



RDC | DRC

Hemp and Cannabis in Topicals Regulatory considerations for formulators



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Leaders in Chemicals and Ingredients ~ Chefs de file en Produits Chimiques et Ingrédients

WHO IS RESONSIBLE DISTRIBUTION CANADA

- ✓ A NFP Association representing *Canadian* chemical & ingredient distributors and their affiliated supply chain partners
- ✓ 42 member companies with \$6.5 billion dollars in sales
- ✓ 3,700 employees & 170 facilities across the country
- ✓ 50+ Affiliates from the chemical supply chain



WHO IS RESONSIBLE DISTRIBUTION CANADA

RDC Members:

- ✓ Serve 80,000+ customers
- ✓ Distribute 100,000+ products
- ✓ Represent suppliers from almost every country in the world
- ✓ Support 25+ Market Sectors
- ✓ Commit to Responsible Distribution

RDC MEMBERS CONTINUE TO BE PART OF A PROSPEROUS CANADA



RDC MEMBERS GENERATE OVER 603,000 JOBS THROUGHOUT THE SUPPLY CHAIN



RDC MEMBERS SERVICE OVER 25 MARKET SECTORS

RDC’s members make a difference in people’s lives in Canada and globally.



MEMBER COMMITMENT

"The RDC and each of its member companies is committed to taking every practical precaution towards ensuring that products and services do not represent an unacceptable level of risk to its employees, suppliers, customers, the public, or the environment."

Responsible Distribution Canada (RDC) is the voice of organizations involved in the chemical and ingredient supply chain, who champion health, safety & sustainability through RD.

CORE VALUES

Progressive, Protective, Approachable,
Generous, Friendly, Knowledgeable, Inclusive,
Disciplined, and Canadian.

To carry out our mission, Responsible Distribution Canada:



Innovates, adapts and promotes for RD principles.

RD LEADERSHIP



Offers relevant training, examines & informs, and provides accredited education opportunities.

QUALITY EDUCATION



Provides value through tools, communicates with stakeholders and delivers events to strengthen the supply chain community.

MEMBER VALUE &



Influences, collaborates and advocates on policy-related issues to support the membership.

IMPACTFUL ADVOCACY

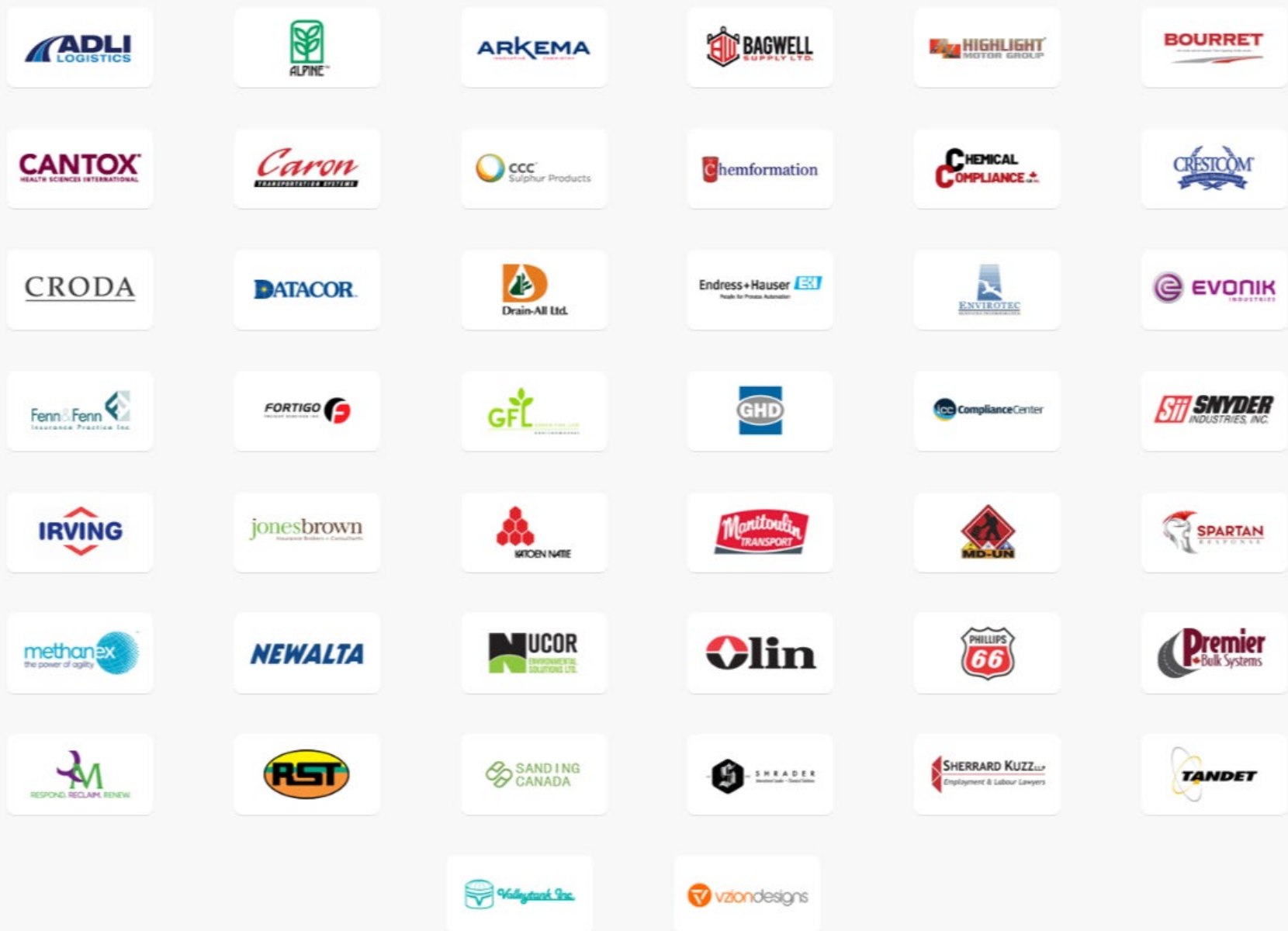
Member Companies



Candidate Members



Affiliate Companies



AGENDA



1. Introductions and participant expectations
2. Important Definitions
3. Cannabis Act
4. Cannabis Regulations
5. Other regulatory considerations
6. Conclusion

DISCLAIMER

This presentation is provided for information purposes only. RDC will not assume any responsibility for the accuracy of the contents of this presentation. It is the responsibility of the viewer to confirm the accuracy of the information if being used for due diligence and to comply with applicable legislation relating the cannabis and its use in topicals.

Participant expectations

This presentation is designed to inform cosmetic manufacturers, importers and ingredient suppliers who wish to explore opportunities in the cannabis topicals market.

Participants will be able to:

- ✓ Understand the costs and processes to obtain the licenses
- ✓ Understand the licensing regimes
- ✓ Must follow Good Production Practices
- ✓ Must follow Promotion and Advertising requirements
- ✓ Reporting, and
- ✓ Enforcement

Cannabis Topical definition

A cannabis topical is NOT a “cannabis extract”

cannabis topical means a substance or mixture of substances that contains or has on it anything referred to in **item 1 or 3 of Schedule 1 to the Act** and that is intended for use, directly or indirectly, **exclusively on external body surfaces, including hair and nails.**

Cannabis Act Schedule 1 (Subsections 2(1) and 151(1))

- 1 Any part of a cannabis plant, including the phytocannabinoids produced by, or found in, such a plant, regardless of whether that part has been processed or not, other than a part of the plant referred to in Schedule 2
- 2 Any substance or mixture of substances that contains or has on it any part of such a plant
- 3 Any substance that is identical to any phytocannabinoid produced by, or found in, such a plant, regardless of how the substance was obtained

Industrial Hemp

Cosmetic Ingredients Hotlist – restriction for hemp derivatives

* CAS 8016-24-8 or 89958-21-4 – Hemp seed oil or hydrolyzed seed protein

“Cosmetics must not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid”

Maximum concentration permitted:

10 µg/g THC (delta-9-tetrahydrocannabinol), as per the Industrial Hemp Regulations.

Non-viable cannabis seeds, mature stalks stripped of leaves, etc and fibre derived from such mature cannabis stalks do NOT require authorizations.

Hemp seed oil or flour packages must clearly state “Contains 10 µg/g THC or less – Contient au plus 10 µg/g de THC”

* Appears on the Revised in Commerce List (89958-21-4 not on any list – therefore a NEW substance)

Cannabis Act is an enabling Act



Structure of the Act

- 15 Parts
- 226 sections
- 6 Schedules
- 8 Regulations

Topicals are listed as Item 8 Under Schedule 4 authorizing sales

Prohibition on sales of products that have not been packaged or labelled in accordance with the regulations

Cannabis Act (S.C. 2018, c. 16): <https://laws-lois.justice.gc.ca/eng/acts/C-24.5/>

Cannabis Act

Regulations under the Act

- Cannabis Act (Police Enforcement) Regulations (SOR/2018-151)
- **Cannabis Fees Order** (SOR/2018-198)
- Cannabis for Medical Purposes Remission Order (SOR/2020-9)
- **Cannabis Regulations** (SOR/2018-144)
- Cannabis Tracking System Order (SOR/2019-202)
- **Industrial Hemp Regulations** (SOR/2018-145)
- Order Designating the Minister of Health as the Minister for the purpose of that Act (SI/2019-125)
- Qualifications for Designation as Analyst Regulations (Cannabis) (SOR/2018-146)

Cannabis Act – Cannabis Fees Order

2 schedules

- Schedule 1 – Item 5 – License for standard processing \$3,277
- Schedule 2 – Item 5 – the greater of 2.3% of cannabis revenue AND \$23,000

Minimum cost to start producing topicals – year 1 =
\$26,277 + 2.3% of revenue



Cannabis Regulations Overview

16 Parts - 375 sections (as of February 26, 2020)

Important sections:

Part 2 Licensing

Part 3 Security Clearances

Part 4 Physical Security Measures

Division 1 for Standard Processing (i.e. cannabis topical)

Part 5 Good Production Practices

Part 6 Cannabis Products

Part 7 Packaging and Labelling

Part 11 Retention of Documents and Information

Part 12 Reporting and Disclosure



Part 2 - Licensing

- You MUST have a license from **Health Canada**
 - Process cannabis into finished products, such as topicals
- You MUST have a license from the **Canada Revenue Agency** to sell cannabis
 - *Buy and apply cannabis excise stamps to their products
 - Calculate duty on their products
 - File their return and send the excise duties collected to the CRA

* Not required for products containing less than 0.3% THC – which would qualify as cosmetics and not cannabis topicals

Part 2 - Licensing

- **s7 Pre-licensing requirements**

Provide written notice to

- a) Local government
- b) Local fire authority, and
- c) Local police

Other important considerations

- s8(1)(b) Class of license will be for Processing
- s17(5)(a)(i) Processing License must have an authorization to sell the cannabis topical
- Act 69 Must be authorized under a Provincial Act
- s18(1) Each shipment must be accompanied by a current copy of Consumer Information – Cannabis –or obtain written confirmation that the receiver will obtain copies through other means
- s19(1) Must retain the services of a qualified Quality Assurance person (up to 2 alternates)
 - Assure the quality; Investigate every complaint; and take immediate measures to mitigate risk
 - Must obtain the Minister's approval to designate or replace QA personnel



Part 2 - Licensing

- s32 amend the license
- s33 site plan changes require Ministers approval
- s37(1) Responsible Person and alternate
- s38(1) Head of Security and alternate
- s43 Destruction requires a witness who holds a security clearance
- s46(1) Establish a system for Recall
 - 46(2) conduct annual simulation
- s47 Safekeeping during distribution

Part 3 – Security Clearances

- s50 security clearance for individuals who holds the processing/sales license
 - Director or officer of the corporation
- s51 must submit an application
- s52/53 Minister may check background / grant security clearance / revoke
 - Criminal background checks



Part 4 Physical Security Measures

- s62(1) follow sections 63 to 72 for standard processing license
- s63 site design must prevent unauthorized access
- s64 visual monitoring of perimeter by recording devices 24/7
- s65 intrusion detection system operating at all times – monitor at all times 24/7
- s66 records for detected occurrences
- s67 storage areas must have restricted access
- s68 record of every individual entering and exiting storage areas
- s69 surrounded by physical barrier
- s70 visual monitoring on recording devices to detect illicit conduct

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- s69 surrounded by physical barrier
- s70 visual monitoring on recording devices to detect illicit conduct
 - Retain for one year plus one day



Part 5 – Good Production Practices

Sections 78 through 92 apply

- Combines GMP and HACCP – similar to Safe Food for Canadians Regulations
- Important definitions
 - Acceptable level
 - Control measure
 - Critical control point
 - Sanitary condition
- Requires written SOPs



Part 5 – Good Production Practices

- Requires pest controls
- Management of sanitizers, and non-food chemical agents
- Storage conditions must maintain product quality
- Building must be kept clean and orderly
 - Effective surface cleaning
 - Contamination prevention
 - Prevents the introduction of extraneous substances to the topical
- Adequate system of filtration and ventilation
- Supply of water

Part 5 – Good Production Practices

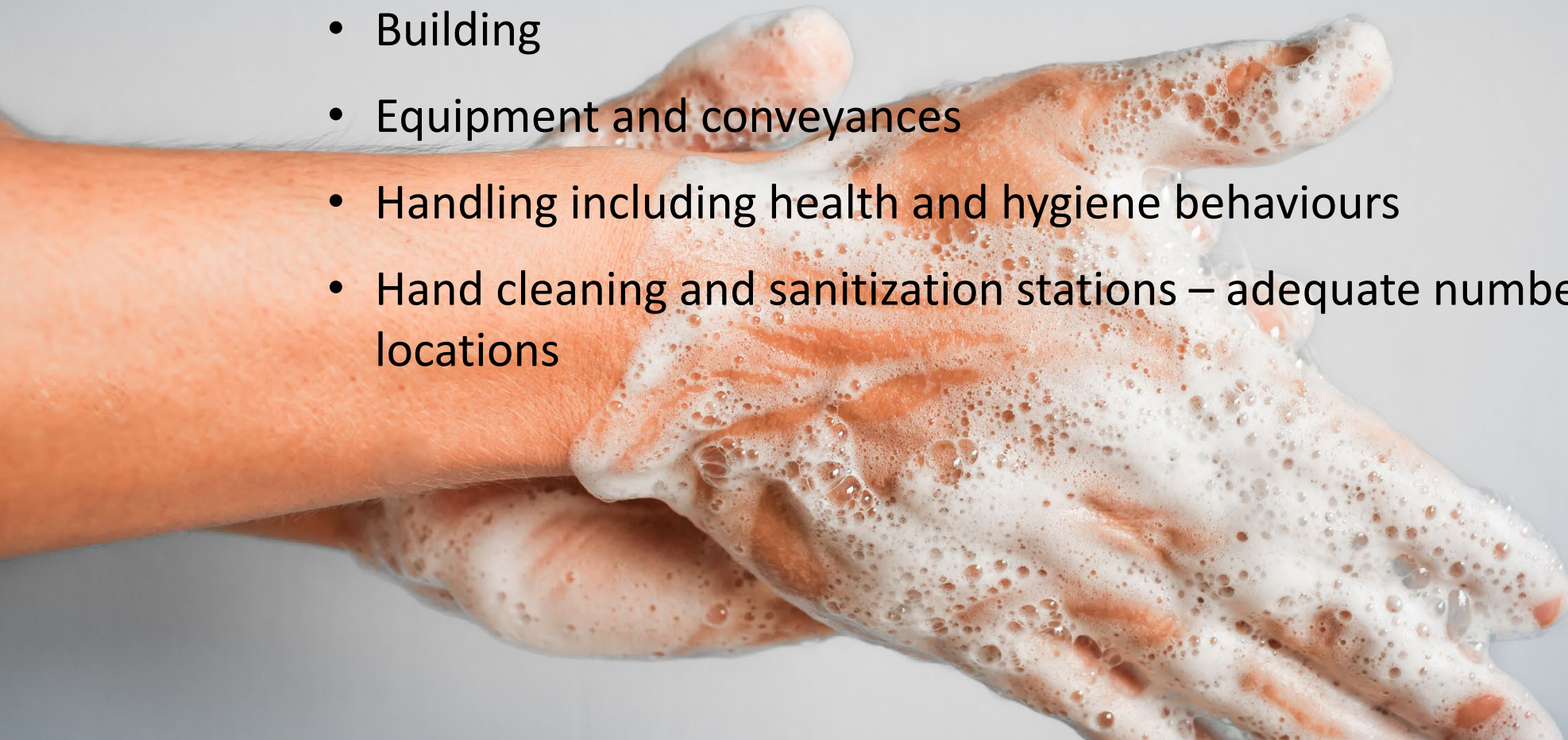
- Lighting must be appropriate for the activity
 - Fixtures must withstand repeated cleaning and sanitization
 - Not present a risk of contamination
- Equipment must be clean, well maintained, prevent contamination and introduction of extraneous substances to the topical
- Prevent and protect the topical against allergen cross-contamination
 - Includes conveyances



Part 5 – Good Production Practices

Sanitation program

- SOPs for effective cleaning
 - Building
 - Equipment and conveyances
 - Handling including health and hygiene behaviours
 - Hand cleaning and sanitization stations – adequate number and locations



Part 5 – Good Production Practices

Quality Assurance program

- Investigations conducted by QA person / alternate
 - **Implement immediate risk mitigation measures**
 - **Approve all ingredients and packages** used to produce topicals
 - **Approve** prior to **release for sale** all lots / batches
 - **Maintain temperature** / humidity to maintain quality and prevent contamination
 - Separate of ingredients from contaminants
 - Ensure **water quality**
 - No presence of animals

Part 5 – Good Production Practices

Quality Assurance program

- Clothing, footwear and protective coverings are suitable and effective
- Conduct identification and analysis of hazards
- Prevent, reduce and eliminate hazards
- Retain documents for 2 years
- Conduct testing to meet the requirements of Section 90 to 92
 - Testing for phytocannabinoids
 - Either before or after being packaged / labelled
 - Test for contaminants to confirm if within tolerances
 - Use validated methods – retain samples and records for 1 year

Part 6 – Cannabis Prodcust

Parts 92 through 98

- Must NOT contain residues of pest control products
- May contain or have microbial or chemical contaminants within accepted tolerances for human use (Schedule B Food and Drugs Act) intended for the cannabis product.
- Must meet maximum residue levels per section 9 or 10 of the Pest Control Products Act
- Maximum quantity of THC or CBD less than 85% or more than 115% of the label quantity or concentration
- Cannot be used in the area of the eye, eyebrows, or on broken/damaged skin

Part 6 – Cannabis Prodcust

Parts 99 through 105

- s101(1) Must NOT contain anything that can cause injury when used for its intended purpose i.e. topical
- Can ONLY contain anything from Item 1 or 3 of the Act i.e. cannabis
 - Residues of pest control products registered for use on cannabis and be within MRLs
 - Microbial or chemical contaminants generally accepted within tolerance limits for human use
- Maximum quantity of THC must NOT exceed 1000 mg per immediate container taking in the potential to convert THCA into THC



PART 7 - PACKAGING AND LABELLING

Part 7 – Packaging and Labelling

Parts 105 through 138

Definitions



Expiry date expressed at minimum as year and month that is the end of the stability period

INCI Name has the meaning as in s2(1) of the Cosmetic Regulations

Standardized Cannabis Symbol means the symbol set out in the document of the same name

Part 7 – Packaging and Labelling

- s108
 - Be opaque or translucent and uniform colour (not fluorescent) - smooth non-embossed / decorative edges
 - Prevent contamination
 - Include a security feature / child resistant packaging
 - NOT contain more than the equivalent of 30g dried cannabis
- s111 NOT display any brand element
- s112 NOT display any image
- s116(2) NOT include a fold out panel



Part 7 Packaging and Labelling

- s122(1) a bar code may only be displayed once
- s122.3 NOT contain more than 90 mL of extract that is in non-solid form at a temperature of $22 \pm 2^{\circ}\text{C}$
- s123(1)(c) name and address of license holder
 - (i) brand name
 - (ii) Lot Number or Lot no. Or Lot or "L"
 - (iii) recommended storage conditions
 - (iv) packaging date
 - (v) expiry date
- (d) WARNING **"KEEP OUT OF REACH OF CHILDREN / TENIR HORS DE LA PORTÉE DES ENFANTS"**



Part 7 Packaging and Labelling

- S130 (3) Other required information
 - Standardized cannabis symbol and health warning message:
 - Colour black, minimum 7 points (font)
 - Single font type
 - White background that extends at least 6 points on all side away from information
 - English and French
 - Colour can not be fluorescent
 - Standardized cannabis symbol must appear in the upper left 25% of the principal display panel
 - At least 1.27 cm x 1.27 cm

Part 7 – Packaging and Labelling

- S132.15 Cannabis Topical discrete units
 - Net weight in grams of the topical
 - Number of units
 - Net weight in grams in each unit
 - Either the quantity of THC in mg or in mg per gram ("total THC per unit")
 - Either the quantity of CBD in mg or in mg per gram ("total CBD per unit")
 - A list of the ingredients of the cannabis topical
 - The identity of the cannabis product in terms of its common name or in terms of its function, and
 - The intended use of the cannabis product

Part 7 Packaging and Labelling

- s132.15 Cannabis Topical discrete or non-discrete units
 - Net weight in grams of the topical
 - Number of units (discrete units only)
 - Net weight in grams in each unit
 - Either the quantity of THC in mg or in mg per gram ("total THC per unit")
 - Either the quantity of CBD in mg or in mg per gram ("total CBD per unit")
 - A list of the ingredients of the cannabis topical (by INCI name/chemical or EU trivial name) - English and French <1% in any order
 - The identity of the cannabis product in terms of its common name or in terms of its function, and
 - The intended use of the cannabis product

Part 11 Retention of Documents and Information

- s221 MUST retain documents
- s225 for each lot or batch:
 - Date of production
 - Date put into discrete units (if applicable)
 - Description
 - Net weight or volume
 - Lot number
 - List of ingredients that is to appear on the label
 - Net weight, volume or concentration of each of the ingredients
 - Brand name
 - Date packaged

RETENTION PERIOD IS 2 YEARS

Part 11 Retention of Documents and Information

INVENTORY AND DISTRIBUTION – IF OBTAINED FROM ANOTHER PERSON – FOR INGREDIENTS ALSO

- s226(1)
 - Name of the person from which the cannabis is obtained
 - Address
 - Date on which the cannabis is obtained
 - Quantity
 - Description and brand name
 - Lot number
 - INCI/common/chemical/CASRN and Lot #

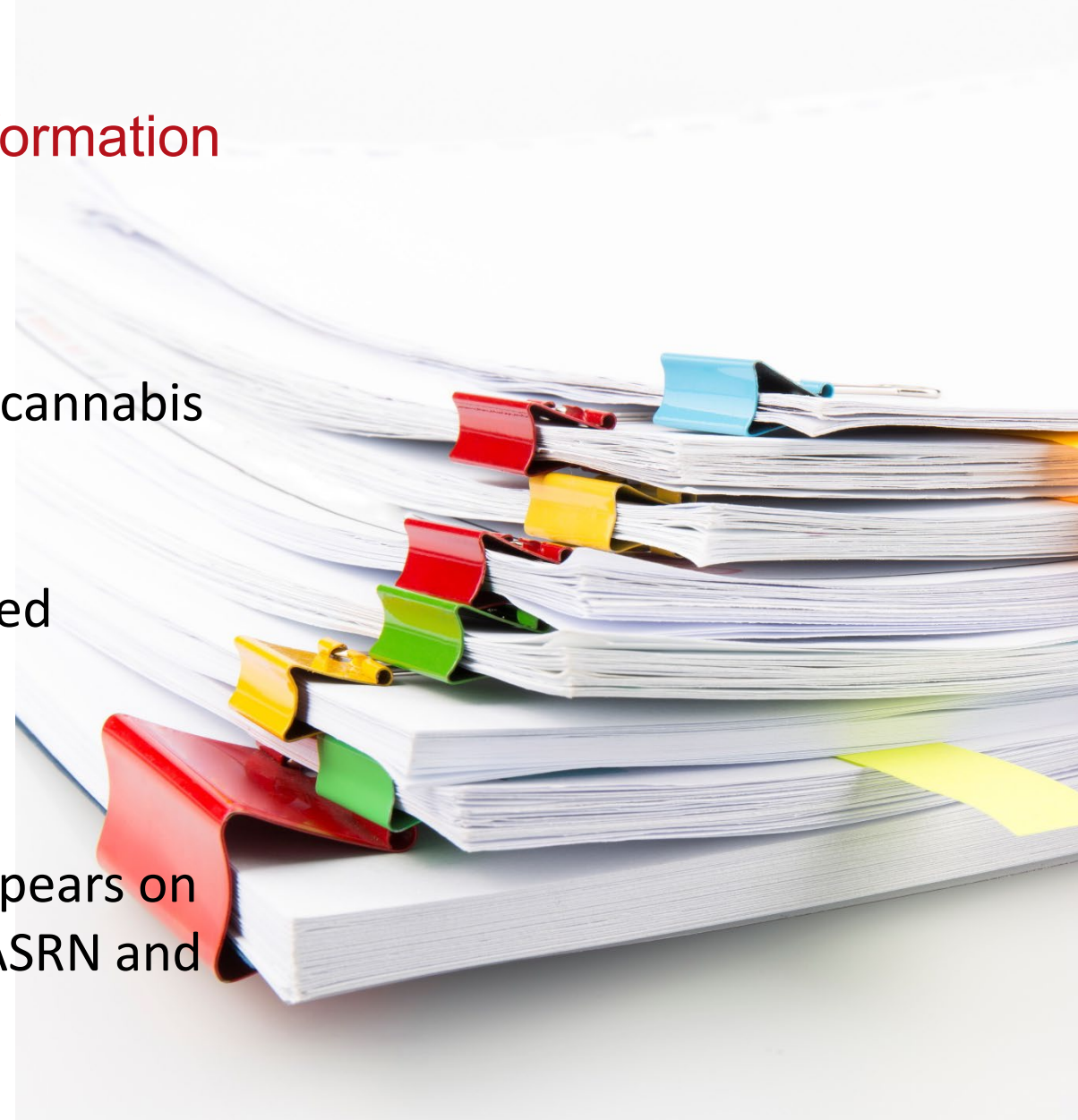
RETENTION PERIOD IS 2 YEARS

Part 11 – Retention of Documents & Information

SALES, DISTRIBUTION and EXPORT

- s227(1)
 - Name of the person from which the cannabis is sold
 - Address
 - Date on which the cannabis is obtained
 - Quantity
 - Description and brand name
 - Lot number
 - TOPICALS: List of ingredients that appears on the label INCI/common/chemical/CASRN and Lot #

RETENTION PERIOD IS 2 YEARS



Part 11 Retention of Documents and Information

ANTIMICROBIAL TREATMENT conducted at a location other than the site specified on the license

- s228(1)
 - Description of cannabis being treated
 - Date and quantity cannabis leaves the site
 - Name of the person that receives the cannabis
 - Address
 - Name of the person from which the cannabis is received after treatment
 - Address of the site to which the treated cannabis is returned after treatment
 - Date on which the cannabis is received and quantity

RETENTION PERIOD IS 2 YEARS

Part 11 Retention of Documents and Information

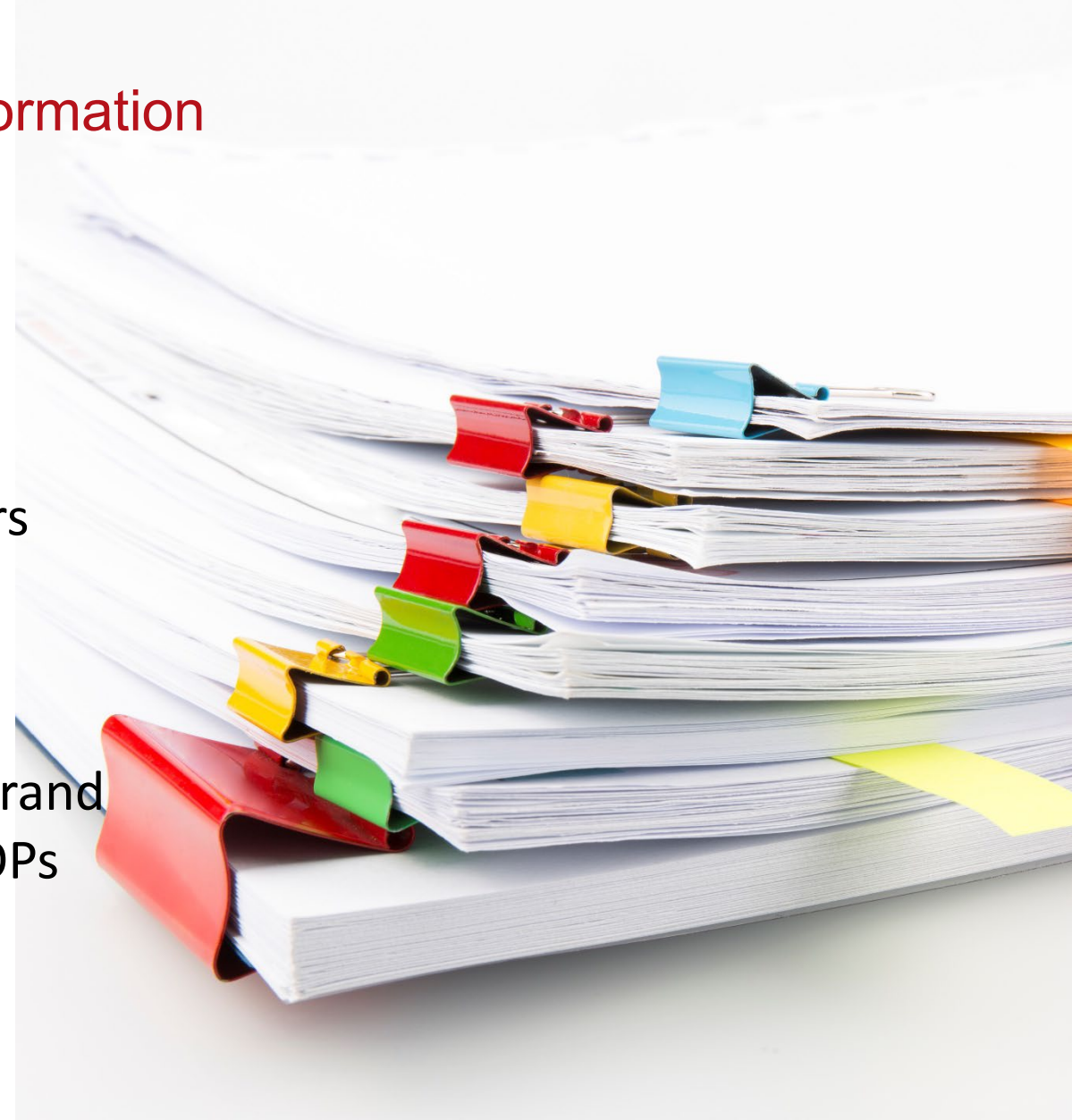
SECURITY

- s230
 - Organizational security plan
 - Submit to the Minister
 - Keep updated plans for at least 2 years

GOOD PRODUCTION PRACTICES

s231 keep batch records, maintain a list of brand names – all documents, registries, forms, SOPs supporting sanitation program

RETENTION PERIOD IS 2 YEARS



Part 11 Retention of Documents and Information

SYSTEM OF CONTROL FOR RECALLS

- s235
 - MUST retain documents for 2 years

GOOD PRODUCTION PRACTICES

s231 keep batch records, maintain a list of brand names – all documents, registries, forms, SOPs supporting sanitation program

KEY INVESTORS

s241 key investors names and addresses

RETENTION PERIOD IS 2 YEARS

Part 12 – Reporting & Disclosure

s242

- MUST be provided in the form and manner specified in the document:

"FORM AND MANNER REQUIREMENTS – Documents Provided to the Minister for the Purposes of the Cannabis Act"

s244

- 60-day written notice before making available a new product
 - Class of cannabis product (i.e. topical)
 - Description and brand name
 - Date on which the product is expected to be available

Part 12 – Reporting & Disclosure

Information related to promotion

s245

- The amount of money spent in a give calendar year on promotion directed at consumers; and type of promotion
- The amount of money spent in a given calendar year on indirect promotion
- Reported annually by March 31st

Part 12 – Reporting & Disclosure

Theft or loss of cannabis

s246

- Theft or Unexplained Loss
 - Notify police within 24 hours
 - Notify the Minister within 10 days

Part 12 Reporting and disclosure

Voluntary Recall

s247 Provide the Minister with a document BEFORE commencing a recall:

- Description of the product
- Number of each lot, and the lot of cannabis used
- The name and address of each person who produced or packaged/labelled the cannabis
- The reason for the recall
- Quantity sold or distributed
- Quantity remaining in possession of the holder
- The number of persons to which the holder sold the product in Canada – and sales period
- The manner in which the recall is to be carried out
- Contact info of person responsible for the recall
- Provide Minister written report within 30 days with results and preventative measures

Part 12 – Reporting & Disclosure

Adverse Reaction

s248 Provide the Minister with a detailed written report within 15 days
And prepare an annual summary report that contains a concise and critical analysis of all adverse reactions to the product that the holder became aware of during the previous 12 months.

RETAIN RECORDS FOR AT LEAST 25 YEARS

- ***adverse reaction*** means a noxious and unintended response to a cannabis product.
- ***serious adverse reaction*** means a noxious and unintended response to a cannabis product that requires inpatient hospitalization or a prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.

CANADIAN ENVIRONMENTAL PROTECTION ACT



Ingredients and CEPA

- Circumstances for Granting Waivers Pursuant to Section 147 of the Act, Regulations Prescribing (SOR/2010-138)
- Environmental Emergency Regulations (SOR/2003-307)
- Masked Name Regulations (SOR/94-261)
- Microbeads in Toiletries Regulations (SOR/2017-111)
- **New Substances Fees Regulations (SOR/2002-374)**
- **New Substances Notification Regulations (Chemicals and Polymers) (SOR/2005-247)**
- New Substances Notification Regulations (Organisms) (SOR/2005-248)
- Ozone-depleting Substances and Halocarbon Alternatives Regulations (SOR/2016-137)
- Persistence and Bioaccumulation Regulations (SOR/2000-107)
- Products Containing Mercury Regulations (SOR/2014-254)
- Prohibition of Certain Toxic Substances Regulations, 2012 (SOR/2012-285)
- Release and Environmental Emergency Notification Regulations (SOR/2011-90)
- Storage Tank Systems for Petroleum Products and Allied Petroleum Products Regulations (SOR/2008-197)

Chemicals Management Plan

Domestic Substance List (DSL)	Revised in Commerce List
Significant New Activity notices	Ministerial Conditions
Section 71 Mandatory Surveys	DSL Inventory Update (every 4 years)
List of Toxic Substances	Import/Export Controls
Categorization status	

Each ingredient in each formulation should be assessed for DSL, R-ICL, SNAC, MC, Toxic and controls status

New Substance Notifications

Substance Type	NSN Schedule	Explanation	NSN Trigger Quantity (kg)	# days review period
Chemical or biochemical	1	Special Category	1,000	30
	4	Not on NDSL	100	5
		On NDSL	1,000	30
	5	Not on NDSL	1,000	60
		On NDSL	10,000	60
		On NDSL high release/exposure	10,000	75
	6	Not on DSL	10,000	75
Polymer of biopolymer	3	Special Category	10,000	30
	9	All polymers	1,000	30
	9 Final	Reduced Regulatory Requirement (RRR)	1,000	30
	10	Non RRR on NDSL or all reactants on DSL/NDSL	10,000	60
		Non RRR on NDSL or all reactants on DSL/NDSL high release / exposure	50,000	60
	11	Non RRR not on NDSL and not all reactants on the DSL/NDSL	10,000	60
Organisms	1 to 5	Dependent on type of organism and containment requirements	VARIES	30-120

Workplace Hazardous Materials Information System

Cannabis topical **ingredients are not exempt**, only finished cannabis topicals are exempted

Ingredient suppliers play an important role by providing:

- Properly labeled hazardous products
- Transmitting a compliant safety data sheet

Competency based training requirements for ingredient users:

- Understand label
- Understand the Safety Data Sheet
- Understand the hazards of the products being handled and used

Packaging and Labelling requirements

A label must be affixed to the outer and inner packages of cosmetic products to assist consumers make informed decisions.

Package contents and potency



ENFORCEMENT

Cannabis Act

Part 1 Offences

(2) Subject to section 51, every person that contravenes subsection (1)

(a) is guilty of an indictable offence and is liable

(i) in the case of an individual who is 18 years of age or older, to **imprisonment for a term of not more than five years less a day,**

(ii) in the case of a young person, to a youth sentence under the Youth Criminal Justice Act, or

(iii) in the case of an organization, to a fine in an amount that is in the discretion of the court; or

(b) is guilty of an offence punishable on summary conviction and is liable

(i) in the case of an **individual who is 18 years of age or older, to a fine of not more than \$5,000 or imprisonment for a term of not more than six months,** or to both,

(ii) in the case of a young person, to a youth sentence under the Youth Criminal Justice Act, or

(iii) **in the case of an organization, to a fine of not more than \$100,000.**

Part 2 Ticketable Offences

Part 10 Administrative Monetary Penalties (AMPs)

(2) Instead of paying the amount of the penalty set out in the notice, the person named in the notice may, in the time and manner specified in the notice,

(a) if the amount of the penalty set out in the notice is \$5,000 or more, request to enter into a compliance agreement with the Minister that ensures the person's compliance with the provision or the order to which the violation relates; or

(b) request a review by the Minister of the acts or omissions that constitute the alleged violation or of the amount of the penalty.

Cannabis Act

Part 2 Ticketable Offences

- (4) For the purpose of paragraph (3)(c), the amount is
- (a) for an offence referred to in any of paragraphs (2)(a) to (h), **\$200 plus a victim surcharge**, calculated in accordance with subsection 737(2) of the Criminal Code, and any applicable administrative fees; and
 - (b) for an offence in respect of a contravention of a provision that is specified in regulations made under paragraph 139(1)(z.6), **the amount specified in those regulations** in respect of that offence plus a victim surcharge, calculated in accordance with subsection 737(2) of the Criminal Code, and any applicable administrative fees.

Cannabis Act

Part 10 Administrative Monetary Penalties (AMPs)

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- (a)** if the amount of the penalty set out in the notice is \$5,000 or more, request to enter into a compliance agreement with the Minister that ensures the person's compliance with the provision or the order to which the violation relates; or
 - (b)** request a review by the Minister of the acts or omissions that constitute the alleged violation or of the amount of the penalty.

Offences and Punishment

Provisions for **contraventions**

- Minimum fines and prison time
- First and subsequent offences
- Criminal liability of corporations, officers and directors
- Offences by employees

Other considerations Occupational Health and Safety legislation

CONCLUSION & THANK YOU





Chemical Supply Chain Management Programs (CSCM)

CSCM Program Rebates for Today's Attendees:

*\$100.00 off the tuition cost of attending any of the following CSCM à la carte courses:

- Canadian Environmental Protection Act (4 lessons)
- Active Pharmaceutical Ingredients Importing
- Safe Food for Canadians Regulations
- Cosmetic Regulations

*10% off any other CSCM course of choice

Visit: www.cscm-edu.com for information about CSCM diploma programs

Contact RDC directly: 905-332-8777 or jennifer@rdcanada.ca



RDC | DRC

Thank you for your attention



www.rdcandada.ca

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