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

New Substances Notification 21364: Ethane, 1,2-dichloro-, polymer with ammonia, *N*-substituted reaction products sodium hydroxide (Confidential Accession Number 13774-4)

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 polymer is ethane, 1,2-dichloro-, polymer with ammonia, *N*-substituted reaction products sodium hydroxide (Confidential Accession Number 13774-4). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains cationic functional groups.

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 of oilfield wastewater treatment. Potential uses may include other industrial and/or municipal wastewater treatment.

Environmental fate and behaviour

Based on its physical and chemical properties, if the notified substance is released to the environment, it will tend to partition to soil and sediment. The substance is expected to be persistent in these compartments based on expected low biodegradability (≤ 10% over 28 days), hydrolytic stability and its partial hydrolysis products. The substance is not expected to bioaccumulate based on its high molecular weight and very low expected octanol-water partition coefficient (log K_{ow} ≤ 0), which will limit its ability to cross biological membranes.

Environmental risk assessment

Based on the available hazard information, the substance has moderate acute toxicity to fish and aquatic invertebrates (median lethal concentration (LC_{50}) and median effective concentration (EC_{50}) 1-100 mg/L) and moderate chronic toxicity to algae (no-observed-effect-concentration 0.1-10 mg/L) under environmental conditions which accounts for mitigation of toxicity by substance binding with dissolved organic carbon in the environment. Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 40 to account for acute to chronic toxicity extrapolation, species sensitivity variation, and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 100-1000 µg/L. This PNEC 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 cleaning of transportation vessels by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-100 µg/L, with the exact value being below the PNEC value. For potential activities such as manufacturing and industrial wastewater treatment, environmental exposure is expected to be mainly from release of the substance to water resulting in PECs in the range of 0.1-1 µg/L and 10-100 µg/L, respectively, and also below the PNEC value.

Comparing these PECs with the PNEC, the ratios are 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 moderate acute toxicity by the oral route (median lethal dose 300-2000 mg/kg body weight). The substance is expected to have moderate subchronic toxicity following repeated oral doses (90-day no-observed-adverse-effect level (NOAEL) 10-100 mg/kg-bw/day) and high subchronic toxicity following repeated inhalation doses (90-day no-observed-adverse-effect concentration < 0.2 mg/L/6 hrs) in mammalian test animals. The substance is expected to have a low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL > 30 mg/kg-bw/day, with no significant toxicity observed at the highest dose tested). It is not expected to be mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in oilfield wastewater treatment, direct exposure of the general population is not expected due to the industrial nature of the use. Potential uses of the substance include treatment of other industrial wastewater where direct exposure of the general population is also not expected. Indirect exposure of the general population from environmental media such as drinking water resulting from notified or potential uses (including manufacturing) is estimated to be at levels in the range of 1×10^{-5}-1×10^{-4} mg/kg-bw/day for adults and children.

The target margin of exposure (MOE_T) was calculated to be 1000 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 estimated level of exposure and is compared to the MOE_T. The NOAEL for subchronic oral toxicity study was used as the point of departure. 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 which 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 the Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or the *Hazardous Products Regulations* for products intended for the workplace.