

Technical Construction File

File No.: TCF(15)-562

Type of Equipment:	PLASTIC BOTTLE FOR E-LIQUID
Model No.:	HL-001, HL-002, HL-003, HL-004, HL-005, HL-006, HL-007, HL-008, HL-009
Issued Date:	2015-11-03
Brand Name/ Trade mark:	HELAN
standard(s):	EN ISO 8317: 2005



Presented by

HELAN PACKING CO.,LIMITED

Zhengding Town, Shijiazhuang City, Hebei Province, China

<p>ASSEMENT REPORT</p> <p>Per</p> <p>EN ISO 8317: 2005</p> <p>Child-resistant packaging —Requirements and testing procedures for reclosable packages</p>
<p>Report</p> <p>Report reference No. : No: TCF(15)-562</p> <p>Tested by(+ signature).....: <i>Janson</i></p> <p>Reviewed by(+ signature).....: <i>Bonnie Zhang</i></p> <p>Date of issue : 2015-11-03</p> <p>Number of pages (Report) : 12</p>
<p>Testing laboratory</p> <p>Name :Shanghai changyi laboratory.</p> <p>Address:Room 612, Cimic Plaza,No.800 Shangcheng Road,Pudong New Zone,Shanghai 200120 P.R.C</p> <p>E-MAIL: changyi_lab@163.com</p>
<p>Client</p> <p>Name: HELAN PACKING CO.,LIMITED</p> <p>Address Zhengding Town, Shijiazhuang City, Hebei Province, China</p>
<p>Test specification</p> <p>Standard : EN ISO 8317: 2005</p>
<p>General product information:</p> <p>The product is PLASTIC BOTTLE FOR E-LIQUID.</p>
<p>Test Result:PASS.</p> <p>The product meets the all test requirements. The details are listed in the following documents.</p>

EN ISO 8317: 2005			
Clause	Requirement-Test	Result-Remark	Verdict
1	Scope		-
	<p>This International Standard specifies the requirements and test methods for reclosable packages designated as resistant to opening by children.</p> <p>Acceptance criteria are given for the package when tested by specified methods. These methods not only provide a measure of the effectiveness of the package in restricting access by children, but also cover the accessibility to the contents by adults.</p> <p>Reclosable packages for any product intended to be exposed or removed from the packaging in normal use are covered by the procedures. This International Standard is intended for type approval only (see 3.1) and is not intended for quality assurance purposes.</p>	The product is within the scope	P
2	Terms and definitions		-
3	General		-
3.1	Compliance with this International Standard		-
	<p>A child-resistant package tested in accordance with the requirements of this International Standard is shown to be capable, when correctly made and used, of providing a satisfactory degree of resistance to opening by children while maintaining accessibility to its contents by adults; in other words, the test is designed for type approval.</p> <p>Manufacturers and fillers of child-resistant packaging shall be required to identify the attributes of the packaging which confer resistance to opening by children of less than 52 months old and to devise and institute tests as part of an implemented and documented quality control procedure to ensure that all packages meet these child-resistance criteria. The type of testing required may be specific to the design of the child-resistant package, but the test parameters of various classifications of the Coleman Research Corporation (CRC) can be found in the American Society for Testing and Materials (ASTM) Standards Annual Volume 15.09 [1], which can be used as a basis for developing an appropriate protocol.</p> <p>The data compiled from mechanical test methods can be used to prove compliance of a package falling within a "series of similar packaging".</p>	Comply with the requirement	P
3.2	Packages for testing		-
	<p>Before child testing is carried out on reclosable child-resistant packages, both manufacturers and fillers shall satisfy themselves that the life expectancy of the child-resistant package will exceed the maximum expected number of openings and correct closings which are likely to occur in practice without resulting in unacceptable impairment of the child-resistant property.</p>	Comply with the requirement	P

EN ISO 8317: 2005			
Clause	Requirement-Test	Result-Remark	Verdict
3.3	Test panels		
	Testing is carried out with two panels of people: a) a test with young children of between 42 months and 51 months old, inclusive; b) a test with adults of between 50 years and 70 years old, inclusive.	Comply with the requirement	P
4	Requirements		-
4.1	Test requirements		-
	Whilst only new packages shall be submitted for testing, the following instructions for the evaluation of a series of similar packaging submitted at one time shall be applied; however the manufacturer and/or filler shall provide a rationale for the series which discloses the degree of commonality.		P
	If a series of closures differs only in diameter, where the largest diameter exceeds the smallest by 1,5 times, then the largest and smallest diameter closures and one intermediate closure size shall be tested.	Comply with the requirement	P
	If the container of the packaging differs only in capacity and the closures are identical, tests shall be carried out only on the largest and smallest container sizes.	Comply with the requirement	P
	If the container of the packaging differs only in capacity and the closures differ only in diameter but are similar in all essential characteristics, the largest and smallest diameters of closure fitted to the largest and smallest container shall be tested, i.e. normally four container/closure combinations subject to the 1,5 times diameter rule above.	Comply with the requirement	P
	The container and closure system tested shall be representative of those in normal use and shall include any wad or liner, if this is an integral part of the closure system.		P
	If all pass the test, containers and closures of intermediate sizes in the same series shall be regarded as conforming to this International Standard.		P
	If several container shapes are involved, but all other characteristics are the same and the closures are identical or differ only in diameter, a selection from the range shall be made to test each body shape and to ensure that the minimum requirement of at least four container/closure combinations are tested.	Comply with the requirement	P
	If all pass the test, containers and closures of other sizes in the same series shall be regarded as complying with this International Standard.		P
	If, after a range of packages has been tested and approved, sizes of packages outside the dimensions of the accepted range are to be added, they shall be tested to extend the	Comply with the requirement	P

EN ISO 8317: 2005			
Clause	Requirement-Test	Result-Remark	Verdict
	range specified.		
	All other variations shall be treated as a separate series and tested accordingly. Minor changes of container or closure can be accommodated by the development and provision of mechanical test data showing compliance.		P
4.2	Safety requirements		-
	A child-resistant package, in addition to satisfying the requirements for child resistance specified in 4.3, shall meet the requirements for packaging, such as being appropriate for the contents, providing mechanical protection and functioning properly for the life of the package.		P
4.3	Performance requirements		-
4.3.1	Requirements concerning children		-
4.3.1.1	Using a test panel of 200 children		-
	When the packaging is tested in accordance with 5.4.3, the following requirements shall be met: a) at least 85 % of the 200 children in the test panel shall be unable to open the package within the first 5 min without a demonstration b) at least 80 % of the 200 children in the test panel shall be unable to open the package within another 5 min after a demonstration has been given to those children unable to open the package in the first 5 min.	Comply with the requirement	P
4.3.1.2	Using the sequential test method		-
	If less than the full test panel is used in accordance with 6.1.2, the result is obtained from completing Figure 1 and Figure 2.		P
4.3.2	Requirements concerning adults		-
	When the packaging is tested in accordance with 5.5.2, 90 % of the eligible adults shall be able to open and properly reclose the packaging.	Comply with the requirement	P
5	Test procedures		-
5.1	Test supervision		-
	All procedures shall be carried out under the supervision of (an) impartial and appropriately qualified person(s). For the child test, the supervisor(s) shall also be skilled in handling children.		P
5.2	Sample packages		-
	Sufficient packages shall be supplied conforming to the container and closure drawings and specifications to enable a representative sample to be selected for testing by the supervisor and to provide a reserve for reference		P

EN ISO 8317: 2005			
Clause	Requirement-Test	Result-Remark	Verdict
	purposes. In every test, a new package shall be provided for each member of the test group.		
5.3	Preliminary checking and preparation		-
	<p>Before packages are tested, each package shall be opened and properly reclosed.</p> <p>Packages which incorporate an exterior tamper-evident seal in addition to being child-resistant shall have the seal broken; they shall be opened and checked by the test supervisor(s) as specified in the previous paragraph, prior to the tests.</p> <p>No hazardous product shall be used to fill any package submitted for test. A suitable substitute product shall be used for both the adult and child tests. When a substitute product is used, packages up to a volume of 1 l shall be filled to their nominal size capacity (i.e. as sold); packages greater than 1 l volume shall be filled with 1 kg of solid or 1 l of liquid substitute product as appropriate. The rationale for limiting the amount of substitute product to 1 kg of solid or 1 l of liquid is that such contents provide adequate weight to the container without causing it to become too heavy for the test panel child to be able to lift or manipulate it during the test period.</p> <p>If the closure system used on the package to be tested is torque dependant, then the packs shall be assembled by the test supervisor by hand and left for 72 h at room temperature prior to conducting tests. This is to allow materials (e.g. closure/liner/wad) to take “a set”. Application torque should be recorded in the test report. Once the packagings have been prepared for testing they should be handled carefully.</p>	Comply with the requirement	P
5.4	Child test		-
5.4.1	Guidance for persons supervising tests		-
5.4.1.1	Surroundings and personnel		-
	The surroundings and personnel should be familiar and friendly.		P
5.4.1.2	Presence of parents		-
	Children perform differently when the package is presented to them in the presence of their parents. Involvement of parents introduces a bias, as children tend to perform in accordance with implicit or explicit parental expectations. It is important, therefore, to avoid parental influence by excluding them from the test area.	Comply with the requirement	P
5.4.1.3	Presence of official observer		-

EN ISO 8317: 2005			
Clause	Requirement-Test	Result-Remark	Verdict
	If required by the regulatory body, an official observer may be present but the requirements of 5.4.1.1 still apply.	Not applicable	N
5.4.1.4	Social circumstances of the children		-
	There is a highly significant correlation between the success rate in opening packagings and the social class of children. Children should be selected to represent as closely as possible the different social, ethnic and cultural origins of the population of the country, not just of the immediate district in which the test is conducted. If this is not possible, any clear-cut deviation from this method of selection should be noted.	Comply with the requirement	P
5.4.1.5	Avoidance of extraneous distractions		-
	During the test, children should be removed from the general student body in the test location and protected from extraneous distractions.		P
5.4.1.6	Seating the children		-
	The children should be seated in pairs at tables or desks arranged in a familiar manner, or they may sit on the floor if they wish.	Comply with the requirement	P
5.4.2	Composition of test group		-
	Enough children to ensure 200 valid participants between the ages of 42 months and 51 months inclusive, with an even distribution of age and sex, shall be available. They shall all be healthy with no evident physical handicap which may affect manual dexterity. They shall not have taken part in more than one previous test and, in that test, a packaging of a different type with opening arrangements based on a different principle shall have been involved. If a child is used on more than one test panel, it is desirable that there should be at least one week between the tests. It is preferable for only one test to be carried out in one testing session, because there may be a statistically significant difference in the results between the first and second packaging tried.	Comply with the requirement	P
5.4.3	Test location		-
	The children shall perform the test in any place with which they are familiar or relaxed, for example, in their usual school or nursery, but they shall be removed from the general school population and separated from extraneous distractions. A minimum of three sites shall be used, selected from different demographic areas. No individual tester shall administer the test to more than 35 % of the children tested.	Comply with the requirement	P
5.4.4	Procedure		-
	The test may be carried out on all 200 children or by a sequential procedure. If the latter is used, the number	On 200 children	P

EN ISO 8317: 2005			
Clause	Requirement-Test	Result-Remark	Verdict
	<p>of children tested will depend on the results obtained (see 6.1.2). When testing sequentially, the age and sex constraints specified in 5.4.2 shall be adhered to. The children shall be tested in pairs, each pair being monitored by one supervisor. If desired, a number of pairs (up to five) may be tested in the same room at the same time, provided that arrangements are such that they cannot distract other pairs. They may adopt any attitude or position they find convenient. Should a child wander off during the test, action by the supervisor(s) shall be limited to leading the child back to its place and requesting that he or she continue the test, without any additional instruction being given concerning the opening of the package; this fact shall be included in the report. Each child shall be given a package with the request that it be opened by whatever means the child wishes to use; in order to achieve this, 5 min shall be allowed. No attempt shall be made to stop a child using its teeth or any other method of opening the package. However, no tools or implements should be accessible which might be used by the child, except where such tools or devices are specifically supplied as part of the design of the child-resistant package; where this is so, the children shall have unobtrusive access to that tool, but it shall not be drawn to their attention until and unless it is used in the demonstration.</p>		
	<p>If a child succeeds in opening the package within 5 min, that child shall remain in the test area until the end of the period. Any child failing to open the packaging in 5 min shall then watch a package being opened and reclosed by the supervisor in full view, without emphasis being placed on the actions of opening and without any verbal instruction. The child shall then have a further 5 min to open the package.</p>		P
5.4.5	Expression of results (see also 6.1)		-
	<p>After each period of 5 min, it shall be recorded whether a child fails to open the package; if the child succeeds, it shall be recorded whether this was before or after a demonstration. It shall also be recorded whether teeth (or any other means) were used to open the package.</p>		P
5.5	Adult test (50 years to 70 years old inclusive)		-
5.5.1	General		-
	<p>Unlike child testing, there is no need for the adults to be tested at any particular place or time.</p>		P
5.5.2	Composition of test group		-
	<p>Enough adults shall be in the test group to ensure that 100 valid participants shall be available to conduct the test</p>	100 valid participants	P

EN ISO 8317: 2005																							
Clause	Requirement-Test	Result-Remark	Verdict																				
	<p>after screening, which is done by obtaining a negative answer to the following question: “Are you professionally concerned with the design, manufacture or use of child-resistant packaging?” In order to elicit this information and, at the same time, to ascertain that the individual is literate, it is possible to present the question on a typed (printed) form and give it to the person to read. Persons with obvious physical handicaps which may affect manual dexterity should not be approached and those unable to understand the instructions should be discounted. The purpose of the test shall be explained in reasonable detail, but no demonstration shall be given. The 100 valid participants shall be randomly selected between the ages of 50 and 70 according to the criteria given in Table 1. Not more than 30 of the adults tested shall be obtained from or tested at any one site. No individual tester shall administer the test to more than 35 adults.</p> <p style="text-align: center;">Table 1 — Composition of the adult test group</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Age range (years)</th> <th>Male</th> <th>Female</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>50 to 54</td> <td>8 or 7</td> <td>17 or 18</td> <td>25</td> </tr> <tr> <td>55 to 59</td> <td>7 or 8</td> <td>18 or 17</td> <td>25</td> </tr> <tr> <td>60 to 70</td> <td>15</td> <td>35</td> <td>50</td> </tr> <tr> <td>Total</td> <td>30</td> <td>70</td> <td>100</td> </tr> </tbody> </table>	Age range (years)	Male	Female	Total	50 to 54	8 or 7	17 or 18	25	55 to 59	7 or 8	18 or 17	25	60 to 70	15	35	50	Total	30	70	100		
Age range (years)	Male	Female	Total																				
50 to 54	8 or 7	17 or 18	25																				
55 to 59	7 or 8	18 or 17	25																				
60 to 70	15	35	50																				
Total	30	70	100																				
5.5.3	Procedure		-																				
	<p>The adult test panel consists of 100 panellists. Those panellists failing the screening test are discounted and their place taken by new panellists. Each adult shall be given a package together with any accessories and written instructions on how to open and reclose it properly that will be printed in or on the package when supplied to a consumer. No demonstration of how to open or reclose the package shall be given. Acting independently, a period of 5 min shall be allowed for the test participants to familiarize themselves with the package to be tested by reading the opening and closing instructions and attempting to open and reclose it properly.</p>	Comply with the requirement	P																				
	<p>If, in this period of 5 min, a panellist is unable to open the package being tested he or she will be given a screening test. This screening test shall consist of asking the panellist to open and reclose two conventional non-child-resistant closures in 1 min each, these being: a) a 28 mm diameter continuous screw thread closure applied at 1,1 Nm torque onto a 25 ml to 50 ml cylindrical plastic container;</p>	Comply with the requirement	P																				

EN ISO 8317: 2005			
Clause	Requirement-Test	Result-Remark	Verdict
	<p>b) a 28 mm diameter “snap-on” closure applied to a 25 ml to 50 ml round plastic container.</p> <p>Panellists unable to open or reclose both of these packages in the 1 min screening test are to be discounted from the adult panel results.</p> <p>Panellists who are able to open both these packages are counted as a failure in the overall result.</p> <p>Those panellists who successfully open the test package within the 5 min period shall be given a new identical package with a request to open and reclose this one as quickly as possible. A 1 min test period shall be allowed for the panellists to open and properly reclose the packaging.</p>		
5.5.4	Expression of results (see also 6.2)		-
	Record whether or not the adult succeeds in opening and properly reclosing the package in the 1 min test periods, including the screening test if carried out, see 5.5.3 and 4.3.2.		P
6	Assessment of results		-
6.1	Child test		-
6.1.1	Success/failure		-
	The result of the test is a failure if the child succeeds in opening the package (or gaining access to the contents).	Success	P
6.1.2	Sequential method		-
6.1.2.1	Recording test results on a graph		-
	<p>As each result is obtained, it shall be plotted on the appropriate chart by filling in a square as follows: fill in a square immediately to the right of the previous result on Figure 1 if the test child failed to open the package (or gain access to the contents) in the first 5 min, and on Figure 2 if the test child failed to open the package (or gain access to the contents) in the second 5 min, i.e. the result is a success (see 6.1.1); fill in a square immediately above the previous result on Figures 1 and 2 if the test child succeeded in opening the package (or gaining access to the contents) in the first 5 min, or only on Figure 2 if the test child succeeded in opening the package (or gaining access to the contents) in the second 5 min, i.e. The result is a failure (see 6.1.1). A separate chart shall be prepared for results obtained before and after a demonstration.</p>	Not applicable	N
6.1.2.2	Determination of the results		-
	<p>The package shall be deemed to have: passed the test as soon as the trail of filled squares passes below limit line 1 on both Figure 1 and Figure 2; failed the test as soon as the trail of filled squares passes above limit line 2 on either Figure 1 or Figure 2;</p>		N

EN ISO 8317: 2005			
Clause	Requirement-Test	Result-Remark	Verdict
	if neither occurs, the results shall be assessed in accordance with the requirements laid down in 4.3.1.		
6.1.3	Full test		-
	If a sequential procedure is not used and the full number of children is tested, the results shall be assessed in accordance with the requirements laid down in 4.3.1.	Comply with the requirement	P
6.2	Adult test		-
	The result of the test is a success if 90 % or more of the eligible adults are able to open the package in the first 5 min test period and open and properly reclose it in the 1 min test period. An eligible adult is one who has not been discounted by the procedure given in 5.5.3. The result of an individual adult test is a failure if the eligible candidate opened the package in the first 5 min test but failed to open and properly reclose the package in the 1 min test period.	Success	P
6.3	Overall test result		-
	Only packaging which satisfies both the child and the adult test criteria as specified in clause 4.3.1.1 and 4.3.2 shall be deemed to conform to this International Standard.	conform to this International Standard	P
7	Test report		-
7.1	General		-
	At least the following information shall be recorded by the supervisor: a) the name of the agency carrying out the test; b) the date(s) on which the test was carried out; c) the name and address of the manufacturer and/or filler/packer of the package tested; d) the name(s) of the person(s) supervising the test; e) the specification number, drawing numbers and a complete description of the package tested; f) a direct quotation of the exact instructions, etc. given to the adults and the children during the test; g) a copy of the manufacturer's instructions on opening and reclosing the package given to the adults during the test; h) a description of the substitute product used in the test.	HELAN PACKING CO.,LIMITED Zhengding Town, Shijiazhuang City, Hebei Province, China	P
7.2	Child test		-
	At least the following information shall be recorded: a) the location of the test; b) the number, name, age and sex of the children involved; c) the number of children, together with their age and sex, who successfully opened the package 1) before a demonstration, 2) after a demonstration,	200 children	P

EN ISO 8317: 2005			
Clause	Requirement-Test	Result-Remark	Verdict
	3) the means used by the children who were successful in opening the packaging; d) if the full child test has been carried out, the percentage number of children who failed to open the package.		
7.3	Adult test		-
	At least the following information shall be recorded: a) the number, age and sex of the adults involved; b) the number, age and sex of adults who successfully opened and reclosed the package properly; c) the number who opened but could not reclose the package properly; d) the number who failed to open the package.	100 valid participants	P
7.4	Additional (optional) information to be recorded		-
	Any other information deemed to be useful in assessing the interpretation of the result, such as the time required for adults and children to open the package and, where appropriate, to reclose it properly, the method used by children to gain access, etc. shall be recorded.	See the instruction book	P
7.5	Overall test result		-
	It shall be recorded whether the overall result of the test was a pass or a failure.		P

Product Picture

