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Overview

In preparing this review I read the Plain English Summary of the Proposal to Nail Products containing Toluene as a Priority Product, the Product-Chemical Profile for Nail Products Containing Toluene – May 2019 – External Scientific Peer Review Draft (referred to as the Peer Review Draft Report in this document), peer reviewed literature, trade articles, and reports referenced in the Peer Review Draft Report as well as additional articles found using literature searches. I have focused particularly on Conclusion 2: issues related to exposure and air concentrations of toluene resulting from the use of nail products in nail salons and homes; and to a lesser extent Conclusion 1: health effects from toluene exposure and Conclusion 3: sensitive subjects as they relate to their exposure to toluene.

In my opinion, the Peer Review Draft Report and the scientific conclusions provided to the Peer Reviewers are based on sound scientific knowledge, methods, and practices as they appear in the current scientific literature. The current literature confirms that there is toluene exposure within nail salons and homes where nail products containing toluene are used. These exposures are to nail technicians, customers who use nail products, and others in proximity to the nail products being used. The air concentrations breathed by nail technicians reported in the literature can exceed the current chronic Reference Exposure Level (REL) for toluene listed in the California Office of Environmental and Health Hazard Assessment of $300\mu\text{g}/\text{m}^3$ for chronic exposure though the levels encountered are less likely to exceed the REL of $37,000\mu\text{g}/\text{m}^3$ for acute exposure (Collins et al., 2004; OEHHA, 2019).

Conclusion 1 – Toluene has hazard traits that can potentially cause significant adverse impacts on human health.

Toluene is a common solvent that has been used in industrial, commercial and consumer products and settings for more than a century. Toxicological and epidemiological studies evaluating adverse health outcomes of toluene has been ongoing since the 1950s, when toluene was studied as one of the alkylated benzene compounds (Wolf et al., 1956). More extensive toxicological and epidemiological studies focusing on the toxicity of toluene were initiated in the 1980s. As described in the Peer Review Draft Report the most prevalent adverse impacts of toluene on human health are neurotoxicity, developmental and respiratory toxicity. Literature studies quoted in the Peer Review Draft Report, but not individually specified in this document, have examined adverse health effects of toluene in epidemiological studies and in animal models.

Neurotoxicity: Epidemiological studies of toluene have focused on occupational cohorts where the workers are exposed chronically to toluene in the 10s to 100s of ppm air concentration. These exposures appear to be associated with increase neurological symptoms such as fatigue, memory and concentration problems, decreased manual dexterity, color discrimination and perception, and visual cognitive ability. The literature includes a cohort of workers in nail salons who expressed mild cognitive and neurosensory changes, though the authors recognize that other solvents are also present in that setting (LoSasso et al., 2001; LoSasso et al., 2002). Studies of individuals who inhaled toluene ‘recreationally’ to obtain an intoxication sensation comparable to alcohol intoxication, a habit labeled toluene abuse, have identified symptoms indicative of neurotoxicity that include: reported slowness in thinking, lower intelligence scores than non-users, tremors, speech difficulty, vision and auditory problems and dementia.

Animal studies have reported clinical signs of neurotoxicity and neurobehavioral alterations (e.g. behavior, memory and motor coordination) at high (>100ppm) acute exposures. Effects on oxidative stress, increased dopamine binding, changes in

neurotransmitter signaling, etc. have been noted providing clues to the mechanisms for toluene's neurotoxicity.

Developmental: Decreased body weight is the most consistently observed developmental endpoint. Animal studies have also identified problems with cognitive function in offspring, recovery time of motor functions, signaling biochemical changes in the hippocampus which may be related to memory and learning processes, and increases in neuroinflammatory gene exposure during pregnancy.

Respiratory Toxicity: The primary effect of toluene on the respiratory tract is irritation. These effects have been observed in human controlled toluene exposures studies, in workers exposed to toluene used as a solvent, and in animal studies. Human studies have observed irritation of the mucous membrane in workers chronically exposed to toluene, nasal irritation after acute exposure, and lung damage and emphysema in individuals who chronically abuse toluene. Animal endpoints associated with toluene inhalation exposure have included upper and lower respiratory tract lesions, reversible nasal olfactory degeneration, inflammatory cell infiltration in peribronchial and alveolar regions, alveolar edema, and interstitial fibrosis and necrosis.

The Peer Review Draft Report cites studies that identified other adverse health endpoints following toluene exposure. A similar list of adverse health conditions associated with exposure to toluene is given in the Agency for Toxic Substance and Disease Registry Toxicological Profile of Toluene (ATSDR, 2017). I concur that toluene inhalation exposure can result in the adverse health effects as outlined in Conclusion 1, based on my review of the Peer Review Draft Report and reading of original literature.

Conclusion 2 - Potential for consumers and workers to be exposed to toluene during use of nail products, and these exposure in nail technicians and salon workers are exacerbated by working conditions

As related in the Peer Review Draft Report, toluene is volatile and when present in nail products it will evaporate when the nail products are applied and from uncapped bottles. Since nail product applications are done indoors, in nail or beauty salons occupationally where multiple individuals are working with the products, and in homes where

individuals use nail products on themselves and/or one or more other individuals (e.g. friends, relatives), indoor and personal toluene air concentrations will become elevated. The air concentrations that workers and customers inhale will be a function of the toluene content in the product, how much product is used, and the ventilation near the individual and within the room. Additional factors such as seasonality, physical layout of the room, weather conditions, and use of personal protection equipment can modify the exposure and body uptake of toluene. When multiple individuals use nail products containing toluene in a single locale the indoor air concentration will increase further, with the impact on personal air dependent upon the proximity of users to each other.

Potential toluene exposure levels given in the Peer Review Draft Report were based on published studies reporting personal and room air concentrations measured in nail salons and, for a smaller data set, in residential settings, and exposure factors.

Exposure factors considered were: the amount of time spent by nail technicians in the nail salons applying nail products, how long consumers were in a nail salon and/or applied nail products to themselves and others at home, the proximity of technicians using nail products to each other, whether appropriate personal protective equipment was used, and the adequacy of the ventilation systems in the room and/or near an individual's work area. Biological sampling to assess exposure to toluene from nail products includes measurement of urinary metabolite hippuric acid (Yang and Han, 2010) and blood toluene levels (Ceballos et al., 2019).

Besides measuring toluene air concentration directly, air concentrations can be calculated using indoor air models based on emission rates, product use, and ventilation. One study employed a screening level exposure model based on a two-zone model for a nail salon and a well-mixed model for a home to determine toluene exposures from nail product and estimate risk (Kopelovich et al., 2015). Using estimated median and maximum toluene content in nail products and single value estimates for the other parameters, the authors indicated that the estimated toluene dose from the mean nail product toluene content was below the current standards but for the dose from the maximum toluene content in nail products exceeded the US EPA RfC value concentration of $5,000\mu\text{g}/\text{m}^3$ (1.23 ppm). More sophisticated indoor air

models that employ distributional parameter inputs can be used to predict the expected distribution of toluene air concentrations and exposures from nail products for nail technicians and consumers, but have not been reported in the literature. Therefore, this approach is not discussed in the Peer Review Draft Report. Such an approach could be useful to ascertain how different scenarios (e.g. altering the allowed level of toluene in each product, changing ventilation conditions, and the number of individuals working within different room sizes and configuration) would alter exposures. A study that has been used to predict acetone air concentrations from nail products (Arnold et al., 2017) and one that used a chamber to measure emission rates from nail polish (Heaton et al., 2019) may be useful for deriving such a model for toluene exposure from nail products.

In 2012, the California Environmental Protection Agency, Department of Toxic Substances Control (DTSC, 2012) tested nail products and reported that 10 of 12 products claiming to be 'toluene free' actually contained toluene at levels as high as 17.7% and 8 of 13 other nail products that did not specify if they contained toluene were between 0.011 and 12% toluene. Zhou et al. (2016) detected toluene in 26 of 34 nail products at levels from 1.35 ppm to 17.3%. Thus, while nail products are marketed as toluene-free, that label has not always been accurate.

The Peer Review Draft Report cites toluene air concentrations measured across studies conducted in California, other locations in the US, and globally. McNary and Jackson (2007) reported median & 95th percentile area and personal air levels of 380 µg/m³ & 520 µg/m³, and 754 µg/m³ & 980 µg/m³, respectively, in California nail salons. Nguyen (2016) detected toluene in 75% of Californian nail salons visited with a maximum detected concentration of 490 µg/m³. These levels are consistent with what has been reported in other states in the US (e.g. (Alaves et al., 2013; Eklund et al., 2008; Quach et al., 2011)). Toluene levels in other countries are more variable, with values from 67 µg/m³ in Greece to 359,000 µg/m³ in South Korea (e.g. (Eli Hollund and Moen, 1998; Gjølstad et al., 2006; Grešner et al., 2016; Park et al., 2014; Tsigonia et al., 2010)). This range likely reflects differences in toluene content in the nail products available and differences in work conditions, particularly ventilation rates, room size and number of technicians working in single area.

Curry et al. (1994) conducted a scripted study in California to measure personal exposure to toluene in residential settings associated with the use of nail products containing 21 to 33% toluene. The personal air and room air concentrations measured during nail polish application ranged from 3,200 to 9,200 $\mu\text{g}/\text{m}^3$ and from 900 to 2,600 $\mu\text{g}/\text{m}^3$, respectively. The toluene air concentrations decreased by one to two orders of magnitude once the application ceased and the nails were dry. The presence of a nail salon within a larger indoor structure, such as a mall or attached stores, can result in elevated toluene air concentration in adjacent or nearby stores due to emissions from the nail salon (Eklund et al., 2008). Studies published since the Peer Review Draft Report was prepared continue to report toluene air concentrations as high as hundreds of $\mu\text{g}/\text{m}^3$ in nail salons throughout the US (Ceballos et al., 2019; Lamplugh et al., 2019; Ma et al., 2019; Moradi et al., 2019; Zhong et al., 2019).

Inhalation exposure depends on the air concentration breathed and the duration of time and frequency that an individual breathes that air. Nail technicians, who are predominantly females, will have the longest and most frequent exposures to toluene from nail products. The median number of hours that nail technicians are reported to work exceeds 36 hours per week. They service 16 to 20 customers during a shift, and 10% of the nail technicians interviewed service more than 36 customers per week. There are approximately 130,000 licensed nail technicians in California. In addition, 98 million people in the US, again predominantly women, use nail polish with 20 million having 4 or more manicures within the previous 6 months (Statista, 2019). Thus, a large number of people are exposed to emission from nail products. The degree of exposure will differ between nail technicians and consumers who visit nail salons or polish their nails privately, since for consumers the median and 90th percentile of nail products use is approximately once per week and once every one to two days, respectively, in the US (USEPA, 2011), though one California study found this to be less frequent with median and 90th percentile use of 2 and 6 per month for users (Wu et al., 2010).

Nail technicians are exposed throughout the workday and week to the emissions from nail products. The time weighted average (TWA) air concentration (i.e. the air

concentration across an eight hour day – a time frame used for standards within occupational settings) is significantly higher for nail technicians than customers who use nail polish. The toluene air concentrations in nail salons and in a home are a function of the toluene content in the products used, how much product is used, and the ventilation/air exchange rate within the room. Several states and municipal governments have stipulated ventilation conditions and/or air filtration to meet a perceived acceptable air quality or minimum ventilation rate as part of their business licensing requirements of nail technicians or nail salons (e.g. (NYS_DLS, 2019; Pavilonis et al., 2018)). The size and layout of nail salons are highly variable. Some have been found to be poorly ventilated based elevated carbon dioxide levels and some are located in enclosed building structures (e.g. malls) which can result in toluene contamination in adjacent stores. Local ventilation at individual work stations and increased air exchange through the whole facility can reduce toluene (and other volatile compound) air concentrations thereby decreasing toluene exposures. It is important to include educational, cultural and economic considerations as part of any implementation plan to improve the air quality across all nail salons ((Ceballos et al., 2019; Hadei et al., 2018; Huynh et al., 2019; Ma et al., 2019; Pavilonis et al., 2018; Quach et al., 2011; Quach et al., 2018a; Quach et al., 2018b; Seo et al., 2019). Whether whole room ventilation would be more effective and cost efficient than localized ventilation at work stations in reducing toluene exposures depends upon the room configuration and proximity of the nail technicians' work stations within a salon. Relying on having doors and/or windows open for nail salons to provide ventilation, while observed to lower air concentrations (Ceballos et al., 2019; Zhong et al., 2019), is not a viable solution since being able to do so is season dependent and will unlikely provide uniform ventilation across an entire store. Having adequate ventilation in homes presents different considerations since ventilation conditions in homes are not set by regulations and vary as a function of the room used and whether windows in that room are opened or closed.

Traditional occupation hygiene approaches to protect workers from a hazard, as outlined in the Peer Review Draft Report, in order of preference are: elimination of the hazard; substitution with a different chemical; engineering controls (i.e. ventilation); administrative controls (i.e. policies to limit exposure and training); and use of personal

protective equipment. Since nail products will continue to be used, the most effective approach to reduce toluene exposure would be to identify a non-hazardous substitute for toluene and to verify that all products which claim to be toluene free do not contain toluene. The next level of protection would require adequate ventilation in nail salons, as is currently being stipulated in licensing requirements in several states and municipalities. Installing proper ventilation may present economic challenges for some small businesses and will not reduce toluene exposure when nail products are used in home settings. If ventilation is to be used to control toluene exposure to nail technicians then guidance on the type of ventilation, individual stations or increased air exchange for the full room (including locating exhaust systems to avoid contamination of nearby stores), should be provided based on the arrangement of the work stations within the salon. Proper policies and training are needed for educating the nail salon owners and nail technicians to minimize their and their customers' exposures. The approach of using personal protective equipment (PPE), which can reduce the dose workers received, is not suggested as the primary approach to reduce exposure for this customer centered business. If PPE are to be used, education and training for the selection of a PPE that can remove toluene from the air and its use (e.g. how to wear and when to replace) should be provided for the PPE to be effective.

In summary the air concentrations measured in some nail salons and some homes exceed the current California REL for chronic exposure to toluene of $300 \mu\text{g}/\text{m}^3$. This presents a particular concern for nail technicians based on the number of hours per day and week and days they often work and considering many are female of child bearing age. While customers at nail salons and individuals who use nail products at home may encounter peak levels above the REL of $\mu\text{g}/\text{m}^3$, their exposure will not be as extensive as nail technicians, though might occur on a near daily basis. Exposures at home could be elevated for an extended time period, dependent upon the ventilation conditions and are likely to include children and pregnant or breast feeding women who are potentially sensitive populations, as discussed in response to Conclusion 3.

Charge Question 3 – Certain sensitive subpopulations may be especially susceptible – Exposure considerations

There are approximately 130,000 licensed nail technicians in California and 81% of parents of young children and 79% of older adults (>55 years) have their nails done professionally (Wu et al., 2010). Nail technicians and their clients are predominantly female (97%), with more than half being of child-bearing age. Because of the gender and age demographics, a reasonable percentage of the nail technicians and clients are likely trying to become pregnant, are pregnant or breast feeding. As toluene is reported to have neurotoxicity and developmental effects, the exposed population should be considered a sensitive group as these health endpoints are problematic at conception, to a fetus during pregnancy, and to infants. Toluene is a lipophilic chemical that has a relatively short half-life in the body. It will be transferred to breast milk on days individuals are exposed to toluene (ATSDR, 2015).

Children, whose neurological systems are developing, can be exposed to toluene from nail products when with their parents in a nail salon or have their own nails polished. In California, 45% of girls ≤ 5 years and 79% of girls over 5 use nail polish by self-application (Wu et al., 2010). In addition, women bring their children to nail salons during their appointment and have the child's nails polished in nail salons at young ages. If multiple individuals from a single family are at a nail salon together the time spent there may be extended beyond the time it takes for a single service. It is also possible that nail technicians occasionally bring their children to nail salons when they are working, such as when child care is not available or school is not in session, particularly at smaller or family run shops. However, data on the frequency that occurs were not found in the literature.

While exposures in homes would be expected to be of shorter durations than those encountered by nail technicians in nail salons, ventilation in homes where nail products are used may be low so elevated air toluene concentrations may last for an extended time period. Applying nail products by adolescent and younger girls is sometimes done as a social activity that may include a number of girls over a several hours' time period. This could result in higher toluene air concentrations than reported in the literature. An

evaluation of the air concentrations associated with this type of activity and the frequency of occurrence should be considered for this population.

In summary, nail technicians are the most highly exposed group and considering that they are predominantly female of child bearing age represent a potential sensitive group. Nail products are used by young girls, a second potentially sensitive group.

The Big Picture

There is a lack of exposure modeling that use distributional based systems that could predict how changes in toluene content in the product and ventilation considerations would be effective in reducing the risk to toluene exposure from nail products.

Consideration of education and implementation of any protocols for reducing exposure in smaller stores among non-native English speaking individuals that might be concerned with official governmental regulations and an understanding of the rationale for the regulations is critical.

Taken as a whole, the proposed regulation is based on sound scientific knowledge, methods and practices. That said, the observation that products marked toluene-free contain percent levels of toluene indicate that implementation of any regulation need to have appropriate considerations for it implementation.

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