CTEH® CENTER FOR TOXICOLOGY AND ENVIRONMENTAL HEALTH, LLC

SAFETY OF POLYETHYLENE COPOLYMER POWDER IN PURPLE® MATTRESSES

On behalf of Purple®

Alpine, Utah

Prepared by CTEH

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Executive Summary

Allegations have arisen that users of Purple® mattresses may be exposed to potentially harmful particles. For this reason, Purple®, the makers of comfort technology available for purchase by consumers, requested that I review toxicity and exposure data for polyethylene copolymer (1-octene and ethylene) and related particle compounds, and evaluate the potential for adverse health effects for consumers using the mattresses. Polyethylene is the most common form of plastic produced in the world and is found virtually everywhere in the U.S. It has enjoyed safe usage for decades in various products, including food containers, water bottles, medical implant devices, cosmetics, and personal care products. The available scientific literature clearly indicate lack of toxicity of polyethylene.

A study recently conducted to evaluate airborne particle release from normal use and setup of Purple® mattresses, showed that the potential exposures to Polyethylene copolymer are vanishingly small. The measured particle levels detected are hundreds of times lower than health-protective standards established by the U.S. EPA for short- and long-term ambient particle exposures that are protective of even sensitive individuals. Thus, allegations of potential for adverse health risks associated with use of Purple® mattresses are not supported by the available scientific literature and are without scientific merit. On the contrary, the available toxicology and exposure data clearly indicate Purple® mattresses are safe for consumer use.

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Scope of Work and Professional Qualifications

Purple® requested that I, Michael H. Lumpkin, PhD, DABT, a toxicologist with the Center for Toxicology and Environmental Health, LLC (CETH), perform an evaluation of the safety of a polyethylene copolymer powder and health risks to consumers using Purple® mattresses manufactured with polyethylene copolymer (polymer of 1-octene and ethylene). Purple® wished to know if typical and reasonable consumer use of Purple® mattresses may result in an increased risk to consumers for adverse health effects from dermal or inhalation exposures to Polyethylene copolymer in Purple® mattresses.

I am a board-certified toxicologist with almost 15 years of experience in regulatory toxicology, product stewardship and consumer product safety assessments, dietary supplement safety and toxicology, worker and consumer exposure reconstruction, chemical dose response assessment, computational toxicology, and chemical incident emergency response. I have authored multiple safety assessments of products including polymer food packing materials, inks and dyes, household and institutional cleaning products, foods, and dietary supplements. I have provided critical reviews and analyses of toxicology data for numerous classes of compounds, including inhaled dust, volatile solvents, metals, reactive aldehydes, PAHs, pesticides, and perchlorates. I have provided analyses of human and animal study data in support of new drugs and medical device applications, and have designed and performed occupational exposure reconstructions for VOCs and diisocyanates using laboratory simulations. I have developed multiple novel occupational exposure limits for pharmaceutical and industrial chemicals. I have developed, critiqued, and applied computer simulation (PBPK) models for volatile organic compounds (VOCs), metals, pesticides and bioterrorism agents for USEPA, CDC and DOD, for use in regulatory standard support and emergency planning. I have coauthored numerous peer-reviewed hazard assessments for USEPA and the Agency for Toxic Substances and Disease Registry (ATSDR). I have served as an expert peer review scientist for the EPA as well as on federal grant review committees and as a peer reviewer for toxicology journals. I have authored textbook chapters in graduate-level toxicology textbooks and have lectured in graduate courses and emergency responder seminars. I am a member of the Society of Toxicology and am certified as a Diplomate of the American Board of Toxicology.

Common Nonhazardous Consumer Product Polyethylene Copolymer Applications

Polyethylene (CAS #9002-88-4) is a chemical polymer used in the manufacture of a wide variety of consumer and medical products. Chemically, it is chain of 2-carbon ethylene molecules linked together to form long hydrocarbon chains, resulting in plastic that can be easily molded into myriad shapes for particular applications. These applications include materials and plastic parts used in Industrial components, pharmaceuticals, food packaging (including bottled water), toys, consumer containers of various types, cosmetics, and chewing gum. Polyethylene is the most common form of plastic produced in the world and is found virtually every in the U.S. It is also a general term for ethylene-based polymers with a semi-crystalline structure. The extent to which polyethylene is primarily long chains (high-density polyethylene) or highly branched, shorter chains with other copolymer molecules (low-density polyethylene) determines its rigidity and/or pliability. The various polyethylene polymer/copolymer mixtures have individual chemical registration numbers.

Flexible low-density polyethylene films are used to make products such as Saran wrap, while high-density polyethylene has been approved by FDA for use in hard plastic food containers. Ultra-high-density polyethylene is integral to medical devices such as artificial joints, cardiac stints, and gynecological devices. Polyethylene power is used in cosmetic products such as mascara, eyeliner, lipstick, eye shadows,

face powders, and foundations (PCPC, 2017). Polyethylene is also used in bath soaps, fragrance powders, and baby lotions (CIREP, 2007). Industrial containers, tarps for greenhouse and other agricultural purposes, and wire and cable coatings are a few other uses of polyethylene.

Polyethylene Copolymer Use in Purple® Mattresses

A particular polyethylene variant used in the manufacture of Purple® mattresses is a polyethylene copolymer (CAS #26221-73-8). The polyethylene copolymer used in Purple® mattresses is a copolymer chain of recurring units of the molecules 1-octene and ethylene. It is in the form of ultra-fine, spherically-shaped particles that are typically between 5 and 20 micrometers (µm, or one millionth of a meter) in diameter.

Polyethylene copolymer is added to Purple® mattresses to adhere to the gel portion of the mattress beneath the mattress cover, where it serves as a solid lubricant. The gel portion of Purple® mattresses are made of a hyper-elastic polymer material that is tacky to the touch when initially manufactured. Purple® mattresses are rolled up, packaged, and shipped to customers. This causes the gel section to stick to itself, making unrolling more difficult when unpackaged. Polyethylene copolymer aids in the separation of the tacky surfaces of the gel layer such that the mattress readily unrolls to its final shape when removed from the packaging. Exposure of mattress users to polyethylene copolymer may potentially occur because some of the polyethylene copolymer particles are small enough the move through the fabric spaces of the mattress cover.

Polyethylene Toxicology Review

In order to determine if a risk to consumers[1] for developing adverse health effects actually exists from Purple® mattress use, the toxicity potential of polyethylene copolymer in general and the plausible exposure level from Purple® mattress use specifically must be understood. This principle holds for any substance. If the daily consumer exposure level of polyethylene copolymer from mattress use is less than the exposure level required to produce an adverse health effect, then the risk for harmful effects does not exist.

Toxicological Data for Polyethylene and/or Polyethylene Copolymer

Bibliographic databases of publically-available toxicological literature were searched to identify toxicity data in humans and laboratory animals. The National Library of Medicine's PubMed database, which references over 24 million articles and studies, was searched, as was the National Library of Medicine's Hazardous Substance Data Bank (HSDB), a compendium of data for potential physical and toxicological hazards for thousands of chemicals. The HSDB also provides information on typical compound uses, potential human exposures, industrial hygiene exposure limits, and other related information. These data bases were consulted to identify data associated with adverse health effects from inhalation and dermal exposures to polyethylene in general and polyethylene copolymer (1-octene/ethylene) in particular.

There are no publically-available toxicology data for polyethylene copolymer specifically. However, there are data for other forms of polyethylene. Given the high chemical structure similarity between polyethylene and polyethylene copolymer, effects data for polyethylene in general are an appropriate surrogate for potential health effects of polyethylene copolymer. Ingested polyethylene was not toxic to laboratory rodents (Lefaux, 1968; Safepharm Labs, 1997a). Rabbit studies of polyethylene skin irritation

[1] Consumers include individuals of the general public, including sensitive sub-populations such as children, elderly, and asthmatics.

or corrosivity were negative (Safepharm Labs, 1997b, 1997c). Guinea pig tests for skin sensitization were also negative (Safepharm, 1997d). No genetic toxicity effects were observed in standard mutagen tests in bacteria (Safepharm Labs, 1997e). The lack of adverse effects from polyethylene for these testing endpoints is expected given that that chemical structure of polyethylene copolymer does not contain functional groups that would be reactive with biological tissues.

Particulate Matter as a Surrogate for Polyethylene Copolymer Exposure

Given the lack of toxicity of polyethylene seen in oral or dermal exposures of laboratory animals, and the lack of toxicity data for inhaled polyethylene, data for particulate matter (PM) is appropriate for evaluating inhalation toxicity risks of polyethylene copolymer at low exposure levels. PM is the general term used for a mixture of solid particles or liquid droplets suspended in the air. Airborne PM can be of different sizes. The extent to which PM is inhaled and where in the lungs it is deposited is determined by the size of the particles. Non-respirable particles are PM that are 10 µm (PM_{10}) or larger in diameter. Particles in this size range are inhaled, deposited in the nose, throat, and upper sections of airways, and are removed to throat to be swallowed or spat out. Respirable particles are generally less than 5 µm and may deposit in the deepest parts of the lungs were pulmonary gas exchange takes place. The respirable fraction of PM in air is typically represented (and measured in regulatory air monitoring) as $PM_{2.5}$, or PM that on average is 2.5 µm in diameter. Respirable PM in air may result from wildfires, cooking, burning of candles and other combustion sources. Non-respirable PM_{10} may come from many sources, including indoor dust, pollen, soil dust, and pet and human skin dander.

The ultimate fate of respirable particles that deposit into the deep lung spaces (alveolar sacs and respiratory bronchioles) depends on the chemical nature of the particle and the amount of particles deposited during a given exposure. For chemically non-reactive polyethylene particles, no chemical interaction will occur between the particles and lung tissue (alveolar epithelium) cells. Specialized immune system cells called alveolar macrophages are always present in the deep lung spaces. These cells move about the internal tissue surfaces of lungs, and engulf bacteria and other foreign objects like respirable particles. Once macrophages have engulfed foreign material such as polyethylene copolymer particles, they migrate from the lung spaces to local lymph nodes and the spleen. Bacteria and particles inside of the macrophages may be destroyed and degraded by specialized chemical systems within the macrophage. Macrophages that engulf particles may migrate to the lung lymph nodes or up the respiratory tree, where they are cleared to the esophagus and excreted. Respirable polyethylene copolymer particles that reach deep lung will not be absorbed and distributed around the body.

Airborne PM is ubiquitous across the earth. However, the physical makeup of airborne PM is highly variable. In urban environments, respirable PM may be produced by construction and industrial processes, vehicular traffic, and fossil fuel combustion by-products to name a few. Because airborne particles can differ in composition, sources, size, and potential health impacts, the United States Environmental Protection Agency (USEPA) has established a National Ambient Air Quality Standards (NAAQS) for $PM_{2.5}$ enforceable under the Clean Air Act for the protection of public health (EPA, 2017). The NAAQS values incorporate an adequate margin of safety against health effects associated with continuous short-term and long-term exposures, and is intended to be protective of children, older adults, persons with pre-existing heart and lung disease, asthma and respiratory conditions, and other at-risk populations. For this reason, it is not uncommon for federal, state, local, and tribal agencies to regularly use the NAAQS for $PM_{2.5}$ as a reference for particle pollution in ambient air to ensure that PM in the air is at levels that will not impact public health and welfare. The 24-hour average NAAQS for $PM_{2.5}$ is 35 $\mu g/m^3$. Unlike polyethylene copolymer, urban $PM_{2.5}$ may be comprised of a variety of compounds, including compounds that are reactive with lung tissues or have been shown to be associated with lung or systemic toxicity.

Thus, likely exposures of inhaled polyethylene copolymer at levels at or below the NAAQS $PM_{2.5}$ value of 35 µm/m^3 would be considered safe with a significant margin of safety.

Purple® Mattress Polyethylene Copolymer Exposure Assessment

Terracon Consultants, Inc. (Terracon) conducted an assessment of personal breathing zone levels of polyethylene copolymer from simulated use conditions in order to determine the extent, if any, to which polyethylene copolymer powder would be released to air during mattress unpacking (minutes) and use (4 hours). Details on the methodology and results are fully described in Terracon's report (Terracon, 2017). In addition to measuring airborne levels of polyethylene copolymer, Terracon characterized the average particle size. **Table 1** shows the polyethylene copolymer sphere characteristics and air concentration data. By multiplying the average sphere volume ($V = \frac{4}{3}\pi r^3$) by the nominal polyethylene copolymer density (0.952 g/cm^3) (value provide by Purple®) and the number of spheres per liter reported, an average air concentration in mass per volume (µg/m^3) was calculated and shown in **Table 1**.

Table 1. – Terracon Results: Breathing Zone Polyethylene Copolymer Concentrations

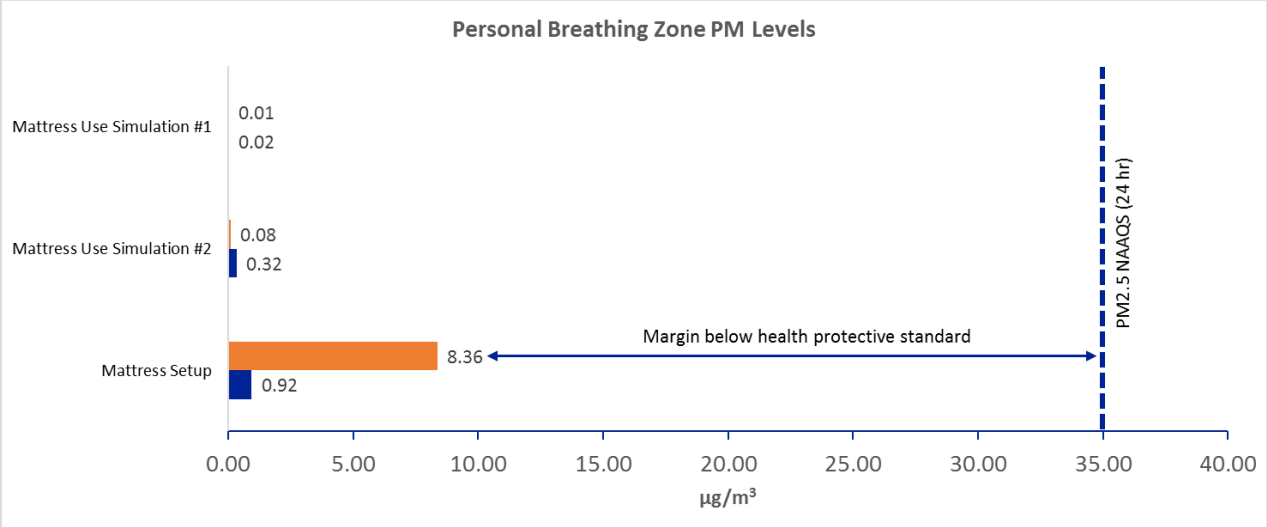
Sample	Average sphere size (µm diameter)	Max sphere size (µm diameter)	Average sphere volume (µm^3)	Nominal polyethylene copolymer density (mg/ µm^3)	Average mass/ sphere (mg)	Terracon sample spheres/L	Average air concentration (µg/m^3)
Unpacking mattress #1	1.07	4.38	0.64	9.52E-10	6.10E-10	1,509.97	**0.92**
Unpacking mattress #2	0.93	1.35	0.42		4.01E-10	20,854.7	**8.36**
Mattress #1: breathing zone 1 of 2	0.99	1.64	0.51		4.83E-10	672.15	**0.32**
Mattress #1: breathing zone 2 of 2	0.97	1.33	0.48		4.55E-10	185.65	**0.08**
Mattress #2: breathing zone 1 of 2	1.05	2.52	0.61		5.77E-10	36.53	**0.02**
Mattress #2: breathing zone 2 of 2	1.26	9.04	1.05		9.97E-10	11.35	**0.01**

Comparison of Terracon Exposure Data to Health-Protective NAAQS

The Terrecon data for polyethylene copolymer levels in the air when unpacking or using Purple® mattresses represent likely consumer exposures measured in minutes to hours. According to Purple®, the average expected useful life of a Purple® mattress is approximately 10 years. Further, there is a finite quantity of polyethylene copolymer added to Purple® mattresses, so average daily breathing zone exposure levels to consumers is expected to decrease over time. The air pollution particle types associated with the NAAQS include particles that, unlike polyethylene, have been shown to cause adverse health effects. So, long-term exposures to polyethylene copolymer particles at levels higher than the NAAQS would not result in adverse effects in a population, including, but not limited to, asthmatics. Nevertheless,

Figure 1 clearly shows that shows the potential polyethylene copolymer exposure from using a Purple® mattress is orders of magnitude less than 24-hour NAAQS value designed to protect even the most sensitive members of the U.S. population from adverse health effects resulting from a continuous, lifetime exposure to environmental $PM_{2.5}$. Unpacking and using a Purple® mattress may potentially result in polyethylene copolymer exposures that are approximately 8-times and 325-times lower than the $PM_{2.5}$ NAAQS. This analysis provides high confidence that adverse health effects will not occur in any consumers from inhaling or touching polyethylene copolymer powder that may migrate from a Purple® mattress over the lifetime of the mattress.

Figure 1. – Calculated Average PM Concentrations from Mattress Use and Setup Conditions



Lack of Basis for Alleged Health Concerns

Given the chemical nature of polyethylene copolymer and the negligible potential exposure to consumers of Purple® mattresses, it is clear that any and all health concerns that have been raised are without any appropriate scientific basis. In particular, the potential health effects opinions of Dr. John J. Godleski stated in his letter dated March 8, 2017, are not scientifically supported. In his letter, Dr. Godleski states that, *"Polyethylene is a common plastic formed into many structures. As inhalable microspheres, these have the potential to cause respiratory irritation especially when inhaled in large numbers as shown in my laboratory."* He did not address the available peer-reviewed lab animal data that indicate no toxicity, or provide any estimate of potential consumer inhalation or dermal exposure. He did, however, cite *in vitro* (i.e., tests in lab containers rather than a living organism) studies of guinea pig and hamster lung immune system cells (alveolar macrophage) responses to protein-coated latex particles (i.e. particles that have been modified to elicit macrophage phagocytosis) to measure oxidative stress responses. These studies used high particle exposure that are not representative of human exposures. He also stated that, "*In addition, polyethylene has been associated with allergy in the form of either asthma or contact dermatitis in sensitized individuals*." However, the scientific literature that he cited for support of this statement are for polyethylene glycol particles, which are chemically and toxicologically dissimilar to polyethylene copolymer. Thus, the opinions proffered in Dr. Godleski's letter are not relevant to measured exposure data or in agreement with sound toxicological science.

Conclusion

There have arisen allegations and suggestions that polyethylene copolymer added to Purple® mattresses may result in risks of adverse health effects in mattress consumers. However, the toxicological literature for chemically-similar compounds do not at all suggest the potential for toxicity. Further, the potential exposure levels to Purple® mattress consumers have been characterized by Terracon, and indicate that polyethylene copolymer exposures would be hundreds of times lower than everyday particulate dust levels that have been determined to be safe even for sensitive individuals. Therefore, there is no scientific or toxicological basis for suggesting that Purple® mattresses represent a consumer health risk.

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