

April 16,2018

## PRODUCT REGULATORY STATUS

**Chemical Name(s):** CARBON BLACK

**CAS #(s):** 1333-86-4

### **Trade Name(s):**

Thermax<sup>®</sup> N990, Thermax<sup>®</sup> N991 Powder, Thermax<sup>®</sup> N990 Ultra Pure, Thermax<sup>®</sup> N991 Powder Ultra Pure, Thermax<sup>®</sup> N908 Stainless Powder Ultra Pure, Thermax<sup>®</sup> N907 Stainless, Thermax<sup>®</sup> N908 Stainless Powder, Fine Thermal, MFT, Carbocolor<sup>®</sup>, Carbocolor<sup>®</sup> Powder.

## **REGULATORY INFORMATION**

### Indication of Danger

Not a hazardous substance or preparation under the Globally Harmonized System (GHS). Not a hazardous substance or preparation under EC-directives 67/548/EEC or 1999/45/EC and their various amendments and adaptations. Not hazardous substance or preparation under CLP-Regulation (EC) No 1272/2008.

### US and EU Pharmaceutical Contact Information

Carbon Black is not mentioned on any of the positive lists of the European Pharmacopoeia section 3.1, Materials Used for Manufacture of Containers (Edition 4.2, 2002). Certain materials that are not on the positive lists can be used for the manufacture of pharmaceutical packaging but it is the responsibility of the manufacturer of the pharmaceutical packaging to perform the appropriate migration tests upon that packaging. This testing must be performed for each type of pharmaceutical packaging and for each pharmaceutical contained in that packaging.

### Cosmetics Applications

Carbon Black does not have an INCI (International Nomenclature of Cosmetic Ingredients) name assigned by The Cosmetic, Toiletry, and Fragrance Association (CTFA) and cannot be included in cosmetic preparations. Cancarb Carbon Blacks have not been tested in humans or animals for cosmetic purposes. For industrial safety reasons, they have been tested in animals for skin sensitization/irritation effects and have been designated as non-sensitizing and non-irritant.

### California Proposition 65

"Carbon black (airborne, unbound particles of respirable size)" is a California Proposition 65 listed substance. Please note that all three listing qualifiers (airborne, unbound (not bound within a matrix), and respirable size (10 micrometers or less in diameter) must be met for this substance to be considered a Proposition 65 substance.

### Carbon Black is listed on the following inventories:

Australian Inventory of Chemical Substances (AICS)  
European Inventory of Existing Commercial Chemical Substances (EINECS)  
Canadian Domestic Substances List (DSL)  
Inventory of Existing Chemical Substances Produced or Imported in China (IECSC)  
Japanese Existing and New Chemical Substances (ENCS)  
Korean Existing Chemicals List (KECL)  
Philippine Inventory of Chemicals and Chemical Substances (PICCS)  
United States Toxic Substances Control Act (TSCA) Inventory

*\*For a complete list of Cancarb's trademarks and the countries where they are registered go to <http://cancarb.com/trademarks.html>.*

**COMPLIANCE OF CANCARB CARBON BLACKS WITH VARIOUS EU AND U.S. HEAVY METAL AND OTHER LEGISLATION:**

Cancarb Carbon Blacks  
Typical Metals Analysis (ppm)

antimony (Sb)	<0.01
arsenic (As)	<0.5
barium (Ba)	<0.01
beryllium (Be)	<0.01
bismuth (Bi)	<0.01
cadmium (Cd)	<0.01
total chromium (Cr)	<0.5
cobalt (Co)	<0.05
copper (Cu)	<0.1
lead (Pb)	<0.01
manganese (Mn)	<0.1
mercury (Hg)	<0.05
molybdenum (Mo)	<0.01
nickel (Ni)	<0.1
selenium (Se)	<0.5
thallium (Tl)	<0.01

These data and conclusions are based on work believed to be reliable; however, we cannot and do not guarantee that similar results and/or conclusions will be obtained by others, and we disclaim any liability resulting from the use of this information.

Dodd-Frank Wall Street Reform and Consumer Protection Act, section 1502, Conflict Minerals

Tantalum, Tin, Gold or Tungsten are not contained in Cancarb Thermal Carbon Blacks and are not necessary to the functionality or production of Cancarb Thermal Carbon Blacks. Trace quantities may exist in Cancarb Thermal Carbon Blacks due to the use of potable water quenching, but none exist with Democratic Republic of Congo origin.

Electrical and Electronic Equipment (EEE) EU Directive 2016/585/EU Restriction of the use of certain Hazardous Substances (2011/65/EU RoHS recast)

The above directive prohibits the use of the following substances above the threshold levels shown below in various EEE placed on the EU market:

- 0.1% by weight in homogenous materials – lead, mercury, hexavalent chromium, polybrominated, biphenyls (PBBs), and polybrominated diphenyl ethers (PBDEs including Decabromodiphenyl ether Deca-BDE),; Bis (2- ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DiBP); and,
- 0.01% by weight in homogenous materials - cadmium

To the best of our knowledge, the substances listed above are not present in Cancarb’s carbon black product(s) at concentrations at or above the threshold levels.

Packaging and Packaging Waste (EU Directive 94/62/EC) and U.S. CONEG

The above legislation applies to packaging and packaging waste but not directly to their constituents. We confirm that the total content of Pb, Cd, Hg and Cr VI in Cancarb Carbon Blacks and packaging is less than 100 ppm.

## End of Life Vehicles (EU Directive 2000/53/EC) Modified by Commission Decision 2002/525/EC

We confirm that we do not use Cd, Cr VI, Hg or Pb and their derivatives during the production of Cancarb Carbon Blacks. Ozone Depleting Substances European Directive 88/540/EEC, amended by the European Directive 91/690/EC and US EPA Clean Air Act, 1993 Amendments (40 CFR 82.104)

We confirm that Cancarb does not add nor does our Carbon Black contain any Ozone Depleting Substances.

## REACH

We confirm that Cancarb Carbon Black does not contain any of the “Candidate List of Substances of Very High Concern” (SVHC) at levels >0.1 % as defined in the REACH legislation and posted on the ECHA website at <http://www.echa.europa.eu/web/guest/candidate-list-table> as of January 15, 2018. None of the Candidate List SVHCs are used in the manufacture of Cancarb Carbon Blacks.

In addition we confirm that Cancarb Carbon Black also does not contain any of the “Consultation List of Substances of Very High Concern” (SVHC) at levels >0.1 % as defined in the REACH legislation and posted on the ECHA website at <http://www.echa.europa.eu/web/guest/proposals-to-identify-substances-of-very-high-concern> as of February 29, 2016. None of the Consultation List SVHCs are used in the manufacture of Cancarb Carbon Blacks.

TCLP Testing (EPA – 40 CFR 261.24): None

Cancarb has performed this testing on a typical sample and has found no listed metals, volatile organic compounds or non-metallic substances over the assigned low thresholds. Pesticides were not tested since they are not present in production and handling processes and they are not expected to be present in concentrations above low levels of concern

## **ORGANIC AND INORGANIC IMPURITIES:**

Cancarb Carbon Blacks are not routinely analyzed for the following regulated chemicals. These chemicals are not involved in our production and handling processes and they are not expected to be present in our carbon blacks in concentrations above low ppm or less, below the levels of concern:

### Inorganic Impurities

- Asbestos
- Heavy metals - please refer to the typical [Cancarb Carbon Black metal analysis](#) above for more specific information.

### 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, PCB's, PCT's, and ozone depleting substances (ODS) like CFC's and HCFC's

Furans

Glycol ethers

Phenols

Endocrine Disrupters, i.e., phthalates and bisphenol - A

Pesticides and biocides

Organotin derivatives

Latex

Formaldehyde

BADGE, BFDGE and NOGE

Acrylamide

Also, within the meaning of various United States and European regulations, Cancarb Carbon Blacks do not contain volatile organic compounds (VOC's) or hazardous air pollutants (HAP's) above trace amounts.

#### TSCA Section 8(a) Information Gathering Rule on Nanomaterials in Commerce

On January 12, 2017, the US Environmental Protection Agency (EPA) published a final rule establishing one-time reporting and recordkeeping requirements for chemical substances when they are manufactured, imported, or processed at the nanoscale. 82 Fed. Reg. 3641 (Jan. 12, 2017).

Cancarb Thermal Carbon Blacks are not subject to the one-time reporting under the Rule, and do not meet the EPA's definition of "reportable chemical substance" which includes substances intentionally manufactured or processed to exhibit "unique and novel properties." The EPA defines "unique and novel properties" as "...any size-dependent properties that vary from those associated with other forms or sizes of the same chemical substance not in the size range of 1-100 nm, and such properties are a reason that the chemical substance is manufactured or processed in that form or size." Thermal Carbon Black is not manufactured to exhibit any size-dependent, unique and novel properties, as defined by the EPA.

#### EU Nanomaterial Definition

The EU adopted a definition of a nanomaterial in 2011 ([Recommendation on the definition of a nanomaterial](#) (2011/696/EU)) as follows: "A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm".

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.

By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials. For further information refer to the [EC Environmental webpage](#).

Cancarb has performed testing on typical samples of our Thermal Carbon Blacks and can confirm that we do not meet the EU definition for Nanomaterials. Thermal Carbon Black exhibits aciniform morphology composed of spheroidal primary particles strongly fused together, with no clearly defined boundaries, to form discrete entities called aggregates. Close to 100% of Thermal Carbon Black primary particles have an average size of 250 nm and are bound in aggregates. The aggregates are loosely held together by weaker forces forming larger entities called agglomerates. Thermal Carbon Black is placed on the market in the form of agglomerates. The agglomerates will break down into aggregates if adequate force is applied (e.g., shear force). However, aggregates will not break down under any foreseeable situation. Thus, primary particle size is not relevant for Thermal Carbon Blacks manufactured, imported or placed on the market as generally such particles do not exist "in an unbound state" as it is mentioned in the EU recommendation on the definition for nanomaterials.

#### **PRODUCTS OF ANIMAL OR PLANT ORIGIN**

Cancarb Carbon Blacks are **not derived** from any products of animal or plant origin or any animal or plant by-products. They do not contain any bovine materials or any materials associated with the development of Bovine Spongiform Encephalopathy (BSE) or Creutzfeldt-Jakobs Disease (CJD). They do not contain any Genetically Modified (GMO) products or materials.

#### **SELF-HEATING SPONTANEOUS COMBUSTION AND READILY FLAMMABLE**

Cancarb Carbon Blacks are of mineral origin. They are not a self heating substance and do not exhibit spontaneous combustion behaviour and are not flammable according to tests carried out in accordance with UN methods or DIN EN 15188 for Transport of Dangerous Goods.

UN methods specify that if the temperature of a 100mm cube exceeds 200 °C after being exposed to 140 °C for 18 hours the substance is considered a self heating substance. Cancarb Carbon Blacks did not exceed 200 °C.

In order to satisfy other requirements (Approved Requirements and test methods for the classification and packaging of dangerous goods for carriage 1996 Health & Safety Commission for the transportation of potentially self-heating substances) that prove a substance is not a self heating substance the self-heating temperature of a 27m<sup>3</sup> cube of the product shall be equal to or more than 50 °C. The temperature at which this volume of Cancarb Carbon Blacks become super-critical as defined by DIN EN 15188 and can self-heat to ignition is found to be 183 °C. Hence, Cancarb's Carbon Black is not classified as a self-heating substance.



President  
Ken Tate