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Toxicological Risk Assessment (U.S. Regulations) Evaluation for “Popsocket Gel” ANSECO #16H-01193

Background

A quantitative list of the ingredients in this gel (0.498 gram of gel in a single consumer product) was submitted to a Board Certified Toxicologist for evaluation. It is assumed that these ingredients contain no contaminants at concentrations that would be toxic or corrosive to an exposed consumer. This gel is intended to be used by responsible adults and children who are under the direct supervision of responsible adults. The ANSECO Group, LLC has requested that this product be evaluated for potential acute and chronic toxicity via dermal contact, inhalation and ingestion as well as corrosive/irritation potential and sensitization (allergic reactions) potential as defined in the U.S. Federal Hazardous Substance Act (FHSA) Regulations (16 CFR Parts 1500.3, 1500.4, 1500.5, 1500.12, 1500.13, 1500.17, 1500.40, 1500.41, 1500.42, 1500.129 and 1500.135). This evaluation was done by subjecting the ingredients in this product to a Toxicological Risk Assessment (TRA).

A TRA is a procedure that was originally recommended by the U.S. National Academy of Sciences and has been used for decades by the Environmental Protection Agency (EPA) to estimate risks from exposures to hazardous substances found in toxic waste sites. This TRA procedure has also been modified to evaluate risks of exposures to hazardous chemicals found in or released from consumer products. A TRA for a chemical of concern is intended to estimate the potential health risks from exposures to that chemical to an individual. One of the key assumptions behind this concept is that health risks from a chemical are a function of exposures to that chemical and the toxicity of that chemical. If exposures do not occur or a chemical is practically nontoxic, the potential health risks from that chemical are toxicologically insignificant. A TRA for a given consumer product is generated by calculating hypothetical worst-case exposure scenario values for the chemicals of concern in or released from that product (Exposure Assessment). These hypothetical worst case exposure values are then divided by appropriate regulatory agency-established toxicity exposure threshold values (Toxicity Assessment) to derive quantitative estimates of potential health risks (Risk Assessment) from the chemicals of concern in or released from that product. The primary assumption throughout this risk assessment process is that the magnitude of the health risk to a chemical depends on the exposures to that chemical and the toxicity of that chemical.

Exposure Assessment

An exposure assessment scenario for a given chemical of concern to a potential consumer consists of creating a series of logical pathways and events whereby that chemical could reasonably be expected to come into contact with that consumer. For this assessment, as much as 0.498 gram of this gel in a single consumer product may be expected to contact the skin of a consumer as frequent multiple exposure events and/or smaller amounts of gel residues may occasionally be ingested (via various hand-to-mouth activities) and/or may rarely contact the eyes (via finger-to-eye contacts) as single exposure events. Residues that evaporate from this gel are expected to be diluted at least 100-fold with fresh ambient air before they are inhaled.
**Toxicity Assessment**

Searches of the National Library of Medicine’s toxicological databases and information from other sources provided no data to indicate that exposures to the ingredients in as much as 0.498 gram of this gel as described above would be expected to cause significant acute or chronic toxicity via dermal contact, inhalation or ingestion or be corrosive or irritating to the skin or the eyes of consumers who may be exposed as described above. None of the ingredients in this gel have been designated “strong sensitizers” under the regulations cited above.

**Risk Assessment/Conclusions**

The potential risk from a chemical substance to an individual is a function of both the exposure to and the toxicity of that chemical. Exposures to the ingredients in as much as 0.498 gram of this gel would not be expected to cause significant acute or chronic toxicity via dermal contact, inhalation or ingestion or be corrosive or irritating to the skin or eyes of consumers who may be exposed as described above, it is reasonable to conclude that these types of adverse health risks from exposures to them are expected to be toxicologically insignificant. Although none of the ingredients in this gel would be expected to cause a sensitization (allergic) reaction in the vast majority of exposed individuals, a remote possibility exists that one or more individuals in the general population who are allergic to one or more of them could exhibit a sensitization (allergic) reaction on contact. Such an event, while expected to be rare, cannot be absolutely ruled out. None of the ingredients in this gel are restricted or prohibited from use in consumer products sold in the U.S.

Based on a review of all the available information provided to date and if the assumptions mentioned above are correct, it is this toxicologist’s opinion that this “Popsocket Gel” product would not be expected to cause acute or chronic toxicity as described above or be corrosive or irritating to the skin or eyes when used as intended or under circumstances involving reasonable foreseeable misuse.

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