

Dear SIEF Member,

Availability of LoAs for the substance CERIUM TRINITRATE

The Lead Registrant Treibacher Industrie AG in collaboration with the Members of the Rare Earth Consortium has prepared the lead registration dossier for the substance CERIUM TRINITRATE (CAS 10108-73-3; EC 233-297-2). The lead registration dossier has already been submitted to ECHA.

The LoAs are available for the lower and higher tonnage bands. The LoA-prices are consistent with 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.

The 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 estimation of the number of co-registrants per tonnage bands as obtained from the SIEF survey of late 2016.
- A reimbursement mechanism.

1. Cost sharing model

REC LoA for a 2013-substance Cerium Trinitrate (non-nano form)									
Calculation T0 (31-12-2016): sales of LoAs according to the Data Sharing Regulation									
D a t a	Costs in €								
	100-1000 tpy	10-100 tpy	<10 tpy						
	Multiplication factor (MF):			1.00	0.70	0.40			
	Costs of New and Existing Data:			105 476.18	105 476.18	21 831.40			
	Dossier costs:			208 498.93					
S h a r i n g	Total Reimbursable provision:			10 000.00	10 000.00	10 000.00			
	Administrative LoA handling costs:			1 500.00	1 500.00	1 500.00			
	Nbr of Co-Registrants:			3	1	4			
	Costs in €								
	100-1000 tpy	10-100 tpy	<10 tpy						
Administrative costs + Costs of New and Existing Data:				105 476.18	105 476.18	21 831.40			
Costs of New and Existing Data:				208 498.93	145 949.25	83 399.57			
Administrative dossier preparation costs:									
Total:				314 975.11	252 425.43	105 230.97			
Joint Registration Compensation per LoA:									
Share registration Specific Expenses:				70 802	49 952	13 154			
Reimbursable Provision				1 250	1 250	1 250			
Administrative LoA handling costs:				1 500	1 500	1 500			
Joint Registration Compensation LoA/tonnage band:				73 552	52 702	15 904			
				€	%	Nbr co-reg involved	Share in LoA	provision (€)	Share in provision
Min 3 tonnage bands				105 231	33%	8	13154	10 000	1 250
Diff between 10-100tpy & <10tpy				147 194	47%	4	36799	0	0
Diff between 100-1000tpy & 10-100tpy				62 550	20%	3	20850	0	0
Total:				314 975	100%				
				LoA components		LoA (€)		Provision components	
100-1000 tpy				13154	36799	20850	70 802.38	1250	0
10-100tpy				13154	36799		49 952.49	1250	0
< 10tpy				13154			13 153.87	1250	1 250

2. Price of the LoA

The prices of the LoA for the substance CERIUM TRINITRATE (CAS 10108-73-3; EC 233-297-2) per tonnage band are:

Substance	Annex IX	Annex VIII	Annex VII	OSII or TII under SCC (<1000 tpy)
CERIUM TRINITRATE	€73 552	€52 702	€15 904	€5000

3. Data used for establishing the price of the LoAs

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

CERIUM TRINITRATE (CAS 10108-73-3; EC 233-297-2)				
	Annex IX	Annex VIII	Annex VII	OSII or TII under SCC (<1000 tpy)
LoA price	€73 552	€52 702	€15 904	€5000
Provision per LoA/tonnage bands	€1 250	€1 250	€1 250	n.a.
The price of the LoA is based on the following main assumptions:				
Total provisions for future costs (°)	€10 000	€10 000	€10 000	n.a.
Number of intentions for co-registration (¹)	3	1	4	n.a.

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

(¹): based on the Survey of late 2016 and including the LR and the Members of the Consortium

The 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 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 cost). 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. 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 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.

You can also find this information on the Rare-Earth Consortium website: <http://www.rare-earth-consortium.eu/>.

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 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:

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 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.

For any further information, please contact us at Rare-Earth-consortium@arcadis.com.

Best regards,

Arcadis on behalf of the Members of the Rare Earth Consortium.