January 12, 2024

To : Scientific Review Panel on Toxic Air Contaminants

The proposed changes in the Proposition 65 NRSL inhalation values to go from 2 ug/day to 0.058 ug/day of ethylene oxide will pose some great challenges for Win Chemicals Ltd. The current NRSL value of 2 ug/day is already a challenge. Ethylene oxide may be found as an unreacted raw material in ethoxylated surfactants. As it is, only our absolute best suppliers provide any data for ethylene oxide content, and only to a detection limit of 1 ppm. We are always below this detection limit with these raw materials in our company. Understanding how these non detect concentrations in a surfactant could correlate to inhalation hazards is very difficult. For example, hypothetically, if one were to inhale the entire amount of ethylene oxide theoretically present in a material with a stated ethylene oxide concentration of <1 ppm, the current NSRL of 2 ug/day could be exceeded in potential ethylene oxide in just over 2 g of the product. Practically speaking, it is highly unlikely that one would inhale even 0.1% of available ethylene oxide, and that would extend the ”safe” amount of surfactant to 2 kg. We have people that work with 20,000 kg of these products daily.

How might one more rationally and with some scientific certainty, quantifiably determine the inhalation hazard possible in these products? A normal person inhales 11,000 litres of air daily or approximately 4,000 litres in a typical 8 hour work shift. A passivated SUMMA canister (as per EPA Method TO-14) could be set up to sample over eight hours in a plant (to get an average concentration for the day) and perhaps 500 ml would be introduced into a GC/MS system (this is a typical volume in this method). From this aliquot, perhaps 1 nanogram of ethylene oxide could be reliably detected in 500 ml of air. Under the current guideline, that would mean that the best level that could be reliably measured from 4,000 litres of air inhaled would be 8,000 ng (8 ug) which would be just 4 times over the current NSRL of 2 ug/day . One might push the detection limit lower with this method by a factor of ten maximum if selected ion monitoring MS was used in detecting the analyte instead of full scan mass spectrometry. This would bring the current NRSL into a place where one could just give some assurance that the NRSL could be met and not exceeded. Nonetheless, one would need to keep in mind that this test would only account for one set of conditions and no doubt, temperature and other environmental factors could influence the result. And I would suspect that finding an analytical laboratory to perform this test would be quite difficult and highly expensive.

If this change is instituted, the new required detection limit would be 35 times lower than current. As it is, I am unaware as to how one could confidently achieve a detection limit that would satisfy the new NRSL limit. It is understandable for regulators to want to lower exposures, but one must be able to confidently measure in these ranges in order to assure compliance. At this time, we don’t believe this to be possible without major analytical methodology developments and significant costs. The likely result may be chemical suppliers ignoring this new requirement since it would appear that there is no viable path to demonstrate compliance. And of course, ethylene oxide boils under 11C, and so most people believe that the compound will have escaped into the air during manufacture or packaging.

Eliminating ethoxylated surfactants from use in our world is not practical and would cause vastly higher amounts of other surfactants to be used in their place. The unintended consequences would likely be significant. This is because of the high efficacy of this class of surfactant in the myriad of cleaning applications encountered day to day.

Thank you for your consideration of our perspective on this matter, we would happily answer any questions that you may have for us.

Sincerely,

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