
**BLISTER PACK
ASSESSMENT**

**For The Child-Safe Packaging Group
By Burford Research Consultants**

Job No: 7/2032

21st July 1995

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BACKGROUND AND OBJECTIVES

The Child-Safe Packaging Group requested an assessment of the child resistance properties of a blisterpack among children aged 42 - 51 months (as specified in BS EN 28317 for child-resistant containers and in the US protocol).

The pack was made from 20 micron hard-tempered aluminium foil, coated on the dull side with heat seal, and 250 micron opaque white UPVC (pharmaceutical grade).

Each blister pack contained 15 placebo tablets. 300 units were supplied from which the test samples were selected at random.

There is no UK protocol for testing bubblepacks, de facto or in draft.

The USA protocol was examined and it was decided:

- a) to follow the procedures outlined in this document.
- b) to restrict the quota sample of children tested to 40 and to enter the results sequentially using the statistical charts employed currently for EN ISO 28317 and hitherto for BS 6652.

METHOD

A quota sample of 40 children aged 42 - 51 months was recruited (Appendix A). 3 nursery schools and playgroups were visited, sufficiently diverse in catchment area to cover social classes B/C1/C2/D. Two children were from ethnic minorities.

The children were tested in pairs in the environment familiar to them.

Initially they were handed a blisterpack and told:

"I want you to try and open these, you can do anything you like".

50% received the pack blister uppermost and 50% foil up.

5 minutes was allowed for opening and the number accessed in that time was recorded.

After 5 minutes children who had not yet accessed all 15 tablets received a demonstration from the Behavioural Researcher and were told:

"Please go on trying to open these, you can use your teeth if you like".

A further 5 minutes was allowed for opening i.e. 10 minutes in total.

All children remained in the test area for the full 10 minutes unless both of the pair had accessed all 15 tablets.

This procedure accords with the USA protocol.

Behavioural researchers noted:

- a) The number of tablets accessed pre-demonstration.
- b) The number of tablets accessed post-demonstration.
- c) The number of tablets accessed in total.
- d) Whether 3 tablets had been accessed because 3 paracetamol can kill a child of this age, and the time taken to achieve this.
- e) Whether all 15 tablets had been accessed and the time taken.

SUPERVISION OF TESTING

All testing was carried out under the supervision of:

Jill Cawthorne, MBE: Senior Partner
Siobhan Palluel: Senior Behavioural Researcher

of Burford Research Consultants (see Appendix B).

On the first day of testing Ian Parker of Dragon Plastics was present as an observer.

LOCATION AND TIMING OF TESTING

Testing was carried out between 6th and 17th July 1995 in Bracknell, Maidenhead and Woodley, Berkshire.

RESULTS

The following comments are based on data in tables 1 - 4.

1 Number accessed

37 (92.5% of the 40 children accessed at least 3 tablets pre-demonstration.
18 (45%) accessed all 15) 60%
6 (15%) opened 11 - 14)
9 (22.5%) opened 6 - 9

In total, after 10 minutes testing:

36 (90%) had accessed all 15 tablets and only 1 child had opened less than 3. (Table 1)

2 Times taken to access tablets

a) 3 tablets

16 (40%) children accessed 3 tablets on one minute or less.
10 (25%) took 1.01 - 3 minutes and a further 8: 3.01 - 4 minutes. i.e. 34 (85%) took under 4 minutes.

b) 15 tablets

1 - 2 mins	3)	5 - 6 mins	7)
2 - 3	3) 17	6 - 7	3) 17
3 - 4	7) (42.5%)	7 - 8	5) (42.5%)
4 - 5	4)	8 - 9	2)

Time taken has been analysed in Table 3 by sex and age. Sub-bases are too low for valid comment but no observable weighting vis à vis sample structure is recorded. One might have anticipated that older children would outstrip younger ones. (Tables 2 and 3)

3 Methods used to open

These can be summarised as follows:

	%	No
Initially: Flexed pack	35	14 (13 foil uppermost)
Picked foil open		
With nail/fingertip	32.5	13
Pushed down on bubbles	25	10
Pressed up on bubbles	10	4
	%	No
Subsequent activities:		
Poked out tablets with finger/nail	45	18
Tablets released as pressed down	30	12
Peeled off foil after tearing	25	10 (2 bent off corner of pack)

- Notes :
- : flexing of pack
 - : ease of picking foil open and tearing off in a strip
 - : one third used pressure on bubbles to access tablets
 - : facility with which small fingers poked out tablets

CONCLUSION

This pack can not be considered to be child-resistant.

Appendix A

SAMPLE STRUCTURE OF CHILDREN

Age (months)	Boys	Girls	Total
51	3	2	5
50	3	1	4
49	2	2	4
48	2	2	4
47	2	1	3
46	1	3	4
45	2	2	4
44	2	2	4
43	2	2	4
42	1	3	4
<u>TOTAL</u>	<u>20</u>	<u>20</u>	<u>40</u>

Appendix B

Burford Research Consultants was founded in 1967 as an independent research house. It remains independent.

CRC Testing

From	1975:	CRC testing formalised by BSI for pharmaceuticals. BRC accredited (BS5321).
	1985:	CRC testing extended to non-pharmaceuticals. BRC accredited (BS6652 which later subsumed 5321)
	1993:	ISO EN 28317 replaced BS6652. BRC is the sole UK company accredited by NAMAS.

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Table 1

NUMBER OF TABLETS ACCESSED PRE AND POST DEMONSTRATION

Base: 40	Pre-dem. (5 minutes)		Pre and Post-dem (10 minutes)	
	No.	%	No.	%
15	18	45.0	36	90.0
14	1	2.5	-	-
13	1	2.5	-	-
12	2	5.0	-	-
11	1	2.5	-	-
10	1	2.5	-	-
9	1	2.5	-	-
8	3	7.5	-	-
7	1	2.5	-	-
6	3	7.5	1	2.5
5	3	7.5	-	-
4	1	2.5	1	2.5
3	1	2.5	-	-
2	-	-	-	-
1	1	2.5	1	2.5
0	2	5.0	-	-
Not recorded ø	-	-	1	2.5

ø excluded due to timing failure post-dem.

Table 2
TIME TAKEN TO ACCESS: 3 TABLETS
: 15 TABLETS

Base: 40	3	15
1 - 5 secs	7	-
10	1	-
20	1	-
30	3	-
40	1	-
45	2	-
1 minute	1	-
1.01 - 2.00	4	3
2.01 - 3.00	6	3
3.01 - 4.00	8	7
4.01 - 5.00	1	4
5.01 - 6.00	1	7
6.01 - 7.00	1	3
7.01 - 8.00	-	5
8.01 - 9.00	-	2
9.01 - 10.00	-	-
Failed to access	1	3
Time not recorded	2	3

- Notes :
- : Less than five minutes or less = pre-demonstration
 - : Maximum time available = 10 minutes
 - : Some times not recorded on Day 1 as not all children on video.
 - : Subsequent test days timings taken with stopwatches.
 - : This is not part of the US protocol.

Table 3

ANALYSIS OF OPENING TIMES BY AGE AND SEX

A: 3 Tablets	42/44m	45/47m	48/51m	Male	Female	Total
Pre-Dem						
1 minute or less	4	5	7	9	7	16
1.01 - 3.00	4	2	4	5	5	10
3.01 - 5.00	3	3	3	3	6	9
Post-dem						
5.01 - 7.00	-	-	2	-	2	2
7.01 - 10.00	-	-	-	-	-	-
Failed/ not recorded	1	1	1	3	-	3
TOTAL OPENED	11	10	16	17	20	37
SAMPLE	12	11	17	20	20	40
B: 15 Tablets						
Pre-dem						
1 minute or less	-	-	-	-	-	-
1.01 - 3.00	2	2	2	4	2	6
3.01 - 5.00	3	4	4	5	6	11
Post-dem						
5.01 - 7.00	1	4	5	5	5	10
7.01 - 9.00	4	-	3	2	5	7
9.01 - 10.00	-	-	-	-	-	-
Failed to access	2	-	1	2	1	3
Time not recorded	-	1	2	2	1	3
TOTAL OPENED	10	10	14	16	18	34
SAMPLE	12	11	17	20	20	40

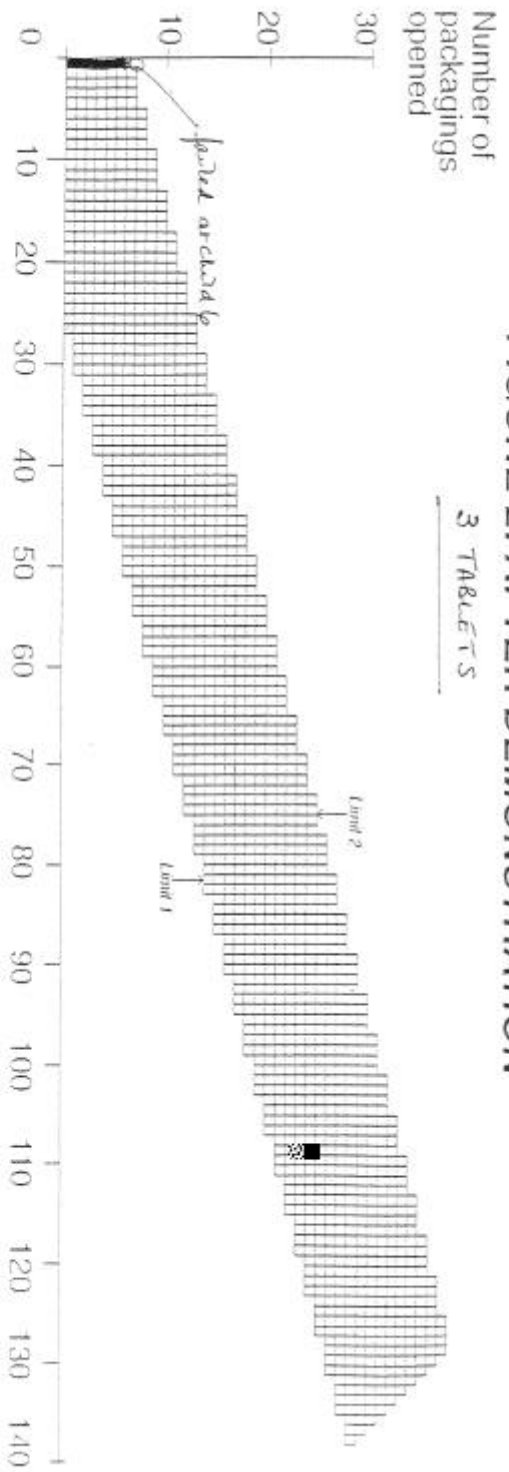
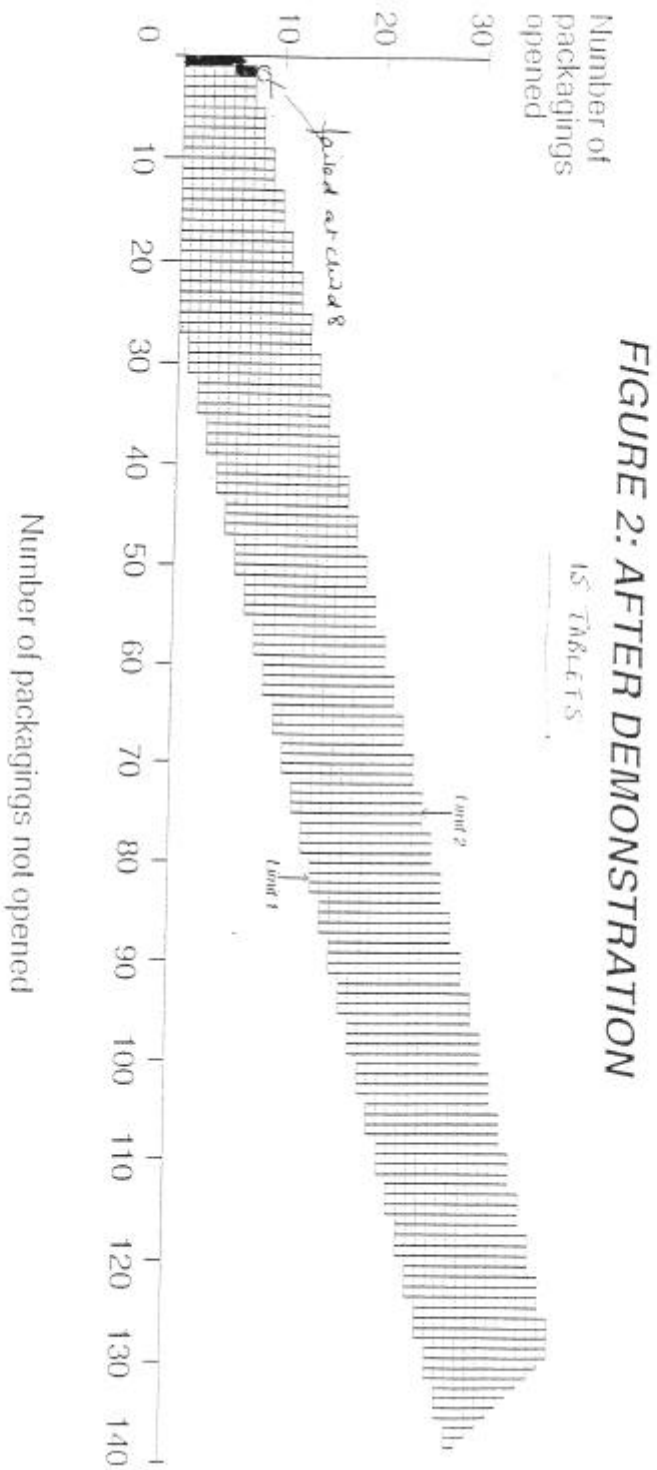


FIGURE 2: AFTER DEMONSTRATION

Note: this chart includes opens pre-demonstration as well as post-demo.



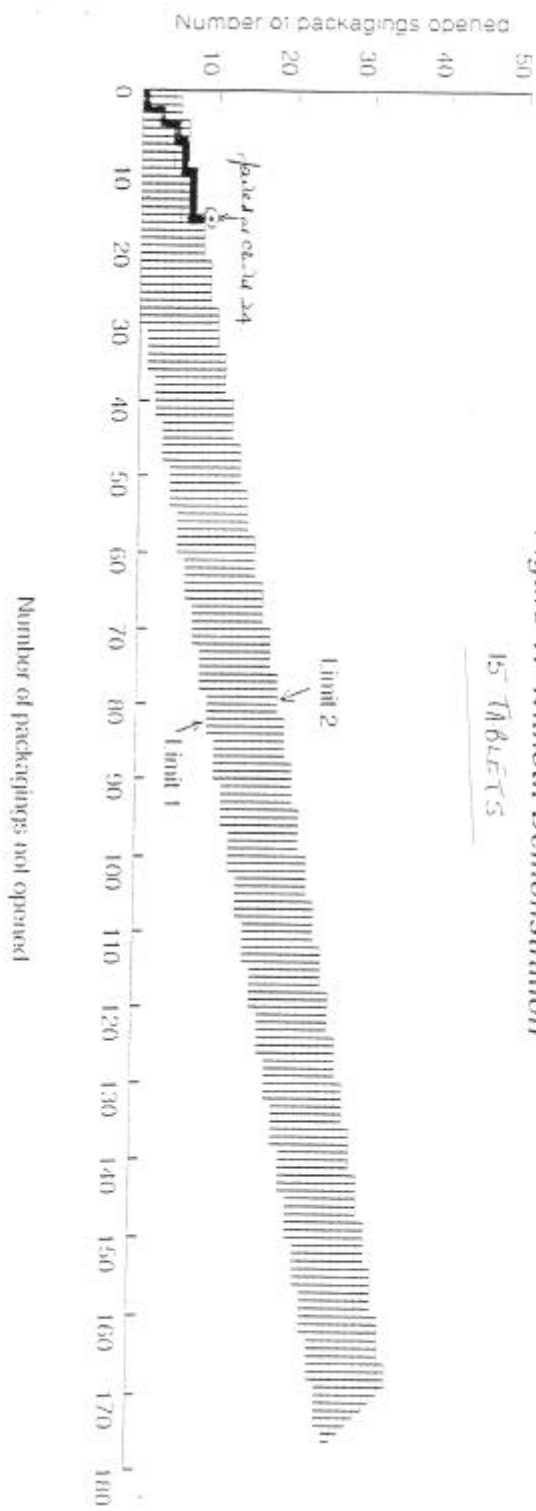


Figure 1: Without Demonstration

15 TABLETS