EUROPEAN CHEMICALS AGENCY

Helsinki, 15 November 2016

Addressee: [redacted]

Decision number: CCH-D-2114348016-55-01/F
Substance name: Anthraquinone
EC number: 201-549-0
CAS number: 84-65-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 20.09.2013
Registered tonnage band: 1000+ T

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. **Composition of the registered substance (Annex VI, Section 2.3.);**
   - **Nature of impurities, including isomers and by-products**

2. **Spectral data (Annex VI, Section 2.3.5.);**
   - **Nuclear magnetic resonance or mass spectrum**

3. **High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.);**
   - **Complete chromatogram**

4. **Description of the analytical methods (Annex VI, Section 2.3.7.);**
   - **Identification and quantification of the main constituent(s) and impurities**

5. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats with the registered substance;**

6. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2; test method: EU B.31/OECD TG 414) in a first species (rats or rabbits), oral route with the registered substance;**

7. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2; test method: EU B.31/OECD TG 414) in a second species (rabbits or rats), oral route with the registered substance;**

8. **Extended one-generation reproductive toxicity study in rats, oral route (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) with the registered substance according to the following study-design specifications:**
   - **Ten weeks premating exposure duration for the parental (P0) generation;**
   - **Dose level setting with the aim to produce some toxicity at the highest dose level;**

- **Cohort 1A (Reproductive toxicity);**
- **Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;**
- **Cohorts 2A and 2B (Developmental neurotoxicity); and**
- **Cohort 3 (Developmental immunotoxicity);**

9. **Growth inhibition study aquatic plants (Annex VII, Section 9.1.2; test method: Alga, growth inhibition test, EU C.3/OECD TG 201 and OECD GD 23) with the registered substance;**

10. **Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.; test method: Activated sludge, respiration inhibition test (carbon and ammonium oxidation), OECD 209) with the registered substance;**

11. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210 and OECD GD 23) with the registered substance;**

12. **Exposure estimation and risk characterisation (Annex I, Section 5.2.1., 5.2.4. and 6.) for workers:**
    - revise exposure estimates for the dermal route without the use of local exhaust ventilation (LEV) as an exposure modifier and revise risk characterisation accordingly;
    - revise exposure estimates for the dermal route using pre-defined values for glove effectiveness and revise the risk characterisation accordingly *or* provide a detailed justification explaining why in this specific case using higher efficiency values of 98% is considered appropriate;

13. **Development of exposure scenarios (Annex I, Section 5.1.1.): provide documentation for the recommended personal protective equipment, i.e. Hand protection: specify the type of glove material, thickness and breakthrough times.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **22 May 2020. You shall also update the chemical safety report, where relevant.** The timeline 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. 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, shall 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/web/guest/regulations/appeals.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[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. Composition of the registered substance (Annex VI, Section 2.3.)

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

Annex VI, Section 2.3. of the REACH Regulation requires that each registration dossier contain sufficient information for establishing the composition of the registered substance and therefore its identity. In that respect, according to chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, you shall note that, for well-defined substances, the following applies:

- Each main constituent (i.e. the constituent present at ≥80% for mono-constituent substance or each constituent present at ≥10% and ≤ 80% for multi-constituent substance) shall be identified and reported individually; and
- Each impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually.
- For each constituent, the typical, minimum and maximum concentration levels shall be specified regardless of the substance type.

In the present dossier you have identified the registered substance as a well-defined mono-constituent substance [redacted] and specified a minimum concentration level of [redacted]% (w/w) for the main constituent. However, you did not report the presence of any impurity in the composition in IUCLID Section 1.2. The chromatogram attached displays a limited range of retention time between 4-10 minutes and therefore the possibility of impurities present at ≥1% to be eluting outside of this range cannot be excluded.

ECHA notes that up to [redacted]% of the composition has therefore not been accounted for. The attached "Certificate of Analysis" indicates that impurities are present only at a low level. However, in the absence of a full chromatogram displaying an extended retention time together with a detailed peak table, the absence of impurities at ≥1% or relevant for classification and/or PBT assessment (that shall be reported as part of the composition) cannot be excluded.

ECHA therefore concludes that the compositional information has not been provided to the required level of detail.

Accordingly you are requested to clarify the information provided on the composition of the registered substance and especially the part of the composition that is not reported, including impurities.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: you shall report individually any impurity required to be identified and specify at least one of the following identifiers: chemical name, CAS number, EC number and/or molecular formula, as well as the minimum, maximum and typical concentration, in the appropriate fields in Section 1.2 of the IUCLID dossier.

Further technical details on how to report the composition of well-defined substances in IUCLID are available in the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website.

You shall ensure that the composition is verifiable and therefore supported by a description of the analytical methods for the identification and quantification of the constituents required to be reported, as required under Annex VI, Section 2.3.7. of the REACH Regulation.

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you agreed to perform the request and you also inidcated your intensions to update the dossier.

2. Spectral data (Annex VI, Section 2.3.5.)

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

Spectral data are a formal information requirement of Annex VI Section 2.3.5.

ECHA concludes that you have not provided nuclear magnetic resonance (NMR) or mass spectrum (MS) in the registration dossier.

ECHA regards this required information scientifically relevant for the registered substance as a 1H-NMR or a 13C-NMR are powerful tools for structure characterisation and elucidation due to characteristic chemical shifts and spin-spin coupling which also reflects the relative abundance of individual atoms.

You are therefore requested to submit an NMR spectrum, such as a 1H-NMR or a 13C-NMR. As an alternative to an NMR spectrum, mass spectrum generated as part of mass spectroscopic analysis for the elucidation of the structure of the constituents in the substance can be provided.

As for the reporting of the spectral data in the registration dossier, the information should be included in IUCLID Section 1.4.

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you agreed to perform the request and you also inidcated your intensions to update the dossier.

3. High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.)

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

Chromatographic data is a formal information requirement of Annex VI Section 2.3.6.

ECHA observes that the chromatogram provided shows only a limited range between 4-10 minute retention times and therefore any constituent(s) eluting outside of this range cannot be seen. Furthermore the main peak is displayed truncated.

A peak table with the associated retention times, peak areas and concentration values for the constituent(s) has not been included. The "Certificate of Analysis" reported together with the copy of the chromatogram, where concentration values of constituents are displayed, cannot be correlated to the chromatogram provided as the information is missing on how the listed constituents relate to the detected peaks.

ECHA regards the chromatogram together with the peak table scientifically relevant for the registered substance as the information requested will allow the composition of the substance to be confirmed.

You are required to provide a chromatogram displaying all peaks eluting during the GC analysis and a report of the chromatographic analysis in the form of a table listing the retention times, identifiers, peak areas, peak areas % and concentration %(w/w) for all identified peaks present in the chromatogram in order to enable the identification of the substance composition.

As for the reporting of the spectral data in the registration dossier, the information should be included in IUCLID Section 1.4.

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you agreed to perform the request and you also inidcated your intensions to update the dossier.

4. Description of the analytical methods (Annex VI, Section 2.3.7.)

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

Description of the analytical methods is a formal requirement of Annex VI Section 2.3.7.

ECHA observes that you did not provide sufficient description of the analytical methods used for the identification of the registered substance and quantification of the different constituents present in the registered substance.

More specifically ECHA notes that the descriptions of the UV and NMR or MS methods have not been provided in the registration dossier. You have included a UV spectrum of the registered substance, but the corresponding method description is absent. Furthermore you did not attach an NMR or MS spectra and the relevant method description.

This information is essential to confirm the identity of the registered substance.

Accordingly you are required to provide a proper description of the analytical methods used for the identification and quantification of all individual constituents and impurities of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

As for the reporting of the data in the registration dossier, the information should be attached in IUCLID Section 1.4. You shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you agreed to perform the request and you also indicated your intentions to update the dossier.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to Xof the REACH Regulation.

Pursuant to Article 10(a)(vii) of the REACH Regulation, the information set out in Annex VII to XI must be provided in the form of a robust study summary. Article 3(28) defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the Practical Guide 3: 'How to report robust study summaries'.

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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.

Furthermore, pursuant to Article 10 (a)(vii) and Annex I, Section 1.1.4. if there are several studies addressing the same effect, then, having taken into account possible variables (e.g. conduct, adequacy, relevance of test species, quality of results, etc.), normally the study or studies giving rise to the highest concern shall be used to establish the DNELs and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust summaries will be required of all key data used in the hazard assessment.

You have provided a study record for a sub-chronic toxicity study [redacted] to meet the information requirement of Annex IX, Section 8.6.2. and to establish the DNEL(s). However, ECHA notes that, contrary to Article 3(28) of the REACH Regulation, the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard assessment. In particular, the following elements are missing: details on histopathological examination and detailed results on examination on clinical signs and mortality, body weight and body weight gain, food consumption and compound intake, haematology, clinical chemistry, organ weights, gross pathology and histopathology examination. Therefore, you need to provide a complete robust study summary with the above missing elements for this study.

Furthermore, ECHA notes that this study was not performed according to GLP. To consider a study to be equivalent to the test method referred to in Article 13(3) the criteria of Annex XI, Section 1.1.2. of the REACH Regulation need to be met. For example, you need to document in the robust study summary that the key parameters of a sub-chronic toxicity study according to EU B.26./OECD 408 (see also paragraph 41 of OECD TG 408) are adequately and reliable covered by the available study. Furthermore, it needs to be justified why deviations from the current test method do not have an impact on the adequacy of this study.

ECHA further notes that sub-chronic and chronic studies performed with anthraquinone are publicly available (NTP 2005). However, those studies were performed with high doses only, and do not allow derivation of DNEL(s). Hence, those studies are not appropriate to fulfill the standard information requirement of Annex IX, Section 8.6.2.

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you indicated the wish to perform a new oral sub-chronic toxicity study according to the applicable OECD methodology (OECD TG 408), including examination of thyroid hormones to investigate the suspicion that anthraquinone is an "endocrine disruptor".

ECHA acknowledges that in the sub-chronic toxicity study ([redacted]) increased absolute thyroid gland weights were observed in male rats at the highest dose tested of 126 mg/kg bw/day. Furthermore, in the 14 week toxicity study (NTP 2005), thyroid follicular cell hypertrophy was observed in all male and female rats at doses ≥ 275 mg/kg bw/day. In addition, in the carcinogenicity study with mice (NTP 2005) some animals developed thyroid gland tumors. Hence, a further sub-chronic toxicity study is not expected to refute the suspicion that anthraquinone has an effect on thyroid gland.
Nevertheless, in light that the provided sub-chronic toxicity study ([redacted]) was not performed according to GLP, ECHA agrees that there is no guarantee that this study will be sufficient to meet the information requirement. Therefore, new information on sub-chronic toxicity should be provided.

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.

ECHA has evaluated the most appropriate route of administration. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration. More specifically, even though 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), the available information indicates effects following oral administration which need to be further investigated. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.According to the test method EU B.26./OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.).

Notes for your consideration

ECHA notes that the available information on sub-chronic and chronic toxicity together with information from the requested extended-one generation reproductive toxicity study might sufficiently inform on sub-chronic toxicity as required in Annex IX, Section 8.6.2. Thus, you might consider to perform the requested extended one-generation reproductive toxicity study before deciding on the need for further information on sub-chronic toxicity.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

A "pre-natal developmental toxicity study" (test method B.31./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.

In the technical dossier you have provided a study record for a"reproduction/ developmental toxicity screening test" (test method: OECD TG 421). However, this study does not provide the information required by Annex IX, Section 8.7.2. This is because, contrary to Article 13(3) and Annex XI, Section 1.1.2. of the REACH Regulation, it does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations. Therefore, your adaptation of the information requirement cannot be accepted.

Hence, 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.
In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you agreed to perform this test.

According to the test method EU B.31/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 rats or rabbits as a first species.

According to the test method EU B.31/OECD TG 414, the test substance is usually administered orally. On the basis of this default consideration, ECHA considers testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a first species (rats or rabbits) by the oral route.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

Pre-natal developmental toxicity studies (test method B.31./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).

As indicated above under Appendix 1, Section 6, you have provided in the technical dossier a study record for a"reproduction/ developmental toxicity screening test" (test method: OECD TG 421). Since this study does not provide the information required by Annex IX or X, Section 8.7.2. your adaptation of the information requirement cannot be accepted.

Hence, 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.

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you indicated the following: "*In case of the results of OECD TG 414 on rats are clear (either positive or negative), this requirement should be waived. The test will be needed only in case of ambiguous results. We suggest to wait with decision on this requirement until the results of the test from point 6 are completed*".

With regards to you comment on the need of a pre-natal developmental toxicity study in a second species, ECHA refers to the "*Notes for your consideration*" below. ECHA also notes that a pre-natal developmental toxicity study in a second species can be adapted in case the first test is positive meeting the criteria for classification of the substance for developmental toxicity category 1B and the available data are adequate to support a robust risk assessment (see Annex X, Section 8.7.2., column 2). ECHA further notes that a negative result of a pre-natal developmental toxicity study in a first species is usually not sufficient to adapt the standard information requirement for a pre-natal developmental toxicity study in a second species. In addition, ECHA notes that the deadline to provide the required information was set to allow sequential testing.

According to the test method EU B.31/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 used in the first pre-natal developmental toxicity study.

According to the test method EU B.31/OECD TG 414, the test substance is usually administered orally. On the basis of this default consideration, ECHA considers testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a second species (rabbits or rats) 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 enable such adaptation, testing in the second species should be omitted and the registration dossier should be updated containing the corresponding adaptation statement.

8. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

The basic test design of an extended one-generation reproductive toxicity study (test method B.56./OECD TG 443 with Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex X. If the conditions described in column 2 of Annex X are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided study records for a reproduction/developmental toxicity screening test (OECD 421) to cover the information requirement for Annex X, Section 8.7.3. However, this study does not provide equivalent information to the information required by Annex X, 8.7.3 This is because, contrary to Article 13(3) and Annex XI, Section 1.1.2. of the REACH Regulation, it does not cover the key aspects/ parameters, exposure duration, statistical power and the same life stages than in an extended one-generation reproductive toxicity study. The main missing key aspect/element is an extensive evaluation of the F1 generation. The following specific conditions of Annex XI, Section 1.1.2. are not met: 1.1.2. (2) adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test method referred to in Article 13(3); and 1.1.2. (3) exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter. Thus, the general adaptation rule of Annex XI, Section 1.1.2. is not met. Therefore, your adaptation of the information requirement cannot be accepted.

Hence, 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.

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you agreed to perform an extended-one generation toxicity study. You have specfically stated that the study design should be decided based on the results of the "*new OECD 408*" or from the "[redacted]" included in the registration dossier. In addition, the results of OECD TG 414 will also play a role in the study design.

However, ECHA considers that based on the available information the criteria for inclusion of the Cohort 2A and 2B, and Cohort 3 are already met, as explained below in the respective section. Hence, you are requested to perform the study as required in this decision. ECHA considers that it is unlikely that the newly performed sub-chronic toxicity study and the pre-natal developmental toxicity study will alter this conclusion.

Thus, an extended one-generation reproductive toxicity study according Annex X, Section 8.7.3. is required. The following refers to the specifications of this required study.

Premating exposure duration and dose-level setting

To ensure that the study design adequately addresses the fertility endpoint, the duration of the premating exposure period and the selection of the highest dose level are key aspects to be considered. According to the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, July 2015) Chapter R.7a, section R.7.6, the starting point for deciding on the length of the premating exposure period should be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required because there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, July 2015) Chapter R.7a, section R.7.6. Ten weeks exposure duration is supported also by the lipophilicity of the substance (log Kow 3.4) to ensure that the steady state in parental animals has been reached before mating.

The highest dose level shall aim to induce some toxicity to allow comparison of effect levels and effects of reproductive toxicity with those of systemic toxicity. The dose level selection should be based upon the fertility effects with the other cohorts being tested at the same dose levels.

It is recommended that results from a range-finding study (or range finding studies) for the extended one-generation reproductive toxicity study are reported with the main study. This will support the justifications of the dose level selections and interpretation of the results.

Cohorts 2A and 2B

The developmental neurotoxicity Cohorts 2A and 2B need to be conducted in case of a particular concern on (developmental) neurotoxicity as described in column 2 of 8.7.3., Annex X. When there are triggers for developmental neurotoxicity, both the Cohorts 2A and 2B are to be conducted as they provide complementary information.

ECHA notes that existing information on anthraquinone that is not reported in the registration dossier, such as the subchronic toxicity studies performed by NTP, 2005 and information on the study performed by [redacted], that is only cited in the CLH report for anthraquinone (2015)[1] show evidence of a particular concern in form of thyroid toxicity in line with column 2 of 8.7.3., Annex X. In particular, the following effects were reported: thyroid follicular cell hypertrophy in all male and female F344/N rats at doses ≥ 275 mg/kg bw/day (NTP, 2005), and increased (42%) absolute thyroid gland weights in male Wistar rats at about 126 mg/kg bw/day ([redacted]).

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you indicated that "*neurobehavioral examination is crucial for design of Cohorts 2*".
ECHA would like to emphasis that neurobehavioral effects would be a trigger for the inclusion of Cohorts 2A and 2B as explained in ECHA *Guidance on information requirements and chemical safety assessment*, (version 4.1, October 2015), Chapter R.7a., Appendix R.7.6-2. However, ECHA consideres that based on the available information the criteria for inclusion of the Cohort 2A and 2B are already met as explained above.

ECHA concludes that the developmental neurotoxicity cohorts 2A and 2B need to be conducted because there is a particular concern on (developmental) neurotoxicity based on the results from the above-identified subchronic toxicity studies performed with the registered substance anthraquinone.

The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

Cohort 3

The developmental immunotoxicity Cohort 3 needs to be conducted in case of a particular concern on (developmental) immunotoxicity as described in column 2 of 8.7.3., Annex X.

[1] CLH report for anthraquinone 2015: CLH report Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2, Anthraquinone, January 2015 (http://echa.europa.eu/harmonised-classification-and-labelling-previous-consultations/-/substance-rev/5803/term).

ECHA notes that existing information on anthraquinone that is not reported in the registration dossier, such as the subchronic toxicity study NTP, 2005, show evidence of a particular concern in form of thymus toxicity in line with column 2 of 8.7.3., Annex X. More specifically, a significantly decreased absolute thymus weights was observed in female rats at doses ≥275 mg/kg bw/day. In addition, congestion, hematopoietic cell proliferation, and iron positive pigmentation of spleen was observed in both male and female at ≥135 mg/kg bw/day; and bone marrow hyperplasia was observed in males at ≥ 275 mg/kg bw/day and females at ≥ 135 mg/kg bw/day. Anaemia was observed, described as follows: "*a minimal, responsive anaemia was apparent in groups of male and female rats exposed to 3,750 ppm (275 mg/kg bw) or greater by day 26 of the study. The (regenerative haemolytic) anaemia persisted and involved all exposed groups of rats at the end of the study*" (NTP, 2005).

ECHA concludes that the developmental immunotoxicity Cohort 3 needs to be conducted because there is a particular concern on (developmental) immunotoxicity based on the results from the above-identified subchronic toxicity study performed with the registered substance anthraquinone. In addition, this is further supported by the skin sensitisation properties of the substance.

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you disagreed to perform this cohort. You propose to perform an *in vivo* skin sensitising test according to OECD TG 406 to reach clarity regarding the sensitising properties of the registered substance.

ECHA however considers that the skin sensitisation properties are not sufficient alone to trigger Cohort 3, but can be used as supportive evidence for triggering the inclusion of Cohort 3, as explained in ECHA *Guidance on information requirements and chemical safety assessment*, (version 4.1, October 2015), Chapter R.7a., Appendix R.7.6-2. Thus, ECHA concludes that a separate *in vivo* skin sensitising test according to OECD TG 406 would not have any impact for triggering the inclusion of Cohort 3 as the available information on the substance related to immunological organs and tissues is suffient to trigger inclusion of Cohort 3.

The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

Species and route selection

According to the test method EU B.56/ OECD TG 443, the rat is the preferred species. On the basis of this default assumption, ECHA considers that testing should be performed in rats.

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 4.0, July 2015) R.7a, chapter 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.

Conclusion

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Extended one-generation reproductive toxicity study (test method EU B.56/ OECD TG 443), in rats, oral route, according to the following study-design specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce some toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;
- Cohorts 2A and 2B (Developmental neurotoxicity); and
- Cohort 3 (Developmental immunotoxicity).

Notes for your consideration

The conditions to include the extension of Cohort 1B are currently not met. However, you may expand the study by including the extension of Cohort 1B if new information becomes available after this decision is issued to justify such an inclusion. Inclusion is justified if the new information shows triggers which are described in column 2 of Section 8.7.3., Annex X and further elaborated in ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.0, July 2015). You may also expand the study to address a concern identified during the conduct of the extended one-generation reproduction toxicity study and also due to other scientific reasons in order to avoid a conduct of a new study. The justification for the expansion must be documented. The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

9. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. 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.

Column 2 of Annex VII, Section 9.1.2 specifies that the study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes.

You have sought to adapt testing on aquatic plants using the following justification: *In accordance with REACH Regulation (EC) No 1907/2006, Annex VII, study does not need to be conducted if the substance is highly insoluble in water. Seeing that the solubility is 74.6 micrograms per liter, substance meets the criteria for insolubility.*

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you indicated that "*ECHA simply decided that the substance is poorly water soluble without providing any scientific evidence or criteria for solubility*" and that "*there is a lot of scientific criteria for solubility available*" according to which anthraquinone is clearly "*practically insoluble*" substance and therefore conditions for data waiving are met.

ECHA notes that various water solubility grading methodologies/approaches might serve very different purposes. ECHA notes that ECHA's Guidance on IR&CSA, Chapter R.7b (Version 2.0, November 2014) underlines that "*there is no scientific basis to define a cut off limit value for solubility below which no toxicity could occur [...] it might be possible to decide on a case-by-case basis, that aquatic toxicity is unlikely to occur due to very low water solubility and unlikelihood to cross biological membranes [...] In any case any proposal to deviate from the standard testing requirements in reference to this clause should be carefully justified. For poorly water soluble substances (e.g. water solubility below 1 mg/L or below the detection limit of the analytical method of the test substance) it should instead of an acute test be considered to perform a long term test (REACH Annex VII and VIII, 9.1) bearing in mind any possibilities for waiving (REACH Annex XI).*"

ECHA notes that there is no justification provided why aquatic toxicity (in aquatic plants, aquatic microorganisms and fish) is unlikely to occur due to very low water solubility of the substance which is below 1 mg/l. Thus, ECHA considers that the substance is not highly insoluble in water (the substance is poorly water soluble, water solubility is 0.0746 mg/l at 20°C). Therefore, your justification for waiving does not meet the criteria of the specific adaptation rules of Column 2 of Annex VII, Section 9.1.2. Therefore, the adaptation cannot be accepted.

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.

ECHA considers that Algae, growth inhibition test (test method: EU C.3./OECD TG 201) is suitable and appropriate to address the standard information requirement of Annex VII, Section 9.1.2. of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Algae, growth inhibition test (test method: EU C.3./OECD TG 201).

Notes for your consideration

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested long-term ecotoxicity tests and for calculation and expression of the result of this test.

10. Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Activated sludge respiration inhibition testing" is a standard information requirement as laid down in Annex VIII, Section 9.1.4. 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.

Column 2 of Annex VIII, Section 9.1.4 specifies that the study does not need to be conducted if there is no emission to a sewage treatment plant, or there are mitigating factors indicating that microbial toxicity is unlikely to occur, for instance the substance is highly insoluble in water, or the substance is found to be readily biodegradable and the applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant.

You have sought to adapt testing on aquatic microorganisms plants using the following justification: *In accordance with REACH Regulation (EC) No 1907/2006, Annex VIII, study does not need to be conducted if the substance is insoluble. Seeing that the solubility is 74.6 micrograms per liter, substance meets the criteria for insolubility.*

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation as summarised in section 5 above, ECHA considers that as the substance is not highly insoluble in water (the substance is poorly water soluble, water solubility is 0.0746 mg/l at 20°C), your justification for waiving does not meet the criteria of the specific adaptation rules of Column 2 of Annex VIII, Section 9.1.4. Therefore, the adaptation cannot be accepted.

As explained above, the information available 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.

ECHA considers that Activated sludge, respiration inhibition test (carbon and ammonium oxidation) (test method: OECD TG 209) is suitable and appropriate to address the standard information requirement of Annex VIII, Section 9.1.4. of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Activated sludge, respiration inhibition test (carbon and ammonium oxidation) (test method: OECD TG 209).

11. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.

ECHA notes that the water solubility of the registered substance is low (0.0746 mg/L at 20°C) and as in your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation as summarised in section 5 above, considers that the substance is poorly water soluble.

You have sought to adapt long-term testing on fish using the following justification: "*In accordance with REACH Regulation (EC) No 1907/2006, Annex VIII, study does not need to be conducted if the substance is highly insoluble in water. Seeing that the solubility is 74.6 micrograms per liter, substance meets the criteria for insolubility.*"

ECHA points out that column 2 of Annex IX, Section 9.1.6. or Annex XI of the REACH Regulation does not contain an adaptation provision based on the insolubility of the substance.

ECHA notes that according to the *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b the Chemical Safety Assessment (CSA) is to be based on all available toxicity information, and that the information used for the derivation of the predicted no effect concentration (PNEC) for water should at least cover species of three trophic levels: algae/aquatic plants, invertebrates (*Daphnia* preferred), and fish. Furthermore, ECHA notes that due to the low solubility of the registered substance the short-term toxicity testing with fish would not be relevant and conclusive. For poorly soluble in water substances the steady state conditions are likely not to be reached within the duration of a short-term toxicity test. For this reason, short-term tests may not give a true measure of toxicity for those substances and toxicity may actually not even occur at the water solubility limit of the substance if the test duration is too short. Still, long-term toxicity cannot be excluded and should be investigated.

Therefore, ECHA considers that it is necessary to provide information on long-term toxicity with fish and, consequently, there is an information gap for the long-term toxicity testing on fish (Annex IX, Section 9.1.6. of the REACH Regulation).

Therefore, your justification for waiving does not meet the criteria of either the specific adaptation rules of column 2 of Annex IX, Section 9.1., or the general adaptation rules of Annex XI. Therefore, the adaptations cannot be accepted.

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.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, Section 9.1.6.1., ECHA considers that the FELS toxicity test according to OECD TG 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b, Figure R.7.8-4). The test method OECD TG 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance Chapter R7b, version 2.0, November 2014). For these reasons, ECHA considers the FELS toxicity test using the test method OECD TG 210 as appropriate and suitable.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test, (test method: OECD TG 210).

Notes for your consideration

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested long-term ecotoxicity tests and for calculation and expression of the result of this test.

12. Exposure estimation and risk characterisation (Annex I, Section 5.2.1., 5.2.4. and 6.) for workers

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation, the registration shall contain a chemical safety report (CSR) which shall document the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Pursuant to Article 14(4), if the substance fulfils the criteria for any of the hazard classes listed in that provision or is assessed to be a PBT or vPvB, the CSA shall include exposure assessment and risk characterisation. Pursuant to Sections 0.6.2 and 0.6.3 of Annex I of the REACH Regulation the CSA performed by a Registrant shall include an exposure assessment according to Section 5 of Annex I. Annex I, Section 5.2.4 of the REACH Regulation, requires the Registrant to perform an estimation of the exposure levels for all human populations (workers, consumer and humans liable to exposure via the environment) for which exposure to the substance is known or reasonably foreseeable. Each relevant route of exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed. Further, the estimation of exposure shall take account of implemented or recommended risk management, including the degree of containment. In addition, Annex I, Section 5.2.5 of the REACH Regulation indicates that appropriate models can be used for the estimation of exposure levels.

Pursuant to Article 41(1)(c) of the REACH Regulation ECHA may verify that any required CSA and Chemical Safety Report comply with the requirements of Annex I and that the proposed risk management measures are adequate.
In the present case, ECHA notes that you have classified the substance as Skin sensitiser, category 1 (H317: May cause an allergic skin reaction), which is one of the hazard classed listed in Article 14(4) of the REACH Regulation. ECHA further notes that you have used a quantitative approach to carry out the exposure assessment and risk characterization in the CSR. The model you have used is the ECETOC TRA. While Annex I, Section 5.2.5. allows the use of appropriate models for estimating exposure, ECHA points out the following inadequancy relating to the model used by you:

Firstly, for dermal exposure estimates using TRA workers, you rely upon a 90% reduction in exposure, achieved from local exhaust ventilation. This exposure modification factor seems very ambitious, and you provide no further explanation on how this will be achieved for a very low vapour pressure substance.

ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R14., section R.14.4.8 (version 2.1, November 2012) states "*The dermal exposure for some situations with local exhaust ventilation is underestimated compared to measured data (e.g. RISKOFDERM project). In the light of knowledge having become available since EASE was published, the LEV effect on dermal exposure assessment may sometimes be overestimated by the model. .....To be more confident on the dermal exposure prediction under LEV conditions, the assessor could continue with higher tier assessment (e.g. Riskofderm). He could also recalculate the dermal exposure level outside the tool by setting the effectiveness of the local exhaust ventilation regarding dermal exposure to "0" or any other value significantly below the 90 to 99% assumed in the TRA (to reach a conservative estimate).*"

Accordingly, you need to re-visit your exposure estimations, considering how safe use can be demonstrated, whilst taking into account ECHA Guidance R.14 on occupational exposure estimation.

As explained above, the information provided on the dermal exposure estimates for the registered substance in the chemical safety report does not meet the general provisions for preparing a chemical safety report as described in Annex I. Consequently it is necessary to revise the dermal exposure estimates.

Secondly, ECHA notes that you have used ECETOC TRA to estimate exposure for a variety of worker exposure scenarios using efficiency for gloves of 98% to estimate the exposure via dermal route. However, ECHA notes that according to the guidance for the model used (ECETOC TR 114) the maximum pre-defined values are 95% for industrial users and 90% for professional users. You have not included in the CSR any case specific justification (e.g. related to the substance or the specific recommended or implemented personal protection measures or based on relevant biomonitoring data) for deviating from the recommended efficiency factor in using ECETOC TRA.

As explained above, the information provided on the dermal exposure estimates for the registered substance in the chemical safety report does not meet the requirements for preparing a chemical safety report as described in Annex I.

In particular, you have not included in the CSR any case specific justification relating to the substance or the specific recommended or implemented personal protection measures or based on relevant biomonitoring data for deviating from the recommended efficiency factor.

Consequently, it is necessary to revise the dermal exposure estimates or to provide a justification explaining why in this specific case using higher efficiency values for gloves 98% is considered appropriate.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to:
- revise exposure estimates for the dermal route without the use of local exhaust ventilation (LEV) as an exposure modifier and revise the risk characterisation accordingly;
- revise exposure estimates for the dermal route using pre-defined values for glove effectiveness and revise the risk characterisation accordingly *or* provide a detailed justification explaining why in this specific case using higher efficiency values of 98% is considered appropriate.

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you agreed to perform the request and you also inidcated your intensions to update the dossier.

Notes for your consideration

ECHA notes that you have used ECETOC TRA version 2 in the exposure estimation while the latest version available is version 3. You should consider using the most updated version of the prediction model when revising the exposure estimates as described above. Any deviation from default values used within a model or published in the ECHA Guidance R.14 must be adequately justified. The use of alternative values without adequate justification is not-compliant with REACH.

13. Development of exposure scenarios (Annex I, Section 5.1.1.)

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation, the registration shall contain a chemical safety report (CSR) which shall document the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Article 14(6) as well as Annex I, 0.1., 5.1.1., 5.2.4. and 6.2. of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in a CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented.

According to Annex I, 0.3., 0.5. and 5.1.1. the applied Risk Management Measures (RMM) have to be described in the CSR. The CSR needs to contain sufficient information to allow ECHA to gain assurance that the risks are adequately controlled and that appropriate risk management measures can be prescribed by actors in the supply chain.

Accordingly, the supplier is required to describe the relevant RMM in detail in the Safety Data Sheet in order to minimise the exposure for workers handling the registered substance (e.g. the type of gloves to be worn, protection equipment for parts of the body other than the hand or respiratory protection shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of exposure in accordance with Annex II, Section 8.2.2.2.(b)(i), (ii) and 8.2.2.2.(c) respectively). The information provided in the Safety Data Sheet (SDS) shall be consistent with information in the Chemical Safety Report (Annex II, Section 0.1.2. of the REACH Regulation).

ECHA notes that specific detailed information on the recommended personal protective equipment is missing both from the CSR and from the information on safe use within the IUCLID dossier. In the CSR, you indicated the following for hand protection in risk management measures described in Section 9 of the CSR "*chemically resistant gloves conforming to EN374.*"

To ensure the safe use of a substance, Annex I Section 5.1.1 requires a description of the risk management measures to reduce or avoid direct and indirect exposure of humans. Gloves are reported in the CSR and IUCLID Section 11 as required personal protective equipment to prevent dermal exposure to the substance. In IUCLID section 11 you have identified leather as the glove material. Leather is not a material normally associated with chemically protective gloves as it has seams, is absorbent and porous. Generally, gloves that are capable of preventing exposure to the skin for a pre-determined duration shall be specified. Typically, this information, as a minimum, has to specify the glove material and, depending on the exposure scenarios, may also need to include the breakthrough time and thickness of the glove material.

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you agreed to perform the request and you also inidcated your intensions to update the dossier.

Therefore, pursuant to Article 41(1)(c) you are requested to provide documentation for the recommended personal protective equipment, i.e. Hand protection: specify the type of glove material, thickness and breakthrough times.

Appendix 2: Procedural history

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 29 September 2015.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:

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

ECHA took into account your comments and amended the request(s).

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

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 request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, 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 substance used for the new test(s) 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 composition 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 substance tested in the new test(s) 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 test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.

4. Besides the data sharing obligations pursuant to Article 53 of the REACH Regulation, please note that Article 11(1) of the REACH Regulation requires several registrants of the same substance to form a joint submission and submit data jointly. More precisely, the lead registrant acting with the agreement of the other assenting registrants shall submit the information listed in Article 11(1) on behalf of all registrants.