TECHNOTES
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Stability Data for Sodium Dichloroisocyanurate

(NaDCC) Bleach Tablets (BruClean TbC™)

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Stability Data for **Sodium Dichloroisocyanurate (NaDCC) Bleach Tablets** (BruClean TbC™)

Introduction

BruClean TbC™ is a premeasured tablet that, when added to one gallon of water, creates a disinfectant cleaner that is effective against a broad array of pathogens, including MRSA, E. coli and Salmonella. This product is EPA registered (71847-2-106) and is a convenient alternative to bleach. Each tablet will produce a 937 ppm disinfectant solution when dissolved in one gallon of water. Bru-Clean TbC™ is a disinfectant and cleaner that disinfects, cleans and deodorizes precleaned, hard, nonporous, inanimate surfaces.

The active ingredient, sodium dichloroisocyanurate (NaDCC), is:

- More stable than bleach (sodium hypochlorite) - consistent strength produced at point of use for cleaning and disinfecting hard surfaces;
- Almost neutral in pH - less corrosive on surfaces than liquid bleach;
- Biodegradable – safe for the environment.

Purpose

Summarize the stability data for NaDCC Bleach Tablets (BruClean TbC).

NaDCC bleach tablets have been manufactured for more than 20 years and have amassed a substantial quantity of tablet analysis data. The purpose of this report is to summarize the stability data for the NaDCC bleach tablet under the storage conditions of 40ºC/75%relative humidity (RH) (104°F/75%RH) and 25ºC/60%RH (77°F/60%RH).

Methodology

The stability study was carried out in accordance with the International Committee on Harmonization* (ICH) guidelines with tablets stored at accelerated aging conditions of (40°C/75% RH) for 12 months and at real time conditions (25°C/60% RH) for 66 months.

Stability data summarized in Tables 1, 2 and 3 are for tub-packed 2.5 gram NaDCC Bleach Tablets stored at 40°C/75% RH and in Tables 4, 5 and 6 for tablets stored at 25°C/60% RH.

NaDCC Bleach Tablet Stability Data

Storage Condition: (40ºC/75%RH)

Table 1: Stability Data for Batch Number 4874(B)

Time (Month)	NaDCC Content (mg)	Disintegration @20ºC	Average Weight (gm)	Hardness (N)	Appearance
0	2564.93	3min 04sec	5.07gm	77-143	Complies
1	2564.90	3min 29sec	5.01gm	184-247	Complies
2	2625.06	3min 56sec	5.01gm	220-251	Complies
3	2568.36	3min 30sec	4.97gm	124-228	Complies
4	2528.85	3min 52sec	5.00gm	236-247	Complies
6	2563.21	3min 48sec	4.99 gm	221-279	Complies
12	2499.61	4min 46sec	5.00gm	210-286	Complies

* *ICH is a joint initiative involving both regulators and industry as equal partners in the scientific and technical discussions of the testing procedures which are required to ensure and assess the safety, quality and efficacy of medicines. There are six parties directly involved in the decision making process. The six parties are the founder members of ICH which represent the regulatory bodies and the research-based industry in the European Union, Japan and the USA.*

Table 2: Stability Data for Batch Number TB1085					
Time (Month)	**NaDCC Content (mg)**	**Disintegration @20ºC**	**Average Weight (gm)**	**Hardness (N)**	**Appearance**
0	2494.49	3min 23sec	5.03gm	94-121	Complies
1	2513.40	3min 08sec	4.95gm	148-172	Complies
2	2484.20	2min 55sec	5.02gm	187-232	Complies
3	2449.82	3min 29sec	4.98gm	135-198	Complies
4	2475.59	3min 14sec	4.99gm	198-242	Complies
6	2467.00	3min 27sec	5.07gm	214-256	Complies
12	2416.41	4min 09sec	5.00gm	215-247	Complies

Table 3: Stability Data for Batch Number TB1086					
Time (Month)	**NaDCC Content (mg)**	**Disintegration @20ºC**	**Average Weight (gm)**	**Hardness (N)**	**Appearance**
0	2446.40	3min 03sec	5.02gm	108-125	Complies
1	2487.60	3min 09sec	5.00gm	180-200	Complies
2	2540.88	3min 38sec	5.02gm	173-234	Complies
3	2508.23	3min 04sec	5.03gm	119-207	Complies
4	2477.31	3min 23sec	5.03gm	184-229	Complies
6	2449.82	3min 39sec	5.01gm	198-273	Complies
12	2392.14	3min 59sec	5.00gm	218-278	Complies

NaDCC Bleach Tablet Stability Data

Storage Condition: (25ºC/60%RH)

Table 4: Stability Data for Batch Number 4874(B)					
Time (Month)	**NaDCC Content (mg)**	**Disintegration @20ºC**	**Average Weight (gm)**	**Hardness (N)**	**Appearance**
0	2564.93	3min 04sec	5.07gm	77-143	Complies
3	2721.26	3min 36sec	5.01gm	138-165	Complies
12	2543.33	3min 51sec	4.94gm	160-207	Complies
36	2624.37	4min 19sec	5.04gm	206-223	Complies
66	2382.00	5min 27sec	5.00gm	185-283	Complies

Table 5: Stability Data for Batch Number TB1085					
Time (Month)	**NaDCC Content (mg)**	**Disintegration @20ºC**	**Average Weight (gm)**	**Hardness (N)**	**Appearance**
0	2494.49	3min 23sec	5.03gm	94-121	Complies
6	2552.90	2min 59sec	5.02gm	138-160	Complies
18	2441.96	2min 50sec	4.82gm	157-186	Complies
48	2571.10	2min 57sec	4.99gm	171-197	Complies
66	2355.00	5min31sec	5.04gm	217-254	Complies

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Customer Service

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Table 6: Stability Data for Batch Number TB1085

Time (Month)	NaDCC Content (mg)	Disintegration @20ºC	Average Weight (gm)	Hardness (N)	Appearance
0	2446.40	3min 03sec	5.02gm	108-125	Complies
9	2530.20	3min 01sec	5.04gm	166-186	Complies
24	2483.00	3min 32sec	5.02gm	177-255	Complies
60	2505.42	3min 39sec	5.02gm	216-235	Complies
66	2373.38	4min 22sec	5.03gm	200-264	Complies

Discussion & Conclusion

The results show that the three batches of tablets are stable at accelerated aging storage conditions for 12 months (40ºC/75%RH) and at 25ºC/60%RH storage conditions for 66 months. The parameters were remained within specification throughout the study.

Note: The 12 month stability assessment at 40°C/75% RH was completed in 2004 and the 66 month stability assessment at 25°C/60% RH was completed in 2009.