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THE RESEARCH NETWORK ŁUKASIEWICZ – ŁÓDŹ INSTITUTE OF TECHNOLOGY

LABORATORY OF MATERIALS AND CONSUMER PACKAGING TESTING

# STUDIES ON THE PACKAGING PROTECTED AGAINST THE UNDESIRED OPENING BY A CHILD (CRP PACKAGING AND CLOSURES)

## BADANIE OPAKOWAŃ ZABEZPIECZONYCH PRZED NIEPOŻĄDANYM OTWARCIEM PRZEZ DZIECKO (OPAKOWANIA CRP I ZAMKNIĘCIA)

**ABSTRACT:** To protect the children against the incidents connected with swallowing of dangerous substances and pharmaceuticals, the packaging intended for medicines and dangerous substances should be so designed as to make their opening by children impossible. The studies of CRP (Child Resistant Packaging) packaging are carried out in accordance with three standards, depending on the destination of the packaging.

**Key words:** children, CRP packaging, designing of packaging, dangerous substances

**STRESZCZENIE:** W celu ochrony dzieci przed wypadkami związanymi z połyknięciem substancji niebezpiecznych, farmaceutyków opakowania przeznaczone na leki oraz substancje niebezpieczne powinny być tak projektowane, aby uniemożliwić ich otwarcie przez dzieci. Badania opakowań Child Resistant Packaging (CRP) wykonywane są zgodnie z trzema normami, w zależności od przeznaczenia opakowania.

**Słowa kluczowe:** dzieci, opakowania CRP, projektowanie opakowań, substancje niebezpieczne

The basis function of packaging is to preserve the quality of the products during their storage, transport, delivery, sale and application. During the design work, the type of the packed product, its properties and, also, individual legislation requirements, are significant. The design guidelines concern the structure of ready packaging as well as raw materials from which the packaging is manufactured. The packaging equipped with the closure making opening for the children difficult and with tactile warning about the danger are especially important group of packaging. The civilisation progress and development of industry which offers new chemical products have caused that the availability of the products, potentially dangerous to man, is increasing. The small children are especially endangered

to acute accidental poisoning, what is connected with the natural need of familiarization with the surrounding world, using sense of taste, with the simultaneous lack of awareness of the possible threats. The group of the products, being the greatest danger for the children includes pharmaceuticals, cosmetics and domestic cleaning agents [1, 2]. The packaging protected against undesired opening by the children must be so designed as to minimize the risk of opening of packaging, containing the products that create a potential hazard. The packaging safe for the children cannot look as the packaging for food, cannot possess shape or graphic decoration which might attract the attention of the children.

TAB.1. CATEGORIES OF SUBSTANCES AND MIXTURES WHICH REQUIRE CRP PACKAGING

Category (class) of hazard	Closures making opening by the children difficult
Acute toxicity (categories 1-3)	x
Specific Target Organ Toxicity (STOT) single exposure (category 1)	x
Specific Target Organ Toxicity (STOT) repeated exposure (category 1)	x
Corrosive effects to the skin (categories 1A, 1B, 1C)	x
Hazard caused by aspiration (category 1) (Except for substances or mixtures in a form of aerosol or in hermetic container with atomizer, under the condition that they are not classified into another hazard category, subjected to the rules in respect of CRF or TWD)	x

The Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and Regulation (EC) No 1907/2006 specifies which substances and mixtures must be packed in a way protected from the children [3]. Packaging of CRP type (Child Resistant Packaging), as containing the hazardous substance or mixture cannot be designed in a way which creates the probability of attracting the attention of the children, induces their curiosity, or misleads the consumers.

List of hazardous substances and hazardous mixtures, the packaging of which are equipped with the closures making the opening by the children difficult is given in Tables 1 and 2.

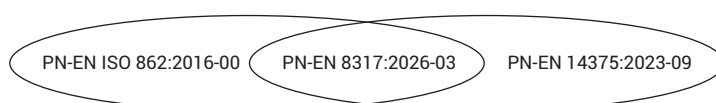
In the case of pharmaceutical product packaging in Poland, there is no legal regulation, commanding the application of specified types of packaging, being protected against undesired opening by a child.

Testing of RCP packaging is conducted according to the following standards [4 – 6]:

- PN-EN 862:2016-09 Packaging-Child-resistant packaging- Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products

- PN-EN ISO 8317:2016-03 Child-resistant packaging- Requirements and testing procedures for reclosable packages.
- PN-EN 14375:2023-09 Child-resistant non-reclosable packaging for pharmaceutical products-Requirements and testing

HAZARDOUS SUBSTANCES/PRODUCTS      PHARMACEUTICAL PRODUCTS



The tests – in conformity with the standards – are employed in relation to the packaging of pharmaceutical and chemical products such as detergents, disinfectants, washing pellets, e-cigarettes and plant protection agents, containing the substances listed in the Regulation [3].

The test packaging must be filled with the appropriate safe replacer e.g. water, peas etc.

The tests of the packaging protected against the undesired opening by a child have two-part procedure of testing. The first one includes the tests in a group of the children at the age of 42 – 51 months of life. In the mentioned group, we have to consider the proportional classification according to age and

TAB.2. SUBSTANCES WHICH REQUIRE APPLICATION OF CRP PACKAGING

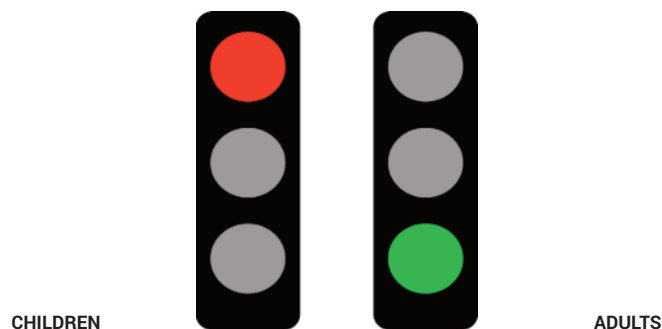
Identification of substance	Concentration limit	Closure making opening by the children difficult
Methanol (No CAS 67-56-1)	3%	x
Dichloromethane (No CAS 75-09-2)	1%	x

gender and, also, representativeness in respect of social, ethnic and cultural origin. During the test, the child should not test more than one package even in the case of their different construction. The test is carried out in the site which is well known to the child (e.g. at the kindergarten), far from the children who do not participate in a given test and far from the external factors, which disperse the attention of the child, and at the presence of a person who supervises the test.



In the second part of the mentioned procedure, the test is carried out with the group consisting of 100 adult persons (30 men and 70 women) at the age of 50-70 years. The test may be attended by the persons not related to designing, production and application of the packaging protected against the undesirable opening by the children. The test with the participation of the adult persons may be conducted at any place and any time.

The packaging is considered as protected against the undesirable opening by the children if at least 85% of the children from the research group were not able to gain an access to the packaging during 5 minutes. The result of the test with the participation of the adults is considered as positive when at least 90% of the adult persons open the packaging during 1 minute.



The packaging recognised as protected against undesired opening by the children cannot be opened by a child whereas a group of the adults must have an easy access to the packaging.

## LITERATURE

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2. J. Bursa, 2020 „Zatrucia u dzieci i młodzieży, Polska Platforma Medyczna (In English: „Poisoning in children and young people”, *Polish Medical Platform*)
3. Rozporządzenie Parlamentu Europejskiego i Rady (WE) nr 1272/2008 z dnia 16 grudnia 2008 r. w sprawie klasyfikacji, oznakowania i pakowania substancji i mieszanin, zmieniające i uchylające dyrektywy 67/548/EEG i 1999/45/WE oraz zmieniające rozporządzenie (WE) nr 1907/2006 (In English: The Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending the Regulation (EC) No 1907/2006)
4. PN-EN 862:2016-09 Opakowania – Opakowania zabezpieczone przed otwarciem przez dziecko-Wymagania i metody badań opakowań nieprzystosowanych do wielokrotnego zamknięcia na produkty inne niż farmaceutyczne. (In English: Packaging-Child-resistant packaging-Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products)
5. PN-EN ISO 8317:2016-03 Opakowania zabezpieczone przed otwarciem przez dziecko – Wymagania i metody badań opakowań przystosowanych do wielokrotnego zamykania. (In English: Child-resistant packaging-Requirements and testing procedures for reclosable packages.)
6. PN-EN ISO 14375:2023-09 Opakowanie do produktów farmaceutycznych, nieprzystosowane do wielokrotnego zamykania, zabezpieczone przed otwarciem przez dzieci. Wymagania i badania (In English: Child-resistant non-reclosable packaging for pharmaceutical products-Requirements and testing).

Laboratory of Materials and Consumer Packaging Testing as acting under the frames of Łukasiewicz research Network-Lódź Institute of Technology conducts the tests of packaging protected against undesired opening by a child in compliance with the standards: PN-EN ISO 862:2016-00, PN-EN 8317:2026-03 and PN-EN 14375:2023-09. The tests are covered with the accreditation of Polish Centre for Accreditation No AB 185.