

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

January 15, 2016

TO: File for Pyrene (CAS # 129-00-0)
FROM: Mike Depa, Toxics Unit, Air Quality Division
SUBJECT: Initial Threshold Screening Level

The Initial Threshold Screening Level (ITSL) for pyrene is 100 µg/m³ with annual averaging time.

Previously, the averaging time (AT) assigned to pyrene was 24 hours, as per the default methodology (see attached memo from Dennis Bush dated June 23, 1993). The current file review concludes that the AT may appropriately be set at annual, based on the nature and duration of the key study and the ITSL value derivation, as allowed under Rule 229(2)(b). Therefore, the AT is set to annual.

Attachment**MICHIGAN DEPARTMENT OF NATURAL RESOURCES**

INTEROFFICE COMMUNICATION

June 23, 1993

TO: File for Pyrene, CAS # 129-00-0

FROM: Dennis Bush, Surface Water Quality Division

SUBJECT: ITSL Derivation

Pyrene is classified as a Class D carcinogen in IRIS (EPA, 1990) because there is insufficient data available to classify it as a human carcinogen. The ITSL for pyrene is based on the RfD listed in IRIS (EPA, 1993) since no RfC is available. The RfD of 0.03 mg/kg/d is based on a subchronic study by EPA (1989). In this study, male and female CD-1 mice (20/sex/group) were administered 0, 75, 125, or 250 mg/kg/day pyrene via gavage for 13 weeks. Body weight changes, food consumption, mortality, clinical pathology, hematology and serum chemistry were examined. Relative and absolute kidney weights were reduced in the higher two dose groups. A greater proportion of females in the higher two dose groups exhibited nephropathy as compared to the control and low dose group females. More males in the high dose group exhibited nephropathy than in the other groups. The dose of 75 mg/kg/day was considered the NOAEL. A total uncertainty factor of 3000 was used to derive the RfD. This uncertainty factor consisted of 10x for each intraspecies, interspecies and subchronic-to-chronic extrapolation. An additional 3x uncertainty factor was used because there was insufficient reproduction/development data as well as insufficient data in a second species.

A review of the Toxicological Profile for Polycyclic Aromatic Hydrocarbons (ATSDR, 1990) revealed no inhalation studies using pyrene. A May 10, 1993 CAS-on-line literature search, covering the period since 1990, also failed to locate any inhalation toxicity studies. Clayton and Clayton (1981) stated that "workers exposed to 3 to 5 mg/m³ noted disturbances that disappeared at levels below 0.1 mg/m³." However, not much weight can be given to this statement since it was based on a study published in a foreign language. No inhalation studies were found which suggest that it is inappropriate to base the ITSL on an oral study. It was therefore considered appropriate to derive an ITSL using the RfD, as follows.

ITSL Derivation:

$$\text{ITSL} = \text{RfD} \times 70 \text{ kg}/20\text{m}^3$$

$$\text{ITSL} = 0.03 \text{ mg/kg/d} \times 70 \text{ kg}/20\text{m}^3 = 0.105 \text{ mg/m}^3$$

$$\text{ITSL} = 0.10 \text{ mg/m}^3 \text{ (the averaging time is 24 hours)}$$

REFERENCES:

ATSDR, 1990, Toxicological Profile for Polycyclic Aromatic Hydrocarbons.

Clayton, G.D. and F.E. Clayton, 1981. Patty's Industrial Hygiene and Toxicology, 3rd Edition. Volume 28,

EPA, 1989, Mouse Oral Subchronic Toxicity of Pyrene. Study conducted by Toxicity Research Laboratories, As cited in IRIS, 1993.

EPA, 1993. Integrated Risk Information System (IRIS database). Chemical file for pyrene (129-00-0). Verification date 11/15/89.

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