EUROPEAN CHEMICALS AGENCY

Helsinki, 05 August 2020

Addressees
Registrants of JS_CalciumTG as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
21 May 2013

Registered substance subject to this decision ("the Substance")
Substance name: Calcium sulphidoacetate
EC number: 249-881-5
CAS number: 29820-13-1

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***13 May 2022***.

Requested information must be generated using the Substance unless otherwise specified.

A. Information required from all the Registrants subject to Annex VII of REACH

1. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: [EU C.3./OECD TG 201)

2. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301B/C/D/F or OECD TG 310)

B. Information required from all the Registrants subject to Annex VIII of REACH

1. Adsorption/ desorption screening (Annex VIII, Section 9.3.1.; test method: OECD TG 106)

C. Information required from all the Registrants subject to Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

Reasons for the request(s) are explained in the following appendices:

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to IX of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 10 tonnes per year (tpa);
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[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 on Reasons common to several requests

1. Assessment of your read-across approach under Annex XI, Section 1.5.

You seek to adapt the following standard information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Ready biodegradability (Annex VII, Section 9.2.1.1.)

ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following appendices.

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (addressed under 'Assessment of prediction(s)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6[2] and related documents[3,4].

You read-across between the structurally similar substances:

- Thioglycolic acid or TGA, EC No. 200-677-4 (CAS No. 68-11-1)
- Diammonium dithiodiglycolate or DADTG, EC No. 269-323-4 (CAS No. 68223-93-8)
- Sodium methanethiolate, EC No. 225-969-9 (CAS No. 5188-07-8)

as source substances and the Substance as target substance.

For the prediction of aquatic toxicity, you have provided a read-across justification in Section 7.1 of your Chemical Safety Assessment (CSA). You have provided the following reasoning:

- "*Diammonium dithioglycolate occurs rapidly in the environment* [...] *and therefore is a good surrogate for thioglycolic acid ecotoxicity*"

For the prediction of biodegradation, you have provided a read-across justification in Section 4.1.3 of your Chemical Safety Assessment (CSA). You have provided the following reasoning:

- the target and source substance(s) are grouped have similar molecular structure;
- the target and source(s) substance have similar reactivity:
    - "thioglycolate in water, at a neutral pH, in the presence of 20 ppm of iron III or 20 ppm of manganese II salt can be oxidized by air to dithiodiglycolate within

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals. 2008 (May) ECHA, Helsinki, 134. pp. Available online: https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9

[3] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki, 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[4] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki, 40 pp. Available online: https://doi.org/10.2823/794394

less than 3 hours" and "*Oxidation of thioglycolate is increased by dilution*";
    - "TGA is quantitatively oxidized to Dithiodiglycolate (DTDGA) and that there is no other decomposition compound after 2 days";
- "*It has also been demonstrated that DTDGA can undergo a rapid biodegradation at a concentration of 150 ppm, although some acclimatising of bacteria is necessary*";
- "*Considering the overall information available* [the source and target substances] *are ready biodegradable and do not raise concern in terms of persistency*".

For the read-across from Diammonium dithiodiglycolate ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on the formation of common (bio)transformation products. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

For the read-across from Sodium methanethiolate, ECHA notes that you have not provided any specific justification including a read-across hypothesis.

ECHA notes the following shortcomings with regards to prediction of ready biodegradability:

1) Absence of read-across documentation for the read-across from Sodium methanethiolate

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies).[5]

You have provided studies conducted with Sodium methanethiolate, EC No. 225-969-9 (CAS No. 5188-07-8) in order to comply with the REACH information requirement for Growth inhibition study on aquatic plants and Ready biodegradability. You have not provided documentation as to why this information is relevant for your Substance.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on Sodium methanethiolate.

2) Adequacy and reliability of the selected source studies

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must provide adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

For the following endpoints, we identified issues with regard to the reliability of the source studies:

- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Ready biodegradability (Annex VII, Section 9.2.1.1.)

Those issues are addressed under the corresponding endpoints.

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

[5] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.6.1

Appendix A: Reasons to request information required under Annex VII of REACH

1. Growth inhibition study aquatic plants

A growth inhibition study in aquatic plants is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5 (read-across) and you have provided the following studies:

a) a toxicity study to aquatic algae and cyanobacteria by [redacted] (2005) performed according to OECD TG 201 with Diammonium dithiodiglycolate, EC No. 269-323-4 (CAS No. 68223-93-8);
b) a toxicity study to aquatic algae and cyanobacteria by [redacted] (2004) performed according to EU Method C.3/OECD TG 201 (with deviations) with Sodium methanethiolate EC No. 225-969-9 (CAS No. 5188-07-8).

For all the reasons explained in the Appendix on Reasons common to several requests, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5 (read-across) and is rejected. More specifically, in relation to section 1.2) of that Appendix (*Adequacy and reliability of the selected source studies*), we have identified the following issues:

A. To fulfil this information requirement, a study must provide an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case the OECD TG 201, and follow the requirements of GD 23 if the substance is difficult to test. Therefore, the following conditions must be met:
   - the study must provide information on inhibition of growth, expressed as the logarithmic increase in biomass (average specific growth rate) during the exposure period;
   - the initial biomass concentration must be compliant with the technical guideline requirements;
   - the results of analyses to determine the concentration of the test substance in the test vessels must be provided. Where concentrations do not remain within 80-120 % of nominal, analysis must be conducted at 24 hour intervals on all test concentrations in order to better define loss of the test substance;
   - the algal biomass in each flask must be determined at least daily during the test period and reported in a tabular form.

   On study (a)above:
   - You specify the final test was conducted at a single nominal concentration of 100 mg/L (as test material). You indicate that the test material has an active ingredient content of 45.8%. You have not provided information on the presence of impurities and/or co-solvent (if any);
   - You have not reported any information on the stability of the exposure to the active substance during the test;
   - You report that the study was conducted on *Desmodesmus subspicatus* and that the initial cell density was 10^4 cells per mL;
   - You have not provided biomass data for each flask at each measuring point.

   On study (b) above:
   - You indicate that the test material has an active ingredient content of 32.9%. You have not provided information on the presence of impurities and/or co-solvent (if any);
   - You specify that "*final test substance concentrations measured in non-inoculated*

flasks at 72 hours decreased [by] *>80%* [...]";
- You report that analytical monitoring of exposure concentrations was conducted but you have not reported the corresponding results;
- You have not provided biomass data for each flask at each measuring point.

For studies (a) and (b) you have not provided adequate information on the identity of the test substance including an unambiguous estimate of the content in active ingredient and of the presence of impurities. For study (a) and (b), you have not provided adequate information to appropriately characterise exposure throughout the exposure period. In addition, for these studies, you have not provided biomass data for each flask at each measuring point and therefore it is not possible to verify that the validity criteria of the OECD TG 201 were fulfilled. Furthermore, for study (a), the initial cell density was two times higher than the value specified for *Desmodesmus subspicatus* in the OECD TG 201 and this may have impacted the sensitivity of the test. Hence, none of the studies from your dossier provides an adequate coverage of the key parameters of the OECD TG 201.

Therefore the information requirement is not fulfilled.

In your comments on the draft decision, you acknowledge that further data based on OECD TG 201 will be produced and will be used to update your read-across grouping approach. However, we stress that at least all the deficiencies described above in the Appendix on Reasons common to several requests have to be resolved for a read-across approach to be considered valid.

2. Ready biodegradability

Ready biodegradability is a standard information requirement in Annex VII to REACH.

You have adapted the standard information requirement according to Annex XI, Section 1.2. of REACH (weight of evidence). In support of your adaptation, you have provided the following source of information:

a) a ready biodegradability study by [redacted] (1994) performed according to OED TG 301 A with Thioglycolic acid, EC No. 200-677-4 (CAS No. 68-11-1);
b) a ring test by Painter & King (1985) according to modified EU Method C.4-F (MITI I Test with deviations) with Thioglycolic acid, EC No. 200-677-4 (CAS No. 68-11-1);
c) a published study by Blok *et al.* (1985) reporting the result of ring tests for various ready (similar to OECD TG 301B/C/D/E) and inherent biodegradability (similar to OECD TG 302B/C) test methods with Thioglycolic acid, EC No. 200-677-4 (CAS No. 68-11-1);
d) a ready biodegradability study by [redacted] (2005) according to OECD TG 301 B with Diammonium dithiodiglycolate, EC No. 269-323-4 (CAS No. 68223-93-8)
e) a ready biodegradability study by van Ginkel & Stroo (1992) performed according to OECD TG 301 D with Thioglycolic acid, EC No. 200-677-4 (CAS No. 68-11-1);
f) an inherent biodegradability study by [redacted] (1992) according to OECD TG 302 C with Thioglycolic acid, EC No. 200-677-4 (CAS No. 68-11-1);
g) a ready biodegradability study by [redacted] (1995) performed according to OECD TG 301 D with Sodium methanethiolate, EC No. 225-969-9 (CAS No. 5188-07-8).
h) a read-across justification in Section 4.1.3. of your Chemical Safety Assessment (CSA).

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or

has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance of the information for the given regulatory information requirement. Subsequently, relevance, reliability, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

However, for each relevant information requirement, you have not submitted any explanation why the sources of information provide sufficient weight of evidence leading to the conclusion/assumption that the Substance has or has not a particular dangerous property.

In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation and identified the following issue with regard to the relevance of the information provided by you.

To fulfil the information requirement, normally a study performed according to OECD TG 301 or 310 must be provided. The key parameter to be investigated in an OECD 301 or 310 study is the the ultimate aerobic biodegradation under low inoculum concentration as measured by parameters such as DOC, CO2 production and oxygen uptake at sufficiently frequent intervals to allow the identification of the beginning and end of biodegradation.

a) *Assessment of the relevance of the information provided in support of your adaptation*

As explained above, to provide relevant information on biodegradation, a ready biodegradability study must be conducted under low inoculum concentration.

The OECD TG 302B and OECD TG 302C are conducted at an inoculum concentration of 0.2-1.0 dry matter/L and 100 mg/L, respectively. Ready biodegradability tests methodologies using sewage sludge as an inoculum must always be conducted at an inoculum concentration corresponding to ≤ 30 mg/L suspended solids.

Therefore these technical guidelines are not relevant to study ultimate aerobic biodegradation under low inoculum concentration. Therefore, the OECD TG 302B/C from Blok *et al* (1995) and the OECD TG 302C from [redacted] (1992) do not provide information that would contribute to the conclusion on the above key parameter.

b) *Assessment of the reliability of the information provided in support of your adaptation*

The sources of information (a), (b), the OECD TG 301B/C/D/E in (c), (d), (e) and (g) provide relevant information on ultimate aerobic biodegradation under low inoculum concentration.

However, the reliability of these sources of information is significantly affected by the following deficiencies:

i) *Reliability of the experimental data provided in your dossier*

To be considered a reliable source of information, a study must provide an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case the OECD TG 301A, B, C, D, E, F or 310. Therefore, the following conditions must be met:

- an appropriate description of the test material must be provided including the degree of purity and the presence of impurities and/or co-solvents;

a) the source of the inoculum must be described. It must originate from a predominantly domestic sewage treatment plant and not be adapted to the test substance;
b) the test material and inoculum concentrations must be within the range specified in the corresponding test guideline;
c) all validity criteria specified in the corresponding test guideline must be fulfilled;
d) the variation between the replicates must be less than 20%;
e) results of measurements (at sufficiently frequent intervals) must be reported in a tabular form.

You have provided:

b) a study by van Ginkel & Stroo (1992) according to OECD TG 301D on Thioglycolic acid showing 67% biodegradation (based on O_2 consumption) after 28 days;
c) a study by [redacted] (1994) according to OECD TG 301A on Thioglycolic acid showing 21% DOC removal after 28 days;
d) a published study by Blok *et al.* (1985) summarizing the results of ring tests for various ready and inherent biodegradability test methods. The tests conducted on thioglycolic acid show biodegradation above the pass criteria (i.e. > 70% DOC removal at 28 days or > 60% BOD/ThOD or CO_2/TOC at 28 days) in 60% of the Sturm tests (i.e. similar to OECD TG 301B; n=5), 40% of the MITI I tests (i.e. similar to OECD TG 301C; n=10), 13% of the modified OECD tests (i.e. similar to OECD TG 301E; n=16) and 0% of the closed bottle test (i.e. similar to OECD TG 301D; n=7);
e) a ring test by Painter & King (1985) according to modified EU Method C.4-F (MITI I Test with deviations) on Thioglycolic acid showing an average of 47% biodegradation (based on ThOD) after 28 days. The report states that "*only 5/20 laboratories reached 60%ThOD* [within the 10-day window]*, rising to 8/20 at 28d*";
f) a study by [redacted] (2005) according to OECD TG 301B on Diammonium dithiodiglycolate showing 80% biodegradation (based on CO_2 production) after 28 days but failing the 10-day window criterion;
g) a study by [redacted] (1995) according to OECD TG 301 D on Sodium methanethiolate showing 64% biodegradation after 21 days. From your study summary, it is unclear if the parameter monitored for biodegradation was DOC removal or consumption of dissolved O_2.

On the study (a), no information on the composition of the test material used to conduct the studies is provided. The test material and inoculum concentrations are not reported and therefore it is not possible to verify if the test conditions were adequate. In this study "*Ammonium chloride was omitted from the medium to prevent nitrification*" which may artificially reduce the endogenous respiration in the inoculum blank (*i.e.* one of the validity criteria of the OECD TG 301D). No reporting of the test results is provided and it is not possible to verify if all validity criteria of OECD TG 301D were fulfilled and if the conclusion that the % biodegradation was above the pass criteria is reliable.

In the study (b) the inoculum concentration was 4 x 10^3 cell/mL which is below the acceptable range of 10^4 to 10^5 cell/mL as specified in OECD TG 301 A. Therefore it does not provide a reliable basis to conclude if the Substance is readily biodegradable or not.

On the studies (c) and (d), the information reported in the original publications lacks critical elements to evaluate the reliability of the reported results. In particular, no information is provided on the composition of the test materials, the origin of the inocula or on the methodology (of methodological differences, if any) used to conduct individual studies. No reporting of the results of these studies is included in the publication and it is not possible to verify if the validity criteria of the corresponding technical guidelines were fulfilled and if the conclusion that the % biodegradation was above the pass criteria in any of these tests is reliable.

In study (e) you report that the active ingredient content of the test material is 45.7%. You have not reported information on the presence of impurities or co-solvents (if any). Based on the information reported by you, it is unclear if the initial test concentration was 5 mg/L as test material (i.e. equivalent to 0.5 mg DOC/L) or 5 mg DOC/L. However, in both cases the initial test concentration is below the OECD TG 301 B (i.e. 10-20 mg DOC/L) and reducing the test concentration below the limits defined in the technical guideline will change the ratio of substance to inoculum in a way that is deemed to be too favourable. Finally, no reporting of the test results is provided and it is not possible to verify whether the other validity criteria of OECD TG 301B were fulfilled.

In study (f), you have not reported information on the composition of the test materials and on the origin of the inoculum. You have not reported any information on the study design except the initial test substance concentration. No reporting of the results is provided and it is not possible to verify if the validity criteria of OECD TG 301D were fulfilled.

Hence, none of the studies from your dossier provides a reliable coverage of the key parameter of the OECD TG 301 or 310 and therefore cannot be considered as a reliable source of information to support your weight-of-evidence adaptation.

ii) Grouping of substances and read-across approach

For the reasons explained in section 1.1.) (*Absence of read-across documentation for the read-across from Sodium methanethiolate*) and 1.2.) (*Adequacy and reliability of the selected source studies*) of Appendix on Reasons common to several requests, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5 (read-across) and cannot be considered as a reliable source of information to support your weight-of-evidence adaptation.

In your comments on the draft decision, you also refer to a publication by Rücker et al. (2018, Environ. Sci. Pollut. Res., 25:18393-18411) which you consider supportive of the fact that the Substance is readily biodegradable. In this publication TGA was consistently found as not readily biodegradable based on OECD TG 301D. It was however considered readily biodegradable based on a modified OECD TG 301F test.

In any case (eco)toxicological studies relied upon to comply with information requirements must comply with GLP or another recognised international standard (Art. 13(4) of REACH). The study you invoke does not. Despite this critical deficiency, we have assessed this information and identified the following issue:

To be considered a reliable source of information, a study must provide an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case the OECD TG 301F. Therefore, the following conditions must be met:

- the concentration of the test material is 100 mg /L, corresponding to 50 to 100 mg ThOD/L;
- the concentration of the inoculum is set to reach a bacterial cell density of 10^7 to 10^8 cells/L in the test vessel;
- the oxygen uptake of the inoculum blank does normally not exceed 20-30 mg O_2/L at the end of the test;
- the test material identity is provided, including information on purity, presence of impurities and compositional information (if applicable);
- the results of measurements at each sampling point in each replicate is reported in a tabular form;

However, in the publication by Rücker et al. (2018):

- the authors indicate deviations from the standard OECD TG 301F test conditions as the test material concentration was 30 mg ThOD/L;
- the inoculum concentrations is reported as 80 mL secondary effluent/L but no information is provided on cell density. Furthermore, no information is reported on the oxygen uptake of the inoculum blank at the end of the test apart from the fact that it was claimed to be < 60 mg O_2/L;
- the test material is described as to be of "technical grade [...] used without purification". No further information is provided;
- no detailed results are provided.

The authors report that a lower test material concentration was used compared to the requirement of OECD TG 301F. Therefore, the test material to inoculum concentration was too favourable and this study may overestimate the percentage biodegradation that would be achieved under standard test conditions. Furthermore, the authors have not provided adequate data to demonstrate that the inoculum density was within an acceptable range (*i.e.*, bacterial cell density estimate and oxygen uptake values in the inoculum blank). Then, this publication does not provide adequate information on the purity of the test material. Finally, as no detailed reporting of oxygen uptake measurements is available, insufficient information is available to conduct an independent assessment of the study reliability on the interpretation of the results. Therefore, this publication does not meet the information requirement.

As a conclusion, the sources of information from your dossier and your comments on the draft decision in support of your weight-of-evidence adaptation provide information on ultimate aerobic biodegradation. However, for the reasons explained above, these sources of information do not provide a reliable basis to conclude that the Substance meets the criteria to be considered readily biodegradable.

Accordingly, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular property foreseen to be investigated in an OECD TG 301 or 310 study. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

Appendix B: Reasons to request information required under Annex VIII of REACH

1. Adsorption/ desorption screening

Adsorption/desorption screening is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement according Annex VIII, Section 9.3.1., column 2 based on the following justification: "[...] *the study does not need to be conducted, because the substance has a low octanol water partition coefficient. Moreover thioglycolic acid and its main degradation product (diammonium dithioglycolate) decompose rapidly* [...]".

We have assessed this information and identified the following issues:

A. Annex VIII, Section 9.3.1., column 2 specifies that a study does not need to be conducted if the substance can be expected substance to have a low potential for adsorption (e.g. the log K_{ow} is low). To adapt this information requirement based on low Log K_{ow}, lipophilicity must be the sole characteristic driving the adsorption potential of a substance. However, for some groups of substances (e.g. ionisable substances, surfactants) other mechanisms than lipophilicity may drive adsorption.

   You have justified the low potential for adsorption because the partition coefficient value (log K_{ow}) of the source substance Thioglycolic acid, EC No. 200-677-4 (CAS No. 68-11-1) was determined to be -2.99 at pH 7 (ionised form) and 1.89 at pH 1.7 non-ionised form) based on OECD TG 107. You have provided dissociation constant data indicating that the Substance is ionized at environmentally relevant pH.

   However, while anionic substances may be expected to have lower tendency to sorb compared to cationic substances, ionic binding to positively charged soil constituents (e.g. hydrous oxides of aluminium and iron) cannot be excluded. Therefore log K_{ow} is not a valid descriptor for assessing the adsorption potential of the Substance and your adaptation is rejected.

B. Annex VIII, Section 9.3.1., column 2 specifies that a study does not need to be conducted if the Substance and its relevant degradation products decompose rapidly.

   However, for the reasons explained under request A.2, the information provided on ready biodegradability does not fulfil the information requirement. Therefore, your technical dossier currently does not demonstrate that the Substance and its relevant degradation products decompose rapidly.

Therefore, your adaptation according to Annex VIII, Section 9.3.1., column 2 is rejected and the information requirement is not fulfilled.

Appendix C: Reasons to request information required under Annex IX of REACH

1. **Long-term toxicity testing on aquatic invertebrates**

   and

2. **Long-term toxicity testing on fish**

Long-term toxicity testing on aquatic invertebrates and Long-term toxicity testing on fish are standard information requirements in Annex IX to REACH.

You have adapted these information requirements according Annex VIII, Section 9.1., column 2 based on the following justification: "*According to column 2 in Annex IX of Regulation (EC) 1907/2006, long-term toxicity tests with aquatic organisms are not needed if the outcome of the chemical safety assessment indicates no unacceptable effects on aquatic organisms. As the risk to aquatic organisms that are exposed to the thioglycolate anion is acceptable (please refer to the chemical safety report), a long-term test*[s] [are] *not required.*".

We have assessed this information and identified the following issue:

> As specified in Annex IX, Section 9.1., Column 2, long-term toxicity to studies on aquatic invertebrates and on fish must be performed unless the Chemical Safety Assessment demonstrates that risks towards the aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). The justification must be documented in the Chemical Safety Assessment.
>
> In particular, the Chemical Safety Assessment must take into account the following elements to support that long-term toxicity testing is not required:
> - all relevant hazard information from your registration dossier,
> - the outcome of the exposure assessment in relation to the uses of the Substance,
> - the outcome of the PBT/vPvB assessment including information on relevant degradation products and constituents present in concentration at or above 0.1% (w/w).
>
> To justify why the risks of the substance are controlled you rely on PNEC estimations derived from the results of short term toxicity studies on algae, fish and aquatic invertebrates.
>
> As specified in request A.1, the data on Growth inhibition on aquatic plants are not compliant. Hence your dossier currently does not include adequate information to characterize the hazard property of the Substance.
>
> Without this information your Chemical Safety Assessment does not demonstrate that the risks of the Substance are adequately controlled. As a consequence, your adaptation is rejected as it does not meet the specific rules for adaptation of Annex IX, Section 9.1., Column 2.

Therefore these information requirements are not fulfilled.

According to the integrated testing strategy (ITS) (ECHA Guidance R7b,Section R.7.8.5 including Figure R.7.8-4), the *Daphnia* study is to be conducted first. If based on the results of that study and the application of a relevant assessment factor no risks are observed (PEC/PNEC<1), the long-term fish study may not need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

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

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

3. 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 on How to report robust study summaries[6].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)
   The Test Material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - 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.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[7].

[6] https://echa.europa.eu/practical-guides
[7] https://echa.europa.eu/manuals

Appendix C: General recommendations when conducting and reporting new tests for REACH purposes

A. Aquatic toxicity testing of difficult to test substances

Due to the rapid oxidation and potential for high adsorption, you need to consult the OECD Guidance Document (GD) 23 and ECHA Guidance, Chapter R7b, Table R.7.8-3 relating to the aquatic toxicity testing of difficult substances, so that you choose the most appropriate design of the requested ecotoxicity test(s) and you best calculate and report the results of the test(s).

B. Testing strategy for aquatic toxicity testing

You are advised to consult ECHA Guidance R.7b, (Section R.7.8.5) which describes the Integrated Testing Strategy, to determine the sequence of aquatic toxicity tests and testing needed.

Appendix D: Procedure

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

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 03 July 2019.

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

ECHA took into account your comments and did not amend the requests and the deadline.

With reference to your comments, the timeline indicated in the draft decision to provide the information requested is 18 months from the date of adoption of the decision.

In your comments to the draft decision, you requested an extension of the timeline as you intend to improve the read-across approach. Also, you invoke your nature of SME and the fact that read-across/grouping and waiving approaches are complex and therefore require time to be developed.

However, in your comments you have not indicated any issues (including laboratory capacity) related to the performance of the studies requested in this decision. Therefore, the arguments provided above do not justify your request to extend the timeline and ECHA has not modified the deadline of the decision.

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 E: List of references - ECHA Guidance[8] and other supporting documents

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

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 where relevant.

Read-across assessment framework (RAAF, March 2017)[9]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[9]

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

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

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

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

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

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

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[10]

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

Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix F: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.