



Sasol Germany GmbH  
SHE & Operation/Business Services (QA)  
Stephan Doll  
Marl site  
Paul-Baumann-Strasse 1  
45772 Marl / GERMANY  
Telefax +49 2365 49 6935  
[Stephan.Doll@de.sasol.com](mailto:Stephan.Doll@de.sasol.com)  
Telephone: +49 2365 49 4864  
Marl, 04.05.2018

To whom it may concern

### Confirmation

According to our risk based approach, there is no intentionally addition of elemental impurities (class 1 and 2A). Following the **ICH Q3D guideline**, we routinely analyze selected products with respect to the 4 class 1 and the 3 class 2A metals.  
With these results we show the compliance with the requirements for oral use and additionally the compliance with the max. 30% limitation of ICH Q3D. This table shows the last results by ICP-MS:

|    | Unit  | detection limit | LIPOXOL 400 MED | LIPOXOL 4000 MED SP | LIPOXOL 6000 MED powder |
|----|-------|-----------------|-----------------|---------------------|-------------------------|
| As | mg/kg | 0,1             | <0,1            | <0,1                | <0,1                    |
| Pb | mg/kg | 0,1             | <0,1            | <0,1                | <0,1                    |
| Cd | mg/kg | 0,1             | <0,1            | <0,1                | <0,1                    |
| Co | mg/kg | 0,1             | <0,1            | <0,1                | <0,1                    |
| Ni | mg/kg | 0,1             | <0,1            | <0,1                | <0,1                    |
| Hg | mg/kg | 0,1             | <0,1            | <0,1                | <0,1                    |
| V  | mg/kg | 1               | <1              | <1                  | <1                      |

We do not intentionally add elements listed in the Guidance for Industry ICHQ3D elementals impurities during the production process of LIPOXOL 400 MED, LIPOXOL 4000MED SP and LIPOXOL 6000 MED powder.

Please note that by this declaration we do not assume any liability additional to the liabilities stipulated in the sales contract or our general business conditions.

Yours sincerely

Sasol Germany GmbH

i. V. Hauke Steinhardt

i. A. Stephan Doll

#### Sasol Germany GmbH

Anckelmannsplatz 1, 20537 Hamburg      Postanschrift: Postfach 26 18 05, 20508 Hamburg  
Telefon: +49 40 63 684-1000      Telefax: +49 40 63 684-3700      [info@de.sasol.com](mailto:info@de.sasol.com)      [www.sasol.com](http://www.sasol.com)  
Geschäftsführung: Dr. Kay Luttmann (Vorsitzender)      Vorsitzender des Aufsichtsrats: Christian Schindler  
Sitz der Gesellschaft: Hamburg      Registergericht: Amtsgericht Hamburg HRB 78475