

Stability data

Beta-Carotene 10% DC

Version 3, 07.2020

PRD no. 30061834
Manufacturing site: BASF A/S, Ballerup, Denmark

Stability study (no.) FS-000068

Storage conditions

Defined climatic conditions: 25°C ± 2°C/ 60% r.h. ± 5% r.h.
30°C ± 2°C/ 65% r.h. ± 5% r.h.
40°C ± 2°C/ 75% r.h. ± 5% r.h.

Packaging

The stability study has been performed in water-resistant aluminum foil bags, similar to the primary packaging material used for the storage and distribution of sales product.

Test attributes

The stability study includes testing of those attributes that are susceptible to change during storage and are likely to influence the quality, safety and/or efficacy.

Therefore, assay, as the most important measure for product quality and efficacy, is summarized below.

Analytical methods

Beta-Carotene 10% DC assay: spectrophotometry [%]

Long term stability results

Beta-Carotene 10% DC stored at 25°C ± 2°C/ 60% r.h. ± 5% r.h. (m: months)

Batch	Start of the study	Parameter	Specification	Start	9 m	12 m	18 m	24 m	36 m
73066264A0	2008	Assay	≥ 10.0 %	10.5	10.3	10.4	10.5	10.7	10.7
02062864A0	2008	Assay	≥ 10.0 %	10.3	10.7	10.6	10.4	10.4	10.6
20063164A0	2008	Assay	≥ 10.0 %	10.5	10.6	10.8	10.7	10.8	10.5

Intermediate stability results

Beta-Carotene 10% DC stored at 30°C ± 2°C/ 65% r.h. ± 5% r.h. (m: months)

Batch	Start of the study	Parameter	Specification	Start	9 m	12 m	18 m	24 m	36 m
73066264A0	2008	Assay	≥ 10.0 %	10.5	10.7	10.4	10.6	10.8	10.4
02062864A0	2008	Assay	≥ 10.0 %	10.3	10.5	10.5	10.4	10.4	10.6
20063164A0	2008	Assay	≥ 10.0 %	10.5	10.6	10.5	10.6	10.6	10.7

Accelerated stability results

Beta-Carotene 10% DC stored at 40°C ± 2°C/ 75% r.h. ± 5% r.h. (m: months)

Batch	Start of the study	Parameter	Specification	Start	3 m	6 m
73066264A0	2008	Assay	≥ 10.0 %	10.5	10.4	10.5
02062864A0	2008	Assay	≥ 10.0 %	10.3	10.3	10.4
20063164A0	2008	Assay	≥ 10.0 %	10.5	10.4	10.5

Conclusion:

Based on the results listed above, Beta-Carotene 10% DC is stable for at least 36 months, when it is stored in the original unopened bag at max. 25°C.

Transport temperature: max. 50°C.

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