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(54) Title: PACKAGE UNIT AND METHOD FOR EXTENDING SHELF LIFE OF A PACKAGED PRODUCT

(57) Abstract: The present invention discloses a package unit comprising an outer flexible bag enclosing one or more sterilized packaged products hermetically sealed within. The outer flexible bag provides a protective barrier for the sterilized packaged products, ensuring their integrity and cleanliness. The hermetic sealing of the packaged products within the outer flexible bag maintains the integrity of the primary packaging. This package unit offers a convenient and secure way to store and transport sterilized products, suitable for various applications where maintaining product sterility is essential.

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PACKAGE UNIT AND METHOD FOR EXTENDING SHELF LIFE OF A PACKAGED PRODUCT

TECHNICAL FIELD

[0001] This disclosure is related to sterilized packaged products and a system and method for extending the shelf life of those packaged goods.

BACKGROUND

[0002] Previous approaches to packaging units for sterilized products have typically involved using rigid containers or pouches to ensure the sterility of the packaged products. These rigid containers or pouches are often highly engineered with multiple materials in order to deliver excellent performance through the sterilization process and during the shelf life of the product.

[0003] In some instances, flexible packaging materials have been utilized for sterilized products to improve flexibility, reduce bulkiness and increase sustainability efforts. However, these flexible packaging solutions have often lacked the ability to provide a truly high performance barrier throughout the shelf life of the product, leading to concerns about the long-term sterility and shelf-life of the packaged products. Furthermore, the design and construction of these flexible packaging units have not always been optimized for efficient storage, handling, and transportation of the sterilized products, resulting in potential challenges in maintaining product integrity and sterility.

[0004] Overall, the existing packaging solutions for sustainable sterilized products have presented limitations in terms of flexibility, hermetic sealing, and efficiency in storage and transportation. However, none of these approaches have provided a comprehensive solution that combines the features described in this disclosure.

SUMMARY OF INVENTION

[0005] In some aspects, the techniques described herein relate to a package unit including: an outer flexible bag and one or more sterilized packaged products hermetically sealed inside the outer flexible bag.

[0006] In some aspects, the techniques described herein relate to a package unit wherein the outer flexible bag includes an oxygen transmission rate (OTR) of less than 2 cc/m²/day according to ASTM F1927 using conditions of 1 atmosphere, 23 °C and 50% RH).

[0007] In some aspects, the techniques described herein relate to a package unit wherein the outer flexible bag includes a moisture vapor transmission rate (MVTR) of less than 2 g/m²/day according to ASTM F 1249 at 38°C/90%RH.

[0008] In some aspects, the techniques described herein relate to a package unit further including an inert headspace within the outer flexible bag.

[0009] In some aspects, the techniques described herein relate to a package unit wherein the inert headspace includes inert gas and an oxygen level less than 5% by volume.

[0010] In some aspects, the techniques described herein relate to a package unit further including an air headspace within the outer flexible bag.

[0011] In some aspects, the techniques described herein relate to a package unit wherein the sterilized packaged products are vacuum packaged inside the outer flexible bag.

[0012] In some aspects, the techniques described herein relate to a package unit wherein the sterilized packaged products have been sterilized in an environment including elevated temperature and moisture.

[0013] In some aspects, the techniques described herein relate to a package unit wherein the environment further included inert gas.

[0014] In some aspects, the techniques described herein relate to a system for storing sterilized packaged products including: an outer flexible bag and one or more sterilized packaged products hermetically sealed inside the outer flexible bag.

[0015] In some aspects, the techniques described herein relate to a system further including an inert headspace inside the outer flexible bag.

[0016] In some aspects, the techniques described herein relate to a system further including an air headspace inside the outer flexible bag.

[0017] In some aspects, the techniques described herein relate to a method for extending shelf-life of sterilized packaged products including: hermetically sealing a product in a package including one or more primary package components to result in packaged products; sterilizing the packaged products in a sterilizing cycle including elevated temperature and moisture to result in sterilized packaged products; and sealing one or more sterilized packaged products in an outer flexible bag.

[0018] In some aspects, the techniques described herein relate to a method wherein sealing the sterilized packaged products in an outer flexible bag further includes an inert headspace inside the outer flexible bag.

[0019] In some aspects, the techniques described herein relate to a method wherein sealing the sterilized packaged products in an outer flexible bag further includes an air headspace inside the outer flexible bag.

[0020] In some aspects, the techniques described herein relate to a method wherein sealing the sterilized packaged products in an outer flexible bag further includes removal of most of the headspace prior to the final sealing.

TERMS AND DEFINITIONS

[0021] As used herein, "package unit" refers to one or more products packaged in a primary package, all within a secondary package of an outer flexible bag.

[0022] As used herein, "primary package components" refers to the package that is in contact with the packaged product.

[0023] As used herein, "sterilized packaged products" refers to hermetically sealed primary packages that contain a product and have gone through a sterilization process such as retort. The sterilization process rids the product of harmful microbial activity, rendering the product stable even at room temperature.

[0024] As used herein, "hermetic" or "hermeticity" refers to a seal or sealed package that is completely closed and essentially airtight. Hermetically sealed packages generally have a need for storage and package integrity over a period that is greater than a few days. Package integrity includes a consistent appearance, maintenance of barrier properties, maintenance of lamination bonds, and maintenance of seals. As used herein, "hermetic package" or "hermetically sealed" refers to a package that is closed in some manner such that the inside of the package and the product therein are isolated from the environment outside of the package. Generally, sealed hermetic packages are significantly airtight and moisture proof. For medical products, hermetic packages are often maintaining a sterile environment inside, preventing ingress of bacteria or other living microorganisms.

[0025] The headspace within a hermetically sealed package is the gas filled space between the packaged product and the packaging material. As used herein, "air headspace" refers to the gas within a package as consisting of a composition generally the same as air (i.e., 80% nitrogen, 20% oxygen). During the process of packaging the product, the package is sealed without any attempt to flush or change the gas mixture inside. As used herein, "inert headspace" refers to the gas with a package as consisting of a composition that includes a significant proportion of an inert gas. During the process of packaging the product, the package is sealed after flushing the package to at least 50%, at least 80% or at least 90% inert gas. The inert headspace may include less than 5% oxygen or less than 2% oxygen.

[0026] As used herein, "inert gas" refers to non-reactive gasses such as nitrogen or carbon dioxide.

[0027] The package barrier may reduce the influx of moisture or water through the barrier film during the shelf-life of a packaged product (i.e., while the package is hermetically sealed). The moisture vapor transmission rate (MVTR or WVTR) of the barrier film is an indication of the barrier provided and can be measured according to ASTM F1249 using conditions of 1 atmosphere, 23°C and 90% RH.

[0028] The package barrier may reduce the influx of oxygen or escape of headspace gas through the barrier film during the shelf-life of a packaged product (i.e. while the package is hermetically sealed). The oxygen transmission rate (OTR) of the barrier film is an indication of the barrier provided and can be measured according to ASTM F1927 using conditions of 1 atmosphere, 23°C and 50% RH.

DETAILED DESCRIPTION

[0029] Described in this application are package units that are designed to the extend the shelf life of sterilized packaged products. These sterilized packaged products may have package components (i.e., primary package components) that are designed for increased sustainability such as, but not limited to, recyclability. To achieve the sustainability targets the primary package components may include fewer types or lower quantities of high performance materials that offer excellent protection through the sterilization process and throughout shelf life. The package units described assist in extending the shelf-life of the sterilized packaged products.

[0030] In general, the package units include one or more sterilized packaged products. The sterilized packaged products are food or medical products that require or benefit from the sterilization process (i.e., retort or autoclave), rendering them shelf stable or otherwise safe. The sterilized packaged products are hermetically sealed in packaging that is designed to survive the abusive sterilization process and provide necessary barrier after the sterilization process, among other functions. As noted, upon designing with sustainability targets in mind, the packaging may be more susceptible to environmental conditions, lowering performance of the primary packaging primary package components.

[0031] The sterilized packaged products may be in the form of a pouch, a bag, a tray/lid or any other configuration of polymer based packaging. The primary package components may be clear or opaque and may be printed. The primary packaging components of the sterilized packaged products provide an oxygen transmission rate (OTR) of less than 2 cm³/m²/day, less than 1 cm³/m²/day, less than 0.5 cm³/m²/day, or less than 0.1 cm³/m²/day (measured according to ASTM F1927 using conditions of 1 atmosphere, 23 °C and 50% RH). This ensures that following the sterilization process, the product remains sufficiently protected.

[0032] In some cases, certain primary package components are highly affected by the sterilization process and/or by the environment after sterilization. For example, after the sterilization process the primary package components may experience decreased OTR upon exposure to high humidity levels, such as RH greater than 70%. Another example includes primary package components that suffer an extended retort shock, having a lower than normal oxygen barrier level (high OTR) for a temporary period of time. These types of properties may be the result of the primary package components being designed using materials that are more sustainable, such as those appropriate for specific recycling processes.

[0033] For the package units described herein, the sterilized packaged products are sealed inside an outer flexible bag or other similar secondary package. There may be one sterilized packaged product or ideally, more than one hermetically sealed inside the outer flexible bag. The sterilized packaged products may be stacked tightly inside the outer flexible bag or there may be a tray or strap keeping the sterilized packaged products neatly organized. The outer flexible bag will provide either or both of oxygen barrier and water vapor barrier as will be discussed in the embodiments and depending on the specific application needs. The outer flexible bag may be clear or opaque and may be printed. The hermetic seal of the outer flexible bag may be achieved by any means, such as heat sealing.

[0034] The outer flexible bag may be vacuum packaged around the sterilized packaged products, wherein most or nearly all of the headspace in the package is removed before sealing. Alternatively, there may be headspace within the package containing either normal air or a modified atmosphere. If a modified atmosphere is used, the headspace may contain an inert gas such as nitrogen. Each of these packaging options is described in more detail below.

[0035] AIR HEADSPACE

[0036] Certain embodiments of the package unit may include sterilized packaged products hermetically sealed inside of an outer flexible bag and having an air headspace. An air headspace may have a composition essentially identical to the normal earth atmosphere. An air headspace may also have a bit of inert gas flushing, but not enough to lower the oxygen level in the headspace below 5%, by volume. In other words, in this situation, if the primary package components loses oxygen barrier properties, there is oxygen available to travel through to the product.

[0037] The main circumstance where an air headspace may be appropriate is when 1) the primary package components have high oxygen barrier properties which are susceptible to

moisture and 2) the outer flexible bag provides excellent moisture barrier properties (i.e., low moisture vapor transmission rate (MVTR)). In this way, the product can be sterilized within the primary package components, benefitting from the oxygen barrier and the high oxygen barrier of the primary package components can be sustained because of the moisture barrier of the outer flexible bag.

[0038] The outer flexible bag may be applied to the sterilized packaged products after the sterilization process is completed and may be kept in place through distribution, being removed prior to stocking for retail sale or other storage. Alternatively, the outer flexible bag may remain hermetically sealed until the point of use of the product.

[0039] Prophetic examples of a primary package component that may be used for a package unit containing air headspace include those that incorporate inorganic oxide coatings (i.e., SiO_x or AlO_x) on olefin base films as oxygen barrier. Examples of primary package components include but are not limited to OPP / OPP- SiO_x / PP or OPP / OPP- AlO_x / PP wherein OPP is oriented polypropylene film and PP is a polypropylene based sealing layer that may be a cast or blown film. The '/' represents a connection of layers or films which may be made by adhesive layers.

[0040] Prophetic examples of a primary package component that may be used for a package unit containing air headspace include those that incorporate one or more EVOH or polyamide layers. These materials are known to degrade in oxygen barrier upon exposure to high humidity levels and may exhibit a more severe retort shock (i.e., temporary loss of oxygen barrier). Examples of primary package components include but are not limited to OPP / PP-EVOH-PP or OPP with EVOH / PP wherein PP-EVOH-PP is a coextruded non-oriented film containing polypropylene and EVOH and OPP with EVOH is a coextruded oriented film containing polypropylene and EVOH.

[0041] The sterilized packaged products may have a primary package component having an oxygen barrier of less than $2 \text{ cm}^3/\text{m}^2/\text{day}$, less than $1 \text{ cm}^3/\text{m}^2/\text{day}$, less than $0.5 \text{ cm}^3/\text{m}^2/\text{day}$, or less than $0.1 \text{ cm}^3/\text{m}^2/\text{day}$ (measured according to ASTM F1927 using conditions of 1 atmosphere, 23°C and 50% RH), before the sterilization process takes place. This oxygen barrier level may be temporarily (hours, days or weeks) lowered due to the sterilization process. The oxygen barrier level may be lowered upon exposure to a high humidity environment, such as humidity greater than 70%, 75%, 80%, 85% or 90%.

[0042] Advantageously, the package unit includes an outer flexible bag having a low moisture vapor transmission rate such as lower than $2 \text{ g}/\text{m}^2/\text{day}$ or lower than $1 \text{ g}/\text{m}^2/\text{day}$. In this way, the outer flexible bag protects the primary package components of the sterilized

packaged products from environmental moisture, thus maintaining the oxygen barrier at the desired high level during distribution and storage and maintaining the integrity of the product therein.

[0043] Prophetic examples of an outer flexible bag structure that may be used for a package unit containing air headspace include those with high moisture barrier. The outer flexible bag structure may include a metalized OPP layer. Examples of the outer flexible bag include, but are not limited to, OPP/metOPP, OPP/OPP-SiO_x, thick (circa 200 micron) CPP or HDPE monoweb, aluminum/heat seal coating or OPET/aluminum/PE, wherein metOPP is vacuum metalized oriented polypropylene film, CPP is cast polypropylene, HDPE is high-density polyethylene, OPET is an oriented polyester film, aluminum is a thin sheet of aluminum alloy and PE is polyethylene.

[0044] INERT HEADSPACE

[0045] Certain embodiments of the package unit may include sterilized packaged products hermetically sealed inside of an outer flexible bag and having an inert headspace. An inert headspace may have a composition including one or more inert gases including, but not limited to, nitrogen (N₂) or carbon dioxide (CO₂). An inert headspace has an oxygen level below 5%, by volume. In other words, in this situation, if the primary package components loses oxygen barrier properties, there is no oxygen available to travel through to the product.

[0046] The main circumstance where an inert headspace may be appropriate is when 1) the primary package components have high oxygen barrier properties which are susceptible to moisture and 2) the outer flexible bag provides inert gas barrier properties. In this way, the product can be sterilized within the primary package components, benefitting from the normally good oxygen barrier. Additionally, in the case that the primary package components lapse in oxygen barrier, such as due to retort shock, there is no oxygen in immediate proximity to the sterilized packaged products to permeate.

[0047] The outer flexible bag may be applied to the sterilized packaged products after the sterilization process is completed and may be kept in place through distribution, being removed prior to stocking for retail sale or other storage. Alternatively, the outer flexible bag may remain hermetically sealed until the point of use of the product.

[0048] Prophetic examples of a primary package component that may be used for a package unit containing inert headspace include those that incorporate inorganic oxide coatings (i.e., SiO_x or AlO_x) on olefin base films as oxygen barrier. Examples of primary

package components include but are not limited to OPP / OPP-SiO_x / PP or OPP / OPP-AIO_x / PP.

[0049] Prophetic examples of a primary package component that may be used for a package unit containing inert headspace include those that incorporate one or more EVOH or polyamide layers. These materials are known to degrade in oxygen barrier upon exposure to high humidity levels and may exhibit a more severe retort shock (i.e., temporary loss of oxygen barrier). Examples of primary package components include but are not limited to OPP / PP-EVOH-PP or OPP with EVOH / PP.

[0050] The sterilized packaged products may have a primary package component having an oxygen barrier of less than 2 cm³/m²/day, less than 1 cm³/m²/day, less than 0.5 cm³/m²/day, or less than 0.1 cm³/m²/day (measured according to ASTM F1927 using conditions of 1 atmosphere, 23 °C and 50% RH) before the sterilization process takes place. This oxygen barrier level may be temporarily (hours, days or weeks) lowered due to the sterilization process. The oxygen barrier level may be lowered upon exposure to a high humidity environment, such as humidity greater than 70%, 75%, 80%, 85% or 90%.

[0051] Advantageously, the package unit includes an outer flexible bag having a low inert gas transmission rate. A low inert gas transmission rate is most easily selected by using a low oxygen transmission rate structure such as lower than 1 cm³/m²/day or lower than 0.5 cm³/m²/day. In this way, the outer flexible bag maintains the inert gas within the headspace and preventing oxygen ingress through the primary package components during distribution and storage and maintaining the integrity of the product therein.

[0052] Prophetic examples of an outer flexible bag structure that may be used for a package unit containing inert headspace include those with high oxygen barrier. The outer flexible bag structure may include a metalized OPP layer. Examples of the outer flexible bag include, but are not limited to, OPP/metOPP, OPP/OPP-SiO_x, aluminum/heat seal coating or OPET/aluminum/PE.

[0053] VACUUM PACKAGE

[0054] Certain embodiments of the package unit may include sterilized packaged products hermetically sealed and vacuum packaged inside of an outer flexible bag. In other words, in this situation, most if not nearly all of the headspace in the outer flexible bag is removed before the final seal is made and there is very little oxygen available to travel through to the product.

[0055] The outer flexible bag may provide low moisture vapor transmission rate and/or low oxygen transmission rate, as necessary for the application. The product can be sterilized

within the primary package components, benefitting from the normally good oxygen barrier, and then vacuum packaged in the outer flexible bag for additional protection. In the case that the primary package components temporarily lapse in oxygen barrier, such as due to retort shock, there is no oxygen in immediate proximity to the sterilized packaged products to permeate. In the case that the primary package components lapse in oxygen barrier due to exposure to moisture, an outer flexible bag with high moisture barrier will prevent this from occurring.

[0056] The outer flexible bag may be applied to the sterilized packaged products after the sterilization process is completed and may be kept in place through distribution, being removed prior to stocking for retail sale or other storage. Alternatively, the outer flexible bag may remain hermetically sealed until the point of use of the product.

[0057] CLAUSES

[0058] Clause 1. A package unit comprising: an outer flexible bag and one or more sterilized packaged products hermetically sealed inside the outer flexible bag.

[0059] Clause 2. The package unit of clause 1 wherein the outer flexible bag comprises an oxygen transmission rate (OTR) of less than 2 cc/m²/day according to ASTM F1927 using conditions of 1 atmosphere, 23 °C and 50% RH).

[0060] Clause 3. The package unit of clause 1 or 2 wherein the outer flexible bag comprises a moisture vapor transmission rate (MVTR) of less than 2 g/m²/day according to ASTM F 1249 at 38°C/90%RH.

[0061] Clause 4. The package unit of any one of clauses 1 to 3 further comprising an inert headspace within the outer flexible bag.

[0062] Clause 5. The package unit of clause 4 wherein the inert headspace comprises inert gas and an oxygen level less than 5% by volume.

[0063] Clause 6. The package unit of clause 1 or 3 further comprising an air headspace within the outer flexible bag.

[0064] Clause 7. The package unit of any one of clauses 1 to 3 wherein the sterilized packaged products are vacuum packaged inside the outer flexible bag.

[0065] Clause 8. The package unit of any one of clauses 1-4 or 6-7 wherein the sterilized packaged products have been sterilized in an environment including elevated temperature and moisture.

[0066] Clause 9. The package unit of clause 8 wherein the environment further included inert gas.

[0067] Clause 10. A system for storing sterilized packaged products comprising: an outer flexible bag and one or more sterilized packaged products hermetically sealed inside the outer flexible bag.

[0068] Clause 11. The system of clause 10 further comprising an inert headspace inside the outer flexible bag.

[0069] Clause 12. The system of clause 10 further comprising an air headspace inside the outer flexible bag.

[0070] Clause 13. A method for extending shelf-life of sterilized packaged products comprising: hermetically sealing a product in a package comprising one or more primary package components to result in packaged products; sterilizing the packaged products in a sterilizing cycle including elevated temperature and moisture to result in sterilized packaged products; and sealing one or more sterilized packaged products in an outer flexible bag.

[0071] Clause 14. The method of clause 13 wherein sealing the sterilized packaged products in an outer flexible bag further comprises an inert headspace inside the outer flexible bag.

[0072] Clause 15. The method of clause 13 wherein sealing the sterilized packaged products in an outer flexible bag further comprises an air headspace inside the outer flexible bag.

[0073] Clause 16. The method of clause 13 wherein sealing the sterilized packaged products in an outer flexible bag further comprises removal of most of the headspace prior to the final sealing.

CLAIMS

What is claimed is:

1. A package unit comprising: an outer flexible bag and one or more sterilized packaged products hermetically sealed inside the outer flexible bag.
2. The package unit of claim 1 wherein the outer flexible bag comprises an oxygen transmission rate (OTR) of less than 2 cc/m²/day according to ASTM F1927 using conditions of 1 atmosphere, 23 °C and 50% RH).
3. The package unit of claim 1 or 2 wherein the outer flexible bag comprises a moisture vapor transmission rate (MVTR) of less than 2 g/m²/day according to ASTM F 1249 at 38°C/90%RH.
4. The package unit of any one of claims 1 to 3 further comprising an inert headspace within the outer flexible bag.
5. The package unit of claim 4 wherein the inert headspace comprises inert gas and an oxygen level less than 5% by volume.
6. The package unit of claim 1 or 3 further comprising an air headspace within the outer flexible bag.
7. The package unit of any one of claims 1 to 3 wherein the sterilized packaged products are vacuum packaged inside the outer flexible bag.
8. The package unit of any one of claims 1-4 or 6-7 wherein the sterilized packaged products have been sterilized in an environment including elevated temperature and moisture.
9. The package unit of claim 8 wherein the environment further included inert gas.
10. A system for storing sterilized packaged products comprising: an outer flexible bag and one or more sterilized packaged products hermetically sealed inside the outer flexible bag.
11. The system of claim 10 further comprising an inert headspace inside the outer flexible bag.

12. The system of claim 10 further comprising an air headspace inside the outer flexible bag.

13. A method for extending shelf-life of sterilized packaged products comprising:
hermetically sealing a product in a package comprising one or more primary package components to result in packaged products;
sterilizing the packaged products in a sterilizing cycle including elevated temperature and moisture to result in sterilized packaged products; and
sealing one or more sterilized packaged products in an outer flexible bag.

14. The method of claim 13 wherein sealing the sterilized packaged products in an outer flexible bag further comprises an inert headspace inside the outer flexible bag.

15. The method of claim 13 wherein sealing the sterilized packaged products in an outer flexible bag further comprises an air headspace inside the outer flexible bag.

16. The method of claim 13 wherein sealing the sterilized packaged products in an outer flexible bag further comprises removal of most of the headspace prior to the final sealing.

INTERNATIONAL SEARCH REPORT

International application No

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A. CLASSIFICATION OF SUBJECT MATTER INV. B65D77/04 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) B65D		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 22 January 2025		Date of mailing of the international search report 10/02/2025
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Bridault, Alain

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