

# **Analysis of Batch 5 Challenge Substance Draft Assessment and Management Reports**

March 19, 2009

Prepared by Environmental Defence

## Introduction

On February 21, 2009 the federal government published the draft screening assessments for the fifth batch of the Industry Challenge of the Chemicals Management Plan. At this time, draft assessments were published for 19 substances and draft risk management scope documents for 2 substances. All of the above documents can be found at [http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot\\_5\\_e.html](http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_5_e.html).

Members of the public have until **April 22, 2009** to submit comments and feedback on the risk assessments for all 19 substances; the risk management proposals for the 2 substances that are proposed to be designated as “toxic” and added to the List of Toxic Substances in Schedule 1 of CEPA 1999; and the Government proposal to amend the DSL to apply the Significant New Activity (SNAC) provisions.

It is hoped that the information presented will help civil society organizations and their members to prepare comments on the government’s proposals and advocate for the sound management of these chemicals. All data, unless otherwise indicated, comes from the assessment and risk management scope reports.

## Our Use of Symbols

Note that in the assessment, the following symbols are used to identify chemicals that may be of possible concern to northern communities. As a result of these concerns are not often explicitly cited within the government assessments, the following symbols are being used by Environmental Defence to flag chemicals of potential interest on the basis of the information contained within the assessments:

- \* May have long range transport ability in air on the basis of its persistence in this media
- ◆ May be used in oil, mining, or forestry operations on the basis of information presented

## Our Priority Setting Criteria

For Batches 1-3, priority identification was only done at time of the final report. However, after some thought and consultation, attempting to assist NGOs wade through the large volume of information at the draft stage when risk assessment submissions are primarily considered was deemed most relevant. We have therefore identified priorities to help facilitate the ease with which NGOs tackle the draft data.

It is important to acknowledge that the line between high, medium, and low priorities is not always clear and that because and different organizations have different interests, it remains at the discretion of the reader to identify individual/organizational priorities. Criteria used to sort priorities by Environmental Defence are as follows:

- Designation as persistent, bioaccumulative, and/or inherently toxic;
- Volume of use and estimated level of exposure;
- Types of exposure (pathways);
- Quantity & quality of evidence for toxicity;
- Essentiality of the uses; and
- Availability of alternatives

## Batch 5 Challenge Substances Summary

Chemical	Volume in Canada	PBiT	Human Health Concern	CEPA "Toxic"	Use and Rationale for Concern	Priority for Action
◆ *Formamide (CAS 75-12-7)	Unknown *	No	Carcinogen, reproductive/developmental toxicant	No	Lack of commerce data with potentially dispersive use in oil and gas, plastics, chemical, pharmaceutical, agricultural, industrial, and consumer product industries.	High
◆ Acrylamide (CAS 79-06-1)	Very High	No	Carcinogen, genotoxic, neural toxicant, reproductive/developmental toxicant	Yes	High commercial volume and dispersive use in oil and gas, plastics, chemical, agricultural, industrial, building, appliance, and consumer product industries, as well as water clarification.	High
Ethanol, 2-chloro-, phosphate (3:1) (CAS 115-96-8)	Medium	No	Carcinogen, reproductive toxicant	Yes	Volume, probability of carcinogenicity at any exposure level, and use in furniture, building and textile industries; the manufacture of cars, railway cars and aircraft; polyvinyl chloride compounds; flame resistant paints and varnishes; various resins; and in wood resin composites.	High
◆ Phosphoric acid tributyl ester (CAS 126-73-8)	Medium-High	No	Carcinogen, reproductive/developmental toxicant	No	Volume, probability of carcinogenicity, potential inadequacy of the margin of exposure for health effects, and use in hydraulic fluids, automotive lubricants, adhesives, as well as the plastics, paper, and mining industries.	High
Disperse Orange 5 (CAS 6232-56-0)	Very Low	Yes	Unknown	No (SNAC)	A colourant, pigment, dye, ink, and with use in textiles such as polyester fiber, yarn, and other fabrics.	Medium
◆ Acetamide, N,N-dimethyl- (CAS 127-19-5)	Low-Medium	No	Developmental toxicant	No	Probability of reproductive toxicity, residual presence in consumer products (e.g., textiles), and use in oil, pharmaceutical, and agricultural industries.	Medium
2-Chloroacetamide (CAS 79-07-2)	Unknown	No	Reproductive toxicant	No (SNAC)	General lack of information and concern that existing Pest Control Products Act (PCPA) data and controls are out of date.	Medium

Disperse Orange 30 (CAS 5261-31-4)	Low-Medium	No	Unknown	No	A colourant, pigment, dye, ink, and with use in textiles. Literature shows it may be used for dyeing textiles for clothing and home uses.	Low
Disperse Blue 79 (CAS 12239-34-8)	Low-Medium	No	Unknown	No	Primarily used as a textile dye suitable for thermosol dyeing and printing, polyester, acetate, nylon and wool/polyester blends.	Low
ANAM (CAS 16421-40-2)	Low	No	Unknown	No	A colourant in the textile knitting and dyeing industry, as well as for the dyeing of apparel and automotive textile.	Low
AADM (CAS 16421-41-3)	Very Low	No	Unknown	No	Use is indicated as a colourant in textile manufacturing.	Low
Disperse Brown 1:1 (CAS 17464-91-4)	Very Low	No	Unknown	No	Use is indicated as a colourant in textile manufacturing.	Low
Disperse Brown 1 (CAS 23355-64-8)	Very Low	No	Unknown	No	Used in the textile industry for the dyeing of polyester and polyester blend fabrics. Also used in the tinting of eyeglass lenses and formerly used in hair dye in Europe.	Low
Disperse Red 167 (CAS 26850-12-4)	Low	No	Unknown	No	Used in the textile industry for the dyeing for polyester fabrics. Used on automotive textiles, which have high light-fastness requirements.	Low
BANAP (CAS 29765-00-2)	Low	No	Unknown	No	Use is indicated as a colourant in textile manufacturing.	Low
BDAP (CAS 52697-38-8)	Medium	No	Unknown	No	Information suggests it is a black textile dye suitable for polyester and polyester/cellulose blends for apparel and industrial fabrics.	Low
Disperse Orange 61 (CAS 55281-26-0)	Low-Medium	No	Unknown	No	Information suggests it is primarily used an ingredient in a black textile dye and has been sold to companies producing webbing, zippers, other sewing notions, and apparel for children and adults.	Low

EDD (CAS 55619-18-6)	Very Low	No	Unknown	No	A colourant with use patterns of structurally similar azo dyes suggesting its use in textiles.	Low
DNAN (CAS 72927-94-7)	Very Low	No	Unknown	No	A colourant with use patterns of structurally similar azo dyes suggesting its use in textiles.	Low

\* but a OECD, US, and EU HPV chemical

**Volume Scale**

Very Low	None reported
Low	100 - 1000 kg
Low-Medium	1 000 -10 000 kg
Medium	10 000 – 100 000 kg
Medium-High	100 000 - 1 000 000 kg
High	1 000 000 – 10 000 000 kg
Very High	> 10 000 000 kg

## HIGH PRIORITIES

### ◆\* Formamide CAS No. 75-12-7

Categorization	Assessment
Considered to pose intermediate potential for exposure to individuals in Canada and had been classified by the European Commission on the basis of reproductive toxicity. Environmental Defence notes indicated it was originally categorized for developmental toxicity.	Proposed that it “formamide does not meet any of the criteria set out in section 64 of CEPA 1999.”

### Manufacture & Use

There are no known sources of formamide. Oddly, there is no manufacture, import, or commercial use volume information cited in the draft assessment. While categorization indicated that there was no recent information on the use of this substance in Canada, it has been identified as high production volume (HPV) chemical by OECD, the US, and EU. There is significant concern over this lack of information, particularly in light of the conclusion that the general population is “not expected to be exposed.”

Formamide has a variety of uses. According to submissions made under section 71 of CEPA 1999, formamide is used in conventional oil and gas extraction and as a corrosion inhibitor. It is used in the manufacturing of pharmaceuticals, plastics, various chemicals, crop protection agents, fungicides, pesticides, and inks and paper. It is used in analytical reagents, emulsifiers, wire enamel coating removal from copper conductors, ink for fiber and felt-tip pens and markers, and may be used in lubricating oil and hydraulic fluid, de-icing fluids for airport runways, curing agents for epoxy resins, plasticizers, dye enhancers, and fertilizers. It has not been notified in cosmetics in Canada, but two skin cleansing products contain greater than 30% polyvinyl formamide.

### Releases

Release was cited to occur as a result of its manufacture and use as an intermediate and solvent; no mention was made of the potential for it to be released during the usage of products containing it. It has been detected in wastewater from chemical and wastewater treatment plants. It will primarily be found in water (if released to water) or soil (if release to air or soil). Empirical and modelled data indicate it is not persistent in these two media, but it is in air. Empirical and modelled data also indicate it is not acutely toxic and modelled data shows it to not be bioaccumulative.

### Human Exposure

While submissions made under section 71 of CEPA 1999, formamide is used in conventional oil and gas extraction and as a corrosion inhibitor, however, the most probable exposure of the general population to formamide was thought to be through ink formulations. A recent US study estimated acute exposure following 10 min of marker

use to be 0.2 µg/kg-bw per event (5–11 years of age) - 1.2 µg/kg-bw per event (6 mo. - 4 years of age).

## **Health Concerns**

The EU has classified formamide as a reproductive and developmental Category 2 substance (may cause harm to the unborn child). Studies have shown it to harm the fetus of rabbits, rats, and mice from oral (all) and dermal exposure (rats and mice). Maternal toxicity included reduced food consumption, body weight gain and uterine weight and fetal toxicity included reduced weight and increased incidences of death. It also resulted skeletal malformations, cleft palate, and fused ribs. The lowest lowest-observed-adverse-effect levels (LOAELs) for developmental toxicity was 79 mg/kg-bw (rabbits, oral exposure) and the LOAEL for the reproductive toxicity was 750 mg/L (mice, 144–226 mg/kg-bw per day). Repeat-dose, short-term, and subchronic toxicity resulted decreased weight gains, hematology changes (LOAEL 40 mg/kg-bw per day), reflex loss, organ size decline, tissue disintegration, increased non-neoplastic lesions (oral), testicular tubular atrophy (dermal), and increased kidney lesions and weight (inhalation).

A recent US National Toxicology Program (NTP) showed no evidence of carcinogenic activity of formamide in male or female rats; however, this was not the case for male mice (liver, dose-related, significant increases at 40 and 80 mg/kg-bw per day). Based on the weight of evidence, formamide is not considered to be mutagenic; it showed no evidence for mutagenicity in a series of short-term bioassays. However, at 160 mg/kg-bw increased incidences of lesions of several tissues/organs and decreased body weights have been seen in mice. Based on the evidence of carcinogenicity observed in only one organ (liver), one gender (male) and one species (mice) and the data indicating that formamide is not mutagenic, the tumours observed in the experimental animals are unlikely to have resulted from direct interaction with genetic material.

Toxicokinetic studies with rats or mice following a single oral administration show formamide to be rapidly and completely absorbed. The elimination half-life was about 15 h in rats and 4–6 h in mice, with most being excreted unchanged in urine or as carbon dioxide in breath.

As a result of the above, the critical effect was considered carcinogenicity. It was concluded that there was a practical threshold for non-mutagenic carcinogenicity. However, there is concern over the establishment of such a threshold when data shows carcinomas increased in a dose-related manner and when a threshold level was not clearly indicated within the assessment. Reproductive, developmental and hematological toxicity were considered the non-cancer critical effects. Based on the evidence presented, this is considered appropriate. Differences between LOAELs associated with the two most sensitive endpoints (hematological and developmental toxicity) and the upper estimate of population exposure (1.2 µg/kg-bw, after 10 min of marker use) to formamide resulted in margins of exposure considered adequately protective for non-cancer effects.

## **Recommendations**

1. There is concern that commercial volume, comprehensive release, and environmental concentration information, and exposure data beyond that from marker use, is missing. This data is absolutely pertinent to concluding whether or not formamide is entering the environment in a quantity or concentration or under conditions that may harm health and it is considered irresponsible to make a conclusion in the absence of it.
2. Ascertain commercial volume, comprehensive release, and environmental concentration information, and general population exposure data beyond ink. Exposure pertaining to oil and gas extraction, particularly exposure within occupational settings and northern communities, needs to be identified since this use appears to be the only use data submitted under section 71 of CEPA 1999.
3. It is unclear whether or not it can be concluded that there is a practical threshold for non-mutagenic carcinogenicity since data shows carcinomas in male rates to increase in a dose-related manner. This “practical threshold”, as well as “uncertainty with respect to the extent of exposure from [felt-tip pens and markers]” and “significant uncertainty...with regard to the release of formamide into the Canadian environment” should not be relied upon to conclude that formamide not 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 should also be noted again that it is considered an HPV chemical by the OECD, the US, and EU.
4. Conduct substitution analysis and label products containing formamide so that consumers are aware of its presence.
5. Environmental data requires strengthening as there was no empirical chronic toxicity data with risk assessment calculations being based on acute effects and there being no data on toxicity to soil-dwelling organisms despite this being an important medium of exposure.

## ◆ 2-Propenamide (Acrylamide) CAS No. 79-06-1

Categorization	Assessment
Considered to pose the greatest potential for exposure to individuals in Canada and had been classified by the European Commission on the basis of carcinogenicity, genotoxicity and reproductive toxicity.	Proposed that "acrylamide meets one or more of the criteria set out in section 64 of CEPA 1999."

### Manufacture & Use

Between 1 million and 10 million kilograms of acrylamide was imported into and between 100 and 1000 kg was manufactured in Canada in 2006. It has been identified as an HPV chemical by the OECD, US, EU and an HVI chemical by Australia.

Section 71 submissions indicate a variety of uses. These include use in adhesives; sealants; water treatment chemicals; functional fluids (i.e., hydraulic, dielectric or their additives); analytical reagents; drilling mud additives; as well as, oil recovery, oil well treating, and various other agents. Literature indicates that the majority (>90%) of acrylamide is used in the manufacture of various polymers, such as polyacrylamide used in some of the above agents (e.g., those for water/wastewater treatment, pulp and paper processing, mineral/ore processing), cosmetics, soil stabilization, plastics, food manufacturing and packaging materials, the textile industry, crude oil production, home appliances, building materials, automotive parts, explosives, adhesives, printing inks, adhesive tapes, contact lenses, and many others. In Canada, polyacrylamide is used in the clarification of drinking water and is present as a non-medicinal ingredient in several licensed natural and therapeutic health products. Acrylamide may be present as a residual in these products and others (e.g., cosmetics, health products, potting soils, pest control products, paperboard, livestock feeds). It can also be found as a component of cigarette smoke, and formed in starchy foods under high-heat cooking. Neither acrylamide nor polyacrylamide is listed on the Cosmetic Ingredient Hotlist

### Releases

It may be released to polyacrylamide-treated water, as well as wastewater during its production and use in polymer manufacturing. The largest end use is within the mineral mining and water treatment industries. Less than 20 companies reported releases, but the total amount released is not provided. The National Pollutant Release Inventory (NPRI) data is considered low. It will primarily be found in water (if released to water) or soil (if released to soil). Empirical and modelled data indicate it is neither persistent nor bioaccumulative, but may be inherently toxic to aquatic organisms and plants.

### Human Exposure

In Canada, the highest concentrations of acrylamide have been detected in french fries, potato chips, but it has been found in other starchy foods cooked (e.g., cereals, cookies, and bread products). Other sources report detection in various non-starchy foods (e.g., olives, nuts). It has been found in breast milk at differing concentrations. Estimates for Canadian intakes from food and environmental media ranged from 0.48 µg/kg body

weight (kg-bw) per day in infants to 1.76 µg/kg-bw per day in children aged 6 months to 4 years. For most age groups, approximately 90% of the daily intake was from food. Other sources of exposure were also calculated. Residual levels of acrylamide in personal care products and soil conditioning in Canada were not identified, but estimates indicate such exposures are negligible.

## **Health Concerns**

Acrylamide has been classified as an IARC “probably carcinogenic to humans” and US EPA probable human carcinogen (based upon inadequate evidence in humans and *sufficient evidence* in experimental animals). It is considered a “non-threshold carcinogen” (EURAR 2002) and has received various other carcinogenicity designations by external bodies. The database for carcinogenicity includes increased incidences of benign and/or malignant tumours at multiple sites in both sexes of rats and carcinogenic effects in 1-year bioassays in mice by several routes of exposure. Dose-related increases have been seen. All of the data presented indicates that there is no question regarding its carcinogenicity in animals. As the assessment states, the epidemiological studies are considered to mixed to draw a clear conclusion that it is carcinogenic to humans. Carcinogenicity is considered the critical effect for characterization of risk to human health.

The EC and Australia similarly concluded that it “may cause heritable genetic damage” Based on the information presented (heritable translocations and chromosomal and cell nucleus changes), this is considered an appropriate conclusion. While the US EPA (2007) recently released a toxicological review of acrylamide acknowledging that altered hormonal responses may be the mode of action, the data was considered insufficient to make such a determination. Other jurisdictions have concluded that there insufficient to support non-genotoxic mechanisms.

Acrylamide has also induced non-cancer effects. Dose-response neurological effects have been seen experimental animals. Neuropathological effects have also been reported in case reports and workplace surveys, but human dose-response relationships cannot be determined. Additionally, the EC states that it has a “possible risk of impaired fertility” and an NTP Expert Panel concluded it is a developmental and reproductive toxicant in both mice and rats. The margin of exposure for non-cancer effects using the estimated total daily intake of the general population (1.76 µg/kg-bw per day) results in a margin of exposure considered inadequate to protect human health.

## **Proposed Risk Management**

Cited options for risk management include focusing on using the *Food and Drugs Act* to reduce the inadvertent production of acrylamide in certain processed foods intended for human consumption. Additionally, the Government will investigate the utility of developing a future use notification requirement.

## **Recommendations**

1. Considering the weight of evidence, its carcinogenicity for which there may be a probability of harm at any level of exposure, as well as the potential inadequacy of the margin of exposure for other health effects, acrylamide should be designated at CEPA “toxic”.
2. In light of the evidence presented, the proposed risk management approach is not considered appropriate; it does not involve the reducing polyacrylamide in products and must include substitution of safer alternatives where possible and the labelling of products containing it.
3. Add acrylamide and polyacrylamide with it as a residual to the Cosmetics Hotlist.
4. Exposure data should be updated to reflect possible cumulative exposures within the general population. Additionally, particular attention needs to be paid to the role of different diets, for example, those of northern communities, in terms of exposure.

## Ethanol, 2-chloro-, phosphate (3:1) (TCEP) CAS No. 115-96-8

Categorization	Assessment
Considered to pose intermediate potential for exposure to individuals in Canada and had been classified by the European Commission on the basis of carcinogenicity.	Proposed that “[TCEP] does meet the criterion in paragraph 64(c) of CEPA 1999.”

### Manufacture & Use

TCEP does not occur naturally in the environment. Submitted data shows it to have been imported into Canada in 2006 in the range of 10 000 to 100 000 kg. It is primarily used as a flame retardant and as a plasticizer in thermoplastic resins in Canada. Products containing TCEP are used in “furniture, building (e.g., roofing insulation) and textile industries (e.g., back-coatings for carpets and upholstery); in the manufacture of cars, railway cars and aircraft; in polyvinyl chloride compounds; in flame resistant paints and varnishes”; various resins; and in wood resin composites (e.g., particleboards, adhesives and lacquers).

### Releases

During formulation/processing, TCEP mainly into wastewater and, to a lesser extent, exhaust gases. It may also be released during use and disposal of consumer products. “Significant leaching from landfills is expected as a result of TCEP’s high water solubility” (OECD 2006). It has been found in various water systems and landfill leachate. Submitted information shows that no TCEP was released into the environment in 2006. The predicted environmental concentration (PEC) based on Canadian data is  $9.4 \times 10^{-6}$  mg/L. It meets the persistence criteria in water, soil and sediment, but is not bioaccumulative (according to models) or inherently toxic to aquatic organisms (according to models and experimental data). The data does indicate these conclusions are valid.

### Human Exposure

Various studies have been conducted in Canada, Japan and Europe. The maximum concentrations found in various media considered applicable to exposure estimates are as follows: outdoor air concentration (58.4 ng/m<sup>3</sup>); indoor air (380 ng/m<sup>3</sup>); drinking water (52 ng/L); surface waters (754 ng/L), rain (52.3 ng/L); sediment (0.07 mg/kg); school dust (2200 mg/kg); and house dust (44 mg/kg).

The upper bounding estimate of daily intake for the general Canadian population was 0.5 µg/kg body weight (kg-bw) per day (children 0.5–4 years). Dermal exposure to dust ranged from 0.4 - 0.5 µg/kg-bw per day.

The general Canadian population is also potentially exposed to TCEP from consumer products that contain polyurethane foam, such as furniture or mattresses, and from electronic equipment (mainly television sets). The highest consumer product exposure estimate is 0.04 mg/kg-bw per day (infants aged 0–6 months mouthing foam or fabric containing TCEP). Maximum inhalation from furniture containing TCEP and from

watching television was 1.1 µg/kg-bw per day and 0.006 µg/kg-bw per day (children 6 months - 4 years), respectively. Dermal exposure from sitting on furniture containing TCEP may also occur.

## **Health Concerns**

The EU has classified TCEP as Category 3 for carcinogenicity (*causes concern for humans owing to possible carcinogenic effects*), but the International Agency for Research on Cancer has classified it as Group 3 (*not classifiable as to its carcinogenicity to humans*).

It has induced tumours at multiple sites (thyroid, kidney, liver, stomach, blood) in both rats and mice exposed orally over 1-2 years, with dose-related increases. Also, the LOAEL for non-neoplastic effects (changes to the kidney) was 44 mg/kg-bw per day. There was reportedly no significant increase in tumours in dermally exposed mice. Long-term inhalation studies using TCEP were not identified. Short term studies show the same non-neoplastic LOAEL. The possibility of mutagenicity cannot be precluded.

The EU has also classified it as a Category 2 reproductive toxicant (*may impair fertility*) based on studies in mice showing decreased birth numbers, decreased relative testes weight, decreased sperm motility, and increased number of abnormal sperm in mice. The LOAEL for reproductive effects was considered to be 700 mg/kg-bw per day. Maternal toxicity has been observed at 200 mg/kg-bw per day in rats (general weakness and death) and at 940 mg/kg-bw per day in mice (decreased body weight gain and mortality). Neurotoxicity in rats was observed at 275 mg/kg-bw.

In light of the above, the critical effect is considered carcinogenicity. Since the “modes of induction have not been elucidated, it cannot be precluded that TCEP induces tumours via a mode of action involving direct interaction with genetic material.” Margins of exposure (88,000) for increased tumours and non-cancer effects we considered protective. While this was based on upper bounding estimates (0.5 µg/kg-bw per day), the large margin indicates that exposures would have to be substantially bigger to be of concern. However, the margin of exposure (1,300) for reproductive effects via inhalation of indoor air is considered inadequately protective, as is the margin of exposure (1,100) for consumer product use exposure via a child mouthing foam or fabric containing TCEP.

## **Proposed Risk Management**

The risk management scope document indicates that “options for risk management would focus on investigating the potential options within the various use patterns for replacement of TCEP with an alternative.”

## **Recommendations**

1. Considering the weight of evidence, its carcinogenicity for which there may be a probability of harm at any level of exposure (there were increase tumor incidences at the critical effect level for non-cancer effects in oral studies in rats at the lowest

2. Since the margins of exposure between critical effect levels and exposures could be smaller (if the lowest oral exposure level for reproductive toxic effects in rats was determined, the margin of exposure for predicted exposures from some consumer products would be twofold lower), it is even more pertinent that the above designation stands.
3. Improve upon information pertaining to potential toxicity of TCEP following inhalation, particularly for rats which appear to be the most sensitive species, and dermal exposure, routes of relevance to population exposure.
4. Employ the precautionary approach to account for any differences between humans and experimental species sensitivity to effects. Human toxicity and epidemiological studies would be advantageous to the assessment.
5. Improve Canadian population exposure data since there is a current reliance on external jurisdiction data. Also, indoor air exposures may be underestimated; exposures of infants and toddlers may be overestimated; and there is uncertainty regarding the estimates of population exposure via food, the assumptions incorporated into the consumer product scenario models, and dermal exposures to consumer products.
6. Toxicity data pertaining to soil dwelling organisms and experimental bioaccumulation data is needed. This is especially true since input to the models was also estimated (e.g.,  $K_{oc}$ , Henry's Law constant).

## ◆ Phosphoric acid tributyl ester (TBP) CAS No. 126-73-8

Categorization	Assessment
Considered to pose intermediate potential for exposure to individuals in Canada and had been classified by the European Commission on the basis of carcinogenicity.	Proposed that “[TBP] does meet the criterion in paragraph 64(c) of CEPA 1999.”

### Manufacture & Use

TBP does not occur naturally in the environment. It was not manufactured in, but imported at a total quantity of approximately 260 000 kg in 2006.

Its major use (80%) is as a flame retardant component of aircraft hydraulic fluid and as a solvent for rare earth extraction and purification from its ores. It is also used in lubricants; transmission and motor oils (e.g., brake fluid); industrial adhesives; nuclear fuel processing; as a corrosion inhibitor, plasticizer (e.g., that for barcode printing), and defoamer in textile and paper industries. As an effective solvent, it is also used for inks and in the preparation of concentrates for agricultural herbicides and fungicides. In Canada, it is listed on the PMRA list of formulants, but is currently not used in agricultural products. Limits are placed on its use in Canadian inks, paints, and paperboard. It has been proposed for use in adhesives at levels of 20 mg/kg.

The US has listed it as an indirect food additive and it is prohibited in EU cosmetic products. Its properties also make it suitable for latex paints and lacquers in cold weather applications, floor finishes and some dyes.

### Releases

Submitted information suggests approximately 9000 kg of TBP were released into the environment, mostly water, in 2006. Another 10 000–100 000 kg was transferred to hazardous waste facilities, and 100–1000 kg were transferred to non-hazardous waste facilities in 2006. It will primarily end up in soil (if released to soil or air) or water (if released to water). Empirical and modelled evidence show it to not meet persistence criteria in these mediums or air, but that it is moderately-highly hazardous to aquatic organisms. It also fails to meet bioaccumulation criteria. The conclusion that it is unlikely to harm sensitive aquatic organisms is perhaps weak since the predicted environmental concentration (0.003mg/L) was based on receiving water from only two facilities.

### Human Exposure

Estimates were derived from international data. The maximum intake was 0.40 µg/kg-bw per day for non-formula-fed infants (0–6 months old). Indoor air and food were estimated to contribute the most to the total estimated daily intake. Contributions from the other environmental media were minimal in comparison. While Canadian data was limited, maximum environment concentrations used in the assessments and where they were determined are as follows: ambient air, Japan (33.0 ng/m<sup>3</sup>); indoor air, Japan (178 ng/m<sup>3</sup>); drinking water, Canada (62 ng/L); food, Canada estimate based on US data (0.35 µg/kg-

bw per day for non-formula-fed infants); house dust, Sweden (610 mg/kg). In light of the available data, the use of all of these is considered appropriate. It has also been found in Canadian surface water. Although most TBP uses are industrial, “consumer products that may result in exposure to TBP during their use by the general population in Canada are paints and brake fluid.” Dermal exposure during paint use contributed most to the overall exposure estimates. Exposure to additional consumer products beyond brake fluid was not identified.

## **Health Concerns**

It has been classified as Category 3 carcinogen by the EU. It has caused dose-related carcinogenicity in the urinary bladder of male and female rats (significant increase at 3000 mg/kg). It has also showed carcinogenicity male mice livers (significant increase 3500 mg/kg). This and bladder cell changes were considered the critical effects. Liver tumours were not considered a critical effect since tumors were benign throughout the course of the study, were not seen in all mice, and may be the result of elevated liver weights and cell size. However, “the incidence of hepatocellular adenoma was statistically significantly different for the current control group.” While most bacteria and mammalian cell assays showed TBP to not be mutagenic, one did show a positive result. Two jurisdictions have concluded it was not mutagenic and given the data presented, the conclusion that it is not genotoxic is considered valid.

The non-neoplastic effects induced by TBP included decreased body weight gain; increased liver, kidney or brain weight; salivation; and kidney cell enlargement (critical effect, 15 mg/kg-bw per day) from short-term repeated-dose, subchronic or chronic toxicity studies.

TBP was not considered to be a teratogen, developmental or reproductive toxicant at levels that were not maternally toxic. These levels caused decreased maternal body weight and decreased feed intake. The data also suggests that TBP is not a neural toxicant based evidence showing effects that were seen at extremely high doses or inconsistent. These conclusions are considered appropriate. It is an irritant to the eyes and skin of humans and laboratory animals.

Dermal absorption rates range from 4% to 56%, however it was rapidly metabolized and eliminated from experimental animals. There was no bioaccumulation and the major route of elimination was via the kidney.

Since it was concluded to not be mutagenic, the assessment states that, “protecting humans from the precursor events, such as urinary bladder hyperplasia, is considered to be sufficient to protect humans from TBP’s potential carcinogenic effects.” Thus the margin of exposure for this indication was calculated using the LOAEL for non-neoplastic effects (15 mg/kg-bw per) and maximum exposure (0.4 µg/kg-bw per day) and determined to be protectively adequate. However, contrary to the draft assessment, margins of exposure for inhalation during use of waterborne, waterborne wall and solvent-rich paints, and brake fluid are not considered protective. They were considered to be adequate in the assessment since paint use is only once-twice a year. Thus, the

overall conclusion was that Canadian exposures were protective. Additionally, there is significant concern with the use of critical effect levels from oral studies being used for the calculation of an MOE via inhalation or dermal exposure.

## **Recommendations**

1. Considering the weight of evidence, its carcinogenicity potential, as well as the potential inadequacy of the margin of exposure for health effects, “limited data on critical effects via the inhalation or dermal route of exposure”, as well as population exposures via this route, despite a the weigh-of-evidence for genotoxicity that was considered to be negative even though “the mode of action for the observed carcinogenicity in mouse liver has not been fully elucidated”, the government should employ a precautionary approach and designate TBP as “toxic” under CEPA 1999.
2. At the very least, it should be subject to SNAc provisions with their presence made aware of in products via labelling.
3. Particular attention should be paid to occupational exposures to paint and exposure during TBP use in manufacturing, since the calculated margins of exposure (500-750) are not considered protective.
4. Improve on studies indicating carcinogenicity in experimental animals through the oral route of exposure.
5. Utilize Canadian data to estimate population exposures. Estimates were derived from data from other jurisdictions and “default assumptions” in modelled consumer product scenarios were made. Using the dermal absorption rate from the minipig study also produces result uncertainty.
6. Increase reliance on experimental data used in the environmental assessment. There is concern over it toxicity to aquatic organisms, and in light of it partitioning to water or soil, experimental data pertaining to its toxicity to soil-dwelling organisms is needed.

## MEDIUM PRIORITIES

### Ethanol, 2-[[4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl]methylamino] - (Disperse Orange 5) CAS No. 6232-56-0

Categorization	Assessment
PBiT and believed to be in commerce in Canada.	Proposed that it “does not meet the definition of toxic as set out in section 64 of CEPA 1999.” However, it is “recommended that the above substance be subject to the Significant New Activity provisions specified under subsection 81(3) of the Act, to ensure that any new manufacture, import or use of this substance in quantities greater than 100 kg/year is notified and will undergo ecological and human health risk assessments as specified in section 83 of the Act, prior to the substance being introduced into Canada.”

#### Manufacture & Use

Disperse dyes, including Disperse Orange 5 are non-ionic and exhibit low solubility in water. Thus, they are primarily used for dyeing polyester fabrics. Based on information currently available, Disperse Orange 5 is considered to be inherently toxic to non-human organisms, and also meets the criteria for both persistence and bioaccumulation.<sup>1</sup>

The draft assessment states that Disperse Orange 5 was not imported into or manufactured in Canada above the 100 kg reporting threshold during 2006. It was believed to be in commerce in 2005 due to one stakeholder expressing interest in it. DSL use codes indicate that it is used in colourants (pigment/stain/dye/ink). It has also been known to be used as a textile dye for polyester fiber, yarn, and other fabrics.

#### Environmental Concerns

No significant new data regarding PBiT properties were received and in light of there being any significant commercial activity for the substance, no additional efforts in investigating PBiT properties were made.

#### Recommendations

1. Given its hazardous properties and concern that new activities could lead to Disperse Orange 5 meeting the criteria set out in section 64 of the Act, it is proposed to be subjected to the SNAc provisions specified under subsection 81(3) of the Act.
2. Re-evaluation of this assessment under the SNAc program is necessary.

<sup>1</sup> US Environmental Protection Agency (EPA). September 1996. *Manual: Best Management Practices for Pollution Prevention in the Textile Industry (EPA/625/R-96/004)*.

## ◆ Acetamide, N,N-dimethyl- (DMAc) CAS No. 127-19-5

Categorization	Assessment
Considered to pose intermediate potential for exposure to individuals in Canada and had been classified by the European Commission on the basis of developmental toxicity.	Proposed that “[DMAc] does meet the criterion in paragraph 64(c) of CEPA 1999.”

### Manufacture & Use

DMAc does not occur naturally. It was not manufactured in Canada in 2006, but imported at a total quantity between 1000 and 10 000 kg.

It is reportedly used strictly for industrial purposes, with principal use in the man-made fibre production industry, including polyvinyl fluoride (PVF) and polyesters. It may end up as a residue in some of the end products containing these polymers (e.g., containers used to transport water, wine and juice; disposable medical clothing, spandex, acrylic carpet, wigs, sleeping bags, sweaters, knit shirts and unprocessed and processed fabrics). The assessment states it is not anticipated to be present in cosmetic products in Canada although it may be used as a solvent in the pharmaceutical and cosmetic industry. It may also be used to in make agrichemicals, finishes, fragrances, latex, dyes and pesticides, and as a solvent in the production of photography industry compounds. It is a feedstock in the coating and lacquer industry, solvent for various chemical processes, including those for crude streams and extraction, sealant in aircraft windshields and fuel tanks. It is present in three Canadian chemotherapeutic drugs and has been recognized as an impurity in a drug for sheep. It must be accompanied with Material Safety Data Sheets when it is present at a minimum concentration of 1% by weight.

### Releases

In 2006, less than 100 kg of DMAc was released to air, water or land. Some transfers to hazardous waste facilities also occurred. Information beyond this was considered confidential. Emissions from hazardous waste facilities may occur since there was detection in surrounding liquid waste impoundment. The Canadian PEC was calculated using a quantity of 10 000 kg, assuming the chemical was used in one facility, and assuming an effluent discharge of 5% (default value); the resulting PEC is  $3.35 \times 10^{-2}$  mg/L. A Risk Quotient was also calculated using the modeled EC50 data for *Daphnia magna* and applying an assessment factor of 100 to account for uncertainty, resulting in a Risk Quotient of 0.02; which is less than the “limit” of 1. The model used is considered to be somewhat conservative; however, it relies heavily on the assumption of the effluent default value.

DMAc will primarily reside in water and soil. There is a lack of empirical and modeled soil exposure data available in the assessment documents. The assessment indicates that if the chemical is released to soil, one third of the chemical is predicted to remain in the soil with the remainder partitioning to the aquatic environment. However, empirical and modelled data indicate that it will not persist in these soil or air, and it is not highly

hazardous to aquatic organisms. Modelled bioaccumulation models using experimental and modelled log Kow values also indicate it does not meet bioaccumulation criteria.

## Human Exposure

There is no Canadian exposure information. Estimated maximum daily intake was 17.94 µg/kg body weight (kg-bw) per day (children 0.5 - 4 years) and for all age groups, exposure was predominantly through air. Of the available data, the input values used are considered appropriate. The following levels from other jurisdictions were used: indoor air (34 µg/m<sup>3</sup>); outdoor air (930 ng/m<sup>3</sup>); surface water (0.093 µg/L, Japan); drinking water (undetectable, 1 µg/L used as a conservative estimate). Modelled estimates for Canadian air, water, soil and sediment were 658 ng/m<sup>3</sup>, 180 ng/L,  $8.5 \times 10^{-4}$  ng/g, and  $8.3 \times 10^{-4}$  ng/g respectively.

Consumer product exposures were not considered in the exposure assessment above. This is despite the possibility of its presence as residual solvent in some textile articles. Experiments measuring uptake have showed ranges between 0.30 (10 hours, socks) - 2.1 µg DMAc/kg-bw (3 hours, bathing suit). It has also been found to be emitted from fibreboard at a maximum of 0.068 76 mg/m<sup>2</sup> per hour and resulting in a maximum indoor air concentration of 9.8 µg/m<sup>3</sup> occurring 4.9 h after installation. Extraction tests performed on food packaging material revealed no detectable DMAc so the detection limit of 0.09 µg/L was used to estimate a probable daily oral intake of 0.000 23 µg/kg-bw per day (adult). Emissions from carpet, latex balloons, and toothbrush stems are considered negligible. It is recommended that exposures from consumer products be calculated, although the effect of these on overall exposure via direct contact or contribution to indoor air is anticipated to be negligible.

## Health Concerns

It has been classified as Category 2 for developmental toxicity (May cause harm to unborn child) by the EU. This is based primarily upon rodent studies, which showed fetal malformations. The LOAEL for developmental effects (e.g., cleft palate, fused ribs, microphthalmia (small eyes) and reduced body weight) was via oral exposure at 282 mg/kg-bw per day. Additional lowest levels with developmental effects were 700 mg/m<sup>3</sup> for inhalation and 500 mg/kg-bw per day for dermal exposure. While developmental toxicity is considered a critical effect, in one study, maternal toxicity was seen at concentrations less than those for developmental effects.

Liver toxicity is identified as a critical effect based on observations in short-term and chronic exposure studies in experimental animals and supported by information from human occupational exposure studies. The LOAEC used to assess exposure was 356 mg/m<sup>3</sup> (increased serum cholesterol and glucose levels), although it is argued that the actual LOAEC is 107 mg/m<sup>3</sup> (elevated serum proteins). Data from the epidemiological studies indicate that DMAc-induced hepatic injury is dose dependent.

Data indicates it is not reproductively toxic via inhalation, carcinogenic, or genotoxic in a variety of assays. It is considered a mild skin and eye irritant by the OECD.

MOEs were derived from the lowest exposure levels associated with the critical effects. Since the principal source of exposure was considered indoor air, the aforementioned LOAELs and air concentration level of 0.034 mg/m<sup>3</sup> were used. This resulted in a margin of exposure considered adequately protective. However, this was not Canadian concentration data dependent on the volume of DMAc in commerce and released. It also did not account for exposures from outdoor air; although the level was taken 300 feet from an evaporation lagoon, the exposures of vulnerable populations must be considered.

Margins of exposure for drinking water and consumer products were also considered adequately protective. Exposure from drinking water is considered negligible, however, there is concern that individuals wearing consumer products containing DMAc daily in physically strenuous situations could be exposed to levels of concern.

### **Recommendations**

1. Given its reproductive toxicity potential, reliance on environmental monitoring from other jurisdictions, and concern that new activities could lead to DMAc meeting the criteria set out in section 64 of the Act, it should at the very least, be subjected to the SNAc provisions specified under subsection 81(3) of the Act.
2. Reevaluate its PBiT, human toxicity, environmental concentrations, and exposures under SNAc. There is concern that environmental concentration levels used in the assessment were either from other jurisdictions or modeled.
3. Monitor DMAc concentrations in food under the Canadian Food Inspection Agency.

## 2-Chloroacetamide CAS No. 79-07-2

Categorization	Assessment
Considered to present intermediate potential for exposure and had been classified by the European Commission as a reproductive toxicant.	Proposed that “2-chloroacetamide does not meet the definition of “toxic” set out in section 64 of CEPA 1999” and that it “be subject to the Significant New Activity provisions specified in CEPA 1999.” While this was not indicated on the CMP website, it was in the assessment and Canada Gazette. <sup>2</sup>

### Manufacture & Use

The assessment shows that there was only one non-pesticidal use above the reporting threshold of 100 kg in 2008. No information was reported on what it was used for, but it was stated that “further available data indicates that this use is specialized and that the product it is used in may no longer be imported into Canada by the submitter of the information.”

It is registered as a pesticide for use in paint, adhesive, dyestuff, detergent, textile and related industries and subject to re-evaluation by the Pest Management Regulatory Agency (PMRA), as required by the *Pest Control Products Act* (PCPA). Searching the PMRA revealed that it is registered under # 14373 and the trade mark Parmetol. It is used for preventing microbial contamination and originally registered in 1977. The expiry date of its registration is December 31, 2009.<sup>3</sup> The assessment states that there is currently only one registered product containing it and this use being discontinued by the registrant, so it is inferred that it will not be re-registered after 2009.

According to information on the chemical profile after categorization, DSL use codes indicate that it is also used as a reagent, in strippers, surfactants, health and veterinary, pharmaceuticals, printing, and publishing. Literature also indicates use for adhesives, glue and gelatine, hides, paintings, detergents and soaps, emulsions, and non-food paper coating. US FDA cites it as an indirect food additive through coated paper and paperboard contact with certain foods. It used to be used as a preservative and antiseptic in cosmetics.

### Releases

No information was found on current non-pesticidal uses or releases of this substance in Canada. The assessment states that no efforts were made to collect PBiT or human toxicity data since “no uses or releases of the above substance other than that covered by the PCPA have been identified in Canada.”

<sup>2</sup> Government of Canada. Canada Gazette. Vol.143, No.8. Feb 21, 2009. Retrieved from <http://www.gazette.gc.ca/rp-pr/p1/2009/2009-02-21/html/sup1-eng.html#m119> on March 10, 2009.

<sup>3</sup> Pest Management Regulatory Agency. PARMETOL\* K-50. Jan 25, 2008. Retrieved from [http://pr.pmra-arla.gc.ca/PR\\_SOL/pr\\_web.ve1?p\\_ukid=964](http://pr.pmra-arla.gc.ca/PR_SOL/pr_web.ve1?p_ukid=964) on March 10, 2009.

## **Human Exposure**

It is considered inherently toxic to humans on the basis of reproductive toxicity and inherently toxic to aquatic organisms, but it is not considered to meet the criteria for persistence or bioaccumulation.

## **Recommendations**

1. Given its inherently hazardous properties and concern that new activities could lead to 2-Chloroacetamide meeting the criteria set out in section 64 of the Act, it should at the very least, be subjected to the SNAc provisions specified under subsection 81(3) of the Act.
2. Reevaluate its PBiT, human toxicity, environmental concentrations, and exposures by PMRA under the PCPA.
3. Ensure all information used in the assessment is provided on the government website. There is significant concern over only a “Summary of Information Used as Basis for Screening Assessment”, particularly in light of it being considered inherently toxic to humans.

## LOW PRIORITIES

**Disperse Orange 30 CAS No. 5261-31-4; Disperse Blue 79 CAS No. 12239-34-8; ANAM CAS No. 16421-40-2; AADM CAS No. 16421-41-3; Disperse Brown 1:1 CAS No. 17464-91-4; Disperse Brown 1 CAS No. 23355-64-8; Disperse Red 167 CAS No. 26850-12-4; BANAP CAS No. 29765-00-2; BDAP CAS No. 52697-38-8; Disperse Orange 61 CAS No. 55281-26-0; EDD CAS No. 55619-18-6; DNAN CAS No. 72927-94-7**

Categorization	Assessment
PBiT and believed to be in commerce in Canada.	Proposed that each “does not meet any of the criteria set out in section 64 of CEPA 1999”. Met persistent criteria only.

These substances were categorized separately, but assessed together due to their similar structures, use, analog data, and fate. However, note that import and use volumes vary.

### Manufacture & Use

The draft assessment states that none of these substances are naturally produced in the environment. In 2006, a total of 1,000 - 10,000 kg of Disperse Orange 30, Disperse Blue 79, and Disperse Orange 61 was imported into and used in Canada. A total of 10,000-100,000 kg of BDAP was imported and used during the same time period. One company reported importing a total of between 100 and 1000 kg of ANAM, one company reported importing approximately 1000 kg of Disperse Red 167, and one company reported importing 875 kg of BANAP into Canada in 2006. No information on manufacturing, importation or use of AADM, Disperse Brown 1:1, Disperse Brown 1, EDD, or DNAN above the reporting thresholds was reported for 2006

Disperse Blue 79, Disperse Brown 1, and BDAP are European Union (EU) low production volume (LPV) chemical substance indicating production between 10 and 1000 tonnes/year. In 2002, 10,000 – 500,000 pounds of each of these and Disperse Orange 61 were produced in the US.

While more detailed information can be found in the chart above, generally stated, these dyes are used in the textile industry. Some may be used in the production of chemicals for this purpose and others are used more directly. The fabrics which they may be used for include polyester and polyester blend, automotive, clothing, and home use. Business activities indicate that Disperse Blue 79 may also be used for cotton, spandex, wool, fleece, interlocks, nylon, other fabrics, and printing, acetate. Disperse Brown 1 is prohibited by companies wishing to comply with the Oeko-Tex Standard 100, a safety standard indicating textile products are harmless for health. It has also been used for the tinting of eyeglass lenses and used to be used in hair dye in Europe.

### Releases

Modelled data indicates that for all, 85.2% will be found in waste management sites and 14.8% in sewer water due to product formulation and eventual disposal. This is the Mass Flow Tool value for known in-commerce azo dyes and extrapolated for those without known commercial volume information. Sewer water would receive the greatest proportion during processing. That released to water is ultimately expected to be transferred to sediment. Removal rate in a sewage treatment plant of Disperse Orange 30 is expected to be 68.5%.

### **Environmental Concerns**

With moderate-high Kows (via a range of analogs), all may have affinity for solids and resist biodegradation. They may also be applied to agricultural lands as a component of sludge. Volatilization is unlikely and their low water solubility means that they will mostly be present as a solid and remain in a relatively biologically unavailable form when released to water. Modelling indicates that they meet persistence criteria for water, soil, and sediment as per the regulations.

However, they were not found to meet the bioaccumulation criteria. This conclusion was reached on the basis of data arising from other azo dyes and experimental data for Disperse Orange 30 (used as an analog for Disperse Blue 79, ANAM, AADM, Disperse Brown 1:1, Disperse Brown 1, Disperse Red 167, BANAP, BDAP, Disperse Orange 61, EDD, DNAN) that showed it to have limited solubility in lipids and low potential to partition into fish tissue from aqueous systems. This experiment was conducted according to OECD standards by Shen & Hu in 2008. However, it is important to note that the Shen & Hu study is limited by true values of the concentration in the water being unknown and exhibiting some uncertainty.<sup>4</sup> Also, their high experimental (some) and analog (all)-derived Kow values (just above 4 for all), its molecular weight and structure suggest that may bioaccumulate. Modelling was not used since modeled results of higher molecular weight pigments and azo dyes are not considered reliable. However, in light of all the data, the bioaccumulation conclusion arrived at is considered reasonable. Experimental data (for Disperse Orange 30, Disperse Blue 79), ecotoxicity data for a structurally similar substance (molecular weight 471.46) through the New Substance Notification Regulations, and empirical data from a variety of analogs showed them to not be highly hazardous to aquatic organisms. Toxicity potential is also likely to be low in sediment dwelling species considering the lack of bioaccumulation potential and bioavailability as well as their physical-chemical properties.

### **Ecological Risk**

Using conservative exposure scenarios, the predicted effect concentration (PEC) for water ranged from 0.0018 mg/L (AADM, Disperse Brown 1:1, Disperse Brown 1,

---

<sup>4</sup> Shen, Genxiang and Hu, Shuangqing. 2008. Bioconcentration Test of C.I. Disperse Orange 30 in Fish. Prepared by Environmental Testing Laboratory, Shanghai Academy of Environmental Sciences, Shanghai, China for Dystar in the name of Ecological and Toxicological Association of the Dyes and Organic Pigments Manufacturers (ETAD) Basel, Switzerland. Report No. S-070-2007. Submitted to Environment Canada in April 2008. Challenge Submission ID#8351

Disperse Red 167, EDD, DNAN) to 0.0394 (Disperse Orange 61). The substance with the greatest commerce volume (BDAP with and import volume 10,000-100,000 kg) only had a PEC of 0.014 mg/L; this was less than those with much smaller volumes despite similar mass flow scenarios (e.g. ANAM and BANAP). The information presented indicates that the data used makes this a less conservative PEC estimate.

The only real-world concentration data was for Disperse Blue 79 in water, suspended solids, and sediment; the highest concentration was in the latter and between 0.1- 4.2 mg/kg (dw). All risk quotients (RQs) were less than 1, indicating that concentrations in surface waters are unlikely to cause adverse effects on populations of aquatic organisms. However, Disperse Orange 61 had a RQ of 0.88. Again, BDAP had a RQ (0.35) smaller than substances with less volume in commerce (and thus release), but with similar mass flow scenarios and ecological effect based on shared analog data (e.g. ANAM and AADM).

However, while risk quotient calculations do not carry regulatory weight, there is concern with the values derived. This concern results from the use of effects data derived from aquatic exposure (used in PEC and PNEC calculations), even though this medium may not be the primary long-term concern based on the expected environmental partitioning of the chemical(s). Therefore, PEC, PNEC, and derived Risk Quotients should be used with caution, as they may not be representative of the medium in which the chemicals are likely to reside. On the basis of incomplete ecological information and assessment, in addition to varying commerce volumes, these calculated risk values are likely underestimated and should be interpreted cautiously.

## **Recommendations**

1. Considering it may potentially be discharged to soil from the disposal of products that degrade and from biosludge, toxicity data for soil organisms should be obtained. This is of particular importance since it has been shown that dyes strongly adsorb to wastewater treatment plant sludge and particulates. Toxicity data for sediment dwelling organisms should be investigated; this is a medium that showed Disperse Blue 79 to have a concentration between 0.1-4.2 mg/L.
2. The lack of exposure, experimental (empirical) or predicted-effects data for non-aquatic organisms in sediment and soil is of concern, due to the chemicals ability to partition into soil and sediment.
3. Reduce reliance on Disperse Orange 30 data and increase reliance on experimental (empirical) data for bioaccumulation potential. The reliance on Disperse Orange 30 data, data from a substance considered to have a similar structure to all, and analogs has resulted in a repetitive conclusion that requires further verification. A number of chemicals studied via their analogs, did not have a “similar structure percentage” reported, even though these analogs were used to derived PNEC and Risk Quotients.
4. The lack of information on environmental concentrations in Canada is concerning in light of its likely fate and should be addressed. The only monitoring data available was for Disperse Blue 79, and focused on aquatic organisms. This data should be used to inform actual ecological risk posed both by product processing and consumer good disposal.