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Specification

DURAN PURE Premium screw cap, STERICLIN

for DIN thread	Article number
GL 25	89 299 13 04
GL 45	89 299 28 06

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Product Specification
DURAN PURE Premium screw cap, STERICLIN
GL 25 article number: 89 299 13 04
GL 45 article number: 89 299 28 06

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1 Generally Admitted

The product properties, the product characteristics and the material are defined in the specification and the article-related drawing.

The articles described in this specification fulfill the quality standard stipulated in the specification and drawing.

2 Scope

This product specification is the basis for quality assurance at DWK Life Sciences. It applies, from the validity date of this specification, to all articles supplied with article number:

89 299 13 04
89 299 28 06

Description:

DURAN PURE Premium screw cap GL 25 and GL 45 STERICLIN made from TpCh260 TZ for DURAN PURE bottles with DIN thread GL 25 and GL 45.

3 Validity

This product specification is valid from the date of release and supersedes all prior versions.

4 Product

DURAN PURE Premium screw cap made of fluorothermoplastic (TpCH260 TZ) with press-fit PTFE coated silicone seal to fit thread GL 25 and GL 45.

The screw cap is produced from fluorothermoplastic (TpCH260 TZ) without additional colourants.

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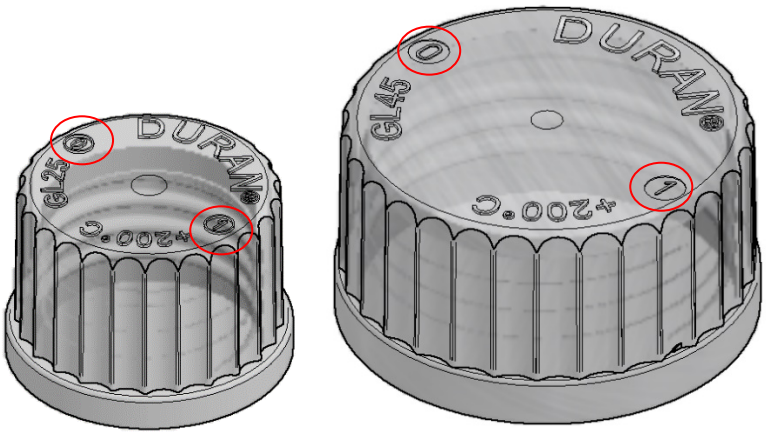
4.1 Material properties

Property	Test method	Unit	Value
Relative density	ASTM D792	g/cm³	2.15
Melting point	ASTM D4591	°C (°F)	308 (586)
Melt flow rate (372°C/5 kg)	ASTM D1238	g/10 min	15
Hardness Shore D	ASTM D2240		60
Breaking stress	ASTM D638	MPa (psi)	30 (4350)
Elongation at break	ASTM D638	%	410
E-module	ASTM D790	MPa (psi)	620 (89,900)
Temperature resistance: - Combination with PTFE-coated silicone seal - Material TpCh260 TZ itself		°C	 200 260

5 Traceability

The DURAN PURE Premium screw cap STERICLIN has a lot number.
The qualification documentation can be accessed via the DWK certificate database (https://cert.dwk.com) by entering the 2-digit lot number and/or the article number.

GL45: The 2-digit Lot Number consist of either two numbers (applicable to caps manufactured before 2025) or of a letter and a number, e.g. “A0” (applicable to caps manufactured 2025 onwards).
GL25: 2-digit Lot Number consists of two numbers



Example for lot numbering system on DURAN PURE Premium screw cap GL 25 / GL 45: 2 digit Lot Number: „01“

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6 Quality

The DURAN PURE Premium screw cap STERICLIN is manufactured in accordance with the valid specification documents. Specification documents are the specification and the drawing. The geometrical design is in accordance with the valid drawing.

In-process tests are carried out in the manufacturing process and also final acceptance tests.

All tests are random sampling tests in accordance with AQL DIN/ISO 2859-1. They are based on the single random sampling of general test levels II and III reduced in accordance with the single random sampling instruction for reduced test (guide table).

The test lot is determined by the lot and supply quantity.

Particles of either screw cap and / or silicon seal between the screw cap and the silicon seal cannot be ruled out due to the production process.

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7 Characteristics

The drawing is the basis for assessing the dimensional characteristics.

Acceptance test – example for GL 25:

Random sampling scope		**AQL**		
Visual inspection		**0.10**	**0.40**	**2.50**
Total errors				
Acceptance number				

Random sampling scope		**AQL**		
Tests		**0.10**	**0.40**	**2.50**
Bottle test				
Thread abrasion				
Total errors				
Acceptance number				

Random sampling scope						
Dimension test	**Reference dimension**	UT	LT	**Min**	**Max**	**Mean**
Overall height (mm)	21.80	+0.20	-0.20			
Internal depth (mm)	18.80	+0.20	-0.20			
Thread core diameter (mm)	22.74	+0.30	-0.00			
Thread outside diameter (mm)	25.10	+0.30	-0.00			
Outside diameter bottom (mm)	31.90	+0.20	-0.20			

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Acceptance test – example for GL 45:

Random sampling scope		**AQL**		
Visual inspection		**0.10**	**0.40**	**2.50**
Total errors				
Acceptance number				

Random sampling scope		**AQL**		
Tests		**0.10**	**0.40**	**2.50**
Bottle test				
Thread abrasion				
Total errors				
Acceptance number				

Random sampling scope						
Dimension test	**Reference dimension**	UT	LT	**Min**	**Max**	**Mean**
Overall height (mm)	26.50	+0.30	-0.30			
Internal depth (mm)	24.40	+0.20	-0.20			
Thread core diameter (mm)	42.45	+0.40	-0.00			
Thread outside diameter (mm)	45.15	+0.40	-0.00			
Outside diameter bottom (mm)	51.00	+0.30	-0.30			

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8 Compliance with standards

8.1 US Pharmacopeia (USP)

The Premium Cap is **non-cytotoxic and biocompatible:**
The material has passed the **L929 MEM Elution Test – ISO.**
The study was conducted based upon the following references:

- ISO 10993-5, 1999, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro Cytotoxicity.*
- ISO 10993-12, 2007, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials
- United States Pharmacopeia 31, National Formulary 26, 2008. <87> Biological Reactivity Tests, *In Vitro*
- ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.
- Compliance: The study conformed to the current FDA 21 CFR, Part 58 – Good Laboratory Practice for Non-Clinical Laboratory Studies

The material passed the **CLASS VI Test – USP** and therefore meets the requirements of the USP guidelines for Class VI Plastics – 121 °C.
The study was conducted based upon the following references:

- USP 31, National formulary 26, 2008 <88> Biological Reactivity Tests, *In Vivo*
- ISO/IEC 17205, 2005, General Requirements for the Competence of Testing and Calibration Laboratories

The Premium Cap is compliant with:

- **USP Class VI plastics - 121°C**

8.2 Statement on Food Contact

We confirm that this product fulfills the requirements on materials used for articles or components of articles intended to come into contact with food as described in:

EU

The monomers used to produce the resin are listed in EU Regulation No. 10/2011 and amendments on plastic materials and articles intended to come into contact with food in accordance with BGVO.

Limits are given for:

TFE: SML = 0,05mg/kg

PPVE: SML = 0,05mg/kg

The monomers of the above mentioned product comply in respect of species, quantity and purity with the German Recommendations LI “Temperaturbeständige Beschichtungssysteme…” and LII “Füllstoffe für Bedarfsgegenstände aus Kunststoffen” as issued by the “Bundesinstitut für Risikobewertung” BfR.

There are no objections against the use of the above mentioned material for articles intended to come into contact with food as referred to in the German

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	"Lebensmittel- und Futtermittelgesetzbuches" (LFGB) of 1. September 2005 § 2 sect. (6), No. 1 (materials and articles intended to come into contact with food, EU Regulation No. 1935/2004) and No.5 (Toys). Due to the fact that the EU Regulation No. 10/2011 applies to all EU Member states of the EU, a verification regarding certification on federal state level of the EU is therefore not necessary.
USA	This product meets the FDA criteria in 21 CFR § 177.1550 for food contact applications.

8.3 Statement on BSE/TSE

Finished product:
The manufacturing of the product does not involve the use of materials of animal origin.

Tallow
Tallow derived additives are not intentionally used in the manufacture of or formulation of this product.

Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)/"Mad Cow"
No components derived from animal sources are used in the manufacture or formulation of this product.

8.4 Statement on Chemicals, regulations and standards

REACH Regulation (EC) No. 1907/2006

This product is defined as a preparation under REACH. All components of this preparation as supplied in the European Union are compliant with the pre-registration requirements of REACH.
This product does not contain any restricted Substances of Very High Concern as intentionally added components or as expected process impurities (above corresponding threshold limits) as stated in REACH Regulation No. 1907/2006.

RoHS Directive 2011/65/EU

We hereby confirm that the product complies with the requirements of EU Directive 2011/65/EU concerning the limits of cadmium, lead, mercury, hexavalent chromium, PBB and PBDE (listed in Annex II of this Directive: 0,1% (w/w) and 0,01% (w/w) for Cd.) and with Directive 2012/19/EU WEEE.

Kosher

The manufacturer states that no products of animal origin are used in the product which has been proved by a Kosher certification.

Latex

"Natural rubber latex", "dry natural rubber", "synthetic latex" or "rubber that contains natural rubber" are not used in the manufacture of or the formulation of this product.

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Coalition of Northeastern Governors (CONEG)

Cadmium, chromium (VI), lead and mercury are not used in the manufacture of or the formulation of this product. In addition, this product meets the CONEG requirements of less than 100 ppm for total incidental cadmium, chromium, lead and mercury.

California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)

This product is an industrial product, produced outside of California. It has not been evaluated for sale or for the use of the customer.

Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)

BHT and BHA are not used in the manufacture of or formulation of this product.

Ozone Depleting Chemicals (ODCs)

We confirm that the product contains no ODC`s according to „Annex I of EU Regulation 1005/2009/EC“.

Toys

The phthalates listed in Annex XVII of Regulation (EU) No. 1907/2006 are not added in the manufacture of or the formulation of this product.

Phthalates

Phthalates, as defined by the regulations REACH, RoHS and California Proposition 65, are not intentionally used in the manufacture or the formulation of this product.
The limits for Phthalates, as stipulated by REACH, RoHS and California Proposition 65 are not exceeded by this product.

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Melamine

Melamine are not used in the manufacture of or formulation of this product:

Adenine
Albumin
Amino Acids derived from casein protein hydrolysates
Ammonium salts
Calcium pantothenate
Caseinate or Sodium caseinate
Chlorophyllin copper complex sodium
Colloidal oatmeal
Copovidone
Crospovidone
Dihydroxyaluminum aminoacetate
Gelatin
Glucagon
Guar gum
Hyaluronidase
Imidurea
Lactose
Melphalan
Povidone
Povidone-Iodine
Protamine sulfate
Protein hydrolysate (powder) for injection
Taurine
Thioguanine
Urea
Wheat bran
Zein

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Acrylamide

Acrylamide (CAS number 79-06-1) is not used in the manufacture of or the formulation of this product. However, we do not test this product for acrylamide.

Aromatic Amines

Aromatic amines are not used in the manufacture of or formulation of this product.

Asbestos

Asbestos is not used in the manufacture of or formulation of this product.

Bisphenol A

Bisphenol A is not used in the manufacture of or the formulation of this product.

Dioxin

Dioxin is not used in the manufacture of or formulation of this product. Dioxin is not known to be formed during processing of this product.

Epichlorohydrin

Epichlorohydrin (CAS number 106-89-8) is not used in the manufacture of or the formulation of this product.

Nonylphenol

Nonylphenol and Nonylphenol ethoxylates are not used in the manufacture of or the formulation of this product.

Alkylphenol

Alkylphenol is not used in the manufacture of or the formulation of this product

Organo-tin Compounds

Tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT) or any other organo-tin compounds are not used in the manufacture of or the formulation of this product.

Polychlorinated Biphenyls (PCBs), Polychlorinated Terphenyls (PCTs), Polychlorinated Naphthalenes (PCNs), Polybrominated Biphenyls (PBBs), Polybrominated Diphenyl Ethers (PBDEs) and Polybrominated Terphenyls (PBTs)

These substances are not used in the manufacture of or formulation of this product.

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Styrene and Polystyrene

Styrene (chemical name: ethenylbenzene) (CAS number 100-42-5) and polystyrene resins are not used in the manufacture of or the formulation of this product.

Vinyl Chloride and Polyvinyl Chloride (PVC)

Vinyl chloride (CAS number 75-01-4) and PVC resins are not used in the manufacture of or the formulation of this product.

Benzotriazole and 2-Mercaptobenzothiazole (MBT)

2-(2H-1, 2, 3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol [also called 2-(2'-Hydroxy-3',5'-di-t-butylphenyl) benzotriazole] (CAS No. 3846-71-7) and 2-Mercaptobenzothiazole [also called 2(3H)-Benzothiazolethione or Benzothiazole-2-thiol or MBT] (CAS No. 149-30-4) are not used in the manufacture of or formulation of this product.

Nanomaterials

NANOMATERIALS (insoluble or biopersistent and intentionally manufactured materials with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm) are not used in the manufacture of or the formulation of this grade.

Polycyclic Aromatic Hydrocarbons (PAHs)

The manufacturer does not intentionally use the following polycyclic aromatic hydrocarbons (PAHs) in the manufacture of or formulation of this product:

- 1,2-dihydro-acenaphthene (CAS# 83-32-9)
- Acenaphthylene (CAS# 208-96-8)
- Fluorene (CAS# 86-73-7) anthracene (CAS# 120-12-7)
- Benz(a)anthracene (CAS# 56-55-3)
- Benzo(a)pyrene (CAS# 50-32-8)
- benzo(b)fluoranthene (CAS# 205-99-2)
- Benzo(e)pyrene (CAS# 192-97-2)
- Benzo(ghi)perylene (CAS# 191-24-2)
- Benzo(j)fluoranthene (CAS# 205-82-3)
- Benzo(k)fluoranthene (CAS# 207-08-9)
- Chrysene (CAS# 218-01-9)
- Dibenzo(a,h)anthracene (CAS# 53-70-3)
- Fluoranthene (CAS# 206-44-0)
- Fluorene (CAS# 86-73-7)
- Indeno(1,2,3-cd)pyrene (CAS# 193-39-5)
- Naphthalene (CAS# 91-20-3)
- Phenanthrene (CAS# 85-01-8)
- Pyrene (CAS# 129-00-0)

Dimethyl Fumarate (DMF) - Regulation (EU) No. 1907/2006 Annex XVII

Dimethyl fumarate [2-butenedioic acid (2E)-, dimethyl ester] (DMF) (CAS#: 624-49-7): The product does not contain this restricted substance as intentionally added component.

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Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) - Commission Decision of 19 March 2010 (2010/169/EU)

Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) Cas. N.3380-34-5 is not used in the manufacture of or formulation of this product.

Consumer Product Safety Improvement Act of 2008 (CPSIA 2008; 15 USC)

The product does not contain restricted substances mentioned under "CPSIA 2008; 15 USC", as intentionally added components or as expected process impurities:

	Limits:
Lead (Pb) and Lead compounds	0.03
Butyl benzyl phthalate	0.1
Di-n-Butyl phthalate	0.1
Di-(2-ethylhexyl) phthalate	0.1

Composting - CEN Standard prEN 13432

This product is not suitable for composting.

8.5 Statement on Heavy Metals

Heavy metals (ELV Directive 2000/53/EC)
The material meets the requirements of the ELV Directive 2000/53/EC and its amendments.

European Union (EU) Directive - Packaging and Packaging Waste - 94/62/EC (as amended)
Cadmium, chromium (VI), lead and mercury are not used in the manufacture of or the formulation of this product. This product meets the requirements of less than 100 ppm for total incidental cadmium, chromium (VI), lead and mercury.

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9 MSDS - Material Safety Data Sheet

Material Safety Data Sheet according to ***1907/2006/EC, Article 31***.

9.1 Product and Company Identification

Product Name:	TpCh260 TZ (DURAN PURE Premium screw cap STERICILIN material name specified by manufacturer of premium screw caps) Product name of raw material will be given after signing confidentially agreement
Manufacturer:	Manufacturer of raw material will be given after signing confidentially agreement
Address:	Address of manufacturer and raw material supplier will be given after signing confidentially agreement

9.2 Composition/ Information on Ingredients

The material of the premium screw cap is a Fluoropolymer.
Ingredient: Tetrafluorethylene-Perfluoro (Propyl Vinyl Ether) Copolymer
C.A.S. No.: 26655-00-5
% by Wt: 100

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9.3 Hazards Identification

Emergency Overview

Specific Physical Form:	Granules
Odor, Color, Grade:	Transparent, odorless
General Physical Form:	Solid
Immediate health, physical, and environmental hazards:	May cause thermal burns May cause target organ effects

Potential Health Effects

Eye contact:

During Heating — Vapors from heated material may cause eye irritation.
Signs/symptoms may include redness, swelling, pain, tearing, and blurred or hazy vision.

Thermal burns — Signs/symptoms may include severe pain, redness and swelling, and tissue destruction.

Skin contact:

During Heating

Thermal burns — Signs/symptoms may include intense pain, redness and swelling, and tissue destruction.

Inhalation:

During Heating — Vapors from heated material may cause irritation of the respiratory system.
Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.
Polymer Fume Fever: Sign/symptoms may include chest pain or tightness, shortness of breath, cough, malaise, muscle aches, increased heart rate, fever, chills, sweats, nausea and headache.
If thermal decomposition occurs:
May be absorbed following inhalation and cause target organ effects.

Ingestion: No health effects are expected.

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9.4 First Aid Measures

First aid procedures
The following first aid recommendations are based on an assumption that appropriate personal and industrial hygiene practices are followed.

Eye contact:	Immediately flush eyes with large amounts of water for at least 15 minutes. DO NOT ATTEMPT TO REMOVE MOLTEN MATERIAL. Get immediate medical attention.
Skin contact:	Immediately flush skin with large amounts of cold water for at least 15 minutes. DO NOT ATTEMPT TO REMOVE MOLTEN MATERIAL. Cover affected area with a clean dressing. Get immediate medical attention.
Inhalation:	Remove person to fresh air. If signs/symptoms develop, get medical attention.
Ingestion:	No need for first aid is anticipated.

9.5 Fire-Fighting Measures

Flammable properties

Autoignition temperature	Not Applicable
Flash Point	No flash point
Flammable Limits (LEL)	Not Applicable
Flammable Limits (UEL)	Not Applicable
Extinguishing media:	Non-combustible. Choose material suitable for surrounding fire.

Protection of fire fighters

Special Fire-Fighting Procedures:	Exposure to extreme heat can give rise to thermal decomposition. Wear full protective equipment (Bunker Gear) and a self-contained breathing apparatus (SCBA).
Unusual Fire and Explosion Hazards:	Not Applicable

Note: See STABILITY AND REACTIVITY for hazardous combustion and thermal decomposition information.

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9.6 Accidential Release Measures

Personal Precautions, equipment and emergency procedures:	Evacuate unprotected and untrained personnel from hazard area. The spill should be cleaned up by qualified personnel. Ventilate the area with fresh air.
Environmental precautions:	Place in a closed container approved for transportation by appropriate authorities. Dispose of collected material as soon as possible.
Clean-up methods:	Observe precautions from other sections. Call HELPS line (1-800-364-3577) for more information on handling and managing the spill. Collect as much of the spilled material as possible. Use wet sweeping compound or water to avoid dusting. Sweep up. Clean up residue.

9.7 Handling and Storage

Handling:	Avoid skin contact with hot material. For industrial or professional use only. Store work clothes separately from other clothing, food and tobacco products. No smoking: Smoking while using this product can result in contamination of the tobacco and/or smoke and lead to polymer fume fever caused by the formation of the hazardous decomposition products mentioned in the Reactivity Data section of this MSDS.
Storage:	Keep container tightly closed.

9.8 Exposure Controls/ Personal Protection

Engineering Controls:	Provide appropriate local exhaust when product is heated. For those situations where the material might be exposed to extreme overheating due to misuse or equipment failure, use with appropriate local exhaust ventilation sufficient to maintain levels of thermal decomposition products below their exposure guidelines.
Personal protective equipment	
Eye/Face Protection:	Avoid eye contact. The following eye protection(s) are recommended: Safety Glasses with side shields Indirect Vented Goggles
Skin Protection:	Avoid skin contact with hot material. Wear heat insulating gloves when handling this material to prevent thermal burns.
Respiratory Protection: During Heating:	Avoid breathing of vapors. Use a positive pressure supplied-air respirator if there is a potential for exposure from an uncontrolled release, exposure levels are not known, or under any other circumstances where air-purifying respirators may not provide adequate protection.

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	Select one of the following NIOSH approved respirators based on airborne concentration of contaminants and in accordance with OSHA regulations: Half facepiece or fullface air-purifying respirator with N95 particulate filters. Select and use respiratory protection to prevent an inhalation exposure based on the results of an exposure assessment. Consult with your respirator manufacturer for selection of appropriate types of respirators.
Prevention of swallowing	Do not eat, drink or smoke when using this product. Wash exposed areas thoroughly with soap and water.
Exposure Guidelines:	None established

9.9 Physical and Chemical Properties

Specific Physical Form	Granules
Odor, color, Grade	transparent, odorless
General Physical Form	Solid
Autoignition Temperature	Not Applicable
Flash Point	No flash point
Flammable Limits (LEL)	Not Applicable
Flammable Limits (UEL)	Not Applicable
Boiling Point	Not Applicable
Density	2.1 – 2.2 g/cm3
Vapor Density	Not Applicable
Vapour Pressure	Not Applicable
Specific Gravity	2.1 – 2.2 (@ 23 °C) (Ref Std: WATER=1)
pH	Not Applicable
Melting Point	>= 300 °C
Solubility in Water	Negligible
Evaporation rate	Not Applicable
Volatile Organic Compounds	Not Applicable
Kow – Oct/Water partition coef	Not Applicable
Percent volatile	Not Applicable

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VOC Less H2O & Exempt Solvents	Not Applicable
Viscosity	Not Applicable
Materials to avoid	Reactions with metals in powder form occur from 370 degrees C onwards.

9.10 Stability and Reactivity

Stability	stable
Conditions to avoid	None Known
Materials to avoid	Alkali and alkaline earth metals Reactions with metals in powder form occur from 370 degrees C onwards.
Hazardous Polymerization	Hazardous polymerization will not occur.

Hazardous Decomposition or By-Products

Substance	**Condition**
Carbonyl Fluoride	At Elevated Temperatures
Carbon Monoxide	At Elevated Temperatures
Carbon Dioxide	At Elevated Temperatures
Hydrogen Fluoride	At Elevated Temperatures
Perfluoroisobutylene (PFIB)	At Elevated Temperatures
Toxic Vapor, Gas, Particulate	At Elevated Temperatures

9.11 Toxicological Information

Please contact the address listed on the first page of the MSDS for Toxicological Information on this material and/or its components.

9.12 Ecological Information

Ecotoxicological Information	Not determined
Chemical Fate Information	Not determined

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9.13 Disposal Considerations

Waste Disposal Method:
Reclaim if feasible. Dispose of waste product in a facility permitted to accept chemical waste. Incinerate in an industrial or commercial facility in the presence of a combustible material. For quantities <100 lbs. (50kg): dispose of waste product in a sanitary landfill. Combustion products will include HF. Facility must be capable of handling halogenated materials.

EPA Hazardous Waste Number (RCRA): Not regulated

Since regulations vary, consult applicable regulations or authorities before disposal.

9.14 Transport Information

ID Number(s):
97-5000-1136-2, 98-0213-1298-2

9.15 Regulatory Information

US FEDERAL REGULATIONS
Contact DWK Life Sciences for more information.

311/312 Hazard Categories:
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No
Immediate Hazard - No
Delayed Hazard - No

STATE REGULATIONS
Contact DWK Life Sciences for more information.

CHEMICAL INVENTORIES
The components of this product are in compliance with the chemical notification requirements of TSCA.

All applicable chemical ingredients in this material are listed on the European Inventory of Existing Chemical Substances (EINECS), or are exempt polymers whose monomers are listed on EINECS. The components of this product are listed on the Canadian Domestic Substances List.

The components of this product are listed on the Australian Inventory of Chemical Substances.

The components of this product are listed on Japan's Chemical Substance Control Law List (also known as the Existing and New Chemical Substances List.)

The components of this material are in compliance with the new chemical notification requirements for the Korean Existing Chemicals Inventory.

The components of this product are in compliance with notification requirements in the Philippines.

INTERNATIONAL REGULATIONS
Contact DWK Life Sciences for more information.

This MSDS has been prepared to meet the U.S. OSHA Hazard Communication Standard,

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29 CFR 1910.1200.

9.16 Other Information

NFPA Hazard Classification
Health: 1 **Flammability:** 0 **Reactivity:** 0 **Special Hazards:** None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

HMIS Hazard Classification
Health: 1 **Flammability:** 0 **Reactivity:** 0 **Protection:** X - See PPE section.

Hazardous Material Identification System (HMIS®) hazard ratings are designed to inform employees of chemical hazards in the workplace. These ratings are based on the inherent properties of the material under expected conditions of normal use and are not intended for use in emergency situations. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint and Coatings Association (NPCA).

Intended Use of Product: Fluoroplastic

The information on this Data Sheet is based on our experience and is correct to the best of our knowledge at the date of publication, but we do not accept any liability for any loss, damage or injury resulting from its use (except as required by law). The information may not be valid for any use not referred to in this Data Sheet or use of the product in combination with other materials. For these reasons, it is important that customers carry out their own test to satisfy themselves as to the suitability of the product for their own intended applications.

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10 Packaging

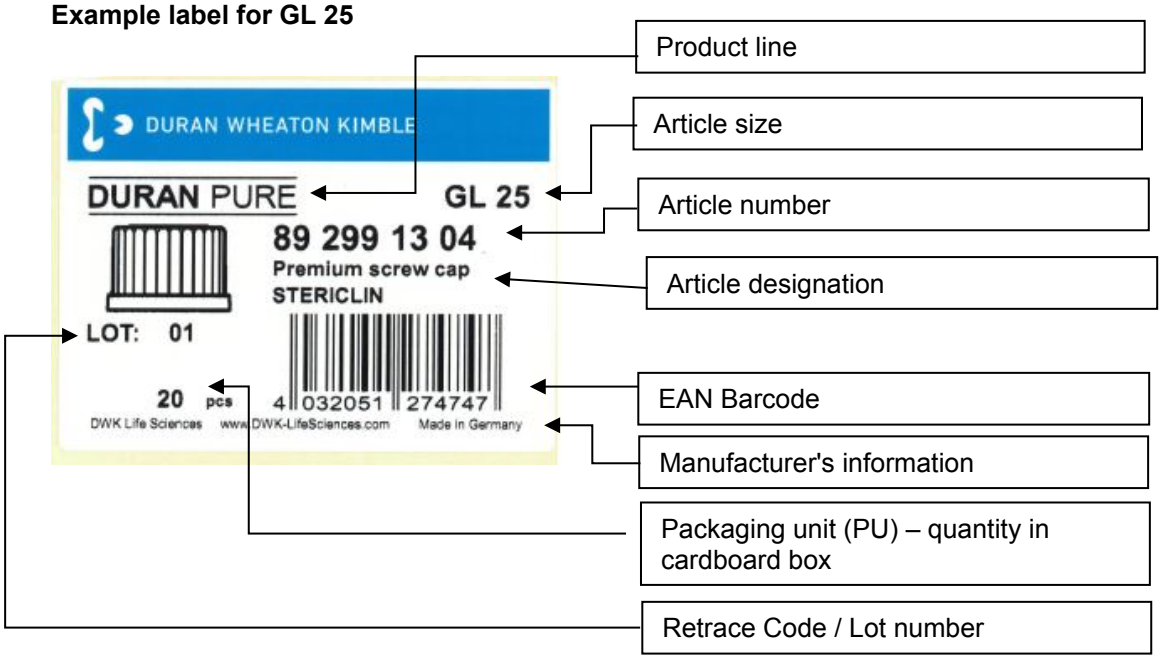
The DURAN PURE Premium screw cap STERICLIN is packed in accordance with the DWK Life Sciences packaging standard.

11 Packaging labelling

Each packaging unit (cardboard box) has a DWK Life Sciences label containing the following information:

- Article number
- Article designation
- Article size
- Retrace Code/ Lot number
- EAN barcode
- Quantity (number) in the cardboard box/ Packaging unit
- Manufacturer's information

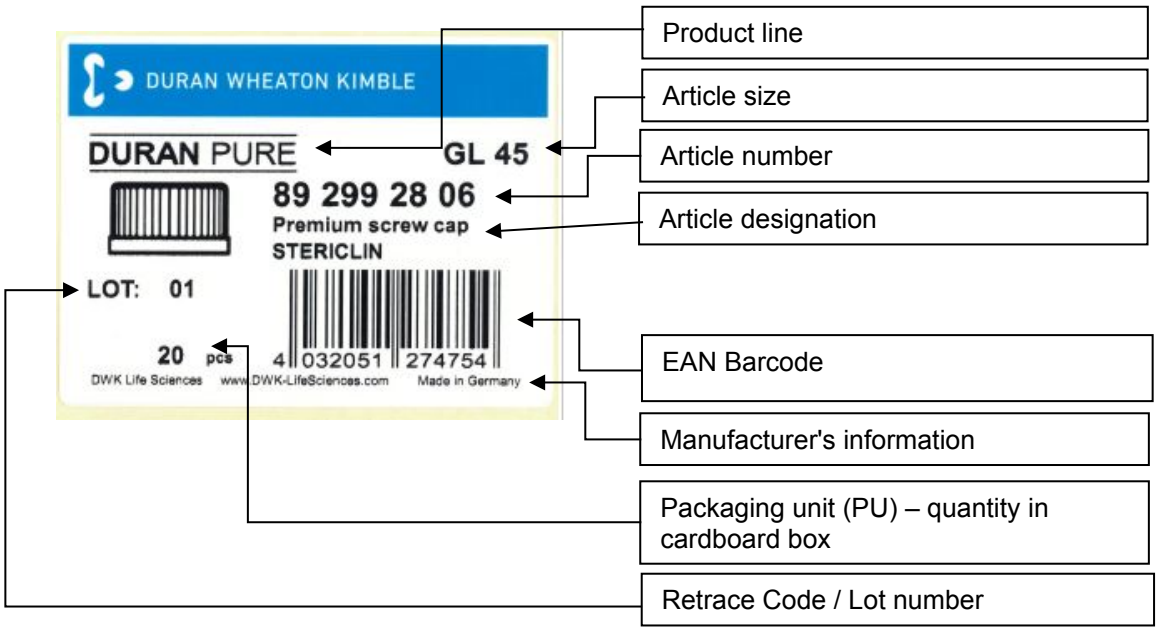
Example label for GL 25



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Product Specification
DURAN PURE Premium screw cap, STERICLIN
GL 25 article number: 89 299 13 04
GL 45 article number: 89 299 28 06

Example label for GL 45



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12 Specification Sterile barrier system - STERICLIN

The STERICLIN® packaging is a sterile barrier system in accordance with DIN ISO 11607.

Product name	Transparent pouches or tubes quality MM70-1/PP50-1
Description	Packaging material for medicinal products
Application	Depending on customer's requirements
Sterilisation suitability	Steam, ethylene oxide and formaldehyde sterilisation Prescribed sterilisation process: steam sterilisation in prevacuum, from 121°C for 20 minutes to 134°C for 20 minutes
Ground contamination	≤ 10^2 KBE/100 cm^2 ≤ 10^2 CFU/100 cm^2 ≤ 10^2 CFU/100 cm^2
Resistance to ageing	The products can be used for five years from the date of manufacture if stored appropriately (see recommended storage conditions).

12.1 Properties (STERICLIN® packaging)

Pouch specification

Pouch width	Tolerance ± 2 mm
Pouch length	Tolerance ± 3 mm
Side fold	+ 5 mm/ - 2 mm
Edge seal	Tolerance ± 1.5 mm
Top edge seal	Tolerance ± 5 mm
Thumb cut	Tolerance ± 3 mm
Opening aid paper/film size difference	Tolerance ± 1 mm

Secondary packaging

Transparent pouches are shrink wrapped in PE film in packs of 100 and packed in cardboard boxes.

Roll specification

Roll length	100 to 300 lfm. (tolerance +0.5 - 0 lfm)
Core diameter	76 mm (tolerance ± 1 mm)
Core material	Cardboard (plastic is also available in 76 mm upon request)
Roll width	48 to 450 mm (tolerance ± 1 mm)
	451 to 900 mm (tolerance +2 -3 mm)
Roll outside diameter	max. 400 mm

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Roll winding	Film wound inwards
Adhesion to core	Double-sided adhesive tape 19 mm
Number of splices	60% of rolls without splices, 30% of rolls with one splice, max. 10% of rolls with two splices
Splice design	Single-sided with heat-resistant double-sided adhesive tape 19 mm
Core/winding offset	± 1 mm

Roll labelling

The rolls have a label inside the core. The roll label has the following information:

- Supplier lot code
- Customer article number
- Customer order number
- VP material code
- Roll width
- Repeat (AL) section length
- Roll length
- Date (date of manufacture)
- Name (machine operator)
- Consecutive no. (master roll)
- Roll number

Single-roll packaging

Transparent tubes are wrapped in PE film.

12.2 Traceability (STERICLIN® packaging)

Complete traceability by lot identification on the pouch or roll.

12.3 Quality (STERICLIN® packaging)

The manufacturing processes and materials comply with the specifications of DIN EN ISO 11607. In-process inspections and final inspections are carried out for every production lot.

12.4 Characteristics (STERICLIN® packaging)

Technical characteristics

Paper weight	Paper weight: 70 -5/ + 3 g/m²
Composite film	Composite film blue PET-O/PP 12/40
Thickness	55 ± 10% µm
Printing inks/indicators	max. 4 printing inks/indicators

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Print characteristics – tolerances

- Misalignment MD of 1 colour ± 1 mm
- Misalignment CD of 1 colour ± 1 mm
- Misalignment MD of 2 colours ± 2 mm
- Misalignment CD of 2 colours ± 2 mm
- Misalignment MD of front/back ± 2 mm
- Misalignment CD of front/back ± 2 mm

12.5 Compliance with standards (STERICLIN® packaging)

The paper complies with DIN EN ISO 11607 Part 1 and DIN EN 868 Part 3

The film complies with DIN EN ISO 11607 Part 1 and DIN EN 868 Part 5 Sections 4.2.2.1 to 4.2.2.5.
The packaging material complies with DIN EN ISO 11607 Parts 1 and 2.

12.6 Packaging (STERICLIN® packaging)

Sealing information (guide values)

Sealing temperature: 175 - 200°C

Shipping packaging

Pallet format	Standard Euro/non-returnable pallet size 800 x 1,200 mm, various special pallets upon request
Pallet height	Maximum 1450 mm incl. pallet
Pallet weight	Maximum gross weight/pallet 600 kg
Outer packaging	Cardboard boxes are supplied on pallets and shrink-wrapped in film

12.7 Labelling (STERICLIN® packaging)

The cardboard boxes, in which the STERICLIN rolls or pouches are supplied for reuse, are identified by the manufacturer with a label on the front of the cardboard boxes. The cardboard box label has the following information:

- Customer
- Supplier lot code
- Manufacturer order no. (VK no.)
- Customer article number
- Material designation
- Manufacturer article no.
- Size
- Package contents
- Cardboard box no.
- Date (date of manufacture)

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13 Storage

Do not open packaging until the product needs to be used

Storage conditions for non-sterile and sterile units: according to USP <659> “Packaging and Storage Requirements”, articles must be protected from moisture, freezing, excessive heat and from light during shipping and distribution.
Damaged packages may **not** be used.
Storage period prior to sterilisation: 5 years from manufacture of the SBS.
Storage period after sterilisation: if the storage conditions for sterile products are met, the storage periods according to DIN 58953-8:2010 apply, e.g. 6 months from date of sterilisation if recommended storage conditions are met.

14 Disposal Considerations

The uncontaminated product has no hazardous properties and is therefore not hazardous waste as defined by the order on the European Waste List (AVV).
The exact disposal code must be established in relation to origin and use. Potential disposal codes for the uncontaminated product are as follows:

- 07 02 13 (plastic waste)
- 20 01 39 (plastic from separately collected lots)

15 Complaints

In case of complaints, please contact your distributor and the DWK Life Sciences service team by using the following email address: complaint@dwk.com
Complaints can only be made about not maintained quality limit values or characteristics defined in this DWK Life Sciences specification.
Agreement will be necessary between the customer and the DWK Life Sciences in each case prior to processing, as costs may be incurred through reworking, sorting, destruction or return of faulty units if applicable.

The following information will be necessary as well as the reason for the complaint:

- Article designation
- Article number (DWK pallet document)
- Retrace Code/ Lot number
- Complaint quantity in relation to the corresponding delivery quantity
- Goods received date at the customer's
- Order and/or Invoice number

A sample (free of contamination) shall also be provided.

16 Associated documents

Respectively valid drawing of the DURAN PURE Premium screw cap STERICLIN.
Respectively valid specification of the DURAN PURE PTFE coated silicone seal
Respectively valid drawing of the DURAN PURE PTFE coated silicone seal.