

Technical Statement

Microbiological Assessment

DL-alpha-Tocopherol

PRD: 30054571

DL-alpha-Tocopherol is a pure product of synthetic origin. The water activity is very low (a_w value ~ 0.3). According to USP-NF <1112> "Application of Water Activity Determination to Nonsterile Pharmaceutical Products" products with water activity below 0.6 are not susceptible to microbial growth. In addition, the product is manufactured under the requirements of FSSC 22000 certification, which includes an approved HACCP concept. Within this HACCP system, microbiological hazards are assessed, and appropriate measures are established to prevent them. The risk for a microbiological contamination is very low.

Analysis is carried out for selected parameters on random samples.

In case of further questions or need of support please contact your local BASF representative.

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