MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

TO: File for Naptha, catalytic reformed (CAS # 68955-35-1)

FROM: Robert Sills, AQD Toxics Unit Supervisor

SUBJECT: Naptha, catalytic reformed ITSL change in the averaging time from 24 hrs to annual

DATE: January 17, 2017

The current ITSL for Naptha, catalytic reformed is 350 ug/m^3, with annual averaging time (AT).

Previously, the ITSL was established on June 11, 1999 at 350 ug/m^3 with 24 hr averaging time (see attached justification memo). The averaging time (AT) assigned to the ITSL previously was 24 hours, as per the default methodology at that time (Rule 232(2)(b)). The ITSL derivation applied a total uncertainty factor (UF) = 1000, which consisted of a UF = 10 for each interspecies extrapolation, intraspecies variability, and subchronic-to-chronic conversion. The current file review concludes that the AT for the ITSL 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).

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

June 11, 1999

TO: File for Naphtha, Catalytic Reformed (CAS No. 68955-35-1)

FROM: Michael Depa

SUBJECT: Initial Threshold Screening Level

The initial threshold screening level for catalytic reformed naphtha is 350 µg/m³ (24-hour averaging time).

The following references or databases were searched to identify data to determine the ITSL: EPA's Integrated Risk Information System (IRIS), Registry of Toxic Effects of Chemical Substances (RTECS), American Conference of Governmental and Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), National Institute of Occupational Safety and Health (NIOSH) Pocket Guide to Hazardous Chemicals, Environmental Protection Bureau Library, International Agency for Research on Cancer (IARC) Monographs, Chemical Abstract Service (CAS) Online (1967 – April 27, 1999), National Library of Medicine (NLM), Health Effects Assessment Summary Tables (HEAST), and National Toxicology Program (NTP) Status Report.

The CAS Registry file for "68955-35-1" defines "naphtha (petroleum), catalytic reformed" as:

> A complex combination of hydrocarbons produced by the distillation of products from a catalytic reforming process. It consists of hydrocarbons having carbon numbers predominantly in the range of C4 through C12 and boiling in the range of approximately 32°C to 211°C (90°F to 430°F). It contains a relatively large proportion of aromatic and branched chain hydrocarbons. This stream man contain 10 vol. % or more benzene.

Additional chemical and physical data on catalytic reformed naphtha was found on a Material Safety Data Sheet (MSDS) provided by Marathon Oil Company. The name used by Marathon for the CAS No. 68955-35-1 is "catalytic reformed full range naphtha." The components are listed as:

paraffins	30 – 50%
cycloparaffins	1 – 6%
olefins	0.1 – 2%
aromatic hydrocarbons	40 – 60%
benzene	1 – 5%

A toxicity report was found in the literature consisting of a subchronic and a developmental study (Dalbey and Feuston, 1996). In the developmental study performed by Dalbey and Feuston (1996), groups of 11-12 pregnant Sprague-Dawley rats were exposed to concentrations of 2160, or 7080 mg/m³ catalytic reformed naphtha on days 6-19 of gestation. Animals received whole body exposures. Untreated controls and sham-exposed controls were used. In maternal rats that were exposed there was no difference from controls in body weights, gravid uterine weight, liver weight or thymus weight. However, serum glucose concentration ($p<0.05$) was decreased and serum potassium ($p<0.05$) was increased compared to untreated controls in the 7800 mg/m³ exposure group. There were no differences in these parameters when the sham-exposed rats were used as the control group. There was no difference in the number of females pregnant, preimplantation loss, resorptions, mean viable litter size, and male and female fetal body weight. There appeared to be no differences between control rats and the treated rats with respect to external, visceral, and skeletal anomalies of fetuses. There were two control groups: untreated and sham-exposed. The untreated control rats in both the developmental and subchronic study had higher or lower biological parameters when compared to the sham-exposed control rats. Since, in many instances biological parameters in the dosed groups were statistically different from the untreated controls but not the sham-exposed, it seems likely that the control group that is the most appropriate for comparison purposes is the sham-exposed group. Sham-exposed rats were treated in the same manner of way that the exposed rats were, except for the exposure. Therefore, comparison of the dose groups to the untreated control rats was deemed inappropriate. Since there was no difference between the rats in the sham-exposed groups and the dose groups it was concluded that the highest dose level tested (7800 mg/m³) is a developmental NOAEL.

In the subchronic study performed by Dalbey and Feuston (1996), groups of 15 male and 15 female Sprague-Dawley rats were exposed to 0, 410, 1970 or 8050 mg/m³ catalytic reformed naphtha for 13 weeks. The number of hours that the animals were exposed per day, and days exposed per week were not mentioned; however, in the developmental study the female rats were exposed for 6 hours per day. It was assumed that the same exposure routine was used in the subchronic study. It was assumed that the researchers exposed the rats 5 days per week since this is standard procedure for subchronic studies. **Results:** Body weights of males exposed to 1970 or 8050 mg/m³ tended to be higher than those of controls throughout the study and were significantly higher for 8050 mg/m³ near the end of the study. No treatment related abnormalities were noted in clinical signs during the course of the exposure or in serum chemistry or parameters of the male reproductive system at the terminal sacrifice. In the hematological data, white blood cell (WBC) count was significantly lower in sham-exposed controls and in all three exposed groups compared to untreated controls in both males and females. In addition, WBC count was decreased by 24% in the high-dose females compared to sham-exposed females. No other parameters were affected in female rats. Of the several organs weighed at necropsy, only the liver and kidney of males exposed to 8050 mg/m³ were significantly heavier than those of sham-exposed (but not untreated) controls. Mean kidney weight was 13% greater than sham-exposed controls and mean liver weight was

14% greater. No treatment-related gross lesions were observed at necropsy. No treatment-related abnormalities were noted in any of the tissues examined histologically from the high-dose group. The authors did not mention whether there was inflammation or other irritancy related effects in the lungs of the rats exposed to 8050 mg/m³. The authors stated that the tissues of the low and mid dose groups were not evaluated because of the lack of a response to the highest concentration. A lowest-observed-adverse-effect-level (LOAEL) was identified at 8050 mg/m³ based on decreased WBC in female rats (significantly different from sham-exposed controls, $p<0.05$) and increased liver and kidney weight in the male rats. The no-observed-adverse-effect-level (NOAEL) was identified as 1970 mg/m³.

EPA (1994) reference concentration (RfC) methodology was used to derive an RfC for catalytic reformed naphtha. Petroleum distillates are relatively insoluble in water and unreactive therefore catalytic reformed naphtha was determined to be a category 3 gas. The subchronic NOAEL of 1970 mg/m³ (Dalbey and Feuston, 1996) was adjusted (ADJ) for duration by assuming that the rats were exposed 6 hours per day, 5 days per week. This is done as follows:

$NOAEL_{ADJ}$ = NOAEL x 6hours/24hours x 5days/7days

$NOAEL_{ADJ}$ = 1970 mg/m³ x 6/24 x 5/7

$NOAEL_{ADJ}$ = 350 mg/m³

Since the effects (e.g., decreased WBC count in female rats, and increased liver and kidney weight in male rats) were observed to be extrarespiratory, or outside the respiratory tract, the human equivalent concentration (HEC) is found by taking the $NOAEL_{ADJ}$ and multiplying it by the ratio of the blood:gas partition coefficient. However, since this ratio is unknown, the default value of 1 was used. This means that the $NOAEL_{ADJ}$ = $NOAEL_{HEC}$. The uncertainty factors used to calculate the RfC are as follows:

10 for animal to human
10 for human to sensitive human
10 for subchronic to chronic

RfC = $(NOAEL_{HEC})/(10 \times 10 \times 10)$

RfC = (35 mg/m³)/1000

RfC = 0.35 mg/m³

RfC = 350 µg/m³

Pursuant to Rule 232(1)(a) the initial threshold screening level (ITSL) is equal to the reference concentration (RfC). The ITSL for catalytic reformed naphtha (CAS No. 68955-35-1) is 350 µg/m³ based on a 24-hour averaging time.

REFERENCE:

Dalbey W, Feuston M. 1996. Partially vaporized full range catalytic reformed naphtha: subchronic and developmental toxicity studies in rats. Inhalation Toxicology. Volume 8, pages 271-284.

EPA. 1994. Methods for derivation of inhalation reference concentrations and application of inhalation dosimetry. EPA/600/8-90/o66F, October 1994. United States Environmental Protection Agency, Office of Research and Development, Washington DC 20460.

MD:ST