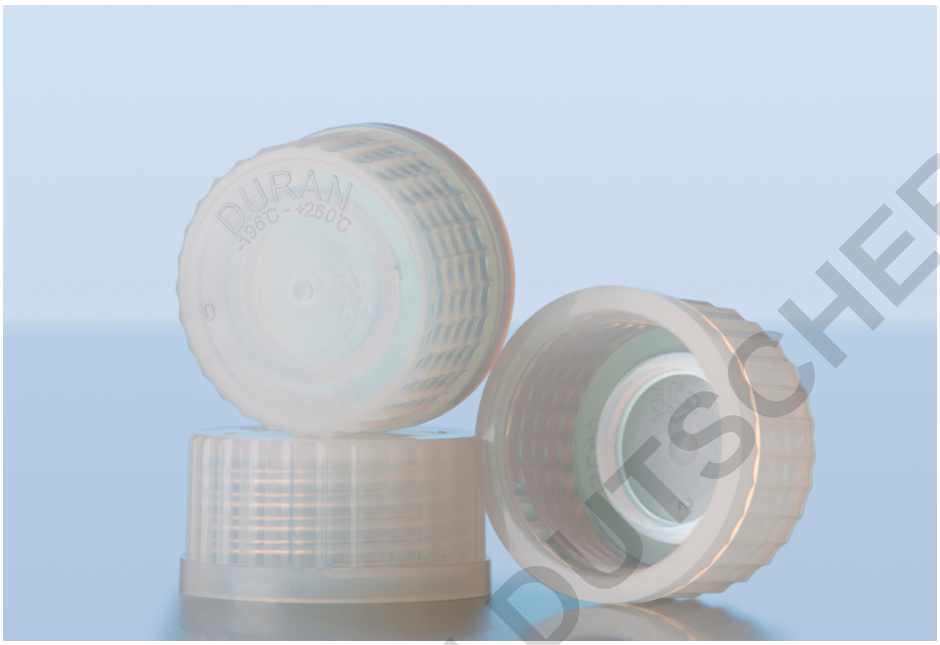
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Product Specification

DURAN PURE Premium lip seal cap, GL 45

Article: 89 886 28 02

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Product Specification
DURAN PURE Premium lip seal cap, GL 45
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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:

89 886 28 02

Description:

DURAN PURE Premium lip seal cap, GL 45 for DURAN PURE bottles with DIN Thread GL 45

3 Validity

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

4 Product

DURAN PURE Premium lip seal cap made of fluoroplastic (PFA 6515TZ) to fit DIN thread GL 45.

The screw cap is produced from fluoroplastic (PFA 6515TZ) without additional colourants.

4.1 Material properties *

Property	Test Method	Unit	Value
Specific Gravity	DIN EN ISO 12086	g/cm³	2.15
Melting point	DIN EN ISO 12086	°C (°F)	308 (586)
Melt flow rate (372°C/5 kg)	DIN EN ISO 1133	g/10 min	15
LOI	ASTM D2863	%	> 95

* typical values

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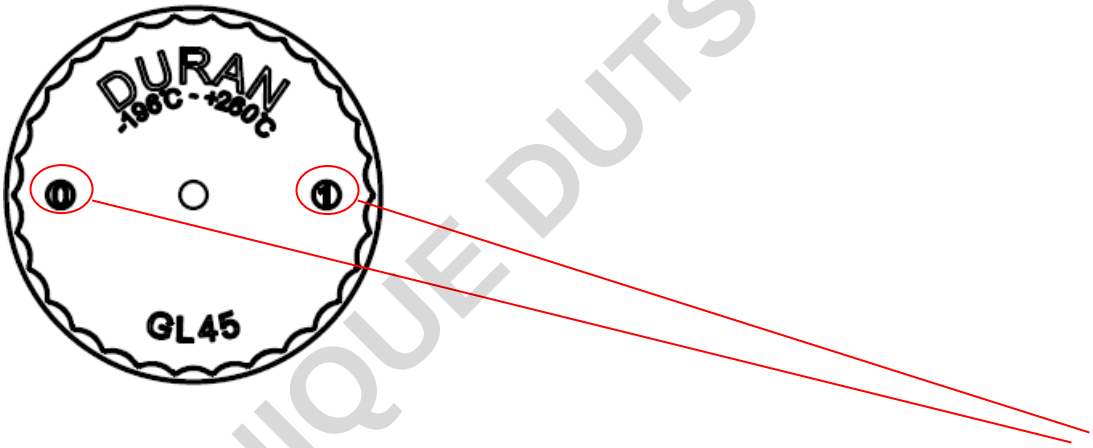
4.2 Mechanical properties of the Material*

Property	Test Method	Unit	Value
Hardness Shore D	ASTM D2240/SO 868		60
Tensile strength at break (23 °C)	DIN EN ISO 527-1	MPa	28
Elongation at break (23 °C)	DIN EN ISO 527-1	%	420
Flexural Modulus	ASTM D790	MPa	620

* typical values

5 Traceability

The DURAN PURE Premium lip seal cap 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.



Lot numbering system on DURAN PURE Premium lip seal cap, GL 45: 2 digit lot number: „01“

Definition Lot Number:

A lot is defined as the amount of an uninterrupted production order.

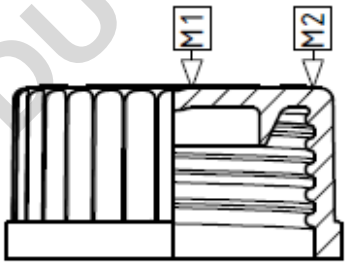
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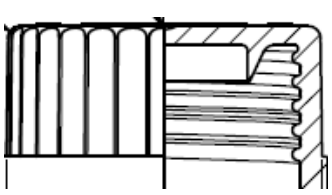
6 Characteristics

6.1 Dimensional characteristics according to drawing

Drawing: D173645-GZA-0GL45 (respectively valid index)

Reference to drawing	Dimension
1	Thread core diameter
2	Outer thread diameter
3	Outer diameter
4	Height
5	Inner diameter cone
6	Wall thickness, table top of the lid
7	Evenness, table top of the lid
Evenness of the head plate	Height difference between the measuring points M1 and M2 according to drawing
	

6.2 Other characteristics of the product

Weight per cap	41 g
Service temperature	-196° - +260°C
Key parameters	Cone
	

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Production standard	Produced and packed under class 7 clean room conditions in accordance to EN ISO 14644-1.
Leak tightness	According to DWK work instruction: Dok ID 18570 “Durchführung Leckagentest”
Outer Surface finish - mould	Surface of the cap: polished. Circle in the middle of the cap: eroded - rough
Inner Surface finish - mould	Polished
Defined cap tightness in Nm	4 NM
Microwave heating	The cap may be heated in the microwave however the cap thread must be lessened before heating bottles or containers in a microwave oven.

6.3 Chemical Resistance

Classes of substances + 20 ^{0}C	**Material PFA6515TZ** *
Alcoholics, aliphatic	++
Aldehydes	++
Alkaline solutions	++
Esters	++
Ethers	++
Hydrocarbons, aliphatic	++
Hydrocarbons, aromatic	++
Hydrocarbons, halogenated	++
Ketones	++
Acides dilute or weak	++
Acides, conc. Or strong	++
Acides, oxidising	++

*++ very good persistence
+ good persistence
- small persistence

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7 Quality

The DURAN PURE Premium lip seal cap, GL 45, 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.

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Product Specification
DURAN PURE Premium lip seal cap, GL 45
Article number: 89 886 28 02

Defect evaluation and classification according to:

> Editio Cantor Verlag, Aulendorf, Vol.22: „Quality Assurance of Pharmaceutical and Cosmetic Packaging Materials. Section: Defect Evaluation List for Injection-moulded Parts Made of Plastic: Closures, Sealing Disks and Dosage Aids (Droppers, etc.).”

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

Basic scheme for defect evaluation and for weighting defects (Editio Cantor Band 22):

Basic scheme for defect evaluation and for weighting defects.

Classification or defect	Effect of defects	Defect class	Individual permitted defect (ID) AQL	Total permitted defect (TD) AQL	Consequence
Critical defect (CD)	Critical defects are defects which endanger: – human life and health – contravene legal requirements – lead to destruction or alterations of the filling material – seriously impair the reliability of production tools, filling and packaging equipment	1			Packaging material not usable
Major defect (MD)	Major defects are defects which lead to: – inefficient function and so to the deficiency of the packaging material or the pack – or result in complaints by the user – or lead to reduced efficiency in production – or impair reliability of production tools and filling and packaging equipment	2 A	0,1	0,4	Packaging material not usable
		2 B	0,4	1,0	Usability of packaging material moderately impaired
Minor defect (MinD)	Minor defects are defects which lead to reduction of general quality	3	2,5	6,5	Usability of packaging material slightly impaired

(Definition in accordance to the DGQ-Pamphlet 11-04 and Mil. Std. 105 E)

Attribute	Defect No.	Defect / Individual characteristics	Individual defect AQL	Test method	Defect class
Delivery, labelling, packaging	22.01.01	Pallet and / or outer pack does not correspond to the specification	0,1	Visual testing, checking of the DWK specification	2A
	22.01.06	Individual packs damaged, soiled, incomplete	0,1	Visual testing	2A
Raw material	22.02.01	Material must comply with the specification		Identification control	1
	22.02.02	No coloration		Identification control, limit samples	1

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Attribute	Defect No.	Defect / Individual characteristics	Individual defect AQL	Test method	Defect class
Intermixing	22.03.01 / 22.03.02 / 22.03.03	Intermixing from other exemplars as agreed in this specification	0,1	Visual testing	2A
Cleanliness, hygiene	22.04.01	Contamination with foreign bodies or material residues or considerably soiled and / or dusty		Visual testing	1
	22.04.02	Foreign bodies incorporated in the material	0,4	Visual testing	2B
	22.04.03	Burn marks: - Marks >2 mm diameter - Dots 0,5 to 2mm diameter	 0,1 0,4	Visual testing	 2A 2B
	22.04.05	Parts produced and packed under low contamination conditions		According to clean room conditions class 8	1
	22.04.06	Agreed maximum number of particles may not be exceeded		According to clean room conditions class 8	1
Processing errors	22.05.01	Roughness in the area of the dropping rim and of the sealing areas - Seal not possible		Visual testing and leak tightness testing according to DWK work instruction “Durchführung Leckagentest”	1
	22.05.02	Roughness in the area around the injection point	2,5	Visual testing	3
	22.05.03	Injection point not sharp-edged	0,1	Visual testing	2A
	22.05.06	Deformation -function impaired	0,1	Visual testing	2A
	22.05.07	Tears, clefts, holes parts incompletely injected, seam breaks open -function not ensured		Visual testing and leak tightness testing according to DWK work instruction “Durchführung Leckagentest”	1

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Product Specification
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Attribute	Defect No.	Defect / Individual characteristics	Individual defect AQL	Test method	Defect class
	22.05.09	Over-injection, flash at the sealing points	0,1	Visual testing and leak tightness testing according to DWK work instruction “Durchführung Leckagentest”	2A
Dimensions	22.06.02.01	Outer diameter out of tolreance (see drawing, measuring point 3)	0,1	Inspection equipment: Digital gauge	2A
	22.06.02.02	Thread and / or thread core diameter out of tolerance (see drawing, measuring point 1 and 2)	0,1	Inspection equipment thread core: Digital gauge Inspection equipment outer thread diameter: Inside calipers	2A
	22.06.02.03	Height out of tolerance (see drawing, measuring point 4)	0,1	Digital gauge	2A
	22.06.02.04	Wall thickness, table top of the lid out of tolerance (see drawing, measuring point 6)	0,1	Inspection equipment: Outside calipers	2A
	22.06.02.05	Inner diameter cone out of tolerance (see drawing, measuring point 5)	0,1	Inspection equipment: Inside calipers	2A
	22.06.02.06	Evenness of the head plate out of tolerance (see drawing, measuring point 7)	0,1	Inspection equipment: Digital height gauge	2A
	22.06.02.07	Thread missing or only inadequately formed	0,1	Visual testing	2A
	22.06.02.08	Thread-form and / or –pitch do not correspond	0,1	Visual testing	2A
	22.06.02.09	Rotational or snapping properties not adequate	0,1	Visual testing	2A
	22.06.02.18	Cone deformed	0,1	Visual testing	2A
Decoration	22.07.03	Overprinting /embossed text not clean but still legible	0,1	Visual testing	2A
		Lot number must be existing and legible		Visual testing	1

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8 Recommendations

8.1 Sterilisation Recommendations

Autoclaving	Yes	121 °C, 20 minutes 134 °C, 5 minutes
Chemicals	Yes	Chemical Ethylene Oxide, formaldehyde, hydrogen peroxide.
Disinfectants	Yes	Disinfectants such as Benzalkonium chloride, formalin/formaldehyde, ethanol, etc.
Dry Heat	Yes	Typical data: 180 °C minimum 30 min 170 °C minimum 60 min 160 °C minimum 120 min

8.2 Cleaning Recommendations

Hand washing process	Yes. Neutral (around pH. 7.0) detergents. Do not use cleaners containing solvents, or chlorine.
Automated washing process	Yes. Neutral (around pH. 7.0) detergents. Do not use cleaners containing solvents, or chlorine.
Ultrasonic Cleaning baths	Yes. Ultrasonic cleaning units may be used to clean this product as long as it does not come into direct contact with the transducer.

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9 Compliance with standards

9.1 US Pharmacopeia (USP)

The DURAN PURE Premium lip seal cap, GL 45, 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

9.2 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 (incl. amendments) about materials and articles made of plastics and intended to come into contact with foodstuffs (in compliance with BGVO in its valid version).

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 XIV “Kunststoff-Dispersionen” 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 foodstuffs or toys as referred to in the german “Lebensmittel- und Futtermittelgesetzbuches“ (LFGB) § 2 Section (6), No. 1 (EC) 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.

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USA	This product meets the FDA criteria in 21 CFR § 177.1550 for food contact applications.

9.3 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.

9.4 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 (Article 57, Regulation No. 1907/2006).

RoHS Directive 2011/65/EU

None of the substances referenced in the EU Directives 2011/65/EU and 2012/19/EU WEEE are intentionally added during the manufacturing of the above mentioned product.

Therefore we can act on the assumption that these substances might appear only in ubiquitary concentration.
For this reason the following regulations and standards are fulfilled: RoHS and WEEE Directive including amendments and appendixes.

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.

Coalition of Northeastern Governors (CONEG)

Cadmium, chromium (VI), lead and mercury are not used in the manufacture of or the formulation of this product.

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

The material of the DURAN PURE Premium lip seal cap, GL 45, is a Fluorpolymer, that consists amongst others Tetrafluoroethylen (TFE) that is listed under „California Proposition 65 list“. According to analysis of the raw material producer the concentration of the residual monomer TFE is below the limit of quantitation (LOQ < 0.1 ppm).
Under certain conditions such as high temperatures, it is possible that TFE may be produced as a decomposition product.

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 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.

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.

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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.

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.

DOWNLOAD DUTSCHER SAS

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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.

9.5 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 following 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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10 MSDS - Material Safety Data Sheet

Material Safety Data Sheet according to ***1907/2006/EC, Article 31***. The content is written by the original resin manufacturer.

10.1 Product and Company Identification

Product Name:	PFA 6515TZ (Premium Cap 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

10.2 Composition/ Information on Ingredients

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

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10.3 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.

10.4 First Aid Measures

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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.

10.5 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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10.6 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.

10.7 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.

10.8 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. 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.

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	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

10.9 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
VOC Less H2O & Exempt Solvents	Not Applicable
Viscosity	Not Applicable

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Materials to avoid	Reactions with metals in powder form occur from 370 degrees C onwards.

10.10 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

10.11 Toxicological Information

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

10.12 Ecological Information

Ecotoxicological Information	Not determined
Chemical Fate Information	Not determined

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10.13 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.

10.14 Transport Information

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

10.15 Regulatory Information

US FEDERAL REGULATIONS
Contact DURAN Group 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 DURAN Group 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 DURAN Group for more information.

This MSDS has been prepared to meet the U.S. OSHA Hazard Communication Standard,
29 CFR 1910.1200.

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10.16 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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11 Packaging

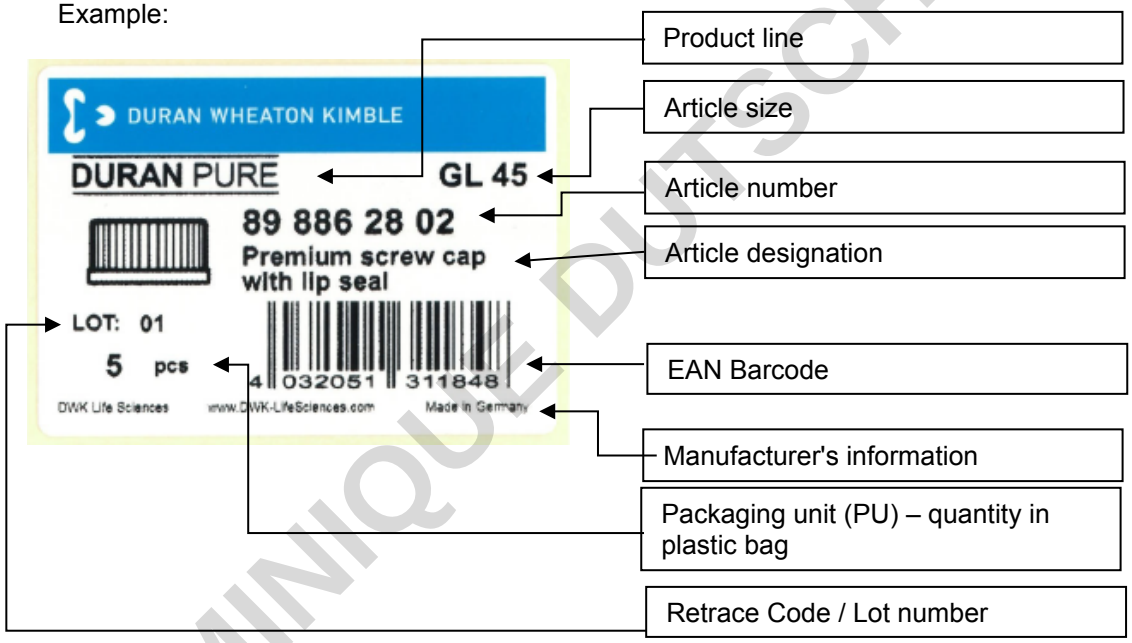
Supplies will be assembled according to order quantity of the customer. Bags will be packed into adequate cardboard boxes.

12 Sales packaging labelling

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

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

Example:



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13 Storage

According to USP <659> “Packaging and Storage Requirements”, articles must be protected from moisture, freezing, excessive heat and from light during shipping and distribution.

The storage duration of the article before use should not exceed 5 years after production. Shelf life depends on the application and media. We recommend a maximum shelf life of 5 years.

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 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 lip seal cap, GL 45

Title

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