

Performance Measurement Evaluation for Risk Management of 2-Naphthalenol, 1-[(4-methyl-2-nitrophenyl)azo]- (Pigment Red 3)

1 – About Performance Measurement

The Government of Canada is conducting performance measurement (PM) on the risk management of toxic substances to ascertain whether actions taken to help protect Canadians and their environment are meaningful and effective over time. Performance measurement will help determine how well the risk management actions have reduced or eliminated the risk associated with each toxic substance. Adjustments may be required when risk management tools are not achieving the desired outcome.

The Government of Canada establishes goals in order to help protect Canadians and their environment from risks posed by toxic substances. The Government attempts to achieve these goals by setting human health, environmental and risk management objectives, and then developing a strategy to meet those objectives. Performance measurement assesses how risk management actions contribute to protecting Canadians from toxic substances and identifies any areas of improvement that should be addressed moving forward.

2 – Background

2-Naphthalenol, 1-[(4-methyl-2-nitrophenyl)azo]-, (CAS RN: 2425-85-6) known as Pigment Red 3, is an organic azo pigment that is primarily used in Canada and elsewhere as a red pigment in paints. This substance was identified for assessment of potential risks to human health as it met the criteria for greatest potential for exposure. Moreover, it also met the ecological categorization criteria for persistence, bioaccumulation potential and inherent toxicity to non-human organisms.

At the time of assessment, the most common uses of Pigment Red 3 included industrial and commercial applications as an organic pigment in enamel gloss paints for both interior and exterior applications including anti-rust proofing, in plastics, printing inks (toner), textiles and polyurethane coatings, and cosmetic products such as soap and nail polish (Environment Canada 2008).

According to the risk assessment (Canada 2009a), and based on consideration of relevant available information, including weight-of-evidence based assessments by the International Agency for Research on Cancer (IARC 1993), a critical effect for the characterization of risk to human health for Pigment Red 3 was carcinogenicity.

Additionally, a US National Toxicology Program study concluded that Pigment Red 3 may be considered a genotoxic carcinogen based on the finding that multiple exposure-related tumours were observed at multiple sites in both female and male rats and mice (NTP, 1992).

The major source of population exposure to Pigment Red 3 was from dermal contact with products available to consumers. Pigment Red 3 had been used as a colouring agent in cosmetic products in Canada, and handwashing with soap containing the substance presented the greatest dermal exposure to Pigment Red 3 (Canada 2009a).

Pigment Red 3 was selected for performance measurement and evaluation because key indicator data is available, and actions have been in place for a sufficient amount of time to measure the impact.

3 – Risk Assessment and Risk Management approaches

The [risk assessment](#) under the Chemicals Management Plan in 2009 concluded that Pigment Red 3 may have been entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. It was therefore concluded that Pigment Red 3 meets the criterion in paragraph 64(c) of the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 2009a; Canada 2016). Subsequently, Pigment Red 3 was added to Schedule 1 of CEPA by Order in the *Canada Gazette* on February 16th, 2011 (Canada 2011).

A [risk management approach \(PDF, 208 kB\)](#) was published which set out objectives to be achieved to prevent or control the risks posed by exposure to Pigment Red 3. The human health objective was to minimize exposure to, and hence risk to human health associated with, exposure to Pigment Red 3 to the extent practicable. Concordantly, the risk management objective for this substance was to prevent increases in exposure to Pigment Red 3 to the extent practicable (Canada 2009b).

3.1 Health Canada's Cosmetic Ingredient Hotlist (the Hotlist)

The Government of Canada took action to help prevent deliberate use of Pigment Red 3 in cosmetic products by describing the substance as a prohibited ingredient on Health Canada's Cosmetic Ingredient Hotlist. Using this administrative tool, Health Canada informed manufacturers and others that Pigment Red 3 may contravene section 16 of the *Food and Drugs Act* (FDA) (Canada 1985). Compliance with FDA section 16 is monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations*, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada (Canada 2019a).

3.2 Significant New Activity provisions

A significant new activity (SNAc) is an activity conducted with a substance in a different quantity, concentration or in different circumstances that could affect the environmental or human exposure to the substance. The significant new activity provisions of CEPA were applied for Pigment Red 3 (Canada 2012). This action triggers an obligation to provide the Government of Canada with a Significant New Activity Notification (SNAN) which includes information about the substance when proposing to use, import or manufacture it for a significant new activity as defined in the SNAc Order. The Government of Canada then assesses the substance for potential risk to human health and/or the environment. If risks are identified with the new activity with the substance, the Government may impose new risk management measures (Canada 2019b).

4 – Performance Measurement Indicators

4.1 Market Data

The performance measurement baseline was formed by data obtained from industry using mandatory information gathering under section 71 of CEPA (Environment Canada 2008), including direct outreach to companies.

Data from notifications submitted under the *Cosmetic Regulations* to Health Canada was used to assess effectiveness of adding Pigment Red 3 to the prohibition section of the Hotlist.

4.2 Significant New Activity Notifications (SNANs)

Significant New Activity Notifications submitted in response to provisions set out in the published Significant Activity in Canada Order allow the government to monitor the activities related to Pigment Red 3 in Canada. Currently, any activity involving more than 100 kg of the substance, other than activity in enamel paints, industrial or commercial printing inks, polyurethane coatings or in textile products, requires notification to the Government of Canada.

5 – Available Data

5.1 Section 71 Market Data

According to 2006 data obtained from the mandatory information gathering initiative under section 71 of CEPA, twelve companies were identified as manufacturers, importers, or users of Pigment Red 3 (Environment Canada 2008).

Reported uses for Pigment Red 3 include industrial and commercial applications as an organic pigment in primarily alkyd and acrylic enamel gloss paints for both interior and exterior applications, including anti-rust proofing, in plastics, printing inks (toner), textiles

and polyurethane coatings. Industrial applications include manufactured or imported industrial enamel paints for use on metal tools or equipment. Other industrial applications include plastic compounding, plastic colouration and manufacturing of industrial printing inks. Pigment Red 3 was also used as a pigment in cosmetic products (Environment Canada 2008).

5.2 Cosmetic Notifications

Prior to Health Canada's decision to describe Pigment Red 3 as being a prohibited ingredient on the Hotlist, Health Canada had received notifications under the *Cosmetic Regulations* from manufacturers of four cosmetic products containing the substance. Notifiers of products with Pigment Red 3 were contacted prior to the addition of the substance to the Hotlist in 2011, and these products are no longer available to consumers. Since 2011, there has been one product notified containing the substance, and the product was voluntarily removed from sale due to the presence of the substance on the Hotlist (Canada 2019c).

6 – Performance Measurement Evaluation

6.1 Impacts of Interventions

Pigment Red 3 was present in cosmetic products and posed a risk to human health until the Government of Canada took action in 2011. Following Health Canada's decision to describe the substance as a prohibited ingredient on the Hotlist, cosmetic products containing Pigment Red 3 were no longer available to consumers in Canada. Since 2011, Health Canada was notified of only one product that contained the substance, and that product was voluntarily removed from sale. This demonstrates that Health Canada's communication to manufacturers and others through the Hotlist continues to be an effective means of helping to prevent Canadians' exposure to Pigment Red 3.

The SNAc provisions allow the Government to monitor the activities related to Pigment Red 3 in Canada. Since the provisions were put in place, no significant new activities have been reported as defined in the SNAc Order. This confirms Pigment Red 3 is only found in products such as paints and cosmetics, where it has been assessed to have a lesser concern of exposure to Canadians, and is not expected to be present in products where it would be a greater health concern, such as cosmetic products.

6.2 Objective Outcomes

The human health objective identified in the risk management approach was to minimize exposure to Pigment Red 3 to the extent practicable. The main concern with dermal exposure to Pigment Red 3, through use of cosmetic products, has been managed as currently there are no known uses of Pigment Red 3 in cosmetic products.

The risk management objective for Pigment Red 3 was to prevent increases in exposure. The risk management objective has been met as no SNANs have been submitted by industry, indicating that there are currently no new uses or increases in exposures. The presence of Pigment Red 3 on the Hotlist also prevented the introduction of a product containing the substance into the Canadian market.

It is therefore concluded that the Government of Canada has achieved its objectives set out to protect Canadians from the risks posed by this substance.

7 – Conclusion

The Government of Canada took action to reduce dermal exposure to Pigment Red 3 by using Health Canada's Cosmetic Ingredient Hotlist to describe the substance as a prohibited ingredient in cosmetics under section 16 of the FDA, and by introducing SNAc provisions. Historical cosmetics notifications and data obtained from a section 71 mandatory information gathering initiative created the baseline that identified uses for the substance in Canada (Environment Canada, 2008). Considering the absence of Pigment Red 3 in cosmetic products in Canada and that no SNANs have been received at the time of publication of this PM Evaluation, it is concluded that the risk management actions taken have achieved their desired results in helping to protect the health of Canadians from concerns that were identified in the final screening assessment, published in 2009.

Currently, the SNAc provisions and monitoring of cosmetic notifications are sufficient to notify the government of any potential exposures of concern. Moving forward, the Identification of Risk Assessment Priorities process is in place to identify and evaluate any newly available information to determine if further assessment may be warranted (Canada 2017).

8 – References

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