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EPA Proposes to Ban Most Uses of Methylene Chloride

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The U.S. Environmental Protection Agency (EPA) has proposed to ban almost all uses of methylene chloride (also called dichloromethane), a widely-used solvent and processing aid. The chemical was manufactured or imported in volumes of 100 million to 250 million pounds in 2019, so this proposed ban would have a substantial impact on many industrial sectors. The few remaining uses, including use as a reactant to make HFC-32, would be restricted much more heavily than under the current OSHA standard.

EPA announced the proposed ban and restrictions in a proposed rule published May 3, 2023, 83 Fed. Reg. 28284. The proposal would ban all remaining consumer uses of methylene chloride. All industrial and commercial uses of methylene chloride, including use as a heat transfer fluid or other processing aid and most solvent uses, would also be banned except for ten specific uses, two of which are very specialized. The banned and excluded uses are listed at the end of this alert. A future significant new use rule would likely cover any uses not included in either list.

The ten uses not covered by the ban would trigger a requirement to implement a workplace chemical protection plan (WCPP) based on the OSHA methylene chloride standard but with an existing chemical exposure limit 92% lower than the OSHA permissible exposure limit.

Stakeholders have until July 3, 2023, to submit comments on the proposed rule. EPA has asked for comments on 44 topics including whether WCPP requirements should replace the ban for particular uses, and whether the brisk schedule for implementing the ban is feasible. EPA has also solicited comments on whether any banned uses would qualify as critical or essential uses for which no feasible safer alternative is available.

This proposal is EPA's second addressing the first ten chemical substances that were the subjects of risk evaluations under section 6 of the Toxic Substances Control Act (TSCA). The first was a proposed ban on all remaining uses of chrysotile asbestos. The third, on perchloroethylene, has been under review by the Office of Management and Budget (OMB) since February 23, 2023. A draft final rule on chrysotile asbestos (see our alert here) has been under OMB review since March 20, 2023.

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The Proposed Ban

The June 2020 risk evaluation determined that all but six conditions of use of methylene chloride present an unreasonable risk. All six now appear on the proposed list of conditions of use subject to WCPP requirements. A November 2022 revised risk determination found that methylene chloride as a whole presents an unreasonable risk, with only one condition of use (distribution in commerce) not contributing to that determination. The proposed ban would include distribution in commerce for banned uses but not for uses subject to WCPP requirements. Having found that methylene chloride presents an unreasonable risk, EPA is now required by TSCA section 6(a) to adopt a risk management rule for the chemical to the extent necessary so that it no longer presents such risk.

EPA previously banned consumer uses of methylene chloride for consumer paint and coating removal, 40 C.F.R. § 751.105. Now EPA proposes to ban all consumer uses not covered by section 751.105, including manufacture, processing, and distribution in commerce of methylene chloride and products containing it for those uses.

Further, EPA proposes to ban all industrial and commercial uses of methylene chloride not covered by the WCPP requirements, including manufacture, processing, distribution in commerce, and use for those conditions of use.

The 45 industrial, commercial, and consumer conditions of use proposed for banning are listed at the end of this alert. That list comes from the 2020 risk evaluation. In addition, EPA is planning to adopt a significant new use rule (SNUR) applicable to any use of methylene chloride or products containing it not considered in that risk evaluation. The Regulatory Agenda released in January predicted a proposed SNUR by April 2023 (EPA has missed that date already) and a final SNUR by March 2024.

EPA estimates that the ban would account for about one-third of the total annual production volume of methylene chloride manufactured or imported for both TSCA and non-TSCA uses.

The ban would not directly affect non-TSCA uses. The preamble notes that:

[T]his proposed rule does not apply to any substance excluded from the definition of “chemical substance” under TSCA section 3(2)(B)(ii) through (vi). Those exclusions include, but are not limited to …, any food, food additive, drug, cosmetic, or device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device …

To the extent that bonding agents in the production of specialty batteries for medical applications qualify as a “device” as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, those particular uses that qualify as a “device” would be excluded from the “chemical substance” definition if “manufactured, processed, or distributed in commerce for use as a ... device,” and would

therefore not be subject to the rule if finalized.

In addition, the EPA final risk evaluation found that:

methylene chloride use as a functional fluid in a closed system during pharmaceutical manufacturing entails use as an extraction solvent in the purification of pharmaceutical products, and [EPA] has concluded that this use falls within the aforementioned definitional exclusion and is not a “chemical substance” under TSCA.

Compliance deadlines for the bans would come in stages:

- 90 days after the publication date of the final rule for manufacturers
- 180 days after the publication date of the final rule for processors
- 270 days after the publication date of the final rule for distributing to retailers
- 360 days after the publication date of the final rule for all other distributors and retailers
- 450 days after the publication date of the final rule for industrial and commercial users

The ban on use would limit incentives for stockpiling methylene chloride and products containing it while they remain available. EPA requests comments on whether additional time would be needed, for example, for banned products to clear the channels of trade. Given this request for comments now, EPA may be less willing to consider requests for extended deadlines later.

As shown by the 45 conditions of use proposed for banning, many industries use methylene chloride, including as a solvent and processing aid. Thus, this proposal, if finalized, would affect dozens of industries. The 2020 risk evaluation highlighted some uses:

Methylene chloride has a wide-range of uses, including in sealants, automotive products, and paint and coating removers . Methylene chloride has known applications as a process solvent in paint removers and the manufacture of pharmaceuticals and film coatings. It is used as an agent in urethane foam blowing and in the manufacture of hydrofluorocarbon (HFC) refrigerants, such as HFC-32. It can also be found in aerosol propellants and in solvents for electronics manufacturing, metal cleaning and degreasing, and furniture finishing.

The prospect of a ban on most uses of methylene chloride raises the urgent question of feasible alternatives. EPA has addressed this in an Alternatives Assessment, which the preamble characterizes as saying:

For conditions of use for which products currently containing methylene chloride were identified, EPA identified several hundred commercially available alternative products that do not contain methylene chloride, and listed in the Alternatives Assessment, to the extent practicable, their unique chemical components, or ingredients ...

EPA identified 65 total alternative products in the paint and coating remover category, of which furniture refinishing is a subcategory (Ref. 48). As described in the Economic Analysis, while not all of these alternative products may meet the specific use for some furniture refinishing uses, mechanical

or thermal methods may be non-chemical alternatives to using products containing methylene chloride for paint and coating removal … EPA finds that there are technological and economically feasible alternatives in the marketplace …

[A]lternatives for methylene chloride as a processing aid were not identified. EPA requests information on potential alternative processing aids to methylene chloride as it relates to the proposed regulatory option for this COU.

The lack of identified alternatives for use as a processing aid is a potential concern. EPA describes that condition of use as:

the industrial or commercial use of methylene chloride to improve the processing characteristics or the operation of process equipment or to alter or buffer the pH of the substance or mixture, when added to a process or to a substance or mixture to be processed. Processing agents do not become a part of the reaction product and are not intended to affect the function of a substance or article created.

Among the "processing aid" uses of methylene chloride is use as a heat transfer fluid in a closed system. The proposed rule would also ban this use of methylene chloride, despite its low exposure potential. However, the preamble added:

EPA requests comment on the degree to which other entities using methylene chloride as a processing aid may otherwise comply with the proposed WCPP requirements for methylene chloride. In the case that several entities are able to demonstrate the continued use of methylene chloride without subjecting workers to unreasonable risk is possible, through a combination of monitoring data and process description, EPA acknowledges its willingness to finalize a regulation under which this particular sub-use of the condition of use [i.e., use as a heat transfer fluid], or the condition of use as a whole [use as a processing aid] could continue under the WCPP …

Thus, companies using methylene chloride in uses with low exposure potential, such as heat transfer fluid use, have an opportunity to request that EPA change the proposed ban on such uses to a requirement to implement a WCPP – so long as they can demonstrate to EPA that they can meet the WCCP requirements, discussed below. EPA also said:

In the event that EPA is not able to identify any alternatives for this condition of use, and additional information is not provided that would allow EPA to determine that the WCPP could address unreasonable risk driven by this condition of use, EPA will consider finalizing a prohibition that allows for an appropriate phaseout in accordance with TSCA section 6(d).

Section 6(d) requires EPA to require compliance as soon as practicable, but not later than 5 years after promulgation of the final rule. In other words, this use might qualify for an extended compliance deadline.

Alternatives to a Ban

For the ten conditions of use listed below, including manufacture and processing to produce HFC-32, recycling, and disposal, EPA has proposed workplace controls on exposure (i.e., a WCPP) as an alternative to a ban. The controls include requirements on exposure limits, regulated areas, exposure monitoring (including a new requirement to conduct monitoring in accordance with good laboratory practice regulations), methods of compliance, respiratory protection, dermal protection, and training.

These provisions supplement OSHA's methylene chloride standard, 29 C.F.R. § 1910.1052, but they are largely based on that standard – with an important change.

The OSHA standard (originally adopted in 1997) has a permissible exposure limit (PEL) of 25 ppm (8-hour time-weighted average (TWA)) and a short-term exposure limit (STEL) of 125 ppm (15-minute TWA). In contrast, the TSCA rule would have an existing chemical exposure limit (ECEL) of 2 ppm (8-hour TWA) and a STEL of 16 ppm (15-minute TWA). Thus, the ECEL would be just 8% of the OSHA PEL, and EPA's STEL would be 12.8% of the OSHA STEL. The ECEL and STEL would have to be met using the hierarchy of controls, which put engineering controls first and use of personal protective equipment as a last resort.

This means that persons in compliance with the OSHA standard might be unable to meet the proposed ECEL and STEL. Doubts about the feasibility of meeting these exposure limits were factors in EPA's proposal to ban most industrial and commercial uses of methylene chloride and products containing it.

In addition to the listed manufacturing and processing uses, the WCPP provisions would also apply to the disposal and recycling of methylene chloride and products containing it. Waste disposal companies and recyclers, who may not be familiar with TSCA requirements, would thus have to go beyond compliance with the OSHA standard.

The Importance of Commenting on the Proposed Rule

Commenting on this proposed rule may be more important than usual, given the wide-ranging proposed ban and the many user industries that may be affected. Comments are due to EPA by July 3, 2023. The preamble suggests that entities should direct comments on paperwork requirements to OMB by June 2, 2023.

Before commenting, companies and trade associations (with respect to their members) may want to consider the following:

- Do they use methylene chloride or products containing it?
- If so, for what purposes do they use them?
- Are there alternatives to methylene chloride for those uses?
- How long would it take to qualify alternatives for those uses?
- Could they transition to qualified alternatives by EPA's proposed compliance dates?
- If not, by when could they transition to qualified alternatives?
- Could they meet the WCPP requirements, including the 2 ppm ECEL and the 16 ppm STEL?

Commenters may want to describe in detail their uses of methylene chloride; their engineering controls that limit exposure; their OSHA methylene chloride compliance programs already in place; their industrial hygiene monitoring results for methylene chloride (and how they compare with the ECEL and STEL); the technical challenges to identifying or transitioning to an alternative to

methylene chloride for their uses; the dates by which they could transition to an alternative (if that is possible); and the importance of their use of methylene chloride.

Such comments could support an extended compliance deadline for their uses or a request under TSCA section 6(g) that EPA exempt their particular uses of methylene chloride from the ban. Section 6(g)(1) provides:

The Administrator may, as part of a rule promulgated under subsection (a), or in a separate rule, grant an exemption from a requirement of a subsection (a) rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that—

(A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;

(B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or

(C) the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

Under section 6(g)(2)(4), EPA may:

include conditions, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

The preamble suggests that EPA would consider a section 6(g) exemption where there are no feasible alternatives and meeting the WCPP requirements is not practical:

Alternatively, in the event that EPA is unable to identify alternatives for this condition of use [use as a heat transfer fluid], and EPA determines through new information provided that prohibition of the use would significantly impact national security or critical infrastructure, EPA will consider an exemption under TSCA section 6(g).

Commenters may want to indicate whether they could meet the WCPP requirements, or, if not, what exposure control requirements they could meet.

For assistance in commenting, please contact the authors.

List of Uses of Methylene Chloride That Would Be Banned

1. Manufacturing (domestic manufacture) for uses other than those that would be banned

2. Manufacturing (import) for uses other than those that would be banned

3. Processing: as a reactant (e.g., to manufacture HFC-22)

4. Processing: incorporation into a formulation, mixture, or reaction product for uses other than those that would be banned

5. Processing: repackaging for uses other than those that would be banned
6. Processing: recycling
7. Industrial and commercial use as a laboratory chemical
8. Industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft that are owned or operated by the U.S. Department of Defense, the National Aeronautics and Space Administration, the U.S. Department of Homeland Security, and the Federal Aviation Administration that is performed by the agency or the agency's contractor at locations controlled by the agency or the agency's contractor
9. Industrial or commercial use as a bonding agent for acrylic and polycarbonate in mission-critical military and space vehicle applications, including in the production of specialty batteries for applications that are performed by the U.S. Department of Defense, the National Aeronautics and Space Administration, or the U.S. Department of Homeland Security or their contractors at locations controlled by the agency or the agency's contractor
10. Disposal

List of Uses of Methylene Chloride That Would Be Banned

1. Industrial and commercial use as solvent for batch vapor degreasing
2. Industrial and commercial use as solvent for in-line vapor degreasing
3. Industrial and commercial use as solvent for cold cleaning
4. Industrial and commercial use as solvent for aerosol spray degreaser/cleaner
5. Industrial and commercial use in adhesives, sealants and caulks
6. Industrial and commercial use in paints and coatings
7. Industrial and commercial use in paint and coating removers
8. Industrial and commercial use in adhesive and caulk removers
9. Industrial and commercial use in metal aerosol degreasers
10. Industrial and commercial use in metal non-aerosol degreasers
11. Industrial and commercial use in finishing products for fabric, textiles and leather
12. Industrial and commercial use in automotive care products (functional fluids for air conditioners)
13. Industrial and commercial use in automotive care products (interior car care)

14. Industrial and commercial use in automotive care products (degreasers)
15. Industrial and commercial use in apparel and footwear care products
16. Industrial and commercial use in spot removers for apparel and textiles
17. Industrial and commercial use in liquid lubricants and greases
18. Industrial and commercial use in spray lubricants and greases
19. Industrial and commercial use in aerosol degreasers and cleaners
20. Industrial and commercial use in non-aerosol degreasers and cleaners
21. Industrial and commercial use in cold pipe insulations
22. Industrial and commercial use as solvent that becomes part of a formulation or mixture
23. Industrial and commercial use as a processing aid
24. Industrial and commercial use as propellant and blowing agent
25. Industrial and commercial use for electrical equipment, appliance, and component manufacturing
26. Industrial and commercial use for plastic and rubber products manufacturing
27. Industrial and commercial use in cellulose triacetate film production
28. Industrial and commercial use as anti-spatter welding aerosol
29. Industrial and commercial use for oil and gas drilling, extraction, and support activities
30. Industrial and commercial use in toys, playground and sporting equipment
31. Industrial and commercial use in lithographic printing plate cleaner
32. Industrial and commercial use in carbon remover, wood floor cleaner, and brush cleaner
33. Industrial and commercial use as laboratory chemical
34. Consumer use as solvent in aerosol degreasers/cleaners
35. Consumer use in adhesives and sealants
36. Consumer use in brush cleaners for paints and coatings
37. Consumer use adhesive and caulk removers
38. Consumer use in metal degreasers

39. Consumer use in automotive care products (functional fluids for air conditioners)
40. Consumer use in automotive care products (degreasers)
41. Consumer use in lubricants and greases
42. Consumer use in cold pipe insulation
43. Consumer use in arts, crafts, and hobby materials glue
44. Consumer use in an anti-spatter welding aerosol
45. Consumer use in carbon removers and other brush cleaners

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