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

New Substances Notification 21059: Alanine, *N*,*N*-bis(carboxyalkyl)-, sodium salt (Confidential Accession Number 19604-2)

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 chemical is alanine, *N*,*N*-bis(carboxyalkyl)-, sodium salt (Confidential Accession Number 19604-2).

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 in consumer dish washing products. Potential uses may include various industrial applications, household cleaners, consumer laundry products and cosmetics.

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 water based on its high ready and inherent biodegradation (> 60% over 28 days). The substance is not expected to bioaccumulate based on expected low bioconcentration and bioaccumulation factors (< 250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low acute toxicity to fish (median lethal concentration [LC_{50}] > 100 mg/L), aquatic invertebrates (median effective concentration [EC_{50}] > 100 mg/L), algae (EC_{50} > 100 mg/L; when corrected for nutrient deficiencies), terrestrial plants (EC_{50} > 1000 mg/kg dry soil) and terrestrial invertebrates (LC_{50} > 100 mg/kg dry soil). The substance is expected to have low chronic toxicity to fish (no-observed-effect-concentration [NOEC] > 10 mg/L and 10% effective concentration [EC_{10}] > 10

mg/L) and algae (NOEC and EC_{10} > 10 mg/L; when corrected for nutrient deficiencies), and moderate to low chronic toxicity to aquatic invertebrates (NOEC > 1 mg/L).
Using the NOEC from the most sensitive organism (aquatic invertebrates) and by applying an appropriate assessment factor of 2 to account for mode of action, the predicted no effect concentration (PNEC) was calculated to be in the range of 1-10 mg/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 activity is expected to be mainly from use in consumer dish washing products from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.1-1 mg/L, with the exact value being below the PNEC value. For potential activities such as use in higher quantities of consumer dish washing products, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 1-10 mg/L, with the exact value also below the PNEC. For potential activities such as manufacturing, formulation and cleaning of transportation vessels, environmental exposure is expected to be mainly from release of the substance to water resulting in PECs in the range of 0.001-0.01 mg/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 is expected to have a low acute toxicity by the oral and dermal routes (median lethal dose > 2000 mg/kg body weight) and low to moderate subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level [NOAEL] 30-300 mg/kg-bw/day; 90-day NOAEL > 100 mg/kg-bw/day). The substance is expected to have a low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL > 300 mg/kg-bw/day). It is not expected to be a dermal sensitizer (0% response in a guinea pig maximization test). Carcinogenicity studies with mammalian test animals indicate that the substance is not expected to be carcinogenic. It is not mutagenic *in vitro* and is clastogenic *in vitro* but not *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in consumer dishwashing products, direct exposure of the general population is expected to be mainly by ingestion at levels in the range of 1-10 µg/kg-bw/day for children and 0.1-1 µg/kg-bw/day for adults. Indirect exposure of the general population from environmental media such as drinking water is estimated to be at levels in the range of 0.1-1 µg/kg-bw/day for children and adults and mainly by ingestion. Potential uses of the substance include household cleaners, consumer laundry products and cosmetics. When the substance is used in household cleaners, direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 0.01-100 µg/kg-bw/day for children and adults, by inhalation in the range of 0.001-100 µg/kg-bw/day for adults, or by

ingestion in the range of 0.001-0.01 µg/kg-bw/day in infants. When the substance is used in consumer laundry products, direct exposure of the general population is expected to be mainly by contact with the skin in the range of 1-10 µg/kg-bw/day for adults. When the substance is used in cosmetics, direct exposure of the general population is expected to be mainly by contact with the skin in the range of 0.1-1 µg/kg-bw/day for teens and adults. Indirect exposure of the general population from environmental media such as drinking water is estimated to be at levels in the range of 0.1-10 µg/kg-bw/day for children and adults and mainly by ingestion.

The target margin of exposure (MOE_T) was calculated to be 100 based on the available information. The MOE_T is the level of exposure at or above which there is no expected risk to the exposed population. The derived margin of exposure (MOE_D) is the ratio of the point of departure value to the available exposure doses and is compared to the MOE_T. As the MOE_D is higher than the MOE_T for all estimated human exposures, 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 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 the *Hazardous Products Regulations* for products intended for the workplace.