Rhenium project tier 2 testing programme

OECD guideline	Study	Test material	EC number	CAS number	Quantity required (g)	Concentration of material*	Cost of study** (€)	Estimated start date	Estimated end date	Estimated reporting date	Comment	wca comments
tbc	Flammability	Rhenium	231-124-5	7440-15-5	tbc	tbc	1.700,00 €	tbc	tbc	tbc		
tbc	Self-ignition temperature	Perrhenic acid	237-380-4	13768-11-1	tbc	tbc	1.700,00 €	tbc	tbc	tbc	Depend on outcome of melting point test. Already in highest oxidation state (no reason for it to burn as it is completely associated with oxygen): is test really needed?	Although guidance states that flammability can be waived if a substance is in its highest oxidation state, this is not the case for self-ignition temperature and therefore testing may still be required - see melting point.
		Ammonium perrhenate	237-075-6	13598-65-7	tbc	tbc	1.700,00 €	tbc	tbc	tbc	Already in highest oxidation state (no reason for it to burn as it is completely associated with oxygen): is test really needed?	Although guidance states that flammability can be waived if a substance is in its highest oxidation state, this is not the case for self-ignition temperature and therefore testing may still be required - see melting point.
tbc	Oxidising properties	Perrhenic acid	237-380-4	13768-11-1	tbc	tbc	4.900,00 €	tbc	tbc	tbc	Oxidising properties mean that the substance itself is reduced and being already in the highest oxidation state means that it can be reduced. If it is needed, confirm protocol that is applicable to solutions UN O.2 (or change to powder form; dirhenium heptaoxide now out and too hygroscopic anyway). If powder, check particle size (influences results - part of Ag project experience). Since according to Phase II draft report dated 2 Dec 2009, "*proprietary data, with a Klimisch score of 1 determined that Ammonium Perrhenate does not have oxidising properties*" and the NH4+ ion is just replaced by a H+ should it not be possible to read across from APR to Perrhenic acid? Workers handling perrhenic acid say that they have never been aware of any oxidising properties.	Data is available for ammonium perrhenate and this will be read across to perrhenic acid as they are both in the same oxidation state. - Read-across of physico-chemical properties cannot be done, need to test perrhenic acid
429	Skin sensitisation - LLNA	Ammonium perrhenate	237-075-6	13598-65-7	tbc	tbc	3.950,00 €	tbc	tbc	tbc	LLNA test was performed on silver and some difficulties were encountered due to the irritating nature of the test item (not the case of APR): need to make sure test is performed according to OECD guideline (variants exist).	This substance is not a dermal irritant, therefore interference by irritation will not be a factor in the LLNA. The full LLNA will be performed; any procedural modifications necessary will be discussed and authorised before incorporation - ok
	Eye irritation (*in vitro*)	Rhenium	231-124-5	7440-15-5	tbc	tbc		tbc	tbc	tbc	Depends upon evaluation of study on APR. If not valid or of read-across not possible: two options - perform Bovine Corneal Opacity and Permeability or Isolated Chicken Eye *in vitro* tests or read-across from *in vivo* eye irritation on APR. Before test is actioned, wait for *in vivo* test result on APR. If *in vitro* test confirmed, need to clarify on which test item these will be performed.	An existing HET-CAM *in vitro* eye irritation study on dirhenium heptaoxide shows the potential for severe eye damage, hence this will not be used to read-across to rhenium. The results from the proposed *in vivo* test on APR (and T/D test on rhenium) will then determine the need for alternative testing of rhenium species - ok
405	Eye irritation (*in vitro* possibly followed by *in vivo*)	Ammonium perrhenate	237-075-6	13598-65-7	tbc	tbc	900,00 €	tbc	tbc	tbc	Need to clarify whether Annex VIII *in vivo* tests can be performed or whether these require a testing proposal/ECHA's approval in advance - cf. Articles 12(1)e, 22(1)h, and 40(1) of the REACH regulation + UK HSE already confirmed ok to test.	No prior testing proposal is required for Annex VIII *in vivo* tests. An initial *in vitro* assessment (approved test, eg BCOP, etc) of eye irritation is proposed to assess whether APR causes severe eye irritation, before an *in vivo* test is initiated - ok
487	Cytogenicity in mammalian cells (*in vitro*) - Micronucleus	Ammonium perrhenate	237-075-6	13598-65-7	tbc	tbc		tbc	tbc	tbc	Part of silver project experience - no major issue to consider.	This test (micronucleus) assess chromosomal effects, and therefore does not 'replicate' the Ames test (which assesses direct effects on DNA - ie genotoxicity). The geneotxicity of APR will be assessed using the mouse lymphoma assay as per HERAG recommendations - ok, so micronucleus test needed
476	Gene mutation in mammalian cells (*in vitro*) - AMES replaced by MLA	Ammonium perrhenate	237-075-6	13598-65-7	tbc	tbc	15.200,00 €	tbc	tbc	tbc	Also covering cytogenicity in bacteria (AMES test - not applicable to metals as per HERAG). Part of silver project experience - no major issue to consider. Part of silver project experience - no major issue to consider.	This study replaces the Ames test, ie assesses gene mutations in mammalian cells as opposed to bacterial DNA in the Ames test - ok so MLA test needed
403	Acute toxicity (hour-basis), inhalation route (to derive LD50)	Ammonium perrhenate	237-075-6	13598-65-7	tbc	tbc		tbc	tbc	tbc	Inhalation decided to be the most representative route considering exposure pathways (also for test below). Experience with the Ag project showed that a test derogation had to be considered because it was not possible to have a stable test atmosphere for the disilver oxide - could this be the case for APR too?	The choice of route is still under discussion with PMC. The aerodynamic particle size distribution will determine whether inhalable particles are likely. Currently laser diffraction PSD data is available, but this requires conversion to aerodynamic size before a decision is made - Results available and show particle size too large to be inhalable, test is waived on the basis of absence of exposure
412 + 422	Short-term (28 days) repeated dose toxicity test, inhalation route (to derive NO(A)EL) combined with reprotox screening test (on rats)	Ammonium perrhenate	237-075-6	13598-65-7	tbc	tbc	75.000,00 €	tbc	tbc	tbc	Two tests in one to reduce number of animals used. Would it be useful to wait for the OECD 403 to be finalised before launching the 412+422? Need to clarify with MS CA whether Annex VIII *in vivo* tests can be performed or whether these require a testing proposal/ECHA's approval in advance - cf. Articles 12(1)e, 22(1)h, and 40(1) of the REACH regulation + UK HSE already confirmed ok to test.	The option to conduct a combined study will depend on the final choice of exposure route in the 28-day toxicity study (see above). Normally a reproductive toxicity screen is performed using the oral route because of potential adverse effects of the trauma associated with other routes. Hence, if the inhalation route is agreed for the 28-day study, then a separate reproductive screen study is proposed, using oral administration - Results above show that the combined study by oral route is needed
N/A								**GENERAL COMMENTS:** (1) could lab send all testing protocols to PMC secretariat? (2) applicable to any test proposed for APR: For read-across purposes, need to evaluate need of running test with sodium rhenate as well; in parallel or after results from test with APR have been received (to be decided). (3) Are both AQura and Evonik confirmed to work according to GLP principles for all these tests?			All final test protocols will be held by the PMC Secretariat. Choice of laboratory for toxicology studies, need for the use of sodium rhenate, and any other issues, will be mutually agreed with PMC before studies are performed. Both labs are confirmed to work to GLP principles - ok to continue working with Evonik but need alternative laboratory for physico-chemical tests
				Total	0		105.050,00 €					

* As recommended in OECD guideline (to compare with available LD50)