



Chemical Trade Secret Requirements: Jurisdictional Overview

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AGENDA

1. Concept of Chemical Trade Secrets or CBI

2. Major Jurisdictional Examples

- US, EU, China, Canada

3. Q & A



KEY CONCEPTS

What is a Trade Secret or Confidential Business Information (CBI)?

1. CBI > Trade Secret
2. Trade secret has strict legal criteria for secrecy and value
3. Trade secret has independent economic value
4. Trade secret is an intellectual property
5. CBI is non-public info that may or may not have direct commercial value

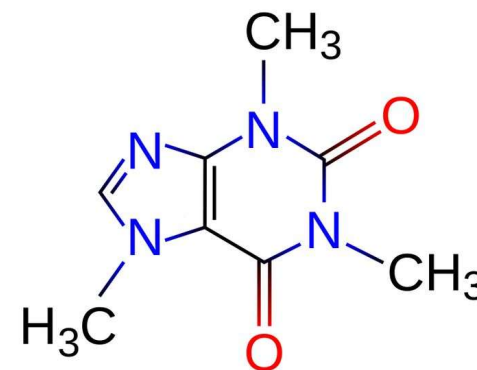
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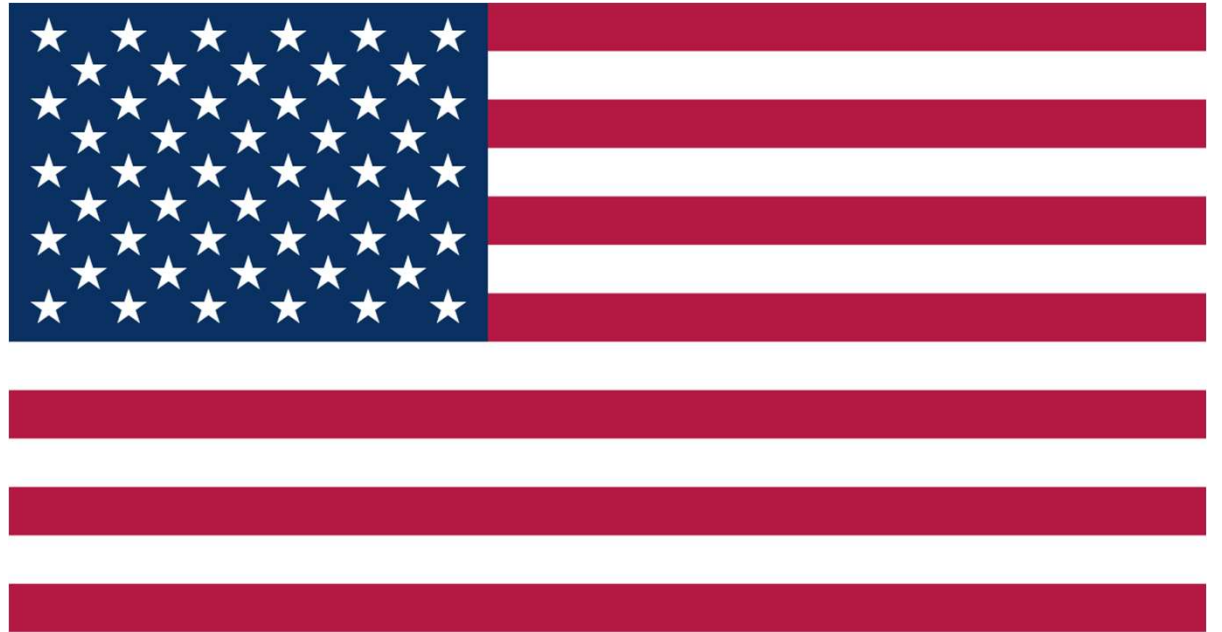
KEY CONCEPTS

What can be generally protected as trade secrets under chemical regulations?

1. Specific chemical identity, formulas
2. Ingredient compositions
3. Production and import volumes
4. Sales data
5. Commercial/financial data
6. Use and function info



**United
States**



PROTECTION UNDER US TSCA



- Toxic Substances Control Act (TSCA) Section 14 is the legal framework for claiming CBI protection re: trade secrets, such as specific chemical identities (e.g., CAS RN, specific chemical name (IUPAC name), specific molecular formula).
- Submitters must identify CBI elements, certify claim validity, justify confidentiality, and provide sanitized public copies.
- Certain info does **not** need to be substantiated under §14(c)(2): manufacturing processes, marketing and sales data, supplier or customer identities, mixture composition, use and function, production or import volumes, pre-commercial chemical identity.

PROTECTION UNDER US TSCA



- TSCA limits what qualifies as CBI and allows exceptions for emergencies and access by responders or medical personnel.
- Health and safety studies typically **cannot** be protected as CBI.
- Companies must proactively manage and monitor claims to maintain confidentiality and comply with TSCA requirements.

PROTECTION UNDER US TSCA

- US EPA regulation in 40 CFR 703.5 lists substantiation requirements for specific chemical identity – for listing on the confidential portion of the TSCA Inventory with a generic chemical name:
 - 1) How the disclosure of information is likely to cause substantial harm to the competitive position.
 - 2) Reasonable measures taken to protect the confidentiality.
 - 3) No disclosure under any other Federal law.
 - 4) Explain that the info is not readily discoverable through reverse engineering.
 - 10 substantiating questions to answer via CDX



PROTECTION UNDER US TSCA

- Generic Naming Guidelines
 - Companies must supply generic chemical names revealing general structural info without disclosing protected identities as per EPA guidance.
- EPA periodically reviews confidentiality claims and may deny insufficient claims, leading to public disclosure requirements.
- With the 2016 TSCA amendment, the chemical identity CBI protection lasts **10 years** and must be renewed periodically via CDX.



PROTECTION UNDER US TSCA



- **Denial and Public Disclosure**

- When EPA denies claims, companies get advance notice to withdraw or adjust submissions before public disclosure to maintain compliance.

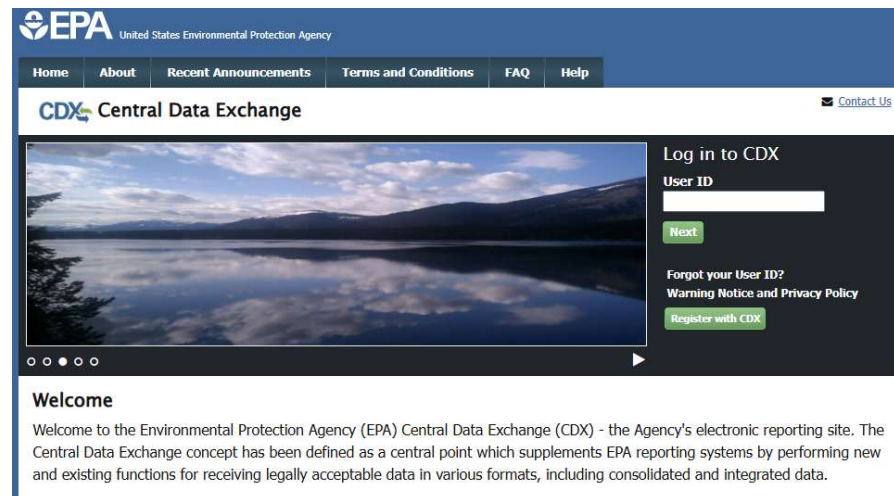
- **Transparency and Accountability**

- EPA posts expiring claims and determination statistics online to promote transparency and ensure industry compliance.
 - The first set of chemical identity CBI expiration occurring in June 2026.

PROTECTION UNDER US TSCA



- **How to renew the chemical identity CBI via CDX**
 - Go to <https://cdx.epa.gov/>
 - Log in and resubstantiate your CBI claim in the appropriate section.
 - See <https://www.epa.gov/tsca-cbi/cbi-claim-expiration> for updates.



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PROTECTION UNDER US OSHA HCS



- Specific chemical identities (e.g., CAS RN, specific chemical name (IUPAC name), specific molecular formula) and exact ingredient compositions may be masked in SDSs and labels.
- No formal approval process. Claim trade secrets on Section 3 of the SDS.
- For mixture composition, OSHA mandates the narrowest practicable concentration % ranges on SDSs, explicitly forbidding overly broad ranges.
- Even though the protection may be perpetual, companies must maintain records supporting trade secret claims for regulatory review and compliance practice.

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European Union



PROTECTION UNDER EU REACH



- Under Article 119, may request confidentiality of the chemical identity (IUPAC name and all associated identifiers, such as CAS RN and molecular formula) from ECHA, if hazardous under CLP and “new” or non-phase-in substance or intermediate/in-product and process R&D/scientific R&D chemical.
- Justification elements:
 - Explain the need for confidentiality
 - Demonstrate the commercial/financial interest
 - Explain the potential harm if disclosed

PROTECTION UNDER EU REACH



- Must provide a public name to:
 - Support public understanding
 - Masks only truly confidential structural features
 - May need to do “masking justification” if multiple levels of redaction are applied.
- Submit the claim and justification via REACH-IT system, and pay the fees.
- CBI protection for the chemical identity lasts **6 years**.



PROTECTION UNDER EU CLP



- Article 24 of CLP allows use of an alternative chemical name on the GHS labels and SDSs to claim trade secret protection.
- An alternative name is only granted if:
 - 1) No established workplace exposure limit
 - 2) Fall under certain GHS classification categories:
 - Any physical hazard
 - Acute toxicity (Category 4)
 - Skin corrosion/irritation (Category 2) or Serious eye damage/irritation (Category 2)
 - STOT SE (Category 2 or 3) or STOT RE (Category 2)
 - Chronic aquatic toxicity (Category 3 or 4)

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PROTECTION UNDER EU CLP



- **Request Dossier Content:**
 - Provide the CBI chemical identity details to ECHA.
 - Propose an alternative name.
 - Justify the business risk and/or intellectual property at risk.
 - Evidence that the alternative name provides sufficient info to protect health and safety in the workplace.
- Submit the dossier with SDS via REACH-IT, pay the fee, and wait for the ECHA decision (takes about six weeks).
- This CBI protection may be perpetual.

PROTECTION UNDER EU REACH & CLP



- Use REACH-IT portal:

- Go to <https://reach-it.echa.europa.eu/reach/>.
- Register an EU-based user (a company or Only Representative).
- Put together a REACH Article 119 dossier or CLP Article 24 dossier
- Substantiate and provide a public name for the chemical
- Don't forget to pay the fee.

A screenshot of the REACH-IT login page. The page has a blue and yellow header with the ECHA logo. Below the header, there is a "WELCOME" message and a prompt to enter login information. The login form includes fields for "Username *" and "Password *", each with a "Forgot" link. There are two main login buttons: "Login with 'ECHA Account'" and "Login with 'EU Login'". Below these, there is a link for "Don't have an account? Create an ECHA account" and a link for "What type of account do I need?". A "Need help?" link is also present in the bottom left corner of the page.

People's Republic of China



PROTECTION UNDER MEE ORDER 12



- Ministry of Ecology and Environment of China (MEE) allows CBI protection at the time of initial chemical registration or filing.
- Lasts **only 5 years** and renewable **once** for another **5 years (Max 10 yrs)***.
- **Steps to claim CBI protection**
 - 1) Select the CBI option in MEE's New Chemical Substance Online Registration System (e.g., chemical name, CAS RN, structural formula).
 - 2) Provide a generic chemical name for public disclosure.

PROTECTION UNDER MEE ORDER 12



3) Submit justification materials

- Evidence of the chemical's commercial value
 - Proof that the info is not already in the public domain (e.g., patents or chemical databases)
 - Details on the measures taken to maintain secrecy
- “Record notifications” involving < 1 metric ton/yr import or production volume are generally exempt from the justification materials.

PROTECTION UNDER MEE ORDER 12



- **Notable limitations**

- Highly hazardous chemicals may be denied protection
- After 5 years, substance to appear on the public Inventory of Existing Chemical Substances in China (IECSC);
- If the registrant does not claim CBI during the initial submission, they **cannot** apply for it later.



PROTECTION UNDER MEE ORDER 12

- Using the National Integrated Online Government Services Platform
 - Go to: <http://zwfw.mee.gov.cn/ecdomain/>
- Navigation:
 - Select the "New Chemical Substances" category.
 - Click on the column titled "13002 New Chemical Substances Environmental Management Registration Certificate Issuance Approval Items".
 - Follow the prompts to enter the "Item Declaration Entrance (New System)" for MEE Order No. 12.
- **Account Requirement:** You must first register a legal entity account. Actions must be through a **Chinese agent** (similar to an "Only Representative" under EU REACH) who handles the login and submission on a foreign company's behalf.



PROTECTION UNDER CHINA GHS GBS



- Notably, GB/T 17519-2013 and GB 15258-2009 allow companies to withhold specific chemical identities and exact concentrations, if they meet certain disclosure requirements.
 - 1) May mask the exact chemical substance name and CAS RN.
 - 2) Must disclose all hazard information on SDS and label, even if an ingredient is a trade secret.
 - 3) Must use a generic chemical name on section 3 of SDS
 - 4) Instead of exact percentages, may provide concentration ranges.
- No formal pre-approval process and **no expiration** of the protection.

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四乙基苯胺	
CAS# 96-03-7	EC# 202-025-4
警告	
 	
引起严重的眼睛刺激。对水生生物有害并且有长期持续影响。	
【预防措施】 避免吸入粉尘/烟雾/蒸气/喷雾/气溶胶。 避免与皮肤直接接触。 避免与眼睛接触。	
【事故响应】 如接触眼睛：用大量水冲洗至少15分钟。如接触皮肤：用大量水冲洗。脱去污染衣物。继续冲洗。 如吸入：移至新鲜空气处。如呼吸困难：移至新鲜空气处。如发生窒息：立即就医。	
【安全储存】 无。	
【废弃处置】 本品：按照当地法规进行回收处理。	
供应商：XXXXXXXXXXXX	请参阅化学品安全技术说明书
地址：XXXX	电话：XXXX
传真：XXXX	邮编：XXXX
	化学事故应急咨询电话：

Canada



PROTECTION UNDER CEPA 1999



- The specific chemical identity (e.g., CAS RN, specific chemical name (IUPAC name), specific molecular formula) may be hidden from the public portion of the DSL Inventory by:
 - 1) Submitting a written request under section 313 of the Act, which includes specific reasons supporting the request, such as proving the information is indeed a trade secret and disclosure would cause financial or competitive loss
 - 2) Proposing a masked name
 - 3) Completing the New Substances Notification (NSN) package with clear substantiation of CBI claims
 - 4) Paying the fees

PROTECTION UNDER CEPA 1999

- Chemical identity CBI claims are reviewed every **10 years**.
- If the Environment and Climate Change Canada (ECCC) intends to disclose the identity,
 - It must publish a notice in the Canada Gazette at least 60 days before disclosure.
 - This allows the stakeholder to file comments to maintain protection.
- Renewal is permissible for an additional 10 years by updating the claim and resubstantiating upon receiving notice



Environment and
Climate Change Canada
Environnement et
Changement climatique Canada

PROTECTION UNDER CEPA 1999

- **Renewal Portal**

- Use Environment and Climate Change Canada's Single Window (SWIM): <https://ec.ss.ec.gc.ca/>
- Once logged into SWIM, select the Chemicals Management Plan (CMP) module to create a submission.

- Again, 60 days to respond to the Canada Gazette notice and validate the CBI claim.



PROTECTION UNDER HMIRA

- The Hazardous Materials Information Review Act (HMIRA) allows masking specific chemical identities on GHS SDSs and labels.

- **Process**

- 1) Prepare justification

- Demonstrate that the chemical identity is a trade secret: the info is not publicly available, reasonable steps to keep confidentiality taken, the disclosure would cause material financial loss or loss of competitive advantage.

- 2) Complete the application

- Provide specific chemical identity info to Health Canada and propose a generic chemical name



PROTECTION UNDER HMIRA

- **Process (cont'd)**
 - 3) Submit supporting documents, including SDSs and product labels.
 - 4) Pay the fees.
- **Post-submission requirements**
 - Once the application is approved, obtain an HMIRA Registry Number (RN).
 - Display HMIRA RN and date of filing (or date granted) on the SDS and label in place of the chemical identity.
 - Valid for **3 years** and must be refiled to maintain the protection.



PROTECTION UNDER HMIRA



- **CBI Online Application Form**

- Go to <https://healthycanadians.gc.ca/apps/radar/HPP-PPD-0001.08.html> (Claim for Exemption under the Hazardous Materials Information Review Act - Application Form)
- Fill out the application and provide the required supporting documentation (justification, generic chemical name, SDS, and labels).
- Submit the completed application to Health Canada and pay the fee (Currently, 2,254.99 CAD per claim).



EMERGING TRENDS

- Globally, authorities are limiting CBI claims by requiring more substantiation and setting expirations.
- Companies have “over-claimed” CBI protection for many years.
- Regulators are recognizing the advancement of analytical chemistry and reverse engineering capabilities.
- Public interest groups demand more transparency.
- It is debatable whether CBI protection or expiration fosters scientific innovation.



SUMMARY

1. Important concepts:
 - Trade secret and confidential business information (CBI)
 - Specific chemical identity
 - Chemical ingredient composition
 - Substantiation
2. Four major jurisdictions discussed have similar (with subtle differences) substantiation requirements.
3. The key is **not** to miss the expiration dates if applicable.

SUMMARY (CONT'D)

Jurisdiction	Chemical Inventory Reg.
US	<ul style="list-style-type: none"> Substantiate: <ol style="list-style-type: none"> Substantial harm to the competitive position. Reasonable measures taken to protect the confidentiality. No disclosure under any other Federal law. The info is not readily discoverable through reverse engineering. Renew every 10 years.
EU	<ul style="list-style-type: none"> Substantiate: <ol style="list-style-type: none"> Need for confidentiality. Commercial and financial interest. Potential harm if disclosed. Expires in 6 years.

Jurisdiction	Chemical Inventory Reg.
China	<ul style="list-style-type: none"> Substantiate: <ol style="list-style-type: none"> Evidence of chemical's commercial value. Info is not already in the public domain. Measures taken to maintain secrecy. Expires in 5 years and renewable only once for another 5 years*.
Canada	<ul style="list-style-type: none"> Substantiate: <ol style="list-style-type: none"> Info is indeed a trade secret. Financial interest. Competitive advantage loss if disclosed. Renew every 10 years.

SUMMARY (CONT'D)

Jurisdiction	GHS Reg.
US	<ul style="list-style-type: none"> • No formal approval process. • No substantiation. • Simply claim CBI on SDS. • Use generic chemical names. • No expiration.
EU	<ul style="list-style-type: none"> • Seek approval for: <ol style="list-style-type: none"> a) Alternative chemical name. b) Justifying the business risk and/or intellectual property at risk. c) Evidence that the alternative name provides sufficient info to protect health and safety. • No expiration.

Jurisdiction	GHS Reg.
China	<ul style="list-style-type: none"> • No formal approval process. • No substantiation. • Simply claim CBI on SDS. • Use generic chemical names. • No expiration.
Canada	<ul style="list-style-type: none"> • Substantiate: <ol style="list-style-type: none"> a) Chemical identity is indeed a trade secret. b) Info is not publicly available. c) Reasonable steps to keep confidentiality. d) Material financial loss or competitive advantage loss if disclosed. • Renew every 3 years.

Q & A

