



FORMATION OF IRON SALTS SUPER-SIEF

Webinar for all pre-SIEF members
2. March 2010 at 13:00 – 14:30 CET

Agenda

13:00	Opening and introduction	H. Huttunen, Kemira Oyj
13:10	Letter of Access	A. Renard and B. Vandebulcke, ReachCentrum
13:30	Results of the 2nd SIEF survey Joint Submissions Progress Update	M. Silvennoinen, Kemira Oyj Peter Fisk Associates
13:40	Next steps for SIEF formation	H. Huttunen
14:00	Practical aspects	
14:15	Review of questions submitted via the webconferencing tool	Participants
14:30	Closure	

Introduction to SIEF formation

All potential pre-SIEF members to be contacted and the SIEFs officially formed after substance sameness agreed

Three waves of SIEF communication:

- 1st wave in January – August 2009: pre-SIEFs - done
- 2nd wave ongoing: SIEF formation - ongoing
- 3rd wave: SIEF collaboration
- 4th waves: Dossier submissions in 2010, 2013, 2018
- 5th wave: Maintenance (until at least 2022)



Introduction - Substances Covered

SIPs, first phase

Diiron tris(sulphate), EC 233-072-9, CAS 10028-22-5

Iron chloride sulphate, EC 235-649-0, CAS 12410-14-9

Iron dichloride, EC 231-843-4, CAS 7758-94-3

Iron sulphate, EC 231-753-5, CAS 7720-78-7

Iron trichloride, EC 231-729-4, CAS 7705-08-0

Substances recommended to be merged under other SIEFs

Sulfuric acid, iron(3+) salt, basic, EC 307-289-5, CAS 97592-90-0

Iron chloride (FeCl₃), hexahydrate, EC 600-047-2, CAS 10025-77-1(*)

Sulfuric acid, iron(2+) salt (1:1), monohydrate, EC 605-688-1, CAS 17375-41-6 (*)

Sulfuric acid, iron(2+) salt, heptahydrate (1:1:7), EC 616-510-7, CAS 7782-63-0 (*)

Sulfuric acid, iron(3+) salt (3:2), hydrate, EC 604-849-3, CAS 15244-10-7(*)

Sulfuric acid, iron(2+) salt (1:1), hydrate, EC 603-840-1, CAS 13463-43-9(*)

(* For hydrates, the water free form should be registered)

Proposed Registration Approach

- SIP** Diiron tris(sulphate), EC 233-072-9, CAS 10028-22-5
- SIP** Iron chloride sulphate, EC 235-649-0, CAS 12410-14-9
- SIP** Iron dichloride, EC 231-843-4, CAS 7758-94-3
- SIP** Iron sulphate, EC 231-753-5, CAS 7720-78-7
- SIP** Iron trichloride, EC 231-729-4, CAS 7705-08-0

SIP:
Substance
Identity
Profile

Joint submission IUCLID 5 dossier

Letter of Access

- content
- estimated costs
- planning for 2010, 2013 and 2018 registrations

SIEF Survey Results

- Extracted from SIEFreach
- Results handled and archived per survey
- Master list created consisting all SIEF members (status 1-4), their current SIEF status and registration deadline
 - Updated according to email requests sent by pre-SIEF members

Results of the 2nd SIEF survey (20.2.2010)

Name / Synonym	Pre-SIEF members	Answers in Total	Answer %	LR agreed	Animal Tests
Fe					
diiron tris(sulphate)	257	31	12,1	31	1
Sulfuric acid, iron(3+) salt, basic	19	10	52,6	10	0
iron dichloride	305	41	13,4	41	0
iron chloride sulphate	86	18	20,9	18	0
iron sulphate (*)	793	87	11,0	87	0
iron trichloride	617	74	12,0	74	0

The questionnaire was sent to all pre-SIEF members, and contain also answers of ALFE Consortium members. For the future, separate lists for Consortium and SIEF members Need to be maintained.



General progress update on Joint Submissions of Iron Salts

Category CSR covering all 5 salts – property data discussion well advanced, based on SIARs

Exposure scenarios for relevant common applications

Data sets in IUCLID 5:

- PFA is using the TCC tool
- PFA will provide as Inherit Template to the LR

Some new testing is under way; access to some data source reports are still being negotiated





Supporting reports

Position papers against further testing:

- repro/developmental toxicity
- longer term ecotox effects and effects in birds

Reports:

- mode of toxic action
- Toxicokinetics
- Environmental fate and behaviour of iron salts
- PNEC situation (annex to position paper)
- DNEL derivation
- PBT/vPvB assessment
- Glove permeation research

Letter: PFA input on classification and labelling

Next Steps for SIEF formation

- A SuperSIEF agreement will be prepared by Kemira using the CEFIC template
- One Iron Salt SuperSIEF agreement grants access to any of the 5 substances
- The Agreements will be distributed via Kemira's SIEF tool as SIPs have been approved for any SIEF member to join in (via a simple electronic process)
- Foreseen timing for release: April – May (as SIPs have been agreed)

Formation of ALFE Super-SIEFs – next steps

Task	Document	Implementation	Week
2. pre-SIEF collaboration and communication	<ul style="list-style-type: none"> • 3rd SIEF communication letter 	<ul style="list-style-type: none"> • Kemira (emails) 	8
3. Substance sameness check	<ul style="list-style-type: none"> • update of Consortium advertisement 	<ul style="list-style-type: none"> • RC (ALFE web), Kemira (SIEFreach public) 	8
4. SIEF Agreement/ Opt-out	<ul style="list-style-type: none"> • Substance Identity Profiles • testing method recommendation • 3rd, 4th, ... SIEF surveys 	<ul style="list-style-type: none"> • Kemira/PFA (SIEFreach) • Kemira (SIEFreach) • Kemira (SIEFreach) 	8 12...
5. JS Object and Token creation, confirmation of membership	<ul style="list-style-type: none"> • Super-SIEF agreements (incl. NDA) • 4th SIEF communication letter on progress of dossier status 	<ul style="list-style-type: none"> • Kemira (SIEFreach + other SIEF tool) • Kemira (emails) 	14... 21 20
6. SIEF Payments			
7. LoA and Token delivery	<ul style="list-style-type: none"> • 5th (6th, ...) SIEF communication on data and cost sharing, C&L proposals, JS schedule, ES and CSRs, PNEC and DNELs 	<ul style="list-style-type: none"> • Kemira (emails/other SIEF tool) 	20... 26
8. LR Dossier submission	<ul style="list-style-type: none"> • JS names, tokens, email communication 	<ul style="list-style-type: none"> • Kemira (REACH-IT + other SIEF tool/email) 	33
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11. CoR subsequent submission	<ul style="list-style-type: none"> • invoices, LoA, i5 html dossiers, Word-CSRs (if sufficient) 	<ul style="list-style-type: none"> • Kemira (other SIEF tool/email) 	34

Next steps for a SIEF participant:

- The 5 SIPs have been published in SIEFreach (under the correct EC and CAS numbers)
- Each and every registrant (Legal Entity) to make their substance identity analyses to verify how they fit into these SIPs and SIEFs and start to fill in their chapters 1...3 in IUCLID 5.2
- Test method recommendation has been published in SIEFreach
- New SIEF survey will be conducted since late March – June
- SuperSIEF agreements will be released in April – May via Kemira's SIEF communication tool (an url address will be delivered separately at that stage)

Practical aspects

Practical aspects

ALFE Consortium webpage: www.reachcentrum.eu > Consortium management > Aluminium and iron salts

SIEFreach public website: <https://www.siefreach.com/wps/portal> > Public SIEF information

SIEF communication tools:

- SIEFreach system Reachlink admin [admin@reachlink-eu.com]
- Another SIEF communication tool (link to be provided later)

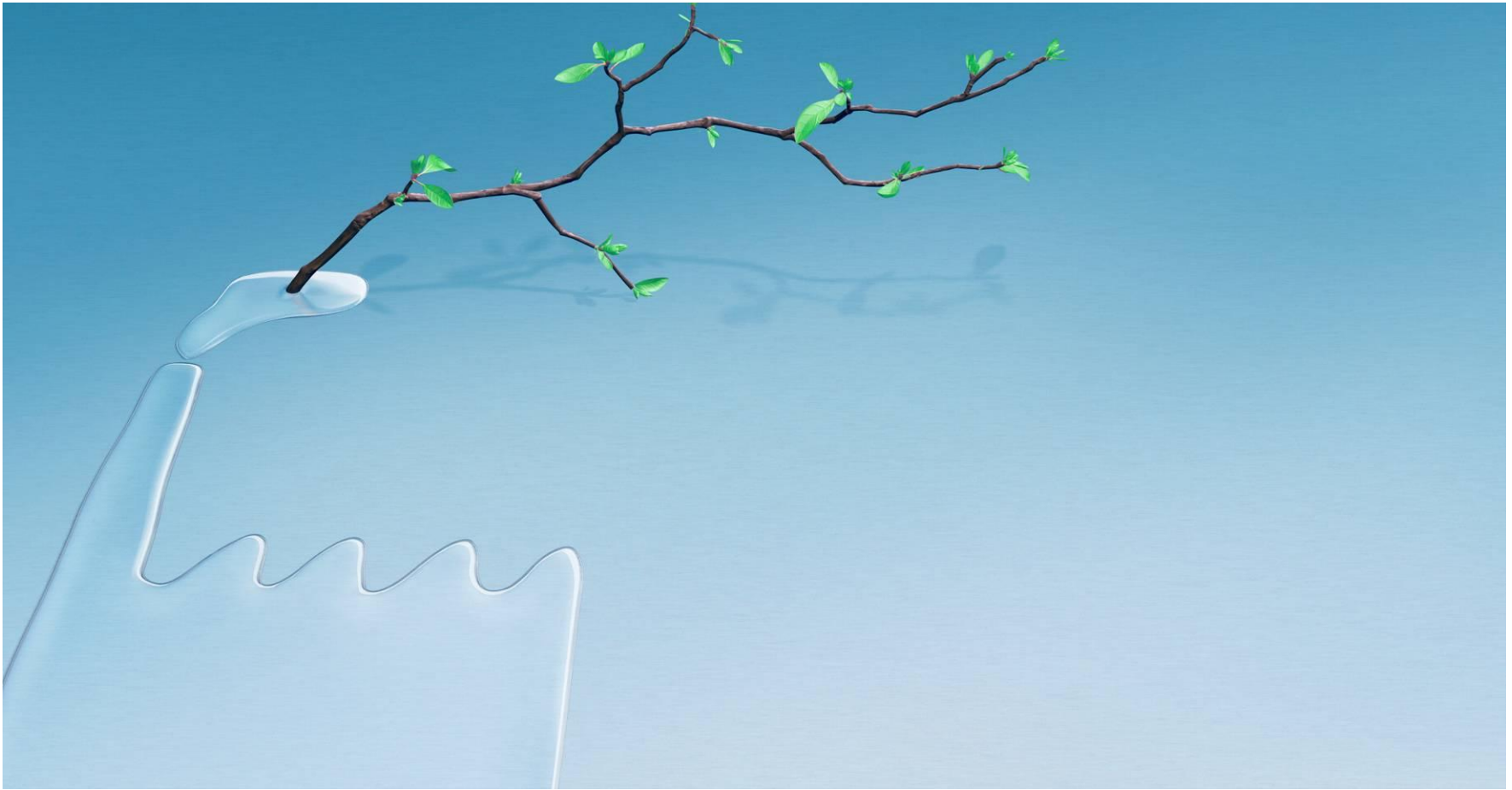
SIEF email contacts: newly launched email addresses based on the EC number of a specific substance

- i.e. iron sulphate 231-753-5@kemira.com
- To be used for all SIEF communication by Kemira and towards Kemira
- Organized archiving (per quarter year) as advantage

Consortium contact: are@reachcentrum.eu

Legal Disclaimer in any SIEF communication

"No representations or warranties are made and no liability will be accepted for damages of any nature whatsoever resulting from the action of the Lead Registrant or the results generated by it, as long as there is no contractual arrangement in place between a SIEF member and the declared Lead Registrant."



Thank you for your attention!
Please type in your questions on the webconf tool