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

New Substances Notification 20614: Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane and 4,4'-methylenebis[cyclohexanamine (Chemical Abstracts Service Registry Number 38294-67-6)

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 determined that the substance is anticipated to enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

In order to ensure that the substance does not cause harm to the Canadian environment or human health, its manufacture and import are authorized subject to conditions as described in Ministerial Condition No. 20614 published in the *Canada Gazette* Part I, Vol. 155, No. 17, April 24, 2021.

Substance identity

The notified chemical is phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane and 4,4'-methylenebis[cyclohexanamine (Chemical Abstracts Service Registry Number[1] 38294-67-6), and is considered a substance of Unknown or Variable composition, Complex reaction product or Biological material (UVCB).

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 a curing agent in industrial floor and metal coatings. Potential uses may include use as a curing agent in grouts, coating products, paints, putty and modelling clay.

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 soil and sediment with some presence in water. The substance is expected to be inherently biodegradable. The substance is not expected to bioaccumulate

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based on the low modelled bioaccumulation and bioconcentration factors (<250 L/kg) and high water solubility.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have moderate acute toxicity to fish (median lethal concentration 1-100 mg/L), aquatic invertebrates (acute no-observed-effect concentration (NOEC) 1-100 mg/L), and algae (median effective concentration 1-100 mg/L) under environmental conditions when mitigated by humic acid. Using the NOEC from the most sensitive organism (aquatic invertebrates) and by applying appropriate assessment factor of 50 to account for acute to chronic extrapolation, species sensitivity variation, and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 µg/L, which 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 activity is expected to be mainly from formulation, use and cleaning of transportation vessels, resulting in predicted environmental concentrations (PECs) in the range of 0.1-10 µg/L, with the exact values being below the PNEC value. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC < 10 µg /L, with the exact value being below the PNEC value.

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 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) and high subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) < 30 mg/kg-bw/day). The substance is a strong dermal sensitizer (estimated concentration required to produce a stimulation index of 3 (EC3) 0.1-1% (local lymph node assay)). The acceptable exposure limit (AEL) was calculated to be in the range of 1-10 µg/cm^2 based on the EC3 of the local lymph node assay in mammalian test animals. The AEL is the level of exposure below which no skin sensitization induction is expected in exposed individuals. It is not mutagenic or clastogenic *in vitro* or genotoxic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in industrial coatings, 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 once the product is cured and will be unavailable for uptake. Potential uses of the substance include consumer paints and coatings, where direct exposure of the general population is expected to be mainly by contact

with the skin at levels in the range of 10-2000 μg/cm^2. If the substance is used in consumer grout types of products, direct dermal exposure of the general population is expected to be similar or lower to that of the use in consumer paints and coatings. Potential uses of the substance also include modelling clay, where direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 10-2000 μg/cm^2 for children and by ingestion at levels in the range of 0.1-10 mg/kg-event for children. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 10^{-5}-10^{-4} mg/kg-bw/day for adults and 10^{-4}-10^{-3} mg/kg-bw/day for children, for both the notified and potential uses of the substance.

The derived margin of exposure (MOE_D) is the ratio of the point of departure (POD) value to the available exposure doses and is compared to the target margin of exposure (MOE_T). The MOE_D for the potential use of the substance in modelling clays was calculated to be in the range 1-100, based on the POD derived from subchronic toxicity in the repeated oral toxicity study in mammalian test animals. Because the MOE_D is less than the derived MOE_T and because the dermal exposure is higher than the AEL, the substance is anticipated to be harmful to human health. These risks are associated with use of the substance in consumer products such as modelling clay and coatings.

The assumptions made in the assessment and the risk management measures applied 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

The substance is suspected to constitute a danger to human health according to the criteria under paragraph 64 (c), but is not suspected to have a harmful effect on the environment according to the criteria under paragraph 64 (a) or (b) of the Act.

Due to the identified risk to human health related to the subchronic toxicity and sensitization, a Ministerial Condition was issued to restrict the manner in which the notifier may manufacture or import the substance with conditions on its use and handling in order to mitigate these potential risks. Ministerial Condition No. 20614 was published in the *Canada Gazette* Part I, Vol. 155, No. 17 on April 24, 2021.

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 the workplace.