Helsinki, 15 October 2020

Addressees
Registrants of JS_Graphite listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
12/09/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Graphite
EC number: 231-955-3
CAS number: 7782-42-5

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***20 September 2022***.

We note that the Substance has been notified as a nanoform under the Belgian nano-particulate substances reporting system[1]. This indicates that the Substance can be possibly manufactured or imported in the European Union in nanoforms by any addressee of the present decision. However, the REACH Regulation (as amended by Regulation Commission Regulation (EU) 2018/1881) sets out explicit information requirements for nanoforms of substances. Manufacturers and importers of nanoforms must have fulfilled these specific information requirements by 1st January 2020. As far as the registration dossier currently submitted on the Substance does not cover any nanoform, the incompliances identified in the present decision relate only to information required on non-nanoforms.

Based on the above, the information requested in this decision must be generated using exclusively non-nanoforms of the Substance.

A. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day), inhalation route (Annex IX, Section 8.6.2.; test method OECD TG 413) in rats with the Substance; The study must include measurements of lung burden and bronchoalveolar lavage fluid (BALF) analysis as described in the current version (25 June 2018) of the OECD TG 413.

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.

To identify your legal obligations, please refer to the following:

[1] Royal Decree on the placing on the market of substances produced in nanoparticular state" of May 27 May 2014 (ref. KB20140527).

- you have to comply with the requirements of Annexes VII to X of REACH, if you have registered a substance at above 1000 tpa.
- you have to comply with the requirements of Annexes VII to IX of REACH, if you have registered a substance at 100 to 1000 tpa.

Registrants are only required to share the costs of information that they must submit to fulfil the information requirements for their registration.

The Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must also update the chemical safety report, where relevant, including any changes to classification and labelling based on the newly generated information.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Approved[2] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix A: Reasons for the requests to comply with Annex IX of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII to IX to REACH.

1. Sub-chronic toxicity study (90-day), inhalation route (Annex IX, Section 8.6.2.)

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have provided the following key studies in your dossier:

i. Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test with Expanded Graphite Powder, oral route (OECD TG 422) (2010)
ii. 28-day inhalation toxicity study of a synthetic graphite powder in rats (OECD TG 412) (2010)
iii. 28-day inhalation toxicity study of an expanded graphite powder in rats (OECD TG 412) (2010)

You also provided an adaptation, whereby in your dossier and in your comments to the draft decision you stated that:

- the OECD TG 422 study "*did not show any signs either for maternal or developmental toxicity*" and the high dose applied (limit dose) can be considered as the NOAEL for maternal and reproductive/developmental toxicity; and
- the 28-day studies "*did not exhibit any systemic toxicity*" and that "*systemic uptake via the lung is unlikely as graphite is insoluble in water and consequently can be expected to show no solubility in lung fluid.*" You also referred to a 90-day study with sulphuric acid treated with graphite where no relevant signs of toxicity or effects on organs were observed. Furthermore you indicated that "*All effects observed were those to be expected for poorly soluble dusts with low toxicity. Exposure of general population to respirable/inhalable fractions of Graphite is not likely and not expected.*"

We have assessed this information and identified the following issues:

Available studies in the dossier

Tests on substances must be conducted in accordance with the OECD test guidelines or another recognised international test method (Article 13(3) of REACH). To fulfil the information requirement, the study has to meet the requirements of OECD TG 413. The key parameters of this test guideline include, among others:

- At least 10 female and 10 male animals should be used at each dose level (including control group)
- dosing of the Substance daily for a period of 90 days until the scheduled termination of the study
- Clinical observations, ophthalmological examination, sensory reactivity to various stimuli and functional observations of the animals, Recording of body weight, haematology, clinical biochemistry, and pathology of sexual (male and female) organs, Full detailed gross necropsy and subsequent histopathology of both types tissues/ other

With reference to study i. above, this study (OECD TG 422) does not have the required exposure duration of 90 days as required in OECD TG 413, because the exposure duration of the screening test is approximately 63 days (for females) and 28 days (for males). Furthermore the organ weight and histopathological investigations in OECD TG 422 are only

conducted using 5 animals per sex per group and not 10 per sex per group as in OECD TG 408.

As regards ii. and iii. above, both studies (OECD TG 412) do not have the required exposure duration of 90 days as required in OECD TG 413, because you indicated an exposure duration of 28 days, and it was conducted with less than 10 animals per sex per test dose group. The statistical power of the information provided is not sufficient because it does not fulfil the criterion of 20 animals (10 males + 10 females) for each test group set in OECD TG 413.

Therefore the studies available in the dossier are not adequate to fulfil the standard information requirement.

Adaptation provided

As indicated above, you also have provided an adaptation. While you did not specifically indicate the adaptation, ECHA has evaluated the information provided, according to Annex IX, Section 8.6.2., column 2.

As provided in Annex IX, Section 8.6.2, Column 2, you may adapt the information requirement, provided you fulfil the following (cumulative) criteria:

- the Substance is unreactive, insoluble and not inhalable and there is no evidence of absorption/ of toxicity in a 28-day 'limit test', particularly if it is coupled with limited human exposure.

However, the substance cannot be considered as "*not inhalable*" as it is a powder with a significant inhalable fraction (D10 2.50 µm for Expanded graphite powder and D50 4.45 µm for the Synthetic Graphite Powder). In addition, the claim of limited human exposure is not supported as there are industrial, professional (with spray application) and consumer uses. Furthermore the studies available in the dossier (studies i. to iii. above) provide evidence for local respiratory effects as well as potential systemic exposure.

Therefore, you have not met the criterion above and your adaptation is rejected.

Based on the above, the information you provided in the dossier does not fulfil the information requirement.

Study design

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the inhalation route is the most appropriate route of administration to investigate repeated dose toxicity, because the available information in the dossier and the chemical safety report on the properties of the Substance and its uses indicate that human exposure to the Substance by the inhalation route is likely. More specifically, the Substance is reported to occur as a dust with a significant proportion (>1% on weight basis) of particles of inhalable size (MMAD < 50 µm). Furthermore, the Substance is respirable, of low water solubility and consequently there is a potential for accumulation of the Substance in the lungs.

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 413, in rats and with administration of the Substance by inhalation.

Additional parameters

There is evidence that the lower respiratory tract is the primary site of deposition and retention of the Substance because the substance is slightly soluble in water and respirable. Therefore, you are requested to perform a bronchoalveolar lavage (BAL) as specified in paragraph 50 of OECD TG 413 (version of 25 June 2018).

Appendix B: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The compliance check was initiated on 02 May 2019.

In its comments on the draft decision, the registrants pointed out concerns relating to the coordination between the technical completeness check process and the compliance check process. ECHA took this comment into account and removed the requests for a pre-natal developmental toxicity (PNDT) study in a first species (Annex IX, 8.7.2.) and a PNDT study in a second species (Annex X, 8.7.2.) . Nevertheless, this is without prejudice to the possibility for ECHA to start a new compliance check procedure in order to fulfill these information requirements, while ensuring the correct implementation of the procedural guarantees offered to the registrants.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and amended the requests and the deadline. The timeline indicated in the draft decision to provide the information requested under A.1. was 18 months from the date of adoption of the decision.

In your comments on the draft decision, you requested an extension of the timeline to 24 months. You justified your request by providing timelines from different CROs.

Based on the information provided, ECHA has only partially granted the request and set the deadline to 20 months.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision

ECHA invited you to comment on the proposed amendment(s) and referred the modified draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-71 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix C: Observations and technical guidance

1. The information requirement under Section 8.7.3. of Annex X to REACH (Extended one-generation reproductive toxicity study, EOGRTS) is not addressed in this decision, because the information from the Sub-chronic toxicity study (90-day), requested in the present this decision, is relevant for the design of the EOGRTS.

2. This compliance check decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

3. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

4. Test guidelines, GLP requirements and reporting

   Under Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

   Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses shall be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

   Under Article 10 (a) (vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide: 'How to report robust study summaries'[3].

5. Test material

   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected test material must contain that constituent/ impurity.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

[3] https://echa.europa.eu/practical-guides

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[4].

6. List of references of the ECHA Guidance and other guidance/ reference documents[5]

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 in this decision.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[6]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

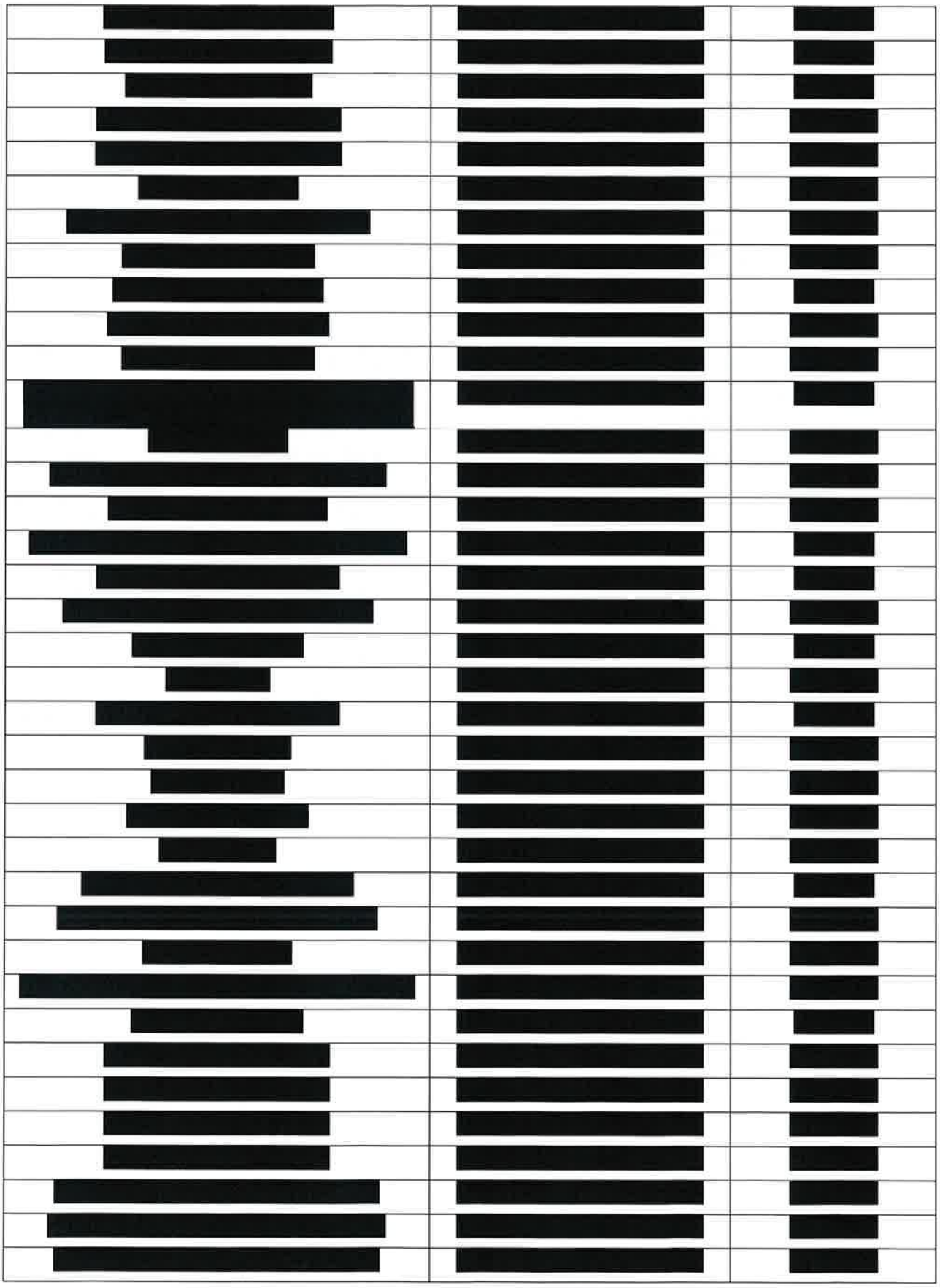
Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

OECD Guidance documents[7]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

[4] https://echa.europa.eu/manuals
[5] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[6] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix D: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[redacted]	[redacted]	[redacted]



Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.