

JBCE Input to Registry of CLH intention/ Multi-Walled Carbon Nanotubes, MWC(N)T

JBCE members are keen to contribute to the promotion of human health and environment as well as innovate for the benefit of society. JBCE believes that the REACH and CLP Regulations make major contributions to the protection of human health and environment is successfully achieved by profound exposure and risk assessment of the uses and setting appropriate measures for protection from chemical substances which have been shown to be hazardous. Therefore, as a cross-sector association with member companies operating in different industries and stages in the supply chain, JBCE welcomes the opportunity to contribute to the public consultation on Registry of CLH intention of Multi-Walled Carbon Nanotubes, MWC(N)T.

1. Diameter cannot be the criteria for MWCNT grouping

In the CLH report, multi-walled carbon nanotubes (MWCNT) were divided into two groups, that are "high diameter MWCNT" (> 30 nm) and "low diameter MWCNT" (≤ 30 nm). According to the report, the low diameter MWCNT (≤ 30 nm) are not subject to the proposed classification, as they are assumed to have a more tangled morphology. To our understanding, there has been no such distinction in pathology so far. Not every low diameter MWCNT type is entangled, and not every high diameter MWCNT type is straight¹. Outer shape, morphology, and chemical characteristics of MWCNT depend mainly on production methods including process parameters rather than on diameter². Factors contributing to the structure of MWCNT are process parameters such as temperature, pressure, carbon loading amount, types of raw material, types of metal catalyst, and types of atmosphere gas³. There is no physical or chemical reason to divide MWCNT into two groups at the threshold 30 nm diameter. Therefore, MWCNT grouping should be done using process parameters, not with diameter.

¹ Please refer an example of the tangled MWCNT (>30 nm) in Cena, Lorenzo G. and Peters, Thomas M., "Characterization and Control of Airborne Particles Emitted During Production of Epoxy/Carbon Nanotube Nanocomposites", *Journal of Occupational and Environmental Hygiene*, 8: 86–92 (2011).

Please refer an example of the straight MWCNT (≤ 30 nm) in Iijima, Sumio, "Helical microtubules of graphitic carbon", *Nature* Vol. 354, 56-58 (1991).

² Generally, there are three different type of manufacturing methods of MWCNT which are Arc Discharge Method, Laser Abration Method, and Chemical Vapor Deposition method. There is tendency that Straight MWCNT to be manufactured by Arc Discharge Method, but tangled MWCNT to be manufactured by Chemical Vapor Deposition method.

³ Dresselhaus, Mildred S., Dresselhaus, Gene, Avouris, Phaedon (Eds.), *Carbon Nanotubes : Synthesis, Structure, Properties, and Applications*, Springer 2001.

MWCT and MWCNT⁴ are toxicologically not in the same group

The proposal is based on the observation that fibers of high diameter MWCT (> 30 nm) have potential similar to asbestos and asbestiform fibers and thus is consistent with the “fiber pathogenicity paradigm”. In the proposal, the higher diameter MWCNT and multi-walled carbon tubes (MWCT) of less than 3 µm diameter are classified in the same group of substances, and the same measures are proposed. However, the fiber pathogenicity paradigm is not universally applicable for MWCNT, as demonstrated in the assessment of carcinogenicity of MWCNT in the International Agency for Research on Cancer (IARC)⁵.

2. Proper classification based on scientific evidence

We fully agree to list in the CLP annex as carcinogenic 1B all those types of MWCNT that cause cancer with sufficient evidence. As an example, the well-assessed MWNT-7 type should be listed as carcinogenic in the 1B class. However, all of high diameter MWCNT and MWCT with less than 3 µm diameter should not be generally classified as carcinogenic 1B in the CLP annex. JBCE supports REACH's science and fact-based approach, evaluation of the substance, hazard and risk assessment using on the scientific information. JBCE therefore would like to strongly propose to introduce scientifically based toxicological distinctions of each material types.

To conclude, JBCE believes that MWNT-7 type should be listed as carcinogenic in the 1B class, but Multi-Walled carbon nanotubes other than MWNT-7 as well as single-walled carbon nanotubes should not be listed as carcinogenic in the 1B class. JBCE is more than happy to further engage and explain in more detail our arguments, views and recommendations.

ABOUT JBCE

Founded in 1999, the Japan Business Council in Europe (JBCE) is a leading European organization representing the interests of about 90 multinational companies of Japanese parentage active in Europe. Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, textiles and glass products.

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⁴ Definition of MWCNT is based on Commission [Recommendation on the definition of nanomaterial \(2011/696/EU\)](#).

‘Nanomaterial’ means 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.

⁵ In 2014, an IARC working group evaluated both SWCNT and MWCNT and classified one type of multiwalled carbon nanotube, MWCNT-7, in Group 2B, IARC's designation for substances that are possibly carcinogenic to humans. The working group based this determination on evidence from studies of experimental animals. Multi-walled carbon nanotubes other than MWCNT-7 as well as single-walled carbon nanotubes were found to be not classifiable regarding their carcinogenicity to humans and were designated as Group 3.