REGULATORY OVERVIEW

Relevant Historical Timeline of D_5 and GreenEarth

YEAR	ORGANIZATION	FINDING	OUTCOME
1943	Dow Corning	Unique properties of silicone help dry, damaged skin.	First use in personal care products: skin lotion.
1944-2009	Various	D_5 silicone an ideal base ingredient in a variety of personal care products.	Widespread use in variety of personal care products.
1994	U.S. EPA	Direct final rulemaking: D_5 specifically exempt from regulation as a Volatile Organic Compound (VOC).	D_5 does not require regulation.
2000	California Industrial Hygienist Services (Roxanne Fynboh)	Air Sampling Analysis: no risk to employee health when used as dry cleaning solvent in dry-to-dry machines.	GreenEarth moves to market after 18 months of Affirmation Site Testing.
2000	Severn Trent Labs	Waste Stream Analysis: D_5, used in dry-to-dry machines both by itself and in conjunction with additives, is not a hazardous waste.	GreenEarth classified by waste haulers as non-hazardous waste.
2003	Silicone Environmental Health & Safety Council (SEHSC)	Preliminary bioassay study: concern around precancerous indicators in female rats subjected to high continuous exposures of D_5 over a two year period.	Additional research to determine relevance of findings.
2005	Silicone Environmental Health & Safety Council (SEHSC)	Follow-On research: disease pathway that exists in rats does not exist in humans; D_5 poses no risk to human health.	SEHSC findings accepted by the Society of Toxicologists.
2006	EPA Region 8	GreenEarth has no known or expected health issues, requires no special handling or permits, is non-toxic whether contact is oral, dermal or from inhalation. The byproduct of the cleaning operation is so benign it is permissible for landfills.	GreenEarth's Colorado Mountain Cleaners recognized with the EPA's Environmental Achievement Award.
2006	Illinois Dry Cleaner Environmental Response Fund (DERTFI)	Typical exposure to D_5, whether occupationally, to consumers or to the general public, would not result in a significant risk to human health. There are no significant environmental risks from the use of D_5 in dry cleaning.	GreenEarth designated 'green' solvent in Illinois by DERTFI.
2008	California Air Resources Board (CARB)	Based on Office of Environmental Health Hazard Assessment (OEHHA) review, D_5 as an alternative dry cleaning solvent does not pose an adverse health risk to the public. No regulation is required.	CARB affirmed GreenEarth as an acceptable alternative dry cleaning solvent that does not require regulation.
2009	Environment Canada	Final Screening Assessment: amounts of D_5 entering the environment do not pose a risk to human health.	No impact to dry cleaning using D_5 is anticipated.
2009	UK Environment Agency	No risks are identified in the air, water and terrestrial compartments, nor to humans exposed via the environment from the production and all uses of D_5.	No impact to dry cleaning using D_5 is anticipated.
2012	Government of Canada	Environment Minister concludes Siloxane D_5 is not harmful to environment. Decision based on independent expert Board of Review[8].	D_5 does not require regulation.

Key Facts About GreenEarth

GreenEarth is the brand name for the patented process of dry cleaning with D_5 (Decamethylcyclopentasiloxane).

D_5 is exempted from regulation as a VOC by the U.S. EPA[1] as well as by the State of California.[2] D_5 does not impact ozone, is not a greenhouse gas and does not interact with greenhouse gases.

GreenEarth has been affirmed by the California Air Resources Board (CARB) as an acceptable alternative dry cleaning solvent that will not pose an adverse health risk to the public and does not require CARB regulation.[2]

D_5 is non-toxic (oral, dermal, inhalation), as measured by EPA protocol.[3]

GreenEarth utilizes D_5 in a closed loop dry cleaning system. Employee exposure level is less than .5 ppm.[4]

D_5 is non-irritating to skin and non-sensitizing. D_5 has no immunosuppressant effects.[5]

D_5 is not a hazardous waste under federal or state laws.[6] Not regulated by EPA, RCRA, CERCLA or California Prop 65.

D_5 is listed by EPA as "SNAP" material, a good substance to use in place of ozone-depleting chemicals.

If released to the environment, D_5 degrades to sand (SiO_2) and trace amounts of H_2O and CO_2.[7] No special permits required (except in BAAQMD, where a permit is required not to have a permit).

Projected future uses of Siloxane D_5 will not pose a danger to the environment or its biological diversity.[8]

CITED RESEARCH STUDIES

[1] 59 Federal Register No. 192, October 5, 1994, pp. 50693-50696.
In a final direct rulemaking, the EPA specifically exempted D_5 from regulation as a Volatile Organic Compound (VOC).

[2] California Air Resources Board, 2008, Dry Cleaning Alternative Solvents: Health and Environmental Impacts Fact Sheet.
After an exhaustive 18-month review of all available research, CARB concluded that D_5 is not a VOC and that available exposure information indicates that the use of D_5 as an alternative dry cleaning solvent will not pose a risk to the public living near businesses using D_5.

[3] Battelle Northwest Toxicology 2001, Plotzke et al. 2002, Dow Corning Corporation 1999, 2003a, 2003b, 2003d, 2005b, Utell 2004, Anderson et al. 2005, Reddy et al. 2005a, 2005b.
Multiple studies cite D_5 as non-toxic regardless of exposure type (oral, dermal, inhalation).

[4] California Industrial Hygienist Services (CIH Services, Inc), 2000, SB32 Air Sampling Study, Environ International Corporation, 2006.
Industrial Hygiene (IH) survey, consisting of both personal and area monitoring, measured employee exposures as both an 8-hour time-weighted average (TWA) as well as for Short-Term Exposure Limits (STELs) for particular tasks within the dry cleaning process. Based on measurement techniques prescribed by the Occupational Health and Safety Administration (OHSA) and the National Institute for Occupational Health & Safety (NIOHS), average employee exposure level was less than .22 ppm on an 8-hour time-weighted average (TWA) in approved dry-to-dry machines, well below estimated Margins of Safety (MOS) limits. Later corroborated by Environ evaluation of exposure to D_5 for consumers, workers and the public prepared for the Silicones Environmental Health and Safety Council. Mean value for occupational exposure to D_5 in workplace air was measured at .143 ppm for dry cleaners.

[5] Burns-Naas et al. 1998.
D_5 was not immunotoxic when administered by inhalation for 28 days at concentrations up to 160 ppm.

[6] Severn Trent Laboratories, 2000, Waste Streams Analysis.
Sampling and analysis of D_5 in dry-to-dry machines, done at intervals over a four-month period, concluded that D_5 by itself (and also when used in conjunction with appropriate additives such as detergent, spotting chemicals, etc.) is not a hazardous waste under federal or California law. The residue sometimes referred to as “still bottoms”, remaining after the D_5 is distilled off for recycling into the dry cleaning process, contains all of the substances cleaned off the clothes as well as any other chemicals introduced into the process, and as such, may be a hazardous waste. Similarly, filter cartridges, designed to remove the larger particulate that may come into the process from soiled laundry, could also potentially lead to a hazardous waste, despite D_5 itself being classified as non-hazardous.

[7] Dry Cleaner Environmental Response Trust Fund of Illinois (DERTFI), 2006, Assessment of the Human Health Risk and the Environmental Fate and Effects of GreenEarth® (Decamethylcyclopentasiloxane) Used in Dry Cleaning.
The environmental fate and effects of D_5, based on fugacity modeling assessments made of potential concentrations of D_5 in the environment resulting from its use as a dry cleaning solvent, were investigated in order to determine potential risk for the general public as well as aquatic species. Using the Equilibrium Criterion (EQC) multimedia fugacity model (Mackay et al. 1996), it was determined that more than 99.9% of the emission of D_5 resides in the air; intermediate exchange of D_5 from air into other environmental compartments (water, soil, or sediment) was insignificant. About 22% of D_5 was removed from the model environment by degradation in air, and 78% was removed by advective transport in air. Total residence time of D_5 in the model environment was about 3.2 days. D_5 will not partition to soil or water in remote regions because it does not have the potential for deposition in the biosphere after transport. While D_5 is not soluble in water and tends to evaporate (Henry’s Law Constant = 0.318 atm m3 mol-1), chronic and acute aquatic toxicity tests were conducted under very stringent laboratory conditions. In most cases, the No Effect Concentrations (NOECs) were determined to be equal to or greater than the limit of water solubility. The environmental modeling and testing clearly indicate that there are no significant environmental hazards from the use of D_5 in dry cleaning. Based on the extensive data available for D_5, the safety of the GreenEarth system was supported.

[8] Siloxane D_5 Board of Review. 2011. Report of the Board of Review for Decamethylcyclopentasiloxane (D_5). Ottawa, ON, Canada. October 20, 2011.
The Board, composed of three independent and renowned toxicologists conducted what was, in essence, a de novo risk assessment of Siloxane D_5 by taking into account the available scientific information about the intrinsic physical and chemical properties of Siloxane D_5, along with its toxicity, uses, exposures, and effects. Executive Summary: 1. The Siloxane D_5 Board of Review (the “Board”) inquired into the nature and extent of the danger posed by decamethylcyclopentasiloxane, or Siloxane D_5, (CAS # 541-02-6; D_5) to the Canadian environment or its biological diversity. 2. Taking into account the intrinsic properties of Siloxane D_5 and all of the available scientific information, the Board concluded that Siloxane D_5 does not pose a danger to the environment. 3. The evidence presented to the Board demonstrated that Siloxane D_5 exceeded the regulatory threshold for persistence. However, Siloxane D_5 did not exceed the thresholds established in the Persistence and Bioaccumulation Regulations (“Regulations”). 4. Siloxane D_5 does not biomagnify through the food chain, although it can be accumulated into organisms from environmental matrices or food. That is, concentrations of Siloxane D_5 do not increase in predators relative to their prey. 5. There is no evidence to demonstrate that Siloxane D_5 is toxic to any organism tested up to the limit of solubility in any environmental matrix. The Board is of the view that Siloxane D_5 will not accumulate to sufficiently great concentrations to cause adverse effects in organisms in air, water, soils, or sediments. 6. Furthermore, the Board concluded that, based on the information before it, the projected future uses of Siloxane D_5 will not pose a danger to the environment or its biological diversity.