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

New Substances Notification No. 18687: 2,4(1*H*, 3*H*)-Pyrimidinedione, 6-amino-1,3-dimethyl-

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 chemical, 2,4(1*H*, 3*H*)-Pyrimidinedione, 6-amino-1,3-dimethyl- (Chemical Abstracts Service Registry No. 6642-31-5), can be classified as a low molecular weight heterocyclic organic compound.

Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for use as an additive in the manufacture of polyvinyl chloride (PVC) pipes. Potential uses may include other applications as an additive in plastics.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is not expected to be persistent in water based on its moderate biodegradability (30-60%). The substance is not expected to bioaccumulate based on its low bioconcentration and bioaccumulation factors (<250 L/kg) and very low octanol-water partition coefficient ($\log K_{ow} \leq 0$).

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has low acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration >100 mg/L). A predicted no-effect concentration was not calculated based on the low potential for 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 activity is expected to be negligible because manufacturing of PVC pipes is carried out

using a closed and automated system and industrial waste management procedures mitigate potential releases to water from the cleaning of equipment. The substance could potentially be used in any application related to plastic additives. A predicted environmental concentration for notified or potential activities was not estimated due to the low potential for ecotoxicity.

Based on the low ecotoxicity and expected low release, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg body weight) and a low potential for subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observed-adverse-effect level >100 mg/kg-bw/d). It is not a dermal sensitizer (0-8% response (guinea pig maximization test scale). It is not mutagenic *in vitro*, weakly clastogenic *in vitro*, and not clastogenic *in vivo*. As such, it is considered to be non-clastogenic, meaning the substance is unlikely to cause genetic damage.

When the notified substance is used as an additive for the manufacture of PVC pipes, direct exposure of the general population is not expected. Exposure from contact with end-use products is expected to be low. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. No potential uses of the notified substance which would result in significantly different exposure scenarios from the notified use were identified.

Based on the low potential for direct or indirect exposure from notified or potential uses in conjunction with the low acute and subchronic toxicity, 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.

Assessment Conclusion

When the substance is used as notified or for other identified potential uses, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of CEPA.

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 workplace use.