

DEPARTMENT OF THE ENVIRONMENT

CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

Significant New Activity Notice No. 16521

Significant New Activity Notice

(Section 85 of the *Canadian Environmental Protection Act, 1999*)

Whereas the Minister of the Environment and the Minister of Health have assessed information in respect of the substance tall oil acids, reaction products with dialkylenamine and acid anhydride, compounds with polyalkylene glycol hydrogen maleate alkyl ethers, under section 83 of the *Canadian Environmental Protection Act, 1999*;

Whereas the substance is not specified on the *Domestic Substances List*;

And whereas the ministers suspect that a significant new activity in relation to the substance may result in the substance becoming toxic within the meaning of section 64 of the *Canadian Environmental Protection Act, 1999*,

Therefore, the Minister of the Environment indicates, pursuant to section 85 of the *Canadian Environmental Protection Act, 1999*, that subsection 81(4) of that Act applies to the substance in accordance with the Annex.

PETER KENT
Minister of the Environment

ANNEX

Information Requirements

(Section 85 of the *Canadian Environmental Protection Act, 1999*)

1. In relation to the substance tall oil acids, reaction products with dialkylenamine and acid anhydride, compounds with polyalkylene glycol hydrogen maleate alkyl ethers, a significant new activity is the use of the substance in Canada, in any quantity,
 - (a) in a personal care product; or
 - (b) in a consumer product where the substance is not adsorbed to or chemically reacted with pigments or other substrates in the product.
2. The following information must be provided to the Minister at least 90 days before the commencement of each proposed significant new activity:
 - (a) a description of the proposed significant new activity in relation to the substance;

- (b) the information specified in Schedule 9 to the *New Substances Notification Regulations (Chemicals and Polymers)*;
- (c) the information specified in item 5 of Schedule 10 to those Regulations;
- (d) the test data specified in paragraphs 11(3)(a), (b) and (c) to those Regulations;
- (e) the test data and the test report from a skin sensitization study in respect of the substance that establishes the concentration of the substance that will generate the minimal dose that will induce a stimulation of proliferation in draining lymph nodes that is threefold the negative control (EC₃ value), conducted according to the methodology described in the Organisation for Economic Co-operation and Development (OECD) Test Guideline No. 429 (Test Guideline) titled *Skin Sensitisation: Local Lymph Node Assay*, and in conformity with the practices described in the *OECD Principles of Good Laboratory Practice (Principles of GLP)* set out in Annex 2 of the *Decision of the Council Concerning the Mutual Acceptance of Data in the Assessment of Chemicals*, adopted on May 12, 1981, and where both the Test Guideline and Principles of GLP are current at the time the test data are developed; and
- (f) all other information or test data in respect of the substance that are in the possession of the person who intends to use the substance for the proposed significant new activity, or to which they have access, and that are relevant to determine whether the substance is toxic or capable of becoming toxic.

3. The above information will be assessed within 90 days after the day on which it is received by the Minister.

EXPLANATORY NOTE

(This explanatory note is not part of the Significant New Activity Notice.)

A Significant New Activity Notice is a legal instrument issued by the Minister of the Environment pursuant to section 85 of the *Canadian Environmental Protection Act, 1999*. The Significant New Activity Notice sets out the appropriate information that must be provided to the Minister for assessment prior to the commencement of a new activity as described in the Notice.

Substances that are not listed on the *Domestic Substances List* can be manufactured or imported only by the person who has met the requirements set out in section 81 of the *Canadian Environmental Protection Act, 1999*. Under section 86 of the *Canadian Environmental Protection Act, 1999*, in circumstances where a Significant New Activity Notice is issued for a new substance, it is the responsibility of every person who transfers the physical possession or control of the substance to notify all persons to whom the possession or control is transferred of the obligation to comply with the Significant New Activity Notice and of the obligation to notify the Minister of the Environment of any new activity

and all other information as described in the Notice. It is the responsibility of the users of the substance to be aware of and comply with the Significant New Activity Notice and to submit a Significant New Activity notification to the Minister prior to the commencement of a significant new activity associated with the substance. However, as mentioned in subsection 81(6) of the *Canadian Environmental Protection Act, 1999*, a Significant New Activity notification is not required when the proposed new activity is regulated under an act or regulations listed on Schedule 2 to the *Canadian Environmental Protection Act, 1999*.

A Significant New Activity Notice does not constitute an endorsement from Environment Canada or the Government of Canada of the substance to which it relates, or an exemption from any other laws or regulations that are in force in Canada and that may apply to this substance or activities involving the substance.