Helsinki, 28 October 2019

Addressee: [redacted]

Decision number: CCH-D-2114484753-38-01/F
Substance name: Ammonium wolframate
EC number: 234-364-9
CAS number: 11120-25-5
Registration number: [redacted]
Submission number: [redacted]
Submission date: 27/11/2015
Registered tonnage band: 100-1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) in a first species (rat or rabbit), oral route either with the analogue substance sodium tungstate (EC no 236-743-4) or with the registered substance;**

2. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) in a second species (rat or rabbit), oral route either with the analogue substance sodium tungstate (EC no 236-743-4) or with the registered substance;**

You have to submit the requested information in an updated registration dossier by ***5 May 2021***. You shall also update the chemical safety report, where relevant. The deadline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

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.

Authorised[1] by **Claudio Carlon**, Head of Unit, Hazard Assessment

[1] 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 1: Reasons

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

A "pre-natal developmental toxicity study" (test method OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing the following information:

> Key study: "*Combined Repeated Dose Toxicity Study with the Reproduction /Developmental Toxicity Study*", rat, oral (equivalent or similar to EPA OPPTS 870.3650; GLP not specified) with read-across substance sodium tungstate at 5 and 125 mg/kg bw/day (EC no: 236-743-4), 70-days, McInturf et al.; 2008 (publication).

Read across Approach

ECHA has assessed the read-across approach applied to fulfill the standard information requirement of a "pre-natal developmental toxicity study" at Annex IX, Section 8.7.2. of the REACH Regulation.

ECHA notes that according to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. Firstly, there needs to be structural similarity between source and target substances which results in a likelihood that these substances have similar physicochemical, toxicological and ecotoxicological properties. Secondly, it is required that the relevant properties of a target substance may be predicted from data for a source substance (read-across approach). ECHA considers that the generation of information by such alternative means should offer equivalence to the information generated by prescribed tests or test methods.

Based on the above, a read-across hypothesis needs to be provided. This hypothesis establishes why a prediction for a toxicological or ecotoxicological property is reliable and should be based on recognition of the structural similarities and differences between the source and registered substances. This hypothesis explains why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern. The read-across approach must be justified scientifically and documented thoroughly, also taking into account the differences in the chemical structures. There may be several lines of supporting evidence used to justify the read-across hypothesis, with the aim of strengthening the case.

Due to the different nature of each endpoint and consequent difference in scientific considerations (e.g. key parameters, biological targets), a read-across must be specific to the endpoint or property under consideration. Key physicochemical properties may determine the fate of a compound, its partitioning into a specific phase or compartment and largely influence the availability of compounds to organisms, e.g. in bioaccumulation and

toxicity tests. Similarly, biotic and abiotic degradation may alter the fate and bioavailability of compounds as well as be themselves hazardous, bioaccumulative and/or persistent. Thus, physicochemical and degradation properties influence the human health and environmental properties of a substance and should be considered in read-across assessments. However, the information on physicochemical and degradation properties is only a part of the read-across hypothesis, and it is necessary to provide additional justification which is specific to the endpoint or property under consideration.

The ECHA Read-across assessment framework foresees that there are two options which may form the basis of the read-across hypothesis- (1) (Bio)transformation to common compound(s)- the read-across hypothesis is that different substances give rise to (the same) common compounds to which the organism is exposed and (2) Different compounds have the same type of effect(s)- the read-across hypothesis is that the organism is exposed to different compounds which have similar (eco)toxicological and fate properties as a result of structural similarity (and not as a result of exposure to common compounds).

Finally, Annex XI, Section 1.5. lists several additional requirements, which deal with the quality of the studies which are to be read-across.

Description of the read-across analogue approach proposed by you

ECHA notes that in section 7.8.2 of the IUCLID dossier you have explained the following: "*Due to similar water solubility and lower toxicity for the target substance (ammonium wolframmate, APT) compared to the source substance (sodium tungstate), the resulting read across from the source substance to the target substance is appropriate as a conservative estimate of potential toxicity for this endpoint. In addition, read across is appropriate because the classification and labeling is the more protective for the source substance than the target substance, the PBT/vPvB profile is the same, and the dose descriptors are, or are expected to be, conservative for the target substance.*".

Additionally, you have provided a read-across approach justification document in Annex I of the Chemical Safety Report (CSR) named "[redacted]".

In the read-across analogue approach justification document you provide the following hypothesis: "*For human health endpoints, it is the relative bioavailability of tungstate at target site(s) that in most cases determines the potential occurrence and the severity of the systemic effects to be assessed for the read-across of tungsten substances. Therefore, tungsten substances of similar release of the tungsten ionic species at the exposure site are expected to result in similar systemic and local toxicity. Ammonium wolframmate (APT) and sodium tungstate have similar physico-chemical properties and release of ionic tungsten species so read-across from sodium tungstate (source) to APT (target) is appropriate*". Additionally you have provided the following justification "*The read-across strategy is predicated on the assumed presence and bioavailability of a common metal anion (WO_4^{2-}) in biological fluids after exposure to tungsten compounds.*"

In your justification you also indicated that the similarity between compounds for the purpose of developing a read-across strategy is based on:

- Water solubility
- Speciation of tungsten substances (Transformation/Dissolution studies)
- Toxicity of tungsten substances

ECHA analysis of the read-across approach for pre-natal developmental toxicity properties

In order to meet the provisions in Annex XI 1.5 to predict physicochemical and toxicological properties from data for a source substance to the target substance, ECHA considers that structural similarity alone is not sufficient. It has to be justified why such prediction is possible in view of the identified structural differences and the provided evidence has to support such explanation. In particular, the structural similarities must be linked to a scientific explanation of how and why a prediction is possible.

ECHA has assessed the read-across approach based on the hypothesis of the transformation in solution (speciation) to a common compound (tungstate WO_4^{2-}) for the target and source substances. In addition, ECHA has assessed whether the proposed read-across from sodium tungstate (EC no 236-743-4) to the target substance represents an appropriate worst-case for pre-natal developmental toxicity properties. ECHA has addressed each line of evidence as follows.

Water Solubility

In your read-across approach justification document you state that substances of similar water solubility would have similar toxicity as the extent of water solubility approximates the bioavailability of a substance and "*since APT and sodium tungstate are both very soluble when measured in the transformation/dissolution protocol, the resulting tungsten release and subsequent toxicity would be expected to be similar between the two substances, thus supporting read-across*".

Your proposed adaptation argument is that the physico-chemical similarity between the source and registered substance is a sufficient basis for predicting the properties of the registered substance.

ECHA agrees that water-solubilities of the source and target substances are similar based on the transformation/dissolution studies at pH 8.5. ECHA also agrees that the comparison of the water solubility is an important aspect in determining the similarity between compounds for purposes of the read-across strategy. ECHA notes, however, that no information on the solubility of the target substance is provided at lower pHs. Information on the water solubility at pH 1-2 would be relevant for the pre-natal developmental toxicity information requirement where the default route of exposure is the oral route. Accordingly, ECHA considers that you have not demonstrated that the water solubility of the source and target substances support the prediction as you have not explained what impact differences in solubility and speciation at different pHs may have.

Additionally, physico-chemical similarity does not necessarily lead to predictable or similar human health properties. Thus physico-chemical similarity per se, and more specifically a similarity in the water solubility, is not sufficient alone to enable the prediction of human health properties of a substance, and more specifically of pre-natal developmental toxicity properties.

Speciation of tungsten substances

ECHA understands that you intend to use a read-across approach where structurally similar substances have a common breakdown products via physical and biological processes. You claim that the hypothesis for the tungsten substances read-across approach relies on the formation of a common WO_4^{2-} ion which is bioavailable.

ECHA agrees that speciation, i.e. the occurrence of the metal in different forms is often a critical parameter in the toxicity of metals affecting e.g. the bioavailability of metals and toxicity at the cellular level.

In terms of data addressing this aspect, in your read-across justification document you report 24 hr transformation/dissolution studies at pH 8.5 for the target and source substances (data at pH 6 were not shown). The total dissolved tungsten was measured using ICP-MS while the speciation to the soluble tungstate anion (WO_4^{2-}) was also measured using HPLC. The results show that the WO_4^{2-} anion is the predominant tungsten-bearing species in solution for the target and source substances examined at pH 8.5. ECHA notes that both substances show almost identical release of tungstate ions under the conditions of the test.

However, ECHA notes that there is no information in your read across justification on the speciation at lower pHs. In particular there is no information available on the speciation at pH 1-2 which could be representative of gastric fluid. ECHA considers this information crucial to establish a read across for the information requirement under consideration given that the oral route is the default route of exposure in pre-natal developmental toxicity studies and so speciation and subsequent bioavailability at this pH are essential elements in any prediction.

ECHA also notes that the target substance is a polyoxytungstate salt. Accordingly, ECHA considers that similar speciation behaviour to the source substance (sodium tungstate), which consists of the simplest form of tungstate WO_4^{2-}, must be demonstrated at all biologically relevant pHs to enable a prediction of toxicity based on speciation and bioavailability. There is evidence in the literature[2] which suggests that tungstate ions (WO_4^{2-}) convert to paratungstate ions at low pH and that dissolution and speciation of ammonium paratungstate involves a number of steps which may not be rapid. This does not support the hypothesis that both source and target substances give rise to the same species in solution at all relevant pHs.

Therefore, ECHA considers that you have not demonstrated the similar speciation behaviour between the target and the source substance to support the prediction.

Toxicity of tungsten substances

In your read-across justification document, you indicate that other supporting information can be used to support the read-across strategy, including similarity in toxicological data. You include considerations on similarities in toxicological properties in certain short-term toxicity studies (e.g. acute oral, dermal and inhalation toxicity, skin sensitisation, skin and eye irritation) between the source and target substance.

ECHA notes that the available data show that the acute oral toxicity is higher for the source substance than the target substance. Additionally, the other available short term studies indicate a similarity in toxicity for the source and target substances.

However, ECHA notes that toxicological similarity in one or multiple endpoints does not necessarily lead to predictable or similar human health properties in other endpoints. Thus

[2] J.W. Van Put. **Crystallization and processing of ammonium paratungstate**
L. Bartha, E. Lassner, W.D. Schubert, B. Lux (Eds.), The Chemistry of Non Sag Tungsten, Elsevier Science, Oxford (1995)

toxicological similarity on certain endpoints is not sufficient to enable the prediction of other human health properties of a substance and more specifically of the pre-natal developmental toxicity properties.

Such comparison of the information from studies with single dosing is of limited value to the assessment of the toxicokinetics of the substances under the conditions of repeated oral exposure which would be investigated in the requested study.

Toxicokinetics

One important aspect in establishing that substances have similar effects or follow a regular pattern is the comparison of absorption, distribution, metabolism and elimination of source and target substances. This allows assessing the qualitative and quantitative internal systemic exposure of the test organism when exposed to source and target.

ECHA notes that there are existing *in vivo* toxicokinetic studies on the source substance and you have not provided them either in your technical dossier or in your read-across justification document. Such studies have been reviewed in Lemus R and Venezia C, Crit Rev Toxicol 2015: 45(5) 388-411. These cited studies elucidate the toxicokinetic profiles of the source substance in rats and/or mice, though oral and inhalation administration and following single or repeated exposures. Such studies are considered necessary to consolidate a read across approach based on the hypothesis that the tungstate ion (WO_4^{2-}) is the predominant bioavailable ion which may cause toxicity. However, ECHA notes that there is no toxicokinetic information presented in the dossier on the target substance and given the issues raised in the above sections on the comparative speciation behaviour of the source and target substances, ECHA considers that your hypothesis of transformation in solution (speciation) to a common compound for the target and source substances does not hold at all biologically relevant pHs based on the provided information. Therefore the impact of the formation of non-common species on the prediction cannot be verified.

In the absence of such information in the registration ECHA is not currently in a position to verify the biological validity of your read-across approach.

Conclusion on the read-across approach for pre-natal developmental toxicity properties

ECHA considers that although you have provided relevant data in the justification document to support read-across approach, you have not fully established why a prediction for a specific human health property is reliable. Additionally, ECHA observes that you did not provide essential information in support of your hypothesis that sodium tungstate (the source substance) represents an appropriate worst-case for prenatal developmental toxicity properties. In particular ECHA notes that your hypothesis of the presence and bioavailability of a common metal anion (WO_4^{2-}) in biological fluids after exposure to the source and target substances is not confirmed for the reasons set out above. In the absence supporting information to demonstrate this ECHA concludes that there is not an adequate basis for predicting the properties of the registered substance from the data obtained with the source substance with respect to the pre-natal developmental toxicity properties.

ECHA notes that you provided comments and included therein a read-across justification document named "Tungstate Read-Across Category Approach", which you indicate is also included in a dossier update.

This document contains *in vivo* toxicokinetic data demonstrating that sodium tungstate is readily absorbed, rapidly distributed to various organs (e.g. intestine, kidney, and femur) and excreted via the urine. This supports the hypothesis that sodium tungstate represents an appropriate worst-case scenario for pre-natal developmental toxicity properties of the registered substance.

Additionally in your comments, you include information on the speciation of both target and source substance at biologically relevant pHs which supports the assumption that the speciation behaviour of sodium tungstate and the registered substance will be the same following oral exposure. ECHA agrees with your conclusion that at gastric pH, both substances will speciate rapidly to tungstic acid which will then speciate to the tungstate ion after passing the stomach as the pH increases. Therefore it can be concluded that both source and target substances give rise to the same species in solution under physiological conditions following oral administration.

Based on the updated read-across justification document and your comments, ECHA concludes that the read-across for the pre-natal developmental toxicity study is supported by adequate and reliable information.

Nevertheless, although the proposed read-across approach is supported by adequate and reliable information, your adaptation of the information requirement is rejected due to lack of an adequate study, as described below.

Analysis of the study provided to fulfil the information requirements of Annex IX, Section 8.7.2

ECHA notes that you provided a "*Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test*" (equivalent or similar to EPA OPPTS 870.3650; GLP not specified) with the read-across substance sodium tungstate to fulfil the standard information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

However, ECHA notes that this study does not provide the information required by Annex IX, Section 8.7.2. since it does not cover key parameters of a pre-natal developmental toxicity study like examination of foetuses for skeletal and visceral alterations. In addition, the dose levels used in the study are considered not sufficient as no toxic effects were observed at the highest dose level which is much lower than the limit dose level. Hence, the results do not have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3) of the REACH Regulation, and data are not adequate for the purpose of classification and labelling and/or risk assessment. Therefore, your adaptation of the information requirement is rejected.

Study requested

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction

as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

ECHA considers that the test shall be performed either with the analogue substance sodium tungstate (EC no 236-743-4), since the read-across is plausible, or with the registered substance subject to the present decision.

Similar requests are made in separate ECHA decisions on tungsten compounds to test either the registered substance or the analogue substance sodium tungstate for the same standard information requirements. You are recommended to consider testing the analogue substance since it could result in less vertebrate animals being tested rather than if each registered substance were tested.

If the test is conducted with the analogue substance, the eventual validity of the read-across approach will be reassessed after the submission of the information requested in this decision.

In your comments on the draft decision, you firstly refer to the coverage of the key parameters of a pre-natal developmental toxicity study by the US EPA Guideline OPPTS 870.3650 (equivalent to OECD TG 422) – Combined Repeated Dose Toxicity Study with the Reproduction-Developmental Toxicity Study. ECHA underlines that a pre-natal developmental toxicity study according to OECD TG 414 includes examination of skeletal and visceral alterations of foetuses as key parameters. The US EPA Guideline OPPTS 870.3650 study requires that the pups should, at least, be carefully examined externally for gross abnormalities. In your comments you state that gross necropsy of the offspring includes also examination of visceral malformations. However, no skeletal alterations (malformation and variations) were examined. Thus, key parameters are still missing.

With respect to the dose levels, you indicate that a 250 mg/kg bw/day dose group was initially included in the study and a significantly decreased body-weight gain in the P0 males and gestational weight gain was observed as well as increasing gestational length (1.2 days) in the dams. Additionally, at such dose level the litter size and the average weight per pup decreased, while the effect was not significant. No clinical signs or effects on pup viability were observed. However, ECHA notes that the dose at 250 mg/kg bw/day, initially included in the study design, has not been included in the study record provided in the IUCLID dossier, neither in the publications by McInturf, S. et al (2008 and 2011). Therefore, ECHA cannot perform a scientific assessment of the relevant findings or assess whether this dose level can be considered to comply with OECD TG 414 in aiming to induce some developmental and/or maternal toxicity.

Moreover, you refer to the preliminary results of an on-going US NTP perinatal study in drinking water in Sprague-Dawley rats on sodium tungstate (EC 236-743-4) conducted according EPA Health Effects Test Guidelines OPPTS 870.3650 (which is similar to OECD TG 422) at doses of 0, 125, 250, 500, 1000, or 2000 mg/L. ECHA underlines that this study will not provide the information required by Annex IX, Section 8.7.2. since the EPA OPPTS 870.3650 TG guideline does not cover key parameters of a pre-natal developmental toxicity study like e.g. examination of foetuses for skeletal alterations. Hence, the results of such study will not have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3) of the REACH Regulation, and data will not be adequate for the purpose of classification and labelling and/or risk assessment.

Finally, you suggest performing an OECD TG 414 in rabbits as the first species, since it can be concluded from the McInturf study (McInturf et al 2008; McInturf et al 2011) that no effects of a prenatal treatment were observed in rats. ECHA underlines that pre-natal developmental toxicity studies (test method OECD TG 414) on two species are part of the standard information requirements of the REACH Regulation for a substance registered for 1000 tonnes or more per year. ECHA notes that the technical dossier does not contain information on any valid pre-natal developmental toxicity study as required according to Section 8.7.2. of Annex IX and X. As indicated in the request section of this decision (first page), it is at your discretion to decide which species to test in the first pre-natal developmental toxicity study.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived either with the analogue substance sodium tungstate (EC no 236-743-4) or with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: OECD TG 414) in a first species (rat or rabbit) by the oral route.

2. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Pre-natal developmental toxicity studies (test method OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

ECHA notes that the technical dossier does not contain information on a pre-natal developmental toxicity study with the registered substance.

Additionally, there is no information provided for a pre-natal developmental toxicity study in a second species.

The technical dossier does not contain an adaptation in accordance with column 2 of Annex X, Section 8.7.2. or with the general rules of Annex XI for this standard information requirement.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default consideration, ECHA considers testing should be performed with rabbits or rats as a second species, depending on the species tested in the first pre-natal developmental toxicity study.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment*

(version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

ECHA considers that the test shall be performed either with the analogue substance sodium tungstate (EC no 236-743-4) since the read-across is plausible (see above), or with the registered substance subject to the present decision.

Similar requests are made in separate ECHA decisions on tungsten compounds to test either the registered substance or the analogue substance sodium tungstate for the same standard information requirements. You are recommended to consider testing the analogue substance since it could result in less vertebrate animals being tested rather than if each registered substance were tested.

If the test is conducted with the analogue substance, the eventual validity of the read-across approach will be reassessed after the submission of the information requested in this decision.

In your comments on the draft decision, you state that the rat oral reproductive/developmental toxicity study (McInturf et al 2008; McInturf et al 2011) on sodium tungstate showed absence of physical birth defects, including missing digits in pups, and the preliminary results of the US NTP perinatal study conducted according to EPA OPPTS 870.3650 (equivalent to OECD TG 422) in rats show lack of birth defects. On these bases, you propose to wait for the result of the ongoing NTP's sodium tungstate rat perinatal study before taking a decision on an OECD TG 414 oral study in rabbits conducted on the read-across substance sodium tungstate.

However, ECHA underlines that a pre-natal developmental study according to OECD TG 414 on a second species is a standard information requirement under REACH (Annex X, Section 8.7.2). A study according to EPA OPPTS 870.3650 will not provide the information required at Annex IX and X, Section 8.7.2, since the EPA OPPTS 870.3650 TG guideline does not cover key parameters of a pre-natal developmental toxicity study like e.g. examination of foetuses for skeletal alterations as explained above.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived either with the analogue substance sodium tungstate (EC no 236-743-4) or with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: OECD TG 414) in a second species (rabbit or rat) by the oral route.

Notes for your consideration

You are reminded that before performing a pre-natal developmental toxicity study in a second species you must consider the specific adaptation possibilities of Annex X, Section 8.7., column 2 and general adaptation possibilities of Annex XI. If the results of the test in the first species with other available information enable such adaptation, testing in the second species should be omitted and the registration dossier should be updated containing the corresponding adaptation statement.

Appendix 2: Procedural history

ECHA notes that the tonnage band for several members of the joint submission is 1 000 tonnes or more per year.

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 25 October 2018.

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 within 30 days of the notification.

ECHA took into account your comments and amended the requests.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix 3: Further information, observations and technical guidance

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

2. Failure to comply with the requests in this decision will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.

4. If the required tests are conducted with an analogue substance in the context of a read-across approach, the identity of the test material used to perform the test should be specified in line with ECHA's Practical Guide on "How to use alternatives to animal testing to fulfil your information requirements" (chapter 4.4). This is required to show that the test material is representative of the analogue substance identified in the read-across approach and used to predict the properties of the registered substance.