

Method for Reducing Microbiological Contaminants of Container Products

The invention relates to a method for reducing the microbiological impact of container products, which are mainly made from plastic material, in which a plastic granulate is supplied to an extruder device, which melts the granulate, which granulate is subsequently transferred to a blow molding, filling and sealing production machine for obtaining the respective container product.

When producing plastic containers including ampule products for foods, cosmetics or for medicinal purposes, in particular ophthalmics, parenterals or for artificial feeding, the microbiological quality of the filling material is critically important. The specifications set out in the international pharmacopoeia must be satisfied. A decisive factor is on the one hand the sterility of the filling material before the filling, which can be achieved for example by means of sterile filtration. Another decisive factor is the sterility of the inner container surfaces of the plastic container products.

In this document, "microbiological contaminants" should be understood as a collective term to refer to bacteria, spores, yeasts, fungi, viruses and endotoxins, which were previously also referred to as pyrogens in technical parlance. The technical English term also used in this regard is "bioburden".

The prior art has already provided suggestions for minimizing or largely preventing microbiological contaminants. For example, document DE 10 2008 032 635 A1 describes a food and drinks industry method and device for microbiologically optimized production of blow-molded plastic containers. In the known solution this involves the supply during the blowing operation for the plastic container of a medium, for example in the form of air, to the inside of the corresponding premolding, at a temperature of between 80°C and 140°C, said measure serving as a sterilization for the killing of bacteria. In order for this method to be effective, in view of the relatively low

treatment temperatures, very long treatment times are required, certainly in the region of several hours, in order to sustainably prevent a build-up of bacteria.

Document DE 10 2011 008 132 A1 furthermore describes a method and a device for the production of blow-molded, at least partially sterile containers, in which a premolding made of a thermoplastic material is initially heated and is then stretched by a stretching rod and has a pressurized fluid applied to it, and a sterilizing agent is additionally supplied in the region of the premolding. The known method preferably uses as a sterilization agent vaporized hydrogen peroxide, which is mixed with hot air, with the hydrogen peroxide concentration being approximately 15 to 35 percent by weight. The breakdown products of such chemical sterilization agents can contaminate the filling material and can have harmful toxicological consequences.

Document DE 695 20 445 T2 disclosed a method and an associated device for the sterile packaging of a drink, in which, as part of the blow molding step for the container, said container is heated to a temperature which is sufficient to sterilize the inside of the container. Because a reliable sterilization requires temperatures significantly higher than 200°C for a time period of several minutes, the choice of plastics for the container material for this known method is correspondingly limited and the polymers preferably used for the packaging of pharmaceuticals, such as polyethylene or polypropylene, can thus not be used at all due to their low working or melting temperatures.

Furthermore, document DE 10 2008 006 073 A1 disclosed a so-called blow molding, filling and sealing production machine, which is particularly suitable for the production of filled containers for medicinal purposes. This also includes ampules as container products for eye drops with filling volumes of for example 0.1 ml to 10 ml as well as ampules for injection solutions in the range of typically 0.5 ml to 50 ml. Standard clock speeds for the production of such filled and sealed blow molding, filling and sealing (BFS) containers

are in the range of 10 to 18 seconds, whereas in modern systems of the type disclosed in document DE 10 2008 006 073 A1 however, the cycle time is just 2 to 4 seconds. Due to these low cycle times alone, the use of the above-mentioned known sterilization methods is ruled out, which methods thus cannot be used for BFS methods because the container molding is immediately followed within a few seconds by the filling and a premolding or even an empty container is not available for a sterilization operation.

The microbiological status of containers produced according to the BFS method was described in the article by Frank Leo et al. "Evaluation of Blow-Fill-Seal Extrusion through Processing Polymer Contaminated with Bacterial Spores and Endotoxin", published in the PDA Journal of Pharmaceutical Science and Technology Vol. 58, No. 3, May-June 2004, pages 147 to 158 for the particular case of a BFS system of type 624 by the company Weiler Engineering with cycle speeds of 12 to 18 seconds (see page 148). Amongst other things, the specialist article discloses that reduction of spores occurs by means of two possible mechanisms, either thermal deactivation resulting from the long-term influence of heat during production (see page 153, bottom left) or as a result of the achieved homogeneous distribution (see page 153, 5th paragraph) of the spores in the molten mass and an associated possible thermal inactivation. In spite of this achieved homogeneous distribution and the long residence time, the authors report only a small bacteria count reduction in the region of only 10^2 to 10^4 colony-forming units per gram (CFU/g).

The results described above are, as the authors explicitly state, not transferable to other systems, in particular not to those BFS systems with significantly lower residence times at a raised temperature, for example in the form of systems made by the company rommelag of type 460, which are the subject of the technical teaching according to document DE 10 2008 006 073 A1, in which the clock speeds, as stated above, are typically in the region of less than 5 seconds. In these systems, no cutting of the warm polymer tube occurs and the filling occurs by means of sterile filling tubes

inside the intact plasticized polymer hose. The hose thus in any case then constitutes a sterile barrier relative to the exterior space or the environment.

Unfortunately it is not, however, always possible to ensure that the polymer granulate used for the BFS process has a sufficiently minimal microbiological contamination. It is thus in practice possible, to some extent also as a result of incorrect transport, storage and handling of the plastic granulate, for microbiological contaminants, for example in the form of spores, to reach the granulate surface, which can lead to an undesirably high microbiological contamination, which is not always reduced to an adequate extent by means of the previous BFS method according to the prior art.

Given this prior art, the problem addressed by the invention is to provide a device which, preferably as part of BFS production processes, can be integrated into same and which helps to significantly deactivate the microbiological contaminants.

This problem is solved by a device having the features of Claim 1 in its entirety and a hose head in accordance with the feature configuration of Claim 10 which is in particular suited to this device.

Because, according to the characterizing portion of Claim 1, said guide device has a flow guide for the melted plastic material in such a way that the microbiologically contaminated plastic material regions of the surfaces are guided into the inside of the polymer hose or polymer strand, so that contaminants of less contaminated plastic material regions of the then fully produced plastic container product are surrounded on all sides, any microbiological contaminants present such as spores, bacteria, endotoxins, etc. are reliably enclosed by uncontaminated plastic material so that they can no longer compromise the microbiological status of the container content, or its sterility. This knowledge for the purpose of obtaining a reliable enclosure of undesirable microbiologically-effective contaminants, i.e. using

an intentional non-homogeneous distribution of biological particles in the polymer, is not identifiable in the prior art and is surprising to the average person skilled in the art of production of plastic container products.

The device according to the invention is advantageous in that, as specified, the starting material plastic granulate is microbiologically contaminated only on its surface, and microbiological contaminants are then guided to the inside of the plastic hose and thus to the inside of a container wall and are thus inactivated.

In particular it has been shown in a surprising manner that bacterial spores specifically can be significantly inactivated through the use of special, mostly distributively mixing additive elements in the extruder or the extruder device mainly by means of this encapsulation mechanism. The installation of such a static melt mixer takes place without the use of additional mobile parts, preferably between the extruder device and a hose head, which discharges a closed plastic shell surface, which later forms the container wall of the container products.

The use of such static mixers in the described BFS method has been avoided by specialists in the past because the static mixers are necessarily associated with a pressure drop, which necessitates a more pressure-resistant design of the extrusion system and significantly increases the energy requirement during operation of the machine. Mixing elements are typically used only to obtain a uniform, homogeneous distribution of dyes, fillers, reinforcing fibers, etc. which are added to the polymer.

Although said static mixing elements - unlike dynamic mixers – do not significantly change the temperature of the polymer used and it is thus possible to rule out a thermal effect (heat sterilization effect) of the mixer on the bacteria count reduction, a significant spore inactivation occurs as a result of the encapsulating enclosure of the spore material by uncontaminated plastic, in other words, an advantageous non-

homogeneous distribution of microbiological contaminants over the cross section of a melt strand and, resulting therefrom in a surprising manner, an advantageous non-homogeneous distribution of microbiological contaminants over the cross section of a container wall. There is no equivalent of this in the prior art.

An additional device according to the invention for reducing microbiological contaminants involves a special flow guide of the melted polymer immediately before discharge from the nozzle of a hose head, which is immediately upstream of the blow molding, filling and sealing production machine.

For said BFS method tools are usually used for the hose head within the realm of easily constructed annular groove distributors, spiral mandrel distributors, spider distributors, screen basket distributors or perforated plate distributors. Such distributors are described in detail in the book by Walter Michaeli: *Extrusionswerkzeuge für Kunststoffe und Kautschuk; Bauarten, Gestaltung und Berechnungsmöglichkeiten* [Extrusion Tools for Plastics and Rubber; Construction, Design and Calculation Methods], Carl Hanser Verlag, 2009.

By contrast with these known distributor tools, the invention advantageously uses a hose discharge head with an oval cross section, consisting of an oval housing and an oval sleeve, with two inputs occurring simultaneously and symmetrically along the discharge oval.

Compared with other standard distributors, the flow guide of the plasticized polymer in the hose head according to the invention results in a very narrow residence time range of the molten polymer along the circumference of the hose to be produced. Due to this consistent residence time of the polymer and the flow in the thin, flat distributor channels, as a component of the flow guide according to the invention in the context of the guide device, an advantageous non-homogeneous alignment of microbiological

contaminants into the inside of the polymer hose is obtained and thus improved bacteria inactivation as a result of plastic material which hermetically encloses microbiological contaminants and prevents contact of the contaminants with the filling material, but also with the outer surface of the container.

Additional advantageous designs of the solution according to the invention are the subject of the dependent claims.

The device according to the invention and the hose head shall be explained in detail below with reference to an exemplary embodiment according to the drawings. Said drawings show, in schematic and not to scale depictions:

Fig. 1 a highly simplified overall depiction of an exemplary embodiment of a blow molding, filling and sealing production machine, in particular according to the teaching according to document DE 10 2008 006 073 A1 (production machines of type 460 by the company rommelag);

Fig. 2 a highly simplified overall depiction, partially drawn in the longitudinal section, of a standard extruder device with input-side feeding hopper for the plastic granulate and a hose head arranged on the output side, which discharges the molten plastic material at the input side on the top side of the BFS device according to Fig. 1 to said BFS device;

Figs. 3a, b, c in longitudinal depictions, in a top view and cut and in elevation, a side depiction of the hose head according to Fig. 2, and

Fig. 4 a schematic cross section through a filled container product (oval ampule) produced according to the invention with an advantageous non-homogeneous distribution of microbiological contaminants, in other words, regions with different contamination concentrations.

Fig. 1 depicts a production section lying at the top in the figure identified as

a whole with the reference numeral 1 and a demolding device connected thereto at the bottom identified as a whole with the reference numeral 3. The production section 1 is a machine device for carrying out a so-called blow molding, filling and sealing method in accordance with the well-known bottelpack® system, and in an embodiment in which various molding steps are carried out at various stations along a production line 5. In a type of carousel arrangement, individual molding parts 7, only some of which are numbered in Fig. 1, are moved in pairs towards one another on a kind of virtual circular arc track in order to form a closed production mold, and are moved apart from one another again in order to open the respective mold. Because machine devices functioning according to the bottelpack® method are known per se, further description of the details of the production section 1 of Fig. 1 is not necessary.

As can also be seen from Fig. 1, the container chain 9 formed by the individual molding parts 7 extends along the production line 5 and, at the bottom end of the production section 1, projects out of same and arrives, at the input side, at the demolding device 3. The container chain 9 is a wide container chain conveyor, in which a number of individual container 11 having an ampule-type design as plastic container products are arranged in the container chain 9 side by side and lying next to one another projecting into the drawing plane of Fig. 1.

To assist with the removal of the containers 11 and thus of the container chain 9 from the walls of the individual molding parts 7 which move apart from one another at the discharge region, the demolding device 3 conveys a displacement movement to the container chain 9, as indicated in Fig. 1 with a double arrow 13. For this purpose the demolding device 3 has a carrying arrangement 15 which, in geared connection with an electric drive motor 17, generates the displacement movement of the container chain 9 in order to reliably detach the containers 11 from the mold wall parts of the molding parts 7. Further details concerning the further construction of this production machine 1 together with the demolding device 3 can be obtained from

document DE 10 2008 006 073 A1.

This blow molding, filling and sealing machine 1 together with the demolding device 3 according to Fig. 1 forms, as part of the overall production method, an additional production chain 9 that connects to a first production chain, the major components of which are the subject of Fig. 2. This first production chain comprises an extruder device identified as a whole with the reference numeral 19 using a so-called screw extruder, the screw conveyor 21 of which can be driven by a drive 23. At the external circumference side heating devices 25 are arranged on the rotatable screw conveyor 21 in order to plasticize or to liquefy the plastic granulate (not depicted) which is supplied by means of a feeding hopper 27. While the feeding hopper 27 is located on the right input side of the screw conveyor 21, a mixer device 31 is arranged on its output side, which transfers the plasticized or partially liquefied plastic material to a hose head 33. This hose head 33 has a kind of oval cross section, as shall be explained in further detail below, in order to thus discharge in the manner of a curtain a plastic hose, closed at the shell side, to the production machine 1. For the sake of simpler depiction, the other production devices of the blow molding, filling and sealing production machine 1, for example in the form of the filling pins for the introduction of the liquid container contents to be stored in the container, were dispensed with as were any blow pins for producing the blow mold and any vacuum devices present for improved contact of the plastic material on the mold inner wall of the individual molding parts 7 of the production machine 1. These production measures are known per se and will therefore not be addressed in further detail here.

The working temperature of polyethylene as the plastic material used is ca. 170°C to 200°C and is ca. 180°C to 250°C in the case of polypropylene materials, with the discharge pressure behind the extruder device 19 with the mixer device 31 at the point of transition to the hose head 33 conventionally being approximately 100 to 400 bar.

According to the invention, the extruder device has in the context of the mixer device 31 a guide device 35, which permits flow guidance for the molten plastic material in such a way that the potentially present microbiological contaminants migrate to the inside of the plastic strand 37, which are enclosed by less contaminated plastic material regions 39. The mostly distributively mixing parts of the respective mixer device 31 form statically designed melt mixers, with a channel guide 41, which distributed plastic content contaminated with biological contaminants such as spores, bacteria or endotoxins, etc., by means of the extruder device 19 in a non-homogeneous manner in the produced plastic strand 43, which leads in a surprising manner to contaminants also in the polymer hose and thus in the wall (Fig. 4) of the container product 11 becoming concentrated mainly on the inside 71 of the wall and which are enclosed by less contaminated plastic content 72, which significantly reduces the action of said contaminants relative to the filling material 73 in the plastic product 11 and thus their damaging effects.

As static mixer devices 31 mixing elements without mobile parts for example are used, of the kind which can be procured with the type designations SMX™ and SMX™plus from the company Sulzer Chemtec AG, Winterthur, Switzerland. SMB plus melt mixers from the company Promix Solutions, Linden, Germany or the melt mixer CSE-X from the company Fluitec, Neftenbach, Switzerland, are likewise suitable for this purpose. Furthermore, such static mixing devices can be used on the basis of their technical construction as described in the US patent 7 077 561 B2 and in the US patent publication 2012/0106290 A1.

According to the invention, said static mixer devices 31 demonstrate achievement of the desired inherently non-homogeneous distribution of microbiological contaminants, although these mixers are actually used for the homogenization of polymer melts, in particular when dyes, filling materials, etc. are added.

In a surprising manner it was thus found that static mixers which are known per se demonstrate a completely different mixing behavior: while dyes, filling materials, reinforcing fibers, etc. and similar particles are homogeneously distributed in the container wall – as is always necessary for dyes for optical reasons –, in the case of microbiological contaminants, the described rather non-homogeneous distribution that is advantageous according to the invention, the described encapsulating effect, is obtained.

As already explained, in a surprising manner the advantageous non-homogeneous distribution of the solid plastic melt strand 43 is advantageously maintained even in the case of forming of the polymer hose and thus in the cross section (Fig. 4) of the container 11.

The reason for this is not known, but it is suspected that this is due to a complex interaction of several factors. On the one hand this involves the surface chemistry and structure of the microbiological contaminants, probably in particular their physical wettability and chemical interactions with hot polymer melts, and on the other hand their size and form factors, which influence the alignment of the microbiological contaminants in the melt flow. It should be taken into account that the rheological properties of the polymer are highly dependent on the temperature, the shear forces and the molecular weight distribution of the polymers themselves, and thus their distribution across the strand cross section or hose cross section.

The previously described guide device for the plastic strand 43 can, additionally or alternatively to the respective mixer device 31, comprise the hose head 33 in the production line before the production machine 1 with an oval-like cross section for the plastic material discharge to the molding tools 7 of the production machine 1. This discharge cross section 45 is formed in the manner of a slit (cf. Figs. 3a, 3b) and is supplied from a central discharge point 47, which is in turn supplied from the outlet 49 of the extruder device 19 and thus permits a curtain-like circumferentially closed shell outlet 51 on the output side of the hose head 33.

As Fig. 3a and the subsequent figures also show, the hose head 33 has a housing 53, in which two guide tracks 55 which are separated from one another extend as part of the guide device 35. The two guide tracks 55 lie, viewed in the viewing direction of Fig. 3b, symmetrically on opposite sides of a longitudinal axis 57 of the hose head 33, which longitudinal axis is arranged parallel to the conveying direction of the extruder device 19. The two pairs of guide tracks 55 are, starting from a highest feed point 59, supplied for the plastic melt lying in a plane which, in the form of supply lines 56 arranged in pairs, descend towards the outside starting from this plane. Viewed in the viewing direction of Fig. 3b, the outlet 49 of the extruder device 19 expands conically in the direction of the hose head 33 and has on the inside a supply channel 61 which, via an additional channel section 63 in the hose head 33 opens into a sheet feeding 65, which supplies the feed point 59. Due to the symmetrical construction of the hose head 33, the supply arrangement described in this respect is also comparably arranged, viewed in the viewing direction of Fig. 3b, relative to the longitudinal axis 57 of the device in a plane lying under same. To this extent, via the respective guide device 35 with the highest feed point 59 the oval sleeve 67 of the hose head 33 is supplied.

The two respective supply lines 56 as part of each guide track/distributor channel 55 with the involvement of the top feed point 59 and towards all sides, starting from the corresponding discharge plane, permit the supply of the slit-shaped discharge cross section 45 at the bottom side of the hose head housing 53. According to the depiction of Fig. 3c, this slit tapering occurs directly after the plastic material leaves the region of the guide tracks 55 or of the supply lines 56.

The guide tracks 55 in the hose head 33 delimit at the external circumference receptacles 69, which can be penetrated by filling pins (not depicted) of the production machine 1. The blow-molded plastic containers can thus be filled in a sterile manner with a filling medium. Thanks to the consistent residence time of the polymer for the container wall and the

through-flow in the thin-faced distributor channels which form the slit-like discharge section 45, there is a non-homogeneous alignment of the microbiological contaminants to the inside of the thus formed polymer hose, which is supplied, viewed in the viewing direction of Fig. 1, to the production machine 1 from the top.

In the context of practical testing of the device solution according to the invention, for all of the exemplary embodiments materials, container sizes and machine settings were selected which represent the worst case regarding the mechanism of reduction of microbiological contaminants. As an example of microbiological contaminants resistant spores of bacillus . atropheus and bacillus pumilus were selected as test bacteria, as is standard in sterility testing. As container materials, polymers that have low BFS working temperatures were additionally used in order to keep at low levels the thermal effects on the artificially added spores. In addition, process parameters were selected which have only minimal effects on the spores, but which lead to container products with useable quality and standard output quantities. The throughput of polymer through the extruder device 19 was thus set to the upper limit in order to thus minimize the duration of the heat effect on the artificially added spores.

Furthermore, a BFS system of the type 460 from the company rommelag, Waiblingen, Germany, was used, as is partially depicted in Fig. 1, with a cycle time for the entire container production of ca. 3.5 seconds. As plastic granulate, which is supplied via the feeding hopper 27 to the extruder device 19, polymers were used such as Purell LDPE of the type 1840 H from the company LyondellBasell and Ineos LDPE of the type Eltex MED 30 PH 23H630 with working temperatures of the extruder 19 and also of the hose head 33 in the range between 160°C and 165°C.

To produce the contaminated granulate tests endospores of bacillus atropheus ATTC 9372 with a D-value $D_{160^{\circ}\text{C}} = 0.285 \pm 0.08$ min were used. In a similar manner, spores of the very small reference bacteria, bacillus

subtilis 1031, were used. The spores were uniformly distributed on the plastic granulate used and the spore content was verified under laboratory conditions. The concentration range was 10^3 to 10^6 CFU per gram. 10 ml containers 11 filled with 6 ml liquid CASO nutrient solution were also produced.

For further clarification: CASO nutrient solution is a complex medium, to which is added, besides glucose, peptone obtained proteolytically from milk protein (casein peptone) and peptone obtained proteolytically from soy flour (soy flour peptone). Casein peptone is rich in free amino acids and the soy flour peptone is distinguished by a high carbohydrate and vitamin content. Such nutrient media are particularly well suited for cultivation of fastidious microorganisms.

For each test batch more than 12,000 container products were produced, with the analytical procedure otherwise corresponding to the content of the above-mentioned article by Frank Leo et al. "Evaluation of Blow-Fill-Seal-extrusion through Processing Polymer Contaminated with Bacterial Spores and Endotoxin".

In a first step, three reference batches, i.e. without application of the methods according to the invention, were prepared for the spore inactivation. For this purpose, a pin wrench distributor with holes, which is standard in extrusion technology, was used as a dynamic mixer device (as shown in the book by W. Michaeli) and a hose head with a circular cross section and a circular cylindrical sleeve was used, with a bacteria count reduction being obtained, in particular due to thermal effects, of on average 10^3 CFU/gram (colony-forming units per gram).

When the polymer granulate contaminated with spores of the bacillus atrophaeus is extruded using the above described static mixer devices 31, with the total length of the extruder device 19 remaining unchanged compared with the reference tests, a deactivation of the contaminant

through said encapsulation was obtained which was improved by a factor of 50-170. In the case of the use of spores of the bacillus subtilis, an increased effect compared with the reference was obtained with an inactivation factor of on average 100.

When, in an additional or alternative manner, the contaminated polymer granulate is introduced with a hose head 33 with an oval sleeve 67 in accordance with the design according to Figs. 3a to 3c, an inactivation of the used spores is in turn obtained which is improved by a factor of 70-230. Further tests were also realized with spores of the bacillus megaterium CDC 684, which are larger compared with the spores of the bacillus atrophaeus and of the rather spherical bacillus sphaericus ATCC 4525 with an average length-to-diameter ratio of ca. 1.27, and with spores of the bacillus stearothermophilus ATCC 12980. The latter have almost double the diameter compared with the spores of the bacillus subtilis. In all tests significantly improved inactivations of the respective spores were obtained compared with the respective reference.

All of the above-mentioned methods according to the invention together with the device according to the invention for minimizing the microbiological contamination have the advantage that it is not an empty container or even an already filled container 11 that is to be sterilized, as is described in the prior art, instead solely the already plasticized polymer suffices as a mechanism of inactivation by encapsulation, and there is no equivalent of this in the prior art.

When producing multilayer containers according to the BFS method, as described for example in document DE 103 47 908 A1, it may be sufficient to use the respective described devices according to the invention solely for the polymer granulate which forms the inner surface of the container 11.

Claims

1. A device for reducing the microbiological contaminants of container products (11), which are mainly made from plastic material, in which a plastic granulate is supplied to an extruder device (19), which melts the granulate, which granulate is subsequently transferred to a blow molding, filling and sealing production machine (1) for obtaining the respective container product (11), with a guide device (35) for targeted guiding of the plasticized plastic material from the extruder device (19) to said production machine (1), at least one guide device (35) has at least one flow guide or channel guide (41, 55) for the molten plastic material in such a way that microbiological contaminants are mainly guided to the interior wall (71) of the polymer hose, which is surrounded by less contaminated plastic material regions (72), characterized in that the guide device (35) has, in addition to or alternatively to the respective mixer device (31) of the extruder device (19), a hose head with an oval-like cross section (oval sleeve 67) for the plastic material discharge to the molding tools (7) of the production machine (1), which is formed in the manner of a slit and initiates a linear shell outlet (51) starting from a central discharge point (47), which is supplied by the outlet (49) of the extruder device (19).
2. The device according to Claim 1, characterized in that the extruder device (19) is equipped with a mixer device (31) at the outlet side towards the direction of the production machine (1).
3. The device according to Claim 1 or 2, characterized in that the mixer device (31) is a statically designed melt mixer with a flow guide or channel guide (41), which distributes microbiological contaminants in a non-homogeneous manner in the plastic strand (43).
4. The device according to one of the preceding claims, characterized in that the hose head (33) has a housing (53), in which two guide tracks (55) are arranged as part of the guide device (35), each of which has, starting from a highest feed point (59) for the plastic melt, two supply lines (56) lying in a plane descending outwards in this plane.
5. The device according to claim 4, characterized in that the two supply lines (56) with involvement of the feed point (59) supply to all sides starting from this plane the slit-like discharge cross section (45) in the hose head housing (53).
6. The device according to claim 4 or claim 5, characterized in that the respective two guide

tracks (55) taper in the direction of the production machine (1) initially with a constant discharge cross section in the manner of a crack in the direction of the production machine (1) such that, on the side of the shell outlet (51) a constant discharge speed is obtained with respect to this shell outlet (51).

7. The device according to one of claims 4 to 6, characterized in that the two guide tracks (55) are arranged extending symmetrically (Fig. 3b) in a longitudinal axis (57) of the hose head (33) parallel to the discharge direction of the extruder device (19).

8. The device according to one of claims 4 to 7, characterized in that the two guide tracks (55) in the hose head (33) delimit at the external circumference receptacles (69), which can be penetrated by filling pins of the production machine (1).

9. The device according to one of claims 4 to 8, characterized in that the two guide tracks (55) in the hose head (33) are delimited at the external circumference in the housing (53).

10. The device according to one of the preceding claims, characterized in that, by means of the extruder device (19) a co-extrusion method is realized, which leads to a multilayer construction of the wall of the closed and filled container product (11) and, in that only the polymer forming the inner surface of the thus co-extruded container (11) is subjected to the reduction of microbiological contaminants.

11. A hose head, in particular for use in a device according to one of the preceding claims, characterized in that the hose head (33) has a housing (53), in which two guide tracks (55) are arranged as part of the guide device (35), which each have, starting from a highest feed point (59) for the plastic melt and lying in a plane, two supply lines (56) descending outwards in this plane which, with the involvement of the feed point (59) to all sides starting from this plane, supply the slit-like discharge cross section (67) in the hose head housing (53) for the purpose of discharge of a closed plastic shell for the subsequent container production; and the hose head has an oval-like cross section (oval sleeve 67) for the plastic material discharge to the molding tools (7) of the production machine (1), which is formed in the manner of a slit and initiates a linear shell outlet (51) starting from a central discharge point (47), which is supplied by the outlet (49) of the extruder device (19).