Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

New Substances Notification 20971: Imidazo[4,5-d]imidazole-2,5(1*H*,3*H*)-dione, tetrahydro-, polymer with dimethoxymethane, cyclized (Chemical Abstracts Service Registry Number 2102021-72-5)

Regulatory decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 83 of the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance and have determined that it is not anticipated to enter 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, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

Substance identity

The notified chemical is imidazo[4,5-d]imidazole-2,5(1*H*,3*H*)-dione, tetrahydro-, polymer with dimethoxymethane, cyclized (Chemical Abstracts Service Registry Number[1] 2102021-72-5), and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use in a variety of industrial and consumer products, such as paints and coatings, paper products, cleaning products and personal care products.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water. The substance is not expected to be persistent in this compartment based on its short hydrolysis half-life (1.5-12 days). The substance is not expected to bioaccumulate based on its very low octanol-water partition coefficient (log $K_{ow} \leq 0$).

Environmental risk assessment

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Based on the available hazard information, the substance has low acute toxicity to fish (median lethal concentration (LC_{50}) > 1 mg/L with no mortality at the highest concentration tested) and moderate chronic toxicity to aquatic invertebrates and algae (no-observed-effect-concentration (NOEC) 0.1-10 mg/L; lowest-observed-effect concentration 0.1-10 mg/L). Using the NOEC from the most sensitive organism (algae) and by applying an assessment factor of 10 to account for species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 µg/L, which was used to estimate the risk to the environment.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly from industrial formulation and blending activities and from consumer use and subsequent release of the substance to water, resulting in predicted environmental concentrations (PECs) in the range of 0.1-1 µg/L and 1-10 µg/L, respectively. No potential activities that could significantly increase environmental risks compared to those notified were identified.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that the substance is unlikely to cause harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral and inhalation routes (oral median lethal dose > 2000 mg/kg body weight; inhalation LC_{50} > 5 mg/L/4hr), and low subchronic toxicity following repeated oral doses in mammalian test animals (32-day no-observed-adverse-effect level (NOAEL) > 300 mg/kg-bw/day). The substance has a low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL > 300 mg/kg-bw/day). It is not a dermal sensitizer (stimulation index < 3 (local lymph node assay)). It is not considered mutagenic or clastogenic, and is therefore unlikely to cause genetic damage.

When the notified substance is used as a component of consumer products or personal care products, direct exposure to the general population is expected to be mainly by contact with the skin at low levels. When the notified substance is used as a component of industrial products, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels that do not pose a concern.

Based on the low toxicity, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

The assumptions made in the assessment are considered adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

The substance is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

A conclusion under CEPA, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or the *Hazardous Products Regulations* for products intended for the workplace.