



LIST OF PARTICIPANTS

1.	Dave Boyd	Consultant	United Kingdom
2.	Peter Fisk	PFA	United Kingdom
3.	Louise McLaughlin	PFA	United Kingdom
4.	Klaus Rothenbacher	EPMF	Belgium

MINUTES

1. Welcome & Introduction (D. Boyd)

- 1.1. Confidentiality and Competition Law
Participants were reminded to adhere to confidentiality and competition law. All participants confirmed that they are covered by specific non-disclosure agreements.
- 1.2. Approval of the agenda
LMcL suggested to add an update on the data gap analysis under AOB. Apart from that, the agenda was approved.

2. Recap of current status

- PMC gave a short update of the status of discussions with Reconcile, other than the MoU. In a recent meeting with Reconcile, it was agreed to:
- Organize an expert group meeting between Reconcile and PMC to discuss SID and sameness of the substance asap. This is the purpose of this meeting
 - It was confirmed that the existing NDA is sufficient to cover this work and ensure proper confidentiality and respect of competition law.
 - In parallel, discussions on the MoU will proceed, based on the assumption that the sameness will have been resolved when the agreement will be signed.

3. Discussion of Reach category

- It is recommended by this group that
- The product to be registered should be the 'Karstedt concentrate' as such, i.e. a solution of Pt(0)-siloxane complexes with ca. 20% Pt content
 - The CAS number 68478-92-2 for "Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes" should be used for the "Karstedt Concentrate"
 - The product fulfills the criteria for a UVCB and should be registered as such.

4. Process description

The process description is proposed:

'A chloroplatinum precursor is added to 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane. Sodium bicarbonate is added to drive the reaction to completion. The resulting insoluble sodium salt is filtered off to produce a liquid product with variable composition; due to the fact that the reaction product of Pt(O) complexes varies according to the stoichiometries of the reactants used.'

5. Spectra required

It is recommended to acquire the following spectral information for the purpose of substance identification and confirmation of sameness:

Recommended spectra

- NMR
 - o C13-NMR (to distinguish complex and free siloxane)
 - o Pt195-NMR for substance ID (Shift ranges to be agreed)



- H-NMR to assist with sameness by 'fingerprinting' (shift ranges to be agreed)
- Raman + IR for fingerprinting (wavenumber range to be agreed)
- Pt and Si content by ICP-OES

In addition, Differential Scanning Calorimetry (DSC) coupled with Thermogravimetric Analysis (TGA): this will give information on phase transitions (melting/ boiling) and can also be used to indicate potential exothermic reactions, assess if the boiling point can be determined at all (e.g., if there is decomposition), assess the amount of volatile organic components, etc.

Additional techniques (useful but not essential for sameness)

- Si-NMR
- Cl content and water content
- Headspace GC for solvents/additives

Not recommended

- UV-VIS
- GC/MS
- Other chromatography (e.g., HPLC, etc.)
- XRF

Discussion

- The oxidation state of Pt in Karstedt concentrate is typically zero. How can we assess the oxidation state of Pt?
- **Action: DB to get expert advice on this and the NMR shift ranges to be examined**
- **Action: LMCL and DB to follow up in a bilateral discussion and make a recommendation by 13th March**

6. Next steps

In order to complete the sameness discussions in time for signature of the MoU (envisaged for June 2015), a tight **schedule** will be required. The following time line is proposed:

- By 6th March: PMC to finalise minutes
- By 20th March: PMC and PFA to circulate minutes to their member for approval
- By end April: registrants to provide recommended spectra
- By end May: finalise sameness discussions

CROs for recording the recommended spectra

- For consistency it was proposed to use the same CROs as much as possible
- Action: DB and LMCL to propose labs and agree on a recommendation by 13th March**

7. AOB, next meetings/calls and closing remarks

- Status of data gap analysis (LMCL): PFA informed PMC that likely hydrolysis data will be required as a first step before a full data gap analysis can be conducted
- PMC suggested to consider metal specific methods, such as transformation/ dissolution protocol