

Canadian Environmental Protection Act, 1999

**Follow-up Report on a PSL1 Substance for which there was
insufficient information to conclude whether the substance
constitutes a danger to human health
Chlorinated Paraffins**

October 2003

Synopsis

Short-chain chlorinated paraffins (SCCP) are imported into Canada for use as additives in extreme-pressure lubricants, plasticizers and flame retardants. Medium- and long-chain chlorinated paraffins (MCCP and LCCP, respectively) are produced in, and imported into, Canada for similar uses.

Chlorinated paraffins were included on the first Priority Substances List (PSL1) under the 1988 *Canadian Environmental Protection Act* (CEPA 1988) for assessment of potential risks to the environment and human health. As outlined in the Assessment Report released in 1993, relevant data identified before August 1992 were considered insufficient to conclude whether

MCCP and LCCP were “toxic” to human health as defined in Paragraph 11(c) of CEPA 1988. As also outlined in the Assessment Report released in 1993, SCCP were considered to be “toxic” as defined under Paragraph 11(c) of CEPA 1988. This conclusion was based principally on the observed carcinogenicity of these compounds, for which available information on mode of action could not preclude it being the result of direct interaction with genetic material. To set context for the update on MCCP and LCCP, more recent data on the effects of SCCP on human health have also been considered here, and the conclusion under Paragraph 11(a) of CEPA 1988 has been updated.

For SCCP, critical data relevant to both estimation of exposure of the general population in Canada and assessment of the weight of evidence for the mode of induction of specific tumours were identified following release of the PSL1 assessment and prior to February 2001, although most of this information has been reported in incomplete published summary accounts or abstracts. These data suggest that several tumours observed in carcinogenicity bioassays in rats and mice exposed to SCCP are induced by modes of action either not relevant to humans (kidney tumours in male rats) or for which humans are likely less sensitive (in rats, liver tumours related to peroxisome proliferation and thyroid tumours related to thyroid–pituitary disruption). Additional documentation of available studies and consideration in additional investigations of the reversibility of precursor lesions in the absence of continued exposure is desirable. However, reported data on mode of induction of tumours in addition to the weight of evidence that SCCP are not DNA reactive are at least sufficient as a basis for consideration of a Tolerable Daily Intake (TDI) for non-cancer effects as protective for carcinogenicity for observed tumours.

Upper-bounding estimates of daily intake of SCCP approach or exceed the TDI for these compounds, which, on the basis of available information, is likely also protective for carcinogenicity.

Therefore, the Ministers of the Environment and of Health confirm that short-chain chlorinated paraffins are “toxic” to human health as defined in Paragraph 64(c) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

For MCCP and LCCP, critical data relevant to both estimation of exposure of the general population in Canada and assessment of effects were identified following release of the PSL1 assessment and prior to December 2000. Based upon these semi-quantitative data, upperbounding estimates of daily intake for MCCP and LCCP are within the same order of magnitude of, or exceed, the TDIs for these compounds.

Therefore, it is proposed that there is reason to suspect that medium- and longchain chlorinated paraffins are “toxic” to human health as defined in Paragraph 64(c) of the *Canadian Environmental Protection Act, 1999 (CEPA 1999)*.

Acquisition of data on levels of these compounds (SCCP, MCCP and LCCP) within foodstuffs in Canada continues to be considered a high priority.