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

New Substance Notification 20547: Formic acid, compd. with 2-methyl-1,5-pentanediamine (1:2)
(Chemical Abstracts Service registry number 1836131-75-9)

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 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 formic acid, compd. with 2-methyl-1,5-pentanediamine (1:2) (Chemical Abstracts Service registry number[1] 1836131-73-7).

Notified and potential uses

The substance is proposed to be manufactured in Canada in quantities greater than 10 000 kg/yr for the notified use in oil and gas operations. Potential uses may include adhesives, building/construction materials, paint, polymerization, and use as a filler, hardener or process regulator.

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, and eventually to sediments. The substance is not expected to be persistent in water and sediment because it is anticipated to biodegrade quickly. The substance is not expected to bioaccumulate based on the very low octanol-water partition coefficient (log K_{ow} ≤0).

Environmental risk assessment

Based on the available hazard information, the substance is expected to have moderate acute toxicity in aquatic invertebrates (median effective concentration [EC_{50}] 1-100 mg/L), low acute toxicity in fish (EC_{50} > 100 mg/L), and moderate chronic toxicity in algae (10 % effective concentration 0.1-10 mg/L). Using the EC_{50} from the most sensitive organism (invertebrate) and by applying an assessment factor of 40 to account for endpoint standardization, species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be 1-100 mg/L, which was used to estimate the ecological risk.

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 use and transportation resulting in predicted environmental concentrations (PECs) <0.1 mg/L. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC <0.1 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 ecological harm 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 (LD_{50}) 300-2000 mg/kg body weight) and has low acute toxicity by the dermal route (LD_{50} > 2000 mg/kg body weight). The substance has a moderate subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level 30-300 mg/kg-bw/day). It is not a dermal sensitizer (the estimated concentration required to produce a stimulation index of 3 could not be determined (local lymph node assay)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in oil and gas operations, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media such as water and air is expected to be at low levels given the low potential for environmental release. No potential uses which could significantly increase human health risks compared to the notified uses were identified.

Based on the 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.