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VIA EMAIL TO: chuck.wakild@ncdenr.gov

May 21, 2012

Mr. Chuck Wakild
North Carolina Department of Environment and Natural Resources
Division of Water Quality
1601 Mail Service Center
Raleigh, North Carolina 27699-1601

Reference: Request for Interim Maximum Allowable Concentration for Propylene Glycol
FLS Energy
St. Pauls, North Carolina

Dear Mr. Wakild:

On behalf of our client, FLS Energy, Inc. (FLS), Duncklee & Dunham, P.C. (Duncklee & Dunham) respectfully submits this formal request to have an Interim Maximum Allowable Concentration (IMAC) of 140 mg/L established for propylene glycol (CAS# 57-55-6) through the Division of Water Quality and Environmental Management Commission rule-making process. There have been several releases of propylene glycol from FLS' solar panel installation located at 4470 Highway 20 East in St. Pauls, North Carolina. FLS uses the solar array panels to generate electricity.

The risk-based residential and industrial preliminary soil remediation goal (PSRG) for direct contact have been calculated by the Division of Waste Management's Inactive Hazardous Sites Branch (IHSB), and are both set at the maximum ceiling concentration of 100,000 mg/kg, which indicates the low toxicity associated with this compound. The availability of these PSRGs demonstrated to us that toxicological data was available for this compound. However, there is no protection of groundwater PSRG currently available and a 15A NCAC 15A 2L groundwater quality standard has never been calculated for this compound. The miscibility of the compound and its low toxicity, it is expected the protection of groundwater PSRG will be the most stringent PSRG and will also be the level to which our client will need to remediate the soil.

If FLS Energy can demonstrate concentrations in soil are below the protection-of-groundwater PSRG and the groundwater concentrations are below the IMAC before August 1, 2012, then they will not need to enter the IHSB's registered environmental consultant (REC) voluntary remediation program. This compound is not deemed toxic and breaks down quickly in the environment. The REC program requirements are more applicable to remediation of hazardous substances that are long lasting in the environment. Therefore, there is a great financial incentive for FLS to meet the IMAC and protection-of-groundwater PSRG in the next few months. The remediation results will be provide the same level of

protection to the environment as would be obtained through the REC Program once the IMAC and soil-to-groundwater PSRG are available.

We have attached support information related to propylene glycol, including our calculated IMAC. We would very much appreciate an expedited review of our calculations, due to the work that must be completed prior to August 1, 2012. If FLS cannot demonstrate closure goals have been met by that time, they will have to enter the REC program to close out the site, and the costs associated with a remedial effort under the REC program is far more expensive while providing no additional protection to the environment. Additionally, the financial incentive to meet this upcoming deadline will result in the expedient remediation of the propylene glycol.

If you or members of your staff have any questions concerning the attached materials or other background information, please feel free to contact Daphne Jones at (919) 858-9898 or via email to daphne@dunckleedunham.com

Sincerely,

Duncklee & Dunham, P.C.

Daphne M. Jones, P.G., R.S.M.
Senior Geologist

Senior Peer Review:

Thomas S. Dunham, P.G.
Senior Geologist

Attachments: Support Information for Propylene Glycol
Proposed IMAC, Propylene Glycol

ec: Sandra Moore, NC DWQ, sandra.moore@ncdenr.gov
Chris Dunbar, FLS Energy, cdunbar@flsenergy.com

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SUPPORT INFORMATION FOR PROPYLENE GLYCOL (CAS# 57-55-6)

Health Effects

Contact dermatitis has been reported in a wide variety of topical preparations. Inhalation may present no significant hazard in ordinary applications but limited human experiences indicate that its mists may be irritating to some individuals (PPRTV 2008)

Toxicity

USEPA's Integrated Risk Information System (IRIS) has not established an oral reference dose for propylene glycol (http://www.epa.gov/iris/subst/0543.htm), nor are there any EPA Health Advisories (http://water.epa.gov/action/advisories/drinking/drinking_index.cfm).

The EPA Regional Table Toxicity Values located at:
http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/Generic_Tables/index.htm
lists the RfD as 2.0E+01 mg/kg/day, referencing the EPA Provisional Peer Reviewed Toxicity Value (PPRTV) as its source.

The PPRTV website http://hhpprtv.ornl.gov/quickview/pprtv_papers.php has the original 176-page document for propylene glycol dated September 1997 and a 17-page addendum dated December 18, 2008. There is also a 26-page summary document from 2008 available.

The PPRTV for propylene glycol has been established by EPA with both a chronic and sub-chronic RfD of 20 mg/kg/day. Propylene glycol is a Food and Drug Administration (FDA)-approved food additive and is certified as generally Recognized as Safe (PPRTV 2008). Using this information, a systemic threshold concentration of **140 mg/L (ppm)** can be established in accordance with 15A NCAC 2L .0202(d)(1).

Propylene glycol is odorless and does not have an odor threshold established. No taste threshold, federal maximum contaminant level or secondary drinking water standard has been established for this chemical. Propylene glycol breaks down quickly in surface water and soil.

The US EPA has not classified propylene glycol as to its human carcinogenicity, but per the PPRTV (1997) there is no indication that propylene glycol is carcinogenic in humans or animals The National Toxicology Program has not classified propylene glycol as a carcinogen and the EPA (IRIS) has not assessed a weight-of-evidence characterization for propylene glycol as a carcinogenic substance. The 1997 document further states "It is unlikely that sufficient amounts of propylene glycol would be inhaled, ingested, or absorbed through the skin to be fatal." .

Proposed Interim Maximum Allowable Concentration (IMAC)

An IMAC established under 15A NCAC 2L .0202(c) are to be the "lesser of" the criteria in 15A NCAC 2L .0202(d) (1-6). These six criteria are:

(1) Systemic threshold concentration calculated as follows: [Reference Dose (mg/kg - day) x 70 kg (adult body weight) x Relative Source Contribution (.10 for inorganics; .20 for organics)] / [2 liters/day (avg. water consumption)]; ***RfD available from PPRTV data.***

(2) Concentration which corresponds to an incremental lifetime cancer risk of 1x10-6; **(*No evidence of propylene glycol being a carcinogen)***

(3) Taste threshold limit value; ***(No taste)***

(4) Odor threshold limit value: ***(No odor)***

(5) Maximum contaminant level; ***(No MCL)*** or
(6) National secondary drinking water standard – ***(No secondary drinking water standard)***

Uses

Propylene glycol is a colorless, odorless, water-soluble liquid considered safe for use in commercial formulations of foods, drugs, and cosmetics. Propylene glycol, like ethylene glycol, is used as an antifreeze, de-icing solution, and in various paints and coatings. Unlike ethylene glycol, however, propylene glycol has been approved as safe in various food flavorings, drugs, cosmetics, and as a direct additive to food. Propylene glycol is commonly used in the pharmaceutical industry as a solvent for drugs, as a stabilizer for vitamins, and in ointment for medicinal applications. Propylene glycol may be found in canned fruit, packaged coconut, as a solvent in drug and cosmetic preparations, and in flavorings and extracts. Propylene glycol is also used in the generation of artificial mists and fogs used in fire safety training and theatrical and stage productions. This widespread use of propylene glycol stems from its low level of toxicity. (1997 ASTDR).

In addition to the websites provided above, information about propylene glycol can be found on http://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=240

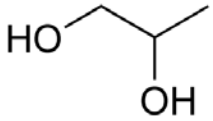
Proposed Interim Maximum Allowable Concentration (IMAC)
Propylene Glycol (CAS# 57-55-6)

Proposed IMAC: An IMAC has been developed for propylene glycol: **140 mg/L**

Reference Dose (Rfd): 20 mg/kg/day

Basis for RfD: EPA's Provisional Peer Reviewed Toxicity Values (PPRTV) for Superfund

Background Information: Propylene glycol is an organic compound belonging to the alcohol family. Also known as 1,2-propanediol, it resembles ethylene glycol in its physical properties. Unlike ethylene glycol, it is not considered to be toxic and is used extensively in foods, cosmetics and oral hygiene projects as a solvent, preservative and moisture-retaining agent. The chemical structure is given below. Its molecular weight is 76.09 g/mol.



Basis for IMAC

The first step in development of an IMAC or groundwater quality standard in accordance with 15A NCAC 2L .0202 (2L) requires an analysis of exiting data to determine whether the proposed concentration is based on carcinogenic or noncarcinogenic effects. The 2L rule states the level is based on the least of a systemic threshold concentration (the non-carcinogenic endpoint) or a concentration that corresponds to an incremental lifetime cancer risk of 1×10^{-6} (cancer endpoint). Propylene glycol only has evidence of non-carcinogenic effects. It is assumed to exhibit a threshold for those effects that is documented in the reference dose (RfD). The Rfd is an estimate of what the daily exposure to humans, including sensitive subgroups, could be without risk of deleterious effects over a lifetime. The RfD is expressed in units of mg/kg (of body weight) per day.

A groundwater quality standard can be calculated by using the lesser of the six criteria listed in 15A NCAC 2L .02.2(d). These criteria are listed on the attached support information document under the heading of "Proposed Interim Maximum Allowable Concentration (IMAC)" at the bottom of page 1. RfD information is available for propylene glycol utilizing the Provisional Peer Reviewed Toxicity Value (PPRTV). As there is no other information is available, the RfD represents the most restrictive method to calculate the IMAC.

Per NCAC 2L .0202 (E) the following references were reviewed to obtain the RfD:

- Integrated Risk Information System (IRIS – EPA)
- Health Advisories (EPA Office of Drinking Water)
- Other health risk data published by EPA or
- Other relevant, published health risk assessment data and scientifically valid peer-reviewed published toxicological data.

For propylene glycol, only scientifically valid peer-reviewed published toxicological data was available.

IMAC Calculation

The following calculation is referenced in 15A NCAC 02L.0202 (d) (1):

$$\text{IMAC for Propylene Glycol} = \frac{\text{RfD x BW x RSC}}{\text{DI}}$$

Where: RfD = 20 mg/kg/day
BW = assumed body weight of an adult, default = 70 kg
RSC = relative source contribution = 20% for organics
DI = daily water intake for an adult = 2 L/day

Therefore the IMAC for propylene glycol would be:
[20 mg/kg/day x 70 kg x 0.20]/2L/day = 140 mg/L

References

North Carolina Department of Environmental and Natural Resources (2010). *Classifications and Water Quality Standards Applicable to the Groundwaters of North Carolina,* Subchapter 2L.

U.S. Department of Health & Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (1997) *Toxicological Profile for Propylene Glycol.*

Agency for Toxic Substances and Disease Registry, Division of Toxicology and Environmental Medicine (2008) *Addendum to the Toxicological Profile for Propylene Glycol.*

Superfund Health Risk Technical Support Center, National Center for Environmental Assessment, Office of Research and Development, U.S., EPA, Cincinnati, OH (3-24-2008) *Provisional Peer Reviewed Toxicity Values for Propylene glycol* (CASRN 57-55-6)

http://hhpprtv.ornl.gov/quickview/pprtv.php?chemical=Propylene+Glycol (see link near top of linked web page for 'PPRTV Derivation Support Document.')