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Specification

DURAN PURE screw cap, GLS 80

Article: 89 116 91 09

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Content

1 Generally Admitted 4
2 Scope 4
3 Validity 4
4 Product 4
4.1 Material properties 4
4.2 Temperature Resistance 5
4.3 Chemical Resistance 5
5 Traceability 5
6 Quality 6
7 Characteristics 7
8 Compliance with standards 8
8.1 Statement on Food Contact 8
8.2 Statement on BSE/TSE 8
8.3 Statement on Chemicals, regulations and standards 9
REACH Regulation (EC) No. 1907/2006 9
RoHS Directive 2011/65/EU 9
Latex 9
PFOA 9
Coalition of Northeastern Governors (CONEG) 9
Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA) 9
Ozone Depleting Chemicals (ODCs) 9
Toys 10
Phthalates 10
Melamine 11
Acrylamide 12
Aromatic Amines 12
Asbestos 12
Bisphenol A 12
Dioxin 12
Nonylphenol 12
Alkylphenol 12
Organo-tin Compounds 12
Polybrominated Biphenyls (PBBs), Polybrominated Diphenyl Ethers (PBDEs) 12
Styrene and Polystyrene 12
Benzotriazol 12
Dimethyl Fumarate (DMF) - Annex XVII Regulation (EU) No. 1907/2006 13
Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether); 5-chloro-2-(2,4-dichlorophenoxy)phenol - Commission Decision of 19 March 2010 (2010/169/EU) 13
Consumer Product Safety Improvement Act of 2008 (CPSIA 2008; 15 USC) 13

Ausgedruckt unterliegt das Dokument nicht dem nderungsdienst. Ausgedruckt am: 25.02.2021.

Composting - CEN Standard prEN 13432 13
8.4 Statement on Heavy Metals 13
9 MSDS - Material Safety Data Sheet 14
9.1 Product and Company Identification 14
9.2 Composition/ Information on Ingredients 14
9.3 Hazards Identification 15
9.4 Composition/Information on Ingredients 15
9.5 First-Aid Measures 15
9.6 Fire-Fighting Measures 15
9.7 Accidential Release Measures 16
9.8 Handling and Storage 16
9.9 Exposure Controls/ Personal Protection 17
9.10 Physical and Chemical Properties 18
9.11 Stability and Reactivity 19
9.12 Toxicological Information 19
9.13 Ecological Information 20
9.14 Disposal Considerations 20
9.15 Transport Information 21
9.16 Regulatory Information 21
9.17 Other Information 21
10 Packaging 22
11 Sales packaging labelling 22
12 Storage 23
13 Disposal Considerations 23
14 Complaints 23
15 Associated documents 23

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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:

89 116 91 09

Description:

DURAN PURE screw cap GLS 80 for DURAN PURE bottles with wide neck, GLS 80.

3 Validity

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

4 Product

DURAN PURE screw cap GLS 80 made of Polyarylsulfone Compound (abbreviated: PSU) with press-fit PTFE coated silicone cap liner to fit thread GLS 80.

4.1 Material properties

Property	Unit	Value
Relative density	g/cm³	1.35-1.45
Melt flow rate (190°C/2,16 kg)	g/10 min	6.30
Hardness	MPa	130
Young`s Modulus	MPa	2.400
Temperature Resistance	°C	180
Tensile Stress at Yield	MPa	80-85

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4.2 Temperature Resistance

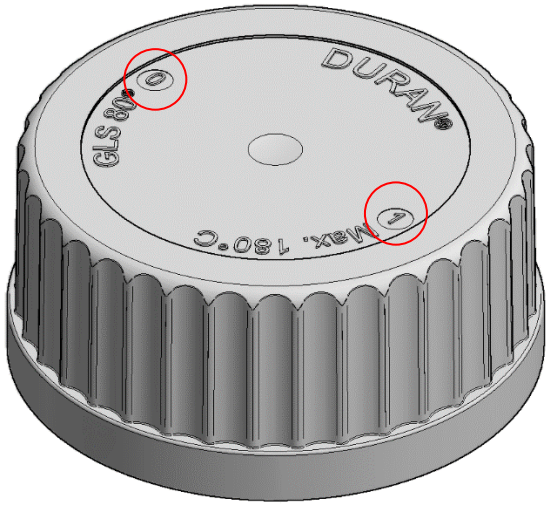
The DURAN PURE screw cap GLS 80 is temperature resistant up to +180°C.
The relative permittivity of the GLS 80 screw cap material stays constant for the used material between -200°C and +200°C.
The material is purely amorphous and has no crystalline structure.
The "glass transition temperature" of the product is 225°C. That means that at room temperature the product is already in "frozen" condition, therefore it is not to be expected that the material will change its behavior at -20, -40 or even -80 degree Celsius.

4.3 Chemical Resistance

Classes of substances at +20°C	PSU
Alkohols, aliphatic	++
Aldehydes	+
Alkaline solutions	++
Esters	+
Ethers	+
Hydrocarbons, aliphatic	+
Hydrocarbons, aromatic	-
Hydrocarbons, halogenated	-
Ketones	-
Acids, dilute or weak	++
Acids, conc. or strong	+
Acids, oxidising (oxidising agents)	-

5 Traceability

The DURAN PURE screw cap GLS 80 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.



Example for lot numbering system on DURAN PURE screw cap GLS 80: 2-digit Lot Number: „01“

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6 Quality

The DURAN PURE screw cap GLS 80 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 controls during production and final acceptance tests are conducted.
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 PTFE-coated silicone cap liner between the screw cap and the PTFE-coated silicone cap liner cannot be ruled out be due to the production process.

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7 Characteristics

The drawing is the basis for assessing the dimensional characteristics.

Acceptance test is done after each production. The following information is part of the certificate.

Sample size				**AQL**		
Visual inspection						
			Total defects			
			Acceptance number			
Extent of random samples				**AQL**		
Tests						
Test on the bottle						
Scraping on the thread						
			Total defects			
			Acceptance number			
Extent of random samples						
Dimensional inspection	**Nominal dimension**	**Upper tolerance**	**Lower tolerance**	**Min**	**Max**	**Mean**
Overall height (mm)						
Inner depth (mm)						
Thread core diameter (mm)						
Thread outer diameter (mm)						
Lower outer diameter (mm)						

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8 Compliance with standards

8.1 Statement on Food Contact

The products listed below may be used to produce articles which are intended for use in processing and handling food, and whose compositions comply with the requirements of 21 CFR 177.2440 "Polyethersulfones".

EU

The composition of the product complies with the requirements of Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and its amendments.

The following restrictions have to be ensured:

- 4,4`-Dihydroxydiphenyl sulphone: SML = 0,05mg/kg
- 4,4`-Dichlorodiphenyl sulphone: SML = 0,05mg/kg

SML = specific migration limit expressed in mg per kg food

Presuming appropriate processing the product can be used in the countries of the European Community for food contact materials or articles according to article 3 of Regulation (EC) No 1935/2004 (Regulation (EC) No 1935/2004 of the European Parliament and the Council of 27th October 2004 on materials and articles intended to come into contact with food).

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 Bedarfsgegenständeverordnung” in the revised version of 23.12.1997.

Due to the fact that the Regulation (EU) 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

The composition of the product complies with the requirements of the „Federal Food, Drug and Cosmetic Act“ and all applicable “Food Additive Regulations” including 21 CFR 177.2440 “Polyethersulfones”.
FDA 21 CFR 177.2440 includes explicit only repeated use applications (multiple contact with food only).
Additionally, since October 9th 2007 the product is subject of Food Contact Notification (FCN). Hence, the product fully complies with the requirements of the Federal Drug and Cosmetic Act, 21 CFR for food contact materials including materials for food packaging for convenience and baby food. The product can be used in articles intended for single and repeat-use in contact with all food types, including microwave applications with temperatures above 120 °C, i.e. under the Conditions of Use A through H, and J, (cooking temperatures above 250°F), as described in Tables 1 an 2 on FDA website: http://www.cfsan.fda.gov/~rdb/opa-fcn3.html

8.2 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"

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The product is free from BSE/TSE causal organisms.
Accordingly, transmission of animal spongiform encephalopathy agents via the mentioned components is extremely improbable.

8.3 Statement on Chemicals, regulations and standards

REACH Regulation (EC) No. 1907/2006

Please be advised that based on the information available to us from our raw material suppliers the current products listed above do not contain as intentionally added raw materials any of the substances of very high concern (SVHC) above a limit of 0.1 % w/w according to the candidate list, article 59 (1, 10) European REACH regulation No. 1907/2006/EC. To the best of our knowledge, none of these materials are generated during production.

RoHS Directive 2011/65/EU

Please be advised that based on the information available to us from our raw material suppliers, the current products listed above do not contain any substances mentioned in EU Directive 2011/65/EU. Based upon knowledge of the manufacturing process and the raw materials utilized, these substances are not expected to be present in the final products in levels exceeding the limitations of EU Directive 2011/65/EU.

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.

PFOA

The substances mentioned in the Directive 2006/122/EC (perfluorooctanoic acid and perfluorooctane sulfonate) are not used as additive or ingredient. Therefore the requirements of the Directive 2006/122/EC are fulfilled.

Coalition of Northeastern Governors (CONEG)

The sum of cadmium, chromium (VI), lead and mercury does not exceed the maximum value of 100 ppm (i.e. 0.01%) as required by the CONEG.

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)

The material of the DURAN PURE screw cap GLS 80 complies with the requirements of the Regulation **1005/2009/EC** (16th September 2009), the Council Directive **2002/215/EC** (14th March 2002) and the US labelling requirements of Section 611 of the **Clean Air Act Amendments of 1990** (CAA), §602 and §611.
The following ozone depleting substances are not intentionally used as additives or ingredients:

- Group I until VII (Class I in USA)
- Group I Chlorofluorocarbons (CFC's)
- Group II Other fully halogenated Chlorofluorocarbons
- Group III Halons
- Group IV Carbontetrachloride

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- Group V 1,1,1-Trichloroethane
- Group VI Methylbromide
- Group VII Hydrobromofluorocarbons
- Group VIII (Class II in USA) Hydrochlorofluorocarbons (HCFC's)
- Group IX Bromochloromethane

Therefore the requirements of the above listed regulations are fulfilled.

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 (CAS # 80-05-7, 137885-53-1, 27360-89-0, 28106-82-3, 37808-08-5) is not used as additive or ingredient.

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.

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 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.

Polybrominated Biphenyls (PBBs), Polybrominated Diphenyl Ethers (PBDEs)

These substances are not generated during production of the raw material.

Styrene and Polystyrene

Styrene (chemical name: ethenylbenzene) (CAS number 100-42-5) and polystyrene resins are not used as intentional additive or ingredient.

Benzotriazol

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) is not used as intentional additive or ingredient.

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

Please be advised that based on the information available to us from our raw material suppliers, the current products listed above do not contain the biocide Dimethylfumarate (DMF) (CAS No 624-49-7) as intentional additive or ingredient.

Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether); 5-chloro-2-(2,4-dichlorophenoxy)phenol - Commission Decision of 19 March 2010 (2010/169/EU)

The material of the DURAN PURE screw cap GLS 80 does not contain the biocide **Triclosan** (2,4,4'-trichloro-2'-hydroxy-diphenyl-ether; 5-chloro-2-(2,4-dichlorophenoxy)phenol, CAS No 3380-34-5) as intentional additive or ingredient.

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.

8.4 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 (2002/525/EC).

European Union (EU) Directive - Packaging and Packaging Waste - 94/62/EC (as amended)
The maximum value for cadmium, chromium (VI), lead and mercury laid down in Directive 94/62/EC is met.

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9 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.

9.1 Product and Company Identification

Product Name:	Raw material of DURAN PURE screw cap GLS 80 - raw material name 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 DURAN PURE screw cap GLS 80 is a Polyarylsulfone basis.

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9.3 Hazards Identification

Label elements
According to Regulation (EC) No 1272/2008 [CLP]

The product does not require a hazard warning label in accordance with EC Directives.

Classification of the substance or mixture

According to Regulation (EC) No 1272/2008 [CLP]

No need for classification according to GHS criteria for this product.

Possible Hazards:
No specific dangers known, if the regulations/notes for storage and handling are considered.
Danger of burns while handling the hot product.

Other hazards

According to Regulation (EC) No 1272/2008 [CLP]

Other Hazards (GHS):
No specific dangers known, if the regulations/notes for storage and handling are considered.

Assessment PBT / vPvB:
The product does not fulfill the criteria for PBT (persistent/bioaccumulative/toxic) or vPvB (very persistent/very bioaccumulative).

9.4 Composition/Information on Ingredients

Mixtures
Chemical nature

Polyethersulfone (PESU)

9.5 First-Aid Measures

Description of first aid measures
On skin contact:
Burns caused by molten material require hospital treatment.

Most important symptoms and effects, both acute and delayed
Symptoms: No significant reaction of the human body to the product known.

Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically

9.6 Fire-Fighting Measures

Extinguishing media
Suitable extinguishing media:
water spray, foam, dry powder

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Special hazards arising from the substance or mixture
At temperatures of > 400 °C can be emitted: carbon monoxide, Sulphur dioxide
Under special fire conditions traces of other toxic substances are possible. Formation of further decomposition and oxidation products depends upon the fire conditions.

Advice for fire-fighters
Further information:
Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

9.7 Accidential Release Measures

High risk of slipping due to leakage/spillage of product.

Personal precautions, protective equipment and emergency procedures
No special precautions necessary.

Environmental precautions
No special precautions necessary.

Methods and material for containment and cleaning up
For small amounts: Pick up with suitable appliance and dispose of.
For large amounts: Pick up with suitable appliance and dispose of.
Reclaim for processing if possible.

9.8 Handling and Storage

Precautions for safe handling
Protection against fire and explosion:
Take precautionary measures against static discharges.

Conditions for safe storage, including any incompatibilities
Suitable materials for containers: Low density polyethylene (LDPE)

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9.9 Exposure Controls/ Personal Protection

Control parameters
Components with workplace control parameters

The limit values will not be achieved if the product is processed proper and suitable ventilation is provided.

Exposure controls
Personal protective equipment

Respiratory protection:
Breathing protection if breathable aerosols/dust are formed. Wear respiratory protection if ventilation is inadequate.

Hand protection:
Use additional heat protection gloves when handling hot molten masses (EN 407), e.g. of textile or leather.

Eye protection:
Safety glasses with side-shields (frame goggles) (e.g. EN 166)

General safety and hygiene measures
No special precautions necessary.

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9.10 Physical and Chemical Properties

Form:	granules	
Colour:	light yellow to brownish	
Odour:	odourless	
Odour threshold:		
not applicable		
pH value:		
not applicable		
glass transition temperature:	225 °C	
Boiling range:		
The substance / product decomposes		
therefore not determined.		
Flash point:		
not applicable		
Evaporation rate:		
not applicable		
Ignition temperature:	580 - 600 °C	(DIN 54836)
Vapour pressure:		
not applicable		
Density:	1,30 - 1,40 g/cm3	(EN ISO 1183-1)
(20 °C)		
Relative density:		
No data available.		
Relative vapour density (air):		
not applicable		
Solubility in water:	insoluble	
Partitioning coefficient n-octanol/water (log Kow):		
not applicable		
Self ignition:	not self-igniting	

Thermal decomposition: > 400 °C
Thermal decomposition above the indicated temperature is possible.

Other information
Bulk density: 700 - 800 kg/m3

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9.11 Stability and Reactivity

Reactivity
No hazardous reactions if stored and handled as prescribed/indicated.

Chemical stability
The product is stable if stored and handled as prescribed/indicated.

Possibility of hazardous reactions
No hazardous reactions known.
The product is chemically stable.

Conditions to avoid
Temperature: > 400 °C

Incompatible materials
Substances to avoid:
No substances known that should be avoided.

Hazardous decomposition products
Hazardous decomposition products:
carbon monoxide, Sulphur dioxide
Gaseous products of degradation can be given off if the product is greatly overheated.

9.12 Toxicological Information

Information on toxicological effects

Acute toxicity

Assessment of acute toxicity:
Contact with molten product may cause thermal burns.

Irritation
Assessment of irritating effects:
The substance is inert.

Experimental/calculated data:
Serious eye damage/irritation: May cause mechanical irritation.

Respiratory/Skin sensitization

Assessment of sensitization:
The substance is inert.

Germ cell mutagenicity

Assessment of mutagenicity:
The substance is inert.

Carcinogenicity
Assessment of carcinogenicity:
The substance is inert.

Reproductive toxicity
Assessment of reproduction toxicity:

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The substance is inert.

Specific target organ toxicity (single exposure)
Assessment of STOT single:
not applicable

Repeated dose toxicity and Specific target organ toxicity (repeated exposure)
Assessment of repeated dose toxicity:
The substance is inert.

Aspiration hazard

No aspiration hazard expected.

Other relevant toxicity information

Based on our experience and the information available, no adverse health effects are expected if handled as recommended with suitable precautions for designated uses.

9.13 Ecological Information

Toxicity

Assessment of aquatic toxicity:
The product has not been tested. The statement has been derived from the structure of the product.
There is a high probability that the product is not acutely harmful to aquatic organisms.

Persistence and degradability

Assessment biodegradation and elimination (H2O):
Experience shows this product to be inert and non-degradable.

The product is virtually insoluble in water and can thus be separated from water mechanically in suitable effluent treatment plants.

Bioaccumulative potential

Bioaccumulation potential:
The product will not be readily bioavailable due to its consistency and insolubility in water.

Mobility in soil (and other compartments if available)

Assessment transport between environmental compartments:
Study scientifically not justified.

Results of PBT and vPvB assessment

The product does not fulfill the criteria for PBT (persistent/bioaccumulative/toxic) or vPvB (very persistent/very bioaccumulative).

9.14 Disposal Considerations

Waste treatment methods

Check for possible recycling.
May be disposed of or combusted with domestic refuse according to local regulations.

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Contaminated packaging:
Packs must be completely emptied.

9.15 Transport Information

Land transport

ADR	Not classified as a dangerous good under transport regulations
RID	Not classified as a dangerous good under transport regulations
Inland waterway transport ADNR	Not classified as a dangerous good under transport regulations
Sea transport IMDG	Not classified as a dangerous good under transport regulations
Air transport IATA/ICAO	Not classified as a dangerous good under transport regulations

9.16 Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

Chemical Safety Assessment

Chemical Safety Assessment not required

Product is not classified as hazardous.

“A safety data sheet for this product is legally not required and is provided by us just as a courtesy to our customers.” (original manufacturer)

9.17 Other Information

In addition to the information given in the safety data sheet we refer to the product specific technical information.

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10 Packaging

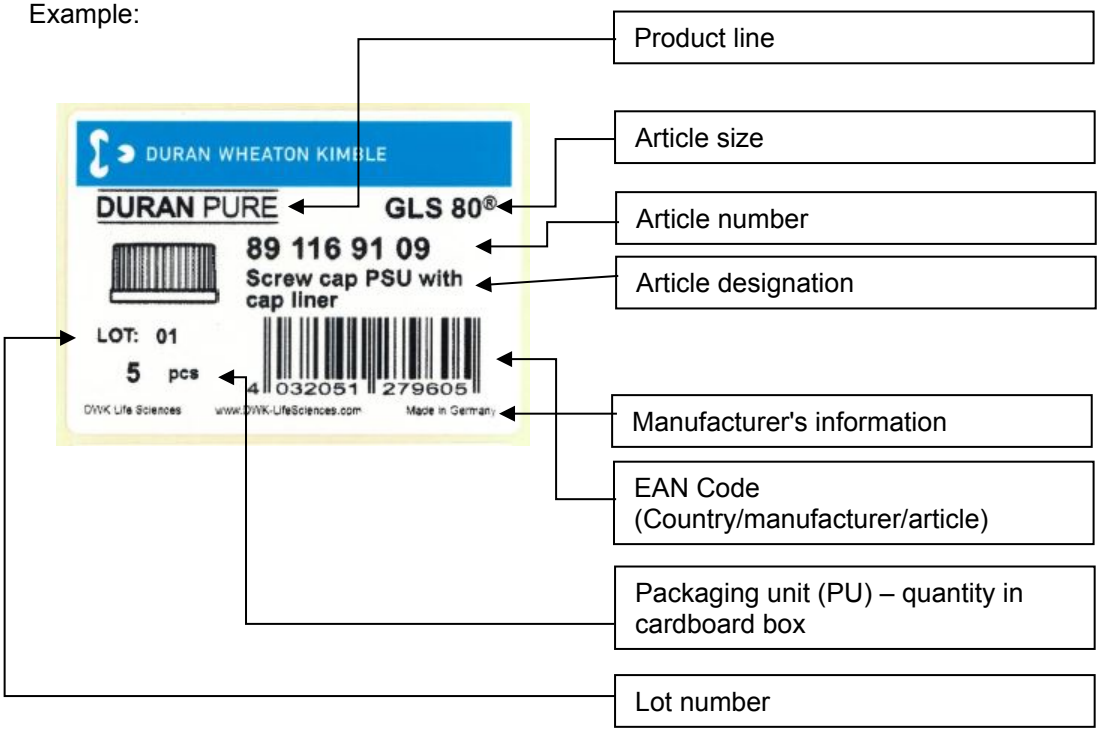
The DURAN PURE screw cap GLS 80 is packed in accordance with the DWK Life Sciences packaging standard.

11 Sales 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:



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12 Storage

Recommended storage conditions: normal storage conditions, protected from wet, damp and direct sunlight. To preserve the quality before use the articles should be stored in dry place under normal conditions without particular measures.
The temperature should be between 20°C and 25°C (excursions between 15°C and 30°C are allowed according to USP <659>). Relative humidity should not exceed 50%-60%. Articles should be protected from UV-light.
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.

13 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)

14 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 numberA sample (free of contamination) shall also be provided.

15 Associated documents

Respectively valid drawing of the DURAN PURE screw cap GLS 80
Respectively valid specification of the DURAN PURE PTFE coated silicone cap liner
Respectively valid drawing of the DURAN PURE PTFE coated silicone cap liner