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

New Substances Notification 21306: Acetic acid, hydroxysulfo-, disodium salt (1:2) (Chemical Abstracts Service Registry Number 29736-24-1)

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 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 acetic acid, hydroxysulfo-, disodium salt (1:2) (Chemical Abstracts Service Registry Number[1] 29736-24-1).

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 as an additive in construction materials. No other uses are anticipated in Canada.

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 this compartment based on its very high ready biodegradation (> 85% over 28 days). The substance is not expected to bioaccumulate based on its very low octanol-water partition coefficient (log K_{ow} < 0). Additionally, the notified substance is ionic and highly biodegradable, further mitigating any bioaccumulation potential.

Environmental risk assessment

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Based on the available hazard information, the substance has low acute toxicity to aquatic invertebrates (median effective concentration > 100 mg/L) and low chronic toxicity to algae (lowest-observed-effect-concentration and 10% effective concentration > 100 mg/L). The substance is expected to have low acute toxicity to fish (median lethal concentration (LC_{50}) > 100 mg/L). A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

A predicted environmental concentration was not calculated due to the low ecotoxicity and high biodegradation potential. No potential activities that could significantly increase environmental risks compared to those notified were identified.

Based on the low potential for ecotoxicity and environmental exposure, 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, dermal, and inhalation routes (oral and dermal median lethal doses > 2000 mg/kg body weight; inhalation LC_{50} > 5 mg/L/4hr). The substance has 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; including a 28-day parental NOAEL 30-300 mg/kg-bw/day in males and 53-day parental NOAEL 30-300 mg/kg-bw/day in females). The substance has low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL > 300 mg/kg-bw/day). It is not a dermal sensitizer (0% response, Buehler test). It is not mutagenic *in vitro* and is not clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an additive in construction materials, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be contained in a stable matrix once the product is cured and hardened, and it will be unavailable for uptake. When the notified substance is used in consumer construction applications, the general population could be exposed to the substance by contact with the skin and/or through inhalation. Direct dermal exposure will be limited by the low concentration of the substance in end-use consumer products (< 1%) and by the ready biodegradation (> 85% over 28 days), the very high water solubility (> 10 g/L) and the low octanol-water partition coefficient (log K_{ow} < 0) of the notified substance. Together these characteristics will tend to reduce potential exposure and minimize systemic uptake. Direct dust inhalation exposure will be limited by the low concentration in end-use products (< 1%) and by the proposed use patterns which are expected to minimize potential exposure and systemic uptake. Indirect exposure of the general population from environmental media is not expected given the specialized use of the substance, as well as the ready biodegradation of the substance in environmental media. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

Based on the low to moderate systemic oral toxicity and low potential for exposure, 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, 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 *Hazardous Products Regulations* for products intended for the workplace.