UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 26, 2026

MEMORANDUM

SUBJECT: Time-Limited Use of a Respirator with an Assigned Protection Factor of 1000 for Industrial Hygiene Monitoring for Mixed Metal Oxides (MMO) in Cathode Active Materials (CAMs) and General Population Exposure Considerations

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Summary

The purpose of this memorandum is to provide scientific evidence in support of a policy decision to permit the use of respirators for workers with an Assigned Protection Factor (APF) of 1,000 during manufacturing, processing (including recycling), and use while initial industrial hygiene monitoring is conducted during the first several months of manufacturing and processing, and to consider potential exposures to the general population arising from these activities. The focus of this scientific analysis is on cobalt, as this metal is common to all mixed metal oxides (MMO) in cathode active materials (CAMs) and is also the most potent component. Cobalt also has a large hazard database for considering a human-specific, refined hazard value.

The memorandum addresses exposures of less than one year; therefore, only noncancer effects were evaluated. The refined, human hazard value is based on cobalt, and because no composition adjustment was applied, this memorandum does not relate to a cobalt-content limit for MMO CAMs and applies to all non-nano-sized MMO CAMs containing cobalt and nickel.

The New Chemicals Division (NCD) concludes that an APF-1000 respirator is protective of risk to workers from MMO CAM inhalation exposures from the start of manufacture until industrial hygiene monitoring data are available to NCD, for a period not to exceed one year. Following the completion of industrial hygiene monitoring activities (including EPA's receipt of results), the appropriate respirator will be determined based on the monitoring results for those scenarios where inhalation exposure is reasonably anticipated.

NCD also concludes that any air releases resulting from manufacturing, initial processing, and use that occur during this monitoring period are unlikely to cause adverse respiratory effects to residents of fenceline communities. By contrast, estimates indicate recycling-related fugitive emissions may present a risk to the general population; however, the estimates do not account for any engineering controls and are expected to begin later than manufacturing and initial processing activities. Accordingly, a time-limited period may be warranted to develop and implement a compliance plan to mitigate general population risks associated with recycling activities.

Problem Formulation

Under TSCA section 5, NCD is responsible for conducting risk assessments of new chemical substances to determine whether these chemicals pose an unreasonable risk to human health and the environment. In recent years, NCD has received multiple new chemical submissions for MMO CAMs used in battery, semiconductors, and energy storage applications. MMO CAMs are crystallized metal oxides typically composed of some combination of lithium, cobalt, nickel, and other additional modifier metal oxides. This memorandum focuses on cobalt-containing CAMs as these types of MMO CAMs are the most common in the New Chemicals Program and cobalt is the most potent component of MMO CAMs.

NCD's standardized approach for MMOs was finalized in 2023 and has provided a consistent approach for conducting health hazard assessment for MMO CAMs used since 2023. To assess inhalation risks to workers associated with MMO CAMs, EPA currently uses a benchmark concentration lower bound ($BMCL_{1SD}$) of 1.7E-2 mg/m^3 as the point of departure (POD) based on respiratory effects (i.e., increased lung weight, macroscopic changes in the lung, and histopathological changes in the respiratory tract) in a 90-day inhalation study in rats (OECD TG 413) for an MMO CAM analogue substance containing aluminum cobalt lithium nickel oxide.[1] MMO CAMs are expected to be produced in high volumes to meet the demand of the automotive manufacturing (electric vehicle battery), semiconductor, and energy storage sectors. Because these manufacturing and processing facilities are new or still under construction, there is an inherent lack of industrial hygiene monitoring at the time of a new chemical submission. In the absence of chemical-specific data, NCD models these exposures using protective assumptions which often identify risks for workers that require respirators with a high APF. Importantly, these modeled exposures yield predicted fold-factors for APFs that are likely over-protective and may not be feasible for many manufacturing and processing occupational tasks.

Additionally, fenceline communities may also be exposed via air releases that occur during this monitoring period. As a result, this memorandum also considers potential risks to those populations as well.

This memorandum provides an updated, refined evaluation of the cobalt POD for use as part of scientific evaluation across manufacturing, processing (including recycling), and use scenarios

[1] Study available upon request

while initial industrial hygiene monitoring activities are completed during the first several months or to show compliance with risk management terms associated with general population exposures. This hazard value allows for an analysis of occupational exposures to cobalt and the resulting respiratory effects to inform a decision to support the use of a respirator with an APF of 1,000 while industrial hygiene monitoring activities are completed and while a compliance plan for mitigation of general population risks is developed.

Scientific Analysis

Comparison of MMO CAM toxicity values

MMO CAMs are comprised of several metals which typically include some combination of cobalt, lithium, manganese, and nickel which form the "base" CAM. These CAMs are frequently "doped" with trace amounts (<1%) of an assortment of metals such as aluminum, zirconium, boron, tungsten, titanium, magnesium and niobium to tailor the performance of the battery (U.S. EPA, 2023). For nearly all the identified individual metals, a risk assessment by an authoritative regulatory body is available for use by NCD. The toxicity values used by NCD were previously described (U.S. EPA, 2023). Only the inhalation values are presented in Table 1. Cancer values are not included because the memorandum addresses exposures lasting less than one year; cancer hazards are not expected under these conditions and are out of scope. Comparison of the inhalation noncancer POD values demonstrate that cobalt is at least 22X more potent than any other component in an MMO CAM.

Table 1. Inhalation Points of Departure

Metal[1]	Inhalation POD (mg/m^3)	POD basis (effect; study; source)	Cobalt toxicity relative to other metals (POD)[2]
Cobalt	NOAEC 5.3e-3; UF=10 (UFH)	Resp. effects; human cross-sectional; ATSDR, 2024	—
Nickel	BMCL 1.17e-1; UF=100 (10 UFA, 10 UFH)	Resp. effects; mouse 104-wk inhal.; OEHHA, 2009	22
Aluminum	LOAEC 1.64; UF=100 (10 UFL, 10 UFH)	Systemic; human worker inhal.; EPA, 2006	309
Manganese	BMCL 0.142; UF=10 (10 UFH)	Systemic; human occupational; ATSDR, 2012	27
Titanium	NOAEC 10; UF=100 (10 UFH, 10 UFA)	Respiratory; rat 2-yr inhal.; NICNAS, 2016	1900

[1]No inhalation values were identified for Magnesium, Niobium, Zirconium, Boron, Tungsten, and Lithium
[2]Relative toxicity= metal POD ÷ cobalt POD

Cobalt as a surrogate for MMO CAMs

Data from close analogues are generally preferred for deriving PODs in risk assessments instead of data from individual components of new chemicals. However, the available inhalation studies on MMO CAM analogues are limited to rodent studies exposed for up to 90-days. When laboratory animal data are used to derive human points of departure, the result is often overly conservative due, in part, to the application of the animal to human extrapolation factor. In addition, there are well-documented differences in the anatomy and physiology between rodents to humans (Stucki et al., 2024) that lead to rodent studies being overly conservative for human exposures for many chemicals. The recently completed health assessment by the Agency for Toxic Substances and Disease Registry (ATSDR) shows this trend is true for cobalt. Specifically, ATSDR did not derive an intermediate inhalation point of departure for cobalt since the subchronic laboratory animal studies yielded PODs lower than the chronic human POD (ATSDR, 2024). Occupational studies describing the effects of cobalt inhalation exposures on workers provide a refined, human-specific POD used by ATSDR. Cobalt is the most potent component of the MMO CAM (U.S. EPA, 2026), thus this human-specific POD derived for cobalt will be protective of the MMO CAM substance for a period not to exceed one year.

Calculating a refined NCEL based on cobalt

NCD assumes that using the chronic cobalt value derived from a human occupational study is a scientifically robust and health protective approach to evaluate potential risks of exposures up to one year in duration to MMO CAMs. The basis for the refined NCEL is a cross-sectional study of the respiratory effects of cobalt exposure in diamond polishers (Nemery et al., 1992). This study is the principal study used for derivation of chronic PODs by regulatory bodies such as ATSDR, U.S. EPA, and Health Canada (ATSDR, 2024; EPA, 2008; Health Canada, 2017). This study identified a NOAEC of 5.3E-3 mg/m^3 and a LOAEC of 1.51E-2 mg/m^3 based on reduced spirometry parameters, coughing, wheezing and upper airway irritation.

The total uncertainty factor applied to this study is 10 to account for human variability (ATSDR, 2024).

To calculate a human NCEL for occupational exposures, the following formula was applied:

$$
\begin{aligned}
\text{NCEL} &= \text{NOAEC} \div \text{UF} \\
&= 5.3\text{E-3 mg/m}^3 \div 10 \\
&= \mathbf{5.3E\text{-}4\ mg/m^3}
\end{aligned}
$$

This value represents the daily occupational exposure a worker could be exposed to a cobalt-containing substance without anticipated adverse respiratory effects. Furthermore, performing the same calculation above with the LOAEC value of 1.5E-2 mg/m^3 yields a LOAEC value of **1.5E-3 mg/m^3** which would be the concentration that these noncancer effects (coughing, wheezing, irritation, etc.) would be expected to occur after multiple years of exposure.

To evaluate general population exposures, EPA used the chronic Minimal Risk Level (MRL) of **1.3E-4 mg/m^3** which adjusts the NOAEC value for 24-hour continuous exposure (ATSDR, 2024).

For informational purposes, the LOAEC value of 1.5E-2 mg/m^3 was also adjusted for continuous exposure using the following formula:

$$
\begin{aligned}
\text{LOAEC}_{\text{continuous}} &= \text{LOAEC} \times \frac{8\ hours}{24\ hours} \times \frac{5\ days}{7\ days} \div \text{UF} \\
&= 1.5\text{E-2 mg/m}^3 \times \frac{8\ hours}{24\ hours} \times \frac{5\ days}{7\ days} \div 10 \\
&= \mathbf{3.6E\text{-}4\ mg/m^3}
\end{aligned}
$$

Comparing the human-specific NOAEC and LOAEC values with the estimated worker exposures

The exposure data in Table 2 are examples of occupational scenarios from recent MMO CAM submissions. In general, the exposures were calculated using one of two methods: 1) the Occupational Safety and Health Adminstration (OSHA) Permissible Exposure Limit (PEL) based on the percent composition of nickel or cobalt in the MMO CAM or 2) monitoring data that NCD has received for similar cases. These exposures were adjusted to account for a worker wearing a respirator with an APF 1,000. Respirator-adjusted exposure was divided by the human NCEL of 5.3E-4 mg/m^3 to determine whether a worker's exposure would exceed this concentration. Every instance where the exposure was estimated using monitoring data, the exposure did not exceed the human NCEL which indicates that there is a low probability of any adverse health effects. Notably, the only examples where the NCEL was exceeded were estimated exposures based on the OSHA PEL.

As previously mentioned, EPA is using the POD identified by ATSDR for the chronic MRL; occupational exposures in the study were based on personal and area sampling and assumed to occur chronically without respirator use. The monitoring phase (including receipt of results) is expected to last a few months, not to exceed one year; therefore, these exposures were also compared with the LOAEC value to characterize the magnitude of exposures. The respirator-adjusted exposure was divided by the refined, human LOAEC value of 1.51E-3 mg/m^3 to determine how much this exposure exceeded the refined, human LOAEC. In every case where the OSHA PEL exposure estimate exceeded the refined, human LOAEC, the exceedance was <2X.

Table 2. Inhalation Risk Estimates for Occupational Exposure Scenarios Assuming a Respirator with an APF 1,000

Chemical	Exposure Scenario (Activity)	8-hr TWA (mg/m^3)	8-hr TWA with respirator of APF 1,000 (mg/m^3)[1]	Basis for exposure estimate	Inhalation Risk Estimates with respirator (Hazard Quotient>1 exceeds effect level)	
					Human NCEL[2]	Human LOAEC[3]
A	Processing (Unloading)	4.20E-03	4.20E-06	Monitoring	0.01	0.0
	Processing (Battery Manufacture)	1.90E+00	1.90E-03	OSHA PEL	**3.58**	**1.3**
	Recycling (Loading)	1.90E+00	1.90E-03	OSHA PEL	**3.58**	**1.3**
B	Processing (Handling)	3.30E-03	3.30E-06	Monitoring	0.01	0.0
	Processing (Handling)	5.30E-01	5.30E-04	OSHA PEL	1.00	0.4
	Recycling (Dust Collection)	5.30E-01	5.30E-04	OSHA PEL	1.00	0.4
C	Manufacturing (Handling)	2.10E+00	2.10E-03	OSHA PEL	**3.96**	**1.4**
	Processing (Unloading)	4.70E-03	4.70E-06	Monitoring	0.01	0.0
	Processing (Battery Manufacture)	2.10E+00	2.10E-03	OSHA PEL	**3.96**	**1.4**
	Recycling (Unloading/ Loading)	2.10E+00	2.10E-03	OSHA PEL	**3.96**	**1.4**

D	Manufacturing (Handling)	2.00E+00	2.00E-03	OSHA PEL	**3.77**	**1.3**
	Processing (Unloading)	4.40E-03	4.40E-06	Monitoring	0.01	0.0
	Processing (Battery Manufacture)	2.00E+00	2.00E-03	OSHA PEL	**3.77**	**1.3**
	Recycling (Loading/ Unloading)	2.00E+00	2.00E-03	OSHA PEL	**3.77**	**1.3**
E	Manufacture (Handling)	1.00E+00	1.00E-03	OSHA PEL	**1.89**	0.7
	Processing (Unloading)	6.70E-03	6.70E-06	Monitoring	0.01	0.0
	Processing (Battery Manufacture)	1.00E+00	1.00E-03	OSHA PEL	**1.89**	0.7
	Recycling (Unloading/ Loading)	1.00E+00	1.00E-03	OSHA PEL	**1.89**	0.7
F	Use (Handling)	1.80E+00	1.80E-03	OSHA PEL	**3.40**	**1.2**
	Recycling (Unloading)	1.80E+00	1.80E-03	OSHA PEL	**3.40**	**1.2**
G	Processing (Handling)	1.00E+00	1.00E-03	OSHA PEL	**1.89**	0.7
	Shredding (Dust Collection)	1.00E+00	1.00E-03	OSHA PEL	**1.89**	0.7
	Recycling (Loading)	1.00E+00	1.00E-03	OSHA PEL	**1.89**	0.7

[1] 8-hr TWA with Respirator of APF 1,000 = 8-hr TWA ÷ 1,000.
[2] Hazard Quotient = 8-hr TWA with Respirator of APF 1,000 ÷ 5.3E-4 mg/m^3.
[3] Hazard Quotient = 8-hr TWA with Respirator of APF 1,000 ÷ 1.5E-3 mg/m^3.

Altogether, this comparison demonstrates that when a worker utilizes a respirator with an APF of 1,000 the exposure estimates based on monitoring data from modern facilities do not exceed the refined, human NOAEC. Furthermore, the worst-case exposure estimates using generic OSHA PEL estimates indicate that a worker wearing a respirator (APF 1,000) would be exposed to roughly the same concentration as the refined, human LOAEC for cobalt. Notably, these adverse effects were based on respiratory irritation and reduced lung function in cobalt workers chronically exposed for years while the MMO CAM exposures are expected to occur only for a few months while monitoring is conducted. Finally, cobalt typically comprises less than 50% of the overall MMO CAM, thus these calculations potentially overestimate exposures by more than 2X.

Comparing the refined, human-derived values with the estimated general population exposures

The data in Table 3 are examples of general population exposure scenarios from recent MMO CAM submissions. The exposure scenarios that lead to air releases for MMO CAMs include all activities throughout the lifecycle of the MMO CAM. Several release pathways had multiple exposure estimates for an exposure scenario. For the sake of brevity, only the worst case exposures for each exposure scenario are presented in the table. Releases that occur because of recycling activities were separated from all other activities that occur during the manufacture and initial processing of an MMO CAM. The estimated air concentration was divided by the ATSDR MRL of 1.3E-4 mg/m^3 to determine whether, and by how much, ambient air levels in fenceline communities would exceed this concentration.

All estimated general population inhalation exposures from expected air releases from activities that occur during the manufacturing, initial processing and use of an MMO CAM are at least an order of magnitude below the ATSDR chronic MRL. Estimated general population inhalation exposures due to recycling activities, particularly those exposures from fugitive air releases, exceed the MRL by at least 2 orders of magnitude. Comparing the estimated general population inhalation exposures with the $LOAEC_{continuous}$, yielded similar results. The estimated fugitive air releases occuring from recycling activities exceeded the $LOAEC_{continuous}$ by at least 67X.

Table 3. Inhalation Risk Estimates for General Population Exposures

Chemical	Release Pathway	Exposure Scenario		Inhalation Risk Estimates (Hazard Quotient>1 exceeds effect level)			
				Compared to MRL[2]		Compared to $LOAEC_{continuous}$[3]	
		Manufacturing/ Processing/ Use (µg/m^3)[1]	Recycling/ End of Life (µg/m^3)[1]	Manufacturing/ Processing/ Use	Recycling/ End of Life	Manufacturing/ Processing/ Use	Recycling/ End of Life
A	Stack	8.23E-06	—	0.00	—	0.00	—
	Incinerator	—	1.05E-03	—	0.01	—	0.00
	Fugitive	—	1.38E+02	—	**1062**	—	**383**
B	Stack	8.23E-06	—	0.00	—	0.00	—
	Incinerator	—	1.05E-03	—	0.01	—	0.00
	Fugitive	—	1.38E+02	—	**1062**	—	**383**
C	Stack	8.23E-06	—	0.00	—	0.00	—
	Incinerator	—	1.05E-03	—	0.01	—	0.00
	Fugitive	—	1.38E+02	—	**1062**	—	**383**
D	Stack	1.06E-04	—	0.00	—	0.00	—
	Incinerator	—	—	—	—	—	—
	Fugitive	—	—	—	—	—	—
E	Stack	1.50E-04	—	0.00	—	0.00	—
	Incinerator	—	7.05E-04	—	0.01	—	0.00
	Fugitive	—	1.06E+02	—	**815**	—	**294**
F	Stack	7.36E-05	—	0.00	—	0.00	—
	Incinerator	—	3.50E-04	—	0.00	—	0.00
	Fugitive	—	5.19E+01	—	**399**	—	**144**
G	Stack	7.36E-05	—	0.00	—	0.00	—
	Incinerator	—	3.50E-04	—	0.00	—	0.00
	Fugitive	—	5.19E+01	—	**399**	—	**144**
H	Stack	2.46E-03	—	0.02	—	0.01	—
	Incinerator	—	1.60E-04	—	0.00	—	0.00

	Fugitive	—	2.42E+01	—	**186**	—	**67**
I	Stack	1.82E-05	—	0.00	—	0.00	—
	Incinerator	—	4.05E-01	—	**3.12**	—	**1.13**
	Fugitive	—	6.06E+01	—	**466**	—	**168**

[1]Worst case release activity
[2]Hazard Quotient= (Exposure ÷ 1,000) ÷ 1.3E-4 mg/m^3
[3]Hazard Quotient= (Exposure ÷ 1,000) ÷3.6E-4 mg/m^3

Altogether, this comparison demonstrates that fenceline communities potentially exposed to MMO CAMs from manufacturing, processing (excluding recycling), and use exposure scenarios that occur during the initial monitoring period do not exceed the no effect level. However, potential exposures to fenceline communities that may occur during the recycling process, which largely occur much later in time than the manufacturing and initial processing, exceed no effect levels by 186X to 1062X in the absence of engineering controls employed in the other scenarios. Notably, the estimated exposures for recycling activities are the most uncertain due to a lack of monitoring data. EPA expects that modern engineering controls would reduce these fugitive releases and fenceline community exposures but is not currently able to estimate the magnitude of reduction.

Weight of Scientific Evidence Conclusion

Based on the scientific analysis comparing inhalation exposure estimates to the refined exposure levels for cobalt, EPA concludes that a properly fitted respirator providing an assigned protection factor (APF) of 1,000 is expected to reduce worker inhalation exposures to MMO CAMs to levels unlikely to cause adverse noncancer respiratory effects while exposure monitoring activities are completed, for a period not to exceed one year. EPA also concludes that any air releases resulting from manufacturing, initial processing (excluding recycling), and use scenarios are unlikely to cause adverse respiratory effects to residents of fenceline communities. Releases from recycling in the absence of engineering controls may present a risk to the general population; however, those exposures would typically occur at a deferred point in time as compared to manufacturing and initial processing activities when the general population risk compliance plan would be developed and implemented. These conclusions are based on several conservative assumptions and observations:

1. Cobalt is a useful surrogate to evaluate MMO CAM exposure in humans because the data are based on occupational exposures.
2. This surrogate is conservative because:
    a. Cobalt is markedly more potent than the other component metals.
    b. The cobalt point of departure is protective for lifetime noncancer respiratory effects.
3. Exposure estimates based on industrial hygiene monitoring are more likely to represent real world exposures than generic estimates (i.e., OSHA PEL) that do not account for modern engineering controls.
4. The workers will be exposed to these concentrations for a few months while monitoring activities are completed.
5. Worst case estimated occupational exposures are ≤2X of the lifetime cobalt concentration known to induce respiratory irritation and reduced lung function effect. The MMO CAMs received by EPA are known to contain <50% cobalt in the final formulation which reduces the probability of adverse effects for exposures not exceeding one year.
6. Estimated fugitive emissions from recycling activities lack any engineering controls but are generally expected to occur at a later time compared to manufacturing and initial processing activities. Accordingly, a time-limited period may be warranted to allow for the development and implementation of a compliance plan to mitigate general population risks

associated with recycling activities.

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