Guidance for Completing the PMRA/EPA Confidential Statement of Product Specifications

Version	Date	Author	Changes
1.0	2012-07-20	Joseph Mikhael	Original draft
1.1	2012-07-26		Included amendments as provided by PMRA CES section
1.2	2012-08-01		Included amendments as provided by PMRA CES section and PMRA MBES section
1.3	2012-09-14		Updated to clearly indicate which fields are required for completion on the paper version of the form

Contents

Introduction

The Confidential Statement of Product Specifications (CSPS) is designed for reporting the composition of technical grade active ingredients (TGAIs), integrated system products (ISPs), manufacturing concentrates (Man. Concen.) and end-use products (EPs) registered by the Pest Management Regulatory Agency (PMRA) or the Environmental Protection Agency (EPA). A separate CSPS must be completed for each type of product.

There are two methods that an Applicant can use to complete the form. The first method, which is highly recommended, is the electronic 'wizard'. This wizard provides a step-by-step process for Applicants to complete the CSPS. Each step changes based upon the inputs to previous steps, helping to ensure the proper completion of the form. Also part of the wizard are validation rules which help in ensuring that the right type of information is input in each field, and 'tool tips' which provide instructions on how to complete each field. Once the Applicant completes the wizard, a PDF version of the form is output, which the Applicant will need to submit to the PMRA or EPA.

The second method for completing the form is the 'paper' method. This method is similar to how the forms were previously completed. The Applicant can either complete the fields on the electronic PDF form and print the completed form, or print the form and then complete it by hand. This method does not have the step-wise and validation checks of the first method. In addition, EPA will accept paper copies of Form 8570-4.

Using the Wizard

- System requirements
- Accessing the wizard
- Choosing language
- Completing each field
- Tool tips
- Saving the form in XML format
- Previewing the PDF
- Downloading the PDF form
- Amending the PDF form

Completing the Paper Form

This section will describe how to complete each section and field in the paper version of the form. This form cannot be completed online, and must be downloaded and printed, or requested for delivery. Each section below will identify which fields are required under what circumstances.

1. Page _ of _

Completing these fields on each page is required.

At the top right-hand corner of ever page, please ensure that you input the page number in the first space, and the total number of pages in the second space.

Preliminary Questions

2. Canadian or US Registration

Checking only one of the two boxes is required.

Indicate whether the form is intended for a Canadian registration (PMRA) or U.S. Registration (EPA) by checking the appropriate box. Both boxes cannot be selected.

3. PMRA Formulation# and Version#

Completing these fields is required only if the form is intended for the PMRA.

The formulation number is used to distinguish multiple formulations of an EP or MA, or sites of manufacture for TGAI, under a single registration number. These formulations are to be numbered sequentially starting at "1". If there is only one formulation, the formulation number will be "1".

The version number tracks changes to a formulation. Each time the formulation is modified under an individual formulation number, this value is incremented by one. For new products and formulations, the version number will start at "1". When amending a formulation, registrants should propose a new version number that will be verified by the PMRA.

4. EPA Basic Formulation

Completing this fields is required only if the form is intended for the EPA, and is for a basic formulation.

Check this box if the CSPS identifies the formulation for which the registration data requirements were reviewed by the US EPA. If this box is checked, then the 'Alternate Formulation No.' field should not be completed.

4. Alternate Formulation No.

Required field only if the form is intended for the EPA, and is for an alternate formulation.

If the CSPS being completed is for an alternate formulation (i.e. not the basic formulation), identify the alternate formulation number. If this box is completed, then the 'EPA Basic Formulation' box should not be checked.

5. Is the product a Repack?

Check this box only if the product is a Repack.

When a product consists of 100% of a registered product within the Agency the CSPS is intended for, it is considered a repackaged product. In this instance, the detailed formulation does not have to be listed. Instead, the name of the product (as registered with the intended Agency) being used must be listed, with registration number and the guarantee as presented on the label. The % w/w is represented as 100% of the repackaged product.

6. Is this product a Microbial?

Check this box only if the product is a microbial.

7. Does the product have food uses?

Check this box only if the product has food uses

8. What is the product type?

Checking only one of these four boxes is required.

These checkboxes allow the Applicant to identify whether the CSPS is for a Technical Grade Active Ingredient (TGAI), Integrated System Product (ISP), End Use Product (EP), or Manufacturing Concentrate (Man. Concen.). Only one of these checkboxes should be selected on the CSPS.

A TGAI typically contains an active ingredient and impurities. When this is selected, 'Formulating Site' should not be selected in the 'Sites & Suppliers' section.

An ISP may be used in manufacture of an end-use product or may itself be an end-use product. It is formed in a manufacturing process in which the ISP contains an active ingredient that is not isolated due to physical limitations or uncertainty as to the specific active component(s), or is purposely left as a mixture of components due to manufacturing or integrity considerations. When this is selected, 'Formulating Site' should not be selected in the 'Sites & Suppliers' section.

An EP typically contains a TGAI, diluent and other formulants. When this is selected, any fields related to impurities should not be completed, and 'Manufacturing Site' should not be selected in the 'Sites & Suppliers' section.

A Man. Concen. typically contains a TGAI and a diluent. When this is selected, any fields related to impurities should not be completed, and 'Manufacturing Site' should not be selected in the 'Sites & Suppliers' section.

General Information

9. Product Name

Completing this field is required.

Input the name of the product as written on the application form and product label.

10. Product Registration No.

Completing this field is required if the product has an assigned registration number from when the product is or has been previously registered by the intended Agency. Do not enter any other number in this space.

11. Name of Applicant/Registrant

Completing this field is required.

Identify the company name that is the legal owner of this product's registration.

12. Formulation Type Code

Completing this field is required.

Select the appropriate descriptive code for the formulation. Please use the two-letter code from the list in Appendix A.

13. Specific Gravity/Density and Units

Completing this field is not required, but is recommended for [need cases].

The specific gravity/density can be expressed as a range (input the lower and upper values), or as a single value. If it is the latter, input the same number in both boxes. If inputting the density, please select the appropriate units listed in Appendix B. Specific gravity has no units (choose N/A as the units) and is defined as the density of the product divided by the density of a reference substance (eg. water).

14. Temperature and Units

Completing this field is not required, but is recommended for [need cases].

Identify the temperature at which the specific gravity/density was determined. For PMRA Registrations, the 'Units' should be '^{o}C', and for EPA Registrations, the 'Units' should be '^{o}F'.

15. Weight/Formulated Piece and Units

Completing this field is not required, but is recommended for [need cases].

If applicable, identify the weight per formulated piece and select the appropriate units.

16. Flash Point and Units

Completing this field is not required, but is recommended for [need cases].

Provide the flash point for combustible liquids for Man. Concen.'s and EPs. For PMRA Registrations, the 'Units' should be '^{o}C', and for EPA Registrations, the 'Units' should be '^{o}F'.

17. Flame Extension and Units

Completing this field is not required, but is recommended for [need cases].

Provide the flame extension for aerosol products, reported in centimetres for PMRA Registrations or inches for EPA Registrations.

18. Viscosity

Completing this field is not required, but is recommended for [need cases].

Enter the value in mPa(s) if the product is a liquid Man. Concen. or EP.

19. pH Range

Completing this field is not required, but is recommended for [need cases].

Enter the value for a liquid product as packaged and for a 1% aqueous dilution if applied as an aqueous dilution. If there is no range, simply input the one value in both fields.

Certification of Approving Official

20. CSPS confidential to a 3rd party?

Check this box only if the CSPS is confidential to a 3rd party.

If this CSPS was submitted on behalf of the applicant/registrant, and the product specifications are confidential from the applicant/registrant, the contact information for an individual that the Agency may contact for any CSPS related communication should be input in the appropriate fields in the '3rd Party Confidential Information' section.

21. Position Title of Approving Official (Applicant/Registrant)

Completing this field is required.

Print the position title of the official certifying the submitted CSPS. This official represents the Applicant or Registrant of the product.

22. Name of Approving Official (Applicant)

Completing this field is required.

Print the name of the official certifying the submitted CSPS. This official represents the Applicant or Registrant of the product.

23. Signature

Completing this field is required.

The signature of the approving official.

24. 25, 26, 27, and 28 Registrant Address, City, Province/State, Country, Postal Code/ZIP

29. Date

Completing this field is required.

The certification date of the CSPS.

30, 31, 32. Phone No, Fax and eMail

Completing these fields is required.

Input the required contact information of the approving official.

Components

Each 'Components' page contains space to input information for three (3) components. Please print the required number of pages in order to be able to input all the components in the product. For example, if the product contains 13 components, then 5 components pages are required.

33. Row#

Completing this field is required.

Input the row# in sequential numerical order. This is needed in order to match components to the Formulant Suppliers in the 'Sites and Suppliers' section, and also aids in inputting and tracking components in the PMRA and EPA databases.

34. Active, Formulant/Inert or Impurity

Checking one of the three boxes is required.

Indicate whether the component is an active (which includes preservatives and safeners), a formulant/inert, or an impurity.

35. Is this a member of multiple active guarantees, or alternate formulants/inerts?

Checking either the 'Yes' or 'No' box is required if the component is an active/preservative/safener or formulant/inert.

If the component is an active ingredient, preservative or safener, select 'Yes' if you wish to identify that the active being listed is a member of a set of multiple active guarantees. For example, DEET and related toluamides are contained within a single TGAI but have separate guarantee values, and are both members of the same 'set'.

If 'Yes' is selected, then the members of the set should be listed sequentially in the CSPS, and each member should have the answer 'Yes' to this question. For EPs and Man. Concen.'s, the %w/w only needs to be input for the first member. For TGAIs and ISPs, the %w/w needs to be input for each member.

If the component is a formulant/inert, also select 'Yes' if you wish to identify that the formulant/inert being listed is a member of a set of formulant/inert alternates. If 'Yes' is selected, then the members of the set should be listed sequentially in the CSPS, and each member should have the answer 'Yes' to this question. The %w/w must only be entered for the first member of the set.

In each case, each member of the set should be identified alphabetically. For example, each member in the first set of alternate formulants/inerts should be labelled as 'A', the each member of the second set 'B', and so on.

If the component is an impurity, or is an active/safener/preservative/formulant/inert that is not a member of a set, then select 'No'.

36. Trade Name

Completing this field is required for actives/preservatives/safereners and formulants/inerts, if one exists.

The brand name for the component, if one exists. A trade name is not required when listing impurities

37. Common Name (ISO Proposed or Accepted)

Completing this field is required if one is assigned.

The proposed or accepted ISO common name, if assigned.

38. Chemical Name (IUPAC or CAS name, if applicable)

Completing this field is required.

The chemical name.

39. Reg. No. or Sub/File No.

Completing this field is required for actives/preservatives/safeners.

The intended Agency's registration number of the product providing the active ingredient used in the formulation. If the product providing the active ingredient is pending registration, enter the registration number if it is known. If a registration number has not been assigned, either enter the submission/file number if it is known or enter "pending". If an unregistered formulation preservative or grandfathered technical is being used, a registration number is not required. If the component being listed is a formulant/inert or an impurity, then this field does not need to be completed.

40. Purity

This field is required for actives/preservatives/safeners.

The purity of the active ingredient, expressed as a %. If the component being listed is a formulant/inert or an impurity, then this field does not need to be completed.

41. CAS#

This field is required for actives/preservatives/safeners.

The Chemical Abstract Services number, when available.

42. Purpose in Formulation

This field is required to be completed for formulants/impurities.

Indicate the purpose of formulant/inert. Examples include: solvent, surfactant, emulsifier, preservative, and dispersant. If the component being listed is an active or impurity, then this field does not need to be completed.

43. % LCL

This field is required for actives/preservatives/safeners or formulants/inerts.

44. % Nominal

This field is required for actives/preservatives/safeners.

45. % UCL

This field is required.

The percent upper certified limit.

46. %w/w

Completing this field is required, except if the component is not the initial member of a set of multiple actives or alternant formulants/inerts.

The percent of the product's weight that this component represents.

47. Label Guarantee

This field is required for actives/preservatives/safeners.

For the active ingredient, preservative or safener, enter the name of the component as it appears on the label. Note that preservatives and safeners may not require labelling for the intended Agency. The common name of the component should be used; if it is not established, then the CAS or IUPAC chemical name of the component should be used. If the component being listed is a formulant/inert or an impurity, then this field does not need to be completed.

48. Value

This field is required for actives/preservatives/safeners.
The numerical value of the guarantee as it appears on the label of the product. For products with microbial active ingredients being registered with the PMRA: The numerical value of the guarantee, expressed in terms of potency or viability, as it appears on the label of the product. In some instances, guarantee may be expressed as % weight. For products with microbial active ingredients being registered with the EPA: The numerical value of the guarantee, expressed as % weight, as it appears on the label of the product. If the component being listed is a preservative or safener, formulant/inert or an impurity, then this field does not need to be completed.

49. Units

This field is required for actives/preservatives/safeners.

The abbreviated units that describe the numerical guarantee. If the component being listed is a formulant/inert or an impurity, then this field does not need to be completed.

50. LCL

This field is required for actives/preservatives/safeners.

For a nominal guarantee only, the lower certified limit.

51. UCL

This field is required for actives/preservatives/safeners.

For a nominal guarantee only, the upper certified limit.

52. Culture Collection Deposit

This field is required for actives/preservatives/safeners and if the product is a microbial.
For microbial products, indicate the culture collection in which the Microbial Pest Control Agent is deposited and the deposit number. If the component being listed is a preservative or safener, formulant/inert or an impurity, then this field does not need to be completed.

53. Potency

This field is required for actives/preservatives/safeners and if the product is a microbial.

The numerical value of the guarantee, expressed in terms of potency. For products with microbial active ingredients being registered with the PMRA: this field may be filled, where appropriate. This field does not need to be completed for non-microbial actives, formulants/inerts or impurities.

54. Viability

This field is required for actives/preservatives/safeners and if the product is a microbial.

The numerical value of the guarantee, expressed in terms of viability. For products with microbial active ingredients being registered with the PMRA: this field may be filled, where appropriate. This field does not need to be completed for non-microbial actives, formulants/inerts or impurities.

55. Other information

Documentation of any information related to the ingredient (e.g. other label claims, certified limits outside the standard range).

56. Total weight (%)

This field is required.

The calculated total weight of the formulation. This value should be calculated from your inputs to the other %w/w boxes. For an ISP/EP/Manufacturing Concentrate, please ensure that this totals 100% before submitting the CSPS. For a TGAI, the total weight must be between 98.5-101.5% as reflected in the batch data. Ensure that that the Total Weight (%) field is complete and identical for each Components page.

The following three fields are the limits associated with the product specifications.

The percent lower certified limit.

The calculated percent nominal concentration of the active ingredient.

The following two fields are the limits associated with the label guarantee.

Sites and Suppliers

Each 'Sites & Suppliers' page contains space to input information for eight (8) sites and/or suppliers. Please print the required number of pages in order to be able to input all the sites and/or suppliers used in the manufacturing or production of the product. For example, if the product has one (1) formulating site and ten (10) formulant suppliers, then two (2) 'Sites & Suppliers' pages are required.

57. Manufacturing Site/Formulating Site/Formulant Supplier

Checking only one of the boxes is required.

The manufacturing site applies only to the manufacture of the TGAI or ISP. The manufacturing site is defined as the name and physical address of the plant at which the material is produced. If the product is an End Use Product or Manufacturing Concentrate, then this box should not be checked. If the product is a TGAI or ISP, and is for a PMRA registration, then only one manufacturing site can be listed per CSPS; If the TGAI or ISP has multiple manufacturing sites, then separate CSPSs are required, each with a different formulation number.

The formulating site applies only to End Use Products or Manufacturing Concentrates. The formulating site is defined as the name and physical address of the facility where the end-use

product/manufacturing concentrate is formulated or repackaged. Multiple formulating sites can be input on each CSPS for End Use Products or Manufacturing Concentrates.

The formulant supplier is the supplier for each individual formulant/inert.

58. Row Number(s) of Component(s) (for Suppliers)

This field is required if 'Formulant Supplier' is selected in the Manufacturing Site/Formulating Site/Formulant Supplier boxes.

The row number(s) of the formulant/inert that is supplied by the formulants supplier. This row number was input by you in the first field in the 'Components' section. Multiple reference numbers can be input, but please separate each number with a comma. Each formulant/inert can have multiple suppliers.

59-64. Name, Address, City, Province/State, Country, Postal Code/ZIP

These fields are required.

The contact information of the manufacturing site, formulating site or formulant supplier.

Submitting the Form

Electronic PDF completed using the Wizard

PMRA

The electronic form can be compiled using the eIndex Builder. It should be identified under 0.1.6003. Instructions on using the eIndex Builder can be found here.

EPA

Please insert text here

Paper form

PMRA

The paper form can be submitted as is or scanned electronically. However, an eIndex still needs to be completed and submitted with the paper CSPS. Instructions on using the eIndex Builder can be found here.

EPA

Please insert text here

For more information

PMRA

Pest Management Information Service
E-mail: pmra.infoserv@hc-sc.gc.ca
Telephone: 613-736-3799

Toll-free: 1-800-267-6315
Facsimile: 613-736-3798
Teletypewriter: 1-800-267-1245 (Health Canada)

EPA

Text to be inserted here.

Appendix A – Definitions and Codes for Formulation Types

Code	Name	Definition
DU	DUST OR POWDER	Dry material composed of active ingredient(s) and non-active ingredients. No requirement for further dilution before application. Insoluble in water and containing no wetting or dispersing agent(s). Material will float on water. Particle diameter usually less than 250 microns. Dusts or powders that contain wetting or dispersing agent(s) belong in WP code; if they are soluble, they belong in SP code.
DF	DRY FLOWABLE	See wettable granules (WG).
DV	DEVICE	Any article, instrument, apparatus or contrivance that, by itself or in conjunction with a control product, is used as a means to control pests.
EC	EMULSIFIABLE CONCENTRATE OR EMULSION	Clear solution of active ingredient(s) in solvent(s) with emulsifier(s) for dilution in water. Also cloudy dispersion of one liquid in another (oil in water, or water in oil) with active ingredient(s) in either phase to form a true emulsion. Includes most lotions.
GR	GRANULAR	Solid mixture of any dry, free-flowing water insoluble particles (usually larger than 500 microns and smaller than 2 mm in diameter) composed of active ingredient(s) and non-active ingredient(s). Sand-based products are included in this code.
IF	IMPREGNATED FABRIC	Fabric(s) or fibre(s) impregnated with active ingredient(s), such as repellent-impregnated jackets, repellent-impregnated towelettes, herbicide wick and pet collars that employ a material impregnated with the active ingredient.
LI	LIQUID	Clear liquid composed of one or more active ingredient(s) (100% active), or with small amounts of production non-active ingredients, fire suppressants, flame inhibitors or indicators (97–100% active). Includes volatile products packaged as a liquid under pressure for release as a gas.
LO	LIVE ORGANISM	A life form capable of reproduction, e.g. bacteria, insects, fungi, mites, nematodes, virus and rickettsia-like organisms.
MS	MICROCAPSULE SUSPENSION	A suspension in which the solid particles consist of the active ingredient(s) within microcapsules that allow a slow release of the active ingredient(s).
PA	PASTE	A grease or ointment composed of active ingredient(s) and semi-solid non-active ingredient(s).
PE	PELLET	Dilute, preformed solid mixture of active ingredient(s) in the form of spheres, ovals or cylinders. Particles should have no dimension less than 2 mm.

PP	PRESSURIZED PRODUCT	May be a liquid, solid, gas, active ingredient(s) and non-active ingredient(s) or mixture thereof discharged by a propellant force of liquefied and/or non-liquefied compressed gas, usually from a disposable type of dispenser through a valve. Includes aerosols, pressurized sprays, pressurized foams and pressurized dusts. Does not include formulations dispersed by a pump mechanism.
PT	PARTICULATE	Dry active ingredient(s) and non-active ingredient(s) in the form of large particles, but not fitting the definitions of a granular or pellet formulation. Most products in this category are rodent or insect baits, formulated on sugar, whole or chopped grains, or other coarse material.
SG	SOLUBLE GRANULES	Solid mixture as in GR, except that the granules are soluble in water.
SN	SOLUTION	Clear liquid composed of active ingredient(s) (liquid or solid) dissolved in solvent(s).
SO	SOLID	Material in solid form composed of active ingredient(s) and/or non-active ingredient(s). Includes all solid materials formulated as blocks, flakes, cartridges, balls, crystals or other formulations that do not come within the definitions of other dry products.
SP	SOLUBLE POWDER	Dry material as in DU, except that it is soluble in water.
SR	SLOW-RELEASE GENERATOR	A combination of a solid base material (e.g. PVC resin) and a volatile liquid or solid toxicant(s) that slowly emits the toxicant(s) as a vapour, e.g. vapour strips.
SU	SUSPENSION	Cloudy liquid composed of solid active ingredient(s) suspended in a liquid phase for further dilution with similar liquids or ready-to-use. Includes aqueous suspensions, paints and flowable concentrates.
TA	TABLET	Solid active ingredient(s) or mixture of active ingredient(s) and non-active ingredient(s) preformed into a small block or sphere.
WD	WATER DISPERSIBLE GRANULES	See wettable granules (WG)
WG	WETTABLE GRANULES	A granular formulation, possibly in dry flowable form, that forms a suspension in water. Includes water dispersible granules—a granular formulation designed to be dispersed in water for application as a spray.
WP	WETTABLE POWDER	Dry material composed of active ingredient(s) and non-active ingredient(s), including wetting or dispersing agent(s), for dilution (usually in water) to form a suspension.

Appendix B – Specific Gravity/Density List of Abbreviated Units

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/mL	grams per millilitre
g/cm3	grams per cubic centimetre
ITU/mg	International Toxic Units per Milligram
MVC/g	Million viable cells per gram
PIBs/g	Polyhedral Inclusion Bodies per gram
lbs/gal	Pounds per gallon
lbs/ft3	Pounds per cubic foot