

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 Gadolinium trinitrate (CAS 10168-81-7 | EC 233-437-2). The lead registration dossier has already been submitted to ECHA and covers a full registration for the tonnage band 1 - 10 tpy.

The LoAs are available for co-registering the substance in 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 Gadolinium Trinitrate (non-nano form)										
Calculation T0 (Initial Price): sales of LoAs according to the Data Sharing Regulation										
D a t a		Costs in €	<10 tpy							
	Specific Expenses:									
	Costs of New and Existing Data:		32 446							
	Dossier costs:	80 306								
	Total Reimbursable provision (future costs: tests and CM):		15 000							
	Administrative LoA handling costs:		1 500							
	Nbr of Co-Registrants:		3							
S h a r i n g		Costs in €	<10 tpy		€	%	Nbr co-reg involved	Share in LoA	provision (€)	Share in provision
	Administrative costs + Costs of New and Existing Data (total tonnages):			< 10tpy	112 752	100%	3	37584	15 000	5 000
	Costs of New and Existing Data:		32 446							
	Administrative dossier preparation costs:		80 306							
	Total:		112 752		Total:	112 752	100%			
	Joint Registration Compensation per LoA:	Costs in €	<10 tpy		LoA components		LoA (€)	Provision components		Provision (€)
	Share registration Specific Expenses:		37 584	< 10tpy	37584		37 584	5000		5 000
	Reimbursable Provision		5 000							
	Administrative LoA handling costs:		1 500							
	Joint Registration Compensation LoA/tonnage band:		44 084							

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:

Gadolinium trinitrate (CAS 10168-81-7 EC 233-437-2)		
	Annex VII (1-10 tpy)	OSII or TII under SCC (<1000 tpy)
LoA price	€ 44 084	€ 5 000
Provision per LoA/tonnage bands	€ 5 000	n.a.
The price of the LoA is based on the following main assumptions:		
Total provisions for future costs (°)	€ 15 000	n.a.
Number of intentions for co-registration (¹)	3	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 join 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). 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 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) 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.

Best regards,

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