



## Saccharomyces boulardii

### STABILITY DATA

#### Description

Stability studies have been performed according to ICH (International Conference of Harmonization) under the following conditions:

- at  $25 \pm 2$  °C and  $60 \pm 5$  % relative humidity

The product put on stability has been packaged in LDPE bag, of small size, placed in fiber drum, of small size.

#### Results

The stability data at long term conditions carried out on three different batches of product show *Saccharomyces boulardii* maintains its qualitative profile for 24 months, according to the expected stability.

#### Conditions: $25 \pm 2$ °C and $60 \pm 5$ % relative humidity

##### Lot# B1D1001

	Time (months)	0	3	6	9	12	18	24
<b>Tests</b>	<b>Specification</b>							
Identification	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
Assay (viable cells) on d.b.	$\geq 2.0 \times 10^{10}$ CFU/g	$3.1 \times 10^{10}$	$3.0 \times 10^{10}$	$2.8 \times 10^{10}$	$2.8 \times 10^{10}$	$2.6 \times 10^{10}$	$2.5 \times 10^{10}$	$2.4 \times 10^{10}$
Dry substance (LoD at 110 °C, 3 h, vacuum)	$\geq 92.0$ %	92.8	92.7	92.5	92.4	92.3	92.2	92.2
Bulk density	$\geq 0.6$ g/ml	0.7	0.7	0.6	0.6	0.7	0.7	0.6
Microbiological purity:								
- Total bacterial count	$\leq 10^3$ CFU / g	Complies	-	-	-	Complies	-	Complies
- Foreign yeasts	$\leq 10^2$ CFU / g	Complies	-	-	-	Complies	-	Complies
- Moulds	$\leq 10^2$ CFU / g	Complies	-	-	-	Complies	-	Complies
- Enterobacteriaceae	$\leq 10^2$ CFU / g	Complies	-	-	-	Complies	-	Complies
- E. coli	Absent / g	Absent	-	-	-	Absent	-	Absent
- S. aureus -	Absent / g	Absent	-	-	-	Absent	-	Absent
- Salmonella sp.	Absent / 10 g	Absent	-	-	-	Absent	-	Absent

(S)Performed at release and then c

#### Conditions: $25 \pm 2$ °C and $60 \pm 5$ % relative humidity

**Lot# B1D1002**

	Time (months)	0	3	6	9	12	18	24
<b>Tests</b>	<b>Specification</b>							
Identification	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
Assay (viable cells) on d.b.	$\geq 2.0 \times 10^{10}$ CFU/g	$3.8 \times 10^{10}$	$3.7 \times 10^{10}$	$3.6 \times 10^{10}$	$3.5 \times 10^{10}$	$3.5 \times 10^{10}$	$3.4 \times 10^{10}$	$3.3 \times 10^{10}$
Dry substance (LoD at 110 °C, 3 h, vacuum)	$\geq 92.0$ %	93.0	92.9	92.8	92.8	92.8	92.6	92.5
Bulk density	$\geq 0.6$ g/ml	0.8	0.7	0.8	0.8	0.7	0.7	0.6
Microbiological purity:								
- Total bacterial count	$\leq 10^3$ CFU / g	Complies	-	-	-	Complies	-	Complies
- Foreign yeasts	$\leq 10^2$ CFU / g	Complies	-	-	-	Complies	-	Complies
- Moulds	$\leq 10^2$ CFU / g	Complies	-	-	-	Complies	-	Complies
- Enterobacteriaceae	$\leq 10^2$ CFU / g	Complies	-	-	-	Complies	-	Complies
- E. coli	Absent / g	Absent	-	-	-	Absent	-	Absent
- S. aureus -	Absent / g	Absent	-	-	-	Absent	-	Absent
- Salmonella sp.	Absent / 10 g	Absent	-	-	-	Absent	-	Absent

(§)Performed at release and then on yearly basis

**Lot# B1D1003**

	Time (months)	0	3	6	9	12	18	24
<b>Tests</b>	<b>Specification</b>							
Identification	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
Assay (viable cells) on d.b.	$\geq 2.0 \times 10^{10}$ CFU/g	$4.0 \times 10^{10}$	$3.8 \times 10^{10}$	$3.7 \times 10^{10}$	$3.6 \times 10^{10}$	$3.6 \times 10^{10}$	$3.4 \times 10^{10}$	$3.2 \times 10^{10}$
Dry substance (LoD at 110 °C, 3 h, vacuum)	$\geq 92.0$ %	93.0	92.9	92.8	92.8	92.8	92.6	92.5
Bulk density	$\geq 0.6$ g/ml	0.8	0.7	0.8	0.8	0.7	0.7	0.6
Microbiological purity:								
- Total bacterial count	$\leq 10^3$ CFU / g	Complies	-	-	-	Complies	-	Complies
- Foreign yeasts	$\leq 10^2$ CFU / g	Complies	-	-	-	Complies	-	Complies
- Moulds	$\leq 10^2$ CFU / g	Complies	-	-	-	Complies	-	Complies
- Enterobacteriaceae	$\leq 10^2$ CFU / g	Complies	-	-	-	Complies	-	Complies
- E. coli	Absent / g	Absent	-	-	-	Absent	-	Absent
- S. aureus -	Absent / g	Absent	-	-	-	Absent	-	Absent
- Salmonella sp.	Absent / 10 g	Absent	-	-	-	Absent	-	Absent

(§)Performed at release and then on yearly basis