EUROPEAN CHEMICALS AGENCY

Helsinki, 19 February 2020

Addressees
Registrants of [redacted] listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
21/03/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 1-hydroxy-4-[[4-[(methylsulphonyl)oxy]phenyl]amino]anthraquinone
EC number: 216-475-4
CAS number: 1594-08-7

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***24 August 2021***.

1. Requirements applicable to all the Registrants subject to Annex VII of REACH

1. Water solubility (Annex VII, Section 7.7.; test method: EU A.6./OECD TG 105) with the Substance

2. Partition coefficient n-octanol/water (Annex VII, Section 7.8.; using an appropriate test method) with the Substance

3. Robust study summary for [redacted] 2015 (Annex VII, Section 9.1.2. in conjunction with Annex I, Section 3.1.5.)

   OR

   Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method EU C.3./OECD TG 201) with the Substance

4. Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1, column 2; test method: EU C.20./OECD TG 211) with the Substance

Conditions to comply with the requested information

Each addressee of this decision is bound by the requests for information listed above.

The test material used to perform the required studies must be selected and reported in accordance with the specifications prescribed in the Appendix entitled Observations and technical guidance.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant,

including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

Appeal

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

Approved[1] under the authority of Christel Schilliger-Musset, Director of 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 A: Reasons for the requests to comply with Annex VII of REACH

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to the REACH Regulation.

1. Water solubility (Annex VII, Section 7.7.);

Water solubility is a standard information requirement in Annex VII to REACH.

You have provided a key study (2015) in your dossier.

We have assessed this information and identified the following issues:

1. EU test method A.6 and OECD TG 105 establish the requirements for the data to be reported for a water solubility study. These test guidelines describe two methods (the column elution method and the flask method) for conducting the study. The test method must be selected based on a water solubility estimate obtained in a preliminary study. For substances with preliminary water solubility below 10 mg/L the column elution method must be used.

   The study you provided was performed with the flask method and you reported a water solubility < 0.25 mg/L, which indicates that the substance is poorly water soluble.

   The reported result falls outside of the applicability domain of the flask method and the test should have been conducted with the column elution method.

2. The EU test method A.6 and the OECD TG 105 test guidelines specifies that a suitable analytical method must be used. The EU test method A.6 further specifies that, for essentially pure substances, the sensitivity of the analytical method must allow the determination of mass concentrations down to 1 µg/L.

   You used a spectrophotometric method to determine the mass concentrations of the test substance. You used different solvents for the calibration curve (i.e. chloroform) and for the determination of mass concentrations in the test (i.e. distilled water). You report a limit of quantification of 0.25 mg/L.

   As water and chloroform have different UV-VIS absorption spectra, the measurements are not comparable. Hence the method is not suitable. In addition, the sensitivity of the method is too low.

Therefore, the information requirement is not fulfiled.

In your comments on the draft decision you acknowledge that the Substance is not in the applicability domain of the flask method. You indicate that you have repeated the study using the column elution method. As an attachment to your comments, you have submitted a full study report for a water solubility study according to OECD TG 105 with the Substance using the column elution method. The concentration of the test substance was determined using HPLC/MS/IT/TOF. The water solubility was determined to be below the limit of detection (reported as 1 µg/L).

We have assessed the study submitted by you and consider that it is adequate to fulfil the information requirement providing that:

1. you describe and justify how the limit of detection (LoD) was determined. Various approaches can be used to estimate LoD, which may result in widely varying estimates. As specified in OECD TG 105, all information relevant for the interpretation of the results must be included in the test report. As the water solubility was determined to be below the LoD, the method used to derive the LoD is critical to interpret the results of the study;
2. you update your registration dossier with a robust study summary for this study fulfilling the requirement set out in Article 3(28) of REACH and taking into account point (i) above.

2. Partition coefficient n-octanol/water (Annex VII, Section 7.8.);

Partition coefficient n-octanol/water is a standard information requirement in Annex VII to REACH.

You have provided a key study (2015) in your dossier.

We have assessed this information and identified the following issues:

1. The EU test method A.8 or the OECD TG 107/117/123 should be used to determine water solubility. These test guidelines describe three methods (the shake flask method, the HPLC method and the slow-stirring method) for conducting the study. The EU test method A.8 specifies that the method selection must be based on the properties of the substance and on a preliminary determination of the partition coefficient using the individual solubilities of the test material in water and n-octanol. This preliminary estimate is considered sufficient only if none of the recommended method are technically feasible due to specific substance properties (e.g. surface active substances).

   The study you provided describes the estimation of the partition coefficient using the individual solubilities of the test material in water and n-octanol (i.e. preliminary determination). However, you did not report the results of a full study. You did not provide any justification that none of the recommended method are technically feasible due to specific substance properties. Therefore this study is not compliant with the recommended guideline.

2. To provide an acceptable determination of the partition coefficient using individual solubilities in water and n-octanol, the calculation must be based on reliable individual solubilities estimates.

   You used the information discussed under request A.1 as the water solubility estimate in the calculation. In addition, you have provided a solubility estimate in n-octanol but no details on how the value was determined.

   However, as explained under request 1, the water solubility data included in your dossier is not compliant. In addition you have not provided adequate information to support the reliability of the solubility estimate of the Substance in n-octanol. Hence the unbounded value you reported in your dossier (i.e. Log Pow > 2.49) is not reliable.

Therefore, the information requirement is not fulfiled.

In your comments on the draft decision you indicate that you have conducted a partition coefficient (n-octanol/water) study using the HPLC method. As an attachment to your

comments, you have submitted a full study report for a partition coefficient study according to OECD TG 117 with the Substance. The Log Pow was determined to be 5.02.

We have assessed the study submitted by you and consider that it is adequate to fulfil the information requirement provided that you update your registration dossier with a robust study summary for this study fulfilling the requirement set out in Article 3(28) of REACH.

3. Robust study summary for [redacted] 2015 (Annex VII, Section 9.1.2. in conjunction with Annex I, Section 3.1.5.) OR Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

Growth inhibition study aquatic plants is a standard information requirement in Annex VII of REACH.

You have provided a key study (2015) performed according to OECD TG 201.

We have assessed this information and identified the following issue:

A robust study summary must be provided for the sole study available or, if more than one is available, for the study/ies giving rise to the highest concern (Articles 3(28) and 10(a)(vii) and Annex I, Section 3.1.5. of REACH). A robust study summary must cover critical information and allows for an assessment of the validity and reliability of the study. For a study conducted according to OECD TG 201, it includes:

1. a clear description of the test material, including impurities;
2. a description of the preparation of test solutions, including the use of a solvent and/or an emulsifier (if any was used);
3. a full description of the analytical monitoring method (e.g. calibration, recovery and sensitivity determination) and of the preparation of the test samples for analysis (including the description of filtration and/or extraction steps, if any);
4. the results of the analytical determination of exposure concentrations and (if necessary) the calculation of effect levels as measured concentrations;
5. adequate raw data relative to cell density determination to allow a verification that the validity criteria of the method were fulfilled.

Your technical dossier does not include the information listed above. Therefore 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.

To allow such assessment, you need to provide a complete robust study summary with the above missing elements for the study. Alternatively, if you cannot submit a complete robust study summary or the robust study summary indicates that the study is not reliable or adequate to fulfil the information requirement, you need to submit the following study for the Substance: Growth inhibition study aquatic plants; test method: EU C.3./OECD TG 201.

In your comment on the draft decision, you specify that your registration dossier was updated on 21 March 2019. You consider that the latest update might not have been considered for the evaluation of the dossier. You also specify that you will verify whether important information is missing and, if necessary, you intend to provide this information through a dossier update.

We acknowledge your comments on the draft decision and confirm that the latest update of your registration dossier (of 21 March 2019) was taken into account before the draft decision was communicated to you. The draft decision communicated to you erroneously contained the submission date of the earlier submission.

4. Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2);

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII of REACH. However, pursuant to Annex VII, section 9.1.1, column 2, 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) long-term toxicity study on aquatic invertebrates (Annex IX, Section 9.1.5) must be considered instead of an acute test.

You have provided a study performed according to OECD TG 202 (1994). In the study, no effects on *Daphnia magna* were observed in a limit test at 100 mg/L (loading). You have not provided any data on long-term toxicity to aquatic invertebrates.

As explained under request A.1, the information submitted as part of your comments on the draft decision confirms that the Substance is poorly water soluble (i.e. water solubility < 1 mg/L).

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for this type of substances. Therefore, a long-term test must be conducted.

In your comments on the draft decision, you acknowledge that the new information submitted as part of your comments on the draft decision support that the substance is poorly water soluble. Furthermore, you agree that therefore long-term toxicity testing on aquatic invertebrates needs to be considered.

However you consider that available information support that further aquatic toxicity testing is unnecessary and that the risks to the aquatic environment are adequately controlled. To support that aquatic toxicity is unlikely to occur, you provide the following justification:

1. the substance has a density of 1.2654 g/cm³ at 20 °C and is therefore expected to be removed from the water column by sedimentation in lakes and ponds. You acknowledge that this may not be true in free-flowing rivers;
2. the substance is mostly used for dyeing textiles used in the automotive sector but it is also used in outdoor articles like awnings;
3. regarding potential release to the environment, you specify that dye is applied by exhaust-dyeing from a dye-bath with confirmed exhaust rates of ≥99 % in case the dye is used below the saturation concentration of 2.4 % in the dyeing solution. You considers that the primary clarifier in local or communal waste-water treatment has an efficiency of 90% in removing the Substance from waste dye solutions. Following adsorption to sludge, the Substance will be further removed by sedimentation in the secondary clarifier. You state that the recovered sludge is then incinerated. You estimate that out of 10 tons used across Europe, far less than 10 kg of Substance enters the environment;
4. you consider that, despite no toxicokinetic data are currently available, the lack of toxic effects observed in acute mammalian toxicity studies and in the short-term toxicity studies in fish, aquatic invertebrate and micro-organisms suggest that the test substance upon absorption does not exert any toxic effects or that the test substance is not absorbed at all. As the genotoxic effect observed in the Ames test was not

confirmed in a mutagenicity and a clastogenicity study in mammalian cells, you consider that it provides little support for absorption in eukaryote cells;

5. aquatic toxicity testing of substance having very low water solubility is technically challenging and may be subject to bias due to secondary effects related to the presence of undissolved particles and/or test medium preparation.

From the information submitted in your comments on the draft decision, we understand that you intend to adapt the information requirement for a long-term toxicity study to aquatic invertebrates based on Annex VII, Section 9.1.1, column 2; Annex XI, Section 3; and Annex XI, Section 2.

Annex VII, Section 9.1.1, column 2 specifies that a short-term toxicity 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.

We have assessed the information provided in your comments on the draft decision and we identified the following issues, starting with your adaptation under Annex VII, Section 9.1.1, column 2:

1. ECHA Guidance, Chapter R.7b, Section R.7.8.5. explains that there is no scientific basis to define a cut off limit for solubility below which no toxicity occur. As specified in ECHA Guidance R.7b, Table R.7.8-3, the justification on why aquatic toxicity is unlikely to occur must take into account uncertainties in the determination of the water solubility limit (e.g. sensitivity of the analytical method, impact of test medium composition). It should be supported by a lack of effects seen in all relevant aquatic toxicity studies.

   You have attached to your comments on the draft decision a full study report for a water solubility study according to OECD TG 105 (column elution method). The water solubility is reported as < 1 µg/L. In a growth inhibition study on aquatic plants according to OECD TG 201 conducted on *Pseudokirchneriella subcapitata* with the Substance, the NOErC and LOErC were determined to be 0.8 µg/L and 3 µg/L (based on nominal concentrations).

   We note that effects were seen in a growth inhibition study on aquatic plants at very low nominal concentrations of the Substance. As explained under request A.1., you have provided relevant new information showing that the water solubility of the Substance in distilled water is below the limit of detection (LoD) of the analytical method used in the OECD TG 105 study (reported as 1 µg/L). However, as already explained under request A.1., clarifications must be provided on how the LoD was determined. Furthermore, it cannot be excluded that differences in the composition of the test medium used in the water solubility study (i.e. distilled water) and in the algae study (i.e. OECD medium) may impact the limit of solubility of the Substance. As effects were seen in the growth inhibition study on aquatic plants at very low nominal concentrations, secondary effects (e.g. physical effects such as shading or adsorption) are not obvious. Considering the uncertainties in the determination of the water solubility limit of the Substance, available ecotoxicological information indicate that toxicity may be observed at concentrations below the lowest measurable concentration. Therefore the low water solubility of the Substance as determined according to OECD TG 105 is not a sufficient justification to adapt the information requirement.

2. ECHA Guidance, Chapter R.7b, Section R.7.8.5. explains that there is no scientific basis to define molecular characteristics that would render a substance unlikely to cross biological membranes. One of the possible line of evidence are the indicators used for low likelihood of a high bioaccumulation potential as described in ECHA Guidance, Chapter R.11, Section R.11.4.1.2.1, for instance if uptake is hindered by molecular size (e.g. D_{max} aver > 17.4 Å) and high lipophilicity (e.g. Log K_{ow} > 10). The indicators for low potential for uptake must also be supported by the lack of toxicity in any toxicity studies in mammals and birds, the lack of uptake in mammalian toxicokinetics studies or by experimental evidence of very low uptake after chronic exposure. As specified in ECHA Guidance R.7b, Section R.7.8.5. indications of lack of a high bioaccumulation potential does not necessarily imply lack of toxicity to aquatic organisms. Therefore the justification must also be supported by the lack of effects seen in all relevant aquatic toxicity studies.

   You have not reported an estimate of the average molecular diameter (D_{max} aver) of the Substance. As explained under request A.2., you have attached to your comments on the draft decision a full study report for a partition coefficient study (n-octanol/water) study according to OECD TG 117 (HPLC method). The log Kow was determined to be 5.02. Finally, as already explained above, your technical dossier includes a growth inhibition study on aquatic plants that indicates that toxicity can be observed at concentrations below the lowest measurable concentration.

   According to the baseline bioaccumulation model ([redacted] 2005), the average D_{max} for the Substance is below 17.4 Å. Furthermore, the Log Kow determined in a reliable guideline study according to OECD TG 117 indicates a potential for bioaccumulation. Along with the fact that toxicity was observed in a toxicity study to algae, this information does not provide an adequate support that the substance is unlikely to cross biological membranes.

Therefore, the adaptation of the information requirement according to Annex VII, Section 9.1.1, column 2 is rejected.

Concerning your adaptation under Section 3 of Annex XI, the first paragraph fo this provision enables testing to be omitted based on the exposure scenario(s) developed in the Chemical Safety Report, if the conditions described in Section 3.2 of Annex XI are met. The adaptation of the information requirement must be supported by adequate justification and documentation which must be based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I.

We have assessed the information provided in your comments and we have identified the following issues:

1. Under section 3.2(a) of Annex XI, the justification must fulfil all the following conditions:
   1. the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5.;
   2. a suitable DNEL or a PNEC can be derived from results of available test data for the Substance taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes;

3. the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC.

However, you have not provided any PNEC estimates for the Substance. In your comments on the draft decision, you have provided some estimates of the release of the substance to the aquatic environment. However no PEC estimates have been derived. Therefore, you did not demonstrate that the derived PNEC is above the exposure of the aquatic environment. Consequently the conditions set out in section 3.2(a) of Annex XI are not fulfilled.

4. Alternatively, the justification provided must fulfil the conditions set out in 3.2(b) and/or 3.2(c) of Annex XI. In particular:
    1. where the substance is not incorporated in an article, strictly controlled conditions as set out in Article 18(4)(a) to (f) must apply throughout the life cycle;
    2. where the substance is incorporated in an article in which it is permanently embedded in a matrix or otherwise rigorously:
        1. the substance is not released during its life cycle, and
        2. negligible workers or general public or environmental exposure occurs under normal or reasonably foreseeable conditions, and
        3. strictly controlled conditions as set out in Article 18(4)(a) to (f) must apply during all manufacturing and production stages including the waste management of the substance during these stages.

However, in your comments on the draft decision, you estimate that for 10 tonnes of the substance that is used for dyeing fabrics, 10 kg is released to the aquatic environment.

First we note that the assumptions made by you are questionable and are not supported by experimental evidence. First, the estimated aggregated tonnage for the Substance is 10-100 tpa and not 10 tpa as stated in your comments. Furthermore only a fraction of sewage sludge are incinerated at the European scale and therefore further release through land application cannot be ruled out. Overall, the information provided by you do not support that strictly controlled conditions as set out in Article 18(4)(a) to (f) apply during all manufacturing and production stages including the waste management of the substance during these stages. Therefore the conditions set out in 3.2(b) and/or 3.2(c) of Annex XI are not fulfilled.

Therefore, the adaptation of the information requirement according to Annex XI, Section 3 is rejected.

Finally you state in your comments on the draft decision that testing of such poorly water soluble substance is technically challenging. Therefore we consider this information as an attempt to adapt the information requirement based on Annex XI, Section 2.

We have assessed this information and identified the following issue:

Annex XI, Section 2 specifies that testing for a specific endpoint may be omitted if it is not technically feasible to conduct a study as a consequence of the properties of the substance. In this context, the guidance given in the test methods referred to in Article 13(3), more specifically on the technical limitations of a specific method, must always be respected.

In your comments, you state that as the substance has very low water solubility, "*it is highly questionable if any data will result out of such tests that allow a save hazard and risk assessment for the aquatic environment. Therefore, the registrant proposes not to conduct further studies on invertebrates*". You describe potential methodological biases in testing poorly water soluble substances that may impact the interpretation of aquatic toxicity test results.

As specified in ECHA Guidance R.7b, Section R.7.8.4.1., EU.C20 and OECD TG 211 are the preferred methods to study the long-term toxicity to aquatic invertebrates. These methods specify that substances should not be tested above their limit of solubility in the test medium. OECD TG 211 further specifies that for substance that are difficult to dissolve, the procedures described in OECD GD 23 must be followed with the aim of achieving test substance saturation in the medium. However, as explained in ECHA Guidance R.7b, Table R.7.8-3, for some substance toxicity may be observed even at concentrations below the lowest measurable concentration. You have not provided an estimate of the solubility of the Substance in a relevant test medium (e.g. Elendt M7 or M4 media). Furthermore you have not provided adequate justification that the study is not technically feasible at concentration below the solubility of the Substance in the relevant test medium.

Therefore, the adaptation of the information requirement according to Annex XI, Section 2 is rejected.

Based on the above the information requirement is not fulfilled.

Appendix B: Procedural history

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

The compliance check was initiated on 22 January 2019.

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 did not amend the requests. However, ECHA notes that you provided relevant information as part of your comments on the draft decisions regarding request A.1. and A.2. ECHA considers that the submitted studies are valid and that they may be used to fulfil the information requirement for the corresponding endpoints providing an adequate robust study summary is included in your registration dossier through a dossier update.

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 C: Observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2019.

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

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

1. Test guidelines, GLP requirements and reporting

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

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

   Under Article 10 (a) (vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide: 'How to report robust study summaries[2]'.

2. Test material

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

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

   Technical reporting of the test material

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

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

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[3].

3. List of references for the Guidance documents[3]

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

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

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

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

[3] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

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

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