

Protected B (when completed)

May 2018

Application for a Class A Precursor Licence

(disponible en français)

Privacy Notice

The personal information you provide to Health Canada is governed in accordance with the Privacy Act. The collection of your personal information is authorized under the Controlled Drugs and Substances Act and the Precursor Control Regulations. This information will be used to process your application for a Class A precursor licence. This information may be used to provide reports to management. This information may also be used for research, planning, audit and evaluation purposes. In limited and specific situations, your personal information may be disclosed without your consent to law enforcement or in accordance with subsection 8(2) of the Privacy Act. Failure to provide the requested information may result in a refusal to process the application. This personal information collection is described online at Info Source: Sources of Federal Government and Employee Information Health Canada. In addition to protecting your personal information, the Privacy Act gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Privacy Coordinator at hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.



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Corporate Name	
Other Name(s)	

Attach a copy of your Certificate of Incorporation, or any document filed with the province stating the applicant's corporate name, and any other name registered with a province with this application, if applicable.

Attach a copy of your Certificate of Incorporation, or any document filed with the federal government stating the applicant's corporate name, and any other name registered with the federal government with this application, if applicable.

If there are no changes to the Certificate of Incorporation previously submitted in this section, it is not required to submit a new copy.

2. Application Type

	New	Amendment	Renewal	
2.1 Licen	ce Number (if	renewal/amendment	t) :	

I would like to renew my existing licence with no changes to the content of the current licence. (Please complete Sections 4, 7, 10 and 11 only)

I would like to amend my existing licence (Please complete sections 4, 10, 11, in addition to any sections relevant to the amendment)

3. Preferred Language of Communication

English French

4. Proposed Site

4.1 Proposed Licensed Site Information

If the applicant intends to conduct licensed activities at **more than one site**, **a separate application** must be made for each site. If applicable, include the establishment licence number issued under section C.01A.008 of the Food and Drug Regulations or the site licence number issued under sections 29 or 36 of the Natural Health Products Regulations.

Street Address	
City	Province
Postal Code	Establishment Licence or Site Licence
Telephone Number	Email Address

4.2 Mailing Address

Same as licensed site address

If the mailing address is different from the proposed licensed site address:

Street Address		
City	Province	
Postal Code		

4.3 Additional Building Information

If the site is comprised of more than one building, and the building information is different than stated above, please list on a separate sheet the address, telephone number, email address and postal address for each building within the site where precursor activity takes place.

Check here if additional pages are included

5. Business Information

There are no changes to the business information previously submitted for this section.

Provide a detailed description of the nature of business conducted or intended to be conducted in relation to precursors. Also include the length of time, if any, applicant has been in business, the hours of operations, the total number of employees and the number of employees in addition to the proposed designated personnel that will have access to the precursors.

Nature o	f Business
Length of time in business	
Hours of Operations	
Total number of employees	
Number of employees, in addition to the proposed designated personnel that will have access to the precursors	

If the proposed licensed site is not owned by the applicant or is a 3rd party site (i.e. logistics provider), please attach a copy of the contract between the relevant parties.

Note: Please submit additional pages if needed.

Click here if additional pages are included

6. List of Class A Precursors and Activities to be Licensed

6.1 Class A Precursor Information

New Application

List the name of each precursor sought to be licensed and for each precursor listed please specify the precursor form and the activity that is sought to be licensed. If applicable, include the name of the preparation/mixture, the brand name and the drug identification number assigned under section C.01.014.2 of the Food and Drug Regulations or the natural product number assigned under section 8 of the Natural Health Products Regulations.

Licence Amendment/Renewal

In the case of a licence amendment or renewal, if the licensed dealer wants to add or delete a precursor or an activity, please fill out the table below. In the case of a deletion of a precursor, only the name of the precursor as it appears on the licence is required.

There are no changes to the precursor information previously submitted for this section.

	Name of precursor (if applicable, the name of the salt)	Precursor Form	Activity(ies) related to that precursor	Name(s) of the preparation(s)/ mixture(s) and brand name(s) (if applicable)	Drug Identification Number or Natural Product Number (if applicable)
Addition Deletion		Raw material Finished product	Produce Package Provide/Sell Import Export		
Addition Deletion		Raw material Finished product	Produce Package Provide/Sell Import Export		
Addition Deletion		Raw material Finished product	Produce Package Provide/Sell Import Export		
Addition Deletion		Raw material Finished product	Produce Package Provide/Sell Import Export		
Addition Deletion		Raw material Finished product	Produce Package Provide/Sell Import Export		

Attach copies of any Material Safety Data Sheet(s) (MSDS) for preparation(s)/mixture(s), if applicable.

Note: Please add additional lines as needed.

Check here if additional pages are included

6.2 Suppliers and Clientele

Provide the name(s) of the supplier(s) from whom you will obtain the precursor and list the type(s) of clientele to whom you intend to supply the precursor(s).

There are no changes to the suppliers and clientele information previously submitted for this section.

Name of the precursor	Name(s) of supplier(s)	Type(s) of clientele
(If applicable, the name of the salt)	(If applicable)	

Note: Please add additional lines as needed.

Check here if additional pages are included

7. Designated Personnel

A Criminal Record Check **MUST** be provided for the following persons, when applying for a new licence, personnel amendment (addition/replacement of designated personnel) and when renewing a licence (even if the personnel remain unchanged).

7.1 Senior Person in Charge (SPIC):

Surname (last name)		Given name(s)
Position with applicant		
Date of Birth	(YYYY/MM/DD)	
Telephone Number		Email Address
Work Hours		

7.1.1 Criminal Record Check

Attach the criminal record check certificate issued by a Canadian police force within the past twelve months.

If the individual resided in another country in the previous ten years, attach the criminal record check document issued by a police force in that country.

7.2 Responsible Person in Charge (RPIC):

Surname (last name)		Given name(s)	
Position with applicant			
Date of Birth	(YYYY/MM/DD)		
Telephone Number		Email Address	
Work Hours			

7.2.1 Criminal Record Check

Attach the criminal record check certificate issued by a Canadian police force within the past twelve months.

If the individual resided in another country in the previous ten years, attach the criminal record check document issued by a police force in that country.

7.3 Alternate Responsible Person in Charge (A/RPIC), if any:

Surname (last name)		Given name(s)
Position with applicant		
Date of Birth	(YYYY/MM/DD)	
Telephone Number		Email Address
Work Hours		

7.3.1 Criminal Record Check

Attach the criminal record check certificate issued by a Canadian police force within the past twelve months.

If the individual resided in another country in the previous ten years, attach the criminal record check document issued by a police force in that country.

7.4 Alternate Responsible Person in Charge (A/RPIC), if any:

Surname (last name)		Given name(s)
Position with applicant		
Date of Birth	(YYYY/MM/DD)	
Telephone Number		Email Address
Work Hours		

7.4.1 Criminal Record Check

Attach the criminal record check certificate issued by a Canadian police force within the past twelve months.

If the individual resided in another country in the previous ten years, attach the criminal record check document issued by a police force in that country.

Note: Please submit Additional Alternative Responsible Person in Charge application, if required.

Click here if you have completed an Additional Alternative Responsible Person in Charge application.

8. Proposed Security Measures

For more details on what is required, refer to the <u>Guidance Document for the Precursor Control Regulations - Application for Class A Precursor Licences</u> and <u>Guidance Document for the Precursor Control Regulations - Requirements and Responsibilities of Licensed Dealers of Class A Precursors.</u>

There are no changes to the information regarding proposed security measures previously submitted for this section.

Attach a copy of an 8 ½" x 11" floor plan indicating where you propose to store the precursor(s).

Attach copies of any Standard Operating Procedures (SOPs) pertaining to security measures for precursors and covering the elements in this section.

Provide a detailed description of the proposed security measures to be used at the site (eg. overall security of the facility, including physical security of all the locations within the facility, eg. cage, vault, locker, cabinet, locked room, etc., where the precursors will be stored and the Security system details eg. security monitoring, access keypads, swipe cards, security guard surveillance, door contact protection, video surveillance, etc.).

Description

Provide a detailed description of the proposed security measures to be used when a precursor is sent, transported or delivered. (eg. any written procedures regarding the transportation, receipt, identification, examination, and handling of the precursor(s) or the precursor containing product(s)).				
		Description		
packaging activity (if app			the site, production activi	ty (if applicable),
		Description		

Provide details on the procedure your company uses to handle returned material that contains precursor(s). Provide details

		Descript	ion		

Note: Please submit additional pages if needed.

Check here if additional pages are included

9. Internal Controls

For more details on what is required, refer to the <u>Guidance Document for the Precursor Control Regulations - Application for Class A Precursor Licences</u> and <u>Guidance Document for the Precursor Control Regulations - Requirements and Responsibilities of Licensed Dealers of Class A Precursors.</u>

There are no changes to the information concerning internal controls previously submitted for this section.

Attach copies of any Standard Operating Procedures (SOPs) pertaining to internal controls for precursors and covering the elements in this section.

returns; records indicating the name, quantity of precursors with the type of activity and date, name and address of seller, buyer, exporter and/or importer) proposed with respect to the Class A precursor activity at the site.
Description
Attach a copy of a sample record pertaining to precursor(s) and precursor product(s), if possible.
Confirm that all original records will be maintained at the licensed site for at least two years after they were obtained.
Attach a copy of the proposed Access Log.
Describe the system that will be used to submit your annual report.
Description

Confirm that you will submit the previous calendar year's annual report by March 31 of each calendar year, which will include a physical inventory taken at the site at the end of the calendar year.

		Description		
Attach a copy of yo	our end use declarat	tion form, if applicable.		
ribe what procedures w	ill be in place for red	cording of suspicious trans	sactions.	
	·	Description		

Attach a sample copy of your suspicious transaction record.

Describe what procedures will be in place for reporting the loss and theft of precursor(s).
Description
<u>L</u>
Describe what quantity, if any, of precursor(s) would be considered a normal loss/waste on the basis of your accepted
business activities.
Description

		Descripti	on	
1				
1				
Attach a sa	mple copy of the de	struction record to be o	otained fro	om the destruction company, if applicable.
Note: Pleas	e submit additiona	I pages if needed.		
Click her	re if additional pages	are included		
10. Declarations				
				ous ten (10) years, of a designated drug offence canada, of an offence that would have constitute
		d criminal offence if com		
				Controlled Drugs and Substances Act (CDSA) a re sufficient knowledge concerning the use and
handling of Class A pr				isk of those precursors being diverted to an illic
market or use.				
10 1 Sonior Borson i	n Chargo (SDIC) —	Occloration		
10.1 Senior Person i	Il Charge (SFIC) –	Deciaration		
Name of Senior Pers	con in Charge			
(SPIC)	off in Charge			
ı				

10.2 Responsible Person in Charge (RPIC) - Declaration

Name of Responsible Charge (RPIC)	e Person in		
Signature:		Date:	(YYYY/MM/DD)
10.3 Alternate Respo	onsible Person in C	ge (A/RPIC) – Declaration	
Name of Alternate R in Charge (A/RPIC)	esponsible Person		
Signature:		Date:	(YYYY/MM/DD)
		ge (A/RPIC) – Declaration	
Name of Alternate R in Charge (A/RPIC)	esponsible Person		
Signature:		Date:	(YYYY/MM/DD)
			on in Charge application, if required. sponsible Person in Charge application.
	cordance with the re		re correct and complete to the best of my Drugs and Substances Act (CDSA) and the
hereby certify that	I am in a position of	ority with respect to the infor	mation provided in the above application form.
Name of Senior Pers (SPIC)	son in Charge		
Signature:		Date:	(YYYY/MM/DD)

12. Submission

New applicants must mail the completed application form with all the required documents to:

Office of Controlled Substances
Authorizations Division
161 Goldenrod Drwy
AL 0300B
Ottawa ON K1A 0K9

Applicants applying for an **amendment or a renewal** can either mail the completed application with all the required documents to the address above or submit it via email to hc.precursors-precurseurs.sc@canada.ca

If you have any questions regarding this application, please contact us by email at: hc.precursors-precurseurs.sc@canada.ca

Application for a Class A Precursor Licence Checklist

This check list is provided to assist you in ensuring that all the required information has been included in your Application for Class A Precursor Licence. Providing all the required information will avoid unnecessary delays in processing your application. Please note that incomplete applications will be returned.

Please ensure the following information is completed in your application:

Completed Information

Section 4	Information for each site has been included, including the Establishment or Site Licence Number, if applicable (Section 14 of the PCR).
Section 5	A description of the nature of your business is provided, as well as the length of time you have been in business (Section 14 of the PCR).
Section 6.1	Included the name of the preparation/mixture, brand name and Drug Identification Number (DIN) or Product Number, if applicable (Section 14 of the PCR).
Section 6.2	Included the names of suppliers and listed types of clientele for all precursors (Section 14 of the PCR).
Section 7	For each designated personnel (Section 14 of the PCR).
Section 8	Information has been included pertaining to the method of controlling access to the precursors, and safekeeping at the site and during transportation (Section 85, 83, and 9 of the PCR).
Section 9	Information has been included pertaining to record-keeping, end-use declarations, loss and theft reporting, and the annual reporting procedure (Section 85, 90, and 87 of the PCR).
Section 10.1	Signed by the Senior Person in Charge (SPIC) (Section 14 of the PCR).

Section 10.2	Signed by the Responsible Person in Charge (RPIC) (Section 14 of the PCR).
Section 10.3	Signed by the Alternate Responsible Person in Charge (A/RPIC), if applicable (Section 14 of the PCR).
Section 10.4	Signed by the Alternate Responsible Person in Charge (A/RPIC), if applicable (Section 14 of the PCR).
Section 11	Signed by the Senior Person in Charge (SPIC) (Section 14 of the PCR).

Attachments

A copy of the Certificate of Incorporation is attached and any document filed with the province and/or federal government stating the applicant's corporate name and any other name registered with a province and/or federal government (if applicable) (Section 14 of the PCR).
Criminal Record Check Certificates is attached (Section 14 of the PCR).
Applicable documents related to security measures are attached (Section 14 of the PCR).
Applicable documents related to internal controls are attached (Section 14 of the PCR).