Message

**From**: Richard E. Engler, Ph.D. [rengler@lawbc.com]
**Sent**: 6/8/2018 9:40:03 PM
**To**: Odusote, Gloria [odusote.gloria@epa.gov]
**Subject**: RE: PMN risk assessment

Thanks

**RICHARD E. ENGLER, PH.D.**
**DIRECTOR OF CHEMISTRY**
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-557-3808 | F: 202-557-3836 | lawbc.com

**From:** Odusote, Gloria <odusote.gloria@epa.gov>
**Sent:** Friday, June 8, 2018 5:40 PM
**To:** Richard E. Engler, Ph.D. <rengler@lawbc.com>
**Subject:** RE: PMN risk assessment

Ah I see. You are looking at the document with the summaries of the studies, not the one with the chosen LOAEC and NCEL. I'll see if I can get that one for you.

Best,
Gloria

**From:** Richard E. Engler, Ph.D. [mailto:rengler@lawbc.com]
**Sent:** Friday, June 8, 2018 5:34 PM
**To:** Odusote, Gloria <odusote.gloria@epa.gov>
**Subject:** RE: PMN risk assessment

The document I have lists a NOAEL of 1 mg/m3.

"Chronic 24-month exposure to toner resulted in dose-related impaired particle clearance, elevated lung particle burden, and lung toxicity (fibrosis, BALF markers of tissue damage, and increased lung weight) at 4 and 16 mg/m3, with a NOAEL of 1 mg/m3 (Muhle et al., 1991; Bellmann et al., 1991)."

**RICHARD E. ENGLER, PH.D.**
**DIRECTOR OF CHEMISTRY**
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-557-3808 | F: 202-557-3836 | lawbc.com

**From:** Odusote, Gloria <odusote.gloria@epa.gov>
**Sent:** Friday, June 8, 2018 5:31 PM
**To:** Richard E. Engler, Ph.D. <rengler@lawbc.com>
**Subject:** RE: PMN risk assessment

That's the one! You should see the LOAEC of 3.3 mg/m$^3$ with the concern for fibrosis.

**From:** Richard E. Engler, Ph.D. [mailto:rengler@lawbc.com]
**Sent:** Friday, June 8, 2018 5:30 PM

**To:** Odusote, Gloria <odusote.gloria@epa.gov>
**Subject:** RE: PMN risk assessment

I take it back. I only have poorly soluble polymers, waterproofing, cationic binding, and surfactants.

I do not yet have the new poorly soluble particles category document.

**RICHARD E. ENGLER, PH.D.**
**DIRECTOR OF CHEMISTRY**
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-557-3808 | F: 202-557-3836 | lawbc.com

---

**From:** Odusote, Gloria <odusote.gloria@epa.gov>
**Sent:** Friday, June 8, 2018 5:28 PM
**To:** Richard E. Engler, Ph.D. <rengler@lawbc.com>
**Subject:** RE: PMN risk assessment

Great! I'll still give you an update on Monday or whenever I talk to Matt unless you email me that you've found it.

Best,
Gloria

---

**From:** Richard E. Engler, Ph.D. [mailto:rengler@lawbc.com]
**Sent:** Friday, June 8, 2018 5:27 PM
**To:** Odusote, Gloria <odusote.gloria@epa.gov>
**Subject:** RE: PMN risk assessment

Thanks.

I have a copy of the poorly soluble category (somewhere!).

**RICHARD E. ENGLER, PH.D.**
**DIRECTOR OF CHEMISTRY**
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-557-3808 | F: 202-557-3836 | lawbc.com

---

**From:** Odusote, Gloria <odusote.gloria@epa.gov>
**Sent:** Friday, June 8, 2018 5:25 PM
**To:** Richard E. Engler, Ph.D. <rengler@lawbc.com>
**Subject:** RE: PMN risk assessment

Hi Rich,
There are updated lung toxicity category documents, which I thought some other program managers might have sent to you. If not, they should be out publicly soon, so I'll ask Matt LLoyd on Monday when I can provide them to you. So, I don't know for sure why RAD updated their NCELs for poorly soluble respirable particles, but the NCEL they used here is consistent with the new category documents.

The study with the LOAEC is in the lung overload category document. Once again, I'll check with Matt about the status of the category document.

Best,
Gloria

---

**From:** Richard E. Engler, Ph.D. [mailto:rengler@lawbc.com]
**Sent:** Friday, June 8, 2018 5:08 PM
**To:** Odusote, Gloria <odusote.gloria@epa.gov>
**Subject:** RE: PMN risk assessment

Thanks for the update.

Do you know why did RAD not use the chemical category for titanium oxide analogs (also in the poorly soluble respirable category)?

Also, can you point me to the study that LOAEC is based upon (presumably it's in ChemView)?

**RICHARD E. ENGLER, PH.D.**
**DIRECTOR OF CHEMISTRY**
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-557-3808 | F: 202-557-3836 | lawbc.com

---

**From:** Odusote, Gloria <odusote.gloria@epa.gov>
**Sent:** Friday, June 8, 2018 4:20 PM
**To:** Richard E. Engler, Ph.D. <rengler@lawbc.com>
**Subject:** RE: PMN risk assessment

Hi Rich,
There is another health assessment though usually the POD is listed in the SAT. I'll work on getting that to you.

The endpoint is lung toxicity due to lung overload. The POD is based on the LOAEC for poorly soluble respirable particles, which is 3.3 mg/m$^3$ with an acceptable benchmark of 1000. Thus the NCEL is .0033mg/m$^3$.

Best,
Gloria

---

**From:** Richard E. Engler, Ph.D. [mailto:rengler@lawbc.com]
**Sent:** Friday, June 8, 2018 2:20 PM
**To:** Odusote, Gloria <odusote.gloria@epa.gov>
**Subject:** PMN risk assessment

Gloria:

Is there a health assessment somewhere? The focus report goes into significant detail about the ecotox assessment (in Section IV) but provides no insight into the health hazard assessment. The Focus report goes directly to exposures (in section V) and the Decision/rationale (in Section VI) without any additional detail.

The OPPT new chemical category document specifies that TiO2 (and analogs) would have a NCEL of 5 mg/m3.

Furthermore, although the submitter does not have specific information about all potential customer sites, we expect that such sites will handle titanium dioxide pigments, so must have dust control measures to keep ambient concentrations below the 10 mg/m3 OSHA PEL for nuisance dust (and below the 15 mg/m3 assumed in the engineering assessment) as well as below the PEL for titanium dioxide 5 mg/m3.

Please advise what POD or NCEL that RAD used in its risk assessment and the analog upon which that POD is based.

Rich

--

**RICHARD E. ENGLER, PH.D.**
**DIRECTOR OF CHEMISTRY**
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-557-3808 | F: 202-557-3836 | lawbc.com

---

**From:** Odusote, Gloria <odusote.gloria@epa.gov>
**Sent:** Wednesday, June 6, 2018 7:10 PM
**To:** Richard E. Engler, Ph.D. <rengler@lawbc.com>
**Subject:** RE: My contact information

Hi Rich,
I faxed you all of the reports but I can't tell if it went through. Please let me know if you received it.

Also, your Day 90 is coming up, so I'll suspend 15 days.

Best,
Gloria

---

**From:** Richard E. Engler, Ph.D. [mailto:rengler@lawbc.com]
**Sent:** Monday, May 14, 2018 5:26 PM
**To:** Odusote, Gloria <odusote.gloria@epa.gov>
**Subject:** My contact information

Gloria:

Thank you for giving me an update. I look forward to reviewing the reports.

Rich

--

**RICHARD E. ENGLER, PH.D.**
**SENIOR CHEMIST**
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-557-3808 | F: 202-557-3836 | lawbc.com