

Summary of Public Comments received on the Challenge substance Solvent Red 49 (CAS 509-34-2) Draft Screening Assessment Report for Batch 9

Comments on the draft screening assessment report for Solvent Red 49 to be addressed as part of the Chemicals Management Plan Challenge. Comments were provided by Dow Chemical Canada.

A summary of comments and responses is included below, organized by topic:

- Surrogates
- Significant New Activities

TOPIC	COMMENT	RESPONSE
Surrogates	In the draft risk assessment no health concerns were raised with solvent red 49 itself but it is noted that the read-across surrogate rhodamine B did have some health issues flagged. Why are concerns raised for a surrogate automatically extended to the substance in question without thorough analysis?	The draft risk assessment does not indicate that there were no health concerns for solvent red 49. It proposes that there is a low risk due to low exposure to the general population of Canada. In the absence of Solvent Red 49 toxicological information, rhodamine B information was used as it is considered toxicologically equivalent under physiological conditions.
Significant New Activities	Solvent Red 49 is not an environmental concern and not a health concern, therefore it should not be considered toxic under CEPA section 64 and no further action should be taken.	As proposed in the draft assessment report, under the current use patterns, Solvent Red 49 does not meet the criteria under section 64 of CEPA 1999. However, there is the potential that changes in the use pattern of Solvent Red 49 could lead to health concerns; therefore, the Significant New Activity (SNAC) provisions are considered to be the appropriate action for this substance. The application of the SNAC provisions under CEPA 1999 would require that any proposed new manufacture, import or use be subject to further assessment, and would determine if the new activity requires further risk management consideration. The SNAC provisions will prevent any new activity in relation to Solvent Red 49 that may result in it meeting the criteria set out under section 64.
	Should a substance properly listed on the DSL be subject to a SNAC if the substance has no	The Challenge is designed to evaluate risks associated with substances listed on the <i>Domestic Substances List</i> (DSL). In some

	unacceptable risks identified?	<p>cases, a SNAC will be applied after evaluations of these substances. This is done in situations in which changes in use patterns (such as new uses, or changes in the quantities used) could have the potential to increase exposure to the substance, and consequently, increase the risk the substance poses to human health or the environment.</p> <p>Solvent Red 49 is not believed to be entering the environment in a quantity or concentration or under conditions that have a harmful effect or constitute a danger to the environment or human health. However, given the hazardous properties of this substance, there is concern that new activities which have not been identified or assessed could lead to the substance causing harm in Canada to human life or health.</p>
	Should substances in commerce in low quantities (e.g, below the Challenge S. 71 notice thresholds) be subject to a SNAC or should usage at or below this threshold be considered "safe"?	Each substance presents different potential hazards to human health and the environment. In addition, each use presents different potential hazards to human health and the environment and therefore inherent hazard and actual exposure of a substance are considered when designing a SNAC. For many substances, activities (including manufacturing, import, or use) below certain thresholds, such as the Challenge S.71 notice thresholds, will not be subject to a SNAC. However, for other substances, lower thresholds for activities may be applied depending on the chemical, physical, or toxicological properties (i.e. hazard) and use patterns of the substance.
	If a threshold of 100 kg/yr (or of more concern, a zero threshold) is specified; instant non compliance with an immediate disruption in commerce can result. This type of action can have significant impact on society in Canada especially if current actions are being undertaken in good faith.	Any stakeholders importing or manufacturing more than 100 kg or using more than 1000 kg are required to report under section 71, and their activity would be addressed under the SNAC. Any stakeholders not subject to the section 71 notice because they fall below the reporting thresholds are strongly encouraged to self-identify at that time as well and to inform the Government of Canada of their activities relating to substances by responding to the Challenge Questionnaire. Regardless of whether the information is provided on a voluntary basis or as a requirement

		<p>under s. 71, if the Government has a better understanding of the use profile of a substance, the Notice of Intent (NOI) to SNAc will more accurately reflect use patterns. If a particular use is not identified during the formal information gathering phase, stakeholders have opportunities to inform the government of their activities after the publication of the draft Screening Assessment Report (dSAR) (and RM Scope and RM Approach documents, if applicable) as well as after the publication of the NOI to SNAc. It is important to note that the publication of the NOI to SNAc does not result in instant non compliance. There is a 60-day comment period, within which additional uses may be disclosed. Any comments received would be considered in the development of the final order to apply the SNAc provisions to the substance.</p> <p>The government will issue a 60-day public comment period on the notice of intent to impose the Significant New Activity provisions to Solvent Red 49 on September 18, 2010.</p>
	<p>The requirement to submit a Schedule 6 report is a challenge. A Schedule 6 is a full New Substance Notification (NSN) registration package with a complete set of data and studies. This could be prohibitively expensive and time consuming, thereby preventing the use of a DSL substance. Immediately requiring a Schedule 6 does not align with the approach used in the NSN regime where increasing information and data is used as greater volumes are imported or manufactured.</p>	<p>The Government of Canada acknowledges that the requirement to submit a Schedule 6 report is a challenge. The data requirements for each substance are determined at the time of creation of the SNAc to reflect the information that already is available in the public domain. In the case of Solvent Red 49, it will be proposed that only partial Schedule 6 reports will be required since some information requested on Schedule 6 is already available to Government of Canada scientists.</p>
	<p>As it was disclosed that Solvent Red 49 is in commerce, is a SNAc required in the first place? If so, can the SNAc be tailored to recognize non-emissive or captive uses when created and implemented. Alternatively can a Ministerial Order be put in place allowing the current specific use(s) and establishing requirements for reintroduction in greater quantities in other uses?</p>	<p>Because of the potentially hazardous properties of Solvent Red 49 a SNAc is required even though it was disclosed that Solvent Red 49 was being used below the reporting threshold. The SNAc is proposed to exempt current uses in registered pest control products; and to require disclosure for all other activities above 100 kg/yr. Any proposed new manufacture, import or use will be subject to further assessment that would determine if the new activity requires further risk management consideration. Affected</p>

		stakeholders are encouraged to provide comments on the Notice of Intent.
	Stakeholders impacted should be consulted in the policy framework for Solvent Red 49 actions and consulted in the drafting of an applicable SNAc. If risk management is needed, the SNAc should be written to recognize existing uses in heat transfer fluids as colouring agents as acceptable. These applications are captive and non-emissive and as such have little to no risk to the environment or human health.	Consultation with stakeholders is an essential part of any risk management process. The Government of Canada encourages those impacted by a SNAc provision for Solvent Red 49 to provide comments during the public comment period that follows the publication of the Notice of Intent to apply SNAc provisions on Solvent Red 49.
	<p>Another option for risk management is to consider the creation of SNAc Regulations under Section 89(1)(k), that could specify exemptions or alignment as per the New Substance Notification Regulations. This could remove the circumstances where SNAcs seem to be or are in conflict with the intent and practice of the New Substances Notification Regulations.</p> <p>This would also remove the perception that a substance is being banned or prohibited by the imposition of a zero or minimal threshold.</p>	Any exemptions for reporting and the data requirements for each substance are determined at the time of creation of the SNAc to reflect the assessment report as well as the information that already is available in the public domain. In the case of Solvent Red 49, it will be proposed that only partial Schedule 6 reports will be required.