

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

New Substances Notifications 21410, 21519 and 21520: Confidential Accession Numbers 19691-9, 19692-0 and 19693-1

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 substances and have determined that they are 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 following three substances were submitted as consolidated New Substances Notifications (NSNs), which take place when the technical information provided for one substance is used to address the technical information requirements for the remaining substance(s). The substances in consolidated notifications are very similar and are expected to have the same exposure and hazard profiles.

The notified chemicals are:

- NSN 21410: 12-Hydroxyalkanoic acid, reaction products with carbomonocycle dimethanamine (Confidential Accession Number 19691-9)
- NSN 21519: 12-Hydroxyalkanoic acid, reaction products with alkylenediamine (Confidential Accession Number 19692-0)
- NSN 21520: 12-Hydroxyalkanoic acid, reaction products with polymethylenediamine (Confidential Accession Number 19693-1)

Notified and potential uses

The substances are proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as additives in industrial coating applications. Potential uses may include other industrial uses such as adhesives and sealants, and consumer applications such as coatings, inks and toners.

Environmental fate and behaviour

Based on their physical and chemical properties, if the substances are released to the environment, they will tend to partition to soil and sediment. Components of the substances will also be dispersed in water but will adsorb to the suspended organic matter and settle to sediment. The substances are not expected to be persistent in these compartments based on their inherent biodegradation (10-20% over 28 days). The substances are not expected to bioaccumulate based on their high molecular weights, their low predicted bioaccumulation and bioconcentration factors (< 250 L/kg), and their insolubility in water, all of which will limit their ability to cross biological membranes.

Environmental risk assessment

Based on the available hazard information, the substances are expected to have low acute toxicity to fish and aquatic invertebrates (median lethal loading rate and median effective loading rate > 100 mg/L), low chronic toxicity to fish (no adverse effects observed in saturated solution), low chronic toxicity to aquatic invertebrates (10% effective concentration (EC₁₀) > 10 mg/L), and low to moderate chronic toxicity to algae (no-observed-effect concentration (NOEC) > 0.1 mg/L, 10% effective loading rate > 0.1 mg/L). The substances are expected to have low acute toxicity to soil invertebrates (median lethal concentration > 100 mg/kg dry soil), low to moderate chronic toxicity to soil invertebrates (lowest-observed-effect concentration (LOEC) > 10 mg/kg dry soil, NOEC > 0.1 mg/kg dry soil), moderate chronic toxicity to sediment invertebrates (LOEC, NOEC and EC₁₀ 0.1-10 mg/kg dry sediment), and moderate acute toxicity to terrestrial plants (NOEC and LOEC 1-100 mg/kg dry soil). A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substances throughout their life cycle. Environmental exposure is expected to be negligible as a result of the notified activities including cleaning of transportation vessels, formulation and use of the substances in coating applications. A predicted environmental concentration was not calculated due to the low potential for environmental exposure. No potential activities were identified that could significantly increase environmental risks compared to those notified.

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

Human health risk assessment

Based on the available hazard information, the substances have a low acute toxicity by the oral and dermal routes (median lethal dose > 2000 mg/kg body weight), and low acute toxicity by the inhalation route (median lethal concentration > 5 mg/L/4 hour). The substances have high subchronic toxicity following repeated inhalation doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) < 0.06 mg/L/6 hour). The substances have a low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL > 300 mg/kg-bw/day). They are mild dermal sensitizers (9-28% response in a guinea pig

maximization test). They are not mutagenic or clastogenic *in vitro*. Therefore, the substances are unlikely to cause genetic damage.

When the notified substances are used in industrial coating applications, consumers may come into contact with end-use products containing the substances; however, direct exposure is not expected because the substances will be encapsulated within a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media is not expected given the specialized industrial use of the substances, which results in little or no release to the environment. Potential uses of the substances include a variety of consumer applications, where direct exposure of the general population is expected to be mainly by contact with the skin. The potential for dermal penetration and systemic uptake of the substances is expected to be low because the substances have a high molecular weight, low water solubility, and high octanol-water partition coefficients which will limit their ability to cross biological membranes. Indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low potential for exposure, the substances are not likely to pose a significant health risk to the general population, and are 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 substances are used as notified or for other identified potential activities, they are 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 these substances, 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.