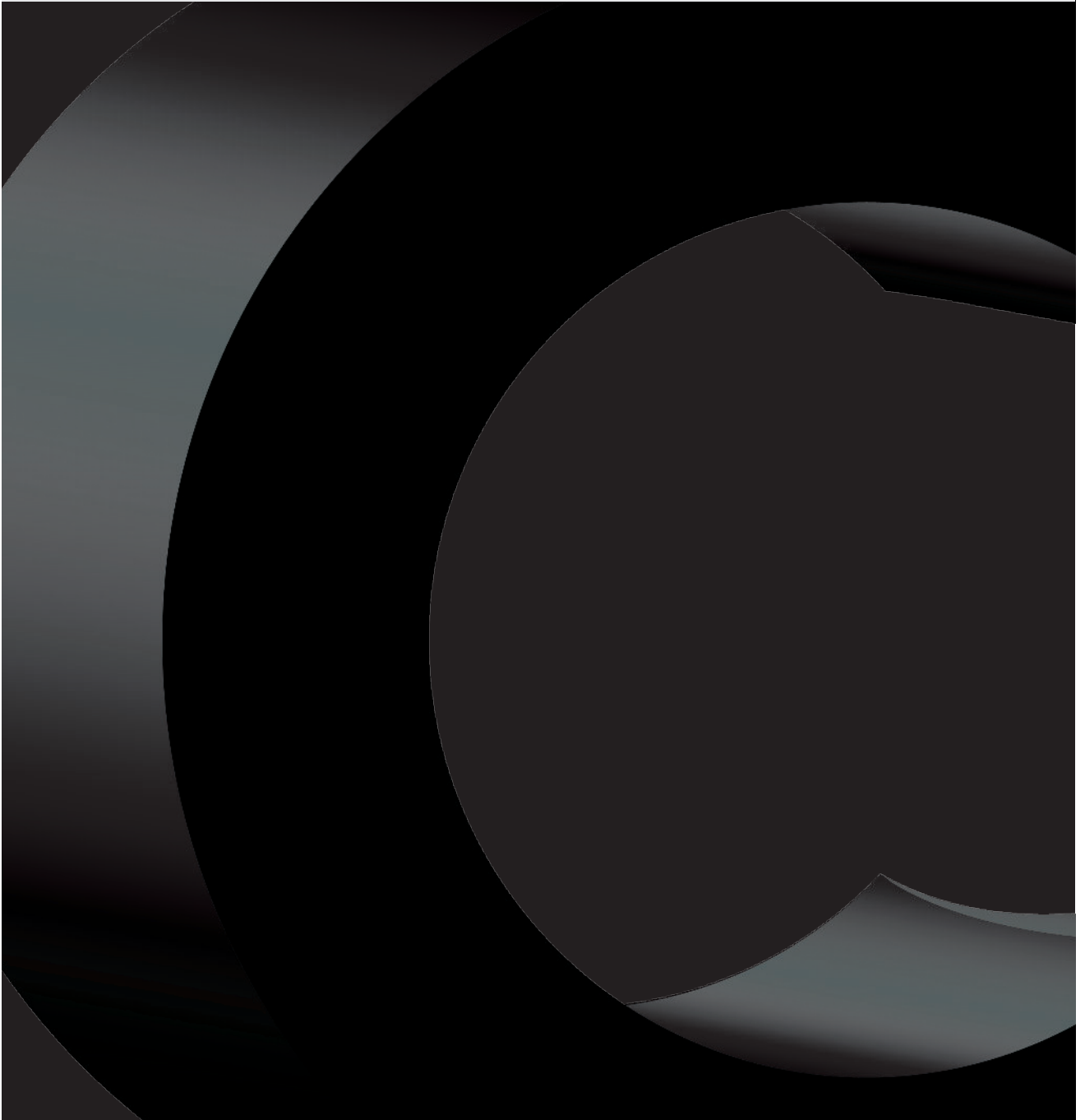


## Carbon Black – PAH and Regulations



## WHAT ARE PAHs

The term polycyclic aromatic hydrocarbons (PAHs) refers to a class of chemicals that occur naturally in coal, crude oil, tar, and gasoline. PAHs can be found in consumer products. They are not added intentionally and do not perform any specific function, but are produced by the incomplete combustion of the organic substances.

### Health/Environmental effects

PAHs are an alarming group of substances for humans and environmental organisms. PAHs are also found throughout the environment in the air, water, and soil, and can persist in the environment for months or years.

The effects on human health will depend mainly on the extent of exposure (length of time, etc), the amount one is exposed to (or concentration), the innate toxicity of the PAHs and whether exposure occurs via inhalation, ingestion or skin contact.

### Types of PAHs

Although hundreds of PAHs exist, seventeen individual PAHs get more attention because of possibility of exposure and harmful health affects. These 17 PAHs are:

- acenaphthene
- acenaphthylene
- anthracene
- benz[a]anthracene
- benzo[a]pyrene
- benzo[e]pyrene
- benzo[b]fluoranthene
- benzo[j]fluoranthene
- benzo[g,h,i]perylene
- benzo[k]fluoranthene
- chrysene
- dibenz[a,h]anthracene
- fluoranthene
- fluorene
- indeno[1,2,3-c,d]pyrene
- phenanthrene
- pyrene

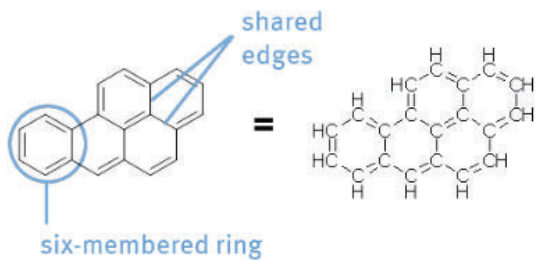
These 17 PAHs are included in this profile because they are suspected to be more harmful than some of the others, and they exhibit harmful effects that are representative of the PAHs. Also there is a greater chance that you will be exposed to these PAHs than to the others and of all the PAHs analyzed, these were the PAHs identified at the highest concentration.

### Benzo[a]pyrene (BaP)

Benzo[a]pyrene (BaP) is commonly used as an indicator species for PAH contamination. If benzo[a]pyrene is contained in a substance or product, this typically applies to all other PAHs of concern, which have very similar properties. Benzo[a]pyrene was selected because this compound is particularly carcinogenic.

PAHs are composed of two to six benzene rings fused together such that any two adjacent benzene rings share two carbon bonds.

Figure 1 – Example Benzo(a)pyren



### (Low) PAH in Carbon Black

According to different market regulations, some applications (household, tools, inks, plastics, selected rubber parts and food contact applications) require a limited concentration of PAH.

Industrially manufactured Carbon Black is produced by pyrolysis of hydrocarbons at high temperatures under controlled process conditions.

The lower the temperature of the fire and the less oxygen is available, the more incomplete PAHs are burned (high amount of PAH's), the higher the temperature, the more PAH's are burned (low amount of PAH's).

PAHs are firmly bound to the Carbon Black surface under normal handling and use.

Research at the University of Düsseldorf showed that PAHs adsorbed onto the Carbon Black surface are not "bioavailable" 1)

The purpose of the study was to determine if body fluids would leach PAHs from the Carbon Black surface, where the PAHs could interact with tissue.

The study found that the PAHs were not leached by artificial lung fluid from the Carbon Black surface.

Another study performed at Münster Analytical Solutions demonstrated that PAHs coming from Carbon Black, once incorporated into a rubber matrix, were not migrating to aqueous simulants representing typical human or environmental liquids like sweat, saliva or rainwater 2).

These results were subsequently confirmed by Bergmann 3).

PAHs can only be extracted from the surface of the Carbon Black under forceful laboratory conditions such as Soxhlet extraction with strong organic solvents f.e. toluene, at elevated temperatures.

Based on laboratory analyses, most Carbon Black grades will typically have PAH levels 4) not exceeding 0.1 %.

To this end, the Carbon Black industry contributed to the development of the International Test Standard ASTM D7771-11, "Standard Test Method for Determination of Benzo-(a)-Pyrene (BaP) Content in Carbon Black".

Please note that these extraction conditions are not at all representative of normal industrial processing or environmental conditions.

Furthermore, various Carbon Black applications and finished articles are regulated in their overall PAH content or in their potential PAH migration level.

When evaluating exposure to Carbon Black, note that in the various products and finished articles containing Carbon Black in a wide range of loadings, the Carbon Black itself is not readily available, nor is it exposed to the outside environment. The Carbon Black is embedded and firmly bound into a polymeric matrix (e.g. rubber, plastics, coatings, ink, etc.).

As a result, Carbon Black itself cannot migrate out of the products or finished articles, thus reducing the probability of exposure to PAHs.

In consideration of all this, the risks to human health associated with the presence of PAHs originating from the Carbon Black in the final products or finished articles is extremely low.

1) Borm, P.J., Cakmak, G., Jermann, E., Weishaupt, C., Kempers, P., van Schooten, F.J., Oberdorster, G., Schins, R.P. Formation of PAH - DNA adducts after in vivo and vitro exposure of rats and lung cells to different commercial Carbon Black. *Toxicol. Appl. Pharmacol.* , 2004 June, 1:205(2):157 - 67.

2) Hamm, S., Frey, T., Weinand, R., Moninot, G., Petiniot, N. Investigations on the extraction and migration behavior of polycyclic aromatic hydrocarbons (PAHs) from cured rubber formulations containing Carbon Black as reinforcing agent. *Rubber Chemistry & Technology*, Volume 82 (2009), Issue 2.

3) C. Bergmann, J. Trimbach, M. Haase - Held, A. Seidel. "Consequences of European Directive 2005/69/EC for Tire Industry", *KautschukGummiKunststoffe*, October 2011.

4) Listed in the EU Directive 2005/69/EC of the European Parliament relating to restrictions on the marketing and use of certain dangerous substances and preparations (polycyclic aromatic hydrocarbons in extender oils and tyres

## REGULATIONS

There are various regulations that stipulate limitation of PAHs in specific products and in the environment.

The EU REACH regulation contains provisions on the handling of PAHs.

All our Carbon Black grades are REACH-registered.

CAS number: 1333-86-4

EG number: 215-609-9

REACH registration number: 01-2119384822-32-XXXX

We are able to provide grades according to EU Regulation 10/ 2011, FDA 21CFR 178.3297, Mercosur No 15/10 Colorants No 32/07 Positive list of additives, Swiss SR 817.023.21, Japan, China GB9695-208 and the Oeko-Tex 100 Standard.

### **Compliance with food contact regulations (European Union)**

For plastics, the Regulation EU 10/2011 has harmonized the purity criteria applicable to Carbon Blacks used in plastics coming into contact with food, this means the same purity criteria and restrictions are applicable to Carbon Black in all the countries of the European Union.

We offer specialty Carbon Blacks that meet the requirements of the current plastics regulations applicable For the most up-to-date compliance information, feel free to contact us.

### **Regulation EU 10/2011 (Europe)**

The Commission Regulation EU No 10/2011 is applicable in all the countries of the European Union. The purity requirements and specifications for compliance are:

- In the final food contact item, a maximum of 2.5% Carbon Black by weight is allowed
- Toluene extract <0.1%\* (according to ISO 6209)
- Cyclohexane extinction at 386 nm <0.02 for 1 cm cell or < 0.1 for 5 cm cell using the German BfR method
- Benzo(a)pyrene <0.25 mg/kg (250 ppb)
- Primary particles of 10-300nm, aggregates of 100-1200nm, agglomerates 300nm+

### **FDA - 21 CFR 178.3297 (United States of America)**

The U.S. Food and Drug Administration has listed to 2 types of Carbon Blacks for indirect food-contact applications, where Carbon Black is used as pigment in colorants for polymers.

#### **Channel Carbon Black**

Carbon Black, which is made from stripped natural gas according to Channel black process. According to the FDA there are no purity or other specifications defined for the channel Carbon Black related to safety for food contact.

#### **Furnace Carbon Black**

The second type are the high purity Furnace Carbon Blacks.

The applicable purity requirements for compliance with U.S. FDA regulations are:

- Total PAHs not to exceed 0.5 ppm
- Benzo(a)pyrene not to exceed 5.0 ppb

The content of Carbon Black should not exceed 2,5 % per weight of the polymer.

Heavy metals like lead (10 ppm), mercury (1 ppm) and arsenic (3 ppm) are also strongly limited.

### **Mercosur No 15/10 Colorants No 32/07 (South America)**

South American Mercosur has adopted the following purity criteria:

- Toluene extract ≤ 0.1%
- Cyclohexane extinction at 386 nm < 0.02 for 1 cm cell or < 0.1 for 5 cm cell
- Benzo(a)pyrene ≤ 0.25 mg/kg (250 ppb)
- In the final food contact item, a maximum of 2.5% Carbon Black by weight

### **Switzerland SR 817.023.21**

Switzerland has adopted the following purity criteria:

- Toluene extract ≤ 0.1%
- Cyclohexane extinction at 386 nm < 0.02 for 1 cm cell or < 0.1 for 5 cm cell
- Benzo(a)pyrene ≤ 0.25 mg/kg (250 ppb)
- In the final food contact item, a maximum of 2.5 % Carbon Black by weight is allowed

## Japan

Each product must be specifically approved by the Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA). Japan has adopted the following purity criteria:

- Toluene extract  $\leq$  0.1%
- Benzo(a)pyrene  $\leq$  0.25 mg/kg (250 ppb)

## China GB9695-208

China has adopted the following criteria:

- Toluene extract  $\leq$  1%
- Benzo(a)pyrene  $\leq$  0.25 mg/kg (250 ppb)
- Colorant Purity requirements of China food contact material
- In the final food contact item, a maximum percentage of Carbon Black by weight is allowed, depending of the type of polymer:
  - In PMMA, PVC, PVDC, PU, UP, PF, PEI, PPE, PBT, PPS, POM & LCP: max. 2.5%
  - In PE: max. 3%
  - In PP, PS, AS, ABS, PA, PET and PC: dosage as necessary

## REGULATIONS – FINISHED PRODUCTS

The following regulations apply only to the finished product. There are no regulatory restrictions on the Carbon Black itself.

- GS (Geprüfte Sicherheit) Marking (technical & consumer products)
- OEKO-TEX® - Standard 100 (textiles & leather products)
- European Directive 2005/69/EC (PAH in extender oils and tyres)
- GADSL Initiative (PAH limits arbitrarily set on global automotive parts)
- EU no. 1272/2016 (EU8) (cured rubber product)

Please note that the above regulations apply only to finished products and not to raw materials like Carbon Black. If you want to assess the suitability of specific Carbon Black grades, please contact us.

When evaluating exposure to Carbon Black, note that in the various products and finished articles containing Carbon Black in a wide range of loadings, the Carbon Black itself is not readily available, nor is it exposed to the outside environment. The Carbon Black is embedded and firmly bound into a polymeric matrix (e.g. rubber, plastics, coatings, ink, etc.).

As a result, Carbon Black itself cannot migrate out of the products or finished articles, thus reducing the probability of exposure to PAHs. In consideration of all this, the risks to human health associated with the presence of PAHs originating from the Carbon Black in the final products or finished articles is extremely low\*.

\* Source: <http://www.carbon-black.org/files/ICBA-PAH-Statement-2014-01-15-final.pdf>