# A Response to the Proposed Risk Management Approach for Chemicals Management Plan Industry Challenge Batch 4 Substances Published in *Canada Gazette* Part I, Vol. 143, No. 31 — August 1, 2009

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# Introduction

The Canadian Environmental Law Association (CELA) and Chemical Sensitivities Manitoba (CSM) are submitting the following comments in response to the *Canada Gazette,* Part I, Vol. 143, No. 31— August 1, 2009 release of the proposed risk management approach reports for selected substances identified under the Chemicals Management Plan (CMP), Batch 4 of the Industry Challenge.

CELA (www.cela.ca) is a non-profit, public interest organization established in 1970 to use existing laws to protect the environment and to advocate for environmental law reform. It is also a legal aid clinic that provides legal services to citizens or citizens' groups who are unable to afford legal assistance. In addition, CELA also undertakes substantive environmental policy and legislation reform activities in the area of access to justice, pollution and health, water sustainability and land use issues since its inception. Under its pollution and health program, CELA has been actively involved in matters that promote the prevention and elimination of toxic chemicals addressed in the *Canadian Environmental Protection Act*, including the categorization process and implementation of the CMP.

Chemical Sensitivities Manitoba (CSM), a volunteer organization, was founded in 1997 by four individuals who saw the need to address the affects of toxic chemicals on human health and the possible link between the onset of chemical sensitivities and chemical exposure and, in particular, chronic low-level exposure. CSM raises awareness of the presence of toxic chemicals in the home and the environment and strongly advocates for the safe substitution of these toxins.

Our respective organizations along with other Canadian environmental and health non-governmental organizations (NGOs) submitted substantial comments on assessment results for substances covered under Batches 1 to 6, including the final assessments and draft risk management options for Batches1 to 3. For these batches, our organizations have supported some of the proposed assessment results but, at the same time, have elaborated on the gaps and limitations on specific aspects of the risk assessment and the proposed management instruments for specific chemicals. Consequently, we have developed appropriate substantial recommendations to address these gaps and limitations.

For this submission, we have provided detailed commentary to the proposed risk management measures on three substances in Batch 4 considered toxic under CEPA 1999.

For other substances in Batch 4 (CAS RNs: 1154-59-2; 1176-74-5; 64325-78-6; 68443-10-7; 70776-86-2; 75-28-5; 106-97-8; 110-54-3; 1154-59-2), including the substances proposed for Significant New Activity (SNAc), we have provided additional general comments and recommendations for your consideration. However, the comments presented below are examples of the range of concerns we have on the final decisions made by the government on many substances assessed to date. They also emphasize the level of protection that should be required for human health and the environment.

You will note that this submission does not address all issues of concern on the Batch 4 substances. Therefore, we urge your departments to review comments and

recommendations by CELA and CSM in response to draft assessment reports on these chemicals. They continue to be relevant to the findings of the final assessments and impact the proposals made for management of chemicals found to be toxic under CEPA, 1999. Our organizations want to ensure that the government utilizes the full extent of its authority under *CEPA 1999* to promote and implement the elimination or phase out of the most toxic substances found on the Canadian market.

## Results of Final Risk Assessments for substances under Batch 4 of Industry Challenge of the Chemicals Management Plan

Table 1 provides a summary of the results from the final screening level risk assessments conducted on substances under Batch 4 of the Industry Challenge of the Chemicals Management Plan.

**Table 1: Final results of Categorization and Screening Level Risk Assessment (SLRA) Batch 4 substances of the Chemicals Management Plan (CMP), Challenge Program**

| **Substances (CAS RN)** | **Categorization results** | **Proposed results of draft SLRA under CEPA S.64**<br><br>**Toxicity** | **Draft SLRA**<br><br>**Human health concerns** | **Draft SLRA**<br><br>**Persistence, Bioaccumulation, inherently Toxic**<br><br>**(PBiT)** | **Final SLRA decisions under CEPA S. 64** | **Final SLRA decisions on PBiT**<br><br>**Proposal for Significant New Activity (SNAc)** |
|---|---|---|---|---|---|---|
| 64-67-5<br>Sulphuric acid, diethyl ester<br>(Diethyl suphate) | • IPE<br>• Carcinogenicity and genotoxicity | Toxic | • IPE<br>• Classified by other agencies on the basis of carcinogenicity and genotoxicity. | Not P or B | Toxic | Not P or B<br>No SNAc proposal |
| 77-78-1<br>Sulphuric acid, dimethyl ester<br>(Dimethyl sulphate) | • IPE<br>• Carcinogenicity and genotoxicity | Toxic | • IPE<br>• Classified by other agencies on the basis of carcinogenicity and genotoxicity. | Not P or B | Toxic | Not P or B<br>No SNAc proposal |
| Benzenamine, *N*-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene (BNST)<br><br>**(CAS RN 68921-45-9)** | PBiT | Yes | No | PBiT | Toxic | PBiT<br>No SNAc proposed |
| Propane, 2-methyl<br><br>(Isobutane)<br><br>**Containing 1,3-** | • GPE<br>• Carcinogenicity<br>• Reproductive toxicity<br>• Genotoxicity | No | No | No | N/A | Not P or B |

| **Substances (CAS RN)** | **Categorization results** | **Proposed results of draft SLRA under CEPA S.64**<br><br>**Toxicity** | **Draft SLRA**<br><br>**Human health concerns** | **Draft SLRA**<br><br>**Persistence, Bioaccumulation, inherently Toxic**<br><br>**(PBiT)** | **Final SLRA decisions under CEPA S. 64** | **Final SLRA decisions on PBiT**<br><br>**Proposal for Significant New Activity (SNAc)** |
|---|---|---|---|---|---|---|
| **butadiene**<br><br>**(CAS RN 75-28-5)** | | | | | | |
| Butane<br><br>**Containing 1,3-butadiene**<br><br>**(CAS RN 106-97-8)** | • GPE<br>• Carcinogenicity<br>• Reproductive toxicity<br>• Genotoxicity | No | No | No | N/A | Not P or B |
| n-Hexane<br><br>**(CAS RN 110-54-3)** | • GPE<br>• Reproductive toxicity | No | • GPE<br>• Classified by the European Commission on the basis of reproductive toxicity | No | No | Not P or B |
| 4,4'- (3*H*-2,1-benzoxathiol-3-ylidene)bis[2,6-dibromo-, *S*,*S*-dioxide (Bromophenol Blue)<br><br>**(CAS RN 115-39-9)** | PBiT | No | No | P | No | P |
| Phenol, 4,4'- (3H-2,1-benzoxathiol-3-ylidene)bis[2-bromo-6-methyl-, *S*,*S*-dioxide (Bromcresol Purple)<br><br>**(CAS RN115-40-2)** | PBiT | No | No | P | No | P |
| Phenol, 4,4'- (3*H*-2,1-benzoxathiol-3-ylidene)bis[2,5- | PBiT | No | No | P | No | P |

| **Substances (CAS RN)** | **Categorization results** | **Proposed results of draft SLRA under CEPA S.64**<br><br>**Toxicity** | **Draft SLRA**<br><br>**Human health concerns** | **Draft SLRA**<br><br>**Persistence, Bioaccumulation, inherently Toxic**<br><br>**(PBiT)** | **Final SLRA decisions under CEPA S. 64** | **Final SLRA decisions on PBiT**<br>_____<br><br>**Proposal for Significant New Activity (SNAc)** |
|---|---|---|---|---|---|---|
| dimethyl-, *S*,*S*-dioxide (Xylenol Blue)<br><br>**(CAS RN 125-31-5)** | | | | | | |
| Phenol, 4,4- (3*H*-1,2-benzoxathiol-3-ylidene)bis[2,6-dibromo-3-methyl-, *S,S*-dioxide, monosodium salt (PBTBO)<br><br>**(CAS RN 62625-32-5)** | PBiT | No | No | P | No | P |
| Adenosine, *N*-benzoyl-5 - *O*-[bis(4-methoxyphenyl)phenylmethyl]-2 -deoxy-<br><br>**(CAS RN 64325-78-6)** | PBiT | No | No | PBiT* | **Yes** | PBiT<br>_____<br>SNAc |
| Benzamide, 3,5-dichloro-N-(3,4-dichlorophenyl)-2-hydroxy- (3,3',4',5-Tetrachlorosalicylanilide) ( 3,3',4',5-Tetrachlorosalicylanilide)<br><br>**(CAS RN 1154-59-2)** | PBiT | No | No | PBiT* | **Yes** | PBiT<br>_____<br>SNAc |

| **Substances (CAS RN)** | **Categorization results** | **Proposed results of draft SLRA under CEPA S.64**<br><br>**Toxicity** | **Draft SLRA**<br><br>**Human health concerns** | **Draft SLRA**<br><br>**Persistence, Bioaccumulation, inherently Toxic**<br><br>**(PBiT)** | **Final SLRA decisions under CEPA S. 64** | **Final SLRA decisions on PBiT**<br><br>**Proposal for Significant New Activity (SNAc)** |
|---|---|---|---|---|---|---|
| Benzoic acid, 2-[(3,5-dibromo-4-hydroxyphenyl)(3,5-dibromo-4-oxo-2,5-cyclohexadien-1-ylidene)methyl]-, ethyl ester<br><br>**(CAS RN 1176-74-5)** | PBiT | No | No | PBiT* | **Yes** | PBiT<br><br>SNAc |
| 2-Butanone, 4-[[[1,2,3,4,4a,9,10,10a-octahydro-1,4a-dimethyl-7-(1-methylethyl)-1-phenanthrenyl]methyl](3-oxo-3-phenylpropyl)amino]-, [1R-(1α,4αβ,10aα)]-<br><br>**(CAS RN 70776-86-2)** | PBiT | No | No | PBiT* | **Yes** | PBiT<br><br>SNAc |
| Amines, C18-22-tert-alkyl, ethoxylated<br><br>**(CAS RN 68443-10-7)** | PBiT | No | No | PBiT* | **Yes** | PBiT<br><br>SNAc |
| 5H-Dibenz[b,f]azepine-5-propanamine, 3- | PBiT | No | No | P | No | PiT |

| **Substances (CAS RN**) | **Categorization results** | **Proposed results of draft SLRA under CEPA S.64**<br><br>**Toxicity** | **Draft SLRA**<br><br>**Human health concerns** | **Draft SLRA**<br><br>**Persistence, Bioaccumulation, inherently Toxic**<br><br>**(PBiT)** | **Final SLRA decisions under CEPA S. 64** | **Final SLRA decisions on PBiT**<br><br>**Proposal for Significant New Activity (SNAc)** |
|---|---|---|---|---|---|---|
| chloro-10,11-dihydro-N,N-dimethyl-, monohydrochloride (clomipramine hydrochloride)<br><br>(**CAS RN 17321-77-6)** | | | | | | |
| Amines, tallow alkyl, ethoxylated, phosphates (ATAEP)<br><br>**(CAS RN 68308-48-5)** | PBiT | No | No | iT | No | iT |
| Amines, C18-22-tert-alkyl, (chloromethyl)phosphonates (2:1) (ATACP)<br><br>**(CAS RN 79357-73-6)** | PBiT | No | No | P | No | P |

**Notes: PBiT (persistent,bioaccumulative, inherently toxic); GPE (Greatest Potential for Exposure); IPE (Intermediate Potential for Exposure)**

**N/A – Not available**

# Substances Proposed for Significant New Activity (SNAc) provisions

On August 19, 2009 an Order amending the *Domestic Substances List* (DSL) to Significant New Activity (SNAc) provisions specified under subsection 81(3) of CEPA 1999 to five of the substances in Batch 4 was published in the *Canada Gazette, P*art II. These substances are:

- CAS RN: 1154-59-2; Benzamide, 3,5-dichloro-N-(3,4-dichlorophenyl)-2-hydroxy- (3,3',4',5-Tetrachlorosalicylanilide) ( 3,3',4',5-Tetrachlorosalicylanilid
- CAS RN: 1176-74-5; Benzoic acid, 2-[(3,5-dibromo-4-hydroxyphenyl)(3,5-dibromo-4-oxo-2,5-cyclohexadien-1-ylidene)methyl]-, ethyl ester
- CAS RN: 64325-78-6; Adenosine, N-benzoyl-5 - O-[bis(4-methoxyphenyl)phenylmethyl]-2 -deoxy-
- CAS RN 68443-10-7; Amines, C18-22-tert-alkyl, ethoxylated
- CAS RN: 70776-86-2; 2-Butanone, 4-[[[1,2,3,4,4a,9,10,10a-octahydro-1,4a-dimethyl-7-(1-methylethyl)-1-phenanthrenyl]methyl](3-oxo-3-phenylpropyl)amino]-, [1R-(1α,4αβ,10aα)]-

These chemicals were all found to be persistent, bioaccumulative and inherently toxic (PBiT) based on the categorization process. The following are our recommendations:

***Comments & Recommendations***

Our organizations have on-going concern and opposition with the government's proposal to use SNAcs for chemicals that are believed to be not in use in Canada, particularly for chemicals found to be PBiT. The government's position is currently based on the absence of information gathered from the Industry Challenge. The primary reason for our opposition is the lack of confidence that such provision will not result in a complete prohibition of such toxic substances. The intent of the SNAc is not so much in question. However, its application to these chemicals is a problem, since the government has gathered adequate information to suggest that these chemicals should be considered toxic. The provisions under SNAc are intended to ensure that the government is aware of proposals of new uses or activities for these chemicals in Canada. We are concerned that the SNAc process itself lacks the rigour required to ensure that the SNAc assessments will result in a prohibition or phase out of such chemicals. This concern is compounded by the fact that the process does not include a comprehensive public engagement component.

The use of SNAc will permit on-going opportunities by industry to use these substances in quantities lower than 100 kg, the threshold that is required for reporting. The current assessment framework does not consider the aggregate impact of use from these "lower" quantities despite that these substances are persistent, bioaccumulative and inherently toxic. Further, we know that such substances may have detrimental impacts

regardless of quantity. The timing of human exposure to such substances is another factor that has not been fully considered in the proposal.

The most significant flaw in applying the SNAc to these chemicals is the lack of public engagement in assessments conducted on chemicals through the New Substances Notification Regulations. It is inappropriate that these PBiT substances, which were originally listed in the Domestic Substances List but used at volumes lower than the100 kg threshold, will be assessed under a different regime. This provision does not stop the use of these chemical at the lower volumes, therefore it permits industry to use these substances with no real oversight or accountability to the public or government. The wait and see approach of government is not precautionary but rather supports a reactive approach.

It is much more practical and protective of the environment and human health to consider proposing these toxic substances for addition to the *Prohibition of Certain Toxic Substances Regulations*. In addition, the listing of these substances would send a clear signal for those interested in reintroducing these toxic substances in Canada that they should consider the replacement of these toxic chemicals with other chemicals or processes that do not have the same hazardous properties.

***Rec.: Conclude the five PBiT chemicals as CEPA toxic (Schedule 1) and add to the Prohibition of Certain Toxic Substances Regulation. Despite the evidence gathered that these chemicals are not in use in Canada (above the notification trigger of 100kg) and that no other data was submitted by industry to challenge the decision on chemicals with CAS RNs: 1154-59-2, 1176-74-5, 64325-78-6, 68443-10-7 and 70776-86-2 are PBiT substances, we recommend that these substances be considered CEPA toxic.***

***Rec.: Require the prohibition and phase out of all PBiTs. To ensure protection to human health and environment from these PBiT chemicals, they should be added to the Prohibition of Certain Toxic Substances Regulations 2005. This would ensure that no future use, manufacture, import or sale of these substances be permitted in Canada. This response would be in keeping with the precautionary principle.***

***Rec.: The application of SNAc provision not appropriate. Substances with CAS RNs: 1154-59-2, 1176-74-5, 64325-78-6, 68443-10-7 and 70776-86-2 should not be flagged for SNAc provisions since the data required by government under the New Substances Notification Regulations (NSN) Schedule 6 is limiting and substances assessed under the NSN do not include a public comment period on subsequent assessments conducted using SNAcs. Given that these substances have been identified through the initial categorization as being PBiT, it is imperative to retain an opportunity for the public to comment on future assessment of these chemicals.***

***Rec.: All uses, including uses below the reporting threshold of 100 kg/year should be reported. The application of the 100 kg/year threshold for reporting to the s. 71 survey is a gap in the government approach. All uses should be reported regardless of volume. Therefore, the 100 kg/year threshold for reporting should be deleted in the survey. The removal of the threshold will allow for consideration of aggregate users of these chemicals. The lack of consideration on the aggregate use of these chemicals raises significant concerns as to the validity of the conclusion made for a SNAc application.***

***Rec.: Strengthen New Substances Program. We urge the government to strengthen the New Substances Notification Regulations, with emphasis on the application of SNAc, to include public comment period in the assessment framework. The lack of transparency in the decision making process for conducting assessments under the NSN is unacceptable.***

# Comments on Specific Chemicals in Batch 4 without Risk Management Scope Report

## *a) Propane, 2-methyl (Isobutane) (CAS RN 75-28-5) and Butane (CAS RN 106-97-8) (containing 1,3-butadiene)*

The assessments focus on Isobutane and Butane containing 1,3-Butadiene is very limiting in scope and its conclusions are weak. First, 1,3 butadiene is already found to be toxic under CEPA and has a management regime in place. The assessment provides some details on the human health effects but fails to provide updated information on this substance in the assessments. Second, the assessment does not include an investigation on the full use and impact of isobutane and butane. The absence of this information creates a gap in the knowledge of these chemicals which then impacts the type of management regime that should be undertaken. Regardless of its designation in the medium priority category of the Chemicals Management Plan, these chemicals should have been moved up in priority based on the high volume use of chemicals containing 1,3 butadiene.

The reports provide no conclusion on the toxicity of isobutene and butane and proposes to imply that consideration will be given to investigation on the management of 1,3 butadiene. This area of the reports need significant improvements and a clear indication of the intent of the government to strengthen the management regime for 1,3 butadiene. The government indicates that revisions will be considered for the management regime on 1,3 butiadiene based on “new exposure information.” It is our view, that this proposal is not protective of human health, given the extensive types of products that may contain this substance. In keeping with the principles of precaution listed in CEPA, the findings of the final assessment should lead the government to take actions that go beyond those proposed.

One product that requires greater government focus is 1,3 butadiene releases in outdoor wood burning stoves. This source of 1,3 butadiene may be significant and should not be excluded from the management regime. Other areas include consumer and cosmetic products and food packaging products.

**Rec.: Promote the elimination of 1,3-butadiene from outdoor wood burning stoves. Although 1,3-butadiene from outdoor wood burning stoves has not been specifically addressed in the proposed risk management, we recommend that the government outline an action plan that aims to eliminate this source of 1,3 butadiene and particularly, in those areas of the country where the occurrence of smog is common for many months of the year, including winter.**

**Rec.: Prohibit 1,3 butadiene from commercial and consumer products including cosmetics. The risk management program does not target action to prohibit 1,3 in these products. Since 1,3-butadiene is known to be a human carcinogen, the government should take a more precautionary approach, with specified timelines, to prohibit the presence of this chemical in the products listed above. This may include but should not be restricted to the addition of 1,3-butadiene to the Health Canada's Cosmetic Ingredient Hotlist, which should be accompanied by enhanced enforcement measures.**

**Rec.: Prohibit 1,3-butadiene in food contact products. Based on the properties of 1,3-butadiene, we recommend that the government take regulatory action to phase out the presence of this substance as a contaminant from food contact products with specified timelines. The use of alternative food packaging would probably be required.**

**Rec.: Require substitution with a safer alternative. We recommend that the government and industry, over a specified time period, identify, review and implement the use of safer alternatives to butane and isobutane containing residual 1,3-butadiene, in all consumer and commercial products.**

**Rec.: Require monitoring programs for 1,3-butadiene in consumer and commercial products. A revised management strategy aimed at 1,3-butadiene should include a government monitoring program that would quantify the levels of 1,3-butadiene in commonly used consumer and commercial products.**

**Rec.: Phase out Propane, 2-methyl (CAS RN 75-28-5) and Butane (CAS RN 106-97-8) as sources of 1,3-Butiediene. Based on the information gathered in the assessment report, we urge the government to establish an action plan that aims to phase out the use of propane, 2-methyl and butane in industrial and consumer application because of their contribution to the release of 1,3-butadiene. An action plan for elimination should include consideration of alternative chemicals and technologies as well as a transition process to address the needs of affected workers.**

**Rec.: Conduct an assessment that evaluates the fate and impact of isobutene and butane regardless of the presence of 1,3 butadiene as a residual. This type of an assessment will provide a more comprehensive understanding of the impact of these substances.**

**Rec.: Strengthen the management regime on 1,3 butadiene due to its carcinogenic, genotoxicity and reproductive toxicity. The government has adequate information to demonstrate the impact of this chemical.**

**Rec.: Based on the data on toxicity of 1,3 butadiene, isobutene and butane, a consideration of phase out of these substances is warranted.**

## *b) n-Hexane (CAS RN 110-54-3)*

The screening assessment conducted on n-Hexane suggests that this chemical results in impaired fertility and is suspected of neurotoxicity. However, the assessment conclusion for n-Hexane suggests that it does not meet the criteria to be classed as toxic under CEPA. Such a conclusion should be re-examined since the report indicated that the scope of the assessment has not investigated the impacts from metabolites of n-Hexane that may contribute to the neurotoxicity effects of the chemical. This data gap should be fully addressed so as to understand the impacts of this chemical and its metabolites on the general population and specifically to children's health. Based on information gathered through the U.S. Scorecard (www.scorecard.org), n-Hexane is a suspected developmental toxicant, neurotoxicant, reproductive toxicant, and may also affect respiratory health.[1] Additional consideration should be given to these health effects when making a conclusion of toxicity under CEPA. These data along with the release data gathered through the National Pollutant Release Inventory for 2006 – when reporting facilities released 4.438 tonnes (4,438,000 kg) to air, 0.0855 tonnes (85,500 kg) to water and 1.2 tonnes (1,200,000 kg) to land – are high levels that have not been fully addressed in the assessment report.

The assessment report also noted that many of the products that contain n-Hexane are targeted for automotive maintenance and repair with a few applications for cosmetic products. However, the assessment has not explored the effectiveness of management measures undertaken by the public that use these products or by the workers that may be exposed to these products on a daily basis. The lack of consideration from exposure to cosmetic products is a glaring gap in the assessment.

**Rec.: The conclusions of the assessment on n-Hexane should be reviewed and it should be considered toxic under CEPA given the extent of use of this chemical in consumer products, releases to the environment, and the health effects associated with this chemical.**

[1] See: U.S. Scorecard at http://www.scorecard.org/chemical-profiles/summary.tcl?edf_substance_id=110-54-3#hazards.

**Rec.: We urge the government to expand the scope of the assessment of n-Hexane and all chemicals identified through categorization to include their metabolites. The government should require additional data by industry to fill in critical data gaps that exist for n-Hexane. In particular, additional data should be required by industry to demonstrate that n-Hexane and its metabolites do not result in neurotoxicity or impaired fertility.**

### *c) Benzamide, 3,5-dichloro-N-(3,4-dichlorophenyl)-2-hydroxy-(3,3',4',5-Tetrachlorosalicylanilide) ( 3,3',4',5-Tetrachlorosalicylanilide) (CAS RN 1154-59-2)*

The assessment on Benzamide, 3,5-dichloro-N-(3,4-dichlorophenyl)-2-hydroxy-(3,3',4',5-Tetrachlorosalicylanilide) ( 3,3',4',5-Tetrachlorosalicylanilide) with CAS RN 1154-59-2 has been proposed as a persistent, bioaccumulative and inherently toxic substances and therefore CEPA toxic. We are supportive of this conclusion. However, the assessment does not provide any information on potential health effects from this chemical. Based on preliminary research, this substance is a suspected immunotoxicant according to the U.S. Scorecard web site.[2]

**Rec.: We urge the government to expand the management measures for all persistent, bioaccumulative and inherently toxic substances such as Benzamide, 3,5-dichloro-N-(3,4-dichlorophenyl)-2-hydroxy- (3,3',4',5-Tetrachlorosalicylanilide) ( 3,3',4',5-Tetrachlorosalicylanilide) (CAS RN 1154-59-2) because of their potential health effects. A complete prohibition and phase out of this chemical is recommended to ensure protection to the environment and human health.**

## Comments on Specific Chemicals in Batch 4 with Proposed Risk Management Scope Reports

### *a) Diethyl sulphate (CAS RN 64-67-5)*

Our specific comments on the final assessment results and proposed management measures for Diethyl sulphate (DMS) (CAS RN 64-67-5**)** are provided in table 2.

[2] See : U.S. Scorecard at http://www.scorecard.org/chemical-profiles/summary.tcl?edf_substance_id=1154-59-2#hazards

## Table 2: Diethyl sulphate (CAS RN 64-67-5) - Comments and recommendations to specific risk management proposals

| Specific sections of risk management scope - diethyl sulphate CAS RN 64-67-5 | Proposed government measures & other measures | CELA & CSM Comments | Recommendations |
|---|---|---|---|
| Section 1.3<br>Proposed measure | • It is proposed for the Ministers to recommend the addition of diethyl sulfate to the List of Toxic Substances in Schedule 1.<br>• The Ministers to develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance. | • Given the carcinogenic potential of diethyl sulphate, it is appropriate for this chemical to be listed on the Toxic Substances List (Schedule 1) of CEPA.<br>• Although the assessment indicated that the total quantity of diethyl sulphate imported in 2008 was 1000kg, this figure may be an underestimation of the presence of this chemical in Canada. This chemical has a wide range of uses for industrial and consumer applications as well as imported products (used as an intermediate). Therefore, it is surprising that the proposed management options do not emphasize or provide some level of detail on what a regulatory measure would include.<br><br>• This chemical has also been identified as a residue in some products (including imported products) which may mean that the assessment report may be underestimating the exposure to human health and the environment. This level of uncertainty should be addressed in a more precautionary manner regarding the proposals for risk management. Consideration of non-regulatory instruments will not create the level of certainty required to address the various sources of this chemical while regulatory measures can be more protective of human health and the environment and can be enforced. | Rec: We support the listing of diethyl sulphate on the Toxics Substances List (Schedule 1) of CEPA.<br><br>Rec: However, when there is residual diethyl sulphate in consumer products including cosmetics, there should be an aim towards a phase out for those applications.<br><br>Rec.: Since diethyl sulphate can be present in various consumer products as a contaminant, we urge the government to prohibit the use of diethyl sulphate in these products, regardless of the residual concentration. |
| Section 7.1. Alternative chemicals or substitutes | No information provided under surveys conducted under Section 71 of CEPA. | • The listing of possible alternatives or substitutes should be an integral part of the risk management document and | Rec.: An inventory of possible alternatives to diethyl sulphate should be prepared as part of the risk |

| **Specific sections of risk management scope - diethyl sulphate CAS RN 64-67-5** | **Proposed government measures & other measures** | **CELA & CSM Comments** | **Recommendations** |
|---|---|---|---|
| | | unfortunately, this information was not supplied by industry.<br>• The government should be taking steps that support the identification and promotion of alternatives that do not exhibit toxic properties in the course of conducting its assessment work.<br>• To ensure that alternatives or substitutions do not possess toxic properties, the government should require a process to assess their safety. This requirement will contribute to innovation by industry. | management options.<br><br>Rec.: A process to determine the safety of all substitutes for diethyl sulphate should be undertaken under CEPA before they are used as replacements. This work should be undertaken by a multi-stakeholder task force to review and assess the safety of alternatives. This task force should include participation by government, industry, environmental and health organizations, labour, and indigenous communities. |
| Section 7.2.<br>Alternative techniques or technologies | No information provided in surveys conducted under Section 71 of CEPA. | • Despite the lack of information from the Section 71 survey, attempts should have been directed to investigate any alternative techniques or technologies for diethyl sulphate. | Rec.: Similar to the approach required to assess the safety of alternatives, it is important to undertake an assessment of available alternative technologies and techniques to ensure that they do not produce other toxic chemicals or pose a hazard to the environment or health. |
| Section 7.4.<br>Children's health | Through the Challenge, information received from industry and interested stakeholders, the government has proposed risk management actions to specifically protect children that are not required at this time. | • Diethyl sulphate is used in the production of quaternary ammonium salts which are widely incorporated into hair care products and cleaners that may eventually be used by children. Diethyl sulphate can be detected as residues in these products. However, no risk management options to specifically protect children and babies have been proposed.<br>• The lack of information received through the industry challenge should not lead to a conclusion that no measures are required to protect children's health nor that this substance has no impact on | Rec.: Additional regulatory action to protect children from exposure to diethyl sulphate is warranted because of the type and number of consumer products that may contain residual diethyl sulphate.<br><br>Rec.: The government should use the full scope of its authority to collect data on the impacts to children's health from this chemical. Specifically utilize Section 71(1)(c), to seek mandatory toxicological data from industry focused on |

| Specific sections of risk management scope - diethyl sulphate CAS RN 64-67-5 | Proposed government measures & other measures | CELA & CSM Comments | Recommendations |
|---|---|---|---|
| | | children.<br>• The current approach to collect information on exposure to children is conducted through a voluntary questionnaire. This is highly inadequate. The government should use its full authority under Section 71, in particular Section 71 (1) (c) to require industry to provide toxicological and other tests that address this information gap. This information should inform the assessment report. The absence of acknowledgement of this information will create a significant gap in the proposed management approach for diethyl sulphate.<br>• The government's decision not to propose management options to specifically protect children and babies is not sufficiently precautionary given that this chemical is found extensively in industrial application and in consumer products.<br>• Furthermore, this chemical has not been identified on any list for prohibition. This absence from prohibition lists includes Canada's Cosmetics Ingredient Hotlist. This may mean that it may be used in cosmetic products (including those for children) as well. Although there is a proposal to add this chemical to the Cosmetic Ingredient Hotlist based on the risk management document, an explicit focus to protect children's health from such products has yet to be proposed.<br>• The lack of information gathered on children's health exposures to these chemicals is also applicable for other vulnerable populations (e.g., workers, people of low income, people with chemical sensitivities and aboriginal communities). | exposure to children's health.<br><br>Rec.: Similarly, the management proposals should also recognize and take action to protect other vulnerable sub-populations of society such as people of low income, workers, people with chemical sensitivities and aboriginal communities. |

| **Specific sections of risk management scope - diethyl sulphate CAS RN 64-67-5** | **Proposed government measures & other measures** | **CELA & CSM Comments** | **Recommendations** |
|---|---|---|---|
| Section 8.1. Environmental or human health objective | The proposed human health objective for this substance is to minimize, to the extent practicable, exposure to the substance thereby minimizing risk to human health. | • The human health objectives for developing management measures for diethyl sulphate are considered inadequate since this substance has been identified for its carcinogenicity and genotoxicity. Given its extensive use and the potential for remaining as a residue or contaminant in consumer and cosmetic products, as well as industrial products, a goal of eliminating exposure to this substance is appropriate. | Rec.: The human health objective for diethyl sulphate should be strengthened to aim for the elimination of human exposure to this substance.<br><br>Rec.: We urge the government to revise the word “minimize” to “eliminate” in its environmental or human health objective. |
| Section 8.2. Risk management objective | The proposal is to minimize exposure to this substance. | The proposed risk management objective is weak as it focuses on minimizing exposure to this substance rather than preventing exposure. This objective is considered weak for several reasons:<br>• The focus on concentration to determine a level that protects human health will result only in controlling the use of the chemical at the end of the process rather than eliminating it at the source which is protective of human health and the environment.<br>• Establishing a concentration that is considered protective will depend on the available technology and to some degree, will require some negotiation between industry and decision makers to establish an acceptable level. Given that this chemical is a carcinogen with several possible exposure routes which have not been fully assessed, a protective approach for managing diethyl sulphate would be to aim to phase out its usage (including the presence of residues) in cosmetics, consumer and industrial products. | Rec.: We do note support the current risk management objectives for diethyl sulphate as they do not fully protect human health from exposure.<br><br>Rec.: We urge the government to shift its risk management approach from establishing concentration levels for cosmetic and consumer products to a focus on prohibition of this substance in consumer and industrial products |
| Section 9.1. Proposed risk | The proposed risk management | • While notification would allow the government to be aware of the | Rec.: We do note support the current risk |

| **Specific sections of risk management scope - diethyl sulphate CAS RN 64-67-5** | **Proposed government measures & other measures** | **CELA & CSM Comments** | **Recommendations** |
|---|---|---|---|
| management instrument | instrument for diethyl sulphate is a requirement for notification of the federal government regarding any proposed future uses. | future uses of diethyl sulphate, this instrument is not proactive enough for a substance which is carcinogenic, so widely used and can be a residue in some consumer and industrial products. The government proposals on notification are vague, lacking details on what will be required for notification. The intent of the notification may be appropriate as it aims to monitor the use of this chemical in future use. However, a notification requirement will permit on-going use of this substance at the current level without any efforts to reduce it which could pose a threat to human health and the environment. Such a proposal does not place any responsibility on industry to seek reduction or elimination of this chemical.<br>• This chemical has been categorized for carcinogenicity and genotoxicity. However, the assessment results assumed that there are safe human levels of exposure for this chemical. These objectives focus on concentration levels for cosmetic and consumer products rather than the outright prohibition of this substance in these products as well as industrial products.<br>• In fact, humans are exposed to a variety of other chemicals that are not fully accounted for in these assessments. In the process of considering safe levels of human exposure to a specific chemical, it becomes very problematic to ignore the possibility of the additive, cumulative and synergistic effects from other toxic exposures. These effects are not considered in such assessments.<br>• The efforts to establish levels for safe human exposure becomes a subjective exercise that partially relies on the confidence level for | management objectives for diethyl sulphate as they do not fully protect human health from exposure.<br><br>Rec.: We urge the government to shift its risk management approach from establishing concentration levels for cosmetic and consumer products to a focus on prohibition of this substance in consumer and industrial products. |

| **Specific sections of risk management scope - diethyl sulphate CAS RN 64-67-5** | **Proposed government measures & other measures** | **CELA & CSM Comments** | **Recommendations** |
|---|---|---|---|
| | | the collected data (i.e., effectiveness of technology) and the commitment of decision makers and stakeholders to establish these levels. | |
| Section 9.1. Proposed risk management instrument | Addition to the Cosmetics Hotlist is also proposed. | • We agree to the proposal to add diethyl sulphate to the Cosmetics Hotlist but as a banned substance. However, this listing should be part of a strategy to phase out this chemical.<br>• There was a lack of consideration for the presence of diethyl suphate in imported products. This could potentially increase the presence of the diethyl sulphate in Canada, hence causing a possible increase in human exposure. | Rec.: Diethyl sulphate including its presence as a residue or a contaminant should be added to Canada's Cosmetics ingredient Hotlist as a banned substance. |
| Section 9.1. Proposed risk management instrument | The government is not proposing to add this substance to the *Environmental Emergency Regulations* at this time since quantities in Canada are below the threshold of 9100 kg set through the Risk Evaluation Framework for Sections 199 and 200 of CEPA 1999 (Environment Canada 2002) | • Based on our review of the Risk Evaluation Framework for Section 199 and 200 of CEPA 1999, it remains unclear how the threshold of 9100 kg for this chemical was determined. Regardless of this threshold, this substance should be considered a candidate for environmental emergency plans based on its health impacts and the lack of flexibility in the government's proposal to account for the possibility of an increase in volume in the future. Environmental emergency plans support greater accountability to workers and the community.<br>• The government's current approach to diethyl sulphate is not a prohibition and as such, there may be stockpiles of this chemical in facilities. The presence of stockpiles at the facility plants should provide additional justification for adding this substance to a list under the Environmental Emergency Regulations<br>• The inclusion of emergency plans provides a response plan should | Rec.: The government should propose adding diethyl sulphate to the Environmental Emergency Regulations based on its carcinogenicity. |

| Specific sections of risk management scope - diethyl sulphate CAS RN 64-67-5 | Proposed government measures & other measures | CELA & CSM Comments | Recommendations |
|---|---|---|---|
| | | accidents or spills occur, particularly for workers and the surrounding communities. | |

**Additional issues not addressed in Risk Management scope document for diethyl sulphate**

There are a number of components that have not been included in the proposed Risk Management Scope document for diethyl sulphate. In our view, the consideration of these issues is pertinent to effectively address concerns related to this toxic chemical.

**1) Absence of Imported products that may contain diethyl sulphate**

There was a lack of consideration for the presence of diethyl sulphate in imported products. Since Canada imports many products yearly, this gap could potentially increase the presence of the diethyl sulphate hence causing a possible increase in human exposure.

**Rec.: We urge the government to require importers to provide list of chemicals found in imported products, including residual concentrations. For those chemicals that are listed on Schedule 1 of CEPA, the government should prohibit the entry of any products containing any of these toxic chemicals. Though a difficult approach, it gives a more realistic view of human and environmental exposures, particularly for products that have greater volumes of import as compared to domestic manufacture.**

**2) Adequate reporting under NPRI to the public on releases and transfers**

The risk management scope document has provided no additional proposals to improve reporting on the releases of this substance under the National Pollutant Release Inventory. Although diethyl sulphate is on the list of substances that are reported under NPRI, the threshold for reporting to the federal inventory remains high. The government should consider removing the reporting threshold for all CEPA toxic substances, including diethyl sulphate. This would ensure that all facilities releasing or transferring this chemical would be required to report annually. To date, the government has been slow to make adequate reforms to the NPRI regarding the chemicals targeted under the CMP and the NPRI Work Group. This Work Group investigates and discusses potential changes to the program but has not been mandated to undertake this work.

**Rec.: For all CEPA toxic chemicals, including diethyl sulphate, the reporting requirements under NPRI should be lowered to ensure that all releases and transfers of these substances are reported.**

### 3) Lack of Pollution Prevention (P2) focus

Many of the risk management proposals on CEPA toxic chemicals to date have been focused on minimizing release and exposure to these chemicals rather than supporting a preventative approach. The proposals for diethyl sulphate follow a similar approach. NGOs have urged for a more comprehensive and preventative approach to chemicals that are found to be CEPA toxic, with emphasis on chemicals that are found to be carcinogenic or PBiT. The government proposals have yet to address these recommendations.

One area where the government proposals have been significantly lacking is the requirement for pollution prevention plans on these substances. In our view, mandatory preparation of pollution prevention plans would represent concrete steps to identify areas of efficiency and innovation. In the process, industry may evaluate and consider the potential substitute for these chemicals. These are tools that are required in CEPA but have yet to be utilized to their full extent in the promotion of phasing out the most toxic chemicals in Canada. Such plans should be part of a comprehensive strategy for Canada to phase out the use of diethyl sulphate.

To provide additional support for pollution prevention efforts, it would also be relevant for government to require reporting of pollution prevention activities under the National Pollutant Release Inventory. It is unclear how many reporting facilities undertake and report pollution prevention activities under NPRI but NPRI does provide unique opportunities to outline pollution prevention strategies being undertaken by facilities across Canada. However, to make this information more useful, the government should seek to make the appropriate linkages to the other pollution prevention commitments under CEPA.

**Rec.: We urge the government to require the use of pollution prevention plans as part of a comprehensive strategy aimed at phasing out CEPA toxic chemicals, including diethyl sulphate.**

**Rec.: The government should require mandatory reporting of pollution prevention activities under NPRI for all pollutants, particularly CEPA toxic substances such as diethyl sulphate.**

## *b) Dimethyl sulphate (DMS) (CAS RN 77-78-1)*

Our specific comments on the final assessment results and proposed management measures for Dimethyl suphate (DMS) (CAS RN 77-78-1**)** are provided in table 3.

## Table 3: Dimethyl suphate (DMS) (CAS RN 77-78-1) - Comments and recommendations to specific risk management proposals

| Specific sections of risk management scope - diethyl sulphate (DMS) CAS RN 77-78-1 | Proposed government measures & other measures | CELA & CSM Comments | Recommendations |
|---|---|---|---|
| Section 1.3. Proposed measure | • It is proposed for the Ministers to recommend the addition of dimethyl sulfate to the List of Toxic Substances in Schedule 1.<br>• The Ministers propose to develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance. | • Given the carcinogenic potential of dimethyl sulphate, it is appropriate for this chemical to be listed on the Toxic Substances List (Schedule 1) of CEPA.<br>• Although the assessment indicated that the total quantity of dimethyl sulphate imported in 2008 was 1000kg, this figure may be an underestimation of the presence of this chemical in Canada. This chemical has a wide range of uses for industrial and consumer applications as well as imported products (used as an intermediate). Therefore, it is surprising that the proposed management options do not emphasize or provide some level of details on what a regulatory measure would include.<br>• This chemical has also been identified as a residue in some products (including imported products) which may mean that the assessment report may be underestimating the exposure to human health and the environment. This level of uncertainty should be addressed in a more precautionary manner regarding the proposals for risk management. Consideration of non-regulatory instruments will not create the level of certainty required to address the various sources of this chemical while regulatory measures can be more protective of human health and the environment and can be enforced. | Rec.: We support the listing of dimethyl sulphate on the Toxics Substances List (Schedule 1) of CEPA.<br><br>Rec.: Dimethyl sulphate should be phased out in industrial applications and consumer products through regulatory action, particularly because of its carcinogenic potential and its potential presence as a residue in consumer products and industrial applications.<br><br>Rec.: Since dimethyl sulphate can be present in pharmaceutical products and possibly in natural health products as a contaminant, we urge the government to prohibit the use of dimethyl sulphate in these products, regardless of the residual concentration. |
| Section 6.1. Existing Canadian risk management | The Ingredient Disclosure List of the Controlled Products Regulations under the *Hazardous Products Act*, with a maximum concentration of 0.1% by weight. | • The current regime is wholly inadequate to address dimethyl sulphate. Given that the existing management regime focuses on the presence of dimethyl sulphate rather than preventing its use in industrial and consumer products, a more comprehensive regulatory framework aimed at a phase out should be considered.<br>• The current maximum concentration of 0.1% is considered inadequate as a management measure in protecting | Rec.: The maximum concentration of 0.1% by weight for dimethyl sulphate on the Ingredient Disclosure List of the Controlled Products Regulations under the *Hazardous Products Act* should be removed.<br><br>Rec.: Disclosure of use |

| Specific sections of risk management scope - diethyl sulphate (DMS) CAS RN 77-78-1 | Proposed government measures & other measures | CELA & CSM Comments | Recommendations |
|---|---|---|---|
| | | human health and environment. The requirement to list this chemical in MSDS sheets is inadequate unless accompanied by strong measures that indicate a prohibition. The on-going presence of dimethyl sulphate in consumer products will continue to be a source of exposure to humans and the environment.<br>• There should be no concentration restriction as to the disclosure of dimethyl sulphate on MSDS sheets. This will ensure full disclosure to workers and the public on the full range of application and products that contain this substance. | of this dimethyl sulphate should be broader than listing in MSDS. It should include reporting for releases, uses, disposal and manufacture. This would include a substantial improvement to the NPRI reporting requirements for this chemical (i.e., remove reporting thresholds to require all releases to be reported). |
| Section 7.1. Alternative chemicals or substitutes | No information provided to the survey conducted under Section 71. | • The listing of possible alternatives or substitutes should be an integral part of the risk management document and unfortunately, this information has not been supplied by industry.<br>• The government should be taking steps that support the identification and promotion of alternatives that do not exhibit toxic properties in the course of conducting its assessment work.<br>• To ensure that alternatives or substitutions do not possess toxic properties, the government should require a process to assess their safety. This requirement will contribute to innovation by industry. | Rec.: A phase out regime for dimethyl sulphate should include an inventory of possible alternatives to dimethyl sulphate; this should be prepared as part of the risk management process.<br><br>Rec.: A process to determine the safety of substitutes available for dimethyl sulphate should be undertaken under CEPA. This work should be undertaken by a multi-stakeholder task force to review and assess the safety of alternatives. This task force should include participation by government, industry, environmental and health organizations, workers, and indigenous communities. |
| Section 7.2. Alternative techniques or | No information provided through the survey conducted under Section | • Despite the lack of information from the Section 71 survey, additional efforts should have been directed to investigate | Rec.: Similar to the approach required to assess the safety of |

| Specific sections of risk management scope - diethyl sulphate (DMS) CAS RN 77-78-1 | Proposed government measures & other measures | CELA & CSM Comments | Recommendations |
|---|---|---|---|
| technologies | 71. | any alternative techniques or technologies for dimethyl sulphate. | alternatives, it is important to undertake an assessment of available alternative technologies and techniques to ensure that they do not produce other toxic chemicals or pose a hazard to the environment or human health. |
| Section 7.4. Children's health | Through the Challenge, information received from industry and interested stakeholders, the government has proposed risk management actions to specifically protect children are not required at this time. | • Regardless of its reaction role (alkylation, methylation or the use of quaternary ammonium salts), there is a significant possibility of exposure to children from this chemical because of the wide range of products that may contain residual dimethyl sulphate. The lack of information received through the industry challenge should not lead to a conclusion that no measures are required to protect children's health nor that this substance has no impact on children.<br>• The current approach to collect information on exposure to children is conducted through a voluntary questionnaire. This is highly inadequate. The government should use its full authority under Section 71, in particular Section 71 (1) (c) to require industry to provide toxicological and other tests that address this information gap. This information should inform the assessment report. The absence of acknowledgement of this information will create a significant gap in the proposed management approach for dimethyl sulphate.<br>• The government's decision not to propose management options to specifically protect children and babies is not sufficiently precautionary given that this chemical is found extensively in industrial applications and in consumer products.<br>• Furthermore, this chemical has not been identified on any list for prohibition | Rec.: Additional regulatory action to protect children from exposure to dimethyl sulphate, particularly from consumer and cosmetic products, should be developed because of the types and number of consumer products that may contain residual dimethyl sulphate.<br><br>Rec.: The government should use the full scope of its authority to collect data on the impacts to children's health from this chemical. Specifically utilize Section 71(1)(c), to seek mandatory toxicological data from industry focused on exposure to children's health.<br><br>Rec.: Similarly, the management proposals should also recognize and take action to protect other vulnerable populations of societies such as people of low income, workers, people with chemical sensitivities and |

| **Specific sections of risk management scope - diethyl sulphate (DMS) CAS RN 77-78-1** | **Proposed government measures & other measures** | **CELA & CSM Comments** | **Recommendations** |
|---|---|---|---|
| | | including Canada's Cosmetics Ingredient Hotlist which may mean that it may be used in cosmetic products (including those for children) as well. Although there is a proposal to add this chemical to the Cosmetic Ingredient Hotlist based on the risk management document, an explicit focus to protect children's health from such products has yet to be proposed.<br>• The lack of information gathered on children's health exposures to these chemicals is also applicable for other vulnerable populations (e.g., workers, people of low income, people with chemical sensitivities and aboriginal communities). | aboriginal communities. |
| Section 8.1. Environmental or human health objective | The proposed human health objective for this substance is to minimize, to the extent practicable, exposure to the substance thereby minimizing risk to human health. | • Since this chemical has been found to be toxic under CEPA due to its carcinogenicity and genotoxicity, the proposed human health objectives for developing management measures for dimethyl sulphate are considered inadequate. Given its extensive use and the potential for remaining as a residue or contaminant in pharmaceuticals, consumer products, as well as industrial products, a goal of eliminating exposure to this substance is appropriate. | Rec.: The human health objective for dimethyl sulphate should be strengthened and it should focus on the elimination of human exposure to this substance.<br><br>Rec.: We urge the government to revise the word "minimize" to "eliminate" in its environmental or human health objective. |
| Section 8.2. Risk management objective | The proposal is to minimize exposure to this substance. | The proposed risk management objective is weak as it focuses on minimizing exposure to this substance rather than preventing exposure. This objective is considered weak for several reasons:<br><br>• The focus on concentration to determine a level that protects human health will result only in controlling the use of the chemical at the end of the process rather than eliminating it at the source which is protective of human health and the environment.<br>• Establishing a concentration that is considered protective will depend on the available technology and to some | Rec.: We do not support the proposed management objectives for dimethyl sulphate as they do not fully protect human health from exposure to this substance. We urge the government to focus on the elimination of this substance (particularly as a residue) in pharmaceuticals, consumer and industrial products, in a timely manner. |

| **Specific sections of risk management scope - diethyl sulphate (DMS) CAS RN 77-78-1** | **Proposed government measures & other measures** | **CELA & CSM Comments** | **Recommendations** |
|---|---|---|---|
| | | degree, will require some negotiation between industry and decision makers to establish an acceptable level. Given that this chemical is a carcinogen with several possible exposure routes which have not been fully assessed, a protective approach for managing dimethyl sulphate would be to aim to phase out its usage (including the presence of residues) in pharmaceuticals, cosmetics, consumer and industrial products. | Rec.: The government should develop an action plan to support the elimination of this chemical. |
| Section 9.1. Proposed risk management instrument | The proposed risk management instrument for dimethyl sulphate is a requirement for notification of the federal government regarding any proposed future uses. | • While notification would allow the government to be aware of the future uses of dimethyl sulphate, this instrument is not proactive enough for a substance that is carcinogenic and so widely used even if it is a residue in some pharmaceuticals, consumer and industrial products. The government proposals on notification are vague and lack details on what will be required for notification. The intent of the notification may be appropriate as it aims to monitor the use of this chemical in future use. However, a notification requirement will permit on-going use of this substance at the current level without any efforts to reduce it which could pose a threat to human health and the environment. Such a proposal will not place any responsibility for industry to seek reduction or elimination of this chemical.<br>• This chemical has been categorized for carcinogenicity and genotoxicity. However, the assessment results assumed that there are safe human levels of exposure for this chemical. These objectives focus on concentration levels for cosmetic and consumer products rather than the outright prohibition of this substance in these products as well as industrial products.<br>• In fact, humans are exposed to a variety of other chemicals that are not fully accounted for in these assessments. In the process of considering safe levels of human exposure to a specific chemical, it becomes very problematic to ignore the possibility of the additive, cumulative | Rec.: We do note support the current risk management objectives for dimethyl sulphate as they do not fully protect human health from exposure.<br><br>Rec.: We urge the government to shift its risk management approach from establishing concentration levels for cosmetic and consumer products to a focus on prohibition of this substance in consumer and industrial products. |

| **Specific sections of risk management scope - diethyl sulphate (DMS) CAS RN 77-78-1** | **Proposed government measures & other measures** | **CELA & CSM Comments** | **Recommendations** |
|---|---|---|---|
| | | and synergistic effects from other toxic exposures. These effects are not considered in such assessments.<br>• The efforts to establish levels for safe human exposure becomes a subjective exercise that partially relies on the confidence level for the collected data (i.e., effectiveness of technology) and the commitment of decision makers and stakeholders to establish these levels. | |
| Section 9.1. Proposed risk management instrument | Add to Health Canada's Cosmetics Ingredient Hotlist | • We agree to the proposal to add dimethyl sulphate to the Cosmetics Ingredient Hotlist but as a banned substance. However,such a listing should be incorporated as part of a government strategy to phase out dimethyl sulphate in industrial and consumer applications. | Rec.: We support the addition of dimethyl sulphate to Health Canada's Cosmetics Ingredient Hotlist as a banned substance - as a residue or a contaminant. This listing should be part of a comprehensive plan to eliminate all sources of this substance including – pharmaceutical products, and industrial and consumer products. |
| Section 9.1. Proposed risk management instrument | The government is not proposing to add this substance to the *Environmental Emergency Regulations* at this time since quantities in Canada are below the threshold of 4500 kg set through the Risk Evaluation Framework for Sections 199 and 200 of CEPA 1999 (Environment Canada 2002b). | • Based on our review of the Risk Evaluation Framework for Section 199 and 200 of CEPA 1999, it remains unclear how the threshold of 4500 kg for this chemical was determined. Regardless of this threshold, this substance should be considered a candidate for environmental emergency plans based on its health impacts and the lack of flexibility in the government's proposal to account for the possibility of increase in volume in the future. Such plans support greater accountability to workers and the community.<br>• The government's current approach to dimethyl sulphate is not a prohibition and as such, there may be stockpiles of this chemical in facilities. The presence of stockpiles at the facility plants should provide additional justification for adding this substance under the Environmental | Rec.: The government should propose adding dimethyl sulphate to the Environmental Emergency Regulations based on its carcinogenicity. |

| Specific sections of risk management scope - diethyl sulphate (DMS) CAS RN 77-78-1 | Proposed government measures & other measures | CELA & CSM Comments | Recommendations |
|---|---|---|---|
| | | Emergency Regulations.<br>• The inclusion of emergency plans provides a response plan should accidents or spills occur, particularly for workers and the surrounding communities. | |

**Additional issues not addressed in Risk Management scope document for dimethyl sulphate**

There are a number of components that have not been included in the proposed Risk Management Scope document for dimethyl sulphate. In our view, the consideration of these issues is pertinent to effectively address concerns related to this toxic chemical.

**2) Absence of Imported products that may contain dimethyl sulphate**

There was a lack of consideration for the presence of dimethyl sulphate in imported products. Since Canada imports many products yearly, this gap could potentially increase the presence of the dimethyl sulphate hence a possible increase in human exposure.

**Rec.: We urge the government to require importers to provide a list of chemicals found in imported products, including those in residual concentrations. For those chemicals that are listed on Schedule 1 of CEPA, the government should prohibit the entry of any products containing any of these toxic chemicals. Though a difficult approach, it gives a more realistic view of human and environmental exposures particularly for products that have greater volumes of import as compared to domestic manufacture.**

**3) Lack of focus on prevention of release of dimethyl sulphate and other toxic chemicals in disposal sources (i.e., incineration, landfill, recycling)**

Despite the commentary we provided to government on the draft assessments for chemicals under the Industry Challenge outlining the need to investigate the fate of each chemical throughout its life cycle, there has been a lack of attention to the waste stream or end of life of a product that may contain these substances. In the case of dimethyl sulphate, which is generally a residue or contaminant in products, its bioavailability has not been adequately addressed. The lack of consideration of this factor may have significant impacts on the behaviour of this chemical in waste streams.

We recognize that this chemical hydrolyzes rapidly and in the case of waste streams, if released directly, this chemical can affect the pH levels in the waste stream. This

change in pH levels may pose a problem to the environmental medium (i.e. soil, sediment). While the level of change depends on the quantity of the chemical released, temperature and other physical and chemical properties, the assessment fails to provide such information. The inclusion of such information will inform the development of an effective management regime on CEPA toxic chemicals.

Similarly, information on the rate of leaching from these chemicals in landfills or the production of by-products from incineration processes should also be evaluated when completing assessments. Again, these issues have not been adequately addressed. Finally, some consideration and effort should also be directed to assessing the impacts of recycling products that may contain toxic substances.

**Rec.: The government should provide adequate information investigating the fate of this chemical in waste streams.**

**Rec.: We urge the government to ensure that management measures include a prohibition on the incineration of products or waste stockpiles containing dimethyl sulphate because they may be a source for the formation of other toxic by-products such as dioxins, heavy metals and particulates, to name a few.**

**Rec.: The government should investigate the recycling of products that contain these substances and ensure that dimethyl sulphate is not permitted in the final recycled products.**

### 3) Adequate reporting under NPRI to the public on releases and transfers

As noted with diethyl sulphate, the risk management scope document for dimethyl sulphate has provided no additional proposals to improve reporting on the releases of this substance under the National Pollutant Release Inventory. Although dimethyl sulphate is on the list of substances that are reported under NPRI, the threshold for reporting to the federal inventory is high. The government should consider removing the reporting threshold for all CEPA toxic substances, including dimethyl sulphate. This would ensure that all facilities releasing or transferring dimethyl sulphate would be required to report annually. To date, the government has been slow to make adequate reforms to the NPRI regarding the chemicals targeted under the CMP and the NPRI Work Group. This Work Group investigates potential changes to the program but has not been mandated to undertake this work.

**Rec.: For all CEPA toxic chemicals, including dimethyl sulphate, the reporting requirements under NPRI should be lowered to ensure that all releases and transfers of these substances are reported.**

### 4) Lack of Pollution Prevention (P2) focus

As noted for diethyl sulphate, many of the risk management proposals on CEPA toxic chemicals to date have been focused on minimizing release and exposure to these chemicals rather than supporting a preventative approach. The proposals for dimethyl

sulphate follow a similar approach. NGOs have urged for a more comprehensive and preventative approach to chemicals that are found to be CEPA toxic. The government proposals have yet to address these recommendations.

One area where the government proposals have been significantly lacking is the requirement for pollution prevention plans on these substances. In our view, mandatory preparation of pollution prevention plans would represent concrete steps to identify areas of efficiency and innovation. In the process, industry may evaluate and consider the potential substitutes for these chemicals. These are tools that are required in CEPA but have yet to be utilized to their full extent in the promotion of phase out of the most toxic chemicals in Canada. Such plans should be part of a comprehensive strategy for Canada to phase out the use of dimethyl sulphate.

To provide additional support for pollution prevention efforts, it would be relevant for government to require reporting of pollution prevention activities under the National Pollutant Release Inventory. It is unclear how many reporting facilities undertake and report pollution prevention activities under NPRI but NPRI does provide unique opportunities to outline pollution prevention strategies being undertaken by facilities across Canada. However, to make this information useful, the government should seek to make the appropriate linkages to the other pollution prevention commitments under CEPA.

**Rec.: We urge the government to require the use of pollution prevention plans as part of a comprehensive plan aimed to phase out CEPA toxic chemicals, including dimethyl sulphate.**

**Rec.: The government should require mandatory reporting of pollution prevention activities under NPRI for all pollutants, particularly CEPA toxic substances.**

## *c) Benzenamine, N-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene(BNST) (CAS RN 68921-45-9)*

Our specific comments on the final assessment results and proposed management measures for Benzenamine, N-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene (BNST) (CAS RN 68921-45-9) are provided in table 4.

## Table 4: Benzenamine, N-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene (BNST) (CAS RN 68921-45-9) - Comments and recommendations to specific risk management proposals

| Specific sections of risk management scope - Benzenamine, N-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene - BNST CAS RN 68921-45-9 | Proposed government measures & other measures | CELA & CSM Comments | Recommendations |
|---|---|---|---|
| Section 1.3. Proposed measure | • It is proposed for the Ministers to recommend the addition of BNST to the List of Toxic Substances in Schedule 1.<br>• BNST meets the virtual elimination criteria set out in subsection 77(4) of CEPA 1999<br>• Ministers will develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to BNST. | • Based on the results of the screening level risk assessment on BNST, this chemical should be found to be toxic under CEPA and should be added to the Schedule 1 (Toxic Substances List) under CEPA.<br>• Government's finding that BNST meets the criteria for virtual elimination is supported, however, we urge the government to seek a phase out of this substance based on the volume manufactured and imported into Canada.<br>• Since this chemical meets the virtual elimination criteria, the government has the option to include it on the virtual elimination list. While we would support the inclusion of the chemical on the list, the need to establish a level of quantification to manage BNST is too limiting and simply represents a control measure. Based on its properties, the government proposal to seek the prohibition and phase out of this substance is an appropriate regulatory response.<br>• As noted for other CEPA toxic chemicals and in particular, those chemicals that are persistent, bioaccumulative and inherently toxic, the government response should be undertaken with a regulatory foundation and aim to phase out BNST. At the same time, the government should | Rec.: We support the addition of BNST to Schedule 1 (Toxic Substances List).<br><br>Rec.: We support the listing of BNST for virtual elimination. However, such a listing should not be dependent on establishing a level of quantification. The management goal for this substance should aim for a prohibition and phase out based on its toxicity and high volume usage. |

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| | | promote the use of alternates to support the regulatory measures.<br>• The consideration of a non-regulatory instrument would be inadequate to fully protect human health and the environment particularly for chemicals that are persistent and bioaccumulative and which may result in long term impacts to the environment and wildlife populations. | |
| Section 7.1. Alternative chemicals or substitutes | Some possible alternatives have been listed but cost was a major factor with one of the more suitable alternatives. | • For the listed possible alternatives to BNST, there are several issues such as cost for implementation as well as human health or environmental concerns which should be further discussed. The report provides some details on the cost but does not discuss the cost associated with the impacts to human health or the environment associated with the continued use of BNST.<br>• While cost may be high for these alternatives, in our view that should not be the determining factor for not considering or using alternatives particularly because of the toxicity of BNST. The long term cost to the environment and to human health may be significant. Safety to environment and human health should be the priority over cost.<br>• If an alternative is safer and does not possess the toxicity of BNST, the use of alternatives should be employed. To support this, a rigorous screening for health and environmental effects of any alternatives should be undertaken. | Rec.: Based on its high production and import volume, the use of substitutes is an important component in support of a phase out of BNST.<br><br>Rec.: All possible substitutes for BNST should be identified and assessed for their safety under CEPA prior to consideration as a substitute for BNST.<br><br>Rec.: To support the efforts on alternatives, the government should establish a multi-stakeholder task force to review and assess the safety of alternatives. This task force should include participation by government, industry, environmental and health organizations, labour, and indigenous communities. |
| Section 7.1. Alternative chemicals or substitutes | Some of the alternatives (diarylamines) met the | • Many of the alternatives listed in the risk management scope document are part of the same family of | Rec.: We urge the government not to replace BNST with |

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| | criteria for categorization under the Chemicals Management Plan (for environmental concerns). While some alternatives did not meet the categorization criteria, they were identified as being a priority for human health assessment. Other potential alternatives did not meet the categorization criteria but there was some uncertainty associated with the criteria. All potential alternatives are in the substituted diphenylamine family, and could be subject to a screening assessment at some point in the future. | chemicals (diphenylamine). A few of these chemicals have met the categorization criteria (human health priority) and are expected to be assessed in the future, while the other three chemicals have very uncertain data. This knowledge is very valuable as it demonstrates the gaps that currently exist in the CMP framework – its focus on a chemical by chemical approach.<br>• The assessment should have covered all these substances in the assessment or included a substantial evaluation on the additive, cumulative and synergistic impacts of chemicals of the same family of chemicals. The use and application of these chemicals may be similar if some modification on reformulation is undertaken. We are very concerned that the government will support the on-going use of the vast number of chemicals with potential hazards as noted for the dipheylamines. | substances from the same family of chemicals (diphenylamines) because they may exhibit similar toxic properties. In reformulating, the use patterns are expected to be the same.<br><br>Rec.: We urge the government to undertake an additional data call in using section 71 (1) (c) to require industry to provide toxicity data for all the possible alternative chemicals that are in the same chemical family to demonstrate that they do not affect the environment or human health. In particular, information to demonstrate these alternatives are not endocrine disruptors or neurodevelopmental toxicants is appropriate.<br><br>Rec.: All alternatives should be screened for their safety to confirm that they do not have toxic properties. |
| Section 7.2. Alternative Technologies and/or Techniques | Due to the hydrophobic nature of BNST, it will partition to organic liquids and, as a result, will likely remain present in any waste lubricant that is present in any commercially or industrially generated wastewater. Any wastewater treatment | • This section does not provide the information focused specifically on the alternative technologies and/or techniques available. The report noted that this information was not supplied by industry.<br>• While the report noted that treatment plants that have the capacity to remove free waste oil may also remove BNST, the report doesn't indicate the percentage of | Rec.: We urge the government to expand their efforts to identify and promote technologies and techniques that prevent the use and release of BNST to the environment.<br><br>Rec.: Similar to the approach required to assess the safety of |

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| | that includes removal of free waste oil also removes additives such as BNST (OECD 2004). | municipalities or facilities in Canada that will have this capacity.<br>• Not all waste water treatment plants have the capacity to remove BNST or similar substances. Therefore, it would be misleading for the government to suggest a management regime that considers wastewater treatment plants as adequate in addressing this persistent, bioaccumulative substance. First, treatment plants are control measures and may not prevent the release of this substance to the environment. Second, the cost associated to upgrade treatment plants to address BNST and other toxic chemicals may be prohibitive.<br>• While the data suggest the estimated releases of these substances to the environment are considered low, the potential of spills, other accidents and the presence of possible stockpiles have not been fully discussed in the assessment report. Substances like BNST increase in concentration over time even if releases are at low levels. Based on the high volume of this chemical, some attention to this is required. | alternatives, it is important to undertake an assessment of available alternative technologies and/or techniques to ensure that they do not produce other toxic chemicals or pose a hazard to the environment or health. |
| Section 7.4. Children's exposures | It is proposed that no risk management actions to specifically protect children are required for BNST at this time. | The lack of information received through the industry challenge should not make the assumption that this substance is safe and has no health effects on children.<br><br>• The government should use its authority under section 71 (1)(c) to | Rec.: We urge the government to take precautionary actions to protect vulnerable populations, including children, from exposure to BNST.<br><br>Rec.: Require |

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| | | require mandatory testing data from industry in this regard. Industry should be required to demonstrate the safety of its chemicals. The collection of data on children's exposure in the Industry Challenge is not mandatory and is very general in scope.[3] This effort should be made mandatory through a survey under section 71 of CEPA. A call for specific toxicity data such as neurodevelopmental toxicity and endocrine disruption potential should be required as part of this effort. This information should be included in the assessment process. | government to use section 71 for mandatory reporting by industry to investigate effects of BNST on children. This should replace the voluntary questionnaire currently applied. |
| Section 8.1. Environmental objective | • The environmental objective for BNST is virtual elimination (VE).<br>• Under section 77, BNST be added to the Virtual Elimination List.<br>• For BNST, a level of quantification (LoQ) shall also be specified as per section 65 which will indicate the lowest concentration that can be accurately measured using sensitive but routine sampling and analytical methods. | • We agree that the environmental objective for BNST is virtual elimination with the addition of BNST to the Virtual Elimination List.<br>• However, the requirement for establishing a limit of quantification as required under CEPA is very limiting and will not result in the elimination of this substance. Rather the focus will be a control measure that will permit the on-going manufacture and use of BNST. The focus on managing the risk does not provide sufficient incentive for innovation but rather seeks methods that simply reduce the emissions to meet the level of detection.<br>• A more preferred approach is a phase out of this substance to ensure that sources of BNST are stopped. | Rec.: We support the listing of the BNST for virtual elimination for the purposes of a phase out.<br><br>Rec.: We do not support the need to establish a limit of quantification for BNST because it supports a control measure. Rather, a prevention approach is recommended for BNST. |
| Section 8.2. Risk management objective | The proposed risk management objective is to achieve the lowest | • As noted in the previous section, we seek to promote the phase out of BNST because of its high | Rec.: We urge the government to phase out BNST. We do not support |

[3] See: Challenge Questionnaire **section. 5.3.3** Children's exposure to products at http://www.ec.gc.ca/substances/ese/eng/challenge/batch4/batch4_challenge_questionnaire.cfm

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| | level of release of BNST to the environment that is technically and economically feasible from all life-cycle stages. | production volume and imports into Canada. The reliance on technology to determine the level of quantification is not adequate to protect human health and the environment from this substance. While the substance may be released below the level of detection, the persistence and bioaccumulative nature of BNST may result in increased levels in the environmental media due to continuous use of this substance.<br>• Further, if one focuses on eliminating the source by using safer alternatives or technology, the concern regarding each phase of the life cycle of the chemical is unnecessary. Attempting to achieve the lowest level of release will require monitoring leakages and emissions of this chemical from each phase of the life cycle thereby promoting the on-going use of this chemical. This approach would also need to consider the emissions of other toxic chemicals throughout the process. Currently, the approach does not take this into account. | the current proposal which aims to achieve the lowest level of release of BNST since it would result in the continuous use and release of this persistent, bioaccumulative chemical. |
| Section 9.1. Proposed risk management instrument | Proposal that BNST to be added to the *Prohibition of Certain Toxic Substances Regulations, 2005* in order to prohibit the use, sale, offer for sale and import of BNST and products or formulations containing BNST. | • There is agreement that BNST be added to *the Prohibition of Certain Toxic Substances Regulations, 2005* in order to prohibit the use, sale, offer for sale and import of BNST and products or formulations containing BNST. This proposal will demonstrate a significant step towards phase out.<br>• The above proposal however, will not address three significant areas of concern: the continuation of manufacture of BNST in Canada; export of BNST from Canada to other countries; and the presence of BNST stockpiles. Each of these | Rec.: We support the addition of BNST on the *Prohibition of Certain Toxic Substances Regulations, 2005*. However, such a prohibition should also include the manufacture and export of BNST.<br><br>Rec.: We urge the government to develop a workplan that focuses on the complete destruction of stockpiles of BNST. |

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| | | requires the government's attention.<br>• As we have seen with the export of asbestos, countries that receive these exports may not have the regimes in place to address BNST.<br>• In our efforts on addressing persistent organic pollutants, there is sufficient documentation to demonstrate that stockpiles of persistent bioaccumulative chemicals should be effectively addressed with an aim to eliminate these chemicals.<br>• In this regard, we seek an expansion of the proposed prohibition to include these three areas and establish a workplan for the complete destruction of BNST. We are not in agreement with any proposal that would recommend the continued manufacture of BNST in Canada. | |
| Section 9.1.<br>Proposed risk management instrument | BNST to be considered for addition to the *Environmental Emergency Regulations* if manufacturing activities involving BNST continue to be permitted. | • Regardless of whether BNST is added to the list of Prohibition of Certain Toxic Substances, the addition of this chemical to the *Environmental Emergency Regulations* is warranted. In particular, a prohibition will mean that stockpiles of the chemical may continue to exist. Workplaces and communities should have appropriate plans in place should an accident occur. | Rec.: Add BNST to the Environmental Emergency Regulations, specifically to address potential stockpiles of BNST. |
| Section 9.2.<br>Other information gathering/research | BNST will be monitored in municipal wastewater, sediment and biota, as part of the Chemicals Management Plan monitoring program. Resulting data will indicate to the federal | • There is agreement that a monitoring plan, as specified, is essential in order to determine if levels are changing as a result of the management regime.<br>• Given that the monitoring regimes are not yet developed, there is significant concern that regular monitoring (annual, biennial, etc.) | Rec.: We support the monitoring regime for BNST with qualifications that monitoring should not stall the need to phase out BNST.<br><br>Rec.: The government should ensure that the |

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| | government the releases of BNST to the environment. | may not be planned, air monitoring could be excluded or may be monitored in only selected locations. The monitoring regime should outline the timeframe and frequency of monitoring to be undertaken. In addition, the government should provide a roadmap on how the monitoring data will be used for policy development.<br>• We are concerned that the government will utilize the monitoring program to justify a regime focused on control measures only and use the collected data to review current activities on BNST (including manufacturing) in Canada. | monitoring regime is designed with explicit timeframes, locations, frequencies and environmental media. |

## Additional issues not addressed in the Risk Management Scope document for BNST

### 1) Adequacy of Management Regime for used crankcase oil

The Priority Substances List assessment conducted on used crankcase oil concluded that these emissions are toxic under CEPA. However, no explicit management regime for crankcase oil was proposed, instead there is reliance on existing provincial and federal initiatives. In our view, the RM scope document does a very poor job explaining the management regimes that exist. It simply mentions them. In reality, the government's position that the "main reasons for initiating controls were the leachable amounts of lead, PAHs and chlorinated hydrocarbons in the used oils, especially given the large volumes of used oils in circulation"[4]. With the identification of BNST present in used crankcase oils, we should question the adequacy of the current approach. We seek a comprehensive approach on crankcase oil to accommodate additional toxic chemicals such as BNST and other

[4] Environment Canada. August 2005. *Follow-up Report on a PSL1 Substance For Which There Was Insufficient Information to Conclude Whether the Substance Constitutes a Danger to the Environment - Waste/Used Crankcase Oil*s . See http://www.ec.gc.ca/CEPARegistry/documents/subs_list/LSIP1-PSL1/p5.cfm

toxic chemicals in the Petroleum Stream yet to be evaluated in the Industry Challenge.

**Rec.: The management regime on used crankcase oil should be strengthened to ensure that all persistent bioaccumulative toxic chemicals, including BNST are not released to the environment.**

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