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TRADE SECRETS

Navigating Proprietary Ingredients in Safety Data Sheets

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Thank you for joining us!

In today's webinar, Rennee will be exploring the complexities of Safety Data Sheets with focus on proprietary ingredients and trade secrets.

This discussion is designed for professionals in chemical, manufacturing, and regulatory compliance sectors.

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AGENDA: TODAY’S KEY TOPICS

1. UNDERSTANDING PROPRIETARY INGREDIENTS
2. NAVIGATING TRADE SECRETS
3. COMPLIANCE STRATEGIES
4. PRACTICAL EXAMPLES
5. Q&A

Understanding Proprietary Ingredients

What are Proprietary Ingredients?

Definition: Ingredients in a product whose chemical identity is protected as a trade secret.

Significance in SDS:

- Protects intellectual property
- Ensures competitive advantage

Types of Proprietary Information:

- Chemical names
- Concentrations
- Chemical identifier (CAS/EC #)

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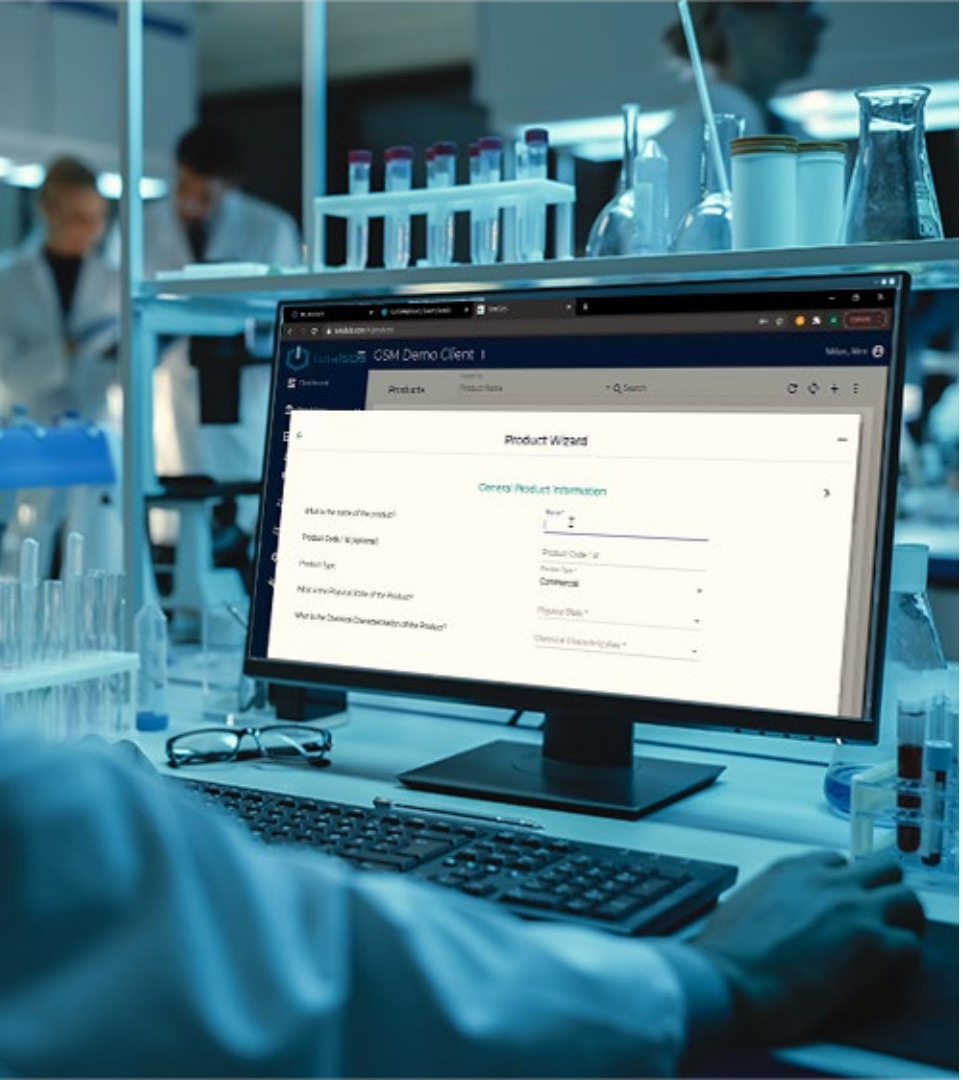

Navigating Trade Secrets When Authoring SDSs

The allowance for withholding ingredient identity as Trade Secret or Confidential Business Information in Section 3 of the SDS is determined by Jurisdiction Specific Regulations.

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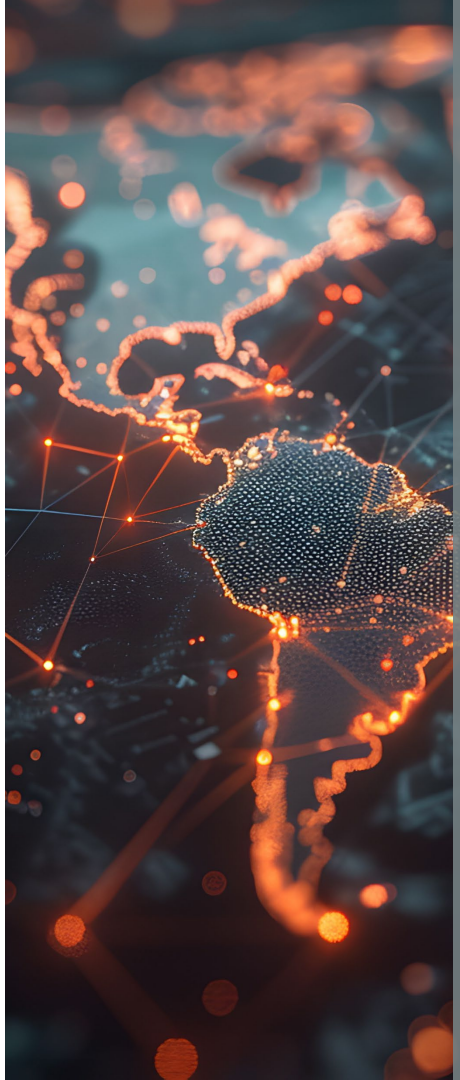
Trade Secret Definition:

- Information that has independent economic value
- Not generally known or readily ascertainable
- Subject to reasonable efforts to maintain secrecy

Relevant Regulations:

- OSHA Hazard Communication Standard (HCS)
- REACH Regulation (EU)
- Canada Hazardous Products Regulation (HPR)



Legal and Regulatory Frameworks

➢ According to OSHA 29 CFR 1910.1200 (HAZCOM 2012)

Requirements

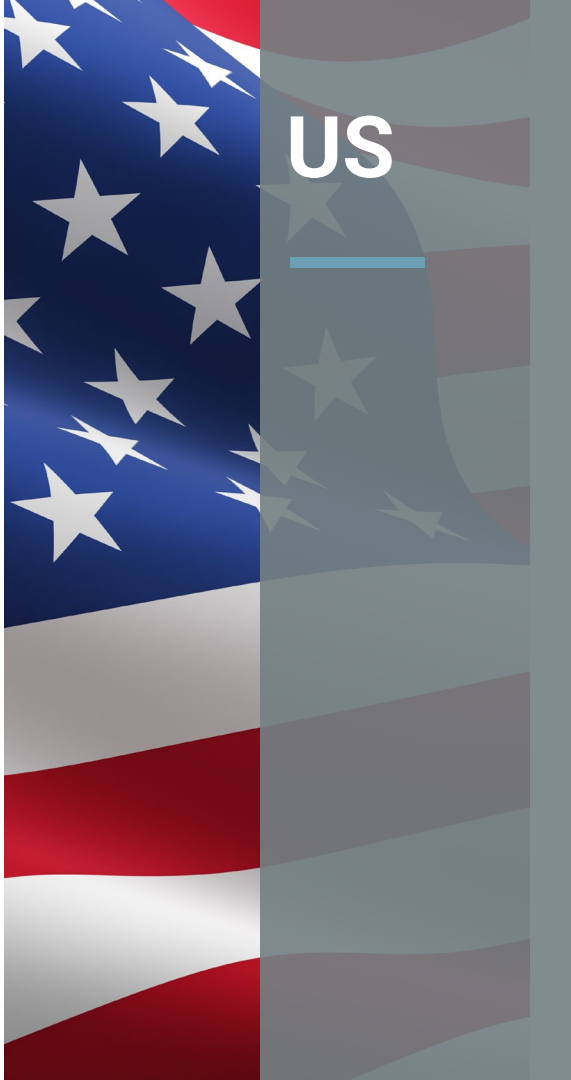
Disclosure of name, CAS number and concentration or concentration range of ingredients that are

- hazardous and
- present above the “concentration limit” per hazard classification and
- Contribute to the product’s hazard classification or have Occupational Exposure Limits

Trade Secret Claim

Allows for non-disclosure of ingredient CAS numbers, chemical name and exact concentration if a trade secret claim is made in accordance with trade secret in accordance with paragraph (i) of 29 CFR §1910.1200.

However, any hazard classifications resulting from “trade secret” ingredients must still be assigned to the product.



➢ According to Canadian Hazardous Products Regulations (SOR/2015-17)

Requirements

Disclosure of chemical name, CAS number and exact concentration of ingredients that are

- hazardous and
- present above the “concentration limit” per hazard classification

Confidential Business Information

Prescribed Concentration Range may be used for “Trade Secret” Claim

0.1 – 1%	15 – 40%
0.5 – 1.5%	30 - 60%
1 – 5%	45 - 70%
3 – 7%	60 – 80%
5 – 10%	65 – 85%
7 – 13%	80 – 100%
10 – 30%	

- **According to Canadian Hazardous Products Regulations (SOR/2015-17)**

Confidential Business Information

A “Claim for Exemption” may be filed with Health Canada.

If approved, the chemical name and CAS number may be substituted with the HMIRA Registry Number assigned by Health Canada.

➢ According to EU CLP and REACH Regulation Requirements

Disclosure of

- Name
- Concentration or concentration range
- Hazard classification(s)
- At least one Product identifier (EC Number, CAS Number or REACH Registration Number)
- Specific Concentration Limits*
- M-factor*
- Acute toxicity estimate for the substance*

**If available, as provided in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or as determined in accordance with Annex I to that Regulation.*

For ingredients hazardous and

- present above the “concentration limit” per hazard classification or lower (for some ingredients with Specific Concentration Limits, M Factors, etc.) and/or
- have Occupational Exposure Limits

➢ According to EU CLP and REACH Regulation

Confidential Business Information

- A concentration range may be used instead of exact concentration.

  As long as the hazard classification of the product is aligned with the high end of the concentration range.

- Application for “Alternative Chemical Name” under Article 24 of REACH Regulation.

  Note: Substances with Occupational Exposure Limits do not qualify for “Alternative Chemical Name” Application.

➢ **According to Japanese Industrial Standard JIS Z 7253:2019 and Cabinet Order No. 265 of ISHL (Industrial Safety and Health Law) and Amendments**

Requirements

JIS Z 7253:2019

Disclosure of name and concentration or concentration range of ingredients that are

- hazardous and
- present above the “concentration limit” per hazard classification
- and contribute to the hazard classification of the mixture.

Disclosure of ingredient name and concentration or concentration range of

- Respiratory sensitizers > 0.1%w/w
- Skin sensitizers > 0.1%w/w
- Carcinogens, category > 0.1%w/w
- Reproductive toxins, category 1 and category 2 > 0.1%w/w
- Specific target organic toxins, category 2 >1%w/w

- **According to Japanese Industrial Standard JIS Z 7253:2019 and Cabinet Order No. 265 of ISHL (Industrial Safety and Health Law) and Amendments**

Requirements

ISHL Cabinet Order No. 265

Disclosure of name and exact concentration of ingredients that are

- present above the “concentration limit” per hazard classification
- and are listed in Table 9 of Cabinet Order No 265

➢ Confidential Business Information

JIS Z 7253:2019

Use of generic chemical name.

Exceptions

- Respiratory sensitizers > 0.1%w/w
- Skin sensitizers > 0.1%w/w
- Carcinogens, category > 0.1%w/w
- Reproductive toxins, category 1 and category 2 > 0.1%w/w
- Specific target organic toxins, category 2 >1%w/w

ISHL Cabinet Order No. 265

Non-disclosure on SDS of Regulated Ingredients that are considered "Confidential Business Information".

However, the information must still be delivered to the recipients by other means, possibly under non-disclosure agreement.

Exceptions

- Ingredients with Occupational Exposure Limits

CN

- **According to NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA GB/T 17519-2013**

Requirements

Disclosure of name, CAS number and concentration or concentration range of ingredients that are

- hazardous and
- present above the "concentration limit" per hazard classification

Confidential Business Information

Allows for non-disclosure of ingredient CAS numbers and real name to protect confidentiality.

However, any hazard classifications resulting from "hidden" ingredients must still be assigned to the product.

In accordance with GB/T 17519-2013, 3.3.2 (f)

Compliance Strategies

Balancing Compliance and Confidentiality

Approaches for Regulatory Compliance:

- Properly classify proprietary ingredients
- Use generic descriptors and concentration ranges when allowed
- Justify the need for confidentiality
- Complete CBI (Confidential Business Information) applications and fees, when necessary

Best Practices:

- Regularly review and update SDS
- Maintain thorough documentation
- Conduct internal audits to ensure adherence

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Example 1:
A company needs to keep the exact concentration (8%) of an ingredient proprietary in a hazardous product going into both Canada and the EU.

Solution:

- **Canada SDS:** Apply a concentration range that best fits the exact concentration, from the list of the HPR's prescribed concentration ranges.
  - Options: 5-10% and 7-13%

- **EU SDS:** Apply a concentration range, ensuring that the product's classification is still reflected with the high end of the range applied.

Real World Scenarios

Example 1

Example 2:
A company needs to list a proprietary ingredient (Ingredient A) on an SDS, while ensuring compliance with both OSHA and REACH requirements for a product. Ingredient A is hazardous, has Occupational Exposure Limits (OELs) for both the US and EU, and is present in the formula at 15%.

Solution:

- **US SDS:** Ingredient A must appear on the SDS. But its name and CAS can be masked, and a concentration range can be applied. You then must place a statement on the SDS that communicates that part of the composition is being withheld. To do this, you must be able to justify the trade secret claim for this ingredient.

- **EU SDS:** Ingredient A must appear on the SDS. A concentration range can be displayed rather than the exact concentration of 15%. However, you cannot mask the name or CAS/EC number. You may apply for an alternative chemical name, which includes a fee. This will allow you to use a generic chemical name, if approved, instead of the exact ingredient name.

Real World Scenarios

Example 2

Q&A

Engage with Our Experts

Interactive Q&A:

- Submit your questions via the chat feature
- Our panel of regulatory experts will address your queries live

Any questions we are not able to address during the presentation will be answered and provided to you after the webinar.

Key Takeaways

- Understanding and handling proprietary ingredients is crucial for SDS authoring.
- Balancing regulatory compliance with the protection of trade secrets is achievable with the right strategies.
- Practical knowledge and real-world examples help in applying best practices.

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How TotalSDS can keep you compliant

TotalSDS's regulatory department performs research and reviews regulatory changes on a global scale. Our company will directly notify software customers when regulatory updates that impact the TotalSDS software become available.

The software easily incorporates changes for a seamless transition to the new standards.

We are available to consult with customers on the updates and what those changes mean for your products and SDSs.

The TotalSDS regulatory team offers SDS authoring and management software solutions, in addition to professional services support and packages.

SIMPLIFYING REGULATORY COMPLIANCE

Thank you for joining us!

Please contact us for a demo: info@totalsds.com or 813-859-5100

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