

CLAIMS

1. A can for use in a pMDI device, said can containing a formulation comprising at least a corticosteroid, a LABA agent, a LAMA agent and a HFA 152a or HFO propellant, being said can internally coated by a coating comprising at least a
5 compound selected from an epoxy-phenol resin, a perfluorinated polymer, a perfluoroalkoxyalkane polymer, a perfluoroalkoxyalkylene polymer, a perfluoroalkylene polymer, poly-tetrafluoroethylene polymer (Teflon), fluorinated-ethylene-propylene polymer (FEP), polyether sulfone polymer (PES), a fluorinated-ethylene-propylene polyether sulfone polymer (FEP-PES), a polyamide,
10 polyimide, polyamideimide, polyphenylene sulfide, plasma, mixtures or combinations thereof, wherein said can is provided with a valve having at least one gasket made of a material comprising at least one polymer selected from low-density polyethylene, butyl such as chlorobutyl or bromobutyl, butadiene-acrylonitrile, neoprene, EPDM (a polymer of ethylenepropylenediene monomer),
15 TPE (thermoplastic elastomer), cycloolefin copolymer (COC) or combination thereof.
2. The can according to claim 1, wherein said corticosteroid is selected from the group consisting of: budesonide, beclomethasone dipropionate, flunisolide, fluticasone, ciclesonide, mometasone, mometasone desonide, rofleponide, hydrocortisone, prednisone, prednisolone, methyl prednisolone, naflocort, deflazacort, halopredone acetate, fluocinolone acetonide, fluocinonide, clocortolone, tipredane, prednicarbate, alclometasone dipropionate, halometasone, rimexolone, deprodone propionate, triamcinolone, betamethasone, fludrocortisone, desoxycorticosterone, rofleponide and etiprednol dicloacetate.
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3. The can according to claim 2, wherein said corticosteroid is beclomethasone dipropionate or budesonide.
4. The can according to any one of the preceding claims, wherein the LABA agent is selected from the group consisting of: fenoterol, formoterol fumarate, formoterol fumarate dihydrate, arformoterol, carmoterol, indacaterol, milveterol, bambuterol, clenbuterol, vilanterol, olodaterol, abediterol, terbutaline and salmeterol.
5. The can according to claim 4, wherein said LABA agent is formoterol fumarate dihydrate.
- 10 6. The can according to claims 1, wherein the formulation agent alternatively comprises an agent selected from the group consisting of salbutamol and (R)-salbutamol.
7. The can according to one of the preceding claims wherein the LAMA agent is selected from the group consisting of glycopyrronium, methscopolamine, ipratropium, oxitropium, tropium, tiotropium, aclidinium and umeclidinium or pharmaceutically acceptable salts.
- 15 8. The can according to claim 7, wherein said LAMA agent is glycopyrronium bromide.
9. The can according to any one of the preceding claims, wherein the HFO propellant is selected from the group consisting of: 1,3,3,3-tetrafluoropropene (HFO-1234ze) and 2,3,3,3-tetrafluoropropene (HFO-1234yf).
- 20 10. The can according to any one of the preceding claims, internally coated by a coating comprising a fluorinated-ethylene-propylene (FEP) polymer.

11. The can according to any one of the preceding claims, containing a formulation further comprising one or more excipients, co-solvents and acids.
12. The can according to claim 11, wherein said co-solvent is an aliphatic alcohol having from 1 to 4 carbon atoms.
- 5 13. The can according to claim 12, wherein said aliphatic alcohol is ethanol, preferably anhydrous.
14. The can according to claims 11-13, containing a formulation further comprising a mineral or organic acid selected from the group consisting of: hydrochloric, hydrobromic, nitric, fumaric, phosphoric and citric acid, maleic acid, acetic acid,
10 xinafoic acid, oxalic acid, lactic acid, 2-methyl propionic acid, malic acid, butanoic acid, tartaric acid, propionic acid, pentanoic acid, succinic acid, glycolic acid, hexanoic acid, malonic acid, glutaric acid, formic ac-id, adipic acid, ascorbic acid, benzoic acid and glucuronic acid.
15. The can according to claim 14, wherein said acid is hydrochloric acid.
- 15 16. The can according to any one of the preceding claims, containing a formulation further comprising a low volatility component selected from the group consisting of: glycols, propylene glycol, polyethylene glycol, glycerol or esters thereof, ascorbyl palmitate, isopropyl myristate.
17. The can according to any one of the preceding claims, containing a formulation
20 in form of a solution.
18. The can according to claims 1 to 17, wherein the valve is provided with 3 gaskets all of them made of EPDM.
19. The can according to claims 1 to 17, wherein the valve is provided with a gasket

made of COC, along with two gaskets made of EPDM.

20. The can according to claims 1 to 17 wherein the valve is provided with two gaskets, both of them made of chlorobutyl polymer.
21. The can according to claims 1 to 17, wherein the valve is provided with a gasket
5 made of butyl rubber, along with two gaskets made of EPDM.
22. The can according to claims 1 to 17, wherein the valve is provided with two gaskets made of bromobutyl, along with one gasket made of a material selected from the group consisting of chlorobutyl, butadiene-acrylonitrile, neoprene, EPDM (a polymer of ethylenepropylenediene monomer), TPE (thermoplastic elastomer),
10 cycloolefin copolymer (COC) or combination thereof.
23. The can according to any one of claims 1 to 22, wherein the propellant is HFA152a and the valve is provided with a gasket made of COC, along with two gaskets made of EPDM; or the valve is provided with two gaskets, both of them made of chlorobutyl polymer.
- 15 24. The can according to any one of the preceding claims, containing a formulation having an apparent pH buffered between 2.5 and 5.
25. The can according to claim 24, containing a formulation having an apparent pH buffered between 3 and 4.5.
26. A pMDI device comprising the can according to any one of the preceding claims.
- 20 27. The pMDI device according to claim 26 for the treatment of a respiratory disease selected from asthma and/or COPD.