



Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): Carbon black

EC Number: 215-609-9

CAS Number: 1333-86-4

Authority: FR MSCA

Date: 22/03/2016

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

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1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Other Substance identifiers

EC name (public):	Carbon Black
IUPAC name (public):	Carbon black
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	Substantially elemental carbon, C
Molecular weight or molecular weight range:	12.01 (elemental carbon)
Synonyms:	Trade names : Carbon Black Chezacarb AC - type A+ Carbon Black Chezacarb AC - type A Carbon Black Chezacarb AC - type B Saze Chezacarb AC - typ A+ Saze Chezacarb AC - typ A Saze Chezacarb AC - typ B Thermax® Carbocolor Carbocolor Powder Colorant residue TB Powder Therblack Theratomic CONTINEX Diamond Carbon Blacks CONTINENTAL CARBON Carbon Black - Grades N-110, N-120, N-220, N-234, N-326, N-330, LH30, N-339, N-351, N-550, N-600, N-650, N-660, N-683, N-762, N-774 IRB #8

Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula: not applicable

Other relevant information about substance composition

Polycyclic aromatic hydrocarbons (PAH) are found as extractable impurities in carbon black (variable levels depending on the type of carbon black manufacture).

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table 2: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check, Final decision
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
	Restriction	<input type="checkbox"/> Annex XVII
Harmonised C&L	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	
Other processes / EU legislation	<input checked="" type="checkbox"/> Other (provide further details below)	

Further details	Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.
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3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification is available for carbon black (CAS 1333-86-4) according to CLP regulation.

3.1.2 Self classification

- In the registration:

No self classification proposed in the joint submission and in one individual submission.

Carc 2 H351 is proposed by the individual submission of Gazprom CSR.

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
 - Self-heat. 1 H251
 - Self-heat. 2 H252
 - Flam. Sol. 2 H228
 - Acute Tox 4 H332
 - Skin Irrit 2 H315
 - Eye Irrit 2 H319
 - STOT SE1 H370
 - STOT SE3 H335
 - STOT RE1 H372
 - STOT RE2 H373
 - Aquatic Chronic 1 H410
 - Aquatic Chronic 4 H413

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Not relevant

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES¹

4.1 Tonnage and registration status

Table 3: Tonnage and registration status

From ECHA dissemination site		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa
<input checked="" type="checkbox"/> 1000 – 10,000 tpa	<input checked="" type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa
<input checked="" type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential
1 joint submission (1,000,000 – 10,000,000 tpa) 2 individual submissions (1000 – 10,000 tpa and 10,000 – 100,000 tpa)		

¹ Please provide here the date when the dissemination site was accessed.

4.2 Overview of uses

3 registrations dossiers are available with various uses:

- 1 joint submission
- 2 individual submissions

Additional information on uses is also available.

Table 4: Uses

Part 1:

<input checked="" type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Article service life	<input checked="" type="checkbox"/> Closed system
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Part 2:

	Use(s)
Formulation	Manufacture of reinforcement material of rubber products such as tyre Additive for rubber (app. 80% of carbon black consumption) Additive for plastics (approx. 10 % of carbon black consumption) Pigment (approx. 9% of total carbon black consumption) Chemical reagent (< 1 % of total carbon black consumption) Refractories (< 1 % of total carbon black consumption) Polymer processings...
Uses at industrial sites	Additive for rubber (app. 80% of carbon black consumption) Additive for plastics (approx. 10 % of carbon black consumption) Pigment (approx. 9% of total carbon black consumption) Chemical reagent (< 1 % of total carbon black consumption) Refractories (< 1 % of total carbon black consumption) Adhesives and sealants...
Uses by professional workers	Additive for rubber (app. 80% of carbon black consumption) Additive for plastics (approx. 10 % of carbon black consumption) Pigment (approx. 9% of total carbon black consumption) Chemical reagent (< 1 % of total carbon black consumption) Refractories (< 1 % of total carbon black consumption) In a mixture...

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<p>Consumer Uses</p>	<p>Use in coatings Use of polymer articles Portable energy and rechargeable batteries Other carbon preparations Pigment</p>
<p>Article service life</p>	<p>Tyre manufacturing with imported mixture which contains the substance (carbon black) Manufacture of reinforcement material of rubber products such as tyre used as compound colorant Additive, filler or pigment for rubber (app. 80% of carbon black consumption) Pigment in coatings and inks (app. 9% of total carbon black consumption)</p>

Uses according to different sources (INRS² 2007, ICBA³ 2004, IARC⁴ monograph 2010, report from Health and Environment Canada 2013, OECD 2006, SCCS⁵ 2014):

The main use is the reinforcement of rubber tyres (automotive, ruck, bus, agricultural, aircraft, industrial) – 70 to 90% of tonnage

Other uses are, but not limited to:

- Use in other automotive and non-automotive rubber products such as: wires, tubes, cables, belts, hoses, O-rings, gaskets, diaphragms, vibration isolation devices, bushings, air springs, chassis bumpers, and multiple types of pads, wiper blades, fascia, conveyor wheels, grommets, roofing, covers for wire and cable, coated fabrics, gloves, boots and other footwear, floor mats, tape, hard rubber products, pontoons, toys...
- Plastics, thermoplastic for automotive parts, electrical/electronics, household appliances, blow-molded containers (use as pigment, stabilizer of UV light, additive for controlling electrical conductivity, reinforcing product)
- Conductive, semi-conductive and antistatic rubber and plastic materials such as packaging, films, fibers, moldings, pipes, bags, photographic containers, agriculture mulch film, stretch wrap
- Packaging including food packaging

² *Institut national de recherche et de sécurité* (National Institute for Research and Safety), France. Fiche toxicologiques FT 264, 2007.

³ International Carbon Black Association. <http://www.carbon-black.org/index.php/carbon-black-uses> consulted in April 2015.

⁴ International Agency for Research on Cancer (World health Organisation). Monograph 93.

⁵ Scientific Committee on Consumer Safety. Opinion on carbon black (nano-form), adopted on 12 December 2013 and revised on 27 March 2014.

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- Pigments in ink, printing ink, lithography ink, letterpress printing, photograph ink
- Pigments in paints (liquids, aerosols), primers, lacquers, varnishes, primers, coatings (automotive, marine, aerospace, decorative, wood, industrial, etc)
- Fibres including glass fibres
- Ceramics, enamels
- Foam
- Cosmetics: leave-on and rinse-off skin products, make-up, blushers, brush-on-brow, foundations, nail enamels, mascaras, eyeliners, eye pencils, eye shadows and other eye decorative products, hair coloring products, etc
- Leather tanning
- Drycell batteries, electrodes, carbon brushes, electrical conductors, shielding against electromagnetic interferences, videodiscs, video tapes
- Electrostatic Discharge (ESD) compounds in electronics packaging, safety applications, and automotive parts
- Isolant materials (high temperature)
- Waterproofing or sealing agent

Use as food additive (E152) is reported in bibliography but is not authorised in EU.

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
 Article 45(5) (Member State priority)

5.2. Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR
 Fulfils criteria as Sensitiser/ Suspected sensitiser
 Fulfils criteria as potential endocrine disrupter
 Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
 Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)
 Fulfils exposure criteria
 Fulfils MS's (national) priorities

5.3. Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input checked="" type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ⁶ <input type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ⁶	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ⁶	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input checked="" type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

⁶ CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

Substance identification:

Different processes are currently used to manufacture carbon black leading to different physical chemical properties (primary particule size, surface area, polycyclic aromatic hydrocarbons levels). These differences have an impact on the toxicity and uses. For example, according to the IARC (monograph, volume 93) more than 40 grades of carbon black are currently used in the rubber industry and all contribute to the physical properties of the finished rubber product, such as tensile strength and resistance to abrasion. Moreover, particule surface area and particule size are important determinants in inflammatory response to carbon black and PAHs can induce genotoxicity. Finally, the evaluation does not differentiate nanoforms from non-nanoforms.

In summary, material characterisation is insufficient and should be clarified in order to be related to a toxicological effect.

Toxicological concerns:

No reliable study for fertility and developmental toxicity has been available. Registrants judge that no study is needed considering that it is unlikely that the substance will reach the reproductive organs, the embryo or the foetus under *in vivo* conditions Based on the available information on toxicokinetics and metabolism. However several publications (no exhaustive literature search) raise potential concern on male reproductive system (Ema *et al.*, 2010⁷; Kyjovska *et al.*, 2013⁸) and on offspring development after *in utero* exposure, with effects on immune system (El-Sayed *et al.*, 2015⁹) and neurofunction (Jackson *et al.*, 2011¹⁰).

Additionally, an increase in benign and malignant lung tumors was observed in rats exposed to carbon black by inhalation. According to IARC monograph volume 93, there is sufficient evidence in experimental animals for the carcinogenicity of carbon black. However, there is inadequate evidence in humans. In this context, IARC considers that carbon black is possibly carcinogenic to humans (group 2B). Therefore, harmonized classification for carcinogenicity might be considered depending on the evaluation outcome.

Workers exposure:

The assessment was made with measured data from monitoring occupational campaigns detailed in the IARC monograph, volume 65 (1996). Wide range of exposure measurement are reported. However, the risk assessment was done by taking into account the geometric and/or arithmetic means which is not sufficiently representative of all exposure events. In particular, peak exposures exceed the proposed DNEL. Finally, the registrants did not provide a link between the process categories and the exposure measurement. In summary, it is not possible to conclude that the risk is appropriately managed.

⁷ Ema M, Kobayashi N, Naya M, Hanai S, Nakanishi J. Reproductive and developmental toxicity studies of manufactured nanomaterials. *Reprod Toxicol.* 2010 Nov;30(3):343-52.

⁸ Kyjovska ZO, Boisen AM, Jackson P, Wallin H, Vogel U, Hougaard KS. Daily sperm production: application in studies of prenatal exposure to nanoparticles in mice. *Reprod Toxicol.* 2013 Apr;36:88-97.

⁹ El-Sayed YS, Shimizu R, Onoda A, Takeda K, Umezawa M. Carbon black nanoparticle exposure during middle and late fetal development induces immune activation in male offspring mice. *Toxicology.* 2015 Jan 2;327:53-61.

¹⁰ Jackson P, Vogel U, Wallin H, Hougaard KS. Prenatal exposure to carbon black (printex 90): effects on sexual development and neurofunction. *Basic Clin Pharmacol Toxicol.* 2011 Dec;109(6):434-7.

Consumer and indirect exposure:

Carbon black is used in a wide variety of consumer product (adhesive, sealants, coatings, paints, finger paints, thinners, paint removes, varnishes, artists supply and hobby preparations, fillers, putties, plasters, modelling clay, ink, lubricants, greases, paper, cosmetics, personal care products, textiles, man-made fibres, leather and leather care products (polish), fur, fine chemicals, rubber products, mastics, building and construction preparations, other non-metallic mineral products (e.g. plasters, cement), plastics products, anti-freeze and de-icing products, wax blends, batteries, vehicles parts, toys, etc). Considering that it is bound into a matrix, no consumer exposure has been considered. Indirect exposure *via* the environment was also considered negligible without any justification. However no evidence of absence of carbon black release from consumer products has been provided. Furthermore, the presence of PAHs and potential release from products/articles were not assessed. In summary, it is not possible to conclude that the risk is appropriately managed.

Environmental concerns:

Carbon Black is a highly produced nanoparticule with wide dispersive uses. Moreover, ecotoxicological and e-fate effects of carbon black cannot be defined due to its physical and chemical properties. No environmental monitoring data were identified. This substance might be considered for CORAP for environment when research and monitoring methods will improve in order to gain relevant ecotoxicological and environmental properties of Carbon Black. At the time being, there is no mean for evaluating Carbon Black as no existing studies would help clarifying the concerns.

5.4. Preliminary indication of information that may need to be requested to clarify the concern

<input checked="" type="checkbox"/> Information on toxicological properties	<input checked="" type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
<p>Information is required on substance identification in order to link a specific form of carbon black (including nano and non-nanofom characterisation) with use and toxicological potency.</p> <p>Both Toxicity for reproduction and carcinogenicity need to be clarified regarding the potential concern raised in the literature.</p> <p>In order to clarify the exposure and the emission pathways, more information on the life cycle of the substance is needed. For each step of the life cycle, an exposure scenario must be proposed, detailed and justified using the identified and relevant forms of the substance. For consumers, the release of the carbon black and PAHs from products/articles must be investigated.</p>	

5.5. Potential follow-up and link to risk management

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<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>Increase in benign and malignant lung tumors was observed in rats exposed to carbon black by inhalation. According to IARC monograph volume 93, there is sufficient evidence in experimental animals for the carcinogenicity of carbon black. However, there is inadequate evidence in humans. In this context, IARC considers that carbon black is possibly carcinogenic to humans (group 2B). Therefore, harmonized classification for carcinogenicity might be considered depending on the evaluation outcome.</p>			