Risk Assessment for Fluorinated HDPE Containers

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Executive Summary

On behalf of Inhance Technologies, LLC (the Company), ToxStrategies, Inc., has performed exposure modeling and risk assessments for long-chain perfluoroalkyl carboxylate substances (LCPFACs) that are produced unintentionally during fluorination of high-density polyethylene (HDPE) containers. The fluorination process, which is conducted at a level according to the customer's needs, imparts a critical barrier to the HDPE containers to protect against permeation of the contents through the containers. The LCPFACs offer no functionality to the fluorinated HDPE containers, and no poly- and perfluoroalkyl substances (PFAS) are ever utilized in any of the Company's production processes. The U.S. Environmental Protection Agency (EPA) has established a significant new use rule (SNUR) to require companies who manufacture or process certain LCPFACs to submit a significant new use notification (SNUN) for the LCPFACs. This exposure modeling and risk assessment report supports consolidated SNUNs for the relevant LCPFACs that the Company unintentionally forms in fluorinated HDPE containers.

When HDPE containers reach the end of their useful service life, they may be disposed of in a landfill. Although it is theoretically possible for residual LCPFACs to migrate to landfill leachate, this report demonstrates that landfill leachate is not a likely complete exposure pathway for LCPFACs in fluorinated HDPE containers to humans or the environment.

During the fluorination process, excess fluorine and hydrofluoric acid (HF) are captured by alumina in scrubbers in accordance with air permits. The alumina media may also contain small amounts of LCPFACs. Spent alumina is sent to a cement company for use as an additive in Portland cement clinker. Clinker pyroprocessing temperatures are well in excess of those known to mineralize LCPFACs.

This report includes conceptual exposure models of SNUN LCPFACs that may reach humans and environmental receptors, as well as the associated concentration estimates and risk assessments. The myriad of products potentially containing LCPFACs from fluorinated HDPE containers were categorized into six conceptual exposure models:

- Indoor spray products,
- Floor products,
- Products directly applied by hand,
- Manual spray pesticides,
- Hose-end sprayer products, and
- Commercial pesticides applied by aerial spraying or ground-level fogging.

Estimates were based on measured LCPFAC migration into solvents (water and mineral spirits) from fluorinated HDPE containers, as well as industrial hygiene studies to estimate Company worker exposure to LCPFACs. Risk assessments (screening-level comparison ratios [SLCRs]) were derived by dividing the modeled exposures (concentration or dose) by human health-based protection levels (HBPLs) or predicted no-effect concentrations (PNECs) for ecological receptors. HBPLs included reference doses (occupational exposures and vegetable consumption), and EPA or state regional screening levels for residential soil (direct contact with soil), soil to protect

groundwater (consumption of groundwater with leachate from soil), and drinking water (consumption of surface water). PNECs included those for aquatic species (exposure to surface water) and terrestrial species (exposure to soil). In each worst-case scenario, the SLCRs were well below one, indicating that the modeled concentrations were not expected to pose an unreasonable health or ecological risk from the LCPFACs.

Potential exposure to workers is most likely from incidental ingestion associated with hand-to-mouth (HTM) transfer of LCPFACs from gloves. Dermal absorption is an unlikely exposure pathway, and Company workers wear new gloves while handling fluorinated HDPE containers. In addition, LCPFACs have low volatility, and the Company's processes do not generate LCPFAC aerosol particles or dust, making LCPFAC inhalation among Company workers unlikely. LCPFAC transfer to gloves was measured for workers who handle HDPE containers across the range of fluorination levels. The amounts of LCPFACs on gloves were then estimated for HTM transfer using conservative estimates. The resulting amounts of LCPFACs that could be incidentally ingested are well below the reference doses (RfDs) for each LCPFAC, with SLCRs ranging from 0.0052 to 0.11 for packers with the greatest exposure.

Consumers may potentially be exposed to LCPFACs in products contained in fluorinated HDPE containers while using the products. Conservative models using data from HDPE containers fluorinated to the highest level indicate that these exposures are well below HBPLs (RfDs) with SLCRs well below 1.0. Adults who use indoor spray products and products directly applied by hand have a maximum SLCR of 7.6×10^{-5}. Children may be exposed to LCPFACs in floor product residue, yet the maximum SLCR for such a scenario is 6.3×10^{-3}.

Indoor spray products containing LCPFACs may potentially be released down the drain to a wastewater treatment plant (WWTP). Conservatively assuming that the WWTP does not remove LCPFACs, LCPFAC concentrations in a surface water body receiving WWTP treated effluent would be well below the HBPLs for drinking water (maximum SLCR of 1.2×10^{-4}). The LCPFAC concentrations would also be well below the PNECs for aquatic species (maximum SLCR of 8.0×10^{-7}).

Outdoor use of products, namely manual spray pesticides and hose-end sprayer products, in fluorinated HDPE containers may potentially release LCPFACs to soil. Worst-case assumptions resulted in modeled soil concentrations and exposures well below HBPLs for residential soil (maximum SLCR of 2.2×10^{-5}), soil to protect groundwater (maximum SLCR of 4.7×10^{-3}). Conservative hose-end sprayer product use models estimated a maximum SLCR of 4.0×10^{-5} for vegetable consumption. Modeled soil concentrations were also well below PNECs for terrestrial species (maximum SLCR of 8.2×10^{-6}). Modeled use of commercial pesticides provided SLCRs of 7.3×10^{-10} for residential soil, 7.3×10^{-7} for soil to protect groundwater, and 7.3×10^{-11} for terrestrial animals.

In conclusion, worst-case exposure assumptions and conservative modeling parameters have demonstrated that LCPFACs in fluorinated HDPE containers would not pose an unreasonable risk to Company workers. Additionally, worst-case modeling for environmental releases for the scenarios and conditions considered also indicated that LCPFAC concentrations do not pose an unreasonable risk to humans, aquatic species, or terrestrial animals based on the assumptions of this assessment.