

**CARBON BLACKS FOR FOOD-  
CONTACT APPLICATIONS BASED  
ON NATURAL AND SYNTHETIC RUBBER**

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Product Application PA R506-GL



## INTRODUCTION

Carbon black is an industrial product which is produced under accurately defined processing conditions and which consists essentially of elemental carbon. Carbon black contains small quantities of hydrogen, oxygen and sulfur in the form of functional groups. Due to the production process, traces of polycyclic aromatic hydrocarbons (PAH) exist, which are tightly bonded to the surface and which can only be extracted with organic solvent with considerable effort<sup>1</sup>.

This product application PA R506-GL presents an overview of selected regulations concerning the use of carbon blacks in indirect food-contact applications based on rubber. A table shows carbon blacks of Orion which are tested on a regular basis for this purpose. In the last part general information regarding toxicology of carbon blacks is provided.

## APPLICATIONS OF CARBON BLACKS FOR INDIRECT FOOD-CONTACT BASED ON RUBBER

Carbon blacks are used on a large scale as a reinforcing filler in rubber. In the applications with food contact, its purity plays an important role. The carbon black which is embedded in the rubber matrix has to fulfill special purity criteria in order to be suited for indirect food-contact commodities.

Food-contact commodities are defined in Section 2, Para. 2 No. 6 of the German Foodstuff, Articles of Daily Use and Feedstuff Code (Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch) as of September 15, 2021:

“Objects, which are destined for use related to production, treatment, placement into circulation or consumption of food and come into contact with foodstuffs or affect them.”

These include:

- packaging materials for food
- food containers for transport
- parts of devices for food production
- hoses, seals, fittings, molded parts
- container coatings (tanks) etc.

## PURITY REQUIREMENTS FOR CARBON BLACKS

Different regulations and recommendations, depending on the respective country, are valid for the use of carbon blacks for indirect food-contact applications, with the aim to avoid any adverse health effect for the consumer.

In the EU, there is no common regulation governing the use of carbon blacks in rubber articles in contact with food; most countries refer to one the national recommendations presented and discussed in the following.

In **Germany** the Federal Department for Risk Assessment (“Bundesinstitut für Risikobewertung, BfR”) has defined the purity requirements for carbon black in food-contact commodities in their XXIst Recommendation Food Commodities on the Basis of Natural and Synthetic Rubber (BfR XXI dated July 01, 2021). Carbon black is part of the “evaluated starting materials” and the requirements for carbon black used as a filler are defined there in table 1 as following:

- Toluene extractables: max. 0.1%, determined according to ISO method 6209
- UV absorption of the cyclohexane extract at 386 nm: < 0,02 AU for a cell of 1 cm or < 0,1 AU for a cell of 5 cm, determined by a generally recognized analytical method
- Benzo(a)pyrene content: max. 0.25 mg/kg carbon black

It should be mentioned that former editions of this recommendation did not include any limits for polycyclic aromatic hydrocarbons (PAH) like benzo[a]pyrene. This new requirement is only matched by very few carbon black grades.

<sup>1</sup> Stephan Hamm, Thomas Frey, Rudolf Weinand, Gilles Moninot, and Nicole Petiniot (2009) “Investigations on the Extraction and Migration behavior of Polycyclic Aromatic Hydrocarbons (PAHS) from Cured Rubber Formulations Containing Carbon Black as Reinforcing Agent”, Rubber Chemistry and Technology: May 2009, Vol. 82, No. 2, pp. 214-228; <http://dx.doi.org/10.5254/1.3548246>

The BfR XXI distinguishes several different applications and categories:

The prerequisite for the approval of an end product as food-contact commodity is the use of suitable ingredients which have been tested accordingly. In addition, the end product itself has to be tested. The concrete requirements for the respective consumer goods are listed in the following recommendations:

#### Recommendation XXI:

Explanatory notes.

Annex: Evaluated starting materials, additives and manufacturing aids

#### Recommendation XXI/1:

Elastomeric commodities in contact with food-stuffs in accordance with § 2 para. 6 sentence 1 no. 1 of the German Food and Feed Code

#### Recommendation XXI/2:

Special commodities made of elastomers according to § 2 para. 6 sentence 1 no. 3 or 5 of the German Food and Feed Code (formerly special category)

#### In preparation

#### Recommendation XXI/3:

Consumer goods made of cross-linked thermoplastic elastomers

Migration tests with model solvents are defined according to the respective category and upper limits are given respectively. In addition to total amount of extract, certain elements or classes of substances are considered (zinc, lead, N-nitrosamines, amines, formaldehyde and others). The manufacturer of the end product is responsible for the observance of these upper limits.

For elastomer products in contact with drinking water, the Elastomer Guidelines as of March 6, 2016 applies<sup>1</sup>.

The Positive List (Annex 1, Table 1.2 Fillers) was issued on December 3, 2019 and adjusted on March 7, 2022. For carbon black it now refers to the purity criteria of the Commission Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food. The criteria are basically the same as described above for BfR XXI.

For the final articles, migration tests shall be carried out to determine PAHs according to the TrinkwV 2011.

This guideline does not apply to thermoplastic elastomers (TPE) and silicones. Silicones can be assessed according to the requirements of the KTW guideline while TPE is assessed according to the TPE transition recommendation<sup>2</sup>.

In **France** the “Arrêté du 05 août 2020 Rubber articles in contact with food” has adopted the same limits for toluene extract, absorbance of a cyclohexane extract and benzo[a]pyrene content as the German BfR XXI.

Throughout the **EU** there is no common regulation regarding the purity requirements of rubber black; almost all countries act in accordance to one of the above mentioned national recommendations.

In the **USA** the recommendation of the Food and Drug Administration (FDA)<sup>3</sup>, which limits the content of channel and furnace blacks as filler for rubber articles for repeated usage to 50 weight %, applies. For products in contact with milk or for the consumption of certain oils, furnace blacks as fillers are authorized up to a maximum of 10 weight % (FDA CFR 21, Sec. 177.2600)<sup>4</sup>. Powder lamp blacks from Orion have recently been listed a usage level up to 50 weight %.

<sup>1</sup> [https://www.umweltbundesamt.de/sites/default/files/medien/5620/dokumente/20160316\\_elastomerleitlinie.pdf](https://www.umweltbundesamt.de/sites/default/files/medien/5620/dokumente/20160316_elastomerleitlinie.pdf)

<sup>2</sup> <https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/guidelines-evaluation-criteria>

<sup>3</sup> The FDA CFR 21, Sec. 177.2600 only furnace and channel blacks are allowed to be used in food contact applications based on rubber. The lamp black DUREX® 0 POWDER has been successfully approved as well (FCN No. 1381). This grade can be used at levels not to exceed 50% by weight in the finished articles. The safety of usage of DUREX® 0 POWDER in contact with infant formula and breast milk has not been evaluated.

<sup>4</sup> According to FDA CFR 21, Sec. 177.2600 DUREX® 0 BEADS - in contrast to DUREX® 0 POWDER - shall not be used in food contact applications based on rubber for the moment. A positive decision for this usage is under investigation.

<sup>5</sup> An explanation how TORs are used can be found here: Sec. 170.39 Threshold of regulation for substances used in food-contact articles <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=170.39>

In Sec. 170.39 it is mentioned that manufacturers other than those that actually made a request for exemption may also be using exempted substances in food-contact articles. However, it is mentioned that only the requestors will be notified if there is any change and/or withdrawn action! Consequently, it is important to understand that it lies within the responsibility of the user to check TORs on a regular basis.

<sup>6</sup> <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=TOR&id=2016-002>

In addition a Threshold of Regulation (TOR) Exemption<sup>5</sup>, TOR No. 2016-002 was published and updated in August 2017. This exemption applies for furnace carbon blacks for use in rubber that come in contact with milk and edible oils<sup>6</sup>.

In **China** the National Food Safety Standard GB 9685-2016 has implemented limits for use of additives in food contact materials and articles. Carbon blacks with a benzo[a]pyrene content of less than 0.25 ppm and a toluene extraction of less than 1% are approved for use in rubber food contact applications with a maximum use level of 50% in the compound.

## RECOMMENDED CARBON BLACKS FOR USE IN INDIRECT FOOD-CONTACT APPLICATIONS BASED ON RUBBER

Orion offers a selection of carbon blacks which are monitored with respect to their suitability in food contact. Those carbon blacks cover a wide range of reinforcing properties, hence the user may choose the proper carbon black to meet the different requirements (see Table 1).

## HEAVY METAL CONTENTS

The products mentioned in table 1 by their nature contain no heavy metals. The total content of the elements lead, cadmium, chromium and mercury amounts to less than 100 ppm and complies with the EU Regulation 2000/53/EC (end of life vehicles directive) and the Arrêté du 05 août 2020 Rubber articles in contact with food.

**Table 1**

**Recommended carbon blacks for rubber food contact applications**

TYPE	STSA	OAN	APPLICATION IN RUBBER ARTICLES
DUREX® 0 POWDER DUREX® 0 BEADS	17 18	133	Extruded articles with high demands on surface smoothness, low gloss and high elasticity
PUREX® HS 45 RP	39	121	Extrudates and molded articles with dynamic application
PUREX® HS 75 RP	74	99	Highly stressed technical articles with high modulus
PUREX® HS 95 RP	94	102	Articles with high abrasion resistance and high tear resistance

## TOXICOLOGY

### Human Experience

In decades of carbon black production and processing using a variety of methods, no significant hazardous effects have been registered.

### Acute Toxicity

Carbon black has an acute (oral) toxicity LD50 of > 8000 mg/kg bw. Carbon black applied on the intact skin and to the eye of the rabbit does not cause irritating or corrosive effects. Carbon black did not induce skin sensitisation effects in guinea pigs (OECD guideline 406). In humans, no cases of skin or respiratory allergies have been reported.

### Repeated Dose Toxicity

Carbon black has a NOAEL of 1 mg/m<sup>3</sup> (respirable) after repeated inhalation of rats for 13 weeks. Based on human data, a NOAEL can be estimated at 2 mg/m<sup>3</sup> (inhalable).

### Chronic Toxicity

In the early 1990s, extended long-term inhalation studies with rats showed lung fibrosis and tumor development in the case where the lungs were overloaded with carbon black particles. Mice and hamsters did not develop lung tumors under similar testing conditions. Although the significance of effects seen in rats under overload conditions for human risk assessment is today still controversially discussed, in October 1995, the International Agency for Research on Cancer (IARC) had evaluated available data on carbon black and amended its initial overall rating of carbon black from Category 3 to Category 2B ("possible human carcinogen") based on two long-term inhalation studies performed in rats under conditions of lung overload. Based on human (epidemiological) data, IARC concluded that there was "inadequate evidence" linking exposure to carbon black to

cancer development in humans. In subsequent evaluations of carbon black in 2006 and 2010, IARC upheld its previous rating. As a consequence of the IARC evaluation, carbon black is now included in the Danish cancer list and classified as a D2 A substance (poisonous and infectious material) in the Canadian Workplace Hazardous Materials Identification System (WHMIS) under the Canadian Environmental Protection Act (CEPA). Also due to the IARC classification, carbon black was included in 2003 in the Californian list "Proposition 65" when in the shape of "air-transported, unbound alveolar particles". The "Proposition 65" classification however does not apply to carbon black which is immobilized in a rubber matrix, i.e. conditions under which carbon black is not present in the air to breathe. The German MAK Commission reviewed carbon black in 1998. The overall rating of this commission is Category 3B ("possible human carcinogen") also based on the long-term inhalation studies on rats under conditions of lung overload.

### Ecotoxicology

Carbon black is an inorganic water insoluble substance. For this reason its bioavailability for aquatic organisms is very low. In acute tests according to OECD test guidelines with fish, daphnia and algae, nominal concentrations of 1,000 mg/l showed no effects. Based on the physicochemical and acute toxicological data no chronic effects and no bioaccumulation are to be expected in aquatic organisms. The general guidelines for the examination of the biodegradability of substances (OECD, EEC-guidelines) can be used only for organic substances. Carbon black is an inert inorganic substance with the structural formula "C" and is not biodegradable by microorganisms. The German commission for the evaluation of water polluting substances has classified carbon black as a "not water endangering" substance (KBwS-No: 1742).

### Registration status

Chemical name: Carbon black, amorphous  
CAS No: 1333-86-4  
See Table 2 for registration by country or region

### Further chemically legal regulations

Carbon black does not belong to the substances ruled by the clauses of the Chemical Weapons Convention. PAHs which are present in traces do not fall under the exclusion criteria of the Chemicals Ban Regulation (ChemVerbotsV).

Carbon black does not belong to the ozone depleting substances and is produced without using any of those (Montreal Convention – Ozone Depleting Substances).

**Table 2**

**Carbon blacks listings worldwide**

REGISTRATION STATUS		
Registration number CAS No 1333-86-4		
Australia	AICS	registered
Canada	DSL	registered
China	IECS	registered
Europe	EINECS REACH	215-609-9 registered
Japan	ENCS	5-3328
Korea	KECI	KE-04682
New Zealand	NZIoC	HSNO approved
Philippines	PICCS	registered
Taiwan	CSNN	listed
USA	TSCA	registered



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