Keeping it confidential

Navigating the intricacies of the EPA's CBI requirements for PMNs

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Claiming chemical identity as confidential is becoming increasingly difficult, especially in this global market. In the EU, the rules are very stringent and require that all hazardous substances be declared on the safety data sheet (SDS), making it nearly impossible to keep chemical names confidential. In the US, for new chemical substances seeking listing on the Toxic Substances Control Act (TSCA) Inventory, the EPA requires that a detailed, written response to 14 standard questions is submitted along with your confidential business information (CBI) claim.

It is clear that industry is entering a new era, and corporate environmental, health and safety (EH&S), product stewardship and legal staff need to decide whether they proactively declassify substances or try to substantiate confidentiality claims.

In the following article, we will outline best practices for developing an effective CBI strategy that addresses the requirements outlined in TSCA Section 5 at 40 CFR Parts 720 – 725.

Optimising your TSCA PMN

Why do we have to detail trade secrets, the processes, and the means of our products? At high level, we detail this information in prior pre-manufacturing notice (PMN) submissions to provide the requisite information and subsequently protect CBI.

For TSCA Section 5, submitting firms are allowed to go through the PMN process providing generic names and uses and sanitising their documents provided in the submissions so that chemical identity, uses, volumes, processes, names of submitters and signatories, percentage concentration, test studies and results, customer names and toll manufacturers can all be held confidential.

On pages 1–13 of the PMN form, and on any and all supporting documentation, the regulations allow one to denote and redact much of the required data and information as CBI. The electronic documents that EPA CDX generates automatically include a sanitised version for placement in the public record. As best practice, PMN preparers and submitters are well advised to follow the guidance that the EPA provides for both nomenclature of generic names and uses.

On day 91, when the 90-day PMN review period is complete, you can start to manufacture or import your new substance. However, you can claim the right to confidentiality all over again by asserting the necessity and value to one's business by answering a series of substantiation questions during the notice of commencement step (NOC) to the EPA that actually lists the PMN substance on the TSCA 8b Inventory.

Hazcom 2012

Appendix E of the new regulatory standard focuses on trade secrets, with the following highlights:

» allowable if CBI claims can be supported by substantiation;
» hazardous data and information and effects are disclosed due to health hazards;
» SDS must include statement that trade secrets are being claimed and by what means (withholding specific chemical identity and or exact percentage concentrations);
» in emergency situations, CBI data and information are to be made available to health officials and first responders, without the existence of non-disclosure agreements (NDA);
» others, in non-emergency scenarios, can request the revealing of trade secrets through a letter and signing an NDA, which chemical manufacturers can refuse to do. The Occupational Safety and Health Administration can then cite the manufacturer and impose restrictions on them for refusal; and
» under Hazcom 2012, process information remains protected as CBI.

Impact on business

Almost every business involved in the chemical industry is impacted by TSCA regulations to some degree (with some exceptions among food, drug, cosmetic, nuclear and pesticides companies). Raw materials, intermediates and finished goods are all regulated by TSCA. Full lifecycle, or cradle to grave, compliance is an essential component of TSCA, and most manufacturing/importing, processing and disposal activities are TSCA regulated.

Penalties for non-compliance can include civil litigation and monetary settlements, criminal prosecution, fines, damage to a company's brand or reputation, and negative impact on a company's ability to do business. Wilful violators can face imprisonment.

With this in mind, it is wise to know the law, seek mitigations where possible from exemptions and exceptions, follow its rules and regulations with vigour, and robustly document one's compliance. But perhaps most important, is to do all that is possible during the R&D phases of any new product to include regulatory compliance policies and strategies in the design and execution. SDS authors and managers need to collaborate to ensure a unified CBI strategy and to ensure CBI is protected. It is more than a truism "that it is far less costly to do it right the first time than to spend extended time and effort afterwards" – it is good business!

The first three substantiation questions ask the following:

» is your company asserting this CBI claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim;

» for what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point; and

» has the information that you are claiming as confidential been disclosed to any other governmental agency or to this agency at any other time? Identify the agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document, reflecting the confidentiality agreement.

But these questions are merely a starting point; other detailed questions aim to provide the EPA with as much information as possible to help evaluate a company's motivation and basis for claiming confidentiality. A full list of questions can be viewed online here.

Optimising the review period

During the review period of both PMN and notice of commencement (NOC), there is often ample opportunity to revisit claims for confidentiality of proprietary data and information. One can even employ the use of CBI as a negotiating tool to see some relief from "outright bans down to volume triggers", if submitting firms agree to relinquish their claims of CBI so that the EPA can provide transparency in rulemaking.

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If your product stewards followed best practice, they should have ensured that your PMN included a newly authored SDS in accordance with the Hazcom 2012 standard. This is especially important since the 1 June 2015 deadline for all SDSs and labels to be in conformance is rapidly approaching, and US compliance with the UN Globally Harmonized System (GHS) for chemicals classification is imminent.

In addition, each component should have been carefully documented and classified according to the GHS, as the final mixture being sold for use in the US would have been. And although the hazard communication standard of 29 CFR 1900 changed dramatically, the treatment of trade secrets remains virtually the same. The only significant difference from the 1994 standard is that showing the percentage composition of all hazardous components is now a requirement, and thus withholding the percentage (or technically even using a range rather than the exact percentage) of a component is considered to be a trade secret. Previously, only names and Cas numbers were considered to be trade secrets and could be withheld.

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