

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

TO: Ethoxylated castor oil file (CAS # 61791-12-6)

FROM: Gary Butterfield

SUBJECT: Withdrawal of screening level for ethoxylated castor oil

DATE: March 16, 2007

An initial threshold screening level (ITSL) of 0.1 ug/m³ annual average for ethoxylated castor oil was established on 1/25/1994, updated on 11/10/1998. This current evaluation includes an updated literature review and reassessment of the original ITSL.

Ethoxylated castor oil is also known by many manufacturer names, cremophor EL, emulphor, alkamuls, and others. There is some variability in the make up of chemicals in the CAS number 61791-12-6, as the amount of the ethoxylation can vary. The cremophor EL has 35 moles of ethoxylation per mole of castor oil. This particular ethoxylated castor oil is widely used as a surfactant for intravenous medicines to assist in making the less water soluble more waterborne. In many of these intravenous solutions the ethoxylated castor oil makes up 50% of what is administered. These ethoxylated castor oil materials are also used in many cosmetics taking advantage of the surfactant ability and low toxicity.

Castor oil is comprised of approximately 90% ricinoleic acid (CAS # 141-22-0), with the remaining made up of palmitic acid, stearic acid, or oleic acid. The molecular weight of ricinoleic acid is 298 g/mol. The molecular weight, as well as, many of the chemical and physical properties of the ethoxylated castor oil depends on how many ethoxy's are added. Generally, the molecular weight is approximately 430 g/mol. This material is a yellow liquid at ambient temperatures. The melting point is 5C. The boiling point is 313C. The vapor pressure is not known, but is expected to be quite low, with some reports of this material being not volatile.

The following references or databases were searched to identify data to determine the screening level: U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS), National Institute for Occupational Safety and Health (NIOSH) Registry for Toxic Effects of Chemical Substances (RTECS), American Conference of Governmental and Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), Michigan Department of Environmental Quality (DEQ) library, International Agency for Research on Cancer (IARC) Monographs, Chemical Abstract Service (CAS) Online (1968 - Jan 2007), National Library of Medicine (NLM) - Toxline, and National Toxicology Program (NTP) Status Report.

The on-line CAS and NLM literature searches were conducted on January 18, 2007. There is surprising little published toxicity data on this widely used material. Many exposures are via the intravenous or intraperitoneal route of exposure, which are not usable for calculation of a screening level. There are no inhalation exposure studies. There are a limited number of oral or dermal exposure studies. This material has been used as a vehicle control in most of the toxicity studies that were located. These particular studies were not actually toxicity studies of ethoxylated castor oil.

There are several secondary references, one of which is CIREP (1997), that indicate the oral LD50 for this material is in the range of 5 to 15 g/kg. In some of these secondary references, there are also summary reports of unpublished, industrial sponsored studies of various durations. Several 90-day feeding studies reported no adverse effects at doses as high as 5% of the diet.

Possible ways to calculate ITSL:

Oral LD50 of 5 g/kg	use 232(1)(h)	17 ug/m ³ = ITSL
Oral LD50 of 15 g/kg	use 232(1)(h)	50
90-day 5% of diet NOAEL	use RfD methodology	13600

The particulate matter national ambient air quality standard (PM10 and PM2.5 NAAQS) need to be considered when evaluating impacts of ethoxylated castor oil. Due to ethoxylated castor oil low volatility, the airborne exposure concern is primarily for aerosols, or particulate matter. The available data suggest that a health based screening level would most likely exceed some or all of the various PM NAAQS if it were based only on the oral toxicity data. Considering this finding and the physical properties of ethoxylated castor oil, the available data are not adequate to establish an ITSL. Furthermore, the data suggest that the existing ITSL of 0.1 ug/m³ is not appropriate, and that emissions of ethoxylated castor oil evaluated in context of the various particulate matter NAAQS should provide adequate protection of public health. Therefore, the existing ITSL for ethoxylated castor oil will be withdrawn, but site specific conditions and emissions need to be evaluated to ensure the NAAQS are not being exceeded.

References:

Cosmetic Ingredient Review Expert Panel (CIREP). 1997. Final report on the safety assessment of PEG-30, -35, -36, and -40 castor oil and PEG-30, and -40 hydrogenated castor oil. Int J Toxicol 16: 269-306.

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