

**Application for the Approval of Spermidine-3HCl Produced by Genetically Engineered *Saccharomyces cerevisiae* CHRYSPD3 for Use as an Ingredient in Conventional Foods, Foods for Total Diet Replacement and Weight Control and Food Supplement Products Pursuant to Regulation (EU) 2015/2283**

Non-Confidential Summary

**Applicant.**

Chrysea Labs, LDA  
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**Non-Confidential Summary.**

Spermidine hydrochloride (spermidine-3HCl) is manufactured by Chrysea Labs using a genetically engineered *S. cerevisiae*. It is an off-white to light brown powder with a minimum spermidine-3HCl purity of 90%. Spermine and putrescine are limited to not more than 1%, respectively in the novel ingredient.

The production strain has been fully characterised and the absence of antibiotic marker genes confirmed. Moreover, no viable cells or DNA from the production strain were detected in the novel ingredient. *S. cerevisiae* has QPS status and the modifications are not anticipated to pose a safety concern.

The ingredient is intended for use as a source of supplemental spermidine in yoghurts, meal replacement bars and foods for total diet replacement for weight control. The amount provided per serving in these food uses will not exceed 20 mg spermidine-3HCl, equating to approximately 11 mg of spermidine. Spermidine-3HCl is also intended for use as an ingredient in food supplement products at a level not to exceed 35 mg/day as recommended by the manufacturer, equating to approximately 20 mg of spermidine/day. The target population is the general population except for food supplements which are not intended for infants and young children.

Spermidine along with spermine and putrescine is present naturally in the diet as well as being a normal component of human tissues.

Taken together, the available data support that spermidine-3HCl as an ingredient in specific conventional foods, foods for total diet replacement for weight control and food supplement products do not pose a safety concern to humans under the conditions of intended use.