

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

November 10, 1998

TO: File for cytarabine (CAS #147-94-4)

FROM: Cathy Simon, Supervisor, Toxics Unit, Air Quality Division

SUBJECT: Change in the Initial Threshold Screening Level (ITSL)

The ITSL for cytarabine has been changed from 0.04 ug/m³ to 0.1 ug/m³ based on an annual averaging time.

The change in the ITSL was made due to a revision in the State's air toxic rules which became effective on November 10, 1998. Previously, the ITSL had been set pursuant to Rule 232(i). This rule sets the ITSL at a default value of 0.04 ug/m³ (annual average) when no specific data are available to determine an ITSL. The November 10, 1998 revisions to the rules changed this default ITSL to a value of 0.1 ug/m³.

No updated review of the literature has been done since the ITSL was originally set at a value of 0.04 ug/m³, to determine if new data are available for this compound.

CAS:SLB

MICHIGAN DEPARTMENT OF NATURAL RESOURCES

INTEROFFICE COMMUNICATION

September 30, 1993

TO: File for Cytarabine (CAS No. 147-94-4)

FROM: Marco Bianchi

SUBJECT: Initial Threshold Screening Level

The initial threshold screening level (ITSL) for cytarabine is 0.04 $\mu\text{g}/\text{m}^3$ based on an annual averaging time.

The following references or databases were searched to identify data in determining an ITSL: IRIS, HEAST, RTECS, NTP Management Status Report, CAS-online, NLM-online, IARC, EPBCCD, EPB library, NIOSH Pocket Guide, and ACGIH Guide to Threshold Limit Values.

Cytarabine is an anticancer agent used alone or in combination with other drugs for cancer therapy. A CAS- and NLM-online search provided an abundance of clinical information about this drug. Dose associated toxicity in cancer patients included, myelotoxicity, intestinal ulceration, plus corneal, cerebellar and cerebral toxicity. No information from these studies could be used to derive an ITSL.

RTECS shows that this chemical appears to be tumorigenic and teratogenic in animal studies, and mutagenic in a host of *in vitro* short term assays. None of the RTECS studies were relevant for further investigation due to unapplicable routes of administration. Additionally, a maternal toxicity NOAEL was provided in a mouse study, but again, the route of administration could not be used to derive an ITSL. NCI cancer studies show no evidence of cancer in rats or mice.

Due to insufficient data, the ITSL for cytarabine is set at trace.

ITSL for cytarabine = 0.04 $\mu\text{g}/\text{m}^3$ based on annual averaging.

MB:ma