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PHASE II DRAFT REPORT ON RHENIUM

DRAFT REPORT ON RHENIUM TO THE PRECIOUS METALS CONSORTIUM FROM WCA ENVIRONMENT LIMITED

December 2009

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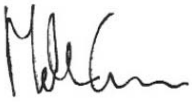
Document Quality Checked by		02 December 2009

EXECUTIVE SUMMARY

Phase II of the project has been carried out for all rhenium categories. This phase consisted of the following:

- Identify all relevant studies, review them, and prepare a robust summary and Klimisch score for each critical study;
- Construct a matrix with the available information for each category;
- Evaluate the physicochemical parameters for each category and assess category viability;
- Evaluate the mammalian and ecotoxicity data for category justification;
- Evaluate relevant information for individual substance registration;
- Identify potential read-across;
- Identify test waivers;
- Identify data gaps;
- Application of REACH derogations (in particular related to Annex III);
- Recommend enabling tests;
- Provide an overall cost for the tests required;
- An updated literature search to ensure completeness

This report clearly identifies where there are data gaps and how to fill these gaps through appropriate testing and read-across.

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1 INTRODUCTION

The Precious Metals Consortium (PMC) commissioned wca environment and bibra to provide consultancy work for Platinum Group Metals (PGMs) and Rhenium REACH Registration projects. Phase II of the project consists of the following:

Test derogation assessments and the design and progression of any enabling tests (such as bioaccessibility determinations) relevant to Intelligent Testing Strategies and test waiving.

The approach agreed upon for completion of Phase II for all the categories consists of the following tasks:

- Identify all relevant studies, review them, and prepare a robust summary and Klimisch score for each critical study;
- Construct a matrix with the available information for each category;
- Evaluate the physicochemical parameters for each category and assess category viability;
- Evaluate the mammalian and ecotoxicity data for category justification;
- Evaluate relevant information for individual substance registration;
- Identify potential read-across;
- Identify test waivers;
- Identify data gaps;
- Application of REACH derogations (in particular related to Annex III);
- Recommend enabling tests;
- Provide an overall cost for the tests required;
- An updated literature search to ensure completeness

This report presents the findings of the Phase II assessment.

1.1 Rationale for Initial Category Groupings for Rhenium

The possibilities for a category approach for metals are outlined in ECHA (2008a). The approach is based on the occurrence of a common metal ion with the use of read-across to fill data gaps, and has been widely used and accepted as appropriate under the previous regulatory framework for chemical assessments within the EU. However, we recognise that there are particular difficulties in evaluating the properties of metals on the basis of data for metal compounds; a conservative approach is to read-across from data for the more soluble compounds, if available, since systemic metal ion availability will normally be reduced with decreasing water-solubility.

ECHA (2008a) provides a stepwise approach to the formation of categories:

- Step 0: Check whether the chemical is a member of an existing category.
- Step 1: Develop category hypothesis and definition, and identify individual members of the category.
- Step 2: Gather data for each category member.
- Step 3: Evaluate available data for adequacy.
- Step 4: Construct a matrix of data availability.
- Step 5: Perform a preliminary evaluation of the category and fill data gaps.
- Step 6: Propose and perform testing.
- Step 7: Perform a further assessment of the category.
- Step 8: If the category appears adequate, document the final category and its rationale.

During Phase I we identified that none of the compounds included in this project is identified as a category member under existing risk assessment programmes (e.g. USEPA, OECD or EU). Therefore we developed an initial category hypothesis and definition and identified which of the compounds fell into each category.

We used oxidation state as the basis for category formation, as the speciation of the metal components of the substances in environmental waters and biological fluids is likely to be similar for compounds with the same oxidation state. The use of oxidation state was a reasonable starting point during Phase I of the project because at that stage in the project most of the effort consisted in identifying potential data sources. It is only

upon evaluation of the data that we can consider whether the different oxidation states exist and are stable in environmental media, if this information is available.

In the Phase I report we also included an assessment of the possible toxicity of the counter-ion in order to identify compounds that may require a separate category. If there are five different toxic counter-ions they may all require a separate category, although it may be possible to group some of these if they are demonstrated to have similar mechanisms of toxic action. If there is evidence to demonstrate that the counter ion is not toxic, or that the effects are the same as the metal ion, then the substances could be included in the general category for that oxidation state.

During Phase I we identified three categories for rhenium. These were based on both oxidation state and potential contribution from the counter ions.

Comment: CB 091209: And potential solubility patterns (e.g.: rhenium metal belongs to a separate category based on the fact it is sparingly soluble).

Table 1.1 Rhenium Categories: Substances and Intermediates

Category	Substance name	CAS number	Type	Tonnage
Re 0	Rhenium	7440-15-5	Substance	1-10
Re 7	Perrhenic acid	13768-11-1	Substance	1-10
	Sodium rhenate	13472-33-8	Intermediate	1-10
	Dirhenium heptasulphide	12038-67-4	Intermediate	1-10
Re 7a	Ammonium perrhenate	13598-65-7	Substance	10-100

Comment: CB 091211: Would it be possible to always mention the name of the substance or the intermediate in the report, instead of its CAS number only?

CAS numbers 13472-33-8 and 12038-67-4 in Table 1.1 are intermediates and, as such, the data requirements under REACH are reduced to data that are already available, if strictly controlled conditions are met. If strictly controlled conditions are not met for an on-site isolated intermediate then a full package of data is required based on tonnage level. At present we have assumed that the intermediates are used under strictly controlled conditions. This needs to be confirmed by PMC member companies.

Comment: CB 091209: We will not confirm this as it is PMC's policy to leave strict control as a responsibility of each Member.

1.2 Category Justification

A category justification document will be prepared for each of the categories included in this assessment. Part of the category justification will include an evaluation of the metal speciation and the influence of any counter ions on the fate and behaviour of the substances, and any additional effects of the counter ions on the toxicity of the category members. This justification will enable any possible read-across within or across the rhenium categories.

At present we have indicated that there are possibly three rhenium categories as follows:

- Rhenium metal with a zero oxidation state. This CAS number was separated from the other substances on the basis of the oxidation state and because it is likely to be sparingly soluble in comparison to the other rhenium substances.

- Rhenium (VII) with a 7+ oxidation state. This category comprises three members, two of which two are being registered as intermediates. Perrhenic acid (CAS 13768-11-1) is being registered as a substance.

- A second rhenium 7+ category was set up for ammonium perrhenate to take into account the possible difference in environmental effects due to the ammonium counter ion. This single member of this category also has an oxidation state of 7+ but was labelled Category 7a to differentiate it from the previous category.

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The speciation of rhenium compounds was evaluated in a separate report (Mitchell 2009). The reported data indicate that perrhenic acid completely ionises in water (Covington et al. 1969). Additional research by Truebenbach et al. (2000) reports that the ReO_4^- (perrhenate) ion is the rhenium species found in solution at pH 2.88 and 10.36. The same study results indicate that it is unlikely that the perrhenate ion is protonated to form a neutral species because this would have significantly altered the ion counts between the acid (pH 2.88) and basic (pH 10.36) solutions, which was not what the study found. Other studies also suggest that the perrhenate ion is the stable species formed from both ReO_2 and Re_2O_7 (Kim et al. 2003).

Therefore, all available information indicates that the perrhenate ion is the stable ion in solution from the different compounds being registered as substances. For this reason it may be possible to read across all rhenium substances in the categories.

In order to confirm the stable rhenium ion in solution UV-VIS spectroscopy (OECD 101) will be carried out on all of the rhenium substances and intermediates.

1.3 General Approach to Data Evaluation

1.3.1 Selection of Studies

During Phase I of this project we identified any available authoritative reports that could be used as the basis of our data evaluation. This is in line with ECHA (2008c) guidance, where it is made clear that many substances have been the subject of extensive critical review and evaluation, and that reviews from regulatory, academic and international organisations are often peer-reviewed and generally accepted by stakeholders. The guidance stresses that it would serve little purpose to add to the overall assessment of a substance by revisiting all of the primary information sources cited in such reviews. They should form the basis of the information collection strategy and help in both the identification of key studies and weight-of-evidence approaches. Therefore, we have

extracted the relevant information from these reports and present this information in later sections.

In the Phase I data search published articles and proprietary studies were selected for each substance and endpoint on the basis of information contained in the study title. In Phase II, further judgement or assessment based on each full study report was made to determine if it was indeed relevant to the substance and to REACH endpoints. If the study was found not to meet these criteria then no further assessment was carried out. If the criteria were met then a robust summary of the study was compiled and scored for relevance and reliability as described in the following section.

A new search was conducted in order to ensure that any relevant studies published within the last year have been identified. Any relevant literature was then subject to the same process applied in Phase I.

Comment: CB 091209:
Please provide references to recently identified studies and relevance/justification.

1.3.2 Relevance and Reliability Scoring

All information available from the data search and from data submitted by the consortium was evaluated for relevance and reliability. If the data proved not to be relevant for the required substance and endpoint then they were not evaluated further. Qualitative analysis of the relevance and validity of individual studies and their assignment is complemented by the Klimisch Scoring system (Klimisch et al. 1997).

Under the Klimisch Scoring system, a study is assessed based on its reliability, relevance and adequacy.

a. Reliability is defined as an assessment of the inherent quality of the report/publication.

b. Relevance is defined as the extent to which the data or test is appropriate for the particular endpoint under study.

c. Adequacy is defined as an assessment of the usefulness of the data for risk assessment purposes.

Although developed for toxicological and ecotoxicological study evaluation this method can also be applied to assess the quality of physicochemical and environmental fate and behaviour studies.

2 PHYSICOCHEMICAL TESTING AND DEROGATION ASSESSMENT

Annex VII of the REACH regulation lists 14 physicochemical endpoints as the minimum data requirements for substances in the 1-10 tonnage band. There are no further physicochemical requirements for substances in the 10-100 tonnage band (REACH Annex VIII).

A matrix of the physicochemical data gaps can be found in Appendix 1 of this report. This uses a traffic light system to indicate data availability and REACH Annex adaptation (green), potential for read across (orange), and data gaps (red).

In our evaluation of the available physicochemical data we have used ECHA (2008b) 'Guidance on information requirements and chemical safety assessment: Chapter R.7a: Endpoint specific guidance' as our starting point for evaluating secondary sources of physicochemical data. This guidance states that *"the secondary sources have to be based on a critical evaluation of peer-reviewed data and a consequent selection of a reliable and representative value for the property under investigation. Information in the review process should be stated in the introduction of the handbook or in the summary information for an electronic database available on Internet. The use of Klimisch codes (Klimisch et al. 1997) can be extended to these secondary sources and a reliability code of (2) valid with restrictions should be assigned when using an authoritative secondary source."*

2.1 UV-VIS spectroscopy and pH testing

UV-VIS spectroscopy testing and pH testing will be carried out on all rhenium substances and intermediates, except for dirhenium heptasulphide (CAS number 12038-67-4). UV-VIS spectroscopy will be carried in accordance with OECD test guideline 101.

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2.2 Category Re 0

Rhenium metal, CAS number 7440-15-5, is the only member of this category.

We must note that although not part of the physicochemical section of IUCLID, each registrant will also need basic information on the following parameters:

Composition information:

- Degree of purity
- Constituents
- Impurities

- Additives

This type of information will also allow us to produce adequately robust category justification documents and any classification and labelling that may be required. Each member company with an interest in registering rhenium metal will need to provide this information to the PMC Secretariat in accordance with PMC's recommended analytical techniques in order for it to be analysed and summarised in the category justification document.

2.2.1 State of the substance at 20°C and 101.3 kPa

Published data, with a Klimisch score of 2, are available for this endpoint. The data have been downloaded into templates ready for IUCLID entry.

2.2.2 Melting/freezing point

Published data, with a Klimisch score of 2, are available for this endpoint.

2.2.3 Boiling point

Published data, with a Klimisch score of 2, are available for this endpoint.

2.2.4 Relative density

Published data, with a Klimisch score of 2, are available for this endpoint.

2.2.5 Vapour pressure

This endpoint will be waived using the following adaptation:

> *In accordance with column 2 of REACH Annex VII, the vapour pressure study does not need to be conducted as this substance has a melting point above 300°C.*

2.2.6 Surface tension

There are no data available for surface tension for this substance. However, this is not surprising given that the substance in this category does not possess chemical functional groups which would make it surface active or a surfactant. Therefore this endpoint can be waived using the following adaptation:

> *In accordance with column 2 of REACH Annex VII, the surface tension study does not need to be conducted because, based on the structure of this substance, surface activity is not expected or predicted.*

2.2.7 Water solubility

No data are available for this endpoint and therefore testing is proposed. As rhenium is expected to be sparingly soluble, OECD test guideline 105 is not appropriate and transformation/dissolution (T/D) testing is proposed (OECD 2001). T/D testing is the internationally recognised guideline for sparingly soluble substances and this approach is compatible with the approach taken for the registration of other sparingly soluble metals.

This test will provide an indication not only of the solubility of the metal but also of any transformation of the metal to an environmentally stable ion or substance. This test is carried out at three different pH levels to take into account acidic, neutral and basic conditions and the potential for these conditions to influence the types of rhenium compounds or ions present in solution. The test also provides us with information through a period of 28 days on the level of dissolution and transformation of the metal into metal compounds. For this reason it is a more appropriate test than the OECD TG 105 methodology in which dissolution of the test substance is only measured after 24 hours of contact with water. The additional benefit of conducting this test is that the UV-VIS test can be co-ordinated with it, which will provide information on the long-term stability of any rhenium ions present in solution over an extended period (i.e. 28 days versus 24 hours for the UV-VIS test). The full T/D test protocol and a comparison between test houses can be found in Appendix 5 and 6.

Comment: CB 091209: Note: Appendix 6 is empty in the draft version – says see attached .PDF.

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2.2.8 Partition coefficient n-octanol / water, shake flask method

This endpoint is not applicable for inorganic substances and therefore we propose to use the following REACH adaptation:

> *In accordance with column 2 of REACH Annex VII, the partition coefficient study (required in section 7.8) does not need to be conducted as the substance is inorganic.*

2.2.9 Flash-point

The flash-point is a measure of the flammability risk of a liquid. It requires that the vapour of a liquid is ignited using a flame to determine the lowest temperature required for the vapour/air mixture to be ignited. Information on this endpoint is only required for liquids and, since the substance in this category is a solid, this endpoint can be waived.

This endpoint will be waived using the following REACH adaptation:

> *In accordance with column 2 of REACH Annex VII, the study does not need to be conducted as the substance is an inorganic solid.*

2.2.10 Flammability

Although it is possible to waive pyrophoricity and contact with water on the basis of an expert statement on handling supplied by the member companies, data on burning rate is still required for flammability. Therefore testing is proposed following either of the methods stated in Ch R.7A of the ECHA guidance on information requirements.

2.2.11 Explosive properties

Rhenium was evaluated against the criteria for explosiveness found in ECHA (2008b). We determined that this substance does not contain functional groups associated with explosive properties. On the basis of this evaluation we can waive this endpoint using the following adaptation:

> *In accordance with column 2 of REACH Annex VII, the explosive properties study (required in section 7.11) does not need to be conducted as the substance does not contain any chemical groups associated with explosive properties.*

2.2.12 Self-ignition temperature

The self-ignition temperature is the minimum temperature at which a specified volume of a solid under specific testing conditions will spontaneously catch fire. Rhenium has a melting point of greater than 400°C. This endpoint can be waived using the following adaptation:

> *In accordance with column 2 of REACH Annex VII, the self-ignition temperature study does not need to be conducted as the substance is a solid and preliminary results exclude self heating of the substance up to 400°C.*

2.2.13 Oxidising properties

Rhenium was evaluated against the criteria for oxidising properties found in ECHA (2008b). We determined that this substance does not contain functional groups associated with oxidising properties. On the basis of this evaluation we can waive this endpoint using the following adaptation:

> *In accordance with column 2 of REACH Annex VII, the oxidising properties study does not need to be conducted as the substance is incapable of reacting exothermically with combustible materials on the basis of its chemical structure.*

2.2.14 Granulometry (particle size distribution)

Proprietary data, with a Klimisch score of 2, are available for this endpoint.

Comment: CB 091211: Is granulometry a parameter that should be reported by each registrant (as it may vary across manufacturers and importers) or can a range be included in IUCLID 5 so it covers all of them? If the latter is the case, can you please let us know what value/range is available to WCA so we can check with the Rhenium SIEF if all other sizes are covered by this value too – part of our ID Card?

2.2.15 UV Spectroscopy

Ultraviolet spectroscopy testing is proposed.

2.3 Category Re 7

This is the largest rhenium category and is made up of the CAS numbers shown in Table 2.3.

Table 2.3 Category Re 7

Category	Substance name	CAS number	Type	Tonnage
Re 7	Perrhenic acid	13768-11-1	Substance	1-10
	Sodium rhenate	13472-33-8	Intermediate	1-10
	Dirhenium heptasulphide	12038-67-4	intermediate	1-10

We must note that although not part of the physicochemical section of IUCLID, each registrant will also need basic information on the following parameters:

Composition information:

- Degree of purity
- Constituents
- Impurities
- Additives

This type of information will also allow us to produce adequately robust category justification documents and any classification and labelling that may be required. Each member company with an interest in registering rhenium substances in this category will need to provide this information to the PMC Secretariat in accordance with PMC's recommended analytical techniques in order for it to be analysed and summarised in the category justification document.

2.3.1 State of the substance at 20°C and 101.3 kPa

Published data, with a Klimisch score of 2, are available for CAS numbers 13472-33-8 and 12038-67-4. Proprietary data (proforma) has been received for CAS number 13768-11-1.

2.3.2 Melting / freezing point

No data are available for CAS number 13768-11-1 and therefore testing is required.

Comment: CB 091211: See comment in attached table (Rhenium testing programme 091211.xls).

2.3.3 Boiling point

No data are available for CAS number 13768-11-1. Testing will be required unless the melting point is greater than 300°C or if decomposition occurs. This is highlighted as a data gap, dependent on the outcome of other tests.

Comment: CB 091209: This test is part of tier 1 testing programme so we are actually not waiting for the test result on melting point to become available, are we?

2.3.4 Relative density

Published data, with a Klimisch score of 2, are available for CAS numbers 13472-33-8 and 12038-67-4.

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No data are available for CAS number 13768-11-1; however, data is available for dirhenium heptaoxide, the anhydrous form of CAS number 13768-11-1, and therefore read-across is possible.

2.3.5 Vapour pressure

No data are available for CAS number 13768-11-1; however, this endpoint may be waived on the basis of the melting point, if determined to be above 300°C or on the basis of Annex XI of REACH because testing is not scientifically justifiable.

Comment: CB 091211: Which one is it?

2.3.6 Surface tension

There were no data available for surface tension for any of the substances in this category. However, this is not surprising given that these substances do not possess chemical functional groups which would make them surface active or surfactants. Therefore this endpoint can be waived using the following adaptation:

> *In accordance with column 2 of REACH Annex VII, the surface tension study does not need to be conducted because, based on the structure of this substance, surface activity is not expected or predicted.*

2.3.7 Water solubility

Published data, with a Klimisch score of 2, are available for CAS number 13472-33-8. The data for CAS number 13472-33-8 will be read-across to the other members of the category.

Comment: CB 091211: My understanding is that basic phys-chem data and especially water solubility data cannot be read-across... Can this be re-formulated/expanded?

2.3.8 Partition coefficient n-octanol / water, shake flask method

This endpoint will be waived for CAS number 13678-11-1 using the following adaptation:

> *In accordance with column 2 of REACH Annex VII, the partition coefficient study (required in section 7.8) does not need to be conducted as the substance is inorganic.*

2.3.9 Flash-point

This endpoint will be waived for CAS number13678-11-1 using the following adaptation:

> *In accordance with column 2 of REACH Annex VII, the flash point study does not need to be conducted as this substance is inorganic.*

2.3.10 Flammability

It is possible to waive pyrophoricity and contact with water on the basis of an expert statement on handling supplied by the member companies. It is also possible to waive the burning rate component of this endpoint for inorganic oxides in which the inorganic element is in its highest oxidation state (ECHA 2008). Further reaction with oxygen is not possible and therefore the substance can be classed as non-flammable.

2.3.11 Explosive properties

CAS number 13768-11-1 was evaluated against the criteria for explosiveness found in ECHA (2008b). We determined that this substance does not contain functional groups associated with explosive properties. On the basis of this evaluation we can waive this endpoint using the following adaptation:

> *In accordance with column 2 of REACH Annex VII, the explosive properties study (required in section 7.11) does not need to be conducted as the substance does not contain any chemical groups associated with explosive properties.*

2.3.12 Self-ignition temperature

Testing on CAS number 13768-11-1 will depend on the results of the melting point test. This is highlighted as a data gap depending on the outcome of other tests.

Comment: CB 091211: See comment in attached table (Rhenium testing programme 091211.xls).

2.3.13 Oxidising properties

This endpoint cannot be waived for CAS number 13768-11-1as they are metal oxides which are associated with oxidising properties (ECHA, 2008) and therefore testing is required. This is highlighted as a data gap.

Comment: CB 091211: See comment in attached table (Rhenium testing programme 091211.xls).

2.3.14 Granulometry (particle size distribution)

This endpoint can be waived for CAS number 13768-11-1 using the following REACH adaptation:

> *In accordance with column 2 of REACH Annex VII, the granulometry study does not need to be conducted as the substance is marketed or used in a non solid or granular form.*

2.4 Category Re 7a

CAS number 13598-65-7 is the only member of this category.

We must note that, although not part of the physicochemical section of IUCLID, each registrant will also need basic information on the following parameters:

Composition information:

- Degree of purity
- Constituents
- Impurities
- Additives

This type of information will also allow us to produce adequately robust category justification documents and any classification and labelling that may be required. Each member company with an interest in this substance will need to provide this information to the PMC Secretariat in accordance with PMC's recommended analytical techniques in order for it to be analysed and summarised in the category justification document.

2.4.1 State of the substance at 20°C and 101.3 kPa

Published data, with a Klimisch score of 2, are available for this endpoint.

2.4.2 Melting / freezing point

Published data, with a Klimisch score of 2, are available for this endpoint.

2.4.3 Boiling point

This endpoint can be waived for CAS number 13598-65-7 using the following adaptation:

> *In accordance with column 2 of REACH Annex VII, the boiling point study does not need to be conducted as this substance decomposes before boiling.*

2.4.4 Relative density

Published data, with a Klimisch score of 2, are available for this endpoint.

2.4.5 Vapour pressure

This endpoint can be waived for CAS number 13598-65-7 using the following waiver:

In accordance with column 2 of REACH Annex VII, the vapour pressure study does not need to be conducted as this substance has a melting point above 300°C.

2.4.6 Surface tension

There are no data available for surface tension for this endpoint. However, this is not surprising given that the substances in this category do not possess chemical functional groups which would make them surface active or surfactants. Therefore this endpoint can be waived using the following adaptation:

In accordance with column 2 of REACH Annex VII, the surface tension study does not need to be conducted because, based on the structure of this substance, surface activity is not expected or predicted.

2.4.7 Water solubility

Published data, with a Klimisch score of 2, are available for this endpoint.

2.4.8 Partition coefficient n-octanol / water, shake flask method

This endpoint is not applicable for inorganic substances and therefore we propose to use the following REACH adaptation for CAS number 13598-65-7:

In accordance with column 2 of REACH Annex VII, the partition coefficient study (required in section 7.8) does not need to be conducted as the substance is inorganic.

2.4.9 Flash-point

This endpoint will be waived using the following REACH adaptation for CAS number 13598-65-7:

In accordance with column 2 of REACH Annex VII, the study does not need to be conducted as the substance is an inorganic solid.

2.4.10 Flammability

Although it is possible to waive pyrophoricity and contact with water on the basis of an expert statement on handling supplied by the member companies, it is also possible to waive the burning rate component of this endpoint for inorganic oxides in which the inorganic element is in its highest oxidation state (ECHA 2008). Further reaction with oxygen is not possible and therefore the substance can be classed as non-flammable.

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The following REACH adaptation will be used:

In accordance with section 1 of REACH Annex XI, this endpoint can be waived as testing does not appear to be scientifically necessary.

2.4.11 Explosive properties

This substance was evaluated against the criteria for explosiveness found in ECHA (2008b). We determined that CAS number 13598-65-7 does not contain functional groups associated with explosive properties. On the basis of this evaluation we can waive this endpoint using the following adaptation:

In accordance with column 2 of REACH Annex VII, the explosive properties study (required in section 7.11) does not need to be conducted as the substance does not contain any chemical groups associated with explosive properties.

2.4.12 Self-ignition temperature

This endpoint cannot be waived and therefore testing is required.

Comment: CB 091211: See comment in attached table (Rhenium testing programme 091211.xls).

2.4.13 Oxidising properties

Proprietary data, with a Klimisch score of 1, are available. This study determined that CAS number 13598-65-7 does not have any oxidising properties.

2.4.14 Granulometry (particle size distribution)

Proprietary data, with a Klimisch score of 2, are available for this endpoint.

2.5 Overall physicochemical testing requirements for Rhenium

Table 2.5 gives an overall view of where physicochemical data is available, potentially available, or not available for the rhenium categories.

Table 2.5 Physicochemical data availability and testing requirements for Re categories

Category	Re 0	Re 7			Re 7a
CAS number	7440-15-5	13768-11-1	13472-33-8	12038-67-4	13598-65-7
State of the substance at 20°C and 101.3 kPa					
Melting/freezing point					
Boiling point					

Category	Re 0	Re 7			Re 7a
CAS number	7440-15-5	13768-11-1	13472-33-8	12038-67-4	13598-65-7
Relative density					
Vapour pressure					
Surface tension					
Water solubility					
Partition coefficient n-octanol/water, shake flask method					
Flash-point					
Flammability					
Explosive properties					
Self-ignition temperature					
Oxidising properties					
Granulometry (particle size distribution)					

Key	
	Testing required
	Testing requirement dependent on outcome of other tests or read-across to data not yet available because the test on the read-across substance has not been commissioned or performed
	Data available, adaptation available, read-across to available data
	Intermediate - data not a requirement

Comment: CB 091211: Minor comment: if it is possible, could another colour be used instead of orange – some printers make it look very similar to red and maybe yellow or another colour would be more contrasting.

The overall number of tests required to fulfil all the physicochemical requirements for the Re categories are shown in Section 6.1.

3 MAMMALIAN TOXICOLOGY TESTING AND DEROGATION ASSESSMENT

This section of the report is not finalised. It has not been signed off by bibra (the mammalian toxicologist experts) and has only been included to provide an indication of possible tests required to fill the data gaps for mammalian toxicity under REACH.

Comment: CB 091211: What is left for it to be finalised besides BASF studies?

Five mammalian toxicity endpoints are required under REACH Annex VII for substances registered at the 1 – 10 tonnes per annum level. In addition, there are 8 further mammalian toxicity endpoints to be considered for substances in the 10 – 100 tpa band as defined in Annex VIII.

The mammalian toxicity data gaps are presented in Appendix 2. This uses a 'traffic light' system to indicate data availability and adaptations to the REACH annexes (green), potential for data read across (yellow), and data gaps (red).

3.1 Category Re 0 (Annex VII Requirements)

3.1.1 Skin irritation (in vitro)

No relevant data were identified for rhenium metal. However, the data available for ammonium perrhenate indicates that it is not a dermal irritant to rabbit skin. This data is appropriate for read-across to rhenium. On this basis, rhenium metal would not be classified as a skin irritant.

3.1.2 Eye irritation (in vitro)

Comment: CB 091211: See comment in attached table (Rhenium testing programme 091211.xls). Not sure if this test is actually needed.

No relevant data were identified for rhenium metal, resulting in a data gap. We proposed that ammonium perrhenate is used to generate information on eye irritancy potential, using an in-vivo test. Ammonium perrhenate is in the Re7a category and requires an in vivo irritation test under Annex VIII and data generated from this test used for read-across to rhenium metal.

Two studies (Bovine Corneal Opacity and Permeability, and Isolated Chicken Eye) have recently been adopted by the OECD for assessment of ocular corrosivity and severe irritancy. From the available information it is unlikely that rhenium metal is corrosive and therefore conducting such in vitro studies on rhenium metal would not be expected to provide additional information. A negative result in the in vitro studies on would require the conduct of an in vivo study on for classification purposes, and the ocular trauma from the physical properties of powdered rhenium metal would probably mask any chemically-induced irritation.

Comment: CB 091211: On which test item? Re metal or APR?

Comment: CB 091211: On which test item? Re metal or APR?

There is a proprietary in-vitro corrosion study on dirrhenium heptaoxide (CAS 1314-68-7) which we will need to review to assess the potential risk to damage to the eyes. This study is not yet available to us but when it becomes available we will assess it suitability for read-across.

3.1.3 Skin sensitization

No data was identified for this endpoint for rhenium metal. Data will be generated on ammonium perrhenate to fill this data gap (murine local lymph node assay) and the results read across to rhenium (see section 3.3.3).

3.1.4 In vitro gene mutation study in bacteria

No relevant data were identified for rhenium metal. However, such a gene mutation assessment in bacteria is not generally considered appropriate for metals (HERAG Factsheet 05, August 2007) due to the low sensitivity to metal genotoxicity of the bacterial strains used. We recommended that a mouse lymphoma assay is used to assess the genotoxicity of metals and inorganic metal salts. Such a study is proposed for ammonium perrhenate (see section 3.3.4) and the results can be read across to rhenium metal.

3.1.5 Acute toxicity, oral route

No relevant data were identified for rhenium. Available data on ammonium perrhenate could be used, together with any available comparative data on bioavailability.

3.2 Category Re 7 (Annex VII Requirements)

3.2.1 Skin irritation

No relevant data were identified for perrhenic acid (CASRN 13768-11-1). However, classification as corrosive can be made on the basis of the very low pH value of < 2 (ECHA Endpoint Specific Guidance R7.2.1). We should note that the correlation between extremes of pH (< 2 and > 11.5) and the potential to cause dermal corrosion is not perfect. If the classification of corrosive is accepted, then no further testing for this endpoint is necessary. Additional dermal irritation/corrosion studies on dirhenium heptaoxide (CASRN 1314-68-7) are available (rabbit in vivo and in vitro corrosivity) and these can also be used to read across to perrhenic acid. These data support the classification as corrosive.

Comment: CB 091211: The Re WG accepted this classification as corrosive at its 4 Dec 2009 meeting in Brussels.

3.2.2 Eye irritation

No relevant data were identified for perrhenic acid. However in view of the extreme acid pH (< 2) this substance would also be expected to show severe eye damage. In any

case it should be noted that the classification of a substance for dermal corrosion also warrants the severe eye damage classification.

Comment: CB 091211: See comment below – corrosion classification accepted.

There is an additional proprietary study on dirhenium heptaoxide (CAS 1314-68-7) referred to above in section 3.2.1 which also provides additional evidence that perrhenic acid should be classified as corrosive. This study is not yet available to us but when it becomes available we will assess it suitability for read-across.

3.2.3 Skin sensitization

No relevant data were identified for perrhenic acid and hence this is a data gap which requires either an appropriate skin sensitization test or read across. The ability to perform a local lymph node assay may be constrained by the corrosivity of perrhenic acid. Alternatively, the proposed in vivo study on ammonium perrhenate could be used to read across.

Comment: CB 091211: What would make it not useable to read-across? Does it depend on the result and on whether the group accepts using a conservative value? Or is the possibility to read-across from APR to perrhenic acid not confirmed?

3.2.4 In vitro gene mutation study in bacteria

No relevant data were identified for perrhenic acid. However, such a gene mutation assessment in bacteria is not generally considered relevant for metals (HERAG Factsheet 05, August 2007) due to the low sensitivity of the bacterial strains used, to metal genotoxicity. We recommend that a mouse lymphoma assay is used to assess the genotoxicity of metals and inorganic metal salts. A study is proposed for ammonium perrhenate (see section 3.3.4) and the results can be read across to perrhenic acid.

3.2.5 Acute toxicity, oral route

No relevant data were identified for perrhenic acid and therefore this is a data gap. However, there is an acute oral toxicity study (the results indicate GHS hazard class 4) on dirhenium heptaoxide (not yet received) and this can be used to read across to perrhenic acid. In addition, the available acute toxicity data on ammonium perrhenate (LD50 >2g/kg) can be used in support. Substances that are classified as corrosive to the skin do not generally require testing for acute oral toxicity (REACH Annex VIII, column 2).

3.3 Category Re 7a (Annex VII-VIII Requirements)

3.3.1 Skin irritation

Proprietary data on ammonium perrhenate (CASRN 13598-65-7) with a Klimisch score 2 indicates that the substance is not a dermal irritant to rabbit skin.

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3.3.2 Eye irritation

No relevant data were identified for ammonium perrhenate, and therefore this is a data gap for this endpoint. *In vivo* data are required (Annex VIII) unless initial *in vitro* tests indicate that this substance is irritating to eyes. In the current absence of a validated *in vitro* test for eye irritation, we propose that an *in vivo* assessment, according to REACH annex VIII section 8.2, be conducted on this substance. Available data indicates that it is not a skin irritant, and hence is unlikely to be a severe eye irritant.

Comment: CB 091211: Does this refer to the Bovine Corneal Opacity and Permeability or Isolated Chicken Eye in vitro tests? If yes, please see request for clarification in comment made above in Re0 category.

3.3.3 Skin sensitization

Comment: CB 091211: See comment in attached table (Rhenium testing programme 091211.xls).

No relevant data were identified for ammonium perrhenate. We propose that a local lymph node assay be conducted on this substance (see also section 3.1.3).

3.3.4 In vitro gene mutation study in bacteria

No relevant data were identified for ammonium perrhenate. However, such a gene mutation assessment in bacteria is not generally considered relevant for metals (HERAG Factsheet 05, August 2007) due to the low sensitivity of the bacterial strains used, to metal genotoxicity. Therefore, a derogation for the bacterial mutation assay will be prepared and a mammalian cell gene mutation assay (mouse lymphoma assay) is proposed below.

3.3.5 Acute toxicity, oral route

Proprietary data, with a Klimisch score of 2, indicate that the rat LD50 >2 g kg^{-1} bw which is the allowable upper limit dose unless there are exceptional circumstances which would require the maximum limit dose to be use. No additional study is proposed.

3.3.6 In vitro cytogenicity in mammalian cells

No relevant data were identified for ammonium perrhenate. This is a data gap and we propose that a micronucleus assay be conducted (as recommended in HERAG Factsheet 05, 2007).

3.3.7 In vitro gene mutation study in mammalian cells

No relevant data for ammonium perrhenate were identified. This is a data gap and we propose that a mouse lymphoma assay be conducted.

3.3.8 Acute toxicity, inhalation

No relevant acute toxicity data by this route were identified for ammonium perrhenate. In addition to the oral route (see section 3.3.5), for substances other than gases information should be provided for at least one other route. The choice for the second route will depend on the nature of the substance and the likely route of human exposure. In accordance with Annex VII column 2 of REACH the inhalation route of

exposure is considered appropriate where the vapour pressure would indicate likely inhalation exposure and/or there is the possibility of exposure to aerosols, particles or droplets of an inhalable size.

Human exposure information indicates that the inhalation route may not be relevant for ammonium perrhenate. However, we will need to assess this with the help of the PMC members who have more experience in handling of these substance and hence the potential for exposure.

Alternatively there is the potential to use a proprietary acute inhalation study conducted on dirhenium heptaoxide (CAS 1314-68-7) to evaluate this endpoint. This study is not yet available to us to review and therefore we cannot determine its suitability for read-across. However an initial evaluation indicates that it may not be possible to read-across although we won't be able to confirm this until the study is reviewed.

3.3.9 Acute toxicity, dermal route

No relevant acute toxicity data were identified for ammonium perrhenate by this route. Testing by the dermal route is considered more appropriate where inhalation of the substance is unlikely, skin contact in production and/or use is likely and the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin (Annex VIII column 2 of REACH). The dermal route of exposure is considered the appropriate choice for the second route for ammonium perrhenate. However we will need to confirm this with the PMC members.

If there is only one route of exposure, information for only that route need be provided then the following REACH adaptation will be used:

> *In accordance with column 2 of REACH Annex VIII, if there is only one route of exposure then information for only that route need be provided.*

3.3.10 Short term repeated dose toxicity oral / dermal / inhalation

No relevant data were identified for ammonium perrhenate (CAS 13598-65-7). If relevant human exposure to this substance cannot be excluded in accordance with REACH Annex XI section 3, this is a data gap. We propose to fill this data gap by conducting of a 28-day study in rats. The route of administration for this study is selected based on the likely route of human exposure. In the case of ammonium perrhenate, this would be either oral or dermal administration. In order to minimize the number of experimental animals, this study can be combined with the reproductive toxicity screen (see section 3.3.11 below) which currently is also identified as a data gap.

Comment: CB 091211: When comparing dermal vs. inhalation route, inhalation is the preferred route for this acute test on APR (powder form). However, this test will be confirmed by PMC as part of tier 2 only after the proprietary study mentioned in the next paragraph has been evaluated and read-across potential has been considered. See also comment in attached table (Rhenium testing programme 091211.xls).

Comment: CB 091211: Is read-across potential difficult to confirm in general from any data on dirhenium heptaoxide to APR or another Re material or in this specific case?

Comment: CB 091211: There is already a value on oral toxicity and we accept to perform an inhalation toxicity test. Is dermal still needed? We understood that a minimum of two acute toxicity routes were needed... See also comment in attached table (Rhenium testing programme 091211.xls).

Comment: CB 091211: See comment above. Dermal not really relevant for APR, inhalation is. See also comment in attached table (Rhenium testing programme 091211.xls).

However if human exposure can be excluded as stipulated in the legislation the following REACH adaptation may be used:

Comment: CB 091211: No it cannot.

> *In accordance with column 2 of REACH Annex VIII, the short-term toxicity study (28 days) does not need to be conducted if relevant human exposure can be excluded in accordance with Annex XI Section 3.*

3.3.11 Reproductive toxicity

No relevant data were identified for CAS number 13598-65-7; however, the following REACH adaptation may be used:

> *In accordance with column 2 of REACH Annex VIII, the screening for reproductive / developmental toxicity study does not need to be conducted if relevant human exposure can be excluded in accordance with Annex XI Section 3.*

In the case that relevant human exposure cannot be excluded a screening test for reproductive/development toxicity in one species is required. The requirement for this endpoint can be combined with the sub-acute toxicity study (section 3.3.10 above) using the OECD Test Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test).

Comment: CB 091211: on rats please. See also comment in attached table (Rhenium testing programme 091211.xls).

Since the annual volume of ammonium perrhenate is < 100 tpa, the 28-day repeated dose combined study cannot be waived on the basis that a 90-day or longer study is required for higher registration volumes (> 100 tpa).

3.3.12 Toxicokinetics

A toxicokinetic assessment (absorption, distribution, metabolism, excretion) of ammonium perrhenate is required based on relevant information. This will be prepared using the available data and information from the proposed test plan.

3.4 Overall Mammalian Toxicology Testing Requirements for Rhenium

Table 3.1 provides an overview of where mammalian toxicology data are available, potentially available, or not available for the rhenium categories.

Table 3.1 Mammalian toxicology data availability and testing requirements for Re categories

Category	Re 0	Re 7			Re 7A
IUCLID Chapter	**7440-15-5**	**13768-11-1**	**13472-33-8**	**12038-67-4**	**13598-65-7**
Skin irritation *in vitro*					
Eye irritation *in vitro*					
Skin sensitisation					
In vitro gene mutation study in bacteria					
Acute toxicity, oral route					
Skin irritation *in vivo*					
Eye irritation *in vivo*					
In vitro cytogenicity in mammalian cells					
In vitro gene mutation study in mammalian cells					
Acute toxicity, inhalation					
Acute toxicity, dermal route					
Short-term repeated dose toxicity oral/ dermal/ inhalation					
Reproduction toxicity					
Toxicokinetics					

Key	
	Testing required
	Testing requirement dependent on outcome of other tests, read-across to data not yet available, possibility of waiving
	Data available, adaptation available, read-across to available data
	Intermediate - data not a requirement

4 ECOTOXICOLOGICAL TESTING AND DEROGATION ASSESSMENT

Annex VII of the REACH regulation lists two ecotoxicological endpoints as the minimum data requirements for substances in the 1-10 tonnage band. There are two further ecotoxicological requirements for substances in the 10-100 tonnage band (REACH Annex VIII).

No proprietary ecotoxicological data were submitted for any of the rhenium substances being registered. The literature search did not produce any published articles for rhenium substances with ecotoxicological endpoints.

A matrix of the ecotoxicological data gaps can be found in Appendix 3. This uses a traffic light system to indicate data availability and REACH Annex adaptation (green), potential for read across (orange), and data gaps (red).

4.1 Category Re 0

Information requirements for this category (short-term toxicity to aquatic invertebrates and growth inhibition of aquatic plants) will be filled using read-across from the soluble species identified after evaluation of Transformation/Dissolution test results.

4.2 Category Re 7

No data are available for short-term toxicity to aquatic invertebrates or growth inhibition of aquatic plants. Testing is proposed for CAS number 13472-33-8. The data generated will be read-across to CAS number 13768-11-1 and to Rhenium after evaluation of T/D test results.

4.3 Category Re 7a

Testing will be required for the following endpoints:

- Short-term toxicity testing on aquatic invertebrates (i.e. water fleas)
- Growth inhibition study on aquatic plants (i.e. algae)
- Short-term toxicity testing on fish

4.4 Overall Ecotoxicological Testing Requirements for Rhenium

Table 4.1 gives an overall view of where ecotoxicology data are available, potentially available, or not available for the rhenium categories.

Table 4.1 Ecotoxicology data availability and testing requirements for Re categories

Category	Re 0	Re 7			Re 7a
CAS number	7440-15-5	13768-11-1	13472-33-8	12038-67-4	13598-65-7
Short-term toxicity testing on aquatic invertebrates (preferably *Daphnia*)					
Growth inhibition study on aquatic plants (preferably algae)					
Short-term toxicity testing on fish					

Key	
	Testing required
	Testing requirement dependent on outcome of other tests or read-across to data not yet available because testing on the read-across substance has not been commissioned or performed
	Intermediate - data not a requirement
	Not required due to tonnage band

The overall number of tests required, and the associated costs, to fulfil all the ecotoxicological testing requirements for the Re categories are shown in Section 7.3: Ecotoxicological test recommendations.

5 ENVIRONMENTAL FATE TESTING AND DEROGATION ASSESSMENT

Annex VII of the REACH regulation lists one environmental fate endpoint as the minimum data requirement for substances in the 1-10 tonnage band. There are three further environmental fate requirements for substances in the 10-100 tonnage band (REACH Annex VIII).

A matrix of the environmental fate data gaps can be found in Appendix 4. This uses a traffic light system to indicate data availability and REACH Annex adaptation (green), potential for read across (orange), and data gaps (red).

5.1 Category Re 0

5.1.1 Biodegradation in water

This endpoint can be waived using the following REACH adaptation:

> *In accordance with column 2 of REACH Annex VII, the ready biodegradability study does not need to be conducted as the substance is inorganic.*

5.2 Category Re 7

5.2.1 Biodegradation in water

This endpoint can be waived for all the category members using the following REACH adaptation:

> *In accordance with column 2 of REACH Annex VII, the ready biodegradability study does not need to be conducted as the substance is inorganic.*

5.3 Category Re 7a

5.3.1 Biodegradation in water

This endpoint can be waived using the following REACH adaptation:

> *In accordance with column 2 of REACH Annex VII, the ready biodegradability study does not need to be conducted as the substance is inorganic.*

5.3.2 Activated sludge respiration inhibition testing

No data are available for this endpoint and therefore testing is required.

5.3.3 Hydrolysis

Hydrolysis is defined as the decomposition or degradation of a chemical by reaction with water. Information from the transformation/dissolution test may provide adequate evidence for this testing requirement, provided that the relevant species (rather than total metal concentrations) can be analysed. We therefore propose that this test is waived using the following REACH adaptation:

> *In accordance with REACH Annex XI Section 1: testing does not appear to be scientifically necessary because this method is used on organic substances to measure the decomposition or degradation of a chemical reacting with water. For inorganics this type of method is not appropriate.*

5.3.4 Adsorption/desorption

No data are available for this endpoint and therefore testing would be required. According to the test guideline (OECD 121) the method may not work for inorganic compounds, the method has not been validated for any inorganic compounds, and none of the recommended reference substances are inorganic compounds. We therefore propose that this test is waived using the following REACH adaptation:

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> *In accordance with REACH Annex XI Section 1: testing does not appear to be scientifically necessary because the specified method may not work for inorganic compounds, has not been validated for inorganic substances and there are no recommended inorganic reference substances listed in the methodology.*

5.4 Overall Environmental Fate Testing Requirements for Rhenium

Table 5.1 gives an overall view of where environmental fate data are available, potentially available, or not available for the rhenium categories.

Table 5.1 Environmental fate data availability and testing requirements for Re categories

Category	Re 0	Re 7			Re 7a
CAS number	7440-15-5	13768-11-1	13472-33-8	12038-67-4	13598-65-7
Biodegradation in water: screening tests					
Activated sludge respiration inhibition testing					

Key	
	Testing required
	Data available, adaptation available, read-across to available data
	Intermediate - data not a requirement
	Not required due to tonnage band

The overall number of tests required, and the associated costs, to fulfil all the environmental fate testing requirements for the Re categories are shown in Section 7.4: Environmental fate test recommendations.

6 ANNEX III DEROGATIONS

Comment: CB 091211: Please consider list of uses (unlikely to be dispersive) to confirm this derogation. Only use (very much controlled is the medical one). Also, could BIBRA consider whether it is useful to perform bio-accessibility tests to see how easily our rhenium materials bio-elute and become available?

REACH Annex III identifies criteria for substances registered in quantities between 1 and 10 tonnes with reference to Article 12 (1)(a) and (b). Taken together, Article 12 and Annex III indicate that for substances registered between 1 and 10 tonnes an Annex III derogation does not apply (i.e. that a full Annex VII data set is required) if:

1. The substance is likely to meet the criteria for category 1 or 2 classification for carcinogenicity, mutagenicity or reproductive toxicity or the criteria in REACH Annex VIII (PBT, vPvB), or

2. a) The substance has dispersive or diffuse uses, particularly where such substances are used in consumer preparations and b) The substance is likely to meet the classification criteria for any human health or environmental effects endpoints under Directive 67/548/EEC.

Note also that Article 12 states that all available physicochemical, toxicological and ecotoxicological information must also be supplied whether or not an Annex III derogation applies. So although additional aquatic ecotoxicity and biodegradation testing may not be required for substances not fulfilling these criteria, all existing data must still be included during substance Registration.

Substances registered between 1 and 10 tonnes and meeting these criteria must fulfil all Annex VII data requirements. For substances manufactured or imported in the tonnage band of 10 to 100 tonnes all the information requirements in Annexes VII and VIII apply.

6.1 1-10 Tonne Substances and Intermediates

Table 6.1 Substances and Intermediates being registered in the 1-10 tonne band

Category	Substance name	CAS number	Type	Tonnage
Re 0	Rhenium	7440-15-5	Substance	1-10
Re 7	Perrhenic acid	13768-11-1	Substance	1-10
	Sodium rhenate	13472-33-8	Intermediate	1-10
	Dirhenium heptasulphide	12038-67-4	Intermediate	1-10

We do not currently have the information required to utilise Annex III derogations for the 1-10 tonne substances.

As stated previously, for the purposes of this report we have assumed that intermediates are only used under strictly controlled conditions, and therefore that the only data requirements are to provide data that already exist. CAS numbers 13472-33-8 and 12038-67-4 have therefore already been assumed to be subject to data requirements that are less than those required, even if an Annex III derogation is applied.

7 INITIAL TEST PLAN RECOMMENDATIONS

7.1 Physicochemical Test Recommendations

Table 7.1 shows the physicochemical tests required and the approximate costs per test.

Table 7.1 Physicochemical test recommendations

Tier	Test required	CAS Number	Number of tests	Comment	Aqura Cost
1	Melting/freezing point	13768-11-1	1		€1560 per test
	Boiling point	13768-11-1	1	Dependent on outcome of mpt testing	€1560 per test
	UV –Vis spectroscopy and pH test	7440-15-5	4		€620 per test
		13768-11-1			
		13598-65-7			
		13472-33-8			
	Transformation/Dissolution testing	7440-15-5	1	T/D testing	€10,870 per test
	Flammability	7440-15-5	1		€1700 per test
	Self-ignition temperature	13768-11-1	4	Dependent on outcome of mpt testing	€1700 per test
		12038-67-4		Dependent on outcome of mpt testing	
		13598-65-7			
	Oxidising properties	13768-11-1	2		€4900 per test

7.2 Mammalian Toxicology Test Recommendations

It is difficult to determine the mammalian toxicological test requirements until Phase II is completed. However, we must note that data are only available for two endpoints and only for ammonium perrhenate. Table 7.2 indicates the approximate costs of the mammalian toxicological tests that may be required.

Comment: CB 091211: This answers my question above to some extent. However, what exactly is needed to conclude the mamm tox testing recommendations? BASF studies? Anything else?

Table 7.2 Mammalian toxicology test costs

Test	Method / Guideline	CAS number	Comment	AQura Cost
Skin sensitisation	OECD 429	13598-65-7		€ 3,950
Eye irritation *in vivo*	OECD 405	13598-65-7		Quote requested (indicative cost = € 900)
In vitro cytogenicity in mammalian cells	OECD 487	13598-65-7		Quote requested
In vitro gene mutation study in mammalian cells	OECD 476	13598-65-7		€ 15,200
Acute toxicity, dermal route	OECD 402	13598-65-7		Quote requested (indicative cost = € 1300)
Short-term repeated dose toxicity oral/dermal/inhalation	OECD 422	13598-65-7	Combined in order to minimise the number of experimental animals	Quote requested (indicative cost = € 75000)

7.3 Ecotoxicology Test Recommendations

Table 7.3 shows the ecotoxicological tests required and the approximate costs per test.

Table 7.3 Ecotoxicology test recommendations

Tier	Test required	CAS Number	Number of tests	AQura Cost
1	Short-term toxicity testing on aquatic invertebrates (preferably *Daphnia*)	13742-33-8 13598-65-7	2	€2100 per test (accompanying analytics (ICP-OES) = €2000-3500)

Tier	Test required	CAS Number	Number of tests	AQura Cost
	Growth inhibition study on aquatic plants (preferably algae)	13742-33-8 13598-65-7	2	€2480 per test (accompanying analytics (ICP-OES) = €2000-3500)
	Short-term toxicity testing on fish	13598-65-7	1	€2420 per test (accompanying analytics (ICP-OES) = €2000-3500)

7.4 Environmental fate test recommendations

Table 7.4 shows the environmental fate tests required and the approximate costs per test.

Table 7.4 Environmental fate test recommendations

Tier	Test required	CAS Number	AQura Cost
1	Activated sludge respiration inhibition testing	13598-65-7	€ 1,870

8 CLASSIFICATION AND LABELLING

Classification and labelling (CLP), under the CLP regulations (EU 1272/2008), requires data that are not required under REACH. Therefore, although the data available and reported in Section 2, 3, 4, and 5, and the testing recommendations reported in Section 7 will fulfil both REACH and CLP requirements for the majority of rhenium substances, it may not fulfil CLP requirements for the intermediates. However, for the intermediates read-across should be possible for most endpoints.

The issue of classification will be addressed in more detail when the full set of data required for REACH has been obtained and/or generated. This process will be started in sufficient time to allow for a full review process to occur before the 1st December 2010 deadline.

Comment: CB 091211: Albania, I believe you have mentioned March 2010 in a previous e-mail... may be wrong? Assuming we would wait for tier 1 to be reported (March 2010) before we launch tier 2, when do you expect a first classification proposal to be ready for discussion by PMC?

9 CONCLUSIONS

A number of endpoints require testing for physico-chemical properties, environmental fate, ecotoxicology, and mammalian toxicology. We have provided the best estimates of the possible costs of each test and which would fill identified data gaps. Wherever possible we have tried to select test substances that would be potentially useful for read-across to other substances in order to minimise testing costs.

In general we have assumed that testing will be conducted on ammonium perrhenate because this substance has the highest data requirements of all the rhenium substances. However we understand that the consortium has indicated their preference to test sodium rhenate as well and use this data for read-across where data on ammonium perrhenate cannot be read-across due to the possible or confirmed influence of the ammonium/ammonia counter-ion in the test result.

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Comment: CB 091211: See also general comment in attached table (Rhenium testing programme 091211.xls).

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10 REFERENCES

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APPENDIX 1 – PHYSICOCHEMICAL DATA GAP MATRIX

Category	Re (0) category	Re (7) category			Re (7A) ca
IUCLID Chapter	Rhenium 7440-15-5 (1-10 tonne substance)	Perrhenic acid 13768-11-1 (1-10 tonne substance)	Sodium rhenate 13472-33-8 (1-10 tonne intermediate)	Dirhenium heptasulphide 12038-67-4 (1-10 tonne substance)	Ammoniur perrhenat 13598-65- 100 tonne substance
State of the substance at 20°C and 101.3 kPa	Silver-grey metal	Liquid, aqueous solution, clear,colourless, odourless, inorganic. (proforma received)exists only in solution (CRC)	crystalline	brown-black tetragonal crystals	colourless
Melting/freezing point	3185°C	Data gap - propose testing	300°C	intermediate	decompos 365°
Boiling point	5596°C	Data gap - dependent on MPT testing	intermediate	intermediate	The boiling study doe need to conducted substar decomposes boilin
Relative density	20.8g/cm^3	read across from direhenium heptaoxide (6.10g/cm^3)	5.39g/cm^3	4.87g/cm^3	3.97g/

Category	Re (0) category	Re (7) category			Re (7A) ca
IUCLID Chapter	**Rhenium 7440-15-5 (1-10 tonne substance)**	**Perrhenic acid 13768-11-1 (1-10 tonne substance)**	**Sodium rhenate 13472-33-8 (1-10 tonne intermediate)**	**Dirhenium heptasulphide 12038-67-4 (1-10 tonne substance)**	**Ammoniur perrhenat 13598-65- 100 tonne substance**
Vapour pressure	The vapour pressure study does not need to be conducted as this substance has a melting point above 300°C.	expert statement	intermediate	intermediate	The vap pressure does not n be conduc this substa a melting above 30
Surface tension	This study does not need to be conducted as, based on the structure of this substance, surface activity is not expected or predicted.	This study does not need to be conducted as, based on the structure of this substance, surface activity is not expected or predicted.	intermediate	intermediate	This study not need conducte based or structure substance, activity i expecte predict
Water solubility	Data gap - T/D testing proposed	read across from 13472-33-8	100g/100ml H_2O at 20°C	intermediate	62300mg/l 20°C (6.23 $H_2$0 at 2
Partition coefficient n-octanol/water, flask shake method	The partition coefficient study does not need to be conducted as this substance is inorganic.	The partition coefficient study does not need to be conducted as this substance is inorganic.	intermediate	intermediate	The part coefficient does not n be conduc this substa inorgar

Category	Re (0) category	Re (7) category			Re (7A) ca
IUCLID Chapter	Rhenium 7440-15-5 (1-10 tonne substance)	Perrhenic acid 13768-11-1 (1-10 tonne substance)	Sodium rhenate 13472-33-8 (1-10 tonne intermediate)	Dirhenium heptasulphide 12038-67-4 (1-10 tonne substance)	Ammoniur perrhenat 13598-65- 100 tonne substance
Flash-point	The flash point study does not need to be conducted as this substance is inorganic.	The flash point study does not need to be conducted as this substance is inorganic.	intermediate	intermediate	The flash study doe need to conducted substan inorgar
Flammability	Data gap	read across from 1314-68-7	intermediate	intermediate	Data g
Explosive properties	The explosive properties study does not need to be conducted as there are no chemical groups associated with explosive properties present in the molecule.	The explosive properties study does not need to be conducted as there are no chemical groups associated with explosive properties present in the molecule.	intermediate	intermediate	The expl properties does not n be conduc there ar chemical g associate explos properties in the mol
Self-ignition temperature	The self-ignition temperature study does not need to be conducted as the substance is a solid and preliminary results exclude self heating of the substance up to	read across from 1314-68-7	intermediate	intermediate	Data g

Category	Re (0) category	Re (7) category			Re (7A) ca
IUCLID Chapter	Rhenium 7440-15-5 (1-10 tonne substance)	Perrhenic acid 13768-11-1 (1-10 tonne substance)	Sodium rhenate 13472-33-8 (1-10 tonne intermediate)	Dirhenium heptasulphide 12038-67-4 (1-10 tonne substance)	Ammoniur perrhenat 13598-65- 100 tonne substance
	400°C.				
Oxidising properties	The oxidising properties study does not need to be conducted as the substance is incapable of reacting exothermically with combustible materials on the basis of its chemical structure.	read across from 1314-68-7	intermediate	intermediate	No oxidi propert (proprie
Granulometry (particle size distribution)	10% Diameter = 8.41, 8.31, 8.57,7.54, 8.61, 8.66. 50% diameter = 28.98, 28.75, 30.30, 27.94, 30.28, 30.30. 90%	The granulometry study does not need to be conducted as the substance is marketed or used in a non solid or granular form.	intermediate	intermediate	**(1)** 80% mass of compoun made up o with a diam 0.175-0.3 **(2)** D (v, 35.98µm, D

Category	Re (0) category	Re (7) category			Re (7A) ca
IUCLID Chapter	Rhenium 7440-15-5 (1-10 tonne substance)	Perrhenic acid 13768-11-1 (1-10 tonne substance)	Sodium rhenate 13472-33-8 (1-10 tonne intermediate)	Dirhenium heptasulphide 12038-67-4 (1-10 tonne substance)	Ammoniur perrhenat 13598-65- 100 tonne substance
	diameter = 60.34, 59.24, 61.70, 58.41, 62.64, 61.93.				= 109.92µr 90) = 210.
pH	Not a REACH requirement	Not a REACH requirement	Not a REACH requirement	Not a REACH requirement	Not a RE requiren

APPENDIX 2 – MAMMALIAN TOXICOLOGY DATA GAP MATRIX

Category	Re (0) category	Re (7) category			Re cat
IUCLID Chapter	**Rhenium 7440-15-5 (1-10 tonne substance)**	**Perrhenic acid 13768-11-1 (1-10 tonne substance)**	**Sodium rhenate 13472-33-8 (1-10 tonne intermediate)**	**Dirhenium heptasulphide 12038-67-4 (1-10 tonne substance)**	**Amm perr 1359 (10-1 subs**
Skin irritation *in vitro*	Read-across from 13598-65-7	Classification will be made based on pH testing and read-across from rhenium oxide	intermediate	intermediate	Data
Eye irritation *in vitro*	Read-across from 13598-65-7 or proprietary data for rhenium oxide (once reviewed)	Classification will be made based on pH testing and read-across from rhenium oxide	intermediate	intermediate	*in viv* pro
Skin sensitisation	Read-across from 13598-65-7	Read-across from 13598-65-7	intermediate	intermediate	Dat **Te pro**

Category	Re (0) category	Re (7) category			Re cat
IUCLID Chapter	Rhenium 7440-15-5 (1-10 tonne substance)	Perrhenic acid 13768-11-1 (1-10 tonne substance)	Sodium rhenate 13472-33-8 (1-10 tonne intermediate)	Dirhenium heptasulphide 12038-67-4 (1-10 tonne substance)	Amm perr 1359 (10-1 subs
In vitro gene mutation study in bacteria	Not appropriate for metals	Not appropriate for metals	intermediate	intermediate	Not ap for
Acute toxicity, oral route	Read-across from 13598-65-7	Read-across from rhenium oxide and 13598-65-7	intermediate	intermediate	LD50
Skin irritation *in vivo*	not required at this tonnage	not required at this tonnage	intermediate	intermediate	non

Category	Re (0) category	Re (7) category			Re cat
IUCLID Chapter	Rhenium 7440-15-5 (1-10 tonne substance)	Perrhenic acid 13768-11-1 (1-10 tonne substance)	Sodium rhenate 13472-33-8 (1-10 tonne intermediate)	Dirhenium heptasulphide 12038-67-4 (1-10 tonne substance)	Amm perr 1359 (10-1 subs
Eye irritation *in vivo*	not required at this tonnage	not required at this tonnage	intermediate	intermediate	Dat Te pro
In vitro cytogenicity in mammalian cells	not required at this tonnage	not required at this tonnage	intermediate	intermediate	Dat Te pro
In vitro gene mutation study in mammalian cells	not required at this tonnage	not required at this tonnage	intermediate	intermediate	Dat Te pro
Acute toxicity, inhalation	not required at this tonnage	not required at this tonnage	intermediate	intermediate	Potent or rea
Acute toxicity, dermal route	not required at this tonnage	not required at this tonnage	intermediate	intermediate	Testin re
Short-term repeated dose toxicity oral/dermal/inhalation	not required at this tonnage	not required at this tonnage	intermediate	intermediate	Dat Te pro

Category	Re (0) category	Re (7) category			Re cat
IUCLID Chapter	Rhenium 7440-15-5 (1-10 tonne substance)	Perrhenic acid 13768-11-1 (1-10 tonne substance)	Sodium rhenate 13472-33-8 (1-10 tonne intermediate)	Dirhenium heptasulphide 12038-67-4 (1-10 tonne substance)	Amm perr 1359 (10-1 subs
Reproduction toxicity	not required at this tonnage	not required at this tonnage	intermediate	intermediate	Dat Te pro
Toxicokinetics	not required at this tonnage	not required at this tonnage	intermediate	intermediate	Will be usi availa

APPENDIX 3 – ECOTOXICOLOGY DATA GAP MATRIX

Category	Re (0) category	Re (7) category			Re (7 categ
IUCLID Chapter	**Rhenium 7440-15-5 (1-10 tonne substance)**	**Perrhenic acid 13768-11-1 (1-10 tonne substance)**	**Sodium rhenate 13472-33-8 (1-10 tonne intermediate)**	**Dirhenium heptasulphide 12038-67-4 (1-10 tonne substance)**	**Ammoniu perrhenat 13598-65 100 tonne substance**
Short-term toxicity testing on aquatic inverts (preferably *Daphnia*)	Read across from soluble species after evaluation of T/D test results	Read-across from 13472-33-8	Testing proposed	intermediate	Data g
Growth inhibition study on aquatic plants (preferably algae)	Read across from soluble species after evaluation of T/D test results	Read-across from 13472-33-8	Testing proposed	intermediate	Data g
Short-term toxicity testing on fish	not required at this tonnage	not required at this tonnage	intermediate	intermediate	Data g

APPENDIX 4 – ENVIRONMENTAL FATE DATA GAP MATRIX

Category	Re (0) category	Re (7) category			Re (7/ categ
IUCLID Chapter	Rhenium 7440-15-5 (1-10 tonne substance)	Perrhenic acid 13768-11-1 (1-10 tonne substance)	Sodium rhenate 13472-33-8 (1-10 tonne intermediate)	Dirhenium heptasulphide 12038-67-4 (1-10 tonne substance)	Ammoniur perrhenat 13598-65- 100 tonne substance
Biodegradation in water: screening tests	The ready biodegradability study does not need to be conducted as the substance in inorganic.	The ready biodegradability study does not need to be conducted as the substance in inorganic.	intermediate	intermediate	The rea biodegrad study doe need to conducted substanc inorgar
Activated sludge respiration inhibition testing	not required at this tonnage	not required at this tonnage	intermediate	intermediate	Data g
Hydrolysis as a function of pH and identification of degradation products	not required at this tonnage	not required at this tonnage	intermediate	intermediate	In accordan REACH An this testing not appea scientific necessar inorga substan
Adsorption/desorption screening study (HPLC method)	not required at this tonnage	not required at this tonnage	intermediate	intermediate	In accordan REACH An this testing not appea scientific


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Appendix 5 Transformation/Dissolution Test House Comparison

	Aqura	ITRI	CANMET
Cost	€4.700 for the reproducibility test (approx £4,300) €9.400 for the screening and full test (approx £8,600)	Screening T/D test per material £2,700.00 Full T/d test per material £12,300.00	Screening T/D test per material £3,300.00 Full T/d test per material £5,027 Final Report £5,229 Final Estimate £15,600
Experience	Lack experience but an audit would be conducted during the T/D test. Aqura do have experience working with a range of metals using other test methods.	Have done T/D testing on one metal.	CANMET are the forerunners in this field and have a wealth of experience
Capacity	Testing can begin mid November, reporting date January 2010	Testing could begin upon receipt of the sample	Due to their experience, they would not have the capacity to start testing until early 2010, and potentially there could be further delays.

Appendix 6 Transformation/Dissolution Testing Protocol

See attached PDF