppliers for a particular formulant (a chemically identical formulant supplied by a different company with the same formulant name). Here, the names and addresses of the alternate suppliers are to be listed on the Alternate Formulating Site / Alternate Formulator Supplier Page.

These fields are **required** for each formulant:

- Supplier's name and address (box 4)
- CAS# (box 7) — not required for trade name formulants
- % w/w (box 9)
- Purpose (box 10)
- % LCL (box 11)
- % UCL (box 13)

Only **one** of these fields is required:

- Trade name (box 1) — required if a formulant has a trade name
- Chemical/common name (box 2 and 3) — if a formulant does not have a trade name, provide the chemical or common name

6.0 Minimum vs. nominal requirements

Complete the correct fields for an active ingredient component, if the source of the active ingredient to formulate the product is registered with a minimum or nominal guarantee.

6.1 How to determine if a registered source of an active ingredient is nominal or minimum

Refer to the label in the Pesticide Product Information Database to determine if a source of the active ingredient is expressed as a minimum or nominal guarantee. This tool can be found on the Canada.ca website. Perform a search for the registered source of the active ingredient. Select the trade name of the active ingredient to view the product information that is related to the active ingredient. The guarantee will be listed as minimum or nominal type at the bottom of the information page in the "Active ingredient(s)" box.

6.2 Guarantee when using nominal and minimum sources of the same active ingredient

The same active ingredient can be acquired from two different sources. If one source of active ingredient is nominal and the other is minimum, the guarantee of the final product

must be stated as **minimum**. Use the lower certified limit of the nominal source to calculate the guarantee for the declared purity of the active ingredient.

6.3 Required fields summary

This table lists the required fields for stating the nominal and minimum active ingredients in the submission of a Statement of Product Specification Form (SPSF) for pesticide products.

Guarantee of the product providing the active ingredient is:	Guarantee of the product must be represented on the SPSF as:	Required fields relating to the guarantee on the SPSF
Nominal	Nominal	Box 11 % LCL Box 12 % Nominal Box 13 % UCL Box 14A Name of active Box 14B Guarantee value Box 14C Guarantee units Box 14D LCL Box 14E UCL
Minimum	Minimum	Box 11 % LCL Box 14A Name of active Box 14B Guarantee value Box 14C Guarantee units

7.0 Summary of the field requirements for different product components

This table lists the component record fields that are required (R); those conditionally required (CR); or, those that are not applicable (N/A).

FIELD	Active Ingredient	Formulation Preservative	Formulant	Impurity
1. Trade Name	R ⁵	R (if it exists)	R (if it exists)	N/A
2. Common Name	R	R	CR ²	CR ⁴
3. Chemical Name	R	R	CR ²	R
4. Supplier Name and Address	R ⁵	R	R	N/A
5. Reg#	R	CR ¹	N/A	N/A
6. Purity	R	R	N/A	N/A
7. CAS#	R	R	CR ³	R ³
8. List#	N/A	N/A	If known	N/A
9. % w/w	R	R	R	R
10. Purpose	R	R	R	R
11. % LCL	R	R	R	N/A
12. % Nominal	R if nominal	R if nominal	N/A	N/A
13. % UCL	R if nominal	R if nominal	R	R

FIELD	Active Ingredient	Formulation Preservative	Formulant	Impurity
14A. Label Guarantee	R	R	N/A	N/A
14B. Value	R	R	N/A	N/A
14C. Units	R	R	N/A	N/A
14D. LCL	R if nominal	R if nominal	N/A	N/A
14E. UCL	R if nominal	R if nominal	N/A	N/A
15. Other Info	As needed	As needed	As needed	As needed

Notes:

- 1 The registration number is required only if the formulation preservative is registered.
- 2 Either a common or chemical name is required if there is not a trade name for a formulant. If a trade name is provided for a formulant, the common and chemical names must not be entered.
- 3 If the ingredient has no CAS#, report the value as N/A (not applicable). If the ingredient has a trade name, leave the CAS# field blank.
- 4 If the applicant has assigned code names to the impurities, these should be entered in the common name field for purposes of cross referencing to the supporting data.
- 5 If the SPSF is for a technical grade active ingredient, trade name, and supplier information are not applicable.

8.0 Certification of approving official

An authorized signing official must approve the declaration to certify that the information provided is true and complete.

The information provided on the SPSF is collected by Health Canada under the authority of the *Pest Control Products Act*, and the Pest Control Products Regulations for regulatory purposes, including product registration or amendment.

9.0 Completing the alternate suppliers/formulators page

This page is for the sole addition of formulating sites for a product and for alternate formulant suppliers. The Row Number identifies the referenced component.

For alternate formulating sites, check the "Multiple Formulation Sites" checkbox in Box H. The row number box in the alternate formulating sites section is always designated as 0. If more sites than available are desired, click the "ADD SITES" button at the bottom right of the table.

Check the "Multiple Suppliers" box in the formulant's row for alternate formulant suppliers. The "Row number" box and formulant trade name (if that field is empty, common name or chemical name is used) will automatically populate in the alternate formulating supplier's section. Clicking "+" next to a "Multiple Suppliers" checkbox adds copies of this partially filled alternate formulating site box. "+" can be clicked as many times as needed. Clicking "GOTO PAGE" next to a "Multiple Suppliers" checkbox will jump to the alternate formulant supplier's section.

Note: A separate SPSF must be completed for each manufacturing site for technical grade active ingredients and ISPs.

10.0 Standard certified limits

The identification of certified limits is required for all product components in accordance with *Guidance for developing datasets for conventional pest control product applications*. The calculated standard certified limits are listed in the table below:

Nominal (N) concentration of the ingredient	Lower limit (LCL)	Upper limit (UCL)
$20\% < N \leq 100\%$	$N - [3\% N]$	$N + [3\% N]$
$1\% < N \leq 20\%$	$N - [5\% N]$	$N + [5\% N]$
$N \leq 1\%$	$N - [10\% N]$	$N + [10\% N]$

Active ingredients require UCL and LCL, unless the source of active ingredient has a minimum guarantee.

Formulants always require lower and upper certified limits.

Impurities only require upper certified limits. However, the limits are based on batch data rather than the standard tolerances above. A guideline for establishing the UCL is to use the mean of the batch data plus three standard deviations (Mean + 3 σ).

11.0 Formula for the calculation of a guarantee as percent or in g/L

A product label guarantee that is expressed in **percent** is calculated:

- [purity of the source of a.i.] \times [w/w of the source of a.i. in product] \times 100% = % guarantee
- A guarantee that is expressed in **grams per litre** is calculated as follows:
- [purity of the source of a.i.] \times [w/w of the source of a.i. in product] \times [specific gravity or density in g/L] = guarantee in g/L

Note: The purity and w/w must be expressed as a decimal fraction to calculate the correct value.

List of document abbreviations

a.i.	active ingredient
CAS	Chemical Abstracts Service
ISO	International Organization for Standardization
ISP	integrated system product
IUPAC	International Union of Pure and Applied Chemistry
LCL	lower certified limit
MA	manufacturing concentrate
PMRA	Pest Management Regulatory Agency
Reg#	Pest Control Product Registration Number
SPSF	Statement of Product Specification Form
UCL	upper certified limit

Reference documents

Guidance for developing datasets for conventional pest control product applications

[DIR2006-02 *Formulants Policy and Implementation Guidance Document*](#)

DIR2001-02 *Guidelines for the Registration of Microbial Pest Control Agents and Products*

PMRA List of Formulants

Appendix A

Field definitions for boxes A to N

Box	Field	Definition
A	Product Classification	Type of product being submitted: technical grade active ingredient, ISP, MA, or end-use product. Choose the type from the drop-down menu.
B	Registration No.	The assigned registration number if the product is registered, or if it has been previously registered under the <i>Pest Control Products Act</i> . Do not enter any other number in this space.
C	Product Name	The name of the product indicated on the application form.
D	Formulation Type Code	The appropriate descriptive code from the list in Appendix C. Use the two-letter code on the SPSF. (The formulation type code must remain consistent during product registration).
E	Formulation #	This box distinguishes the different versions of a product that are registered under a single Registration No., but require separate SPSFs. This number includes the alternate formulations of an end-use product or MA, or separate sites of manufacture for technical grade active ingredients. These formulations are to be numbered sequentially starting at "1". If there is only one formulation, the formulation number will be "1". (Refer to the <i>Formulants Policy and Implementation Guidance Document</i> , DIR2006-02) Summary: This number Increases every time a new [alternate] formulation is added to the same [single] registration number.
F	Version #	This number tracks the changes to a formulation. Each time the formulation is modified under an individual formulation number, this value is incremented by one. The version number starts at "1" for new products and formulations. When a formulation is amended, registrants should propose a new version number that will be verified by the PMRA. Refer to the publication DIR2006-02, for guidance on providing this information. Summary: This number Increases after the approval of an amendment to a formulation by the manufacturer for a product.
G	Name of Registrant/Proposed Registrant	The company name that is the legal owner of the product registration. An address is not required.
H	Names and Addresses of Manufacture/Formulation Site	
H(i)	Manufacturing Site for a technical grade active ingredient, or ISP	A separate SPSF is required to identify each site of manufacture of a technical grade active ingredient or ISP, under a single registration number. This requirement is the physical address of the site of manufacture for a technical grade active ingredient or ISP. Indicate the specific site location as accurately as possible. A P.O. Box or residential mailing address are not acceptable.
H(ii)	Formulation Site for a Manufacturing Concentrate, or End-use Product	Identify the physical location (address) in which the product is formulated. If the product is repackaged or relabelled, provide the company name and address where these relabelling or repackaging activities occur. Identify a single formulator in the box provided. Check the "multiple formulation sites" checkbox to indicate the existence of multiple facilities (Row "0"). Afterward, list the alternate sites on the last page of this form, entitled "Alternate formulating sites / Alternate Formulant Suppliers". Note: Provide the page and Row Number (for example, Page 1, Row 0) on this page to reference the names and addresses for the formulation sites.
I	Third Party Contact Information	Third Party Contact Information: The SPSF was submitted on behalf of the registrant and the product specifications are confidential to the registrant. Provide information for an authorized contact individual. This information is necessary so that the PMRA may contact this individual for any required SPSF communication.

Box	Field	Definition
J	Specific Gravity	Specific gravity is simply the ratio of densities, relative to water (no units). Provide the specific gravity for liquid products, preferably as a range. Density: Provide the density in metric units (g/ml), preferably as a range. If a single value is to be reported, enter this value in both the lower and upper fields (Box "J").
K	Flash Point	Provide the flash point in degrees centigrade (°C) for combustible liquid MAs and end-use products.
L	Flame Extension	Provide the predicted flame extension for flammable aerosol products in centimetres.
M	Viscosity	Enter the dynamic viscosity in mPa(s), if the product is a liquid MA or an end-use product.
N	pH	Enter the pH value for a 1% dilution of products supplied as aqueous solutions, or for pre-packaged liquid products.
(O)	Optional	"O" is an optional field for registrants if they have an internal company ID to identify a product.

Appendix B

Product component definitions

Box	Field	Definition
1.	Trade name	The brand name for the ingredient. This name is the same as that ingredient registered with the PMRA.
2.	Registration No.	The assigned registration number if the product is registered with the PMRA, or if it has been previously registered under the <i>Pest Control Products Act</i> . Any other number is <u>not</u> acceptable in this space.
3.	Chemical name	The IUPAC or CAS chemical name.
4.	Supplier information	The supplier name and full address. If there are multiple suppliers for the same formulant name, select the checkbox to indicate multiple suppliers (Components, Row 1, 2, (4)). Then, enter the supplier name and address on the page entitled <i>Alternate Formulating Sites / Alternate Formulant Suppliers</i> . Provide the page number and row number of the ingredient to which the alternate supplier applies. If the SPSF is for a technical grade active ingredient, a supplier is not required; the technical grade active ingredient is manufactured at the site listed in box H.
5.	Registration #	The registration number of the source of the active ingredient in the formulation. If the source of the active ingredient is pending registration, enter the submission number if it is known, or enter "pending" (box B).
6.	Purity	The nominal guarantee of the source of the active ingredient, expressed as a percent (Components, Row 1, 2, (6)).
7.	CAS #	The Chemical Abstracts Service number, if available (Components, Row 1, 2, (7)).
8	List #	The PMRA list number for the formulant. Refer to the PMRA List of Formulants for this number (Components, Row 1, 2, (8)).
9.	% w/w	The percent weight/weight of the ingredient in the formulation. The % w/w is calculated by: $100\% \times (\text{weight of the ingredient}) / (\text{total weight of the formulation})$ (Components, Row 1, 2, (9)).
10.	Purpose	Identify the active ingredients and impurities and indicate the purpose of the added formulants. Ingredients added to protect the formulation from degradation by pests should be labelled as "formulation preservatives". Refer to DIR2006-02 for more information about formulation preservatives (Components, Row 1, 2, (10)).
11.	% LCL	If the source of the active ingredient is a nominal range of guarantee, the calculated lower certified limit percent is placed in this box. If the guarantee of the source of active ingredient stated as a minimum, the guarantee for the product must also be a minimum. Therefore, the calculated percent concentration of the active ingredient is represented in this box. Section 10 provides additional details about lower certified limits (Components, Row 1, 2, (11)).
12.	% Nominal	The calculated percent nominal concentration of an active ingredient (Components, Row 1, 2, (12)).
13.	% UCL	The upper certified limit expressed as a percent. Section 10 provides more details about upper certified limits (Components, Row 1, 2, (13)).
14.	Guarantee statement	Enter the common name in this box, (if one exists; otherwise, enter the accepted chemical name) and form (for example, acid or salt) of the active ingredient as it appears on the label. If the ingredient contains a formulation preservative, the preservative statement as listed in the <i>Formulants Policy and Implementation Guidance Document (DIR2006-02)</i> is entered in this field (Components Row 1, 2):

Box	Field	Definition
		<p>b) Value: The numerical value of the guarantee as expressed on the label in box 14A.</p> <p>c) Units: The abbreviated units of the guarantee as expressed on the label in box 14B.</p> <p>d) LCL: The calculated lower limit of the guarantee for nominal guarantees in the units of box 14C.</p> <p>e) UCL: The calculated upper limit of the guarantee for nominal guarantees in the units of box 14C.</p>
15.	Other information	<p>Relevant documentation of any information related to the ingredient (Components Row 1, 2, box 15):</p> <p>For example, other label claims, or certified limits outside the standard range). If the product is a repack, include "Repack" in this box.</p> <p>When there are multiple technical grade active ingredient manufacturing sites under a single registration number and their a.i. content varies within the overall label guarantee, include this text: "Boxes 9 -13 are for this site; Box 14 is for all sites."</p>

Appendix C

Definitions and codes for formulation types

Code	Name	Definition
DU	Dust or powder	Dry material composed of active ingredient(s) and non-active ingredients. This material is not to be diluted prior to application. It is Insoluble in water and contains no wetting or dispersing agent(s). Particulates are less than 250 µm in diameter.
DF	Dry flowable	This code has expired. Refer to wettable granules (WG), below.
EC	Emulsifiable concentrate or emulsion	Emulsifiable concentrate: A solution of active ingredient(s) in organic solvent(s) combined with emulsifier(s) for dilution in water to form an emulsion. Emulsion: A dispersion of one liquid in another (oil in water, or water in oil) together with active ingredient(s). Emulsions include most lotions, and suspo-emulsions.
GR	Granule	A solid mixture of dry, free-flowing water-insoluble particles that are composed of active and non-active ingredient(s). Granules are greater than 250 µm, and less than 2 mm in diameter.
IF	Impregnated fabric	Fabric(s) or fibre(s) impregnated with active ingredient(s), like repellent-impregnated jackets, repellent-impregnated towelettes, herbicide wicks, and pet collars.
LI	Liquid	Material in a free-flowing liquid form composed of active and/or non-active ingredient(s) that does not fall within the definitions of other liquid products. These liquids include technical grade active ingredients in liquid form.
MS	microcapsule suspension	A suspension in which the solid particles consist of encapsulated active ingredient(s).
PA	Paste	A gel or viscous liquid that does not freely flow; it is composed of liquid or semi-solid active and non-active ingredient(s).
PE	Pellet	This code has expired. Refer to the Tablet, below (TA).
PP	pressurized product	Active and non-active ingredient(s) discharged by a propellant force of liquefied and/or non-liquefied compressed gas. Usually, the propellant is from a disposable type of dispenser through a valve. These products include aerosols, pressurized sprays/foams/dusts, or bag-on-valve. This category does not include formulations dispersed by a pump mechanism.
PT	Particulate	This code has expired. See Solid (SO).
SG	Soluble granules	A solid mixture of dry, free-flowing water-soluble particles composed of active and non-active ingredient(s). Soluble in water to give a solution. These granules are greater than 250 µm and less than 2 mm in diameter.
SN	Solution	A liquid composed of both active and non-active ingredient(s) that are dissolved in solvent(s).
SO	Solid	Dry material of indeterminate shape and/or size that is composed of active and non-active ingredient(s), but not defined under granule or tablet (in other words, GR, TA). This type of material includes flakes, baits formulated on sugar/grains, and, other coarse materials.
SP	Soluble powder	Dry material composed of both active and non-active ingredient(s), that are soluble in water. This powder is less than 250 µm in diameter.
SR	Slow-release generator	Products that contain one or more volatile active ingredients for aerosol release. Normally, the evaporation rate is controlled with suitable formulations and/or dispensers.
SU	Suspension	A liquid composed of solid active ingredient(s) suspended in a liquid phase for further dilution with similar liquids, or it can be ready-to-use. These products include aqueous suspensions, paints, and flowable concentrates.

Code	Name	Definition
TA	Tablet	A mixture of active and non-active ingredient(s) of a regular, pre-determined shape and size. This designation includes all solid materials in the shape of blocks, tablets, pellets, rods, mosquito coils, balls, etc. Tablets are greater than 2 mm in diameter.
WD	Water dispersible granules	This code has expired. See wettable granules (WG).
WG	Wettable granules	A solid mixture of dry, free-flowing particles. They are designed to be dispersed in water for application as a spray. These products include dry flowable and water dispersible granules. They are greater than 250 µm and less than 2 mm in diameter.
WP	Wettable powder	Dry material composed of active and non-active ingredient(s). It includes wetting or dispersing agent(s), for dilution (usually in water) to form a suspension. This powder is less than 250 µm in diameter.

Appendix D

Scientific unit abbreviations

Abbreviation	Unit Description
BIU/kg	Billion International Units per Kilogram
BIU/L	Billion International Units per Litre
BIU/mg	Billion International Units per Milligram
CFU/g	Colony Forming Units per Gram of Dry Weight
CFU/ml	Colony Forming Units per Millilitre
g/L	grams per litre
g/mL	grams per millilitre
g/m²	grams per square metre
ITU/mg	International Toxic Units per Milligram
MVC/g	Million viable cells per gram
PIBs/g	Polyhedral Inclusion Bodies per gram