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

New Substances Notification 20948: 1-Hexanamine, 2-ethyl-*N*,*N*-bis(2-ethylhexyl)- (Chemical Abstracts Service Registry Number 1860-26-0)

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 based on the available information, that when used as notified, the substance 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.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential human health impacts that could arise as a result of potential new activities. Order 2022-87-07-01 Amending the Domestic Substances List outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 156, No. 19 on September 14, 2022. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified chemical is 1-hexanamine, 2-ethyl-*N*,*N*-bis(2-ethylhexyl)- (Chemical Abstracts Service Registry Number[1] 1860-26-0).

Notified and potential uses

The substance is proposed to be manufactured in and/or imported into Canada in quantities up to or greater than 10 000 kg/yr for the notified use as a reaction catalyst in preparation of powder and spray coatings, as well as a catalyst for biomass conversion. Potential uses may include consumer products such as paints and coatings, and personal care products.

Environmental fate and behaviour

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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 inherent biodegradation (60-85% over 28 days). The substance is not expected to bioaccumulate based on a low bioconcentration factor (<250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance is expected to have high acute toxicity to fish, aquatic invertebrates, and algae (median lethal concentration and median effective concentration < 1 mg/L) and high chronic toxicity to aquatic invertebrates and algae (no-observed-effect-concentration (NOEC) < 0.1 mg/L). Using the EC_{50} from the most sensitive organism (algae) and by applying an assessment factor of 10 to account for acute to chronic extrapolation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 0.1 to 1.0 µg/L, which was used to estimate the risk to the environment.

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 various industrial uses by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.0001-0.01 µg/L, from formulation by release of the substance to water resulting in a PEC in the range of 0.001-0.01 µg/L, and from cleaning of transportation vessels by release of the substance to water resulting in a PEC in the range of 0.01-0.1 µg/L. For potential 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 0.001-0.01 µg/L.

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 route (median lethal dose > 2000 mg/kg body weight) and is expected to have moderate to high sub chronic toxicity following repeated oral doses in mammalian test animals (90-day lowest-observed-adverse-effect level 10-100 mg/kg-bw/day in female rats). The substance is expected to have moderate reproductive/developmental toxicity following repeated oral doses in mammalian test animals (no observed adverse effect level > 30 mg/kg-bw/day). It is a weak skin sensitizer (estimated concentration of >10% required to produce a stimulation index of 3 in the local lymph node assay). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a catalyst in industrial applications, direct exposure of the general population is not expected. Consumers may come into direct contact with end-use products containing the substance; however, exposure is not expected because the substance

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 such as drinking water is expected to be at low levels given the low potential for release to the environment. Potential uses of the substance include personal care products, where direct exposure of the general population is expected to be mainly by contact with the skin at high levels in the range of 0.01-0.1 mg/kg-bw/day. Indirect exposure of the general population from environmental media such as drinking water for potential uses or manufacture of the substance in Canada is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the potential for direct exposure of the general population combined with the risk for subchronic and reproductive and/or developmental toxicity, the substance is anticipated to be harmful to human health. These risks are associated with potential use of the substance in personal care products.

The assumptions made in the assessment and the risk management measures applied 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, it is not suspected to be harmful to human health or the environment according the criteria under section 64 of the Act. However, it is suspected that a significant new activity in relation to the substance could result in the substance meeting those criteria.

Due to the potential risk to human health related to the subchronic toxicity if the substance were to be used in personal care products, the SNAc provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. Order 2022-87-07-01 was published in the *Canada Gazette* Part II, Vol. 156, No. 19 on September 14, 2022.

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.