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(54) **SAFETY CAP WITH A GUARANTEE ELEMENT, ESPECIALLY FOR THE PHARMACEUTICAL INDUSTRY**

(57) A safety cap, having at least, one securing element (1) which engages with a bottle neck, and an internal closing element (4), mounted in the inside of an external element (5), wherein the at least one securing el-

ement is connected and meshes - with its thread (2), made on its lateral side - with the thread (3) of the internal closing element, the external element being movably mounted on the internal closing element.

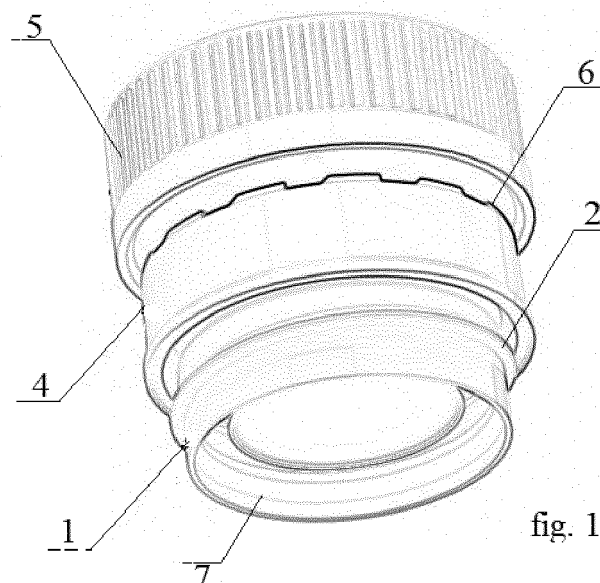


fig. 1

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Description

[0001] The subject of the invention is a safety cap with a securing element, in particular, for the pharmaceutical industry, to prevent opening of the container with active substance, especially by children, provided with a securing element, which allows for an identification of any previous opening of the container.

[0002] Various design concepts of caps have been known, which allow access to the container's contents, e.g., a medicinal substance, for unauthorised persons. Most often, children are regarded to be such unauthorised persons, therefore, special safety caps are used, the opening of which requires the application of certain force, much exceeding the physical abilities of the child. Additionally, in order to determine whether a given product packaging has previously been opened or tampered with in any other way, various securing elements are applied, the breaking of which alerts that the packaging was tampered with before.

[0003] It follows from Patent Description No. US3827592 that "a system of safety cap for a container", has got a system of internal grooves, fitting the container's neck in their shape, so that cap removal is not possible without the use of a special wrench.

[0004] An example of a cap with a tampering/opening indicator is the container, known from Patent Description No. EP0421590, as having a concave top as the opening indicator. When the container is opened, the concave top becomes convex in result of the air, which enters the container and compensates the negative pressure, while the change is visible with bare eyes. After the container is closed again, there is no more negative pressure in it, thus it is not possible to "deceive" closure and create the status, corresponding to the original container's closure.

[0005] Another safety cap, known from Patent Description No. WO8902858, has got an internal, cap sealing element, with an external cover, configured in such a way as to allow its shifting between two locations: the first one, where it freely rotates, and the second one, where it engages with the internal, closing element. The cap has got a tension mechanism, forcing return of the external part from position two back to position one. The closing element becomes relocated or damaged during the shift of the cover from position one to position two.

[0006] There is also a safety cap, known from Patent Description No. US4553678mm which, when turned, a special tooth on its edge, tampers with the film layer, covering the containers neck, cutting or tearing it. The film is attached to the container's neck, for example, by welding. The locking mechanism, which enables opening only, when the cap is pressed, can be removed in order to enable the container opening in a traditional way. This cap may also be used as an indicator of the packaging being opened or tampered with.

[0007] There are also caps with a securing element, made directly or indirectly on their internal or external part; the securing element is annular in shape and, while

rotating the cap around the container's neck, it catches in various way the neck blocking elements. Patent Description No. KR200410173 reveals a design concept of a cap, the internal part of which engages the external part via a system of teeth, made on the lids, which close both parts, while the lower surface of one part of the cap is provided with a securing, annular tape, which is attached to it. The closure tightness is to be ensured by a gasket, mounted between the cap and the neck, preferably as gasket welded into the neck structure.

[0008] The known solutions, despite the effectiveness of access protection systems on containers, e.g., with medicinal products, require, sometimes, very complex production operations, associated with their manufacture or guarantee of container tightness. In addition, in case of caps with securing tapes, annular in shape, it is important to ensure proper thickness of the narrowing parts, connecting the ring of the securing tape, in order to prevent their rupture when the cap is tightened. Therefore, it has been appropriate to design a safety cap, especially for the pharmaceutical industry, which will eliminate the manufacturing problems, associated with ensuring proper connection between the securing tape and the cap, while simultaneously maintaining proper tightness of the container's closure. Additionally, the goal of the invention was the development of design concept for cap, especially for the pharmaceutical industry, eliminating the need of using an aluminium insert, inductively welded to the edge of the container's neck and thus elevating the production costs and increasing container filling and closing process duration.

[0009] The safety cap, according to the invention, has got, at least, one securing element which, with its thread on its lateral side, engages the thread of the internal closing element and a movable external element, mounted on the internal closing element. The internal closing element and the external element are both in shape of unilaterally closed cylinders with mutually matching locking systems, preferably as splines, oriented towards each other and meshing each other. The splines are preferably located on the oriented towards each other bases of unilaterally closed cylinders and, in their contact, they mesh with each other, at least unilaterally, during rotation of the unilaterally closed cylinders vs. each other. In another example, the splines are arranged on the lateral, external surface of the internal closing element and on the lateral, internal surface of the external element.

[0010] The internal lateral surface of the internal closing element has got a thread, meshed with the thread on the lateral surface of the securing element.

[0011] The securing element, preferably manufactured of soft and deformable plastic, which preferably is LDPE, and in basic shape of unilaterally closed cylinder, pressed onto the neck of a container, especially of a container used in the pharmaceutical industry, and locked on the neck of this container with a locking system, mounted on the internal, lateral surface of the securing element.

[0012] The locking system assumes the form of, at least, one narrowing, decreasing the cross-section of the open side of the securing element and, at least, one spline, which preferably is a ring on the container's/bottle's neck, where the spline preferably engages with the locking system.

[0013] There is a cavity in the base of the securing element, in which, at least, one overpress is made, while the central part of the cavity, separated by the overpress, is provided with a cotter pin. It is preferable if the cotter pin assumes the form of an eye, connected with the central part of the cavity.

[0014] The securing element, the internal closing element and the external element are set up together and delivered to the packaging line, especially of pharmaceutical products, whereby, after the containers are filled with products, the sets are pressed or knocked on the necks of containers in one production operation, thus eliminating the actual series of operations, including the installation of an aluminium insert, the inductive welding of the insert with the container's neck and mechanical or manual closing of the container with the cap. With regards to the above, the production line performance increase, while production costs demonstrate a significant decrease, especially the costs associated with packaging container closing operations.

[0015] In the first opening of a container with the cap, according to the invention, the user at first twists the mutually matching internal closing element and the external element, then, using the cotter pin, tears off the internal part of the securing element, separated by the overpress. After the contents of the container are picked up, the internal closing element and the external element are screwed again on the securing element, what ensures further protection of the container against unauthorised access, especially by children.

[0016] Safety cap with a securing element, especially for the pharmaceutical industry, has been presented on the drawing, at which, fig. 1 presents a view of the set up together cap elements, fig. 2 presents a view of the securing element, Fig. 3 presents a view of the internal closing element, fig. 4 presents a view of the set up together cap elements, according to the invention.

Example I

[0017] The safety cap, according to the invention, has got one securing element 1 which, with its thread 2 on its lateral side, meshes with thread 3 of the internal closing element 4 and an external element (5), movable mounted on the internal closing element 4. The internal closing element 4 and the external element 5 are both in shape of unilaterally closed cylinders with mutually matching locking systems, assuming the form of splines 6, oriented towards each other and meshing each other. The splines 6 are located on the oriented towards each other bases of unilaterally closed cylinders and, in their contact, they mesh with each other, at least unilaterally,

during rotation of the cylinders, unilaterally closed vs. each other.

[0018] The internal lateral surface of the internal closing element has got a thread, meshed with the thread on the lateral surface of the securing element.

[0019] The securing element 1 is manufactured of soft and deformable plastic - LDPE - and is in basic shape of unilaterally closed cylinder, knocked onto the neck of a container, especially of a container used in the pharmaceutical industry, and locked on the neck of this container with a locking system, mounted on the internal, lateral surface of the securing element.

[0020] The locking system 7 assumes the form of, at least, one narrowing, decreasing the cross-section of the open side of the securing element 1 and, at least, one spline in the form of a ring 12 on the container's/bottle's neck, where the spline engages with the locking system 7.

[0021] There is a cavity 8 in the base of the securing element 1, in which, an overpress 9 is made, while the central part of the cavity, separated by the overpress, is provided with a cotter pin 10. The cotter pin 10 assumes the form of an eye, connected with the central part of the cavity.

[0022] The securing element 1, the internal closing element 4 and the external element 5 are set up together and delivered to the packaging line, especially of pharmaceutical products, whereby, after the containers are filled with products, the sets are pressed or knocked on the necks of containers in one production operation, thus eliminating the actual series of operations, including the installation of an aluminium insert, the inductive welding of the insert with the container's neck and mechanical or manual closing of the container with the cap. With regards to the above, the production line performance increases, while production costs demonstrate a significant decrease, especially the costs associated with packaging container closing operations.

[0023] In the first opening of a container with the cap, according to the invention, the user at first twists the mutually matching internal closing element 4 and the external element 5, then, using the cotter pin 10, tears off the internal part of the securing element, separated by the overpress 11 of the securing element 1. After the contents of the container are picked up, the internal closing element 4 and the external element 5 are screwed again on the securing element 1, what ensures further protection of the container against unauthorised access, especially by children.

Example II

[0024] The safety cap, according to the invention, has got one securing element 1 which, with its thread 2 on its lateral side, meshes with thread 3 of the internal closing element 4 and an external element (5), movable mounted on the internal closing element 4. The internal closing element 4 and the external element 5 are both in

shape of unilaterally closed cylinders with mutually matching locking systems, assuming the form of splines 6, oriented towards each other and meshing each other. In another example, the splines are arranged on the lateral, external surface of the internal closing element and on the lateral, internal surface of the external element.

[0025] The internal lateral surface of the internal closing element has got a thread, meshing with the thread on the lateral surface of the securing element.

[0026] The securing element 1 is manufactured of soft and deformable plastic - LDPE - and is in basic shape of unilaterally closed cylinder, knocked onto the neck of a container, especially of a container used in the pharmaceutical industry, and locked on the neck of this container with a locking system 7, mounted on the internal, lateral surface of the securing element 1.

[0027] The locking system 7 assumes the form of, at least, one narrowing, decreasing the cross-section of the open side of the securing element 1 and, at least, one spline in the form of a ring 12 on the container's/bottle's neck, where the spline engages with the locking system 7.

[0028] There is a cavity 8 in the base of the securing element 1, in which, an overpress 9 is made, while the central part 11 of the cavity 8, separated by the overpress, is provided with a cotter pin 10. The cotter pin of claim 10, wherein the cotter pin (10) assumes the form of an ear, connected with the central part (11) of the cavity (8).

[0029] The securing element 1, the internal closing element 4 and the external element 5 are set up together and delivered to the packaging line, especially of pharmaceutical products, whereby, after the containers are filled with products, the sets are pressed or knocked on the necks of containers in one production operation, thus eliminating the actual series of operations, including the installation of an aluminium insert, the inductive welding of the insert with the container's neck and mechanical or manual closing of the container with the cap. With regards to the above, the production line performance increases, while production costs demonstrate a significant decrease, especially the costs associated with packaging container closing operations.

[0030] In the first opening of a container with the cap, according to the invention, the user at first twists the mutually matching internal closing element 4 and the external element 5, then, using the cotter pin 10, tears off the internal part of the securing element 1, separated by the overpress 9. After the contents of the container are picked up, the internal closing element 4 and the external element 5 are screwed again on the securing element 1, what ensures further protection of the container against unauthorised access, especially by children.

Claims

1. The safety cap of the invention, has got, at least, one securing element (1), which it engages with the bottle

neck and internal closing element (4), mounted in the inside of the external element (5), wherein, at least, one securing element (1) is connected and meshes - with its thread (2), made on its lateral side - with thread (3) of the internal closing element (4) and with the external element (5), movable mounted on the internal closing element (4).

2. The closing cap of claim 1, wherein the internal closing element (4) and the external element (5) are in shape of unilaterally closed cylinders with a system of mutually matching locking mechanisms.

3. The closing cap of claim 2, wherein the system of locking mechanisms assumes the form of splines (6), oriented towards each other and meshing with each other

4. The closing cap of claim 3, wherein the splines (6) are located on the bases of unilaterally closed cylinders, wherein the bases are oriented towards each other and engage with each other, at least, unilaterally during rotation of the unilaterally closed cylinders against each other.

5. The closing cap of claim 3, wherein the splines (6) are located on the lateral, external surface of the internal closing element (4) and on the internal, lateral surface of the external element (5).

6. The closing cap of claim 1 or claim 2 or claim 3 or claim 4 or claim 5, wherein the internal, lateral surface of the internal closing element (4) has got a thread, meshing with the thread on the lateral surface of the securing element (1).

7. The closing cap of claim 1 or 2 or 3 or 4 or 5 or 6, wherein the securing element (1), made of soft and deformable plastic, is in basic shape of unilaterally closed cylinder, knocked into the neck of a container, especially a container used in the pharmaceutical industry, where the cylinder is locked on the neck of the container with a locking mechanism (7), mounted on the internal, lateral surface of the securing element (1).

8. The closing cap of claim 7, wherein the securing element (1) is made of LDPE plastic.

9. The closing cap of claim 7 and 8, wherein the locking mechanism (7) assumes the form of, at least, one narrowing, which decreases the cross-section of the open side of the securing element (1) and of, at least one spline (12), preferably annular in shape, located on the neck of the container/bottle, where the spline engages with locking mechanism (7).

10. The closing cap of claim 1 or 2 or 3 or 4 or 5 or 6 or

7 or 8 or 9, wherein there is a cavity (8), made in the base of the securing element (1), the cavity having an overpress (9), which separates the central part (11) of the cavity (8), where the central part has got a cotter pin (10).

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11. The cotter pin of claim 10, wherein the cotter pin (10) assumes the form of an ear, connected with the central part (11) of the cavity (8).

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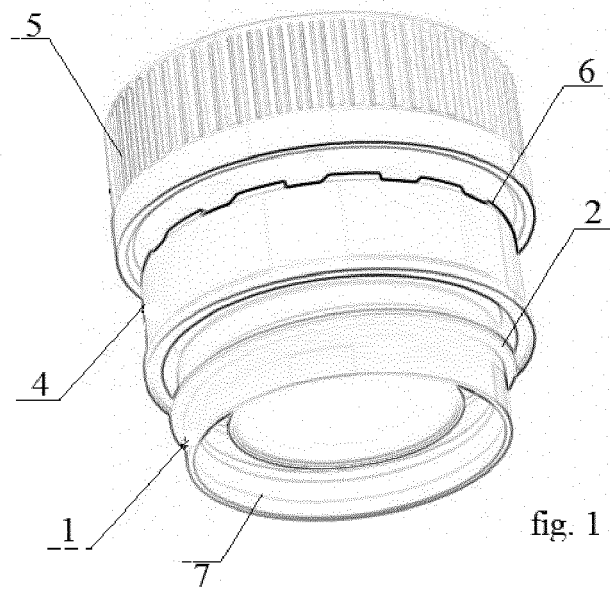
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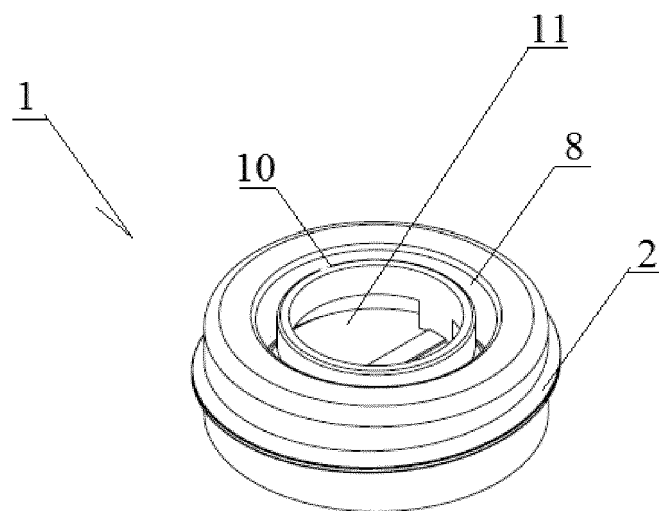


fig. 2

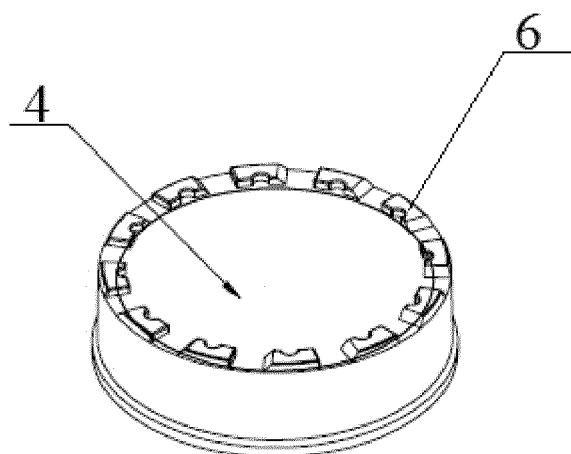


fig. 3

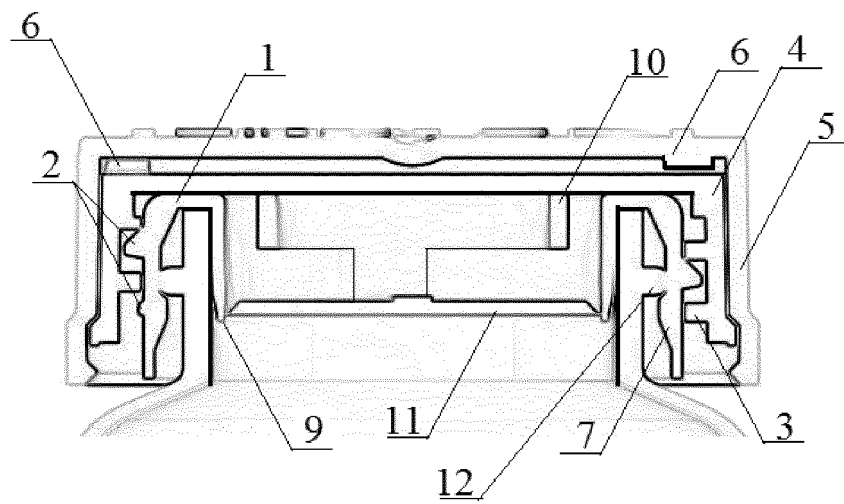


fig. 4



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Application Number
EP 15 16 7038

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Place of search		Date of completion of the search	Examiner
The Hague		1 October 2015	Newell, Philip
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