

**Introduction to Comments on  
Benzo(a)Pyrene  
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# Comment Sponsors

- American Coke and Coal Chemicals Institute
- American Fuels & Petrochemical Manufacturers
- American Petroleum Institute
- Asphalt Institute
- Association of American Railroads
- Beazer East, Inc.
- Pavement Coatings Technology Council

# Thank You, EPA...

- For granting extension
  - We hope the result of the extra time is evident in the thorough review of primary literature
  - Written comments are organized by EPA's draft peer review charge questions
  - The B(a)P & PAH mixture literature is vast. Even 90 days was insufficient to address every draft charge question
- For this opportunity to review and discuss the draft assessment at this stage, before the document is ready for peer review

# Assessment of B(a)P is Unique

- People are not exposed to B(a)P *per se*, but to B(a)P-containing mixtures
  - Of which there are uncounted thousands
  - Each B(a)P-containing mixture has a unique composition with more or less PAH compounds such as BaP *per se*
  - B(a)P-containing mixtures contain a variety of heterocyclic PAH compounds and non-PAH compounds
- B(a)P *per se* is not used in commerce or emitted by itself into the environment from industrial processes
  - Industrial and natural processes produce and use complex mixtures which contain PAHs and hundreds of related and unrelated compounds.
- EPA has designated B(a)P *per se* as the index chemical for the PAHs

# Assessment of B(a)P is an Opportunity

- B(a)P *per se* is arguably the most studied substance in toxicology
  - but no human exposure data
- B(a)P-containing mixtures are arguably the most studied materials in the environment
  - and there are human exposure data including occupational, clinical and ambient data
- We urge EPA to take advantage of the opportunity presented to validate hazard & calculated risk estimates against real world data

# Summary of Estimated Daily BaP-TE Intakes\*

## Summary of Estimated Daily Intakes of Benzo(a)pyrene Toxic Equivalents (BaP-TE)

<b>Source of Exposure</b>	<b>Average Daily Intake (ug/day)</b>
Ambient air and indoor air	0.006 to 0.02
Diet	0.2 to 0.6
Smoking	0.2 to 1
Second hand smoke	0.005 to 0.26
Coal tar pharmaceuticals	33
Coal tar shampoo	0.017

\* From report prepared by ARCADIS in 2013 for PavementCouncil.org  
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# Coal Tar Pharmaceuticals

- Coal tars of all varieties contain an elevated percentage of PAHs
- FDA lists coal tar as “generally recognized as safe and effective” (GRASE) for use as an active ingredient in medicine to treat certain skin disorders
- GRASE-listed materials are approved for use in Over-the-Counter drugs
- Clinical data available

# 21CFR§358.710

**§ 358.710 Active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis.**

**The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient:**

....

**(a) Dandruff**

**(b) Seborrheic dermatitis**

**(c) Psoriasis**

...

**(1) Coal tar, 0.5 to 5 percent.** When a coal tar solution, derivative, or fraction is used as the source of the coal tar, the labeling shall specify the identity and concentration of the coal tar source used and the concentration of the coal tar present in the final product.

# Another way to look at PAHs

## Ingredients for Life

- This artist's conception [next slide, from NASA's "image of the day" gallery] symbolically represents complex organic molecules, known as **polycyclic aromatic hydrocarbons**, seen in the early universe. These large molecules, comprised of carbon and hydrogen, are among **the building blocks of life**. NASA's Spitzer Space Telescope is the first telescope to see polycyclic aromatic hydrocarbons so early--10 billion years further back in time than seen previously. Spitzer detected these molecules in galaxies when our universe was one-fourth of its current age of about 14 billion years. These complex molecules are very common on Earth and form [when] carbon-based materials are not burned completely. They can be found in sooty exhaust from cars and airplanes, and in charcoal broiled hamburgers and burnt toast. **Polycyclic aromatic hydrocarbons are pervasive in galaxies like our own Milky Way, and play a significant role in star and planet formation.**

*Image Credit: NASA/JPL-Caltech/T. Pyle (SSC)*

