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

New Substances Notification 21033: Fatty acids, coco, hydrogenated, reaction products with 2-[(2-aminoethyl)amino]ethanol and sodium 2-chloroacetate (1:1), sodium salts (Chemical Abstracts Service Registry Number 618104-39-5)

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. Significant New Activity Notice No. 21033 outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 156, No. 16 on April 16, 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 fatty acids, coco, hydrogenated, reaction products with 2-[(2-aminoethyl)amino]ethanol and sodium 2-chloroacetate (1:1), sodium salts (Chemical Abstracts Service Registry Number[1] 618104-39-5), and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 1000 kg/yr for the notified use as a surfactant for use in rinse-off facial cleansers and rinse-off face washes. Potential uses may include the full spectrum of cosmetics and home care products.

Environmental fate and behaviour

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Based on the available physical and chemical information, if the substance is released to the environment, it is expected to partition to water. As a surfactant, some of the substance will also be present at the surface of the water or suspended organic matter. The substance is not expected to be persistent in these compartments based on moderate to high ready biodegradation (30-85% over 28 days). The substance is not expected to bioaccumulate based on the substance's very high water solubility (> 10 000 mg/L).

Environmental risk assessment

Based on the available hazard information, the substance is expected to have moderate acute toxicity to fish (median lethal concentration 1-100 mg/L), moderate acute toxicity to aquatic invertebrates (median effective concentration (EC_{50}) 1-100 mg/L) and high toxicity to algae (EC_{50} 1-100 mg/L; 10% effective concentration (EC_{10}) < 0.1 mg/L). The substance is expected to have moderate chronic toxicity to fish and aquatic invertebrates (no-observed-effect-concentration 0.1-10 mg/L). Using the EC_{10} from the most sensitive organism (algae) and by applying an appropriate assessment factor of 10 to account for mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-10 µg/L, which was used to estimate the risk to the environment.

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 expected to be mainly from industrial processing by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L for industrial processing, with the exact value being below the PNEC value, and from consumer use by release of the substance to water resulting in a PEC in the range of 0.1-1 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 is expected to have low acute toxicity by the oral and dermal routes (median lethal dose > 2000 mg/kg body weight) and low subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) > 300 mg/kg-bw/day; 90-day NOAEL > 100 mg/kg-bw/day). The substance is expected to have a high developmental toxicity following repeated oral doses in mammalian test animals (lowest-observed-adverse-effect level (LOAEL) 30-300 mg/kg-bw/day with severe cardiovascular malformations at all doses tested). It is expected to be a weak dermal sensitizer (estimated concentration > 10% required to produce a stimulation index of 3 in a local lymph node assay). The substance is not expected to be mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The point of departure (POD) for the notified substance is in the range of 30-300 mg/kg-bw/day based on the severe cardiovascular malformations observed in the test animals of the oral developmental toxicity study.

An impurity in the notified substance (ethanol, 2-[(2-aminoethyl)amino]-, Chemical Abstracts Service Registry Number 111-41-1) is associated with dermal sensitization, as well as adverse reproductive and developmental effects in mammalian test animals.

When the notified substance is used as a surfactant for use in rinse-off facial cleansers and rinse-off face washes, direct exposure of the general population is expected to be mainly by contact with the skin at levels conservatively estimated to be in the range of 1-10 µg/kg-bw/day. However, if the substance is used in leave-on and rinse-off cosmetics (as a single product or multiple products used on the same day) or in home care products, an increased level of direct exposure may exist when compared to the notified use, and is expected to be by dermal contact at levels in the range of 10-1000 µg/kg-bw/day. 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.

The target margin of exposure (MOE_T) for use in cosmetics was calculated to be 3000 based on the available information. The MOE_T is the level of exposure at or above which there is no expected risk in the exposed population. The derived margin of exposure (MOE_D) is the ratio of the POD value to the available exposure doses and is compared to the MOE_T. The MOE_D for the notified use is higher than the MOE_T. As such, the substance is not likely to pose a significant health risk to the general population when used as notified, and is therefore unlikely to be harmful to human health.

However, the MOE_D for potential uses in household care products or in cosmetics other than those notified was calculated to be in the range of 100-1000 based on the POD, that is, the NOAEL of the oral developmental toxicity study in mammalian test animals. Because the MOE_D is less than the MOE_T, the potential use of the substance in household care products and rinse-off cosmetics at a concentration greater than 2.6% or in leave-on cosmetics at any concentration, could significantly alter the exposure dose resulting in the substance becoming harmful to human health. At concentrations greater than 2.6% in household care products and rinse-off cosmetics, and at any concentration in leave-on cosmetics, the presence of the impurity in the notified substance above 0.1% could result in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

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, it is not suspected to be harmful to human health or the environment according to 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 suspected dermal sensitization, reproductive and developmental toxicity potential of impurities and developmental toxicity of the substance if the substance were to be used in household care products or in cosmetics other than those notified, 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. SNAc Notice 21033 was published in the *Canada Gazette* Part I, Vol. 156, No. 16 on April 16, 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.