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

New Substances Notification 19898: Ethanol, 2-amino-, reaction products with ammonia, by-products from, distillation residues (Chemical Abstracts Service Registry Number 84238-53-9)

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 based on the available information, 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 this substance because of potential human health impacts that could arise as a result of possible new activities. Significant New Activity Notice No. 19898 outline information requirements for those activities and were published in the *Canada Gazette* Part I, Vol. 153, No. 31 on August 3, 2019. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergo further assessment and risk management consideration.

Substance identity

The notified chemical is ethanol, 2-amino-, reaction products with ammonia, by-products from, distillation residues (Chemical Abstracts Service Registry Number[1] 84238-53-9), and is considered a substance of unknown or variable composition, complex reaction products or biological materials (UVCB).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000kg/yr for the notified use in mineral processing.

The potential use of the substance in other consumer products and cosmetics has also been considered and it was determined that insufficient information is available to assess the risks associated with potential uses and activities.

Environmental fate and behaviour

[1] The Chemical Abstracts Service Registry Number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water with some degree of adsorption to sediment and soil. The substance is expected to be persistent in water, sediment and soil based on low potential for biodegradation (10-30% over 84 days). The substance is not expected to bioaccumulate based on its low bioconcentration factor (<250 L/kg).

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have low acute toxicity to fish (median lethal concentration >100 mg/L), moderate acute toxicity to aquatic invertebrates (median effective concentration 1-100 mg/L) and moderate chronic toxicity to aquatic invertebrates and algae (no-observed-effect concentration (NOEC) and 10% effective concentration 0.1-10 mg/L). Using the NOEC from the most sensitive organism (algae), the predicted no-effect concentration (PNEC) was determined to be in the range of 100-1000 µg/L.

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 formulation, cleaning transportation vessels and industrial use by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 10-100 µg/L. For potential activities such as manufacturing and cleaning transportation vessels, environmental exposure is expected to be similar to that of the notified activities

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 ecological harm in Canada.

Human health assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have a moderate acute toxicity by the oral route (median lethal dose (LD_{50}) 300-2000 mg/kg body weight). One component of the substance was reported in the literature to have moderate subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) of 53-60 mg/kg-bw/day). It is an extreme skin sensitizer (100% response (guinea pig maximization test)). It is not mutagenic *in vitro* and is not expected to be clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 100-1000 µg/kg bw/day based on the NOAEL of the oral subchronic toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

When the notified substance is used in do-it-yourself (DIY) consumer coating applications, direct exposure of the general population is possible and is expected to be mainly by contact with the skin at moderate levels. However, if proper personal protective equipment is used, this exposure could be avoided. When the notified substance is used as corrosion inhibitors and in asphalt applications, direct exposure of the general population is not expected due to the industrial nature of these uses. When the notified substance is used in industrial coating applications, 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 and once the product is cured will be unavailable for

uptake. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 1-10 µg/kg bw/day for children and 0.1-1 µg/kg bw/day for adults. However, if the substance is used in other consumer applications or cosmetics, an increased level of direct exposure may be possible. Indirect exposure of the general population from environmental media such as drinking water from these uses is expected to similar to that of the notified use.

Based on the notified DIY consumer coating uses, the substance is likely to pose direct human health risk as it is known extreme skin sensitization effects. This risk can be mitigated by proper use of personal protective equipment. Because all estimated human exposures through drinking water are less than the PTDI when used as notified, 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.

However, based on the potential for increased dermal exposure combined with indications that the substance has known extreme skin sensitization effects, the potential use of the substance in other consumer applications and cosmetics could significantly alter the exposure and conditions of use, resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

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 extreme skin sensitization effects if the substance is used in other consumer and cosmetic applications, the SNAc provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergo further assessment before these potential activities can be undertaken. SNAc Notice No. 19898 was published in the *Canada Gazette* Part I, Vol. 153, No. 31 on August 3, 2019.

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 *Hazardous Products Regulations* for products intended for the workplace.