

January 2021

## **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, S700FA, 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

## **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 procedures. See Section 11 of the Safety Data Sheet for additional information.

### **European Union**

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.

### **Turkey**

According to the criteria and requirements set forth in the Regulation on classification, labelling and packaging of hazardous substances and mixtures published in the Turkey Official Gazette under No. 28848 on December 11, 2013 (otherwise referred to as SEA Regulation), carbon black is not classified as hazardous substance.

## **US**

OSHA Hazard Communication Standard, 2012 (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.

## **China**

Regulations on Safe Management of Hazardous Chemicals (2011) – State Council Decree 591 of March 11, 2011: carbon black is not listed in the Catalog of Hazardous Chemicals 2015.

## **Japan**

Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture (otherwise referred to as Chemical Substances Control Law, CSCL) as amended in 2017 regulates the following categories of substances that pose or suspected to pose risk for human health and / or environment:

- Class I Specified Substances
- Class II Specified Substances
- Monitoring Chemical Substances
- Priority Assessment Chemical Substances
- Specified General Chemical Substances

Carbon black is not designated for any of these categories. According to CSCL carbon black is an existing chemical substance with MITI No. 5-3328.

## **South Korea**

Korean Act on the Registration and Evaluation of Chemical Substances (ARECS), also known as Korea REACH controls substances enlisted in:

- Priority Control Substances List;
- CMR list;
- Restricted Substances list;
- Prohibited Substances list.

Carbon Black is not designated as CMR substance, priority control substance, restricted substance, prohibited substance. Under the ARECS carbon black is a phase-in substance subject to registration.

## **REGULATORY INFORMATION ON CARBON BLACK USE IN FOOD CONTACT APPLICATIONS**

### **European Union**

#### **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 be observed. For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

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%

For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

**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%. For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

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. For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

BfR XXI

Carbon black can be used as filler in linings for commodities stated in the paragraph 2.1.1 and as filler for manufacturing of commodities stated in paragraphs 2.2.1, 2.3.1, 2.4.1 in case it complies with the purity requirements laid down in 82<sup>nd</sup> Communication of the Bundesgesundheitsbl. 15 (1972) 268 and restrictions on carbon black percentage. For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

KTW-Leitlinie

This Guideline establishes certain requirements for substances used in plastics that come to contact with drinking water, in particular, fillers and colorants must comply with the requirements set forth in BfR IX and LII. For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

Elastomerleitlinie

Carbon black is approved for use as filler in elastomers in contact with drinking water provided that it complies with the following requirements: metals and metalloids content: Pb ≤ 0.01%, As ≤ 0.01%, Hg ≤ 0.0005%, Cd ≤ 0.01%, Sb ≤ 0.005%; PAH content according to TrinkwV Ordinance 2001: BaP ≤ 0.00001 mg/l (0.01 ppm), ∑ benzo(b)fluoranthene, benzo(j)fluoranthene, benzo(ghi)perylene and indeno(1,2,3-cd)pyrene ≤ 0.0001 mg/l (0.1 ppm); purity requirements in accordance with BfR XXI. For detailed

information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

## **France**

### **Séance du 7 novembre 1995**

By the Decision of the Supreme Council of Public Health of France on the results of the meeting of November 7, 1995, carbon black is approved for use in inks and varnishes to be printed on packaging intended for contact with foodstuffs provided that it complies with the following restrictions:

The content of metals and metalloids soluble in 0.1 M HCl: Sb  $\leq$  0.05%; As  $\leq$  0.01%; Ba  $\leq$  0.05%; Cd  $\leq$  0.01%; Cr  $\leq$  0.1%; Pb  $\leq$  0.01%; Hg  $\leq$  0.005%; Se  $\leq$  0.01%;

Content of substances extractable with toluene: not more than 0.15%

BaP content should not exceed 30  $\mu$ g / kg.

For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

### **Arrêté du 9 novembre 1994**

By this Decree, carbon black is authorized for use as additive in production of plastic materials and products in contact with foodstuffs provided that it complies with the following requirements:

Content of metals and metalloids soluble in 0.1 M HCl: Pb  $<$  0.01%; As  $<$  0.01%; Hg  $<$  0.005%, Cd  $<$  0.01%; Cr  $<$  0.1%; Se  $<$  0.01%; Ba  $<$  0.01%.

Content of substances extractable with toluene: not more than 0.15%.

UV-Absorption of cyclohexane extract at 386nm:  $<$  0.02 AU for for a 1 cm cell.

SML benzo (a) pyrene from finished products using carbon black as a filler should not exceed the detection limit of the analytical method used (LD = 0.05  $\mu$ g/kg)

The maximum content of carbon black in the product should not exceed 50 % w/w, for products in contact with milk or fats - not more than 30% w/w.

For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

### **Arrêté du 25 novembre 1992**

By this Decree, carbon black is authorized for use as additive in production silicone elastomeric materials and products in contact with foodstuffs provided that it complies with the following requirements:

Content of substances extractable with toluene: not more than 0.15%

BaP content should not exceed 30  $\mu$ g/kg.

For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

### ▪ **Arrêté du 2 janvier 2003**

By this Decree, carbon black is authorized for use as technical filler (not colorant) in plastic materials and products in contact with foodstuffs provided that it complies with the following requirements:

Toluene extractable: maximum 0.1 %, determined according to 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.

Maximum use level of carbon black in the polymer: 2.5% w/w.

For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

## 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.

For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

## 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%.

For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

## US

### FDA 21 CFR § 177.2400

Carbon black is cleared for use in perfluorocarbon cured elastomers provided restrictions on carbon black percentage in terpolymer are observed.

#### *Limitations:*

Total carbon black (channel process or furnace combustion process) content must not exceed 15 parts per 100 parts of the terpolymer. All Omsk Carbon Group carbon blacks are furnace process blacks.

### FDA 21 CFR § 177.2600

Carbon black is cleared 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 must not exceed 50% by weight of the rubber article. Not for use in contact with infant formula and human milk (see TOR 2016-002). All Omsk Carbon Group carbon blacks are **furnace process** blacks.

### FDA 21 CFR § 178.3297

High-purity furnace black is cleared for use as colorant for polymers to be used in food contact products provided restrictions on PAHs content and carbon black percentage in polymer are observed.

#### *Limitations:*

Total polynuclear aromatic hydrocarbons not to exceed 0.5 parts per million, and benzo[a]pyrene not to exceed 5.0 parts per billion.

For use at levels not to exceed 2.5 percent by weight of the polymer.

All Omsk Carbon Group carbon blacks are **furnace process** blacks. For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

## **Australia**

### **AS 2070 —1999**

Colorants used in the manufacture of plastic materials and products must comply with the requirements of the Resolution AP(89)1. Detailed information on the carbon black grades that meet this requirement can be obtained by contacting the Omsk Carbon Group Product Safety Representative.

## **MERCOSUR**

### **GMC/RES. Nº 39/19**

Carbon black (ref. No. 42080) is permitted for use as an additive in the manufacture of food contact plastic articles and polymer coatings provided it complies with the following specifications:

- 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.
- Toluene extractable: maximum 0.1 %, determined according to 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.
- Maximum use level of carbon black in the polymer: 2.5% w/w.

For detailed information about carbon black grades that meet these requirements, please, contact Product Safety Representative of Omsk Carbon Group.

## **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; standard GB/T30512-2014 Requirements for prohibited substances in automobiles, China.

**Electrical and electronic equipment:** Directive EC 2011/65; Act for Resource Recycling of Electrical and Electronic Equipment and Vehicles (Korean RoHS), Korea; standard GB/T 26572-2011 Requirements on concentration limits for certain restricted substances in electrical and electronic products, 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, PRODUCTS FROM ANIMALS AND PLANTS AND OTHER SUBSTANCES OF CONCERN**

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 carbon black production, **these chemicals are not expected to be present in Omsk Carbon Group products:**

### Organic impurities

- Aliphatic and aromatic solvents
- Azo compounds, aromatic amines and dyes, melamine
- Halogenated hydrocarbons including among others, brominated hydrocarbons; chlorinated aliphatic hydrocarbons, fluorinated hydrocarbons, PCBs, PCTs, PFOS, PFOA and other surfactants including fluorosurfactants (PFAS)
- Ozone depleting substances (ODS) like CFCs and HCFCs
- Flame retardants, including among others polybrominated biphenyl (PBBs), polybrominated diphenyl ethers (PBDEs)
- Furans and dioxins
- Persistent organic pollutants (POPs)
- Glycol ethers
- Phenols
- Endocrine disrupting chemicals (EDCs), including among others phthalates, bisphenol-A, DDT
- Volatile organic compounds (VOCs)
- Pesticides, insecticides and other biocides, including dimethyl fumarate
- Organotin and its derivatives
- Latex
- Organic silicon compounds (silicones)
- Formaldehyde
- BADGE, BFDGE and NOGE
- Acrylamide
- Mica
- Isopropyl thioxanthone (ITX)
- Benzophenone and its derivatives

### Inorganic impurities

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

### Products of 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).

Other substances of concern

-Radioactive substances

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 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**

California Proposition 65

"Carbon black (airborne, unbound particles of respirable size)" is a California Proposition 65 listed substance. NOTE: all three listing qualifiers (airborne, unbound, and respirable size) must be met for this substance to be considered a Proposition 65 substance.

Certain polycyclic aromatic hydrocarbons (PAHs), including but not limited to benzo(a)pyrene and benzo(k)fluoranthene, may be found adsorbed onto the surface of carbon black and are California Proposition 65 listed substances.

Certain metals, including arsenic, cadmium, lead, mercury, and nickel, may be found adsorbed onto the surface of carbon black and are California Proposition 65 listed substances.

"Carbon-black extracts" is a California Proposition 65 listed substance.

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.

### Japan

Article 57-2 of the Japan Industrial Safety and Health Law (ISHL) and Article 18-2 of the Enforcement Order determine certain substances, for which an SDS and mandatory labelling shall be produced in case of their presence in concentrations above established cut-off values.

Carbon black is regulated as a chemical substance requiring an SDS (with cut-off value >0.1% w/w) and labeling (with cut-off value >1% w/w) as it is specified as No. 130 (Carbon black) in Article 18-2, Appended Table 9 of the Enforcement Order following Article 57-2 of ISHL.

## **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.

**This document covers the whole range of products manufactured by all plants of Omsk Carbon Group, namely Omsk Carbon Group OOO in Omsk, Russia, the branch of Omsk Carbon Group OOO in Volgograd, Russia, and Omsk Carbon Mogilev IOOO, Republic of Belarus.**

Person in charge for this document:

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The information contained in this document reflects the actual knowledge of our company (Omsk Carbon Group) at the time of the document preparation. The list of considered laws and regulations regulating carbon black directly or indirectly is not exhaustive in this document. Although we believe that information contained herein is accurate, we do not bear any responsibility for its use.

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