HEALTH CANADA

Program: Active Pharmaceutical Ingredients

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PGA: Health Canada

Program: Active Pharmaceutical Ingredients

Active ingredients are the substances in drugs that are responsible for the beneficial health effects experienced by consumers. The active ingredient in a pharmaceutical drug is called an Active Pharmaceutical Ingredient (API). An example of an API is the acetaminophen contained in a pain relief tablet.

The quality of active ingredients in a drug has a direct effect on the safety and efficacy of that drug. Poorly manufactured and contaminated active ingredients have been associated with negative health outcomes, including death, in various incidents over the past decades. For this reason, Canada regulates APIs.

Active Pharmaceutical Ingredients are regulated by Health Canada (HC) under the authority of the Food and Drugs Act and the Food and Drug Regulations. The Food and Drug Regulations (Regulations) were amended by extending the requirements of Establishment Licensing and Good Manufacturing Practices to the manufacturing and importation of active pharmaceutical ingredients.

Implementation of the CBSA Single Window Initiative (SWI)

The CBSA assists Health Canada in administering the following legislation at the border: the Canada Consumer Product Safety Act, the Controlled Drugs and Substances Act, the Food and Drugs Act, the Hazardous Products Act, the Radiation Emitting Devices Act, the Pest Control Products Act, as well as regulations made thereunder.

These activities apply to all drugs and devices as defined by the Food and Drug Act, including APIs.

Under SWI, release requests will be submitted utilizing a new LPCO requirements.

Note: Under SWI, information requirements will remain the same. There are no additional data requirements for the import process.

Harmonized System (HS) Codes

The most common headings for Active Pharmaceutical Ingredients are found throughout chapters 28 and 29 and are too numerous to list. However, there is also a provision under 9913. Which contains a list of pharmaceutical ingredients; salts, esters or hydrates thereof that may be duty free if stated requirements are met. PGA requirements will still apply if Tariff code 9913 is applied.

A complete list of HS codes and ranges applicable to goods regulated by Health Canada (Active Pharmaceutical Ingredients) is found at **https://www.cbsa-asfc.gc.ca/prog/sw-gu/regcom-marreg/hc-sc-eng.html**

Data Element Rationales

The following data element rationales provide additional information of the specific data element requirements under the Single Window Initiative

Importer Contact Name	PGAs to contact the importer for IID clarification.
Importer Contact Telephone Number	PGAs to contact the importer for IID clarification.
Importer Contact Email Address	PGAs to contact the importer for IID clarification.
LPCO Type / Authorization Type	Importer must ensure that the product meets the appropriate licensing type to be imported.

LPCO Reference Number	Importer must ensure that the product has a valid licensing number demonstrating its authorization for sale/use in Canada as applicable (DIN, No Objection Letter, etc.)
Intended Use	The Intended Use, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number.
GTIN Number	Optional for Health Product Border Compliance Program, but may clarify identification of the product and ease need for referral.
Manufacture Date	Manufacture date is optional to make the pre-border admissibility determinations given that inspectors cannot visually inspect the product label in SWI.
Commodity Type	The Canadian Product Category, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number required.
Brand Name	Brand name is requested so that the inspectors can perform compliance verification prior to the shipment's arrival. This results in an expedited admissibility determination.
Batch/Lot Number	Batch/Lot number is optional to make the pre-border admissibility determinations given that inspectors cannot visually inspect the product label in SWI (previously mandated up to 07/26/18).
LPCO Type / Authorization Type	Importer must ensure that the product meets the appropriate licensing type to be imported.
LPCO Number	Importer must ensure that the product has a valid licensing number demonstrating its authorization for sale/use in Canada as applicable (DIN, No Objection Letter, etc.)
Ingredients	PGA needs to be informed of the ingredients being imported.
Ingredient Quantity	Ingredient Quantity is needed to make the pre-border admissibility determinations given that inspectors cannot visually inspect the product label in SWI.
Ingredient Quality	Ingredient Quality is needed to make the pre-border admissibility determinations given that inspectors cannot visually inspect the product label in SWI.

Intended use and Program conditions for Active Pharmaceutical Ingredients:

Commodities regulated by Health Canada's Active Pharmaceutical Ingredients Program are subject to HS classification control and specific intended use provisions, the following are the applicable intend use conditions:

Intended use	Description
HC13	HC - Generic - Manufacturing or Industrial Use

Electronic Commerce Client Requirements Document (ECCRD)

The following table provides the specific rules and conditions associated to each of the data elements. The data elements are: Mandatory (M), Conditional (C) or Optional (O).

Data element name	PGA element definition	Data element status	Data element rules and conditions
Contact Identification	Importer Contact Name	M	For Health Canada, an importer contact name must be provided for this declaration.
Contact method	Importer Contact Telephone Number	C	For Health Canada, either an importer contact telephone number or importer contact e-mail address must be provided.
Contact method	Importer Contact Email Address	C	For Health Canada, either an importer contact telephone number or importer contact e-mail address must be provided.
Document Type (Licence, Permit, Certificate, Other)	LPCO Type /Authorization Type	C	The coded identifier of applicable document types being provided at the declaration level must be provided in this field. Document types provided here must be applicable to all commodities on this declaration. If not applicable to all commodities, please provide the document types at the commodity line level (SG121). Acceptable documents types depend on the Intended Use (SG117 APP) and Canadian Product Category (SG117 PGI) provided. Refer to Appendix A for Intended uses, Canadian product categories and Document type(s).
Document Reference Number	LPCO Number	C	For each document provided at the declaration level, the associated reference number related to that document must be provided as follows: Refer to Appendix B for Document type(s) and Reference number(s).
Intended End Use	Intended Use	M	The intended end-use of the commodity must be provided as below. Depending on the intended end-use code, additional details are required. Refer to Appendix A for Intended uses, Canadian product categories and Document type(s).
Product Identifier	GTIN Number	O	Active Pharmaceutical Ingredients can be identified through their GTIN GS1 Asset Identifier. Although not required, this information will allow a clearer identification of the product and expedite processing in case of referrals. The qualifier for GS1 Global Trade Identification Number (GTIN) must be provided in the 7402, 2 field.
Production/ Expiry Date	Manufacture Date	O	The date on which the commodity was manufactured can be provided. If a format without time zone information is provided the time must be in CBSA Headquarters time (EST, e.g., GTM -5)

Canadian Product Category	Commodity Type	M	A Canadian Product Category must be provided depending on the Intended End-Use Code entered in SG117 APP. See Appendix C for Intended use code(s) and Canadian product category. The qualifier for field 5389 should be the code for HC – Active Pharmaceutical Ingredient
Commodity Characteristic (Brand Name)	Brand Name	O	The brand name of the commodity being imported is optional.
Commodity Lot Number	Batch/Lot Number	O	The batch and/or lot number that the manufacturer assigned to the product may be provided.
Document Type (Licence, Permit, Certificate, Other)	LPCO Type/ Authorization Type	C	The coded identifier of any applicable document must be provided in this field if applicable to a specific commodity line entry. If applicable to all commodities, please provide the documents at the declaration level (SG9). Acceptable documents types depend on the Intended Use (SG117 APP) and Canadian Product Category (SG117 PGI) provided. Refer to Appendix A for Intended uses, Canadian product categories and Document type(s).
Document Reference Number	LPCO Number	C	For each document type provided at the commodity level, an associated reference number related to that document must be provided. Refer to Appendix B for Document type(s) and Reference number(s).
Component / Ingredient Details	Ingredients	M	For regulated active pharmaceutical ingredients, details regarding the chemical identity of the ingredient must be provided. An occurrence of this segment must be provided for each ingredient that is regulated as an Active Pharmaceutical Ingredient, and each ingredient must be flagged as Active (COD. 7505) Field 7506 must contain a detailed free-text description of the ingredient sufficient to identify the component for compliance purposes.
Component / Ingredient Details (Quantity)	Ingredient Quantity	M	The quantity of each ingredient identified in SG128 must be provided, including the unit of measure (in field 6411).
Component / Ingredient Details (Quality)	Ingredient Quality	C	If applicable, the quality (percentage of guaranteed concentration) of each ingredient identified in SG128 must be provided. If this segment is not provided, the assumption will be that the concentration is 100% for this ingredient.

Additional resources

Reference Code Tables

Legislation:

For more information on the importation of active pharmaceutical ingredients, refer to Health Canada's website under the **Importation and Exportation - Compliance and Enforcement - Drugs and Health Products - Health Canada** page.

A list of **certain antimicrobial active pharmaceutical ingredients** is also found on the Health Canada Website.

A **Guidance Document on the Import Requirements for Health Products** under the Food and Drugs Act and its Regulations contains additional information on APIs.

Customs Memoranda:

Requirements Concerning the administration of Health Canada Acts and regulations relating to certain controlled, prohibited or regulated goods are found in **D19-9-1.**

Appendix A: Intended uses, Canadian product categories and Document type(s)

Intended Use	Canadian Product Category	Document Type(s)
Manufacturing or Industrial Use	Active Pharmaceutical Ingredient	Establishment Licence (EL)

Appendix B: Document type(s) and Reference number(s).

Document Type(s)	Reference Number
Establishment Licence (EL)	Establishment Licence Number

Appendix C: Intended use code(s) and Canadian product category

Intended Use Code	Canadian Product Category (SG117 PGI)
Manufacturing or Industrial Use	Active Pharmaceutical Ingredient

Contact Livingston

Have questions or need help with your SWI imports?
Contact your Livingston client services representative.
Write to us at: **clientserviceCanada@livingstonintl.com** or give us a call at **1-855-225-5544**.