

Carbon Black SIEF Information Letter 5:

COMPLIANCE OF THE CARBON BLACK REACH DOSSIER WITH THE AMENDMENTS FOR NANOMATERIALS IN ACCORDANCE WITH COMMISSION REGULATION (EU) 2018/1881

On 3 December 2018, the European Commission adopted revisions of REACH Annexes to address substances in nanoforms (Regulation (EU) 2018/1881, amendment of REACH Annexes I, III and VI-XII). The new rules will apply from January 1, 2020. The Carbon Black REACH Consortium (called CB4REACH <http://www.cb4reach.eu/>) is actively working to update the Carbon Black REACH dossier to comply with the amended annexes for nanoforms.

It is noted that the European Chemicals Agency (ECHA) has not yet finalized the guidance documents that provide advice to registrants preparing registration dossiers that cover nanoforms. Regardless, we have started taking the following steps towards becoming compliant with Regulation (EU) 2018/1881:

- Study and understand the new requirements for substances with nanoforms. We are actively involved in ECHA's activities in developing guidance documents, as our members are delegates in the Partner Expert Groups that consult on guidance documents.
- Compile and evaluate available physical/chemical and analytical data on representative carbon black grades to identify separate 'nanoforms' and define 'sets of nanoforms'; where indicated, new physical/chemical and analytical data will be generated. Upon completion and publication of ECHA's Guidance documents, we will reassess our assumptions and affirm or adjust the groups accordingly.
- Develop a scientific rationale for grouping and read-across: For this purpose, representative candidate nanoforms will be subjected to screening level toxicology tests to help underpin the grouping rationale on hazard outcome by identifying and cataloging similarities and differences in toxicological behaviors between the identified nanoforms or sets of nanoforms. Upon completion and publication of ECHA's Guidance documents, we will reassess our assumptions and affirm or adjust the grouping rationale accordingly.
- Identify and, if any, take necessary steps to fill gaps in data requirements for human health and environmental endpoint.
- Ultimately, we will update and submit the Lead Carbon Black REACH dossier that addresses the new requirements. We plan to complete the update by January 1, 2020.

With kind regards
CB4REACH Consortium
Patrick Wellmann
knoell Germany GmbH, Leverkusen, Germany

Member Companies

Cabot Corporation, Cancarb Limited, Columbian Chemicals Company Inc., Continental Carbon Company, Orion Engineered Carbons GmbH, Tokai Carbon Co., Ltd., Imerys Graphite & Carbon