Texas Commission on Environmental Quality (TCEQ) Responses to Public Comments Received on the Proposed Development Support Document for 2,2,4-Trimethyl-1,3-pentanediol monoisobutyrate (TPM or Texanol™) April 15, 2008

The public comment period for the proposed Development Support Document (DSD) for 2,2,4-trimethyl-1,3,-pentanediol monoisobutyrate (TPM or Texanol™) ended in March 2008. Eastman Chemical Company (Eastman) and the Texas Chemical Council (TCC) submitted comments. The Toxicology Section (TS) of the TCEQ appreciates the effort put forth by Eastman and TCC to provide technical comments on the proposed DSD for TPM. The goal of the TS and the TCEQ is to protect human health and welfare based on the most scientifically-defensible approaches possible (as documented in the DSD), and evaluation of these comments furthered that goal. All of the Eastman and TCC comments are provided below, followed by TCEQ responses. TCEQ responses indicate what changes, if any, were made to the DSD in response to the comment.

A new section entitled *Comparison of ^{acute}ESL to Generic ESL* was added to the DSD since the ESL Guidelines suggest that when a subacute study is used to derive the ^{acute}ESL, a comparison to a generic ESL should be made to determine whether the ^{acute}ESL based on the subacute study is too conservative.

Eastman Chemical Company (Eastman) Comments Regarding the TCEQ DSD for TPM ESL Values

Comment 1: On page 6 3.1.1 line 19. I saw POE and was not sure what it meant, than 3 lines later it was defined. Thus, the point of entry (POE) should be in line 19 versus 21.

TCEQ Response: The TS appreciates comments from Eastman. The TS agrees that point of entry (POE) should have been defined on line 19 instead of line 21 of page 6. The TS corrected this in the DSD.

Comment 2: I do not understand the purpose as to why a RDDR calculation was done in light of no animal inhalation data and since the material is a soluble liquid (as opposed to an insoluble particle). Any and all material entering the respiratory tract (head to alveoli) would ultimately be absorbed for systemic exposure.

TCEQ Response: The DSD was not revised based on this comment. Acute inhalation data were provided to the TS by Eastman and were subsequently cited in the TPM DSD on page 6. However, these data were not deemed sufficient for the development of toxicity factors. According to the TCEQ Air Permit Division there are certain circumstances where a liquid would be considered a mist. On page 8 of the TPM DSD, it states that:

> *TPM can be emitted as a vapor or a mist as outlined by the TCEQ Air Permit Division (TCEQ 2006b). TPM is treated as a vapor (volatile organic compound (VOC)) when the*

> *process temperatures are such that the vapor pressure is greater than 0.1 mmHg. TPM is treated as a mist (particulate matter (PM)) when the process temperatures are such that the vapor pressure is less than 0.1 mmHg. A mist is considered PM for both air permitting and inhalation dosimetry purposes. Acute ReVs and ESLs were derived for TPM as outlined in the following sections based on whether TPM was considered a VOC or PM.*

If the process used is such that the Air Permit Division would consider TPM a mist, then the PM values would apply for that air permit.

Section 2.9.2 Default Dosimetry Adjustments for Particulate Matter on page 33 of the TCEQ's 2006 regulatory guidance document, *Guidelines to Develop Effects Screening Levels, Reference Values, and Unit Risk Factors* (RG-442) (ESL Guidelines) states:

> *According to the RfC Methodology, the RDDR adjusts for the effective dose in a particular region of the respiratory tract… This calculation accounts for breathing parameters and deposition of particles.*

The RfC Methodology refers to USEPA's Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry. The ESL Guidelines follow standard USEPA methodology for performing dosimetry adjustments for PM.

Comment 3: Why is there a 24 hour PM10 exposure level since people are not outdoors and potentially exposed to it on such a basis?

TCEQ Response: The DSD was not revised based on this comment. Page 9 of the TPM Development Support Document states:

> *Since TPM is being treated as a mist (PM_{10})and the derived short-term ESL value is much higher than the PM_{10} National Ambient Air Quality Standards (NAAQS), the short-term ESL for air permit evaluations defaults to the 24 h PM_{10} NAAQS of 150 µg/m^3 (Table 1).*

In order to meet the 24 hour PM_{10} NAAQS, the TS defaults to the standard when the derived ESL is much larger than the NAAQS value.

Comment 4: I believe that you could use an UF of 3 for both intra-species and inter-species variability in light of the fact that no toxicity was identified in the ingestion studies at a maximal dose of 1000 mg/kg and the highest dose levels from the ingestion studies translate into inhalation exposure levels that exceed saturated vapor levels.

TCEQ Response: The DSD was not revised based on this comment. Since there is not an acceptable inhalation study available for TPM, the studies used to develop the ESLs and ReVs

are from a different route of exposure (oral). A route-to-route extrapolation was performed as stated on page 6 of the TPM DSD. Pages 8 and 9 (respectively) of the document state:

> *3.2.4.1 VOC*
> *An interspecies UF of 10 was used because there was not sufficient information available to dosimetrically adjust the POD. An intraspecies UF of 10 was used to account for any variability within the human population.*
>
> *3.2.4.2 PM*
> *An interspecies UF of 3 was used because the MPPD program accounts for toxicokinetic differences and limits uncertainty between rat and human extrapolation. An intraspecies UF of 10 was used to account for any variability within the human population.*

As a VOC there is not enough inhalation information available to classify TPM as a category 1, 2, or 3 vapor for animal to human dosimetric adjustments; therefore, since toxicokinetic differences cannot be accounted for, the TS has opted to use an interspecies UF of 10 for TPM treated as VOC. Unless specific information is available for a chemical on sensitive human subpopulations, the TS opts to use an intraspecies UF of 10 in order to account for any variability (sensitivity) within the human population.

Comment 5: In light of the fact that you are using an 11 day study for setting the acute effects why is there an UF of 3 for incomplete data base (Table 3). I would think that the extra length of this study (11 days) would "over" support an acute end point especially when the acute inhalation data (that while not deemed acceptable) still demonstrated minimal (no) toxicity at a dose 8 fold above the ingestion to inhalation extrapolation. I am asking Kodak, who did the study in 1960, to see if they have more data in their archives in regard to the methodology of the acute inhalation study.

TCEQ Response: The DSD was not revised based on this comment. Pages 8 and 9 of the Development Support Document state:

> *Although only the minimum database was met, a database UF of 3 was used because the acute inhalation study demonstrated no point of entry effects, and the subacute study results are consistent with those of the well designed, high quality subchronic study.*

Table 3-2 on page 50 of the ESL Guidelines lists the minimum database requirements for the derivation of an acute ReV. Based on these criteria, TPM meets the minimum database for estimation of a ReV, but there is low confidence in the database because there are a limited number of studies in a limited number of animal species for TPM. The TS opted to use a database UF of 3 to reflect the limited study availability.

Section 2.2 Overview on page 16 of the ESL Guidelines gives the definitions of acute and subacute studies:

> *Acute – exposure to a chemical for less than or equal to 24 h.*

Subacute – repeated or continuous exposure to a chemical for 1 month or less.

An 11 day study falls under the definition of a subacute study. As stated on page 16 of the ESL Guidelines, "It is acceptable risk assessment practice to incorporate longer-term data from subacute studies to develop acute toxicity values when it is justified by the MOA analysis (Chapter 3)." The TS determined that it was appropriate to use the subacute data to develop the acute toxicity value for TPM. However, use of these data does not affect the limited number of studies reflected in the database UF of 3.

On January 19, 2007, the TS contacted a representative of Eastman to request additional information on the acute inhalation study. The response was that "unfortunately this is all we have on this old study." Should Eastman be able to provide the TS with the original, robust study and were it to meet the criteria for a suitable study, the TS would be happy to re-evaluate the acute section.

Comment 6: In Chapter 2: The first sentence should read "TPM is manufactured in the United States under the trade names Texanol TM Ester Alcohol and UCAR Filmer IBT. Ours is not the only trade name out there, and both should be listed. The way the rest of the paragraph is written is somewhat choppy and inconsistent. See below for alternative. TPM is manufactured in the United States under the trade name Texanol™ Ester Alcohol and UCAR Filmer IBT. TPM is a solvent used mainly as a coalescent for architectural latex paints. Other applications include: industrial maintenance coatings, electrodeposition primers and coatings, high-bake enamels and other solvent-borne coatings, floor polishes, chemical intermediate for synthesis of ester derivatives for plasticizers, lithographic and letterpress oil-based inks, recovery solvent in drilling muds and ore flotation processes, solvents for nail polish, solvents for cosmetics and personal care, and wood preservatives (Eastman 2005b).

TCEQ Response: The TS amended the paragraph to include the other trade names. The new opening sentence will read "TPM is manufactured under the trade names Texanol™ Ester Alcohol, NX 795, and UCAR™ Filmer IBT." The TS recognizes that there are different writing styles and preferred ways of wording sentences. The purpose of this paragraph is to succinctly state the major uses and/or sources of TPM. Therefore, the TS feels that the current wording is sufficient.

Comment 7: The document shouldn't be singling out any one specific product and trade name, especially in the title. This document is not about a product, it's about a specific chemical 2,2,4-trimethyl-1,3-pentanediol monoisobutyrate. In fact the list of synonyms should at minimum include all of the following:

Texanol™ Ester Alcohol
NX 795 (this is Perstorp's trade name)
UCAR™ Filmer IBT (Dow Chemical trade name)

TCEQ Response: The TS has had dialog with an Eastman representative about this topic previously (September – October 2007). Our previous answer follows:

We [the TS] understand Eastman's concern. However, this document is to be used by the Toxicology Section for air permit evaluations. To facilitate the association between Texanol and the chemical name within the section, we have decided to modify the document so that Texanol™ is referenced as an alternative name for 2,2,4-trimethyl-1,3-pentanediol monoisobutyrate on the title page. An acronym for the chemical, rather than the term Texanol™, will be used throughout the rest of the document.

The TS modified the Development Support Document as stated above. The TS has added the two trade names (NX 795 and UCAR™ Filmer IBT) to the title page and list of synonyms on page 5 of the document.

Texas Chemical Council (TCC)
Comments Regarding the TCEQ DSD for TPM ESL Values

TCEQ Toxicology Section:

The Texas Chemical Council (TCC) submits these comments in response to the Texas Commission on Environmental Quality's (TCEQ) request for public comments on its odor based Effects Screening Level (ESL) Development Support Documents.

The Texas Chemical Council is a statewide trade association representing approximately 85 chemical manufacturers at over 200 Texas Facilities. Our industry has invested more than $50 billion in physical assets in the State and pays over $1 billion annually in state and local taxes. TCC's members provide approximately 70,000 direct jobs and over 500,000 indirect jobs to Texans across the State.

ESLs are designed to be protective of public health and welfare. The short-term ESL for Texanol™ is not established to protect human health and data supports that it is not a health issue even at much higher concentrations.

Given the conservative nature of the modeling, an ESL established solely on the odor threshold can be overly restrictive. Odor is a subjective method and should not be used to establish such a hard line limit. TARA could better utilize their efforts than developing over proscriptive odor based ESLs. There is already a process in place that addresses odor complaints as nuisances. If there have been no odor complaints for a site within the last two years, there should at least be a secondary, higher-level ESL acceptable for that compound that is based on health effects. At the very minimum the ESL should be at 110 ppb or more since at this level there were no adverse effects observed.

In the case of odor based limits and in this case specifically Texanol™, TARA is overstepping their directive to protect public health and welfare. The permitting process requires authorization of the worst case, highest emissions so sites must represent what can occur at extreme conditions. As a result, over-proscriptive, odor-based ESLs will be used to limit emissions by

sites that may seldom if ever occur. Large sums of money and effort may be expended to address a problem that really doesn't exist. This is an opportunity for TARA to use reasonable discretion without fear of not protecting public health and welfare.

Again, TCC appreciates the opportunity to comment on this important document and looks forward to future discussions with TCEQ.

TCEQ Response: The DSD was not revised based on this comment. The TS appreciates comments from TCC. Development of an odor-based ESL for TPM is based on directives from Sections 382.0518 and 382.085 of the Texas Health and Safety Code (THSC) that specifically mandate the Texas Commission on Environmental Quality (TCEQ) to

> *conduct air permit reviews of all new and modified facilities to ensure that the operation of a proposed facility will not cause or contribute to a condition of air pollution.*

In addition, Section 382.003 of the THSC defines air pollution as

> *air contaminants that: (a) are or may tend to be injurious to or adversely affect human health or welfare, animal life, vegetation, or property; or (b) interfere with the normal use and enjoyment of animal life, vegetation, or property.*

Furthermore, according to Section 382.002 of the THSC, the powers of the Commission, including the issuance of air permits, are used for

> *controlling or abating air pollution and emissions of air contaminants, consistent with the protection of public health, general welfare, and physical property, including the esthetic enjoyment of air resources by the public and the maintenance of adequate visibility.*

In response to the THSC mandate, TCEQ has historically considered odor in the development of short-term ESLs (< 1 hour) to addresses the Commission's mandate to protect public welfare and public enjoyment of air resources.

The odor-based ESL for TPM adheres to TCEQ's 2006 regulatory guidance document, *Guidelines to Develop Effects Screening Levels, Reference Values, and Unit Risk Factors* (RG-442), that underwent external scientific peer review and two rounds of public comment. Furthermore, development of an odor-based ESL for TPM included a comprehensive literature search, consideration of all available TPM odor studies, and selection of the lowest 50% odor detection threshold among the studies that meet the American Industrial Hygiene Association and USEPA odor evaluation criteria.

It is important to note that ESLs, including odor-based ESLs, are intended to be used as guidelines and not as strict standards. For example, when applying the odor-based ESL in an air permit application review, consideration of the nature of the odor, the surrounding land use, the frequency of odor-based ESL exceedance, and the odor complaint history at the site all play a role in allowing off-site concentrations that exceed the odor-based ESL. TPM is odorous at a

concentration much lower than that expected to cause an adverse health effect. As a result, if the permit applicant's predicted or monitored TPM concentrations are allowable from an odor perspective, they are allowable from a health perspective as well.

Although TCEQ's Toxicology Section recognizes that the body of data and information surrounding available odor threshold values are not very robust for some chemicals, the odor-based ESL for TPM is considered a useful tool in the air permit review process, and it addresses the Commission's mandate to protect public welfare and public enjoyment of air resources.