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

New Substances Notification 20966: Amides, from C_{18}-unsatd. fatty acids dimers, hydrogenated benzaldehyde-diethylenetriamine-triethylenetetramine reaction products and tall-oil fatty acids (Chemical Abstracts Service Registry Number 1277168-16-7)

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 polymer is amides, from C_{18}-unsatd. fatty acids dimers, hydrogenated benzaldehyde-diethylenetriamine-triethylenetetramine reaction products and tall-oil fatty acids (Chemical Abstracts Service Registry Number 1277168-16-7[1]). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains potentially cationic amine groups.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as a curing agent in industrial and commercial coatings. Potential uses may include as a curing agent in consumer 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 soil and sediment. The substance is expected to be persistent in these compartments based on its demonstrated resistance to hydrolysis. The substance is not expected to bioaccumulate based on its high molecular weight, which will limit its ability to cross biological membranes.

Environmental risk assessment

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Based on the available hazard information, the substance has moderate toxicity to algae (median effective concentration 1-100 mg/L), and is expected to have moderate acute toxicity to fish and aquatic invertebrates (median lethal concentration [LC_{50}] 1-100 mg/L) under environmental conditions when toxicity is mitigated by dissolved organic carbon. 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, species sensitivity variation and mode of action, the predicted no-effect concentration was calculated to be in the range of 0.01-0.1 mg/L.

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 activity is not expected. No potential activities that could significantly increase environmental risks compared to those notified were identified. A predicted environmental concentration was not calculated due to the low potential for environmental exposure.

Based on the low potential for environmental exposure, the substance is unlikely to cause harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance is expected to have a moderate acute toxicity by the oral route (median lethal dose 300-2000 mg/kg body weight). The substance does not contain structural features associated with adverse human health effects.

When the notified substance is used as a curing agent in industrial and commercial coatings, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is not expected given the low potential for environmental release. Potential uses of the substance include use as a curing agent in consumer coating or adhesive products, where direct and indirect exposure of the general population is expected to be at low levels that do not pose a concern.

Based on the low potential for exposure, 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 to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

When the substance is used as notified or for other 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 the *Hazardous Products Regulations* for products intended for the workplace.