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

New Substance Notification 19376: Dodecanamide, *N*,*N*-dimethyl (Chemical Abstracts Service Registry Number 3007-53-2)

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 chemicals is dodecanamide, *N*,*N*-dimethyl (Chemical Abstracts Service Registry Number[1] 3007-53-2).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in personal care and cleaning products for industrial, commercial and consumer use. Potential uses are expected to be similar to those notified.

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 soil and sediment. The substance is not expected to be persistent in these compartments based on its high ready biodegradability (60-85% over 29 days). The substance is not expected to bioaccumulate based on its low bioconcentration factor (<250 L/kg) and because it is expected to be readily metabolized.

Ecological assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have moderate acute toxicity in aquatic invertebrates (median lethal concentration (LC_{50}) 1-100 mg/L). Results of the ecotoxicity testing for the analogue substance showed that no fish mortality or reduction in algae growth was observed at the highest tested concentrations (1-10 mg/L). Using the LC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 100 to account for acute to chronic extrapolation and laboratory to field extrapolation, the predicted no-effect

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concentration (PNEC) was calculated to be in the range of 10-100 µg/L, which was used to estimate the ecological risk.

The notified and other potential 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 cleaning of processing vessels and commercial and industrial use by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L, and from consumer use by release of the substance to water resulting in a PEC in the range of 0.01-0.1 µg/L. For activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 1-10 µg/L. For activities such as consumer use in dish soap, environmental exposure is expected to be similar to that of the notified consumer use.

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 ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has a low acute toxicity in male mammalian test animals by the dermal route (median lethal dose (LD_{50}) >2000 mg/kg body weight) and a moderate to high acute toxicity in female mammalian test animals by the dermal route (LD_{50} 200-2000 mg/kg body weight). It has a low subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) >100 mg/kg bw/day). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The NOAEL of the oral subchronic toxicity study in mammalian test animals was used to evaluate the human health risk.

When the notified substance is used in personal care products, direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 0.1-1 mg/kg bw/day for adults and 1-10 mg/kg bw/day for children. When the notified substance is used in laundry detergent, direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 0.1-1 mg/kg bw/day. When the notified substance is used in industrial or commercial dish soap, direct exposure of the general population is not expected due to the industrial and commercial nature of the use. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 10^{-6}-10^{-5} mg/kg bw/day for children and 10^{-7}-10^{-5} mg/kg bw/day for adults. Potential uses of the substance include in consumer dish soap, where direct and indirect exposure of the general population is expected to be similar to that of the notified use.

Based on a comparison of the selected NOAEL to the estimated human exposure, the substance is not likely to pose a significant health risk to the general population, and are therefore unlikely to be harmful to human health.

Assessment conclusion

When the substance is used as notified or for other identified potential activities, it 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 *Hazardous Products Regulations* for products intended for the workplace.