

**Chemical Management Plan
Batch 9 Challenge Substances
Submission on
Draft Screening Assessments and
Scope Documents**



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May 17, 2010

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Re: Submission on findings of Draft Screening Assessments and where applicable, Risk Management Scope Documents, for select Batch 9 substances:

1. Vanadium oxide CAS No. 1314-62-1; and
2. Antimony Oxide (Sb₂O₃) CAS No. 1309-64-4)

(*Canada Gazette* Part I, Part I, Vol. 144 No. 12, March 20, 2010)

A. Introductory Remarks

The Inuit Tapiriit Kanatami (ITK) is an active participant in various aspects of the Chemical Management Program (CMP), including the Stakeholder Advisory Council, the CMP Civil Society Capacity Building Project, and the Challenge Program, for which ITK has since 2009 made regular submissions on a select number of substances to date.

As in its previous submissions, ITK is reiterating the need to incorporate precautionary and preventative measures and give consideration for vulnerable populations in the screening assessments and risk management strategies. It has also stated its view that any substance that is a known, suspected or potential carcinogen be designated toxic under the *Canadian Environmental Protection Act* (CEPA 1999), and that risk management strategies adopt appropriate measures to restrict and/or ban the use and importation of this substance or products containing it. Likewise, this same view holds for substances that are known or suspected genotoxins, mutagens, or reproductive and/or developmental toxins.

The comments submitted by ITK cover a wide range of issues regarding these chemicals. As well, because of concerns about the harm these substances might cause to Inuit, ITK is applying an “Inuit lens” that examines the chemical’s potential for long-range transport; its inclusion in commonly-used products and food; its use in industrial processes, in particular, resource extraction activities; and the disposal of material containing these chemicals.

B. Batch 9 – Overview

The draft screening assessments for Batch 9 substances have proposed that five out of the seventeen substances meet the criteria for toxicity under CEPA 1999, three for human health concerns and the other two for ecological concerns.

With respect to the other twelve Batch 9 substances not proposed toxic, the assessors have recommended that five of these substances that are persistent, bioaccumulative and inherently toxic (PB iT) be subject to Significant New Activity (SNAc) provisions under Section 81(3) of CEPA 1999, in that they may not be presently in commerce in Canada, they could potentially pose harm if they re-enter commerce in Canada.

ITK has previously voiced concern over the application of SNAc provisions. Even though these substances may no longer be in commerce in Canada, products and processes using these substances may still be found and potentially used and disposed of in some manner, such as

incineration or other waste streams, and in turn, be re-released to the environment. This could likely be the situation in a number of communities, including remote northern communities, which is naturally of concern to ITK.

ITK would prefer prohibiting the use and import and hence re-introduction of any PBiT substance under existing regulations over applying SNAc provisions.

ITK has also expressed concern over the relatively small proportion of “high priority” substances in the Challenge program that have been designated toxic under CEPA 1999.

For this particular batch, ITK has chosen to comment on two high-volume substances, namely vanadium oxide, which is a high concern for its human health hazards and has been proposed CEPA-toxic, and antimony oxide, which is similarly of high concern but has not been proposed CEPA-toxic.

1. Vanadium oxide (also vanadium pentoxide) CAS No. 1314-62-1

Part A – Draft Screening Assessment

a. Synopsis

Under categorization, vanadium oxide was identified as a substance posing a great potential for exposure of individuals in Canada and had been classified by other agencies on the basis of its carcinogenicity, genotoxicity and developmental toxicity. It was identified as a high priority for action under the Challenge program.

On the basis of the carcinogenicity of vanadium oxide, for which there may be a probability of harm at any level of exposure, the assessors have proposed that vanadium oxide is entering or may be 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 and thus, would meet the criteria for toxicity under section 64(c) of CEPA 1999.

However, as it was not considered to have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends, it was not considered to meet other criteria for toxicity under Sections 64(a) and (b), CEPA 1999.

Further, vanadium oxide meets the criteria for persistence, but not for bioaccumulation potential as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).

b. Uses

According to information submitted under Section 71 of CEPA 1999, between 1 000 000 - 10 000 000 kg was manufactured in Canada in 2006 (75% produced by the energy sector, 15% by the pulp and paper industry, and 10% from the making of ferrovanadium alloys and others). For that same year, Canadian companies imported quantities between 100 000 - 1 000 000 kg and use amounts of approximately 1 000 000 - 10 000 000 kg.

Only sources of vanadium related to vanadium oxide were considered in the draft screening assessment. This substance is widely used in Canada and globally to make ferrovanadium alloys

for the manufacture of hardened steel, as a catalyst in the production of sulphuric acid, for catalytic cracking applications at power plants and as a corrosion protector.

38 300 kg of vanadium oxide was used for chemical fertilizer manufacturing and 24 900 kg was used for the production of aluminum. (Some vanadium in the form of vanadium oxide is naturally present in alumina).

Uses of vanadium oxide in consumer products were not identified. Vanadium oxide is listed in the Drug Product Database as being present as a medicinal ingredient in final pharmaceutical products and is permitted in natural health products. Two pharmaceutical products are known to contain it as a medicinal ingredient at 5 µg vanadium oxide per tablet. ¹

c. Releases

Based on Section 71-submitted information for 2006 where all vanadium was taken to be in the form of vanadium oxide, 100 - 1 000 tonnes of vanadium oxide was released to air, approximately 8 tonnes to water and 103 tonnes to land. Another 1 000 - 10 000 tonnes were reported as transferred to an off-site waste management facility with 99% being treated as non-hazardous waste.

Vanadium oxide itself is not subject to reporting to the National Pollutant Release Inventory (NPRI). However, vanadium and its compounds (CAS No. 7440-62-2) is a reportable substance. The following table shows releases and transfers reported to the NPRI for vanadium compounds for the years 2006-8. ²

NPRI data – Vanadium Compounds (CAS No. 7440-62-2) (in tonnes)

Year	On-Site releases			Disposal		Off-site recycling
	Air	Water	Land	On-Site	Off-Site	
2006	156	1.1	0.176	1,376	214	1,654
2007	147	1.0	0.149	1,435	210	1,496
2008	130	0.845	0.001	785	224	1,930

The NPRI data far better reflect releases for vanadium compounds rather than the wide range of reported releases under Section 71 for vanadium oxide. However, it cannot be assumed that the substances are the same, although the relationship is noted, in terms of the amounts released to air, disposal and off-site recycling.

Most of the vanadium oxide released into the air is associated with fine Particulate Matter (PM_{2.5}), typically resulting from fossil fuel combustion.

As the above table indicates, the pattern of releases and disposal and recycling amounts is consistent for the three-year period. The majority of releases reported both via Section 71 and

¹Draft Screening Assessment: Vanadium oxide CAS. No. 1314-62-1, March 2010 p. 6,7
http://www.ec.gc.ca/substances/ese/eng/challenge/batch9/batch9_1314-62-1_en.pdf

² NPRI site: <http://www.ec.gc.ca/inrp-npri/default.asp?lang=En&n=4A577BB9-1>

It should be noted that the NPRI does not require that these values are measured or that there is monitoring unless the companies already are required to do so.

NPRI were from oil refineries and electrical power generation plants. Details on releases from metallurgy and steelmaking; smelters; cement production; pulp, paper, and saw mills; use as a catalyst; fertilizers, sewage sludge application, and manufactured items were also provided.³

Monitoring data from 10 Canadian sites suggests 253 kg of vanadium may leach from landfills each year.

While the presence of vanadium oxide in the environment is a result primarily of human activity, it is also found as a naturally occurring substance in titaniferous magnetite deposits worldwide and is recovered from spent catalysts, petroleum residues and vanadium-bearing slag. However, natural sources are considered insignificant compared to anthropogenic sources.⁴

d. Persistence and Bioaccumulation

Once released into the environment, vanadium oxide will partition to water (including that via leaching), soil, sediment, and air. As with other metals and metalloids, soils and sediments may be a “sink”. It was concluded to be persistent in air, water, soil, and sediment but have a low bioaccumulation potential, and hence, found to not meet the criteria for bioaccumulation.

This finding on bioaccumulation is debatable. While vanadium oxide may be characterized as having “low” potential, it still has the ability to bioaccumulate, just not to the levels in the Persistence and Bioaccumulation Regulations. This issue has arisen in previous batches.

Substantial empirical data suggests that vanadium causes harm to various aquatic organisms following acute and chronic exposure at relatively low concentrations, but that it has low toxicity to terrestrial organisms.

e. Long-Range Transport Potential

While Long-Range Transport Potential (LRTP) was neither quantified in the original substance profile on the Challenge website nor in the draft assessment, the draft assessment report stated that “depending on the size of the PM with which vanadium oxide is associated, the PM will travel for a certain distance in air before being deposited to aquatic or terrestrial environments”.⁵

f. Human Exposure

The environment is the primary source of vanadium oxide exposure for the general Canadian population. Air monitoring conducted by environment Canada for vanadium in PM_{2.5} between the years 2004-2008 from nine locations showed maximum vanadium concentrations to be 59.5 ng/m³ (Montreal) in ambient air.⁶

Canadian drinking water data is limited, but a typical concentration in Saskatchewan from 2001-2007 was found to be 1 µg/L. While the proportion of vanadium oxide in environmental media, house dust and foods is unknown, the assessors assume it to be low, despite low confidence in

³ Details of its extensive uses and releases are found in the Draft Screening Report pp. 7-14.

⁴ Draft Screening Assessment: Vanadium oxide CAS. No. 1314-62-1, March 2010 p. 5
http://www.ec.gc.ca/substances/ese/eng/challenge/batch9/batch9_1314-62-1_en.pdf

⁵ Draft Screening report p. 15

⁶ Risk Management Scope Document for Vanadium oxide, March 2010 p.5
http://www.ec.gc.ca/substances/ese/eng/challenge/batch9/batch9_1314-62-1_rm_en.pdf

exposure estimates. This assumption was also made regarding the bioavailability of vanadium oxide from environmental media and food.

Exposures via consumer products were not calculated, since Section 71 data did not identify its presence in any used by the general population. Thus, medicinal exposures were not calculated. No consideration was given to vulnerable population exposures beyond infants and children.

g. Human Health Concerns

Vanadium oxide has been classified as a Group 2B carcinogen by IARC (possible human carcinogen), an EC (European Commission) Category 3 mutagen (suspected mutagen) and Category 3 developmental toxin (possible risk to the unborn child, the latter based on numerous studies showing effects on the developing fetus via various exposure routes. The EC has proposed classifying it as a Category 2 carcinogen (regarded as if toxic to humans) and re-classifying it as a Category 2 mutagen (regarded as if mutagenic to man).

Its critical effect is carcinogenicity as increased incidences of liver tumours were observed in experimental animals from various studies. It has induced benign and malignant liver tumours in rats in a 16 week oral study; metastases were also observed in the lungs of some of the animals. It has also caused multiple hepatocellular carcinomas in rats via inhalation over 6 months and initiated action in rats' livers via intraperitoneal injection or inhalation in the presence of a promoter.

Non-cancer effects include respiratory tract effects (e.g., inflammation, fibrosis and hyperplasia) following repeat-dose inhalation, reduced phagocytosis, as well as spleen, kidney, and lung cell changes following oral exposure.⁷

Part B - Risk Management Scope – Vanadium Oxide

a. Proposed Scope for Risk Management (RM)

The government proposes to recommend its addition to the List of Toxic Substances, Schedule 1. The risk management scope document further suggests that risk management will be focused on⁸:

1. Investigating measures being developed under existing programs to reduce emissions, from combustion of certain fossil fuels that may also reduce vanadium oxide,
2. Requiring federal government notification of any potential changes in the use,
3. Not authorizing its use in Natural Health Products, and
4. Adding it to the Environmental Emergency Regulations.

Given its carcinogenicity and genotoxicity and developmental effects and classifications by various agencies, ITK supports designating vanadium oxide as “toxic” under CEPA, 1999.

At the same time, ITK finds this risk management scope very limited. Given that it is a non-threshold carcinogen, a requirement for changes in use-pattern is not adequate as a risk management tool. Its use in the pesticide industry and pharmaceuticals is not even addressed.

⁷ Phagocytosis: the, process by which certain living cells called phagocytes ingest or engulf other cells or particles.

⁸ Risk Management Scope Document for Vanadium oxide, March 2010

http://www.ec.gc.ca/substances/ese/eng/challenge/batch9/batch9_1314-62-1_rm_en.pdf

Furthermore, relying on co-benefits resulting reductions in PM emissions according to existing programs for the electricity sector is unlikely to be an effective strategy on its own, as many of the requirements or programs are acknowledged as not fully protective of human health.⁹

b. Comments and Recommendations on Risk Management (RM) Scope

1. The RM needs to be expanded to address human exposures more appropriately.
2. Better emissions standards should be mandated and its use in the pesticide industry and pharmaceuticals should be addressed.
3. Given that the primary source of exposure for the general population is via soil and that the highest consumer product exposure estimates are for infants and young children. Measures should be adopted to prevent and minimize vanadium exposure to infants and young children.
4. Several data gaps in the draft assessment require attention, For example,
 - a. Lack of information on accidental releases from industrial processes (e.g., that involving fossil fuel production);
 - b. Unknown concentrations in Canadian environmental media. While most of the vanadium released by industrial processes is considered to be vanadium oxide, this was not the case for “uranium mining and milling because the uncertainty regarding the relative importance of the forms of vanadium released by this industrial activity was deemed too high.”¹⁰ This situation needs further examination.
 - c. Limits for the population’s exposure via the environmental media and food need to be determined. Particular attention needs to be paid to cumulative exposures.
 - d. The epidemiological studies (humans) are limited.
 - e. Long-term toxicity studies should be conducted in species besides from rats alone.
 - f. The dermal data set needs strengthening.
 - g. The potentially synergistic effects of chemical mixtures need to be examined given that exposures to several chemicals occur simultaneously. For example, the effects of simultaneous exposures to vanadium and brominated chemicals used in flame retardants may be a relevant mixture to examine.
 - h. The relationship between vanadium and its compounds and vanadium oxide is not clear. As a result, it is difficult to compare releases reported to the NPRI for vanadium and its compounds with those reported through Section 71 for vanadium oxide.

c. Concluding Comments – Critical Issues

- Public reporting of releases is essential. The NPRI may require revision to reflect releases of vanadium oxide specifically. The range of releases through Section 71, without identifying the sources, gives a completely inadequate picture of environmental releases of vanadium oxide to the environment.
- Nothing can be found in the draft screening assessment report related to the long-range potential as to potential distance, or implications on northern remote areas. ITK finds this a serious omission. ITK chose to comment on this substance primarily because of its

⁹ Risk Management Scope p.6

¹⁰ Draft Screening report for Vanadium Oxide, p. 50

potential impact on Inuit people because of its natural persistence as a metal and long-range potential and deposition pattern. This matter needs to be addressed in the final assessment.

- Bioaccumulation: The potential to bioaccumulate, even if not meeting the regulatory criteria, is a concern to ITK. Caution is needed in such a determination. Otherwise, the effects of bioaccumulation are not addressed.
- In addition, disposal and recycling levels of vanadium oxide are significant, yet this is not addressed. Once again, there is no consideration for vulnerable populations (pregnant women, children, aboriginal populations, occupational groups) that may be adversely affected through use and/or inadvertent exposure to vanadium oxide. This is particularly a concern as it is a developmental toxin, with possible teratogenic effects.

2. Antimony Oxide (Sb₂O₃) CAS No. 1309-64-4

a. Synopsis

Antimony oxide was identified in the categorization of the Domestic Substances List as a high priority for action under the Challenge because it was considered to pose a great potential for exposure of individuals in Canada and had been classified by other national and international agencies on the basis of carcinogenicity

Although antimony oxide meets the ecological categorization criteria for persistence, it did not meet the criteria for bioaccumulation potential or inherent toxicity to aquatic organisms. Furthermore, the assessment indicated that antimony oxide is expected to have a low potential for toxicity to aquatic organisms and is 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. Thus the assessment report proposed that antimony oxide does not meet any of the criteria set out in section 64 of CEPA 1999, based on the information available. Consequently, no risk management has been proposed.

The draft assessment indicates antimony oxide is to be included in the *Domestic Substances List* inventory update initiative, and where relevant, research and monitoring is to be carried out to support verification of assumptions used during the screening assessment.¹¹

ITK is very concerned about the non-toxic proposal for antimony oxide, particularly in light of the acknowledged lack of information and degree of uncertainty mentioned throughout the report, the diversity of its uses which could lead to exposure of many vulnerable populations, including Inuit, its potential for long-range transport, and its potential carcinogenicity and developmental and reproductive toxicity.

b. Uses

Antimony oxide is both naturally occurring and human-made. Based on information obtained through a section 71 notice under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), in 2006, 1 000 000 - 10 000 000 kg was manufactured in Canada and over 1 850 000 kg was imported, while 3 270 000 kg was the quantity used.

¹¹ Draft Screening Assessment Report Antimony Oxide p.(ii)
http://www.ec.gc.ca/substances/ese/eng/challenge/batch9/batch9_1309-64-4_en.pdf

Antimony oxide may enter the country in imported products. Submitted data suggests its use in adhesives, sealants, insulators, colourants, flame retardants, fire extinguishing agents, formulation components, and polymer additives.

In Canada, antimony oxide is used primarily as a plastic catalyst in manufacturing polyethylene terephthalate (e.g., PET plastic used in water bottles, food packaging) and as a synergist with halogenated compounds to provide flame retardancy properties (e.g., PVC). Flame retardants are used in a variety of household items including furniture upholstery, carpets, mattress covers and other textiles

Antimony oxide-associated products include electrical equipment, wires, automotive parts, building materials, furniture, carpets, mattress covers, textiles, paper and plastic. It may also be an impurity in cosmetics and in titanium dioxide which is used in food colour.

c. Releases

Based on Section 71-submitted information, for the year 2006, 1000 - 10 000 kg of antimony oxide was released into the environment in 2006, mostly to land, and 100 000 - 1 000 000 kg and approximately 14 500 kg was transferred to hazardous and non-hazardous waste facilities, respectively. Releases from these waste facilities were not reported.

The National Pollutant Release Inventory (NPRI) collects data only on the mixed release of antimony and its compounds (CAS No. NA-01).¹² The portion of the total antimony that is from antimony oxide is unknown, although according to an Environment Canada indicates that antimony oxide “likely represents most of the total quantity of antimony currently in use in Canada (94% according to the 1984-1986 DSL survey)”. Metal mining and smelting are the main industrial sources of antimony releases in Canada.

NPRI data - Antimony and its Compounds (CAS No. NA-01) in kilograms

Year	On-Site releases			Disposal		Off-site recycling
	Air	Water	Land	On-Site	Off-Site	
2006	888	29,000	1200	30 000	45,000	156,000
2007	1000	10,000	1400	74,000	45,000	141,000
2008	1100	75,000	153	70,000	48,000	159,000

The quantities sent for disposal and recycling are notably large, particularly compared to emissions to air and land. Releases to water are also considerable. As noted for vanadium (oxide), the pattern of releases and disposal and recycling amounts for antimony and its compounds is consistent for the three-year period.

d. Persistence and Bioaccumulation

Once released into the environment, antimony oxide will partition into water (including that via leaching), soil, sediment, and air. As with other metals and metalloids, soils and sediments may be a “sink”. A significant proportion of the fine particulate antimony oxide in the atmosphere

¹² Ibid p.10, also NPRI database for 2006-8

may be water soluble. It was concluded to be persistent “because the trivalent antimony ions that are released into solution when it dissolves cannot be irreversibly degraded”. However, it did not meet the bioaccumulation criteria.¹³

Antimony may be biomethylated to form volatile species such as trimethylstibine in the environment. Methylated species of antimony are less toxic than the inorganic salts. It is therefore possible that they are less bioavailable, but the assessment notes that this remains unconfirmed.¹⁴

Empirical data suggests that it has a “moderate potential to cause harm to aquatic, soil and sediment organisms”. However, according to Risk Quotients (RQ) determined for 1,700 samples, the assessment concluded that antimony oxide does not have the potential to cause ecological harm in Canada.

e. Long-Range Transport Potential (LRTP)

While Long-Range Transport Potential (LRTP) was neither quantified in the original substance profile on the Challenge website nor in the draft assessment, the assessors indicate that according to a report by the European Union, anthropogenic activities may result in long-range transport of a portion of the antimony oxide emitted to air.¹⁵

f. Human Exposures

The primary source of exposure to antimony oxide for the “general Canadian population” is via flame retardants used in furniture upholstery and mattress covers (antimony oxide is released as dust by abrasion or wear). The highest consumer product exposure estimate was 44 µg/kg-bw per day based on infants (aged 0-6 months) lying on a mattress cover containing antimony oxide, mediated by perspiration; and calculated to be 2.2 µg/kg-bw per day mediated by urine.

Dermal exposure to young children from sitting on couches was determined to be 30 µg/kg-bw per day. Oral exposure may occur via flame retardant polyester fabrics used in children’s stuffed toys, but the estimate was low in comparison to the above (0.7 µg/kg-bw per day).

Studies from both Canada and the US show detectable levels of antimony in ambient air (0.0005 and 0.055 µg/m³). The maximum concentrations of antimony found in PET-plastic bottled water are higher than those found in tap water. In several studies conducted globally, antimony has been found to leach from plastic bottles into drinking water.¹⁶

Antimony has also been measured in soil and dust, but few studies exist on the concentrations of antimony in food products.

Beyond infants and children, no vulnerable populations were considered.

g. Health Effects

IARC has classified antimony oxide as a Group 2B carcinogen. While it has not been classified by international regulatory agencies for reproductive or developmental toxicity, there has been some evidence of adverse effects on fertility in limited epidemiological studies, and developmental and reproductive toxicity studies in experimental animals.

¹³ Ibid p. 16-20

¹⁴ Ibid p.20

¹⁵ Ibid p. 14

¹⁶ Ibid p.36-44

Although evidence is inconclusive, the mode of action has yet to be fully elucidated, and it has exhibited some clastogenicity in *in vitro* assays, according to the assessors, the assessors have found that it is not genotoxic.¹⁷

The margins of exposure (MOE) that have been calculated with respect to general population exposure for cancer and non-cancer effects were considered to be sufficiently protective. MOEs were calculated for the following situations;

- from sitting on furniture with upholstery containing antimony trioxide ($0.24 \mu\text{g}/\text{m}^3$) and critical LOEC for inhalation ($1.9 \text{ mg}/\text{m}^3$)
- child mouthing the polyester fabric on a plush toy or upholstery ($0.7 \mu\text{g}/\text{kg}\text{-bw}$ per day) and critical LOEL for oral route ($500 \text{ mg}/\text{kg}\text{-bw}$ per day)
- dermal exposure from lying on a mattress cover and for oral route (no repeated-dose dermal toxicity studies were identified)
- total daily intake from environmental media and food, assuming that all antimony originated from antimony.

An MOE for dermal exposure to young children from sitting on couches was not calculated.

h. Uncertainties in Evaluation of Risk to Human Health

According to the draft assessment, “the determination of margins of exposure within the scope of this screening assessment does not take into account possible differences between humans and experimental animals in terms of sensitivity to effects induced by antimony oxide. Two-year chronic toxicity studies were lacking. Carcinogenicity was observed in two of three 1-year inhalation toxicity studies in rats. As lung tumours were observed in female rats but not in male rats, sex differences might also determine the severity of the health impact. In terms of *in vivo* genotoxicity studies in experimental animals, results from oral studies might not be representative of the effects in the lungs after inhalation exposure.

There is uncertainty regarding the accuracy of the estimated exposures to antimony oxide from environmental media, foods as consumed and consumer products due to the lack of data on the concentrations of antimony oxide in these sources.”¹⁸

i. Recommendations

Given its carcinogenicity, use volume, and potential for adverse developmental and reproductive effects, a precautionary approach is called for. Thus, ITK strongly recommends that antimony oxide should be designated as “toxic” under CEPA 1999.

Furthermore, ITK notes that the primary source of exposure for the general population is flame retardants used in furniture upholstery and mattress covers, and the highest consumer product exposure estimates are for infants from lying on mattress covers containing antimony oxide. Measures are required to prevent this antimony exposure. As well, alternate methods of flame retardation that do not require antimony and brominated chemicals need to be researched.

¹⁷ A clastogen is an agent that can cause one of two types of structural changes. A clastogen can cause breaks in chromosomes that result in the gain, loss, or rearrangements of chromosomal segments. A clastogen can also cause sister chromatid exchanges, which are "homologous chromatid strand interchanges and reunions [that occur] during DNA replication" (Thilly & Call, 1986, p. 181) - Ref: <http://www.canoshweb.org/odp/html/rp6.htm>

¹⁸ Draft Screening Assessment, p.49

In light of the noted gaps in information and uncertainties regarding risks to human health, a re-evaluation of the draft assessment is strongly recommended to fill these data gaps. Such a re-evaluation should include;

- a. Gaps in environmental monitoring, particularly those in water and sediments at industrial sites where antimony oxide is used as a flame retardant (e.g., plastic manufacturers), and in soil near roadways given its use in brake fluid should be filled.
- b. The amounts of antimony (oxide) imported in consumer products should be more thoroughly investigated.
- c. Quantification of exposures from environmental media, foods, and consumer products is needed.
- d. Lack of epidemiological studies (humans) that may address the uncertainty in the carcinogenic potential of antimony oxide. Furthermore, long-term toxicity studies should be conducted in species other than rats. In addition, animal inhalation genotoxicity studies are needed. The dermal data set also needs strengthening.
- e. Exposure estimates need to be more thorough using information derived through environmental and consumer product monitoring.
- f. The potentially synergistic effects of chemical mixtures given that exposures to several chemicals occur simultaneously need to be explored.
- g. Attention needs to be paid to determining vulnerable population exposures (e.g., occupational groups, aboriginal populations, pregnant women, fetuses).

In summary, similar comments that have been made in this submission regarding critical issues pertaining to vanadium oxide (p.6, 7) also apply to antimony oxide.

The ultimate concern that ITK has is the failure of the assessment report to propose antimony oxide toxic under CEDPA 1999.