

How to report robust study summaries

June 2023

ABC

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Version	Changes	
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Version 2	Revision addressing structure and content in relation to the updated sub-chapter R.7.1 'Physicochemical properties' within the 'Guidance on information requirements and chemical safety assessment R.7a: Endpoint specific guidance' and new or revised OECD Test Guidelines.	November 2012
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Glossary

Term	Definition
Author(s)	The terms author(s) refers to the person(s) responsible for preparing the full study report.
CRO	Contract Research Organisation
IUCLID	International Uniform Chemical Information Database
Full study report / lab report	A complete and comprehensive description of the activity performed to generate the information. This covers both, complete scientific publications from the literature or full reports prepared by Contract Organisations (CROs), describing the performed study/ies.
Robust Study Summary (RSS)	A detailed summary of the objectives, methods, results, and conclusions of a full study report. It provides sufficient information to make an independent assessment of the study and its results minimising/avoiding the need to consult the full study report.
UVCB	Chemical substances of unknown or variable composition, complex reaction products and biological materials
WoE	Weight of Evidence
% AR	Refers to the applied radioactivity that originates from the labelled substance, relative to the initial value at time=0.

1. Introduction

To demonstrate the safe use of their substances, REACH registrants and BPR applicants must fulfil the information requirements as stipulated in REACH and BPR, respectively. Both REACH and BPR address details for selected individual endpoints that are crucial for an independent assessment by a technically qualified person. BPR applicants and REACH registrants must provide robust study summaries (RSS) or study summaries for each information requirement in the technical dossier.

- A RSS is a detailed summary of the objectives, methods, results and conclusions of a full study report. The RSS must allow the assessor to **independently assess the study** while minimising/avoiding the need to consult the full study report.
- A study summary outlines/ the objectives, methods, results, and conclusions of a full study report. The study summary must allow the assessor to **conclude on the relevance of the study**.

This guide is a manual on the preparation of individual RSS for the following sections of the IUCLID dossier:

- Physical and chemical properties
- Environmental fate and pathways
- Ecotoxicological information
- Toxicological information

This guide:

- Addresses registrants under REACH and applicants under BPR;
- Provides practical general advice on RSS reporting with the aim of helping you (registrants/applicants) draft compliant RSS;

Moreover, this guide contains a non-exhaustive list of selected endpoints including the respective key information requirements, such as study characteristics. While you are generally required to follow the reporting requirements of the respective OECD Technical Test Guideline (TG), the list reflects ECHA's experience with the most frequently spotted data gaps in submitted dossiers. Reporting both the listed information and the TG-specific information facilitates the assessment.

1.1. When to provide RSS under REACH

As a REACH registrant, you have the obligation to evaluate all available substance information for the preparation of the IUCLID dossier. This process includes

- The evaluation of the quality of data (relevance, adequacy, and reliability),
- The selection of key study(ies) for each endpoint, and
- The drafting of the relevant RSS or study summaries.

While study summaries are sufficient for physical and chemical endpoints, and for supporting studies, you must provide RSS for:

- All key studies, including
 - studies giving rise to the highest concern, and which drive the Derived No-Effect Level (DNEL) for human health endpoints, and the No-Observed-Effect-Concentration (NOEC) for environmental endpoints, respectively;
 - studies providing data that is used in the hazard assessment / chemical safety report;
 - studies that are used in Read-Across and Weight of Evidence;

1.2. When to provide RSS under BPR

As BPR applicant, you have the obligation to evaluate all available substance information for the preparation of the IUCLID dossier. This process includes

- The evaluation of the quality of data (relevance, adequacy, and reliability);
- The selection of key study(ies) for each endpoint;
- The drafting of the relevant RSS or study summaries.

Provide RSS for

- Information derived for approval and authorisation applications;
- All key studies, including
 - studies giving rise to the highest concern and that are used to derive conclusions in the chemical safety assessment;
 - Studies providing data that are used in the risk assessment.

2. How to draft RSS

2.1. Content

- 1) The RSS is a detailed summary of the objectives, methods, results and conclusions of a full study report. The prescribed submission format for RSS is the IUCLID format. It represents a harmonised reporting standard for scientific information and therefore facilitates further processing of the submitted information.
- 2) The RSS should be independent and self-contained. In general, no part of the RSS should rely on another RSS for the assessment. Avoid cross-referencing from one RSS to another.
- 3) Avoid bias and advocacy when reporting the information: Do not refer to or make use of any prior knowledge on the test substance that goes beyond the information from the full study report.
- 4) If you waive a standard information requirement (i.e. a requested study), report a justification in accordance with ECHA Guidance R.5. For biocidal active substances, the BPR guidance on information requirements can be an additional source for justification examples.

- 5) If you apply a weight of evidence (WoE) approach, provide RSS for all studies. Especially in case of conflicting data, good RSS are key for a comprehensible assessment of the data adequacy, relevance, and reliability.
- 6) If you submit supporting studies for the assessment of the substance, a basic study summary is acceptable. In other words, no RSS is required strictly. However, in some situations, RSS may be helpful although not strictly required: Imagine, you want to support a key study against conflicting results from less valid studies. The more details you report to reinforce the invalidity of those conflicting supporting studies, the better, Therefore, if the supporting study contains critical data:
 - Submit a study summary highlighting the weaknesses of the studies, and
 - Flag it as 'disregarded study' in field "Purpose flag" in IUCLID.

2.2. Working with IUCLID

- 1) Complete the template fields, whenever applicable. If you are not able to find adequate or sufficient information within the full study report, do not leave the corresponding IUCLID field blank. Add '*no information available*' into the related IUCLID template field and it will highlight that a particular lack of information was due to the deficiency in the report and not the RSS.
- 2) As it may not always be possible to input all required information within templates, report at least, the requirements listed in the respective OECD Technical Test Guideline (TG) section Material and methods, and Results and discussion. In other words, you need to provide the latter in all cases. Insufficient explanation of the studies hampers the study evaluation and may represent a data gap because ECHA would not be able to conclude on the substance's classification and labelling and/or risk assessment. Therefore, complete the IUCLID fields for all RSS as described below.
- 3) When you re-use large sections of the information from study reports, e.g. by copy and paste (CTRL+C, CTRL+V), do it one sentence at a time. After pasting, read the pasted section to ensure its relevance. Remove irrelevant information to make it more concise. Remember: a RSS is a summary of a full study report. Also, be careful when summing up text from the full study report where text passages include (cross-references). **Tip:** When you copy and paste, it is best to first paste the content in a word processor or text editor, respectively. Edit the text/table/figure, before you paste your final approved text into the relevant IUCLID section.

2.3. Administrative data

2.3.1. Endpoint (pick-list)

The addressed endpoint is defined by the applied OECD TG. Critically assess if the study author / CRO has correctly indicated study TG deviations. Add a remark when the assessed study does not represent a standard endpoint study or deviates significantly from a standard endpoint.

2.3.2. Type of information (pick-list)

Specify what RSS is based on: experimental data, read-across or QSAR, for example. Indicate if the endpoint study record refers to a testing proposal. If that is the case, select 'experimental study planned' or 'experimental study planned (based on read-across)'.

2.3.3. Adequacy (pick-list)

Pick 'key study' or 'supporting study' based on how the information is used. See sections 1.1 & 1.2.

Tip: Key study should be selected when a study is both relevant and reliable to cover the endpoint without any major reservation(s). Studies with Klimisch score 3 and 4 are never used as a key study. Supporting study, should be selected for any other adequate study supportive to the key study.

2.3.4. Robust study summary (checkbox)

Tick the RSS checkbox by default for all RSS submissions.

2.3.5. Study period

Report the start and end date of the experiment. Use an unambiguous format such as 'From 12 MAY 1999 to 15 AUG 2000'. If only the year is available, mention that the date and the month were not available in the report (e.g., in case of scientific publications).

Tip: You may have to specify the in-life period for some (eco)toxicology endpoints. This is the phase in which the test system is alive/growing.

2.3.6. Reliability (pick-list)

Indicate the reliability score according to Klimisch¹.

Tip: populate this section at the end, after writing all other sections. This is because you will have a better idea about the deficiencies of the report once you have created the RSS from it.

2.3.7. Rationale for reliability incl. deficiencies

There is an *add remark* section below the picklist. Provide more details on why you think the chosen reliability score is appropriate. This may include brief statements such as coverage and robustness of the method, appropriateness of the species for a given endpoint etc. Sometimes, even though reports state they are OECD TG-compliant studies, they may contain noticeable deficiencies in the methodology. Record those deficiencies here. This step is especially important

- for academic publications,
- old laboratory reports (pre-GLP, i.e., before 1972),
- reports which refer to a particular test guideline that has been superseded after the study was conducted.

Tip: Be aware of the difference between the term 'deficiency' and 'deviation'. For example, poor reporting of analytical data or missing information on the test substance identification is a deficiency. The temperature deviation within an experiment outside $\pm 1^\circ\text{C}$ range in an OECD TG 202 test is a deviation from the Test Guideline. Any deviation from the OECD TG and its

¹ Klimisch HJ et al. (1997). "A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data". *Regulatory Toxicology and Pharmacology*. 25 (1): 1–5. doi:10.1006/rtph.1996.1076.

consequences to the study should be reported in the full study report. Clearly distinguish the two terms in this section while writing.

2.4. Data source

Enter the correct and complete bibliographic reference of the study report or publication

2.4.1. Reference

To create a new literature reference, click on 'Select' in the 'Reference' field under 'Data source'. The link will take you to the Literature reference inventory. In the pop-up window click on 'Create / New Literature reference'. Fill in the fields in the pop-up window and click Save. For publications, also include DOI number.

For author's name in study reports: report author name (study director). If the author's name is not available, enter the name of the company or organisation.

- Author
- Year
- Testing facility
- Report date
- Report number
- Study sponsor
- Study number;

2.4.2. Data access (pick-list)

Select 'data submitter is data owner' if it is a lab report OR 'data published' if it is a publication.

2.4.3. Data protection claimed (pick-list)

For BPR dossiers, refer to the biocides submission manual 'BSM Process of confidentiality requests for biocide applications'. For REACH dossiers, refer to the manual 'How to prepare registration and PPORD dossiers'.²

2.5. Materials and methods

Whenever possible, report tabulated data & information.

Tip: Include a brief description of study design for preliminary studies such as dose range finding study/range-finding study and for homogeneity and stability studies. This is done in the 'study design' subsection for human toxicology endpoints, and 'any other information on

² <https://echa.europa.eu/manuals>

methods' for ecotoxicology endpoints. Follow endpoint specific details for this information.

2.5.1. Method/guideline and study design

Method is a pick-list (or description if different from the pick-list), along with the organisation(s) (e.g. OECD, EPA, ISO). You may cite multiple guidelines if needed.

- Qualifier (pick-list)
- **Tip:** GLP reports usually already mention any deviations from the guideline. For publications, if deviations are not described directly by authors, confirm by reading the materials and method section.
- Version of the guideline: usually indicated by the year of the guideline publication;

Detailed description of test conditions

- Study/exposure duration
- Sampling times
- Doses/concentrations
- Route of exposure
- Vehicle and justification of choice if other than water;
- Repeatability and sensitivity of the analytical methods applied for identification and quantification of test item and degradation products
 - limit of detection (LOD),
 - limit of quantification (LOQ),
 - recovery %

Housing conditions

- Temperature
- Relative humidity
- Light-dark cycle
- Number of animals/sex/cage
- Cage material
- Bedding material
- Feed and drinking water;

2.5.2. Principles of method if other than guideline:

At least provide the main principle of the test, short description of test condition, and parameters analysed.

2.5.3. GLP compliance (pick-list)

Compliance with good laboratory practice (GLP) is mandatory for toxicological,

ecotoxicological, and environmental fate studies, that were conducted after 1 June 2008. GLP is recommended for physicochemical endpoints.

Confirm that the GLP certificate is provided in the QA section of the study report. In some cases, part of a study may not be GLP: E.g., a dose range finding study may not be a GLP, but the main study is GLP. Clearly mention in the 'remark' box, whether the certificate was included or if the GLP compliance is ambiguous. Also state here if part of a study is not GLP and whether that has any impact on the main study.

Tip: If a certificate is not included, pay very close attention to the language used. Only select option "GLP compliant" if there is an unambiguous statement that the study was fully conducted to GLP at a GLP certificated facility. Pay attention to the validity period of the certification.

2.5.4. Type of test

Sometimes, there are multiple methods available for a particular endpoint. E.g., the boiling point can be measured using dynamic method, distillation methods or several other methods (see 'type of method' box in boiling point IUCLID template). In those cases, report the method type.

Example: 'Type of method' field for boiling point; 'Type of study' field for skin sensitization or 'Test type' field for human acute tox etc in 'material and method' section.

Report the rationale for choosing a particular method in the 'justification' or 'remark' field. In case of publications, provide a rationale on the suitability of the method from your experience (if not discussed in the paper). Moreover, if the applied method is other than OECD or EC guidelines, provide a justification. If a report/publication is old and performed prior to a published guideline, mention it.

2.5.5. Test material information

Section 'Information on test material identity' is mandatory. Go to the 'Test material information' section. To create a new substance record, select 'create' and provide name, composition, test material form, and details on test materials (insert IUCLID template function and add as many details as available). In the composition table, provide 'type', 'reference substance', and 'concentration' as a minimum. If the substance is multi-constituent/UVCB, all components should be added in the composition table. In addition, complete 'test material form' and 'details on test material', using the template function, if relevant (e.g., for nanomaterial).

- Details on test material (go to 'Specific details on test material used for the study' section, use IUCLID template functionality to fill in as much detail as possible). As a minimum, fill following details and any of the information is not available, write the reason (e.g., not provided in report or not relevant):
 - Name and identifier(s) of test material
 - Source of test material
 - Lot/batch number
 - Expiry date
 - Purity and purity test date (include name, isomers and concentration of impurities if the test substance in the study is different from the substance for which information is provided in the 'test material section').

E.g. the test material is a solution or mixture containing the substance.)

- Storage condition of test material
- Stability and homogeneity of test material in the vehicle/solvent
- Stability of the test material in medium
- Solubility and stability of the test substance in the solvent/vehicle under test conditions (e.g. in the exposure medium) and during storage
- Reactivity of the test substance with the solvent/vehicle and with the incubation material used (e.g. plastic ware)
- Treatment of test material prior to testing
- Preliminary purification step
- Final dilution (mention neat, if no dilution)
- Dilution media (if applicable)
- Form and physical state
- Form applied (if different from original form)
- Composition
- For nanomaterials/nanoforms/set of nanoforms specifications for test material reporting apply (see section 4);

2.5.6. Test organism information

- Species
- Strain
- Source
- Number of animals per sex per dose
- Age and body weight at study initiation
- Method of breeding
- Feeding
- Time allowed for acclimatisation (relevant only to eco-toxicity and toxicity endpoints)
- Method of individual identification of animals;

2.5.7. Statistics

Reporting of basics of statistical method and statistical error estimates is mandatory. You need to report in the 'statistics' section:

- Details on the statistical methods
- Assumptions of statistical methods

- Number of replicates
- Unit of measurement
- Number of animals/replicate (if unit of measurement is not individual animal)

2.6. Results and discussions

Whenever possible report tabulated data.

Complete all IUCLID templates on endpoints that correspond to the standard information requirements as far as possible.

You must convey the following aspects of study report in the RSS by inserting information in either **predefined boxes or in free text fields**.

- The summary of all observations as specified in the respective OECD TG.
- Statistically significant result clearly distinguished from others.
- Biological relevance if applicable.
- **For human toxicology**, there might be several categories of adverse effects available in the report e.g., neuropathological effects, immunotoxic effects etc. You must report them all in the RSS in their respective fields in IUCLID. Identify key adverse effects driving the NOAEL derivation and list them in the IUCLID Table in the 'Effect levels' in the results and discussion section, by reporting all effects and selecting the 'key effect' box.
- Do not leave section 'Basis of effects' in the results section blank.

Conclusions must be backed up by results provided within the RSS. Provide a rationale on why an effect is adverse or non-adverse.

- Report any type of dose conversion OR any other information that may help in the evaluation of adverse effects, in the 'remarks' field in the results section.
- 'Any other information on results' section:
 - Present concentration/dose response relationship in tabular form for all major parameters. Assign table numbers to all tables in this section. **Tip:** Avoid pasting tables in IUCLID that you created in MS Word. The reason is that it can lead to formatting errors during the conversion to .pdf documents. Instead, try to create tables directly in IUCLID: Go into the rich text editor provided within the IUCLID field, then go to Table option and create the table.
 - Discuss any significant deviations from the guideline.
 - Write anything unusual about the test and other relevant information which might have influenced the results.

2.7. Overall remarks, validity criteria fulfilled, interpretation and conclusions relevant for human health endpoints

Provide toxicological evaluation of all the findings of the study: adverse and non-adverse effects, reversible and irreversible effects. Consider severity of effects, dose-response relationship and provide historical control values if the justification relies on normal biological variation.

Explain the biological relevance of the effects observed in animals and if needed address human relevance. If it is a lab report, this information is discussed by the study director in the discussion and/or conclusion section. In an academic publication, this information could be found in the discussion section. Include any mechanistic information including adverse outcome pathways (AOP) related discussions.

If relevant, include a summary of confounding factors that may affect the results of the study. Discuss deviations from the guideline.

Discuss whether the validity criteria for the study were met: report the validity results in the 'any other information on material and method' section, and highlight deviations.

In general, explain which conclusions were derived from the underlying data.

Example: in the conclusion section for repeated dose toxicity, you must clearly write the basis of your conclusion such as "Rats ingesting up to 1000 mg/kg/day for 13 weeks survived the in-life portion of the study without clinically adverse effects. The only effects found at 250 mg/kg/day were very slight decrements in RBC parameters. However, all were within the historical control and the effects were not observed at higher doses. Hence, the effects were not considered adverse, and NOAEL was determined to be 1000 mg/kg".

3. Instructions for UVCB or Substances containing multiple constituents

3.1. Test material(s)

- Report the composition of the selected test material for each study, under the *Test material information* section (see 2.5.5), for each respective endpoint study record in IUCLID.
- Report all constituents of each test material and their concentration values and other parameters relevant for the property to be tested (OECD GLP (ENV/MC/CHEM(98)16) and EU Tests Methods Regulation (EU) 440/2008/ OECD TG.
- Assess the impact of each constituent/ impurity on the test results for the endpoint.

This information is needed to assess whether the test material is relevant for the substance. Technical instructions on how to report the above is available in the manual on *How to prepare registration and PPORD dossiers*³. For biocidal active substances, you can find instructions in the *Biocides Submission Manual Technical guide: How to prepare a biocides dossier*⁴.

³ <https://echa.europa.eu/manuals>

⁴ [Biocides Submission Manuals - ECHA \(europa.eu\)](https://echa.europa.eu/biocides-submission-manual-technical-guide)

3.2. Physicochemical endpoints

Evaluate how much the available physicochemical data represents the UVCB substance. Properties known for the whole substance may not reflect the specific properties of individual constituents. Therefore, you may need to generate and report the respective data for the constituents or constituent fractions.

3.3. Environmental testing

For each environmental endpoint, report which of the following recommended testing approaches for persistence, bioaccumulation and aquatic toxicity have been used for the P/vP, B/vB, and/or T assessment. Justify the approach for each environmental endpoint:

- The “known constituents” approach (by assessing specific constituents for their P, B and T status on their own), or
- The “fraction/block profiling” approach, (performed based on fractions/blocks of constituents), or
- The “whole substance” approach, or
- A combination of several approaches described above.

ECHA Guidance R.11⁵ describes the recommended approaches, including advantages and disadvantages.

In IUCLID Section ‘2.3 PBT assessment’:

- Report the PBT/vPvB assessment carried out for all constituents or fractions/blocks present in concentrations $\geq 0.1\%$ (w/w). In specific cases you may consider, for the sake of proportionality of assessment efforts and the level of expected risk, to elevate or reduce the threshold value above or below 0.1% (w/w) for the PBT/vPvB assessment. For further details please refer to ECHA Guidance R.11.
- Conclude the multi-constituent substance or the UVCB as PBT/vPvB if it contains one or more relevant (group(s) of) constituent(s) which fulfil the PBT and/or vPvB criteria. The substance can be deemed as “not PBT/vPvB” if none of the relevant (group(s) of) constituents individually is PBT or vPvB.

4. Instructions for nanomaterials, nanoforms or sets of nanoforms

If a substance fulfils the criteria of the nanomaterial definition⁶, specific considerations on the testing and assessment apply equally to substances under REACH and BPR. Each nanomaterial

⁵ Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment; <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

⁶ Definition of a nanoform and a set of similar nanoforms (REACH Annex VI): On the basis of the Commission Recommendation of 18 October 2011 on the definition of nanomaterial, a nanoform is a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm.

(as worded in BPR), or nanoform⁷ (as worded in REACH) must be fully characterized, including

- The number-based particle size distribution,
- The description of surface functionalisation/treatment,
- The shape,
- Aspect ratio,
- Crystallinity and surface area,
- The chemical composition including impurities.

Furthermore, the information provided on the substance's environmental fate and (eco)toxicity must be specific to each corresponding nanomaterial, nanoform or set of nanoforms of the substance.

Due to their small size, nanoforms have very different properties compared to the non-nanoform of the same chemical composition. Therefore, you must consider specific information on the test material and on human health, fate and ecotoxicological testing. Under REACH, these specific information requirements are explicitly stated. Under BPR these information requirements are requested. Therefore, if you submit an RSS relating to a nanomaterial, nanoform or a set of nanoforms, you must report additional nano-specific information and test material characterisation.

5. Examples for frequent omissions or mistakes concerning individual endpoints

This chapter contains a non-exhaustive list of information requirements for selected endpoints. It reflects ECHA's experience with the most frequently spotted data gaps in submitted dossiers. A registrant and/or applicant generally needs to report the data and information as stipulated in the respective OECD TG.

5.1. Physicochemical properties

5.1.1. Particle size distribution/ Fibre length and diameter distribution (OECD TG 110)

- Approximate information on particle shape (e.g. spheroidal, elongated, platelets) if available;
- For fibres: indicate both mean length and diameter of fibres as well as distribution of length and diameter.

5.1.2. Dustiness

Report at least one of the following:

- Respirable dustiness mass fraction (mg of airborne resp. particles /per of kg tested materials);
- Number based dustiness index from 10 nm to 1 µm (particles per milligram);
- Number based emission rate (particles per milligram/s).

⁷ The term 'nanoform', refers to a nanoform or a set of similar nanoforms, when one has been defined. A 'set of similar nanoforms' is a group of characterised nanoforms where the clearly defined boundaries in the parameters of the individual nanoforms within the set still allow to conclude that the hazard assessment, exposure assessment and risk assessment of these nanoforms can be performed jointly.

5.2. Environmental fate & ecotoxicology

5.2.1. General instructions on environmental fate

- Avoid confusing the terms dissipation and degradation, and their respective D(iss)T50 and D(eg)T50 value outputs, including at 12°C (9°C for marine environment). You can find detailed explanations in ECHA's Guidance documents R.7b⁸ and R.11.

5.2.2. Hydrolysis as function of pH (OECD TG 111)

- Amount of test substance applied and resulting concentrations in test solutions;
- Results of preliminary test;
- Half-life or DT50 at the different pH values and temperatures tested;
- Plots of concentrations versus time for the test substances and, where appropriate, for the hydrolysis products at each pH value and temperature;
- Tabulated results of Arrhenius equation for the temperature 20 °C/25 °C, with pH, rate;
- Constant [h⁻¹ or day⁻¹], half-life or DT50, temperatures [°C] including confidence limits;
- The coefficients of correlation (r²) or comparable information;
- Mass balance during and at the end of the studies (when labelled test substance is used);
- Proposed pathway of hydrolysis and identity of degradation products (if any).

5.2.3. Biodegradation simulation in water/ sediment/ soil (OECD TG 309, 308, 307)

- If measurements are made on multiple time-points, include detailed results for all time-points including, if relevant, on identification and characterisation of non-extractable residues. Use the table provided in the results section in the IUCLID template. (see section 2.6)
- If the test substance is radiolabelled, indicate the position of the label on the structure and initially applied radioactivity.

5.2.4. Aquatic bioaccumulation (OECD TG 305)

Generally, report all information that is needed as input for a re-calculation of the reported BCF/BMF. Report the following:

Dietary exposure tests

- Tabulated data on fish weight and length, linked to individual fish chemical concentrations (and lipid content, if applicable), both for control and exposure groups (for example using unique identifiers for each sampled fish);
- Tabulated test material concentration data in fish, mean measured concentration at end of uptake (C_{0,m}), the derived (overall) depuration rate constant (k₂) and concentration in fish at start of depuration phase (C_{0,d}), together with the variances on these values (slope and intercept);
- Calculations for derived growth rate constant(s) (including a discussion/comparison of growth between the test and the control groups and 95% confidence intervals), calculated growth-corrected depuration rate constant k_{2g} and half-life values (growth-corrected half-life in days);

⁸ Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7b: Endpoint specific guidance; <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

- Curves (including all measured data), showing growth, i.e. fish weight vs. time (including the derived growth rate constant, k_g), uptake (only relevant for the aqueous exposure test) and depuration of the test chemical in the fish.

Aqueous exposure tests

- Tabulated test substance concentration data in fish (C_f , linked to individual fish) and water (C_w) (with mean values for test group and control, standard deviation and range, if appropriate) for all sampling times;
- Curves showing the time to steady-state (if achieved);
- Curves showing natural logarithm transformed concentration vs. uptake time (including the derived uptake rate constant k_1);
- Calculated assimilation efficiency (α) and I (set feed ingestion rate; g food/g fish/day);
- 'Raw' dietary BMF, lipid and growth-corrected kinetic BMF (or BMF_{kgL}) ('raw' and lipid-corrected based on whole fish wet weight), tissue-specific BMF if applicable. Metabolites and their accumulation pattern;
- Starting from the BMF_{kgL} values derived for the test substance, report calculated corresponding fish BCFs, based on the 15 models from the OECD TG 305 BCF estimation tool (Excel® spread sheet Version 2⁹).

5.2.5. General instructions on ecotoxicity

- Always add comments in the 'basis of effect' section in the 'results and discussion' table.
- If measurements are made on multiple time-points, include results of all time points, not just last time point. Do it in the table provided in the results section of the IUCLID. There is a time box available in that table;
- Report measured concentration in the results and discussion table if available. If not available, add a statement clarifying whether measurements were performed. In addition, report measured data should as % of nominal. Clearly describe the method of mean measured endpoints (e.g. geometric, arithmetic, time-weighted etc);
- If the substance is difficult to test, report any preliminary testing investigating suitability of the test solution preparation and exposure system to ensure the stability of the substance in the test solution under the test conditions;
- Provide tabulated raw data for each dose group in section 'any other details on results'. Add images of plots (including slopes) of the effect curves in the 'illustration' subsection of the 'Overall remarks' section.

5.2.6. Short-term toxicity on fish (OECD TG 203)

- Tabular data on observations in each replicate: number of dead fish, abnormal appearance and behaviour.

5.2.7. Long-term toxicity on fish (OECD TG 210)

- Tabular data on observations for treatment and controls: hatching success and post-hatch survival, any abnormal appearance and behaviour, weight and size of individual fish at the end of the test.

5.2.8. Short-term toxicity on fish embryo and sac-fry stages (OECD TG 212)

- Tabular data for each individual replicate and as average per treatment.

⁹ Link to [Section 3 Software: Environmental Fate and Behaviour - OECD](#).

5.2.9. Fish - juvenile growth test (OECD TG 215)

- Tabular data for each individual replicate and as average per treatment.

5.2.10. Short-term toxicity on aquatic invertebrates (OECD TG 202)

- Tabular data for each individual replicate and as average per treatment;
- EC50, IC50 or LC50 after 24 and 48 h, dose-response relationships including EC0 and EC100.

5.2.11. Long-term toxicity on aquatic invertebrates (OECD TG 211)

- Tabular data for each individual replicate and as average per treatment;
- Observations in treatment and controls: number of offspring (daily count), number of dead parents (daily count), size of parents at the end of the test and any other observed effects, presence of living males, ephippia produced, time to first brood;
- Expression of results: i.e. total number of living offspring produced per surviving parent at the end of the test (including control).

5.2.12. Algal growth inhibition test (OECD TG 201)

- Tabular data for each individual replicate and as average per treatment;
- Details on the determination of algal biomass (method for cell counting or biomass determination, cell density, chlorophyll, etc.);
- Report the concentration leading to both, 10 % and 50% inhibition of growth;
- rate (i.e. EC10 and EC50).

5.2.13. Aquatic plants growth inhibition test (OECD TG 221)

- Tabular data for each individual replicate and as average per treatment.

5.2.14. Sediment toxicity (OECD TG 218, 219, 225, 233)

- Report the averages per treatment for the different endpoints where applicable.

5.3. Human health**5.3.1. General instructions on human toxicology**

- Use the "insert existing template" functionality wherever it is available;
- If the full study report includes the historical control data on histopathology, include this information in the 'any other information on results' section. If data values for historical controls are not available but instead a statement on historical control data, include it in the RSS;
- For all repeated dose toxicity studies, provide full dose-response data in the 'any other information on results', and not just the NO(A)EL values. Provide this information in tabular form for all major parameters. Assign table numbers;
- For all types of repeated dose toxicity, always include any secondary effects or non-treatment related effects, if identified by the study director. These effects should be reported by selecting "effects observed, non-treatment related" from picklists available for parameters in the 'Results of Examination' section;
- Wherever relevant, brief study design of a preliminary study (e.g., dose range finding study): provide details such as species/strain/sex, route of exposure (vehicle, if applicable), dose(s), exposure duration, number of groups/animals, replicates, GLP status, measured parameters, results.

5.3.2. Skin sensitisation in vivo (OECD TG 406, 429, 442A, 442B)

Dose level selection rationale needs to be provided to determine appropriate doses used:

OECD TG 406:

- Provide information on dose range finding study results. It is needed to verify the correct concentration used for induction (mild to moderate irritating concentration) and challenge (highest non-irritating concentration), unless neat substance is used.

OECD TG 429, 442A, 442B:

- Provide information on dose range finding study or solubility tests with vehicle(s). It is needed to verify that appropriate concentrations are used, unless neat substance is used.
- If concentrations are selected based on increased ear thickness measurements, provide the respective results.
- If concentration is selected based on solubility considerations, provide results of solubility experiments with suitable vehicles.

5.3.3. Genetic toxicity

5.3.3.1. *in vitro* (OECD TG 471, 473, 476, 487, 490)

Test system

- Bacteria strain(s) tested for OECD 471;
- Cell type(s) or cell line(s) tested for other TGs;
- Bacteria/cell characteristics, source, history of use in the testing laboratory;
- Number of bacteria / cells per culture.

Vehicle

- Identification, concentration and volume used, justification of choice of vehicle.

Positive and negative controls

- Positive and negative substances;
- Concentrations used;
- Positive and negative historical control data, including ranges, means and a measure of variation (e.g. standard deviation or standard error) and 95% control limits for the distribution, as well as the number of data points.

Test conditions

- Description of study design, including testing conditions (i.e. number of test concentrations, with or without metabolic activation, exposure time and duration, and sampling time) and procedure used (e.g. plate incorporation or preincubation method for OECD TG 471; centromere labelling technique for aneugenicity assessment for OECD TG 487);
- Rationale for selection of concentrations (in particular for the highest concentration tested) and number of cultures, including cytotoxicity data and solubility limitations, as well as dose-finding studies;
- Concentration of test chemical expressed as final concentration in the culture medium;
- Culture medium characteristics;
- Solubility and stability of the test substance in vehicle if known;
- Type and composition of metabolic activation system;
- Number of repeat experiments and replicates;
- Details on sample or slide preparation;

- Scoring method (e.g. number of cells or metaphases analysed; number of PCEs and NCEs analysed and PCE/NCE ratio for OECD TG 487);
- Interpretation criteria for considering results as positive, negative or equivocal, including description of the statistical analysis method(s) used where applicable.

Results

- Numerical values of observed effects, including tables of results for all testing conditions (with individual results for each replicate or culture and for each test concentration or control, and mean values with a measure of variation (e.g. standard deviation or standard error));
- Cytotoxicity measurements with and without metabolic activation for all test conditions, including tables of results (i.e. individual results for each replicate or culture and for each test concentration or control and mean values with a measure of variation (e.g. standard deviation or standard error));
- Statistical analysis of the results, including trend tests where applicable;
- Study outcome (i.e. positive, negative or equivocal).

5.3.3.2. *in vivo* (OECD TG 470, 474, 475, 478, 483, 488, 489)

Animals

- Test species and strain;
- Number, sex and age of animals per group;
- Justification if only one sex is tested.

Vehicle

- Identification, concentration and volume used, justification of choice of vehicle.

Positive and negative controls

- Positive and negative substances and doses used;
- Positive and negative historical control data for each analysed tissue/organ, including ranges, means and a measure of within-group variation (e.g. standard deviation or standard error) and 95% control limits for the distribution, as well as the number of data points.

Test conditions

- Description of study design, including testing conditions (i.e. the number of test groups, route and method of administration, exposure time and duration, and sampling time; centromere labelling technique for aneugenicity assessment for OECD TG 474);
- Rationale for dose level selection (in particular for the highest dose tested), including results of dose-range finding studies, and justification if top dose is not the limit test dose;
- Actual doses (mg/kg body weight/day), and conversion factor from diet/drinking water test chemical concentration (ppm) to the actual dose;
- Solvent characteristics;
- Details on sample or slide preparation;
- Scoring method (e.g. number of cells, metaphases or plaques analysed; number of PCEs and NCEs analysed and PCE/NCE ratio for OECD TG 487);
- Interpretation criteria for considering results as positive, negative or equivocal, including description of the statistical analysis method(s) used where applicable.

• *Results*

- Numerical values of observed effects in test and control animals, including tables of results (with individual results, and group mean values with a measure of within-group variation (e.g. standard deviation or standard error));
- Statistical analysis of the results, including trend tests where applicable;
- Cytotoxicity measurements, including tables of results (with individual results, and group mean values with a measure of within-group variation (e.g. standard deviation or standard error));
- Description of clinical signs, systemic and local toxicity signs (including mortality and histopathological data);
- Evidence of target tissue exposure;
- Study outcome (i.e. positive, negative or equivocal).

5.3.4. Reproductive toxicity (OECD TGs 414, 421/422, and 443)

- Rationale for dose level selection if top dose is not the limit test dose
- Results of dose range finding studies
- Actual doses (mg/kg body weight/day), and conversion factor from diet/drinking water test chemical concentration (ppm) to the actual dose
- Historical control data
- Positive control data for DNT and DIT cohorts in OECD TG 443
- Numerical values of observed effects
- Individual and group/litter results in tabular form in the RSS or in a file attached to the RSS (alternatively provide the full study report)
- Explanation why findings are considered treatment-related/ adverse or not
 - Scientific explanation for disregarded effects due to secondary non-specific consequences of other toxic effects, preferably with references to literature to support the explanation

6. Screenshots

This appendix contains IUCLID screenshots of fabricated example data sets. The content is for general orientation and the depicted information does not represent genuine data.

6.1. Environmental fate (OECD TG 301)

Administrative data None None

Endpoint
biodegradation in water: screening test, other

Type of information
experimental study

Adequacy of study
key study

Robust study summary

Used for classification

Used for SDS

Study period
06/1999-10-1999

Reliability
1 (reliable without restriction)

Rationale for reliability incl. deficiencies
guideline study

Data waiving
None

Justification for data waiving
None

Attached justification + New item Import file

#	Attached justification	Reason / purpose	Actions

Cross-reference + New item Import file

#	Reason / purpose for cross-reference	Related information	Remarks	Actions

Data source

Reference
study report | YYY | XXX | 1999 | 1999-10-02 | Z-01

Data access
data submitter is data owner

Data protection claimed
yes, but willing to share

Materials and methods

Test guideline + New item Import file

#	Qualifier	Guideline	Version / remarks	Deviations	Actions
1	according to guideline	OECD Guideline 301 A (Ready Biodegradability: DOC Die Away Test)	None	no	

Principles of method if other than guideline
No information

GLP compliance
yes

Test material

Test material information
TestA | TestA | 000-00-0

Additional test material information
IUPAC / 231-171-1 | guanidinium chloride | amino(imino)methanaminium chloride | EC 200-002-3 | 50-01-1

Specific details on test material used for the study
No information

Specific details on test material used for the study (confidential) ▲
No information

Parameter followed for biodegradation estimation + New item Import file

#	Parameter followed for biodegradation estimation	Actions
1	DOC removal	

Details on analytical methods
 Degradation of testA was monitored by assessing the removal of DOC by the inoculum. DOC was analysed in duplicate at each time point using Dohmann DC-80 Carbon Analyser. Degradation was calculated by subtracting the amount of DOC in the negative (inoculum only) control from that in the test material or positive control sample at any given time point and then dividing it by the initial DOC concentration at time 0.

Details on study design
 TestA was incubated for 20 days in continuously agitated 2 litre open beakers (in duplicate) in the dark with an inoculum originally collected from the local municipal STP. The incubation temperature was 19 - 23 oC, pH was 7.6 and was steady during the test duration. O2 concentration measured with the Oxygen Meter (model xxx) ranged from 8.00 - 8.15 mg/L over the study. The concentration of inoculum was 1 ml of inoculum per litre of test solution. The concentration of testA corresponded to 20 mg/L (30 mg testA/litre).

Controls included:

- reference compound + inoculum
- inoculum only (inoculum blank)
- test substance + reference substance + inoculum (toxicity control)
- test substance + sterilising agent (abiotic sterile control)
- test substance + sterilising agent + inoculum (adsorption control)

Reference substance + New item Import file

#	Reference substance	Actions
1	benzoic acid, sodium salt	

Any other information on materials and methods incl. tables

Data per concentration & time	t0	t1	t2	t3	t4	t5
concentration 1	xx	xx	xx	xx	xx	xx
concentration 2	xx	xx	xx	xx	xx	xx
concentration 3	xx	xx	xx	xx	xx	xx
concentration 4	xx	xx	xx	xx	xx	xx

Results and discussion

[Preliminary study](#)
no data

Test performance not applicable

% Degradation + New item

#	Key result	Parameter	Value	St. dev.	Sampling time	Remarks on result	Actions
1	<input type="checkbox"/>	% degradation (DOC removal)	15	None	7 d	None	
2	<input type="checkbox"/>	half-life in days (QSAR/QSPR)	90.5	None	21 d	None	
3	<input type="checkbox"/>	half-life in days (QSAR/QSPR)	9.9	None	27 d	None	
4	<input type="checkbox"/>	half-life in days (QSAR/QSPR)	90	None	28 d	None	

Details on results
 The 20-day degeneneration was 90 %. This level of biodegradation was reached within the prescribed 10-day window for testA started on the 7 and ended on day 14 where the biodegradation exceeded 70 %. The lag phase occurred by day 7 and the degradation phase mainly between days 7 and 14.

BOD5 / COD results

BOD5 / COD + New item Import file

#	Key result	Parameter	Value	Remarks on result	Actions
1	<input type="checkbox"/>	COD	54 mg O2/g test mat.	None	

Results with reference substance

Data per concentration & time	t0	t1	t2	t3	t4	t5
concentration 1	xx	xx	xx	xx	xx	xx
concentration 2	xx	xx	xx	xx	xx	xx

Any other information on results incl. tables

% Degr.	% Degr. -Replicate	Parameter	Sampling time
0	0	DOC removal	0 d
15	16	DOC removal	7 d
89.5	89	DOC removal	14 d

Overall remarks, attachments

Overall remarks

Data per concentration & time

	t0	t1	t2	t3	t4	t5
concentration 1	XX	XX	XX	XX	XX	XX
concentration 2	XX	XX	XX	XX	XX	XX
concentration 3	XX	XX	XX	XX	XX	XX
concentration 4	XX	XX	XX	XX	XX	XX

Attachments + New item Import file

#	Type	Attached (confidential) document	Attached (sanitised) documents for publ...	Remarks	Actions
Illustration (picture/graph) 1-Line-Chart.png					
	1-Line-Chart.png			3.88 KB / Uploaded: 16/08/2022	

Applicant's summary and conclusion

Validity criteria fulfilled

yes

Validity criterion X vs. reported data / Validity criterion Y vs. reported data / Validity criterion Z vs. reported data

Interpretation of results

readily biodegradable

Conclusions

TestA is readily biodegradable under the conditions of the study.

Executive summary

TestA was incubated for 20 days in continuously agitated 2 liter open beakers (in duplicate) in the dark with an inoculum originally collected from a local municipal sewage treatment facility. In this assay, biodegradation, was measured by the disappearance of dissolved organic carbon (DOC) over time. DOC was measured at 0, 7, 14, 21, 27, and 28 days. The incubation temperature was 19-23,0°C, PH was 7.6, O2 concentration, measured with the Oxygen Meter (model XXX), ranged from 8.0 to 8.15mg/L, over the study, and the concentration of inoculum was 1.0 ml inoculum per liter of test solution. The concentration of testA corresponded to 20 mg DOC/liter (or 30mg testA/liter) Degradation of testA was monitored by assessing the removal of DOC by the inoculum. DOC was analyzed in duplicate at each time point using a (YYY) Carbon Analyzer. Degradation was calculated by subtracting the amount of DOC in the negative (inoculum only) control from that in the test material or positive control sample at any given time point and dividing by the initial DOC concentration at time 0. The 28-day degradation was 90%. This level of biodegradation was reached within the prescribed 10-day window. The 10-day window for testA started on day 7 and ended on day 14 where the biodegradation exceeded 70%. For the positive control (with reference substance) the biodegradation was 92.5%. In conclusion, testA is readily biodegradable under the conditions of this study.

6.2. Ecotoxicity (OECD TG 203)

Administrative data

Endpoint

short-term toxicity to fish

Type of information

experimental study

Adequacy of study

key study

Robust study summary

Used for classification

Used for SDS

Study period

09/1999-11/1999

Reliability

1 (reliable without restriction)

Rationale for reliability incl. deficiencies

guideline study

Data waiving

None

Justification for data waiving

None

Justification for type of information

No info

Attached justification

#	Attached justification	Reason / purpose	Actions	
Cross-reference + New item Import file				
#	Reason / purpose for cross-reference	Related information	Remarks	Actions

Data source

Reference

study report | XXX | Smith | 1999 | 1999-11-10 | Y-YYY

Data access

data submitter is data owner

Data protection claimed

yes, but willing to share

Materials and methods

Test guideline [+ New item](#) [Import file](#)

#	Qualifier	Guideline	Version / remarks	Deviations	Actions
1	according to guideline	OECD Guideline 203 (Fish, Acute Toxicity Test)	None	no	

[Principles of method if other than guideline](#)
No info

[GLP compliance](#)
yes (incl. QA statement)

Test material

[Test material information](#)
testA | TestA | 000-00-0

[Additional test material information](#)
IUPAC / 231-171-1 | guanidinium chloride | amino(imino)methanaminium chloride | EC 200-002-3 | 50-01-1

[Specific details on test material used for the study](#)
No info

[Specific details on test material used for the study \(confidential\)](#) ▲
No info

Sampling and analysis

[Analytical monitoring](#)
yes

[Details on sampling](#)
Concentrations (0.1, 1.8, 3.2, 5.6 and 10 mg/L) measured at 0 and 96 h. 2 mL were taken from the approximate centre of the test vessels. The taken samples were analysed on the day of sampling.

[Details on analytical methods](#)
IDENTIFICATION AND QUANTIFICATION OF TEST SUBSTANCE
-Separation method GC
-Conditions: Column CP-xxx (25mx0.32mm ID, dl=1.2 Om)
-Detection method: ICP-MS
-Internal or external calibration, two independently prepared solutions of the test substance in water were used each day of analysis in order to calibrate the analytical equipment.
Further information: Analytical method was used as described in section 8.

Test solutions

[Vehicle](#)
no

[Details on test solutions](#)
Stock solution of 100 mg/L was prepared by dissolving test substance in the test medium. No additional solvent, emulsifier or dispersants as well as stirring device were used to prepare stock solution.
The test solutions (nominal concentrations: 1, 1.8, 3.2, 5.6 and 10 mg/L) were prepared dissolving stock solution in test medium. The test medium without the test substance or any other additives was taken at a blank control.

Test organisms

[Test organisms \(species\)](#)
Oncorhynchus mykiss (previous name: Salmo gairdneri)

[Details on test organisms](#)
TEST ORGANISMS:
-Common name: rainbow trout
-Source: Commercial "Marchery" ABC, CCC, HHH
-Age at study initiation (mean, range and SD): no data
-Mean length at study initiation (mean, range and SD): 4.0x0.5 cm
-Mean weight at study initiation (mean, range and SD): 1.7x0.4 g
-Feeding during test: none

ACCLIMATION
-Acclimation period: 12 days
-Acclimation conditions: same as test (additional daily feeding with fish food AAAAA, feeding was stopped 24 hours before the test started)
-Any mortalities observed during acclimation period: no

Study design

[Test type](#)
static

[Water media type](#)
freshwater

[Limit test](#)
no

[Total exposure duration](#)
96 h

[Remarks on exposure duration](#)
No info

[Post exposure observation period](#)
No info

Test conditions

[Hardness](#)
80 mg CaCO₃/L

[Test temperature](#)
15 ±3 °C
Temperature was measured at each test vessel at the beginning and at the end of the test, and at 24 hours interval during the test.

[pH](#)
6.8 - 7.5
pH was measured at each test vessel at the beginning and at the end of the test, and at 24 hours interval during the test.

[Dissolved oxygen](#)
7.2 - 8.5 mg O₂/L
Dissolved oxygen was measured at each test vessel at the beginning and at the end of the test, and at 24 hours interval during the test.

[Salinity](#)
No info

[Conductivity](#)
No info

[Nominal and measured concentrations](#)
Nominal 1, 1.8, 3.2, 5.6 and 10 mg/L
Results of analysis of test substance concentrations (0, 1, 1.8, 3.2, 5.6 and 10 mg/L) in test solutions in 0 and 96 h showed that the substance stayed stable through the test duration (measured concentrations were in the range of 93-105% of nominal concentration).

Details on test conditions

- Test vessels: 20 L glass aquaria (35x22x26 cm) with 17 L of water each
- Type: open
- Aeration: slightly aerated
- No. of organisms per vessel: 10
- No. of vessels per concentration (replicates): 2
- No. of vessels per control(replicates): 2
- Biomass loading rate: 10 g mg/L
- Photoperiod: 16 hours daily
- Source/preparation of dilution water: prepared as described in OECD 203 test guideline

Reference substance (positive control)
no

Any other information on materials and methods incl. tables

Data per concentration & time	t0	t1	t2	t3	t4	t5
concentration 1	xx	xx	xx	xx	xx	xx
concentration 2	xx	xx	xx	xx	xx	xx

Results and discussion

Effect concentrations + New item

#	Key result	Duration	Dose descriptor	Effect conc.	95% CI	Nominal / mea...	Conc. based on	Basis for effect	Remarks on re...	Actions
1	<input type="checkbox"/>	96 h	LC50	4.05 mg/L	None	nominal	test mat.	mortality (fish)	None	
2	<input type="checkbox"/>	96 h	NOEC	1 mg/L	None	nominal	test mat.	mortality (fish)	None	
3	<input type="checkbox"/>	24 h	NOEC	10 mg/L	None	nominal	test mat.	mortality (fish)	None	
4	<input type="checkbox"/>	48 h	NOEC	2 mg/L	None	nominal	test mat.	mortality (fish)	None	
5	<input type="checkbox"/>	72 h	NOEC	1 mg/L	None	nominal	test mat.	mortality (fish)	None	

Details on results

conc*/time	0h	24h	48h	72h	96h
0	xx	xx	xx	xx	xx
0	xx	xx	xx	xx	xx
1.8	xx	xx	xx	xx	xx
1.8	xx	xx	xx	xx	xx
3.2	xx	xx	xx	xx	xx
3.2	xx	xx	xx	xx	xx
5.6	xx	xx	xx	xx	xx
5.6	xx	xx	xx	xx	xx
10	xx	xx	xx	xx	xx
10	xx	xx	xx	xx	xx

*mg/L

Results with reference substance (positive control)
No reference substance testing reported

Reported statistics and error estimates
No info

Any other information on results incl. tables

Sublethal observations / clinical signs

Temperature, pH and dissolved oxygen concentration were measured at each test vessel at the beginning and at the end of the test, and at 24 hours interval during the test. Results of analyses of test substance concentrations (0, 1, 1.8, 3.2, 5.6 and 10 mg/L) in test solutions at 0 and 96h showed that the substance stayed stable through the test duration (measured concentrations were in the range of 93-105 % of nominal concentration) and the results of the test were based on nominal concentrations.



Observation of mortalities and abnormalities were performed at 24h, 48h, 72h and 96h. Recorded abnormality - loss of equilibrium. No abnormalities or mortalities were recorded at 24h at any of test concentrations. At 48h losses of equilibrium among the fishes were recorded at the 3.2 mg/L and higher concentrations, and at 72h the same abnormalities were recorded at the 1.8 mg/L and higher concentrations. At 96h time point mortalities and abnormalities were observed at 1.8 mg/L and higher concentrations.

Overall remarks, attachments

Overall remarks

48h	3.2 mg/L and higher concentrations
72h	1.8 mg/L and higher concentrations
96h	1.8 mg/L and higher concentrations

Attachments + New item Import file

#	Type	Attached (confidential) document	Attached (sanitised) documents for publ...	Remarks	Actions
1	full study report			None	

Applicant's summary and conclusion

Validity criteria fulfilled
yes
Validity criterion X vs. reported data / Validity criterion Y vs. reported data / Validity criterion Z vs. reported data

Conclusions
Rainbow trout were exposed under static conditions for 96h to five concentrations of testA (1, 2.8, 3.2, 5.6 and 10 mg/L). The 96 h LC50 value was 4.05 mg/L mg/L). The 96 h NOEC was 1 mg/L (based on mortalities and behaviour abnormalities). Results of this study would lead to the classification of testA as toxic to aquatic organisms in accordance with the criteria set in Directive 67/548/EC and Regulation (EC) 1272/2008.

Executive summary
In order to test acute testA toxicity to fish, the *Oncorhynchus mykiss* (Rainbow trout) were exposed to test solution of 5 nominal concentration of test substance (1, 2.8, 3.2, 5.6 and 10 mg/L) and blank control solution (without test substance or other additive) for a period of 96 hours under static conditions. Mortalities and [...] abnormalities were recorded at 24, 48, 72 and 96 hours. The measured concentrations confirmed that deviation from the nominal concentration was less than 20% (measured concentrations were in the range of 93-105% of nominal concentrations). The 96-h LC50 was 4.05mg/L (nominal concentration). Sublethal effects (loss of equilibrium) were observed at the 1.8 mg/L and higher concentrations (96h). The NOEC (96h) value based on sublethal effects mortality was 1 mg/L. Results of this study would lead to the classification of testA as toxic to aquatic organisms in accordance with the criteria set in Directive 67/548/EC and Regulation (EC) 1272/2008.
This toxicity study is classified as acceptable and satisfies the guideline requirements for the acute fish toxicity study.

↑ TOP

6.3. Human Health (OECD TG 420)

Acute toxicity: oral.001
 UUID: fc1d2ad4-9e5e-4b0e-bbf8-4d0da72534a7
 None None

Administrative data | Data source | Materials and methods | Results and discussion | Overall remarks, attachments | Applicant's summary and conclusion

Administrative data

Endpoint
acute toxicity: oral

Type of information
experimental study

Adequacy of study
key study

Robust study summary

Used for classification

Used for SDS

Study period
03-2008

Reliability
1 (reliable without restriction)

Rationale for reliability incl. deficiencies
guideline study

Data waiving
None

Justification for data waiving
None

Justification for type of information
No info

Attached justification + New item Import file

#	Attached justification	Reason / purpose	Actions	
	Cross-reference + New item Import file			
#	Reason / purpose for cross-reference	Related information	Remarks	Actions

Data source

Reference
study report | XXX | Smith | 1999 | 1999-11-10 | V-YYY

Data access
data published

Data protection claimed
yes, but willing to share

Materials and methods

Test guideline + New item Import file

#	Qualifier	Guideline	Version / remarks	Deviations	Actions
1	according to guideline	OECD Guideline 420 (Acute Oral Toxicity - Fixed Dose Method)	None	None	

Principles of method if other than guideline
No information

GLP compliance
yes

Test type
acute toxic class method

Limit test
no

Test material

Test material information
TestA | TestA | 000-00-0

Additional test material information
TestA | TestA | 000-00-0

Specific details on test material used for the study ⓘ ⌵ ⌶ ⌵

No information

Specific details on test material used for the study (confidential) ▲

No information

Test animals

Species
rat

Strain
Crj: CD(SD)

Sex
male/female

Details on test animals or test system and environmental conditions

TEST ANIMALS

- Source: AAA
- Age at study initiation: 47 weeks
- Weight at study initiation: male: 125-155g; female: 120-137g
- Diet (e.g. ad libitum): ad libitum
- Water (e.g. ad libitum): ad libitum
- Acclimation period: 9 days

ENVIRONMENTAL CONDITIONS

- Temperature (°C): 18-22

- Humidity (%): 70
- Air changes (per hr): 10

Administration / exposure

Route of administration
oral: feed

Vehicle
unchanged (no vehicle)

Details on oral exposure
MAX DOSE VOLUME APPLIED: 1.65 mL/kg bw

Doses
single dose of 1500 mg/kg bw

No. of animals per sex per dose
10 (5 males and 5 females)

Control animals
no

Details on study design

- Duration of observation period following administration: 15 days
- Frequency of observations and weighing: once a day; bw were recorded on day 0, 8 and 15
- Necropsy of survivors performed: yes

Statistics
No information

Any other information on materials and methods incl. tables ⓘ ⌵ ⌶ ⌵

Data per concentration & time	t0	t1	t2	t3	t4	t5
concentration 1	xx	xx	xx	xx	xx	xx
concentration 2	xx	xx	xx	xx	xx	xx
concentration 3	xx	xx	xx	xx	xx	xx
concentration 4	xx	xx	xx	xx	xx	xx

Results and discussion

Preliminary study
No information

Effect levels + New item

#	Key result	Sex	Dose descriptor	Effect level	Based on	95% CL	Remarks on result	Actions
1	<input checked="" type="checkbox"/>	male/female	LD50	None	test mat.	None	not determinable due to absence of adverse	

Mortality ⓘ ⌵ ⌶ ⌵

no mortality occurred

Clinical signs

- ✓ salivation
- ✓ sleep

Body weight
other body weight observations
5%

Gross pathology
No abnormalities were noted

Other findings

Data per concentration & time	t0	t1	t2	t3	t4	t5
concentration 1	xx	xx	xx	xx	xx	xx
concentration 2	xx	xx	xx	xx	xx	xx
concentration 3	xx	xx	xx	xx	xx	xx
concentration 4	xx	xx	xx	xx	xx	xx

Any other information on results incl. tables

Data per concentration & time	t0	t1	t2	t3	t4	t5
concentration 1	xx	xx	xx	xx	xx	xx
concentration 2	xx	xx	xx	xx	xx	xx

Overall remarks, attachments

Overall remarks
no information

Attachments + New item Import file

#	Type	Attached (confidential) document	Attached (sanitised) documents for publ...	Remarks	Actions
1	full study report		None	None	

Illustration (picture/graph)

Applicant's summary and conclusion

Interpretation of results
Category 2 based on GHS criteria

Conclusions
The test substance has not to be labelled with regard to oral toxicity.

Executive summary
A study was performed to determine the acute oral median lethal dose of the test material, administered undiluted, in the CD(SD) rats. The method used followed that described in the OECD Guidelines for Testing of Chemicals (1981) No. 401 "Acute Oral Toxicity" referenced as Method B.1 in Annex V of EEC Commission Directive 84/449/EEC. A group of ten fasted CD(SD) Rats (five males and five females) was given a single oral dose of undiluted test material at a dose level of 1500 mg/kg bodyweight. There were no deaths. No evidence of systemic toxicity was noted during the study period. No toxicologically significant effects on bodyweight were noted during the study period. No abnormalities were noted at necropsy of animals killed at the end of the study.

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