

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

New Substances Notification 19477: Nickel, [1,3-dihydro-5,6-bis[[2-hydroxy-1-naphthalenyl)methylene]amino]-2*H*-benzimidazol-2-onato(2-)-*N*⁵,*N*⁶,*O*⁵,*O*⁶]-, (SP-4-2)- (Chemical Abstracts Service Registry Number 42844-93-9)

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 based on the available information, that when used as notified, the substance 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.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential human health impacts that could arise as a result of potential new activities. [Order 2019-87-08-01 Amending the Domestic Substances List](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 153, No. 14 on July 10, 2019. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified chemical is nickel, [1,3-dihydro-5,6-bis[[2-hydroxy-1-naphthalenyl)methylene]amino]-2*H*-benzimidazol-2-onato(2-)-*N*⁵,*N*⁶,*O*⁵,*O*⁶]-, (SP-4-2)- (Chemical Abstracts Service Registry Number¹ 42844-93-9).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as a pigment in plastics and rubber materials. Potential uses may include use in consumer non-aerosol paints, coatings and printing inks.

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. The substance is expected to be persistent in these compartments based on its very low biodegradability (≤10% over 28 days). The substance is not

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expected to bioaccumulate based on its low water solubility (0.01-10 mg/L) which will limit its bioavailability in aquatic organisms.

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity in fish, aquatic invertebrates and algae (no adverse effects observed in saturated solutions). Using the highest loading rate of the test substance in ecotoxicity tests, the predicted no-effect concentration (PNEC) was determined to be in the range of 100-1000 µg/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 not expected based on the dispersive nature of the use and the low water solubility of the substance (0.01-10 mg/L). A predicted environmental concentration (PEC) for the notified activities was not calculated due to the low potential for environmental exposure and low ecotoxicity. Environmental exposure from potential activities is expected to be mainly by release of the substance to water resulting in PECs in the range of 0.001-0.01 µg/L for paint and coating formulation, 0.01-0.1 µg/L for ink formulation, 0.1-1 µg/L for manufacturing, and 1-10 µg/L for deinking.

Based on the low potential for ecotoxicity and environmental exposure, the substance is unlikely to cause ecological harm in Canada when used as notified. Comparing the PNEC with the PECs for potential uses, 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 ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). It is not a skin sensitizer (0% response (guinea pig maximization test)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. Some nickel and nickel compounds are associated with respiratory toxicity, skin sensitization and carcinogenicity.

When the notified substance is used as a pigment in plastics and rubber materials, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be encapsulated within the stable matrix of end-use products and no significant leaching from products is expected. Indirect exposure of the general population from environmental media such as drinking water is not expected given the low potential for environmental release.

If potential uses of the substance were to include use in consumer printing inks, paints and coatings, direct exposure of the general population is expected to be mainly by contact with the skin at low levels because the substance will be encapsulated within a stable matrix once the product is dried and will be unavailable for uptake. However, if the substance is used in consumer products intended for spray applications, an increased level of direct exposure may exist, and is expected to be by inhalation at potentially significant levels. Dermal contact may also occur but is not expected to result in significant exposure. Indirect exposure of the general population from environmental media such as drinking water is not expected, similar to that of the notified use.

Based on the low potential for exposure when used as notified, 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.

However, based on the potential for increased inhalation exposure combined with indications that the substance has potential toxic effects including carcinogenicity if inhaled, the potential use of the substance in consumer aerosol paint and coating products could significantly alter the exposure and/or conditions of use resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Other considerations

The substance contains nickel which is considered to be a human carcinogen by the United States Environmental Protection Agency and the International Agency for Research on Cancer. Nickel and nickel compounds have been assessed by Environment and Climate Change Canada and Health Canada and as a result oxidic, sulphidic and soluble inorganic nickel compounds have been added to the List of Toxic Substances in Schedule 1 of CEPA.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or environment within the meaning of the criteria under section 64 of the Act. However, it is suspected that a significant new activity in relation to the substance could result in the substance meeting those criteria.

Due to the potential risk to human health related to carcinogenicity of nickel and nickel compounds if the substance is potentially used in consumer aerosol paint and coating products, the SNAc provisions under CEPA were applied to the substance in order to obtain additional information before these activities are undertaken. Order 2019-87-08-01 was published in the *Canada Gazette* Part II, Vol. 153, No. 10 on July 10, 2019.

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.