

STUDY OF PEG 3350 IN THE PEDIATRIC POPULATION

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Disclosures

No financial relationships to disclose



Background

- Reports of “neuropsychiatric events” associated with polyethylene glycol (PEG 3350) 3350
- “Potential neurotoxic contaminants”
 - ethylene glycol (EG)
 - diethylene glycol (DEG)
 - triethylene glycol (TEG)



Purpose of Study

Determine if EG, DEG, and/or TEG are elevated in the blood of children treated with PEG 3350



Study Participants

- Inclusion
 - Functional Constipation
 - 7-12 years of age
 - One capful (17gram) for ≥ 2 weeks
- Exclusion
 - Physiological disorder of GI tract
 - Prior abdominal surgery
 - Psychiatric and behavioral disorders
- 9 participants
- 18 age/sex matched healthy controls



Study Design

- Morning visit prior to PEG 3350 dose
- Measure 2 doses of "home" PEG 3350
 - 1 for participant
 - 1 in glass container for analysis
- Blood samples
 - Placed IV
 - Baseline blood sample
 - Gave PEG 3350 dose
 - Blood samples at 30, 60, 90, 120, 150, and 180 min.



Sample Analysis

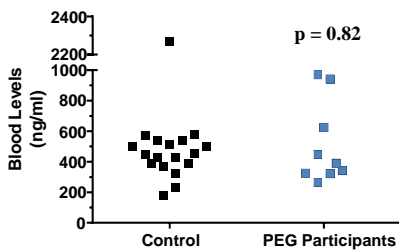
- Serum
- PEG 3350 (suspended in city tap water)
- City tap water
- Liquid chromatography – mass spec/mass spec (LC-MS/MS)
based upon published methods



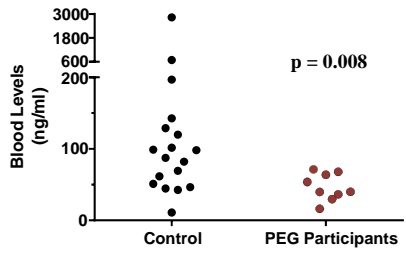
Do Baseline Levels Differ Between Groups?



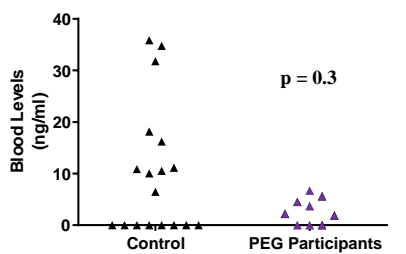
Baseline Levels: Ethylene Glycol



Baseline Levels: Diethylene Glycol

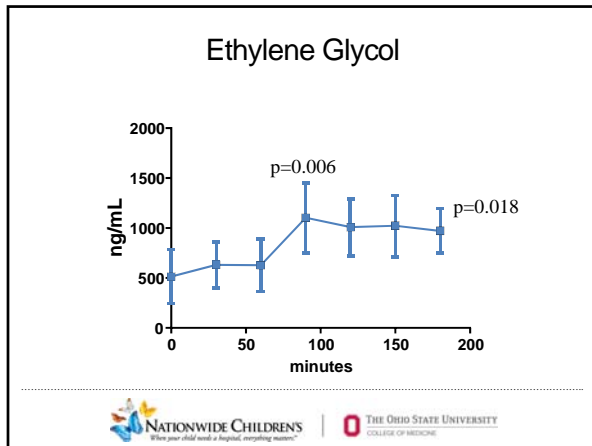


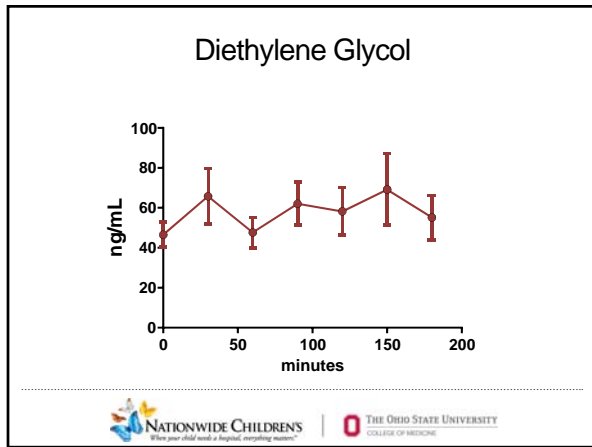
Baseline Levels: Triethylene Glycol

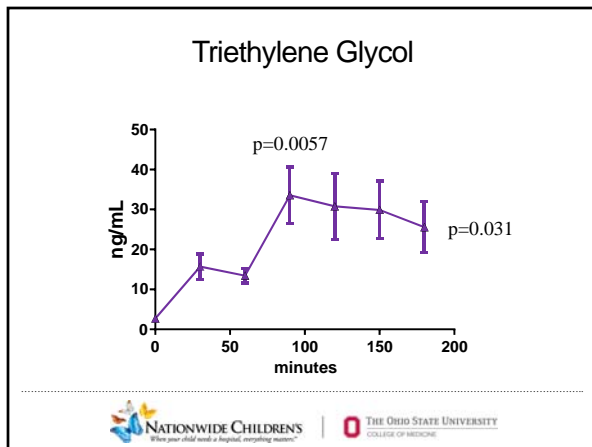


Do Baseline Blood Levels Increase
After PEG 3350 Dose?





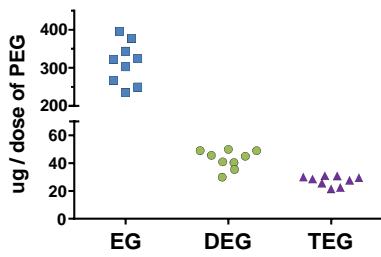




Do PEG 3350 samples contain EG, DEG, and/or TEG ?

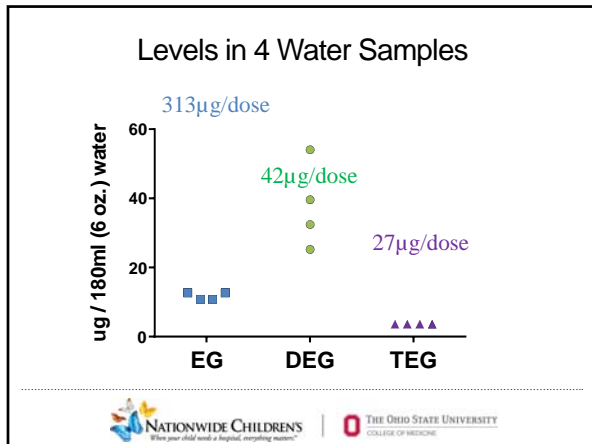


Levels in PEG 3350 Doses



Does Water Contain EG, DEG, and/or TEG ?





Summary

Chronic use of PEG 3350 not associated with sustained elevation of EG, DEG or TEG blood levels

DEG levels significantly lower in PEG 3350 group

EG and TEG blood levels increased after taking PEG 3350

EG and TEG detected in PEG 3350 samples

Discussion

800 µg/kg/day is minimal risk level for EG from daily environmental exposure for intermediate-duration (15-364 days)
(U.S. Department of Health and Human Services)

Effect on development from low level environmental exposures is unknown

Further studies are needed

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Further studies are needed - *Not just on PEG 3350*