

Dear SIEF Members,

The Lead Registrant Rhodia Operations (member of the Solvay Group) in collaboration with the Members of the Rare Earth Consortium has prepared the lead registration dossier for the substance Digadolinium Trioxide (CAS 12064-62-9 | EC 235-060-9). The lead registration dossier has already been submitted to ECHA and covers a full registration for the tonnage band 10-100 tpy.

The LoAs are available for co-registering the substance in Annex VIII, Annex VII and as a TII under SCC (<1000 tpy). The LoA-prices have been derived considering Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), L3/41, 6.1.2016. There is an initial price (to be paid when buying the LoA) and a final price (to be calculated later). For more information, see the news page and the Q&A on the REC website (<http://www.rare-earth-consortium.eu/news/qa-loas-and-co-registration> ).

The initial LoA prices take into account:

- A cost-sharing model
- The actual costs and expenses incurred to establish or maintain the registration dossier
- Provisions for future costs
- The initial estimation of the number of co-registrants per tonnage bands
- A reimbursement mechanism.

## 1. Cost sharing model

REC LoA for a 2018-substance <b>Gadolinium Trioxide</b> (non-nano form)						
Calculation T0 (Initial Price): sales of LoAs according to the Data Sharing Regulation						
		Costs in €	<10 tpy+ 10-100 tpy	<10 tpy		
<b>D</b> <b>a</b>	Multiplication factor (MF):		1.00	0.40		
	Specific Expenses:					
	Costs of New and Existing Data:		141 190	30 931		
	Dossier costs:	132 252				
	Total Reimbursable provision (future costs: tests and CM):		80 000	30 000		
	Administrative LoA handling costs:		1 500	1 500		
	Nbr of Co-Registrants:		6	5		
<b>S</b> <b>h</b> <b>a</b> <b>r</b> <b>i</b> <b>n</b> <b>g</b>		Costs in €	<10 tpy+ 10-100 tpy	<10 tpy	€	%
	Administrative costs + Costs of New and Existing Data (total tonnages):				83 832	31%
	Costs of New and Existing Data:		141 190	30 931	189 610	69%
	Administrative dossier preparation costs:		132 252	52 901		
	Total:		273 442	83 832		100%
	Diff between 10-100tpy & <10tpy				105 778	39%
	Total:				273 442	100%
	Min 3 tonnage bands				83 832	31%
	Nbr co-reg involved				11	
	Share in LoA				7621	
	provision (€)				30 000	
	Share in provision				2 727	
	provision (€)				50 000	
	Share in provision				8 333	
	Total:				273 442	100%
	LoA components					
	LoA (€)					
	Provision components					
	Provision (€)					
	Share registration Specific Expenses:		39 223	7 621	7621	31602
	Reimbursable Provision:		11 961	2 727	7621	7921
	Administrative LoA handling costs:		1 500	1 500		
	Joint Registration Compensation per LoA:					
	Joint Registration Compensation LoA/tonnage band:		51 783	11 848		

## 2. Initial Price of the LoA

The initial prices of the LoA for the substance Digadolinium Trioxide (CAS 12064-62-9 | EC 235-060-9) per tonnage band are:

Substance	Annex VIII (10-100 tpy)	Annex VII (1-10 tpy)	OSII or TII under SCC (<1000 tpy)
Digadolinium Trioxide	€ 51 783	€ 11 848	€5000

### 3. Data used for establishing the initial price of the LoAs

The data used for establishing the initial price of the LoA are summarized in the following table:

<b>Digadolinium Trioxide (CAS 12064-62-9   EC 235-060-9)</b>			
	Annex VIII (10-100 tpy)	Annex VII (1-10 tpy)	OSII or TII under SCC (<1000 tpy)
LoA price	€ 51 783	€ 11 848	€ 5 000
Provision per LoA/tonnage bands	€ 11 061	€ 2 727	n.a.
The price of the LoA is based on the following main assumptions:			
Total provisions for future costs (°)	€ 80 000	€ 30 000	n.a.
Number of intentions for co-registration (1)	6	5	n.a.

(°): total amounts for provisions per tonnage bands (absolute amount before taking the number of co-registrants into account)

(1): Initial estimation of the number of co-registrants per tonnage bands and including the LR and the Members of the Consortium

The initial LoA-prices indicated in this communication are based on the elements currently available and may be subject to change in view of changes in costs or other changes in circumstances.

As foreseen in the above-mentioned regulation, a yearly documentation will be established containing the theoretical recalculation of the LoA prices taking into account of the actual number of LoA sold per tonnage bands as well as the actual use of the provisions foreseen for future costs). The yearly documentation will be established for a period of 12 years after the last submission of data regarding the above-mentioned lead dossier. At the end of this period, the final reimbursement will take place (if any). If the price of the LoAs is recalculated every year, the sales price remains unchanged and equal to the price during the whole 12-years period (unless otherwise decided by the Consortium). No reimbursement below €1000/ LoA unless the related administrative costs are paid by the requesting party.

It is not possible to estimate exactly the provisions for future costs. The amounts considered for the provisions for future costs are therefore subject to a potential revision over time. The members of the Consortium will evaluate at a later stage whether the initial price of the LoAs are still in line with the current and future expenses foreseen for maintaining the registration dossier. If necessary, an additional amount may be invoiced by the Project manager on behalf of the Lead Registrant.

For on-site or transported intermediates manufactured and used under SCC (Strictly Controlled Conditions) below 1000 tpy, it is possible to refer to the joint submission for a lump sum of €5000,00 (Five Thousand Euro). There is no reimbursement mechanism foreseen for the case of on-site or transported intermediates.

If you wish to buy a LoA for the substance mentioned here above, please contact the Project manager ([Rare-Earth-consortium@arcadis.com](mailto:Rare-Earth-consortium@arcadis.com)). The procedure to buy a LoA will be managed by ARCADIS Belgium acting on behalf of the Lead Registrant and the Members of the Rare Earth Consortium.

The procedure is the following:

1. The co-registrant indicates its willingness to purchase a LoA by mail sent to [Rare-Earth-consortium@arcadis.com](mailto:Rare-Earth-consortium@arcadis.com) with the information needed:

- Name of the legal entity:
- Contact name:
- UUID:
- Address (of the legal entity registering the substance):
- Invoicing address (if different):
- VAT number:
- Optional –IBAN / BIC number:
- A PO number if required to be mentioned on the invoice

2. A LoA-Agreement will be issued and sent to the requesting parties. This LoA-Agreement contains all details about the LoA and must be signed and returned to Arcadis as follows:

- a. A (signed) pdf version must be sent by email to ARCADIS ([Rare-earth-consortium@arcadis.com](mailto:Rare-earth-consortium@arcadis.com)) as soon as possible so that the invoice can be issued.
- b. The signed original of the LoA-Agreement needs to be sent to the following address:  
ARCADIS Belgium NV  
F.a.o. Rare Earth Consortium  
Posthofbrug 12  
B-2600 Berchem  
Belgium

3. ARCADIS will issue and send the invoice related to the corresponding LoA fee

4. After reception of the signed LoA-Agreement and the funds related to the LoA fee, ARCADIS will provide you with a token, joint submission name, generic CSR (Annex VIII only) and Guidance on safe Use (GoSU).

Note that this information is necessary for each and all your legal entities registering the substance(s). You need a LoA per legal entity registering the substance.

For any further information, please contact us at [Rare-Earth-consortium@arcadis.com](mailto:Rare-Earth-consortium@arcadis.com).

Best regards,

**Arcadis on behalf of the Lead Registrant and the Members of the Rare Earth Consortium**