

RESIDUAL SOLVENTS STATEMENT

According to EU Directive 2009/32 modified by (EU) 2010/59 and CPMP/ICH/283/95 Q3C.

0432 CALCIUM SULPHATE 2-HYDRATE

We hereby confirm that the product referenced above is NOT manufactured using any of the solvents currently listed in the EU Directive 2009/32 modified by (EU) 2010/59 and CPMP/ICH/283/95 Q3C.

Esparreguera, December 23rd 2024

Laia Galitó
Regulatory Affairs Specialist

