DEPARTMENT OF THE ENVIRONMENT

DEPARTMENT OF HEALTH

CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

Publication of final decision on the screening assessment of a substance — Decamethylcyclopentasiloxane (D5), CAS No. 541-02-6 — specified on the Domestic Substances List *(subsection 77(6) of the* Canadian Environmental Protection Act, 1999*)*

Whereas D5 is a substance on the *Domestic Substances List* identified under subsection 73(1) of the *Canadian Environmental Protection Act, 1999*;

Whereas the *Final decision on the screening assessment of a substance — Decamethylcyclopentasiloxane (D5) CAS No. 541-02-6 — specified on the* Domestic Substances List *[subsection 77(6) of the* Canadian Environmental Protection Act, 1999*]* was published in the *Canada Gazette*, Part I, on January 31, 2009;

Whereas scientific information respecting the substance has been made available subsequent to the conduct and publication of the final screening assessment;

Whereas the Minister of the Environment has established a board of review under subsection 333(1) of the Act to inquire into the nature and extent of the danger posed by the substance;

Whereas the board of review submitted, on October 20, 2011, a report, together with its recommendations and the evidence that was presented to it, to the Minister of the Environment;

Whereas all currently available information pertaining to ecological aspects has been considered by the board of review and by the Minister of the Environment;

Whereas a summary of the scientific considerations in respect of the substance is annexed hereby;

Whereas it is concluded that the substance does not meet any of the criteria set out in section 64 of the Act;

And whereas ongoing scientific and international regulatory activities on D5 will be monitored to keep abreast of new information,

Notice is hereby given that the *Final decision on the screening assessment of a substance — Decamethylcyclopentasiloxane (D5) CAS No. 541-02-6 — specified on the* Domestic Substances List *[subsection 77(6) of the* Canadian Environmental Protection Act, 1999*]* published in the *Canada Gazette*, Part I, on January 31, 2009, is hereby annulled,

And notice is hereby given that the Ministers of the Environment and of Health propose to take no further action on the substance at this time under section 77 of the Act.

PETER KENT
Minister of the Environment
LEONA AGLUKKAQ
Minister of Health

ANNEX

Summary of the scientific considerations

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), the Ministers of the Environment and of Health have conducted a screening assessment on Decamethylcyclopentasiloxane (D5), Chemical Abstracts Service Registry No. 541-02-6. This substance was identified as a high priority for screening assessment and included in the Chemicals Management Plan Challenge initiative because it was found to meet the ecological categorization criteria for persistence, bioaccumulation potential and inherent toxicity (PBiT) to non-human organisms, and it was known to be in commerce in Canada.

A final decision on the screening assessment of D5 was published in the *Canada Gazette*, Part Ⅰ, on January 31, 2009 (www. ec.gc.ca/ese-ees/default.asp?lang=En&n=13CC261E-1), as part of Batch 2 of the Challenge initiative under the Chemicals Management Plan. That screening assessment concluded that D5 was having harmful effects on the environment, but did not constitute a danger to human health, as defined under section 64 of CEPA 1999. Following the proposal to add D5 to the List of Toxic Substances in Schedule 1 of CEPA 1999 published in the *Canada Gazette*, Part Ⅰ, on May 16, 2009, a notice of objection requesting the establishment of a board of review was filed by the Silicones Environmental Health and Safety Council of North America.

Substantial new ecological information that was not available for consideration in the screening assessment was submitted or otherwise became available. This information raised new considerations pertinent to conclusions of the January 2009 screening assessment. A board of review (the Board) on siloxane D5 was established by the Minister of the Environment under subsection 333(1) of the *Canadian Environmental Protection Act,1999* (CEPA 1999) on August 21, 2010, and was directed to inquire into the nature and extent of the danger posed by D5.

On October 20, 2011, the Minister received the Board's report (www.ec.gc.ca/lcpe-cepa/6E52AE02-5E01-48B0-86DE-0C366ACC863F/CdR-BoR-D5_eng.pdf). The Board took into account both the information considered in the 2009 screening assessment plus scientific information that had recently become available. This included 47 new scientific studies from industry, 24 published scientific studies, 6 scientific reports from Environment Canada and 3 reports from other regulatory jurisdictions. Based on the information before it, the Board concluded that siloxane D5 does not pose a danger to the environment.

The substance D5 is an industrial chemical which was not manufactured by any company in Canada in 2006 in a quantity above the reporting threshold of 100 kg, but which is imported into the country as an essentially pure substance, in mixtures with other cyclic siloxanes, as a residual in silicone polymers, and in finished consumer products. From responses to a notice published under section 71 of CEPA 1999, it was determined that between 1 000 000 and 10 000 000 kg of D5 were imported into Canada in 2006.

The substance D5 is released to the environment from the use of personal care products, and from industrial processes in which it is reacted to form silicone polymers and co-polymers and from blending, formulation and packaging operations. Air, surface water, and agricultural soil are the principal receiving environmental media for D5 based on its physical-chemical properties and its use patterns.

Based on available scientific data, D5 is considered persistent in air, water and sediments but not in soils. While there is evidence of significant accumulation of D5 into organisms from environmental matrices and food, there appears to be an absence of effects in organisms in long-term toxicity tests at environmentally relevant concentrations.

Although aquatic toxicity data was available for representative fish, invertebrate, and plant species in the 2009 assessment, the fish toxicity data for D5 was limited by the lack of a sufficient exposure duration for a hydrophobic (i.e. log K_{ow} ~ 8) substance such as D5 to reach steady-state. New, longer term toxicity test results including chronic (>60 days) early life-stage tests for rainbow trout (*Oncorhynchus mykiss*) and fathead minnows (*Pimephales promelas*), became available after the 2009 assessment. The new evidence shows a lack of adverse effects related to egg hatching, growth and survival of fish despite measured test concentrations near the laboratory measured solubility limit of D5 (17 µg/L). These new toxicity data on D5, along with previously summarized studies showing no effects in a 21-day test with *Daphnia magna* up to 15 µg/L, suggest that D5 may not be inherently toxic to organisms in the water column. In addition, more data on the toxicity of D5 to sediment invertebrates and to terrestrial invertebrates and plants are now available. These data show that D5 has the capacity to elicit adverse effects in terrestrial and sediment organisms, albeit at relatively high concentrations. The most sensitive test organism is the amphipod *Hyalella azteca* with a measured LC_{50} of 194 mg/kg dry weight and a no observable effects concentration (NOEC) of 62 mg/kg dry weight.

Several measurements of sediment and water concentrations near points of discharge of D5 to surface waters (11 Canadian sites along with several others from across Europe and the United States) along with concentrations in biosolids-amended soils (11 Canadian sites along with a few others from Europe) are now available. These data indicate that concentrations in sediments and soils, in the ranges of 0.023–5.84 mg/kg dry weight in sediment and 0.006–0.221 mg/kg dry weight in soils are, in general, well below those expected to cause adverse effects in the representative organisms. These new monitoring data along with monitoring data from Europe and the United States, in combination with the currently available ecotoxicology information, reduce the overall concern from exposure to D5. Additionally, while new data have increased the confidence that D5 has the potential to accumulate in organisms, this behaviour does not appear to cause ecological harm at environmentally relevant concentrations.

Based on available information, including the findings and recommendations made by the Board, and review of data obtained since publication of the original screening assessment, it is concluded that D5 is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends.

As no new substantial information was identified on the danger to human health from D5 no further assessment of effects on human life or health was performed. Based on the available information on its potential to cause harm to human health as presented in the final Screening Assessment, D5 is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Ongoing research and monitoring on D5 along with regulatory assessment activities in other jurisdictions will be monitored to keep abreast of new information and any new regulatory decisions on D5.

Conclusion

Based on available information for environmental and human health considerations, D5 does not meet any of the criteria set out in section 64 of CEPA 1999.