



Regulatory Compendium

Certified Child Resistance Packaging of Cannabis for Distribution

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Introduction

CannaPack Solutions Inc. (CannaPack) recognizes that certified child resistant packaging is a critical tool for the cannabis industry in Canada. That is why it has developed this Regulatory Compendium to demonstrate to Health Canada and appropriate authorities in the provinces and municipalities that its packaging system for cannabis meets and exceeds all regulatory standards and requirements.

CannaPack has spent the last two years developing and testing its containers and seeking and getting certification from both the CSA Group (Canadian Standards Association) and the United States Government's Consumer Product Safety Commission. Its containers are designed specifically for cannabis in both Canada and the United States. This means its containers have been independently tested to meet the rigorous standards for both countries.

CannaPack has also met with various officials at Health Canada and based on those discussions, its containers have been designed to ensure complete compliance with all of the packaging requirements set forth for a controlled substance in Canada:

- *Food and Drugs Act and Food and Drugs Regulations.*
- *Controlled Drugs and Substances Act.*
- *Narcotic Control Regulations.*
- *Marihuana for Medical Purposes Regulations.*

Regulatory compliance and standards testing ensure CannaPack's containers are certified for consumer use. In its product design, CannaPack has adopted the Canadian Pharmacy approach to "Best of Class" packaging methods. That means its containers have been designed for the purpose of ensuring the safety of cannabis by keeping it free from contamination, hindering microbial growth, and ensuring product safety through the intended shelf life of the product.

CannaPack believes in doing what it can to protect the environment. That is why all of its containers are made of fully recyclable polypropylene and are manufactured in Canada in accordance with environmental protection laws.

CannaPack's Containers – Description

CannaPack developed the only pharmaceutical vial of its kind: The CannaVault. The CannaVault is an effective and secure system for packaging, labelling, shipping and storing of cannabis. The CannaVault is ergonomically designed with a wide opening to accommodate easy filling/removal of any strain of cannabis.

The CannaVault is child resistant as prescribed and it takes a fraction of the space of conventional cylindrical pharmaceutical vials which means it can be shipped and stored safely and securely.

The CannaVault comes in three sizes:

- Large – 200 drams (7.0" by 3.5").
- Medium – 120 drams (3.5" by 3.5").
- Small – 80 drams (2.0" by 3.5").

The stock colour is white but multiple colours are available as a custom order.

Material

The CannaVault is made out of recyclable polypropylene (it has the number "5" as its resin identification code) which provides extra strength to safeguard cannabis from being damaged during transit. Polypropylene is a thermoplastic polymer used in a wide variety of applications including packaging and labeling, textiles (e.g., ropes, thermal underwear and carpets), stationery, plastic parts and reusable containers of various types, laboratory equipment, loudspeakers, automotive components, and polymer banknotes.

Advantages of using polypropylene include:

- Good moisture vapour barrier.
- Low density, reducing environmental impact.
- Good stiffness/impact balance.
- Chemical and thermal resistance.
- Reduces environmental impact.
- Hot fill and retort capable.

By using recyclable polypropylene, the CannaVault is a container that is rugged and unusually resistant to many chemical solvents, bases and acids ensuring extra safeguards.

Regulatory Compliance

The CannaVault has been designed so it is fully compliant with all of Health Canada's Acts and Regulations. What follows are citations of the various packaging rules and an explanation of how the CannaVault meets these requirements.

Food and Drugs Act (FDA) and Food and Drugs Regulations (FDR)

The FDA states in Part I, Section 9(1):

• No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. Section 9(2) states: A drug that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).

The design and specifications of the CannaVault container ensures it does not provide an erroneous impression regarding its character, value, quantity, composition, merit or safety. Images of the CannaVault are provided on page 9 of this document.

The FDR states in C.01.001(2) to (4):

- A child resistant package is a package that (a) when tested in accordance with an acceptable method;*
- complies with the requirements of one of the following standards, namely:*
- Canadian Standards Association Standard CAN/CSA-Z76.1-M90;*
- European Standard EN 28317:1992; [and the]*
- Code of Federal Regulations (United States), Title 16, Section 1700.15.*

CannaPack has ensured the CannaVault is compliant with not one but two of the standards listed above: Canadian Standards Association Standard CAN/CSA-Z76.1-M90; and the Code of Federal Regulations (United States), Title 16, Section 1700.15.

The design of the CannaVault was focused on ensuring it is not only child resistant, but also falls into the "Best of Class ". The CannaVault lid is based on a lug system (push and turn) instead of a continuous thread (screw). The lug system is a closure system where the container has multiple female locking stations and the lid has an equal number of male lugs or tabs that lock into a corresponding female locking station. CannaPack choose this type of mechanism as it is more "child resistant" and is a better option in containing any odour when compared to a continuous thread system.

A lug closure system is safer than a continuous thread system. The majority of pharmacies in Canada have recognized this fact and use the lug closure system for their containers when fulfilling prescriptions.

The CannaVault is the only container for cannabis available for sale in Canada that meets the child resistance standards of both Canada and the United States. Certificates of proof are available in Appendix A and B of this document.

The FDR states in C.02.017(b)(i)(A):

- *...has evidence satisfactory to the Director to demonstrate that packaging materials sold to him by the vendor of that lot or batch of packaging material are consistently manufactured in accordance with and consistently comply with the specifications for those packaging materials.*

CannaPack provides all of its clients with the required documentation to demonstrate that the CannaVault is consistently manufactured according to its specifications and the standards of the CSA and the US Government's Consumer Product Safety Commission.

Controlled Drugs and Substances Act (CDSA) and Narcotic Control Regulations (NCR)

The CDSA and the NCR are an Act and Regulations that identifies and sets the controls for certain drugs and their precursors. Cannabis is identified in Schedule II of the Act.

Given the CDSA and the NCR identify cannabis as a narcotic it therefore must be packaged according to strict regulatory standards which are outlined in the Marihuana for Medical Purposes Regulations. CannaPack and its product the CannaVault meet all of these requirements for the packaging and labelling of a narcotic.

Marihuana for Medical Purposes Regulations (MMPR)

The MMPR states in section 64:

- *the dried marihuana is packaged in an immediate container*
- *that is in direct contact with the dried marihuana,*
- *that keeps the dried marihuana dry and free from contamination,*
- *that has a security feature that provides reasonable assurance to consumers that the container has not been opened prior to receipt, and*
- *that is a child resistant package that meets the requirements of subsections C.01.001(2) to (4) of the Food and Drug Regulations.*

The CannaVault is made out of recyclable polypropylene. The unique properties of this material ensure it can keep cannabis dry and free from contamination given its has an excellent vapour and moisture barrier. The cylindrical shape and the three sizes of the CannaVault also ensure that when materials are being packaged, it can be done so in a manner that allows for easy handling of the product (lessening the chance of any residual contamination) as opposed to trying to force material into an improperly designed container.

To ensure proper closure between the lid and the container for security/anti-tampering purposes and to control odour, an aluminum foil recessed tamper evident seal is affixed to the CannaVault container prior to the lid being secured. The seal is hermetically attached to the CannaVault vial by a simple heat/pressure applicator which takes less than a tenth of a second. This is accomplished by conduction to make it a tamper evident seal and reduces odour down to practically zero (which safeguards odour from escaping during transit) while also extending the shelf life of the enclosed product.

The seals are manufactured by the German company Ballerstaedt & Co. and are in accordance with the current requirements of the *Food and Drugs Act*, the American Food and Drug Administration, German Health Authorities and the European Union.

Approved by the CSA Group

The CSA Group (formerly the Canadian Standards Association or CSA) is a not-for-profit standards organization which develops standards in 57 areas (which includes healthcare). The CSA is composed of representatives from industry, government, and consumer groups.

The CSA is accredited by the Standards Council of Canada, a crown corporation which promotes efficient and effective standardization in Canada. The CSA Mark shows that a product has been independently tested and certified to meet recognized standards for safety or performance.

To receive the CSA Mark, CannaPack had to submit extensive information that included (but was not limited to):

- Samples, specifications and photographs of the CannaVault.
- Individual contact and company information.
- How and where the product will be used.
- The countries where the product will be sold.
- The government regulatory standard(s) the product has been designed to meet – citations related to the *Food and Drugs Act and Food and Drugs Regulations; Controlled Drugs and Substances Act; Narcotic Control Regulations; and the Marihuana for Medical Purposes Regulations*.
- Marketing brochures and data sheets describing the product (what it is, what it does, and what it looks like).
- The list of all components and materials used in the product including manufacturers' names, model and catalogue designations.
- The alternate materials or components that may be used in manufacturing.
- The name, location, address and identification of a representative from the company manufacturing the product.
- Completed CSA Product Service Agreement.

After successfully receiving the CSA Mark, the CannaVault is now listed in the CSA Group Certified Product Listing (CPL). The CPL can be searched by: product type; industry; manufacturer name or location; and/or certification record information (*file number, class number or class description).

Furthermore, the manufacturing process for the CannaVault has been approved by the CSA. This meant and means that a CSA Field Service Representative conducted and will conduct ongoing facility visits, generally four (4) times per year to determine whether or not the CannaVault continues to comply with the applicable requirements established by the CSA.

These visits/inspections were conducted at the CannaPack manufacturing facility (located in Delta British, Columbia) and: verify that the appropriate CSA Certifications are applied only to eligible products; verify that the factory, on a continuing basis, is capable of producing CSA marked products and is in compliance with Certification Reports under the terms specified in the CannaPack/CSA Product Service Agreement; facilitate the selection of samples required for periodic conformity testing (re-testing) of products and verify conditions of the original certification.

Approved by the US Government, Consumer Product Safety Commission

The Poison Prevention Act of 1970, established the United States Consumer Product Safety Commission (CPSC). The Commission is the American federal regulatory body tasked with protecting children and families from unreasonable risks of injuries or death associated with consumer products. The CPSC regulates the sale and manufacture of more than 15,000 different consumer products and develops and strengthens voluntary safety standards and mandatory standards.

CannaPack and its CannaVault received a Certificate of Compliance from a CPSC Certified third party laboratory (J. Bitner & Associates). In order to receive this Certificate of Compliance, CannaPack had to submit extensive information regarding the CannaVault which included (but was not limited to):

- Identification of the product covered by this certificate which describes the product(s) covered by this certification in enough detail to match the certificate to each product it covers and no others.
- Citation to each consumer product safety regulation to which this product is being certified which must certificate and identify separately each consumer product safety rule administered by the Commission that is applicable to the product.
- Identification of the U.S. importer or domestic manufacturer certifying compliance of the product by providing the name, full mailing address, and telephone number of the importer certifying the product.
- Contact information for the individual maintaining records of test results by providing the name, full mailing address, e-mail address, and telephone number of the person maintaining test records in support of the certification.
- Date and place where this product was manufactured and for the date(s) when the product was manufactured, provide at least the month and year. For the place of manufacture provide at least the city (or administrative region) and country where the product was manufactured or finally assembled.
- Provide the date(s) and place when the product was tested for compliance with the consumer product safety rule(s) cited above: and location of the testing and the date(s) of the test(s) or test report(s) on which certification is being based.
- Identification of the third party laboratory on whose testing the certificate depends.

Seals, Lids and Containers – Images



Containers

Small
80 drams (2.0" by 3.5")



Medium
120 drams (3.5" by 3.5")



Large
200 drams (7.0" by 3.5")



Manufacturing and Packaging of the CannaVault

The CannaVault was designed and produced in British Columbia, Canada. Manufacturing of the CannaVault is done by Plascon Plastics Corp, located at 790 Audley Blvd, Delta, British Columbia. Plascon Plastics is a significant injection moulder and manufacturer of plastic parts for a wide range of clients throughout North America.

CannaPack and Plascon Plastics work in close cooperation to ensure the CannaVault is produced following municipal, provincial and federal health and safety standards. The CannaVault is produced under Good Manufacturing Practices so that it is of a high quality and does not pose any risk to the consumer or public.

CannaPack commissioned Iotron Industries Canada of Port Coquitlam, British Columbia and Mérieux Nutrisciences of Burnaby, British Columbia to test and verify if the production and packaging process of the CannaVault needed to be sterilized. The laboratory results show clearly that the original parts from the production and packaging run require no sterilization. If required, CannaPack would be pleased to provide the results from these tests. And if asked for, CannaPack can have the CannaVault sterilized prior to shipping any inventory to a Licensed Producer.

The CannaVault vials and lids are packaged separately in plastic sleeves containing 20 units. The package is then heat sealed so no contamination can occur. There are 12 sleeves to a case which equals 240 units to a carton. The carton is then sealed and labelled with a unique alpha-numerical identifier so that any issues/problems can be identified, tracked and cross referenced to the original production run.

Appendix A – CSA Certificate of Compliance



Certificate of Compliance

Certificate:	2699190	Master Contract:	260076
Project:	2699190	Date Issued:	October 3, 2014
Issued to:	CannaPack Solutions Inc. 906-120 Milross Ave Vancouver, BC V6A 4K7 Canada Attention: Gary Jackson		

The products listed below are eligible to bear the CSA Mark shown



Sayward Fetterly
Issued by: Sayward Fetterly, Certifier

PRODUCTS

CLASS 8771 01 - CHILD RESISTANT PACKAGING

Child Resistant Packages, Type IIA, Lug Style, Non-liquid dispensing, Model "Canna Vault":

- 200 dram vial fits with 200 dram cap

Notes:

- Vial Colour: Sweet Pea Green, White and Leaf Green
- Cap Colour: White
- Liner Colour: Clear

APPLICABLE REQUIREMENTS

CSA Standard Z76.1-06 , Recloseable Child-Resistant Packages

Certification Notice, Health Care Equipment No. 21, Ref No. N10-155, Revision to Marking Requirements for CSA Standard Z76.1-06

CSA TECHNICAL NOTE TN-126, Test Method and Requirements for Recloseable Child-Resistant Packages, Non Liquid Dispensing for Type IIA and Type IIB



Supplement to Certificate of Compliance

Certificate: 2699190

Master Contract: 260076

The products listed, including the latest revision described below, are eligible to be marked in accordance with the referenced Certificate.

Product Certification History

Project	Date	Description
2699190	Oct 3, 2014	Certification of Class 8771 01, Child Resistant Packages, Type IIA, Lug Style, Non-liquid dispensing, Model "Canna Vault", Size 200 dr vials fit with 200 dr cap, manufactured at Factory #4735210, as per CSA Std Z76.1-06.

Supplement Notes

Project 2699190: Certification of Class 8771 01, Child Resistant Packages, Type IIA, Lug Style, Non-liquid dispensing, Model "Canna Vault", Size 200 dr vials fit with 200 dr cap, Sweet Pea Green, White and Leaf Green vials, white cap and clear liners with alternate liner material, manufactured at Factory #4735210, Plascon Plastics Corp, 790 Audley Blvd, Delta, BC, V3M 5T1, Canada, as per CSA Standard Z76.1-06.

IFE successfully completed at Factory #4735210, Plascon Plastics Corp, 790 Audley Blvd, Delta, BC, V3M 5T1, Canada, as per CSA Standard Z76.1-06 on September 10, 2014.

Appendix B – CPSC Certificate of Compliance



January, 2015

Certificate of Compliance

Product : **Child Resistant Containers**

200 Dram	(7")	Canna Vault Vials
120 Dram	(3.5")	Canna Vault Vials (Bracketed)
80 Dram	(2")	Canna Vault Vials

Manufacturer :

**CannaPack Solutions Inc.,
906 - 120 Milross Ave.,
Vancouver, B.C.
V6A 4K7
Canada
Contact: Gary Jackson
gary@cannapack.ca**

The Consumer Product Safety Commission (CPSC) regulation to which these products are being certified is the Code of Federal Regulations Title 16, Part 1700.20

The date and place where this product was tested for compliance with the regulation cited above :

Dec 5, 2014 to Dec 14, 2014

**Bitner Associates, Inc.,
Chicago and south, west villages thereof**

The third party laboratory that has conducted testing on which this certificate depends:

**Bitner Associates, Inc.,
1001 Forest Trail
Sugar Grove, Illinois
60554
U.S.A.
December 14, 2014
john.bitner@jbitner.com**



906-120 Milross, Ave.
Vancouver, B.C.,
V6A 4K7 Canada

Date:
To:
Address:

Re: Letter of Intent

Dear,

CannaPack Solutions has developed the CannaVault which is a complete solution for all of your packaging needs. Designed and developed to ensure its fully compliant with all municipal, provincial and federal laws and regulations.

Specifically, the CannaVault meets and exceeds the requirements of:

- *The Food and Drugs Act and the Food and Drugs Regulations.*
- *The Controlled Drugs and Substances Act and the Narcotic Control Regulations.*
- *The Marihuana for Medical Purposes Regulations – Section 64.*

The CannaVault is also the only cannabis packaging system in Canada that has met the testing standards of the CSA Group and is allowed to carry the CSA Mark. The CannaVault has also received a Certificate of Compliance from the United States Government Consumer Product Safety Commission.

This letter will confirm CannaPack’s willingness and intent to enter into a formal agreement with XX Inc. to provide a fully compliant packaging system.

We appreciate your confidence in our company and services and look forward to helping you obtain your *Marihuana for Medical Purposes Regulations* license.

We look forward to working with you and your team.

Gary Jackson
Chief Executive Officer
1-604-726-945