Government Affairs
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June 30, 2023

Existing Chemicals Risk Management Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460–0001

Re: EPA Docket No. EPA-HQ-OPPT-2020-0465 Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA)

The American Chemical Society (ACS) is the professional society for chemists, chemical engineers, and workers in the chemistry enterprise across both academic and industrial settings. The ACS's mission is to advance the broader chemistry enterprise and its practitioners for the benefit of Earth and all its people. On behalf of our members, we would like to submit the following comments on the proposed rule regulating methylene chloride.

Safety is a core value of ACS and the Society believes that the practice of chemistry from concept through research, development, manufacture, use, and disposal must be done safely to minimize adverse impacts on human health and the environment. ACS has acted on that belief by advocating for better safety education and training across the chemistry enterprise and through supporting the Green Chemistry Institute which works to promote sustainability, prosperity, and equity across the global chemistry enterprise. ACS is committed to continued support for research and development by universities, industry, government laboratories, and other stakeholders to create safer products, materials, and processes as well as policies, regulations, and incentives that encourage adoption of safer products, materials, and processes.

ACS appreciates the current proposed rule's goal of protecting public health. However, ACS is concerned that the current proposal to regulate methylene chloride, also known as dichloromethane (DCM), fails to account for its use in small scale and particularly academic teaching and research laboratories. Both the EPA (with 40 CFR 262 Subpart K) and OSHA (with 29 CFR 1910.1450) have recognized that regulations aimed at protecting workers in industry do not translate to academic laboratories. As currently structured, the rule would be extremely challenging for academic institutions to implement and would negatively impact research and teaching. The proposed rule is not appropriate for academic laboratories because exposures are low, infrequent, and well managed using existing regulations and engineering controls (e.g. chemical fume hoods).

Academic teaching and research laboratories have several attributes that make the proposed Workplace Chemical Protection Plan (WCPP) difficult to implement.

- Across individual institutions, laboratories are heterogeneous with a range of facilities, use cases and scales, which dramatically increases the challenges of effective ongoing exposure monitoring. Many institutions lack the requisite subject matter experts on staff, such as an

Industrial Hygienist (IH), to implement periodic monitoring. Costs for contracting these services or creating new positions can be significant.

- Personnel tracking of all DCM users in an academic environment with only (relatively) small volumes in use is impractical and would stymie research because researchers would, necessarily, need to contact an IH before working to arrange monitoring or determine that a surrogate sample for that activity already is documented.
- Most laboratories regularly use a variety of volatile organic solvents (VOCs). Monitoring for atmospheric DCM would require sensitive, expensive equipment that would be capable of tracking DCM alone and distinguishing DCM from other VOCs.
- There is tremendous turnover in faculty and students and monitoring new users would be burdensome. The proposed WCPP would require an enormous recordkeeping effort, with Exposure Control Plans, exposure monitoring and control records, training and maintaining "the identity of all other potentially exposed persons whose exposure was not measured but whose exposure is intended to be represented by the area or representative sampling" without a clear indication of who would be responsible for said recordkeeping.
- Large academic institutions can have up to 1,000 laboratories using DCM for a variety of purposes, making recordkeeping and testing for the WCPP burdensome, if not impossible.
- Academic laboratories use small amounts of chemicals on a non-regular basis, and it is unlikely that workers would encounter exposure to DCM for 8-hour time weighted average (TWA). The Methylene Chloride Revised Risk Determination (October 2022) did not consider the use of small quantities in academic laboratories with engineering controls. It is not valid to say that the acute exposure is similar to other industrial laboratory applications.
- In the academic and small-scale laboratory setting, exposure to DCM is controlled by using chemical fume hoods, areas with local exhaust, and other appropriate containment solutions rather than relying on respirators to manage exposure risk.

Given the salient differences between academic laboratories and larger industrial or commercial processes and the unique challenges the proposed rule would create, ACS requests that the proposed rule adopt an alternative Academic Laboratory WCPP that integrates within OSHA's existing regulation of chemical exposures in laboratories i.e., using a Chemical Hygiene Plan (CHP), and not require the additional monitoring and recordkeeping proposed for commercial or industrial research use in the draft. OSHA's lab standard (29 CFR 1910.1450) was specifically written to prevent worker exposure in laboratories where hazardous chemicals are used. Appendix A of the Laboratory Standard, which is based on Prudence Practices in the Laboratory from National Academies Press, provides specific guidance for creating a CHP.

The most recent version of Prudent Practices has specific guidance on working with highly toxic chemicals such as:

- Academic laboratories must use a safer substitute to DCM if one is available for the procedure.
- If not, the smallest quantity necessary for the procedure must be used.
- Stock containers of DCM must always remain closed unless transfer is underway.
- Dispensing and using toxic chemicals such as DCM s in accordance with the institution's CHP [or associated Standard Operating Procedures (SOPs) for a particular process if there are specific hazards not addressed in the CHP]. This specifies controls to be used to prevent or minimize exposures (e.g., transfers are only performed in ventilated enclosures).

- As a substance with a high degree of acute toxicity, DCM is regulated as a particularly hazardous substance under 1910.1450 (e)(3)(viii) of the OSHA Lab Standard. Additional requirements for particularly hazardous substances include, as appropriate:
    - Establishment of a designated area.
    - Use of containment devices (e.g., hood, glove box).
    - Procedures promulgated by the EPA for characterizing hazards and labeling containers with all chemical contents' names are already in place to protect workers who handle and pack hazardous waste from laboratories.
- Recordkeeping requirements are described in 1910.1450 (j)

Compliance with the OSHA Laboratory Standard and a CHP provides an appropriate level of workplace safety for academic laboratories and will promote compliance and safer use of DCM with this cohort where extensive monitoring and recordkeeping is simply not practical. This request is not without precedent as EPA has previously created a separate performance-based standard for hazardous waste generated by academic laboratories (40 CFR § 262.200-216).

In addition to an Academic Laboratory WCPP, ACS strongly urges against the total phase out proposed in section 751.111(d) of the proposed rule. DCM has unique chemical and physical properties, creating situations where there are no substitutes for discovery research – specifically in chromatography and separation. In keeping with the tenets of green and sustainable chemistry, ACS supports academic researchers striving to reduce these exceptions, but DCM should remain accessible for these cases.

Lastly, please note that ACS encourages academic institutions to educate and train scientists, engineers, workers, and K-16 teachers to use risk-based safety management practices. ACS initiatives include:

- The ACS Center for Lab Safety promotes the safe, ethical, responsible, and sustainable practice of chemistry through easy access to authoritative tools, education, training, and guidance.
- ACS Guidelines for Chemical Laboratory Safety in Academic Institutions guides faculty and staff as they develop, enhance, and assess the safety education of their students.
- The ACS initiative, "Creating Safety Cultures in Academic Institutions" aims to strengthen the safety culture in two- and four-year undergraduate, graduate, and postdoctoral programs.
- The ACS Green Chemistry Institute works to inform the chemistry enterprise about more benign alternatives to commonly used harmful substances through resources like peer-reviewed publications, special topic reports, and the Pharmaceutical Roundtable Toolbox, available at www.acsgcipr.org.

As EPA considers this and other rules concerning specific chemicals, ACS welcomes any opportunity to collaborate with EPA on chemical safety programs to educate and train scientists, engineers, workers, and K-16 teachers to use risk-based safety management practices and the best safety practices for purchase, storage, handling, use, and disposal of materials of concern.

Attached are two appendices with further information to supplement this written comment. Please do not hesitate to contact me (c_truppgil@acs.org; 202.872.4098) if ACS can be of further assistance.

Respectfully Submitted,

Caroline Trupp Gil

Appendix A: Details on the Cost of the Proposed Rule to Academic Institutions

Number of Affected Academic Institutions

- Over 1,000 universities in the U.S. offer a degree in chemistry. DCM is a common solvent that could be used in research and teaching at any of them, and perhaps nearly all of them.
- A small university might have 5-20 research users annually. A large institution might have 1,000 laboratories where DCM could be in use. A single laboratory could have several different types of uses.
- DCM is currently used routinely in experiments in teaching laboratories. Here faculty can work to eliminate experiments or utilize micro scale.
- At smaller and public institutions, resources and staffing for safety programs is already severely constrained.

Prerequisites

- Most universities do not have an Industrial Hygienist on staff, so these services would need to be contracted. A typical contract would cost $10,000 or more. A new position could be in the $75K–100K range.
- Most universities do not have centralized purchasing or receiving, so a system would need to be created to track incoming purchases to identify new and current DCM users.

Administrative Costs

- Institutions would need to track each individual for whom a surrogate exposure would be used, and identify which activity, space, duration, and equipment applies to each person. This would be an ongoing, monumental task made particularly difficult by the frequent turnover in academic settings.
- Training would be required to ensure that samples are collected correctly.
- Staff would be necessary to track users, and review and file monitoring results.

Estimated Sampling Program Costs

The sampling program costs would be in addition to the administrative costs described above.

- A conservative estimate for sending out samples collected in-house by a trained Environment, Health & Safety (EHS) professional for analysis is $60/sample (including analysis).
- One large university found DCM usage in 90 labs (10%). To build a cost estimate, assume an average of 0.7 samples ($43/badge at a testing firm) per lab (some may have multiple personnel sampled), and include 1 blank per sampling session, 8 hours of Industrial Hygienist time per session, 1.5 hours of researcher time per session, and 0.5 hours of lab director time per session. With presumed local average salaries, these tasks alone cost a total of approximately $40,000 per year. Although sampling requirements could technically be limited to once every five years, sampling and qualitative assessments would need to be done every year to ensure accurate monitoring.

Appendix B: Considerations for Academic Laboratories

American Chemical Society Comment

Docket No. EPA-HQ-OPPT-2020-0465 Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA)
July 3, 2023

Regulation of Laboratory Waste Burdens on Academic Laboratories

- …significant environmental regulatory burdens are placed on academic, commercial, and government laboratories when regulations designed to address large-scale industrial operations are applied to these settings.
- Applying these regulatory requirements to the laboratory environment can unintentionally create significant operational challenges in managing the environmental impact of laboratories.
- …Applying an industrial regulatory scheme to laboratories places unintended and ineffective burdens on these facilities.

Regulation of Laboratory Waste

Academic Laboratories

Both the EPA and OSHA have recognized that work environments in academic laboratories where hazardous chemicals are used and handled are not equivalent to those in industrial settings.

Academic Laboratories: RCRA Subpart K

On May 23, 2006, EPA proposed a **flexible and protective** set of regulations that addressed the specific nature of hazardous waste generation and accumulation in college and university laboratories.

On December 1, 2008, EPA added a new subpart, subpart K, to the Resource Conservation and Recovery Act (RCRA) hazardous waste generator regulatory requirements in Title 40 of the Code of Federal Regulations (CFR) in Part 262. Subpart K is applicable to eligible academic entities, which are:

- colleges and universities, and
- teaching hospitals and nonprofit research institutes that are either owned by or formally affiliated with a college or university.

Academic Laboratories: Laboratory Standard (29 1910.1450)

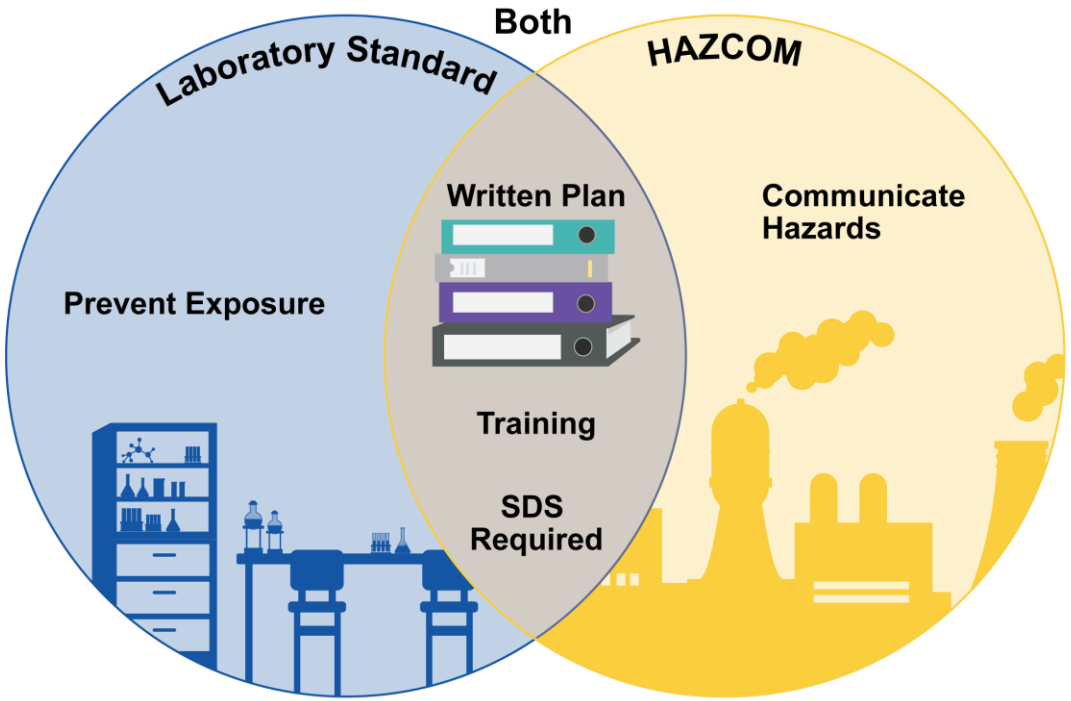
- In 1990, OHSA promulgated **Occupational Exposures to Hazardous Chemicals in Laboratories** (Docket No. H-150, RIN 1218-AAOO, 55 FR 3300)
- From the Laboratory Standard Preamble:

The basis for this standard is a determination by the Assistant Secretary, after careful review of the complete rulemaking record, that laboratories typically differ from industrial operations in their use and handling of hazardous chemicals and that a different approach than that found in OSHA's substance specific health standards is warranted to protect workers.

(Docket No. H-150, RIN 1218-AAOO, 55 FR 3300)

The OSHA Laboratory Standard (29 1910.1450)

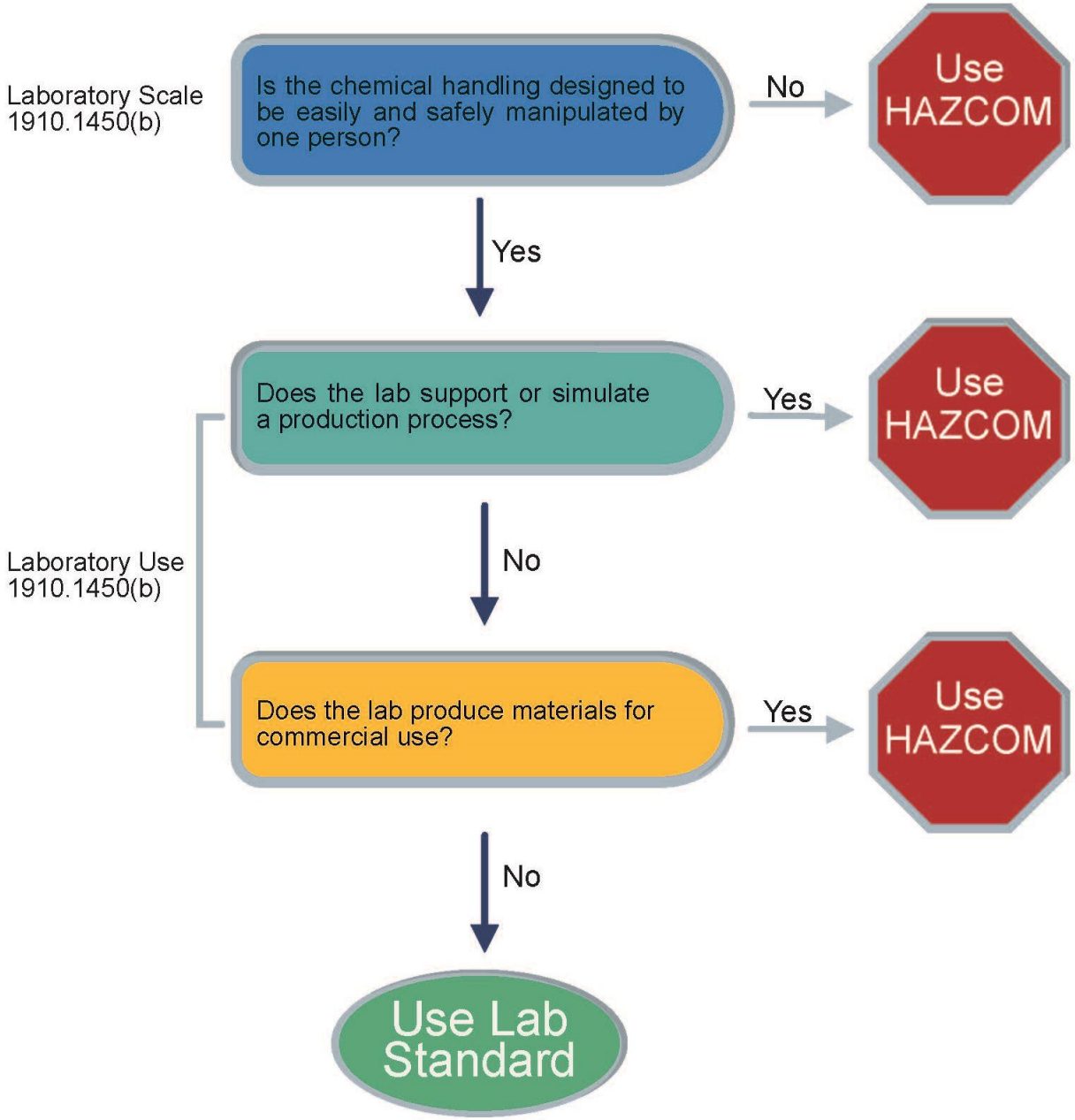
- 1910.1450(a)(2) Where this section applies, it shall supersede, for laboratories, the requirements of all other OSHA health standards in 29 CFR part 1910, subpart Z (with some exceptions).
- *Among other requirements, the final standard provides for employee training and information, medical consultation and examinations, hazard identification, respirator use and recordkeeping.* ***To the extent possible, the standard allows a large measure of flexibility in compliance methods.***[1]
- The Laboratory Standard is based on preventing worker exposure.



[1]Occupational Exposures to Hazardous Chemicals in Laboratories - Preamble

The OSHA Laboratory Standard (29 1910.1450)

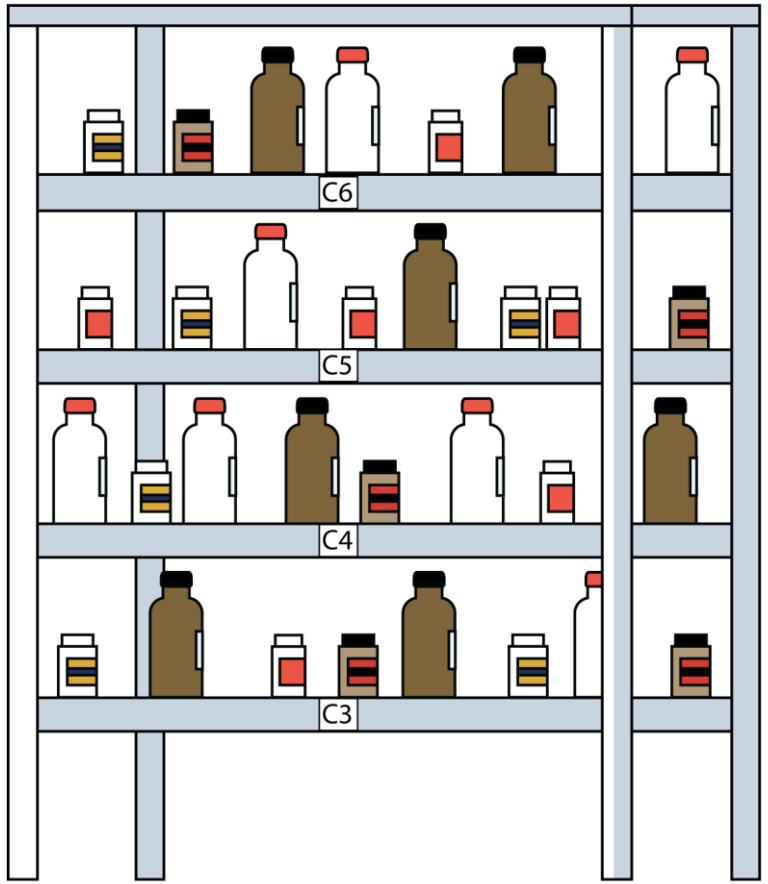
- Most academic laboratories manage worker protection using the Laboratory Standard.
- The Laboratory Standard is based on preventing worker exposure.
- Laboratories that meet the criteria of ***scale*** and ***use*** as defined by OSHA are dissimilar to industrial facilities.



ACS Chemistry for Life®

Risk-Based Safety

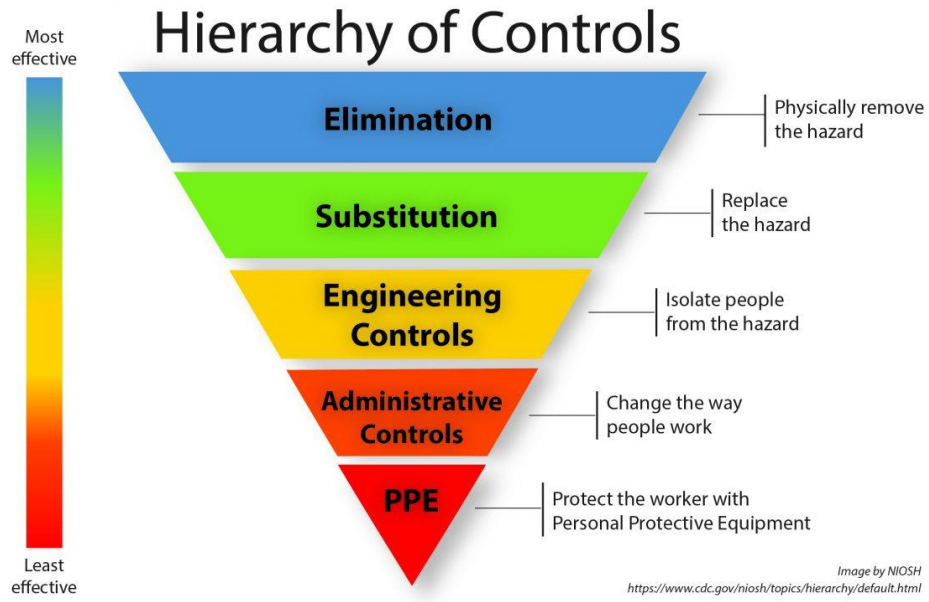
- The Laboratory Standard requires that chemicals are used in quantities that are easily and safely manipulated by one person.
- In academic research laboratories numerous hazardous chemicals are used in small amounts - most solvents are not used in amounts greater than 4 L.



Risk-Based Safety

In academic laboratories exposure to risk from solvents is minimized using higher levels of the NIOSH hierarchy of controls. The risk of acute or chronic exposure is very low in academic laboratories.

- Using elimination and substitution, where possible, is already standard practice in academic laboratories.
- Engineering controls keep exposure well below the current PEL.
- Most chemicals are used in short intervals.
- SOPs for DCM requiring lower PELs can further educate and train laboratory workers as part the required chemical hygiene plan.



Academic Laboratories Policy Considerations

- Academic laboratories have been well regulated for over 30 years using the OSHA Laboratory Standard.
- Chemical hazards are well communicated in academic laboratories using the
  - Globally Harmonized System of Classification and Labeling (GHS),
  - Chemical Hygiene Plans (CHPs),
  - Standard Operating Procedures (SOPs),
  - Safety Data Sheets (SDSs), and
  - Authoritative web information from PubChem Laboratory Chemical Safety Summaries (LCSSs).

Academic Laboratories Policy Considerations

- Work in academic laboratories does not occur on a regular time basis. Very few academic researchers or students work an eight-hour shift.
- Academic laboratories have a workforce that is highly educated and trained to work with small quantities of numerous high hazard chemicals.
- There are some circumstances for research where no substitute offers the separation and low flammability characteristics of DCM. In fact, some substations might have worse impacts on heath and safety in a research laboratory.

Dichloromethane (DCM) Substitutes and Selectivity

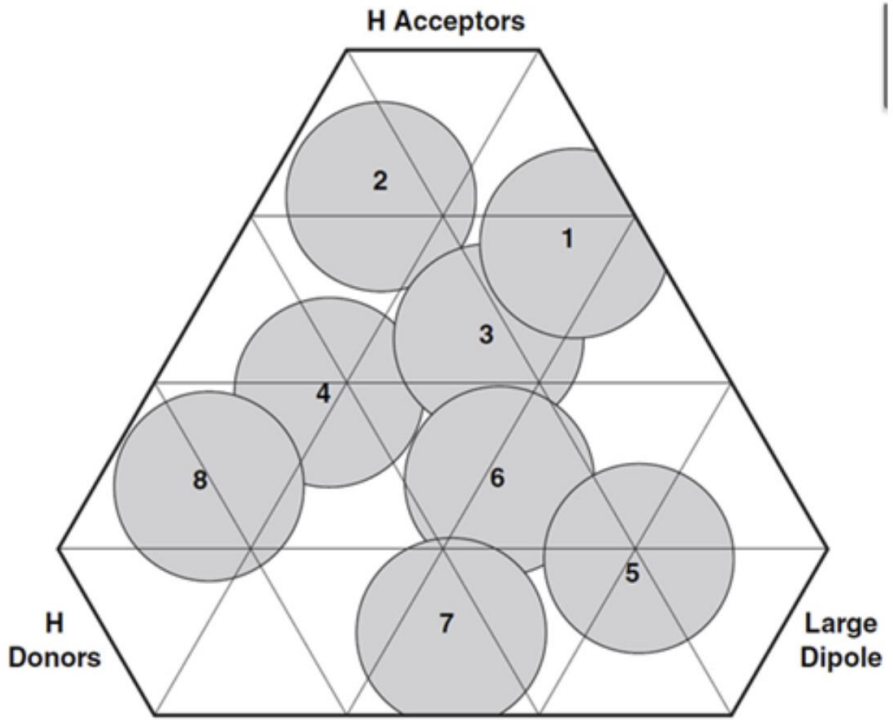


Image: Snyder Selectivity Triangle

Group 1
i-Propyl ether (2.40)
Ethyl ether (2.90)

Group 2
Isobutyl alcohol (3.00)
n-Butanol (3.90)
n-Propanol (4.00)
i-Propanol (4.30)
Ethanol (4.30)
Methanol (6.60)

Group 3
Tetrahydrofuran (4.20)
Dimethyl formamide (6.40)

Group 4
Acetic acid (6.20)
Ethylene glycol (6.90)

Group 5
Methylene chloride (3.40)

Group 6
Ethyl acetate (4.30)
Dioxane (4.80)
Acetone (5.40)
Acetonitrile (6.20)

Group 7
Toluene (2.40)
Chlorobenzene (2.70)
Benzene (3.00)

Group 8
Chloroform (4.40)
Water (10.20)

Policy Considerations
Additional Problems of a WCPP

- Many detectors are limited in their selectivity and their detection limits. Most institutions only have the capability to determine VOCs – not specific to DCM.
- Many Institutions may not have the personnel or resources to dedicate to the prescriptive monitoring proposed in the Workplace Chemical Protection Program (WCPP).
- Confusion will be created in academic institutions over inconsistencies between the OSHA Laboratory Standard and the EPA WCPP.
- All aspects of the EPA WCPP could be incorporated into a Chemical Hygiene Plan as part of the OSHA Laboratory Standard.