

**Assessment of the Human Health Risk and
the Environmental Fate and Effects of
GreenEarth[®] (Decamethylcyclopentasiloxane
(D₅)) Used in Dry Cleaning**

**Prepared for the Drycleaner Environmental Response
Trust Fund of Illinois (DERTFI)
By GreenEarth[®] Cleaning**

May 1, 2006

Executive Summary

The purpose of this document is to provide an assessment of Decamethylcyclopentasiloxane (D₅), the low molecular weight siloxane fluid used in the GreenEarth[®] system, in order to understand and evaluate the fate, transport, and the potential ecological and human health risks of this novel dry cleaning solution in relation to commercial dry cleaning systems.

D₅ is used as a dry cleaning solvent in the GreenEarth[®] system to carry detergent to clothes and rinse away suspended dirt and oils trapped by the detergent. GreenEarth[®] does not interact with textiles and therefore helps maintain the quality and color of clothes that are dry cleaned while minimizing residual on the clothing. Consequently, persons who may be exposed to D₅ as a result of GreenEarth[®] use in dry cleaning include workers in dry cleaning establishments that use GreenEarth[®] as a replacement for other cleaning solvents; consumers who wear clothing dry cleaned using GreenEarth[®]; and the general public living in the vicinity of a dry-cleaning facility using GreenEarth[®].

Workers, consumers, and the general public were assessed for dermal and inhalation exposure to D₅. D₅ is manufactured in closed systems and is transported in closed containers (e.g., pails, drums or tankers) to limit loss and/or contamination of the product and eliminate or reduce exposure to workers or the public. The results of air sampling (both personal and area sampling) in dry cleaning establishments using D₅, demonstrated that the average employee exposure was less than 0.22 ppm in an 8-hour time weighted average (TWA). In addition to workers, consumers and the general public were assessed for dermal and inhalation exposure to D₅. When exposures for each of the three populations were compared with No Observed Effect Levels (NOEL) it was clear that typical exposure to D₅ whether to workers, consumers, or the general public would not result in a significant health hazard. Margins of Safety (MOS) ranged from 3.8×10^7 to 9.8×10^3 , far greater than the MOS of 100 that is considered to be protective of human health. Under the exposure scenarios defined in this assessment, typical exposure to D₅, whether occupationally, to consumers, or to the general public, from use in GreenEarth[®] systems, would not result in a significant human health risk.

The environmental fate and effects of D₅ have also been investigated. A fugacity modeling assessment was made of potential concentrations of D₅ in the environment resulting from its use as a dry cleaning solvent in order to determine potential risk for the general public as well as aquatic species. The fate and distribution of D₅ between environmental compartments (air, water, soil, and sediment) was evaluated using the Equilibrium Criterion (EQC) multimedia fugacity model (Mackay et al. 1996). Simulation of the emission of D₅ directly to air resulted in >99.9% of the total chemical mass residing in the air compartment. Intermedia exchange of D₅ from air into other environmental compartments (water, soil, or sediment) was insignificant. About 22% of D₅ was removed from the model environment by degradation in air, and 78% was removed by advective transport in air. Total residence time of D₅ in the model environment was about 3.2 days. D₅ 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 D₅ is not soluble in water and tends to evaporate (Henry's Law Constant = $0.318 \text{ atm m}^3 \text{ mol}^{-1}$), 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 D₅ in dry cleaning. Based on the extensive data available for D₅, the safety of the GreenEarth[®] system is supported. It can also be concluded that, under the exposure scenarios defined in this assessment, typical exposure to D₅, whether occupationally, to consumers, or to the general public, from use of D₅ in commercial dry cleaning systems, would not result in a significant human health risk.

I. Introduction

The purpose of this document is to provide a human health and ecological assessment to understand and evaluate the fate, transport, and the potential ecological and human health risks of D₅ in the GreenEarth[®] drycleaning system. D₅ is used as a dry cleaning solvent in the GreenEarth[®] system to carry detergent to clothes and rinse away suspended dirt and oils trapped by the detergent. GreenEarth[®] does not interact with textiles and therefore helps maintain the quality and color of clothes that are dry cleaned while minimizing residual on the clothing. Consequently, persons who may be exposed to D₅ from dry cleaning include workers in dry cleaning establishments that use GreenEarth[®] as a replacement for other cleaning solvents; consumers who wear clothing dry cleaned using the GreenEarth[®] solvent; and the general public living in the vicinity of a dry-cleaning facility using GreenEarth[®]. Because of the potential for human exposure, the toxicity of D₅ in laboratory animals and the kinetics of D₅ in laboratory animals and humans, as well as ecologically relevant organisms by relevant routes of exposure have been assessed.

II. Regulatory Status for Air Emission

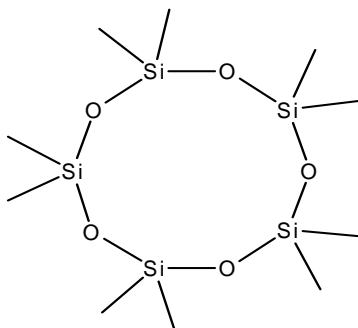
D₅ was exempted from regulation as a volatile organic compound (VOC) by U.S. EPA in a direct final rulemaking (59 Federal Register No. 192, October 5, 1994, pp. 50693-50696), as well as by the State of California. D₅ does not impact ozone, it is not a greenhouse gas, and it does not interact with greenhouse gasses.

III. Chemical Background Information

A. Chemical Description

Chemical Name: Decamethylcyclopentasiloxane (D₅)

Chemical Structure:



CAS No.: 541-02-6
EINECS No.: 208-764-9
Molecular Formula: C₁₀H₃₀O₅Si₅
Molecular wt.: 370

IV. Human Health Risk Assessment of D₅ in the GreenEarth[®] System

A. Introduction

As a result of the use of GreenEarth[®] in dry cleaning, persons who may be exposed to D₅ include workers in dry cleaning establishments; consumers who wear dry cleaned clothing; and the general public living in the vicinity of a dry-cleaning facility. Because of the potential for human exposure, the potential hazard of D₅ in laboratory animals and the kinetics of D₅ in both laboratory animals and humans by relevant routes of exposure have been used to assess the safety of D₅ in dry cleaning.

The purpose of this investigation was to conduct a safety assessment to evaluate the potential hazard to these populations by defining a level at which no effects would be expected and then comparing that to the level of D₅ to which workers, consumers or the general public may be exposed. The technical approach to this assessment for D₅ was consistent with approaches used by the U.S. EPA and other regulatory agencies, and included a hazard assessment, dose-response assessment, exposure assessment, and risk characterization.

B. Hazard Assessment

The extensive experimental hazard database for D₅ was reviewed. The main focus of that review was a 2-year oncogenicity bioassay of D₅ in male and female Fisher 344 (F344) rats (Dow Corning Corporation 2005a). Other studies provided insights into the potential for toxicity of D₅ including toxicokinetic data, mutagenicity and genotoxicity, reproductive/developmental toxicity, immunotoxicity studies, and studies designed to elucidate the mode of action for observed effects in laboratory animals and the relevance of those observations to human health outcomes. The major findings of this review were:

- D₅ was absorbed by the oral, dermal, and inhalation routes of exposure, and was rapidly distributed and excreted without bioaccumulation. Dermal absorption, which is most relevant for the use of consumer products, was small (approximately 0.05% of the applied amount). The majority of the dermally- absorbed D₅ (90%) was rapidly eliminated through exhalation. A PBPK model was used to estimate the internal dose in the animal bioassays and the internal dose corresponding to each of the identified exposure scenarios. (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)
- In subacute and subchronic repeated exposure studies by the oral (at doses up to 1600 mg/kg/day) and inhalation (at levels up to the highest concentration that remains a vapor, 160 ppm) routes of exposure, the only effects observed in rodents were adaptive, non-adverse, transient phenobarbital-like changes in liver weight, and, by the inhalation route, irritation in the nose and lungs consistent with adaptive responses to mild, non-specific irritants. (Dow Corning 1990a, 1990b, Jager and Hartmann 1991, RCC 1995a, 1995b, Experimental Pathology Laboratories 1996a, 1996b, Burns-Naas et al. 1998, Dow Corning Corporation 2000)

- D₅ was not mutagenic or genotoxic in a variety of *in vitro* assays in bacterial or mammalian cells or *in vivo* in a variety of genotoxicity tests both with and without metabolic activation. (Litton Bionetics Inc 1978, Wilcox et al 1990, Dow Corning Corporation 2003c, Dow Corning Corporation 2004b, Dow Corning Corporation 2004f)
- D₅ was not immunotoxic when administered by inhalation for 28 days at concentrations up to 160 ppm. (Burns-Naas et al. 1998)
- No parental toxicity or reproductive toxicity was noted in adult male or female rats, nor was there neonatal toxicity or developmental neurotoxicity in their offspring in a two-generation reproductive toxicity test at inhalation concentrations up to 160 ppm. (WIL 1996, WIL 1999)
- D₅ did not demonstrate estrogenic or anti-estrogenic activity in several assays designed to assess estrogen agonist potential. D₅ did demonstrate dopamine agonist activity. (Dixon and Brown 1979, Dow Corning Corporation 2004a, 2004c, 2004d, 2004e)
- There were no treatment-related, adverse non-neoplastic effects seen in the 2-year bioassay in male and female F344 rats at doses up to 160 ppm (Dow Corning Corporation 2005a). The only neoplastic lesion noted was an increase in uterine endometrial adenocarcinomas in the high exposure group females, found primarily on terminal sacrifice. Because there was a positive finding in this bioassay, a weight-of-evidence assessment was conducted to include consideration of the mode of action of the only carcinogenic response observed in animals following chronic exposure to D₅. The relevance of these tumors for human health safety assessment was considered using a framework proposed by the U.S. EPA (2005) and others (Meek et al 2003). The evidence in the scientific literature indicates that the tumorigenic effect of D₅ in female rats exposed by inhalation to very high concentrations (160 ppm) for two years is related to a rodent-specific imbalance in the normal hormonal milieu that occurs in aging female F344 rats. These changes are common in rodents and are not relevant to humans because the hormonal control mechanisms are different in aging rodents and in aging humans.

C. Dose-Response Assessment

As noted above, the mode of action for the development of tumors in female rats is not relevant in humans. Administration of D₅ did not produce significant, treatment-related noncarcinogenic effects relevant to human health outcomes in either the 2-year bioassay or in the reproductive or immunotoxicity studies, nor were there precursor lesions, such as an increase in uterine hyperplasia, found in the 2-year bioassay. Consequently, there were no relevant chronic effects that would provide data for modeling a potential effect level. Therefore, 160 ppm, the highest concentration tested in the 2-year bioassay, represented the No Observed Adverse Effect Level (NOAEL).

While not considered relevant to human health, dose-response modeling using the tumor data was conducted only as a point of comparison to the experimentally-derived NOAEL and to provide a conservative evaluation of hazard. Typically, when deriving a no effect level for humans, an experimentally-derived NOAEL is adjusted for inherent uncertainties by dividing by

uncertainty factors to account for species extrapolation, human variability, and confidence in the data base.

In this assessment, a comparison of the internal dose associated with the NOAEL to the internal dose estimated for each human exposure scenario was conducted to derive the exposure-specific margins of safety (MOS).

D. Exposure Assessment

The exposure scenarios considered were designed to represent the exposure from the use of D₅ in dry cleaning and attempted to characterize the populations who may be exposed; the pathways or routes by which that exposure could occur; and the frequency, duration, and intensity (amount) of that exposure. The populations considered were:

- Occupational - workers in the dry cleaning industry using D₅;
- Consumers – individuals who wear clothing cleaned with D₅-containing solvent;
- General Public – individuals living in the vicinity of a dry cleaning establishment who may be exposed to ambient levels of D₅ released to the environment.

The PBPK model was used to determine the internal doses that were specific to the population and exposure scenario. Air sampling was conducted to measure actual exposure levels.

Occupational Dermal Exposure to D₅

Workers in a dry cleaning establishment could be exposed to D₅ via dermal contact, e.g., in the event of a spill or leakage from a container during transfer of the solvent to the dry-cleaning machines. Other than for periodic maintenance work on the machines, dermal exposure to D₅ during dry-cleaning operations at times other than solvent-loading of the machines is not expected for workers in the dry cleaning industry because D₅ is used in closed systems with little or no opportunity for dermal contact with D₅. In estimating dermal exposure of workers, it was assumed that transferring D₅ into the machines, with subsequent dermal exposure of workers' hands occurred once per week. Calculations for dermal surface area, number of hours worked, and employment duration were based on U.S. EPA's standard exposure factors.

Occupational Inhalation Exposure to D₅

An industrial hygiene (IH) survey was sponsored by GreenEarth[®] Cleaning[®] utilizing an independent third party Certified Industrial Hygienist (CIH Services, Inc.). The survey consisted of both personal and area monitoring, and 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. These survey results presented here reflect only the "dry to dry" process, as this represents over 99% of the machines using D₅ as a solvent and the practice of "wet transfer" is not supported. These locations included various types of dry cleaning equipment "retrofitted" to utilize the D₅-based dry cleaning process.

Eleven different sites using the D₅-based solvent were examined, most of them on multiple days, simulating different weather conditions (several open doors and windows representing summer and no doors or windows open simulating winter). The kinds of personal tasks monitored were those typical to nearly all dry cleaning facilities, for example, loading and unloading machines, spotting, pressing, hanging, etc. The area monitoring included nearly every point in the cleaning

process from very close to the cleaning machines, to the garment processing areas, to the area where garments were hung awaiting customer pickup.

The results of the IH survey are summarized as follows:

- 1) **Personal monitoring – 8 hour TWA.** One hundred twenty eight (128) samples were collected for the determination of the 8-hour time weighted exposures. The average 8-hr TWA was determined to be less than 0.22 ppm. ('less than' is used here since a majority of the samples were below the limit of detection, in which case the limit of detection number was used.) All of the samples were well below any industrial hygiene guidelines recommended by the industry, with the highest sample being 3.5 ppm and only 6 of the 128 data points being above 1 ppm.
- 2) **Area Monitoring – 8 hour TWA.** Three hundred and twelve (312) samples were taken to determine the 8-hr TWA in various locations of the dry cleaning workplaces. The average 8-hr TWA was determined to be less than 0.19 ppm. (again, 'less than' is used since a majority of the samples were below the limit of detection, in which case the limit of detection number was used.). All of the samples were well below any industry-recommended IH guideline, with the highest sample being 2.2 ppm and only 17 of the 312 data points being above 1 ppm.
- 3) **Short Term Exposure Limits (STELs).** A sampling of 136 individuals was sampled for short-term tasks (as indicated above) where exposures were expected to be highest. Typical sampling times for the various tasks were in the 2-3 minute range, none of the tasks took more than 10 minutes (although the American Board of Governing Industrial Hygienists (ACGIH) allows for 15 minute STEL excursions). All of the STELs were well below the ACGIH recommendation that STELs be set 3-5 times the workplace guideline (for a guideline of 10 ppm, the STEL would be 30-50 ppm), with the highest sample being 14.9 ppm and only 2 of the 136 data points actually reaching the guideline of 10 ppm 8-hour TWA.

The American Conference of Government Industrial Hygienists (ACGIH) sets industry guidelines for acceptable limits of workplace exposures as Threshold Limit Values (TLVs) and the US Occupational Safety and Health Administration (OSHA) determines government exposure limits as measured Permissible Exposure Limits (PELs). The safety limits as set by ACGIH TLV and OSHA PEL do not regulate D₅ solvent and no guidelines have been set. The workplace exposure guideline recommended by the silicone industry is a voluntary guideline, and was initially set based on observed changes in liver weight in rat toxicology studies. Subsequent research has clearly shown this to be an adaptive effect in rats, which is not relevant to humans. Consequently, the IH guideline represents an extremely conservative approach to worker protection.

Internal dose exposure was estimated for the inhalation route using varying assumptions for the duration and frequency of exposure and amount of D₅ measured in air in the work environment. The air concentrations to which workers could potentially be exposed varied depending on the job category or job description of the worker. As described above, eight-hour time-weighted

average air concentrations were calculated at GreenEarth Cleaning® sites. An average of TWA values (0.22 ppm) was used to represent all dry-cleaner workers.

Consumer Exposure

Exposure to consumers wearing clothes cleaned with D₅-based solvent is expected to be limited based on the extremely low concentration of D₅ remaining on the clothes and the rapid volatilization of D₅ from the clothes following removal from the dry cleaning machines. Relative to the potential exposure to workers, exposure of consumers is negligible. If the MOS for workers indicates a lack of hazard, then consumer MOS will also be adequate.

General Public Exposures

Exposure to people who may live near a dry cleaning facility using products containing D₅ was considered. It was assumed that residents, both adults and children, were at their residence 24 hours per day for a lifetime. No data are currently available for ambient air levels outside of dry cleaning establishments, but the data on ambient air levels outside D₅ manufacturing sites was taken as a worse-case scenario. Data were available from outdoor air samples that were collected from 70 facilities and analyzed for D₅ content (Maxim et al. 1998). The average value reported in the ambient air was used to estimate the exposure for the general public.

E. Risk Characterization

A Margin of Safety (MOS) of >100 is generally considered to be sufficiently protective of human health. In the Risk Characterization step, MOS were estimated. A MOS was defined as the ratio of the internal dose associated with the no adverse effect level in animals to the internal dose estimated for each relevant human exposure scenario. Further, uncertainties associated with this evaluation were considered and, where possible, the impact of the assumptions made on these MOS was considered.

Estimated Margins of Safety

The MOS for workers in the dry cleaning industry were about 10,000 or greater. These MOS would indicate that D₅ does not pose a significant hazard to workers in the dry cleaning industry, based on the exposure scenario defined.

As discussed earlier, D₅ will rapidly evaporate from clothes dry-cleaned with D₅-based solvent, virtually eliminating exposure to consumers from the dry-cleaned clothes. Since the MOS for workers is sufficiently protective, consumer exposures will be lower, and exposure to D₅ will not pose a significant risk.

For the general public, exposure to D₅ was assumed to be limited to inhalation of D₅ in ambient air. The MOS determined for this scenario for men, women and children were all greater than 1,000,000. This indicates that residential inhalation exposure to D₅ does not pose a significant risk to human health.

Consideration of Uncertainties

As part of the Risk Characterization, uncertainties in the assessment were considered and were classified into two major categories, PBPK model uncertainties and uncertainties associated with

assumptions, data, and judgments made in the exposure assessment. In balance, the data used and the assumptions made tended to overestimate rather than underestimate exposure.

IV. Environmental Risk Assessment

A. D₅ Physical/Chemical Property Data

Molecular weight (g mol ⁻¹):	371	
Melting point (°C):	-38.0	Patnode and Wilcock (1946)
Boiling point (°C):	211	Flaningam (1986)
Vapor pressure at 25°C (Pa):	33.2	AICHe DIPPR (2005); interpolated value over temperature range -38.0 to 346 °C
Water solubility at 25°C (g m ⁻³):	0.017	Varaprath et al. (1996)
Log K _{OW} (no units):	5.20	Bruggeman et al. (1984)
Henry's constant (atm m ³ mol ⁻¹):	0.318	Kochetkov et al. (2001)
Hydrolysis rate constants at 25°C: <ul style="list-style-type: none"> • k_{H+} (M⁻¹ h⁻¹) • k_{OH-} (M⁻¹ h⁻¹) 	740 3200	Kozerski (2006)
Hydrolysis half-life ($T_{0.5}^{HYD}$; d) <ul style="list-style-type: none"> • at pH 7.0, 25°C • at pH 7.8, 25°C • at pH 7.8, 12°C 	73.4 14.2 40.2	Calculated from measured rate constants (Kozerski 2006)
Oxidation rate constants (cm ³ mol ⁻¹ sec ⁻¹) <ul style="list-style-type: none"> • OH radical (R^{OH}) • O₃ (R^{O_3}) 	1.55×10 ⁻¹² 3.00×10 ⁻²⁰	Atkinson (1991)
Overall Reaction Half-life Data (d): <ul style="list-style-type: none"> • air ($T_{0.5}^{AIR}$) • water ($T_{0.5}^{WATER}$) • soil ($T_{0.5}^{SOIL}$) • sediment ($T_{0.5}^{SED}$) 	10.2 14.2 12.5 142	Calculated from oxidation rate constants (Atkinson 1991) and hydrolysis rate constants (Kozerski 2006) Calculated from hydrolysis rate constants (Kozerski 2006) at pH 7.8 an 25°C Calculated from degradation rate constants in soil (Xu and Chandra 1999) Calculated as 10-times the overall half-life in water

B. Potential for D₅ Emissions to Air, Water, and Soil

The emission of D₅ from the dry cleaning process is limited because D₅ is used in a closed system, limiting exposures to workers and the environment.. Evaluations of worker exposure

were conducted in 2000 and 2005. The results are described in the Human Health section of this multimedia assessment.

Independent testing on D₅ (designated SB32 in the testing report) as used in daily operation at GreenEarth[®] dry cleaning sites was conducted. The study report (IFI 2002) states that D₅ 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. However, the residue sometimes referred to as “still bottoms”, remaining after the D₅ 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, which 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 D₅ itself being classified as non-hazardous.

C. Ecotoxicity Data

Available acute, prolonged-acute, and chronic toxicity data show that D₅ is essentially non-toxic to freshwater aquatic organisms exposed to concentrations up to and above the limit of water solubility of 0.017 mg/L.

Two fish toxicity studies have been conducted at concentrations in excess of water solubility. No effects to juvenile carp, *Cyprinus carpio* were observed in a 96-h semi-static (daily renewal of test solutions) exposure to a water-accommodated fraction prepared at a loading rate of 1 g/L (IUCLID 2005). Similarly, no effects were seen in a 14-d flow-through study with juvenile rainbow trout, *Oncorhynchus mykiss* (IUCLID, 2005). The flow-through test system was pulse-dosed every 17 seconds with D₅ in solvent at a rate designed to deliver a test concentration of 5 mg/L. No mortality or adverse effects were observed during the course of this study.

More realistic fish toxicity studies conducted up to the limit of water solubility have also found no test material related toxicity. A 14-d flow-through toxicity test was conducted with juvenile rainbow trout, *Oncorhynchus mykiss* at concentrations up to the limit of water solubility (Springborn 2000). D₅ has a very high air/water partition coefficient (Henry's constant), thus it is very difficult to maintain D₅ in test solutions unless extraordinary measures are taken. This study was conducted as a flow-through study using completely filled, sealed containers with no headspace (i.e. no air/water interface). D₅ was added in solvent via a continuously flowing serial dilutor system. Nominal concentrations of D₅ were 2.2, 3.7, 6.1, 10, and 17 µg/L. Measured concentrations were 2.1, 3.1, 5.0, 8.6, and 16 µg/L. All guideline test conditions were normal (e.g., dissolved oxygen, temperature, photo-period, pH, etc.) during the course of the study. No dose-related adverse effects were observed during the 14-d exposure period with the results recorded as NOEC = 16 µg/L and the LC₅₀ > 16 µg/L.

Similarly, no D₅-related adverse effects were noted for fathead minnows, *Pimephales promelas* during 35-d exposure to D₅ as part of a bioconcentration study (Drottar 2005). Fish were exposed to measured D₅ concentrations of 1.1 and 15 µg/L throughout the 35-d uptake/exposure period. Radio-labeled D₅ was administered in solvent via syringe pump into a specially designed mixing vessel prior to addition to open-top test vessels. Flow rates were adjusted (i.e., increased) to minimize the impact of test material volatilization in order to retain the test material at the

desired concentrations in the test vessels. All guideline test conditions were normal (e.g., dissolved oxygen, temperature, photo-period, pH, etc.) during the course of the study. Toxicity results included a NOEC of 15µg/L and an LC₅₀ > 15µg/L.

A flow-through 48-h acute toxicity test with *Daphnia magna* was conducted at concentrations below the limit of water solubility (17µg/L) (Machado 2002). Daphnids were exposed to five concentrations of test material in closed, zero-headspace test vessels. Guideline test parameters (e.g., hardness, temperature, dissolved oxygen, photoperiod, pH, etc.) were all within normal ranges. Nominal concentrations were 2.2, 3.6, 6.1, 10 and 17µg/L. Measured concentrations were disappointingly low, and may be reflective of flaws in analytical procedures. Corresponding measured values were 2.1, 1.6, 1.8, 2.5, and 2.9µg/L. Test results at 48-h revealed no immobilization or toxicity at the highest measured dose of 2.9µg/L, and hence the reported 48-h NOEC is 2.9 µg/L and the reported EC₅₀ is >2.9µg/L.

A 21-d chronic toxicity test was conducted with *Daphnia magna* (Springborn Smithers 2003a). Nominal test concentrations of D₅ were 1.1, 2.1, 4.3, 8.5 and 17µg/L. The respective measured test concentrations were 1.1, 1.7, 3.5, 7.2, and 15µg/L. Guideline test parameters (e.g., hardness, temperature, dissolved oxygen, photoperiod, pH, etc.) were all within normal ranges. Test endpoints were mortality, growth (length and weight), and reproduction (cumulative number of offspring). Results for all endpoints were 21-d NOEC = 15µg/L, and 21-d EC₅₀ >15µg/L. The results of the longer term study suggest that the NOEC for the 48-hour acute test would have been significantly higher had the analytical determination of dose been more appropriate.

Toxicity to the sediment-dwelling invertebrate, *Chironomus riparius* was also investigated (Springborn Smithers 2003b). A 28-d full-life cycle study of the midge larva was conducted with spiked sediment at concentrations of 13, 30, 73, 180, and 580 mg/kg (dry weight). Test endpoints included larval survival, larval wet weight, emergence (i.e., maturation to adult fly), and rate of development. Results for larval survival provided a 10-d LC₅₀ = 450 mg/kg and a NOEC of 180 mg/kg. Results for larval wet weight were a 10-d EC₅₀ = 410 mg/kg and a NOEC of 73 mg/kg. Results for emergence indicated a 28-d EC₅₀ = 420 mg/kg and a 28-d NOEC of 180 mg/kg. Development rate results included a 28-d EC₅₀ > 580 mg/kg and a 28-d NOEC of 69 mg/kg.

The toxicity of D₅ to algae was investigated using the unicellular green alga, *Pseudokirchneriella subcapitata*, formerly *Selenastrum capricornutum* (Hoberg 2001). Algae were exposed to D₅ at a single nominal concentration of 20 µg/L in closed test flasks to which additional sodium bicarbonate was added as a carbon source. The measured test concentration at study initiation was 12µg/L. Results for the standard effects endpoints of cell density and growth revealed an EC₅₀ > 12µg/L and a NOEC = 12µg/L. Thus, no effect was seen at a dose approximately equivalent to the limit of water solubility.

As reported above, a bioconcentration study with fathead minnows, *Pimephales promelas* was performed (Drottar 2005). Fish were exposed to measured D₅ concentrations of 1.1 and 15µg/L throughout a 35-d uptake/exposure period. Radio-labeled D₅ was administered in solvent via syringe pump into a specially designed mixing vessel prior to addition to open-top test vessels. The resulting steady state bioconcentration factor (BCF_{ss}) values from this study were 7060 for

the 1.1 µg/L exposure concentration and 1950 for the 15 µg/L concentration. However, in subsequent work, the steady-state, lipid normalized biomagnification factor (BMF, uptake from food) for rainbow trout (*Oncorhynchus mykiss*) exposed to D5 was 0.63 and the one-compartment kinetic BMF was 1.4 (Drottar 2006). Sediment bioaccumulation factors for midge larvae (*Chironomous riparius*) after 10-d exposure to D5 in sediment (steady-state conditions not confirmed) ranged from 0.5 to 1.2 and increased with decreasing exposure concentration (Putt 2003). Laboratory studies with fish indicate that D5 may bioaccumulate in aquatic organisms because of uptake across the gills and to a minor extent by uptake from food. However, laboratory studies only provide an assessment of the potential for bioaccumulation to occur. In the environment, the extent of bioaccumulation is determined by the portion of the material in the environment that exists in a form that can be absorbed or taken up by the organisms. D5 not lost through volatilization will adsorb to suspended solids, sediments, humic acids or other macromolecules and as a result, true environmental bioavailability is expected to be low. If a material is not environmentally bioavailable, for example because exposure concentrations are too low or the material is irreversibly bound to an environmental matrix, then bioaccumulation will be minimal or may not occur.

The other important factors that governs the potential for bioaccumulation is metabolism and elimination processes. In mammals, D5 is readily metabolized to water soluble metabolites (Varaprath 2004). Additional studies are planned to understand the extent of metabolism in aquatic species. Lastly because D5 is rapidly eliminated by pulmonary and metabolic clearance in mammals, tissue concentrations, even in fat, do not increase with repeated exposures (Andersen 2005). Therefore biomagnification up the food chain would not be likely to occur in air breathing animals.

Available ecotoxicity data indicate that D₅ has low potential for harm to the environment. D₅ has been found to be nontoxic to all pelagic aquatic organisms exposed to concentrations up to and above the limit of water solubility. Similarly, the NOEC values for D₅ to the sediment-dwelling invertebrate midge larva are well in excess of concentrations expected in sediment. Concentrations have been measured in sediments ranging from below detection up to 2.0 mg/kg dry weight for D₅ (Nordic Council of Ministers 2005). Consequently, D₅ is not expected to cause any adverse effects in the aquatic environment.

D. Fate and Transport

Assessment of environmental fate and distribution is a complex process best evaluated using multimedia or fugacity-based models. The fate and distribution of D₅ between environmental compartments (air, water, soil, and sediment) was evaluated using the Equilibrium Criterion (EQC) multimedia fugacity model (Mackay et al. 1996). Level I, II, and III models for a Type-1 chemical (i.e., chemicals that partition into all environmental media) were used for the simulations. All simulations were conducted at a data temperature of 25°C using default values of the model for compartment dimensions and properties.

Level I Simulation

A Level I simulation evaluates the equilibrium distribution of a fixed quantity of chemical in a closed environment, with no degradation reactions, no advective processes, and no intermedia transport process (e.g., no wet deposition or sedimentation). Output from the simulation provides a general indication of the likely media into which a chemical will tend to partition and the relative concentrations in each medium.

Results from the Level I simulation indicate that D₅ will partition almost exclusively into the air compartment, which is expected to hold ≥ 99.9% of the total chemical mass. Much smaller amounts of D₅ (≤ 0.1%) are expected to be found in soil and insignificant amounts (≤ 0.01%) in water, sediments, suspended sediments, and fish.

Level II Simulation

A Level II simulation evaluates the equilibrium distribution of a chemical that is continuously discharged to the environment at a constant rate, and achieves a steady-state condition at which the input and output rates are equal. Degradation reactions and advective processes are treated as the mechanism of loss or output. Intermedia transport processes are not quantified (e.g., no wet deposition or sedimentation). Similar to a Level I simulation, output from a Level II simulation provides an indication of the likely media into which a chemical will tend to partition and the relative concentrations in each medium. In addition, the Level II simulation also provides an indication of environmental persistence and the loss processes that are likely to be most important.

The Level I simulation indicated that air would be the primary environmental compartment in which D₅ would be found. Therefore, it was assumed that degradation and transport in the atmosphere would be the dominant mechanisms for removal of D₅ from the environment. The dominant degradation process for most chemicals in the atmosphere is the gas-phase reaction with hydroxyl radicals or other photochemically-produced radicals (Atkinson 1988). Cyclic siloxane materials such as D₅ also undergo hydrolytic degradation upon contact with water or water vapor. Consequently, the overall rate of degradation of D₅ in air (k_{ov}) was estimated by combining the degradation rate constants for hydroxyl radical oxidation (k_{ox}) and hydrolysis (k_{hyd}), as follows:

$$k_{ov} = k_{ox}C + \frac{1}{10}k_{hy} \quad \text{where: } C \text{ is the average concentration of hydroxyl radical}$$

Because of the decreased activity of water, the rate of hydrolysis in air was assumed to be one-tenth (1/10) of the rate in water. The rate constant for hydroxyl radical oxidation of D₅ at 25°C is $1.34 \times 10^{-7} \text{ cm}^3 \cdot \text{mol}^{-1} \cdot \text{d}^{-1}$ (Atkinson 1991) and the average atmospheric concentration of hydroxyl radical based on a 24 hour day is $5.00 \times 10^5 \text{ mol} \cdot \text{cm}^{-3}$ (Prinn et al. 1992). The rate constant for hydrolysis of D₅ at pH 7.0 and 25 °C is $7.43 \times 10^{-3} \text{ d}^{-1}$ (Kozerski 2006). Combining these rate constants using the above equation gives an overall degradation rate constant for D₅ in the atmosphere of $6.77 \times 10^{-3} \text{ d}^{-1}$. This is equivalent to an overall half-life in air of 10.2 days.

Level II simulations were used to evaluate the effect of degradation in air on persistence of D₅ in the environment. For the purpose of these simulations, the reaction half-life in air was fixed at 10.2 days, as previously described. Reaction half-lives in water, sediment, and soil were varied from 1 day to 3650 days (10 years). The simulations demonstrated that degradation and advection in air were the most important parameters determining overall persistence in the model environment. Changes in reaction half-life in water, sediment, and soil from 1 to 3650 days had essentially no effect on distribution or persistence of D₅. In all simulations, $\geq 99.9\%$ of the steady-state mass of D₅ resided in the air compartment. Partitioning to soil, water, and sediment was $< 0.1\%$ and considered insignificant. About 21-22% of the D₅ was removed from the local region by degradation in air and 74-78% was removed by advective transport in air. Degradation in soil accounted for the remaining 0-5% of the D₅ removed from the system. Total residence time of D₅ in the model environment was about 3.1 days.

Level III Simulation

A Level III simulation is similar to a Level II simulation in that a) the chemical is continuously discharged to the environment at a constant rate, b) achieves a steady-state condition at which the input and output rates are equal, and c) the mechanism of loss is determined by degradation reactions and advective processes. However, unlike a Level II simulation, equilibrium between environmental compartments is not assumed and inter-compartmental transport processes are quantified (e.g., wet deposition, sedimentation, re-suspension, soil runoff, aerosols, etc. are taken into account). Output from a Level III simulation provides a more realistic description of a chemical's fate, including the important degradation and advective losses and the intermedia transport processes. In addition, the simulation gives an indication on how source of entry of a chemical to the environment (e.g., to air, to water, and/or to soil) effects distribution and persistence.

Level III simulations were first used to evaluate the effect of source of entry on the distribution and persistence of D₅. The overall reaction half-life in air was set at 10.2 days, as previously discussed. The overall reaction half-life in water was set at 17.3 days based on the hydrolysis rate at pH 7.8 and 25 °C (Kozerski 2006). The overall reaction half-life in soil was set at 12.5 days based on soil degradation studies (Xu and Chandra 1999). Laboratory studies indicate that D₅ does not readily biodegrade. Therefore, the overall reaction half-life in sediment was estimated to be 10-times the half-life in water or 173 days. Emission rates of 0 or 1000 kg/h were used for the single compartment emission rates for each simulation.

As expected on the basis of the Level II simulations, emission of D₅ directly to air resulted in $>99.9\%$ of the total chemical mass residing in the air compartment. Intermedia exchange of D₅ from air into other environmental compartments (water, soil, or sediment) was insignificant.

About 22% of the 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.

Similar results were obtained when D_5 was emitted directly to the soil compartment. Because of its vapor pressure, 58% of the steady-state chemical mass of D_5 was found in the air and 42% in the soil. Intermedia exchange from soil to air (i.e., volatilization) accounted for 89% of the D_5 removed from the soil compartment. Inter-media exchange from soil to other compartments was insignificant. About 31% of the total mass of D_5 was removed from the model environment by degradation in air (20%) and soil (11%). The remaining 69% of D_5 was removed from the model environment by advective transport in air. The overall persistence of D_5 released to soil was 4.9 days.

In contrast to that observed for emission to the air and soil compartments, emission of D_5 to the water compartment resulted in only 5.6% of the total chemical mass residing in air. When released directly to the water compartment, 32% the total chemical mass of D_5 was found in the water and 63% in the sediment. About 49% of the D_5 released to the water compartment was removed by inter-media exchange from water to air (41%) and from water to sediment (8%). About 49% of the total mass of D_5 was removed from the model environment by degradation in air (9.1%), water (33%), and sediment (6.6%). The remaining 51% of D_5 was removed from the model environment by advective transport in air (32%), water (18%), and sediment (1%). The overall persistence of D_5 released to the water compartment was 24 days.

Potential for Long-Range Transport

The Level III simulations indicated that the environmental compartment of concern for D_5 is air. For example, it was predicted that D_5 released directly to soil would be found in air and soil. Similarly, it was predicted that D_5 released directly to water would be found in air, water, and sediment. It is expected that environmental release of D_5 from dry cleaning applications would be directly to air and that release to other compartments would be insignificant. Because of its volatility and partitioning properties, D_5 accidentally released to water or soil would readily partition to the atmosphere. This preferential partitioning to air raises speculation that D_5 may undergo long-range atmospheric transport and deposit to remote regions.

Long-range transport (LRT) and deposition of a chemical to a remote region is a complex interaction between the physical-chemical properties of the chemical and the environmental conditions in which the chemical is released. The process of atmospheric LRT to remote regions consists of three distinct steps (Wania 2003):

- (1) In source regions the chemical must reach the atmosphere from the medium to which it has been emitted.
- (2) The chemical must be transported through the atmosphere to the remote region.
- (3) The transported chemical must have the potential to be significantly deposited in the remote region in order to have a noticeable impact on the local ecosystem.

Most techniques for evaluating LRT focus on the second step of the overall process by relying on estimates of atmospheric degradation and advection to define the distance that a chemical can be

transported in the atmosphere. The need for deposition to the remote ecosystem (i.e., the final step of the process) is virtually always ignored. Simple advective transport models coupled with the degradation half-life in air ($T_{0.5}$) only consider the potential for a substance to undergo long-range transport and cannot identify the potential for a substance transported to a remote region to partition out of the atmosphere and deposit in the biosphere. Substances with an atmospheric half-life of greater than 2 days, may be transported long distances, but may not partition out of the atmosphere. If there is no back-deposition, then there is no potential for exposure to organisms, including humans.

Deposition of a substance depends on physical and chemical properties that control the ability of the substance to partition out of the atmosphere and into the biosphere, for example partitioning from the gas phase to an aqueous phase. The non-dimensional Henry's Law constant (H ; also known as the air-water partition coefficient, K_{aw}) describes the equilibrium partitioning of a chemical between the gas phase and an aqueous solution. When evaluating the combined potential for long-range transport to, and subsequent deposition in, remote regions, both $T_{0.5}$ and H can be used. The strong influence of the combined effects of $T_{0.5}$ and H on the potential for long-range transport and deposition of a substance into a remote region can be illustrated by expanding a simple transport model coupled with the degradation half-life in air to include partitioning (DiToro and Hellweger 1999). Results from the illustrative model demonstrate that for substances with $\log H > 0$, 1% or less will be deposited into the biosphere of a remote region (i.e., greater than 99% remains in the atmosphere), regardless of $T_{0.5}$. For D_5 ($\log K_{ow} = 5.2$, $\log H = 1.1$), less than 0.1% would be expected to deposit). In contrast, the model predicts that deposition of known POPs, for example DDT, PCBs and hexachlorobenzene, all of which have $\log H < -1.0$, would be greater than 50%. These model results also demonstrate the importance of $\log K_{ow}$ (i.e., partitioning between octanol and water) on the potential for deposition. $\log K_{ow}$ is important because it represents the potential for the substance to partition from water to organic (i.e., biological) materials, such as plants, animals and organic coatings on soils. Results from this simple model, which incorporates the combined effects of $T_{0.5}$, H , and $\log K_{ow}$, suggest that substances with a non-dimensional Henry's Law constant greater than 1 and $\log K_{ow}$ greater than 5, including D_5 , will not deposit into the biosphere of remote regions, regardless of the half-life of the substance in the atmosphere.

The conclusion that D_5 will not deposit into the biosphere of remote regions, regardless of the half-life of the substance in the atmosphere, is further supported through a comprehensive investigation of model uncertainty and sensitivity relative to phase partitioning properties. This is achieved by defining a two-dimensional hypothetical chemical space as a function of the equilibrium partition coefficients between air, water, and octanol (i.e., K_{oa} , K_{aw} , and K_{ow}). Multimedia models are used to calculate the range of partitioning coefficients across the entire chemical space to construct maps showing the relation between hypothetical chemical properties and environmental phase distributions that occur within the bulk environmental compartments air, water, soil, and sediment (Van de Meent et al. 1999; Wania 2003; Meyer et al. 2005). Each point in these partitioning space maps corresponds to a hypothetical chemical with a specific combination of partitioning properties. Real chemicals can then be placed within this partitioning space, provided their partitioning properties are known, in order to assess the environmental phase distributions expected to exist across air, water, soil, and sediment.

Wania (2003) used a dynamic, zonally averaged global distribution model (Globo-POP; Wania and Mackay 2000) to produce a partitioning space map for a range of hypothetical chemicals assuming perfect persistence (no degradation) and equal emission to air, water, and soil. When the partitioning properties of D_5 ($\log K_{ow} = 5.2$, $\log K_{aw} = 1.1$, $\log K_{oa} = 3.7$) are plotted on the space map it is apparent that D_5 falls within the partitioning space defining chemicals that will be found predominantly in the atmosphere. Wania (2003) concluded that chemicals such as D_5 that have $\log K_{oa} < 5.5$ and $\log K_{aw} > -1$ will be found predominantly in the atmosphere and will not have the potential for long range transport and deposition in the biosphere of remote regions.

Wania (2003) also used the Globo-POP model (Wania and Mackay 2000) to identify chemical partitioning properties and emission scenarios that favor enrichment in Arctic ecosystems and to define a target-oriented Arctic Contamination Potential (ACP). An immediate and long-term ACP was developed and defined as the fraction of the total chemical mass in global surface media that is in the Arctic after 1 and 10 years of steady emissions (ACP_1 and ACP_{10} , respectively). A partitioning space map was developed showing the calculated ACP for perfectly persistent chemicals as a function of $\log K_{oa}$ and $\log K_{aw}$, with emissions occurring either entirely to air, water, or soil. When the partitioning properties of D_5 ($\log K_{ow} = 5.2$, $\log K_{aw} = 1.1$, $\log K_{oa} = 3.7$) are plotted on the space map it is apparent that D_5 falls within the partitioning space defining chemicals that will not partition to, or accumulate in, the Arctic surface media, regardless if the material is emitted to air, water, or soil. Wania (2003) concluded that chemicals such as D_5 that have $\log K_{oa} < 5.5$ and $\log K_{aw} > -1$ will be found predominantly in the atmosphere and will not have the potential for long range transport and subsequent deposition in the biosphere of remote regions. Moreover, the potential for such chemicals to accumulate in remote regions is limited by failure to deposit to the Earth's surface even at the low-temperatures prevalent in the Arctic. Wania (2006) categorizes D_5 as a "flier", indicating that it has little potential for back deposition in remote regions (arctic) assuming it is persistent enough to reach there.

E. Summary and Conclusions of Environmental Risk Evaluation

D_5 has a very high air-water partition coefficient ($\log K_{AW} > 1$), extremely low water solubility (0.017 mg/L), a high octanol-water partition coefficient ($\log K_{OW} > 5$), but a relatively small octanol-air partition coefficient ($\log K_{OA} < 5.0$ at room temperature). Depending on its mode of release, D_5 will distribute almost entirely into two environmental compartments. When released to air, D_5 will remain in air and not partition appreciably to other environmental compartments. If released to water, D_5 will rapidly volatilize to air or partition to suspended solids that deposit to sediments in the area where released. This partitioning behavior has led to D_5 being identified in the literature as a "flyer", with the atmosphere being the only feasible medium for long range transport and little potential to back-deposit to the terrestrial compartment.

Laboratory studies have been conducted in an attempt to understand the fate of D_5 in the atmosphere. Currently, demethylation by OH radicals in the atmosphere is the major process that has been identified for the degradation of D_5 . The half-life or persistence of D_5 will depend on the reaction rate with OH radicals, which is dependent on the concentration of OH radicals in the atmosphere. The OH radical concentration varies between remote, urban and rural settings. If the OH radical concentration from remote areas is used, the D_5 half-life in air is about 10 days.

However, since D₅ is predominantly released in urban settings, more realistic urban and rural atmospheric OH radical concentrations provide predicted half-lives as short as a few hours to one day.

D₅ does not accumulate in soil. When soil moisture is low, degradation is rapid with half-lives from hours to a few days. When soil is wet, degradation rates are reduced, but rapid volatilization (half-life of 2-4 days) from soil becomes a predominant removal mechanism.

D₅ undergoes hydrolysis in water, but hydrolysis is not the main removal mechanism from water. If released to water, D₅ is expected to either volatilize into the atmosphere or to adsorb onto particles and be removed into the sediment. Model estimates for volatilization of D₅ from water are fairly rapid with half-lives as short as 3 hrs to 6 days, depending on water depth and the amount of mixing in the water bodies.

D₅ can be considered practically non-toxic to aquatic or sediment-dwelling organisms. Due to its unique properties of high volatility, low water solubility and preference for adsorption to solids, D₅ is not expected to remain in a freely bioavailable form in natural aqueous environments. Likewise due to these same properties it is unlikely that aquatic or sediment-dwelling organisms would be exposed to concentrations that would cause adverse effects. A laboratory study (Drottar, 2006) and environmental monitoring (Nordic Council of Ministers, 2005) indicate that D₅ is not likely to bioaccumulate appreciably or exhibit significant biomagnification within the food chain.

VI. Summary and Conclusions

The purpose of this investigation was to conduct a safety assessment to evaluate the potential environmental risk and hazard to selected workers, consumers, and the general public who may be exposed to D₅ from dry cleaning either in the workplace, through the wearing of clothes cleaned with D₅-based solvent or exposed to D₅ in ambient air. This involved a critical review of the available environmental toxicity, mammalian toxicity, carcinogenicity, pharmacokinetic, and mode-of-action studies.

The environmental modeling and testing, as well as results of field sampling, clearly indicate that there are no significant environmental risks from the use of D₅ in dry cleaning.

Exposure for all three populations evaluated was considered to occur via dermal and/or inhalation exposure. As with the dose-response assessment, a PBPK model was used to estimate the internal dose associated with dermal or inhalation exposures for each population. These were then compared to information developed from the rat bioassay, resulting in the calculation of appropriate MOS. A MOS is the ratio of the internal dose associated the animal study to the internal dose estimated for each relevant exposure scenario. A MOS of >100 is generally considered to be sufficiently protective of human health.

Under the exposure scenarios defined in this assessment, typical exposure to D₅, whether occupationally, to consumers, or to the general public, would not result in a significant human health risk.

Margin of Exposure calculations for workers, consumers, and general public exposed to D₅

Type of Exposure	Population	MOS	
		Men	Women
Inhalation	Dry cleaner	9.8×10^3	2.0×10^4
	Consumer	NA	NA
	General Public Adult	1.3×10^6	1.8×10^6
	General Public Child	3.2×10^6	3.7×10^6
Dermal	Dry Cleaner	3.4×10^7	3.8×10^7
	Consumer	NA	NA
	General Public Adult	NA	NA
	General Public Child	NA	NA

NA: Not Applicable

Based on the extensive data available for D₅, the safety of the GreenEarth[®] system is supported.

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