December 20, 2024

Safer Products for WA
Hazardous Waste and Toxics Reduction Program
WA Dept. of Ecology
Olympia, WA 98504-7600

Submitted Electronically to: SaferProductsWA@ecy.wa.gov and online comment form

RE: Draft Identification of Priority Chemicals Report to the Legislature: Safer Products for Washington Cycle 2, Implementation Phase 1

Dear WA Department of Ecology Staff:

Troy Chemical Corporation, an Arxada Company is providing comment on the most recent Washington State Department of Ecology (the Department) Draft Identification of Priority Chemicals Report to the Legislature: Safer Products for Washington Cycle 2, Implementation Phase 1 (Draft Phase 1 Report). Troy Chemical Corporation, an Arxada Company is providing specific comments on the identification of formaldehyde as a candidate priority chemical found in household cleaners and household care products such as laundry detergents. Our comments address formaldehyde and formaldehyde derived from EPA registered formaldehyde releasing biocides which may be used in the preservation of these products.

To ensure the Department has effectively utilized the best available science in their evaluation of this chemical we wish to focus our comments on the following areas:

- Natural production of formaldehyde in the body;
- Current thresholds on formaldehyde exposure;
- Assessment approach: risk versus hazard based analysis;
- Available toxicological studies on formaldehyde and reliance on the most current 2022 IRIS formaldehyde assessment;
- Formaldehyde donor chemistries and potential for emissions of formaldehyde from treated matrices such as household cleaners and laundry detergents. This includes the evaluation of formaldehyde risk from formaldehyde at the Federal level.

Additional comments in each area are found on the succeeding pages.

Formaldehyde is Naturally Produced in the Body

Formaldehyde is ubiquitous in nature and is present in every living organism. It is present in food that we consume and is emitted from various commodities such as wood products, furniture and other household goods[1]. Formaldehyde, for example, is found naturally occurring in apples (6.3-22.3 ppm), bananas (16.3 ppm), grapes (22.4 ppm) and pears (38.7-60 ppm). Formaldehyde

is an end product of human metabolism and as part of normal respiration, humans expire levels of 1-100 ppb (e.g. smokers). We understand the Department has differentiated between endogenous and exogenous sources of formaldehyde and indicated these two sources behave differently. We differ with this statement because formaldehyde is essential to one-carbon metabolism and both forms of formaldehyde (endogenous and exogenous) behave the same. There is no data to support the contention these act differently. Concentrations that do not upset normal variability in metabolic processes and inhaled exogenous formaldehyde do not present added risk. Metabolic detoxification mechanisms and pathways have been well studied are prevalent in the case of formaldehyde toxicity. The Department should not consider banning formaldehyde in consumer products when the concentrations in those products are lower than the concentrations naturally present in our own bodies and in the foods we eat. None of the studies cited in this section have been cited in the Draft Phase 1 Report.

Current Thresholds on Formaldehyde Exposure

The available scientific literature provides considerable evidence of an observed threshold for effects of formaldehyde exposure. In 2010[2] the World Health Organization (WHO) recognized that a threshold -based approach is appropriate for establishing indoor air quality guidelines for formaldehyde. In 2018 the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) also recognized a threshold for formaldehyde exposure when establishing its values for safe long-term exposure. The EU's Scientific Committee on Occupational Exposure Limits (SCOEL) has indicated a threshold limit for workplace exposure of 0.3 ppm). Finally, the US EPA indicated in their most recent Draft Risk Assessment of formaldehyde and paraformaldehyde that the contribution of formaldehyde from formaldehyde donor biocides is negligible to the contribution from our sources in the home.

Assessment Approach: Risk versus Hazard Based Analysis

The most recent draft report indicates the approach used by the Department is based on a hazard assessment and not risk. An assessment of hazard does not include the critical element of risk which is based on exposure by dermal and inhalation routes. Formaldehyde is one of the most studied chemicals and its database is extensive with regards to exposure. The most recent 2022 Draft IRIS assessment which is being finalized utilizes a risk approach in its evaluation of formaldehyde exposure. The route (dermal or inhalation) and duration of exposure ultimately will determine the effects of formaldehyde on workers. Troy Chemical Corporation an Arxada Company therefore advocates for the inclusion of risk in the overall evaluation of formaldehyde. While a potential hazard can be identified with formaldehyde it does not establish the exposure conditions that would pose cancer risks to individuals in their daily lives.

Available Toxicological Studies on Formaldehyde and Reliance on the Most Current 2022 IRIS Formaldehyde Assessment

Since the last 2010 IRIS assessment[3] there have been numerous studies on the effects of formaldehyde conducted by industry and academia. We are aware that the current 2022 draft IRIS assessment and EPA TSCA assessment of formaldehyde have been utilized as reference materials in the current Department Phase 1 Report. The only major government reference

cited in the Report is the National Toxicology Report indicating an association between formaldehyde exposure and leukemia. Unfortunately, the data utilized for this evaluation is suspect since over 100 studies and various international government actions pertaining to formaldehyde exposure and cancer assessment were not incorporated into these actions. These new data indicate, for example, the lack of biological plausibility for a causal association between inhaled formaldehyde and lymphohematopoietic cancers such as leukemia. Additionally, the Report indicates formaldehyde exposure supports it's classification as an asthmagen. The National Academy of Sciences (NAS) reviewed asthma and indoor air exposures. In this review NAS only found limited or suggestive evidence of an association between formaldehyde exposure and asthma incidence. In 2017 Golden and Holm evaluated the literature and found that studies reviewed incorrectly concluded that there was a positive association between formaldehyde exposure and childhood asthma. None of these relatively recent studies are cited in the Draft Phase 1 Report.

The Draft Phase 1 Report relied on the use of third-party assessments to screen relevant formaldehyde literature. This has introduced a level of bias and subjectivity into the Departments rulemaking process. It is contrary to the Departments' statutory obligations that it will evaluate candidate chemicals in a consistent, non-biased manner. It is unclear how the third-party screened the available formaldehyde literature.

Formaldehyde donor chemistries and potential for emissions of formaldehyde from treated matrices such as household cleaners and laundry detergents. This includes the evaluation of formaldehyde risk from formaldehyde at the Federal level.

It is unclear how formaldehyde emissions from household cleaners and laundry detergents were determined or considered in the determination of exposure to consumers. The Department describes several potential exposures to formaldehyde including indoor air and outdoor air as well as dermal exposure. For the cancer endpoint there are a number of publications and reviews that demonstrate consumer exposure does not pose a risk. In a 2017 publication[4] Sheehan et al. evaluated formaldehyde concentrations in approximately 18,000 residences and found that formaldehyde emissions posed virtually no cancer risk. The WHO reviewed epidemiological studies from the NCI and concluded for the purposes of indoor air guideline setting, that no excess nasopharyngeal cancer was reported at a mean formaldehyde exposure at or below 1.25 mg/m^3 [1,020 ppb] and with peak exposures below 5 mg/m^3 [4.100 ppb]. Taking the average indoor exposure levels of 16-32 ppb, which again is for all sources in a home, the average indoor air exposures fall below the threshold for cancer risk. Although dermal exposure to formaldehyde-containing liquid is possible for these types of applications, routine skin contact is not likely. This is because the irritating and absorptive properties preclude ongoing skin contact and systemic effects. Lastly NIOSH states that in vivo toxicokinetic studies in animals indicate formaldehyde has a limited potential to be absorbed through skin (<10%). None of these studies are cited in the Draft Phase 1 Report.

Other Federal Agencies have been involved in the regulation of formaldehyde as an antimicrobial in consumer products such as cleaners and laundry detergents. Most recently the

U.S. EPA Office of Pesticide Programs (OPP) issued a draft risk assessment for the antimicrobial uses of formaldehyde and paraformaldehyde. Unfortunately, this draft risk assessment is based on the draft 2022 IRIS formaldehyde assessment and there is no indication how formaldehyde donor chemistries will be evaluated based on the IRIS conclusions going forward. One key piece of data requested by EPA was emissions data from treated matrices such as cleaners and detergents to bridge between emissions of formaldehyde and treated matrices which Troy Chemical provided on its formaldehyde donor chemistries in various matrices such as cleaners. These data indicate emissions over time were extremely low and varied depending on the formulation and matrix tested. This work exemplified a key issue in the evaluation of donor chemistries which is a) the formation of formaldehyde in a particular matrix is not finite but limited due chemical stoichiometry and finite resources in the matrix such as water, pH and temperature and b) how formaldehyde emissions are measured.

Analytically it is extremely difficult to measure formaldehyde in solution. Measurements of free formaldehyde in liquid matrices has often been conducted using derivatives to bind to available formaldehyde in solution. While this methodology is widely used it does provide erroneous values of formaldehyde because of its destructive nature. There are other methods more appropriate to liquid matrices such as Nuclear Magnetic Resonance (NMR) since they are non-destructive and provide an accurate assessment of the free formaldehyde in any given matrix. As it is unclear how the formaldehyde was determined in the Draft Phase 1 report, we speculate that emission values as currently presented are based on other public literature and not actual measurements of free formaldehyde. If derivatization methods such as the use of DNPH complexing agents, it is clear formaldehyde was created from other raw materials in solution and are not attributable to the use of formaldehyde donor chemistries. In other words, how much formaldehyde is actually emitted from donor chemistries over the background levels normally present in these products?

The use of formaldehyde donor chemistries as preservatives for household products has steadily declined due to regulatory pressure on workplace formaldehyde and lowering of emission standards Federally. We would urge the Department to reconsider listing of formaldehyde donor chemistries as part of the Draft Phase 1 report until a number of key Federal regulatory actions are completed: namely the 2022 IRIS formaldehyde assessment, the TSCA formaldehyde priority risk assessment and OPP registration review of formaldehyde. All of these actions will have direct consequences on the regulation of this compound.

In conclusion Troy Chemical Corporation an Arxada Company questions the listing of household cleaners and laundry detergents due to formaldehyde emissions in the Department Phase 1 Report. Formaldehyde emissions are a normal part of human metabolism and the database on formaldehyde emissions is extensive. It is not clear what data were used in the listing process considering there have been numerous new data on formaldehyde emissions and its role in the development of cancer. Finally, there are a number of key Federal regulatory actions in process for formaldehyde regulation from the 2022 IRIS cancer report to EPA's Office of Pesticide Programs Registration review of formaldehyde/paraformaldehyde. These actions will

have a direct affect on future regulation of this compound, and these must be part of the Department's third-party evaluation for cleaners and household care products. In addition, we urge the Department to exclude EPA -registered antimicrobial formaldehyde donor chemistries from the draft report. There is significant data under review which indicates their use does not contribute to the formation of cancer or respiratory disease.

Should you have any additional questions regarding our comments please contact me directly by phone or email (phone: 973-943-0503 or email: Adrian.Krygsman@Arxada.com. Thank you.

Sincerely,

Adrian Krygsman

Adrian Krygsman
Director Product Registration

References

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2010 IRIS Risk Assessment on Formaldehyde

2022 IRIS Draft Risk Assessment on Formaldehyde