

November 2017

## PRODUCT REGULATORY STATUS

Chemical name: **carbon black**

CAS No: **1333-86-4**

Product trade name:

Carbon black grades:

N115, N120, N121, N134, N220, N220FA, N234, N299, N326, N330, N339, N347, N375, N539, N550, N650, N660, N762, N772, N774.

Carbon black grades of OMCARB® series:

S500, S500A, S500FA, S600FA, S700, S800, S810, S820, H80, H100, C40, C50, C60, C70, C80, C140, CH85, CH200, CH210, CH600, P72, P80, P108, P110, P140.

Carbon black grades of FairBlack series:

R012, R013, R021, R022, R023, R027, R035, R056, R067

## REGULATORY INFORMATION

### Hazard classification

International Agency for Research on Cancer (IARC) has classified carbon black in Group 2B (may cause cancer in humans). The IARC classification is based on sufficient evidence in animals and inadequate evidence based on human health studies. However, it has been demonstrated with reasonable scientific certainty, that specific mechanism of tumor induction by carbon black in animals (specifically, rats) is not relevant to humans.

We continue to believe that carbon black does not present a health hazard when handled in accordance with good housekeeping and safe workplace. See Section 11 of the Safety Data Sheet for additional information.

### Europe

Carbon black is not a hazardous substance under classification criteria of Regulation (EC) 1272/2008 on classification, labelling and packaging of hazardous substances, as well as according to different amendments to this document.

### US

OSHA (29 CFR 1910.1200): Carbon black is considered hazardous substance (combustible dust). Carbon black is not classified for any toxicological or eco-toxicological endpoint.

### Canada

WHMIS (2015) classification: Carbon black is considered hazardous substance (combustible dust). Carbon black is not classified for any toxicological or eco-toxicological endpoint.

## Information on carbon black use in food contact consumer articles

### **Europe**

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

Carbon black is permitted for use as an additive in the manufacture of food contact plastic articles provided the requirements of product specification are observed. More detailed information about carbon black grades that meet these requirements can be presented by Omsk Carbon Group OOO Product Safety Representative.

Ref. No	Specification
42080	<ul style="list-style-type: none"><li>-Primary particles of 10 – 300 nm which are aggregated to a size of 100 –1200nm which may form agglomerates within the size distribution of 300nm – mm.</li><li>-Toluene extractable: maximum 0.1 %, determined according to ISO 6209 method.</li><li>-UV absorption of cyclohexane extract at 386 nm: &lt; 0.02 AU for a 1 cm cell or &lt; 0.1 AU for a 5 cm cell, determined according to a generally recognized method of analysis.</li><li>-Benzo(a)pyrene content: max 0.25 mg/kg carbon black.</li><li>- Maximum use level of carbon black in the polymer: 2.5% w/w.</li></ul>

#### *Resolution AP (89)1*

Carbon black is permitted for use as coloring additive in plastic consumer articles coming into contact with food provided:

-carbon black complies with national requirements for food grade material; -toluene extractable fraction of carbon black does not exceed 0.15%.

- concentrations of metals soluble in hydrochloric acid shall not exceed values as follows: Sb – 0.05%, As – 0.01%, Ba – 0.01%, Cd – 0.01%, Cr - 0.1%, Pb – 0.01%, Hg – 0.005%, Se – 0.01%

More detailed information about carbon black grades that meet these requirements can be presented by Omsk Carbon Group OOO Product Safety Representative.

### **Germany**

#### *BfR IX*

Carbon black is approved for use as coloring additive in plastics for consumer articles production provided the used product complies with requirements of Regulation (EU) 10/2011 and concentrations of metals soluble in hydrochloric acid shall not exceed values as follows: Sb – 0.05%, As – 0.01%, Ba – 0.01%, Cd – 0.01%, Cr - 0.1%, Pb – 0.01%, Hg – 0.005%, Se – 0.01%. More detailed information about carbon black grades that meet these requirements can be presented by Omsk Carbon Group OOO Product Safety Representative.

#### *BfR XIV*

Carbon black is permitted for application as additive in plastics dispersions that are used in the production of coating for food contact articles provided carbon black meets Regulation (EU) 10/2011 requirements. More detailed information about carbon black grades that meet these requirements can be presented by Omsk Carbon Group OOO Product Safety Representative.

Carbon black can be used as filler only in linings, but it must comply with the purity requirements laid down in 82<sup>nd</sup> Communication of the Bundesgesundheitsbl. 15 (1972) 268. More detailed information about carbon black grades that meet these requirements can be presented by Omsk Carbon Group OOO Product Safety Representative.

### **Switzerland**

*SR 817.023.21 2017*

Carbon black is permitted for use as an additive in the manufacture of food contact plastic articles (maximum use level of carbon black in the polymer: 2.5% w/w) (Annex 2) and printing inks (Annex 10) provided it fulfills criteria as follows:

- Primary particles of 10 – 300 nm, aggregates of 100 –1200nm, agglomerates of 300nm – mm.
- Toluene extractable: maximum 0.1 %, (ISO 6209 method).
- UV absorption of cyclohexane extract at 386 nm: < 0.02 AU for a 1 cm cell or < 0.1 AU for a 5 cm cell, determined according to a generally recognized method of analysis.
- Benzo(a)pyrene content: max 0.25 mg/kg carbon black.

More detailed information about carbon black grades that meet these requirements can be presented by Omsk Carbon Group OOO Product Safety Representative.

### **China**

*GB 9685-2016*

Carbon black is permitted for application in the following food contact materials: plastics, coatings, rubber applications (maximum use level of carbon black in the rubber article shall not exceed 50 w/w), inks, paper.

At that carbon black (CAS 1333-86-4), additive code FCA0409, shall meet purity requirements as follows: toluene extractables - <1 %, benzo(a)pyrene content - <0.25 ppm, concentrations of metals soluble in hydrochloric acid shall not exceed values as follows: Sb – 0.05%, As – 0.01%, Ba – 0.01%, Cd – 0.01%, Cr - 0.1%, Pb – 0.01%, Hg – 0.005%, Se – 0.01%.

More detailed information about carbon black grades that meet these requirements can be presented by Omsk Carbon Group OOO Product Safety Representative.

### **US**

*FDA 21 CFR § 177.2600*

Carbon black is permitted for application as filler in food contact rubber articles intended for repeated use provided restrictions on carbon black percentage in rubber article are observed.

#### *Limitations:*

Total carbon black content (channel + furnace carbon black) must not exceed 50% by weight of the rubber article. All Omsk Carbon Group carbon blacks are furnace process blacks.

Furnace carbon black content must not exceed 10% by weight of the rubber article, intended for use in contact with milk or edible oils.

### **Medical use status**

Carbon black is not approved for medical applications. It cannot be used in the manufacture of pharmaceuticals or food colors.

## Pharmaceutical packaging

Carbon black is not mentioned on any of the positive lists of European Pharmacopeia Section 3.1 (Materials Used for Manufacture of Containers). Therefore, carbon black cannot be used in pharmaceutical packaging.

## Cosmetics applications

Omsk Carbon Group OOO does not find any justification for product use in any cosmetic application.

## Carbon black compliance with international requirements on metals content

Directives, regulations and standards listed below apply to finished consumer articles or production facilities rather than to raw materials such as carbon black. Based on available data, as per regulations below the individual content of metals soluble in hydrochloric acid in any of our products does not exceed 10 ppm.

The available information about heavy metals content in produced carbon black can be presented on customer's demand by Product Safety Representative.

*Packaging and packaging waste:* Directive EC 94/62; US Coalition of North Eastern Governors (CONEG).

*End of Life Vehicles:* Directive EC 2000/53/; Act for Resource Recycling of Electrical and Electronic Equipment and Vehicles (Korean RoHS), Korea.

*Electrical and electronic equipment:* Directive EC 2011/65; Act for Resource Recycling of Electrical and Electronic Equipment and Vehicles (Korean RoHS), Korea; standards GB/T 26572, China; JIS C 0950, Japan; CNS 15663, Taiwan; Regulation on Control over electric and electronic equipment waste dated May 22 2012 (Turkish RoHS), Turkey.

*Safety of toys:* Standards Mercosur NM 300-3, EN 71-3, EU; ASTM F963, US; Directive 2009/48, EU; Regulations No. 29847, Turkey; SOR/2011-17, Canada.

## Organic/inorganic impurities, allergens and products from animals and plants

Carbon blacks have not been analyzed for the chemicals listed below, but as far as none of the chemicals listed below are used in our production, these chemicals are not expected to be present in finished goods.

### *Organic impurities*

- Aliphatic and aromatic solvents
- Azo compounds, aromatic amines and dyes
- Halogenated hydrocarbons including among others, brominated hydrocarbons, aliphatic chlorinated hydrocarbons, dioxins, flame retardants, fluorinated hydrocarbons, PCBs, PCTs, PFOS, PFOA, ozone depleting substances (ODS) like CFCs and HCFCs.
- Furans
- Glycol ethers
- Phenols
- Endocrine Disrupters, i.e. phthalates and bisphenol-A
- Volatile organic compound
- Pesticides and biocides, including dimethyl fumarate
- Organotin derivatives
- Latex
- Formaldehyde
- BADGE, BFDGE and NOGE
- Acrylamide
- Isopropyl thioxanthone (ITX)
- Benzophenone derivatives

### *Inorganic impurities*

- Asbestos
- Heavy metals (<10 ppm for each metal: As, Cd, Co, Cu, Cr, Hg, Ni, Pb, Sb, Se).

### *Products from animal or plant origin*

To the best of our knowledge carbon black:

- does not contact with any products of animal/plant origin or any animal/plant by-products in the process of production and processing;
- does not contain any bovine materials or any materials associated with the development of Bovine Spongiform Encephalopathy (BSE) or Creutzfeldt-Jakobs Disease (CJD);
- does not contain any Genetically Modified (GMO) products or materials.

### *Allergens*

Carbon black does not contain any allergens mentioned in:

- Annex II of European Directive 1169/2011;
- US FDA Food Allergen Labelling & Consumer Protection Act, 2004 (FALCPA).

Abovementioned list of chemical substances is not exhaustive. If it does not contain a substance that is of interest to the customer, please, contact Omsk Carbon Group OOO Product Safety Representative.

### Content of hazardous substances that are subject to US Federal Regulations

Carbon black does not contain:

- any components covered by TSCA 12(b) Export Notification;
- any components listed in Clean Air Act Amendments of 1990 (CAA, Section 112, 40 CFR 82) as Hazardous Air Pollutant, Flammable Substance, Toxic Substance or Class 1 or 2 Ozone Depletor;
- any Priority Pollutants listed in Clean Water Act (CWA, 40 CFR 116);
- Hazardous Substances listed in The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, 40 CFR 302);
- Extremely Hazardous Substances listed in Section 302 of Superfund Amendments and Reauthorization Act (SARA), Title III.

### Other information

#### **US**

##### *Massachusetts Right-to-Know Substances List*

Carbon black is listed.

##### *Pennsylvania Right-to-Know Substances List*

Carbon black is listed.

##### *New Jersey Right-to-Know Substances List*

Carbon black is listed

## *Louisiana Right-To Know Law*

Right-to-Know legislation requires inventory reporting through Community Right-to-Know when carbon black is present on-site in amount exceeding 500 pounds on any given day. Spills or releases beyond the site of the facility of greater than 5000 pounds are required to be immediately reported to the state Emergency Response Commission via Office of the State Police, Transportation and Environmental Safety Section, Hazardous material Hotline.

## *SARA Section 313 (40 CFR 372) Toxics Release Inventory (TRI)*

Since carbon black contains traces of Polycyclic Aromatic Compounds (PACs) the consumers are advised to evaluate their own responsibilities for TRI reporting to Environmental Protection Agency (EPA) and State Emergency Response Commission (SERC).

## *SARA Sections 311/312 (40 CFR 370) Hazard Category*

Chronic/Delayed Health Hazard, Fire Hazard. Reporting may be required if the material is present at any time in amounts equal to or greater than 10000 pounds.

### **CARBON BLACK STATUS IN GLOBAL CHEMICAL INVENTORIES**

Carbon black is listed in the following global chemical inventories:

- **TSCA** - US Inventory of Chemical Substances;
- **EINECS** - European Inventory of Existing Commercial Chemical Substances (**No. 215-609-9**);
- **DSL** – Canada Domestic Substances List under the Canadian Environmental Protection Act (CEPA);
- **AICS** - Australian Inventory of Chemical Substances;
- **ENCS** – Inventory of existing and new chemical substances under the Chemical Substances Control Law (**METI No. 5-3328**), Japan;
- **ISHL** – Inventory of substances notified under the Industrial Safety and Health Law (ISHL), Japan;
- **KECL** – Korea Existing Chemicals List (**KE-04682**) under the Korean Chemicals Control Act (CCA);
- **PICCS** – Philippine Inventory of Chemicals and Chemical Substances;
- **IECSC** – Inventory of Existing Chemical Substances in China;
- **NZIoC** – New Zealand Inventory of Chemicals (**HSNO Approval Code: HSR002801**);
- **TCSI** – Taiwan's chemical substance inventory.

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