

Safety data sheet in accordance with regulation (EC) no. 1907/2006



(amended by regulation (EU) no. 453/2010)

Date of issue 23.04.2015	Folidur N	Thermoforming Sheet 581-012-310
Date of revision 22.01.18	in all variations	581-012-048, 581-012-151, 581-012-300,
Valid from 01.01.15	of diameters	581-012-307, 581-012-301, 581-012-308,
Version: 2	round & square	Replaces Version: 1 581-012-302, 581-012-309, 581-012-303,

Section 1: Identification of the substance/mixture and of the company

1.1 Product Identifier

Substances: PET-G polyethylene terephthalate

Index-no.: void

EC-no.: void

CAS-no.: 25640-14-6 PET-G

REACH-registration no.: The substance does not require registration according to regulation (EC) no. 1907/2006 (REACH)

Other means or identification: sheets for orthodontics

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: to be used in dental labs exclusively

Uses advised against: should not be used by untrained personnel

1.3 Details of the supplier of the safety data sheet

Supplier:

al dente Dentalprodukte GmbH

Street:

Am Tobel 15

Address / zip-code / town / country:

88263 Horgenzell Germany

Phone / Fax / Email:

+49 (0) 7504 – 9 70 91-0 / +49 (0) 7504 – 9 70 91-20 / E-Mail: info@aldente.de

1.4 Emergency Telephone Number:

+49 (0) 171 7508 130

Section 2: Hazards identification:

2.1 Classification of the substance or mixture:

Classification according to regulation (EC) no. 1272/2008 (CLP)

This substance does not meet the criteria for classification according to regulation (EC) no. 1272/2008 (CLP).

2.2 Label Elements

Labelling according to regulation (EC) no. 1272/2008 (CLP/GHS)

Hazard pictograms: NONE

Signal word: NONE

Hazardous component(s) for labelling:

Hazard statements: NONE

Precautionary statements: NONE

Supplemental Hazard information (EU):

NONE

Safety data sheet in accordance with regulation (EC) no. 1907/2006



(amended by regulation (EU) no. 453/2010)

Date of issue 23.04.2015	Folidur N	Thermoforming Sheet 581-012-310
Date of revision 22.01.18	in all variations	581-012-048, 581-012-151, 581-012-300,
Valid from 01.01.15	of diameters	581-012-307, 581-012-301, 581-012-308,
Version: 2	round & square	Replaces Version: 1 581-012-302, 581-012-309, 581-012-303,

2.3 Other Hazards:

Results of PBT and vPvP assessment:
PBT not applicable
vPvP not applicable

Section 3: Composition/information on ingredients

3.1 Substances

Principal component of the substance:

Substance name: Polyethylene terephthalate PET-G
Index-no.: void
EC-no.: void
CAS-no.: 25640-14-6

Impurities, stabilizers: none

3.2 Mixtures none

Description of the mixture:

EC-no.: CAS-no. : Index-Nno.: REACH-registration no.:
Content ration: %
Classification according to regulation (EC) no. 1272/2008 (CLP)
none

(Full text of H- and EUH-phrases: see SECTION 16)

Section 4: First aid measures

4.1 Description of first aid measures: No necessity of special measures

Following inhalation: Do not breathe dust when working the sheets. Inhalation of dust may cause irritation of the respiratory system. Dust should be exhausted at the point of origin.

Following skin contact: There are no special measures necessary. In case of contact with melted product, cool down the affected skin by means of cool water. Burnt areas should be immersed in cool water for a length of time and should be clinically treated.

Following eye contact: Rinse thoroughly with water, if necessary seek for medical advice. In case of Persistent symptoms, consult an ophthalmologist. May cause irritations to eyes. Wear dust protection glasses.

Following ingestion: No necessity of special measures

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: none available
Effects: none available

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor: no information available
Special treatment: no information available

Safety data sheet in accordance with regulation (EC) no. 1907/2006



(amended by regulation (EU) no. 453/2010)

Date of issue 23.04.2015	Folidur N	Thermoforming Sheet 581-012-310
Date of revision 22.01.18	in all variations	581-012-048, 581-012-151, 581-012-300,
Valid from 01.01.15	of diameters	581-012-307, 581-012-301, 581-012-308,
Version: 2	round & square	Replaces Version: 1 581-012-302, 581-012-309, 581-012-303,

Section 5: Firefighting measures

5.1 Extinguishing media

Suitable: extinguishing powder, water spray, alcohol resistant foam, carbon dioxide
Unsuitable: Water jet (high power)

5.2 Special hazards arising from the substance or mixture

In case of fire fumes are possible: carbon dioxide (CO₂), -monoxide, sulphur dioxide (SO₂), formaldehyde.

5.3 Advice for fire-fighters

Respiratory protection independent of ambient environment – in case of fumes. Protective clothing.

5.4 Additional indication:

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Protective equipment: no special measures are to be taken.

Emergency procedures: no special measures are to be taken.

For emergency responders

Personal protective equipment: see section 5.3

6.2 Environmental precautions

Do not empty into drains or the aquatic environment. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Clean up mechanically.

6.4 Reference to other sections

More information on disposal see section 13.

Section 7: Handling and storage

7.1 Precautions for safe handling

Fire preventions: Keep away from sources of ignition and heat. Do not smoke.

Aerosol and dust generation preventions: Avoid generation of dust – work under fume hood.

Environmental precautions: No special precautions necessary.

Advice on general occupational hygiene: Observe general hygiene rules.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: No special measures are necessary.

Requirements for storage rooms and vessels

Store in original bundles. Store in a dry place. Keep away from sunlight. Store in original container.

Safety data sheet in accordance with regulation (EC) no. 1907/2006



(amended by regulation (EU) no. 453/2010)

Date of issue 23.04.2015	Folidur N	Thermoforming Sheet 581-012-310
Date of revision 22.01.18	in all variations	581-012-048, 581-012-151, 581-012-300,
Valid from 01.01.15	of diameters	581-012-307, 581-012-301, 581-012-308,
Version: 2	round & square	Replaces Version: 1 581-012-302, 581-012-309, 581-012-303,

Storage class: 11 (TRGS 510) **Materials to avoid:** n.a.

7.3 Specific end uses

Sector specific guidelines: dental / orthodontic laboratories, clinics

Section 8: Exposure controls / personal protection

8.1 Control parameters

Occupational exposure limits

Substances: PET-G ; CAS-no. : see section 3.1
Specification : Does not contain any substances - according to the common EU lists – that have to be monitored at work-places.
Limit value type (country of origin) : n.a.
Peak limitation: n.a.
Toxic to reproduction: n.a.
Source (TRGS) n.a.

8.1.2 DNEL- and PNEC- values none

Substance: PET-G ; CAS-No. : see section 3.1
Specification : n.a.
Value: n.a.

8.1.3 Control-Banding (e.g. ILO, EMKG) none

8.2 Exposure controls The type and extent of usage determine the choice of protective measures.

Appropriate engineering controls Provide good ventilation

Personal protective equipment

Eye / face protection

Safety glasses – to protect from dusts when working the sheets.

Skin protection: not required

Hand protection: not required

Body protection

Appropriate – do not eat, drink, smoke while working. Wash your hands after work.

Respiratory protection

Not required under normal use. Ventilation of workplace.

Thermal hazards

Not required under normal use.

Environmental exposure controls

Do not allow to get into sewer system, surface or ground water.

Safety data sheet in accordance with regulation (EC) no. 1907/2006



(amended by regulation (EU) no. 453/2010)

Date of issue 23.04.2015	Folidur N	Thermoforming Sheet 581-012-310
Date of revision 22.01.18	in all variations	581-012-048, 581-012-151, 581-012-300,
Valid from 01.01.15	of diameters	581-012-307, 581-012-301, 581-012-308,
Version: 2	round & square	Replaces Version: 1 581-012-302, 581-012-309, 581-012-303,

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Physical state:
- Aggregate state: Solid
- colour : Transparent
Odour : Characteristic
Odour threshold : No information available
pH-value: n.a.
Freezing point : n.a.
Initial boiling point/boiling range : n.a.
Flash point: > 450°C
Melting point: 220 – 230°C
Evaporation rate : n.a.
Flammability/Ignition Temp. 450°C
Upper/lower explosive limits Not applicable
Vapour pressure : n.a.
Vapour density: n.a.
Relative density: n.a.
Solubility: Not soluble in water
Partition coefficient: n.a.
Auto-ignition temperature: Not applicable
Decomposition temperature: > 380°C
Viscosity: n.a.
Density: 1,2 g/cm³
explosive properties: none
Oxidising properties: none

Other information

9.2 No further information available

Physical hazards Explosives

Section 10: Stability and reactivity

10.1 Reactivity: no known unusual reactivity

10.2 Chemical stability: reacts with solvents, thinner, acids.

10.3 Possibility of hazardous reactions: no known hazardous reactions

10.4 Conditions to avoid: sunlight

10.5 Incompatible materials: Oxidizing agents, acids, bases.

10.6 Hazardous decomposition products: Hydrocarbons, carbon dioxide (CO₂), carbon monoxide, aldehydes

Safety data sheet in accordance with regulation (EC) no. 1907/2006



(amended by regulation (EU) no. 453/2010)

Date of issue 23.04.2015	Folidur N	Thermoforming Sheet 581-012-310
Date of revision 22.01.18	in all variations	581-012-048, 581-012-151, 581-012-300,
Valid from 01.01.15	of diameters	581-012-307, 581-012-301, 581-012-308,
Version: 2	round & square	Replaces Version: 1 581-012-302, 581-012-309, 581-012-303,

Section 11: Toxicological information

11.1 Information on toxicological effects

When used appropriately no dangers to health are currently known appearing from this medical device product.

Acute toxicity

No information available

Skin irritation

Danger of burns when in properly used.

Eye irritation

No irritation due to dusts when wearing eye protection glasses.

Sensitisation to the respiratory tract / skin

Work on ventilated places in order to avoid dust enter the respiratory tract which may cause irritation.

Germ cell mutagenicity

No information available

Carcinogenicity

No existing information on human carcinogenicity

Reproductive toxicity

No information available

Specific target organ toxicity (single exposure) none

Specific target organ toxicity (repeated exposure) none

Aspiration hazard

void

Symptoms related to the physical, chemical and toxicological characteristics:

In case of ingestion: none

In case of skin contact: may cause burns when hot

In case of inhalation: irritation of the respiratory tract (only when working in not ventilated places)

In case of eye contact: dust may cause irritation – rinse with water – seek for a doctor's advice.

Section 12: Ecological information

12.1 Toxicity

None

12.2 Persistence and degradability

No data available. As to consistency and non-solubility a bioavailability is very unlikely.

12.3 Bioaccumulative potential

Not bioaccumulative

12.4 Mobility in soil

No data available.

12.5 Results of PBT- and vPvB assessment

Not applicable.

12.6 Other adverse effects

None

Safety data sheet in accordance with regulation (EC) no. 1907/2006



(amended by regulation (EU) no. 453/2010)

Date of issue 23.04.2015	Folidur N	Thermoforming Sheet 581-012-310
Date of revision 22.01.18	in all variations	581-012-048, 581-012-151, 581-012-300,
Valid from 01.01.15	of diameters	581-012-307, 581-012-301, 581-012-308,
Version: 2	round & square	Replaces Version: 1 581-012-302, 581-012-309, 581-012-303,

Section 13: Disposal considerations

13.1 Waste treatment methods

Contaminated packaging disposal
Recycle according to official regulations.

Waste codes / waste designations according to EWC / AVV:

20 01 39 - plastics

Special precautions

None

Other relevant provisions for waste treatment national or EC

Dispose of waste according to applicable legislation

Section 14: Transport information

14.1 UN-no.

Not applicable

14.2 UN proper shipping name

ADR/RID

The product is not defined under ADR/RID regulations.

IMDG-Code / ICAO-TI / IATA-DGR

The product is not defined under IMDG regulations.

14.3 Transport hazard class(es) / hazard labels

Not relevant

14.4 Packing group

Not relevant

14.5 Environmental hazards

Environmentally hazardous substance marking

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: yes / XXX no

Marine Pollutant: yes / XXX no

14.6 Special precautions for user

No additional information available.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Pollution category (X, Y or Z) : not applicable

Type of ship (1, 2 or 3) : not applicable

Section 15: Regulatory information

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

EU-regulations, e.g.:

Safety data sheet in accordance with regulation (EC) no. 1907/2006



(amended by regulation (EU) no. 453/2010)

Date of issue 23.04.2015	Folidur N	Thermoforming Sheet 581-012-310
Date of revision 22.01.18	in all variations	581-012-048, 581-012-151, 581-012-300,
Valid from 01.01.15	of diameters	581-012-307, 581-012-301, 581-012-308,
Version: 2	round & square	Replaces Version: 1 581-012-302, 581-012-309, 581-012-303,

Directive /EC) no. 2037/2000 (substances that deplete the ozone layer): not listed

Directive (EC) no. 850/2004 (persistent organic pollutants): not listed

Directive (EC) no. 689/2008 (Import and export of dangerous chemicals): not listed

Directive (EC) no. 648/2004 (Detergents Regulation): not listed

National regulations, e.g.:

Water hazard class (VwVwS) : not water pollutant / registration no. 268

Technical instructions on Air Quality Control (TA-Luft): not applicable

Other relevant regulations: TRGS 500, 510 (Germany): storage class: 11 (combustible solids)

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

Section 16: Other information

Indication of changes

Regulation (EC) no. 1272/2008 (CLP, EU_GHS)
Section1: Emergency number, editorial revision

Abbreviations and acronyms

n.a. Not applicable

Key literature references and sources for data

Gestis Stoffdatenbank - <http://gestis.itrust.de/>
Authority for chemicals www.baua.de

Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:

No classification

Relevant R-, H- and EUH-phrases (number and full text):

No phrases relevant – therefore no listing of these phrases.

Training advice

Not applicable for qualified dental technicians.

Further information

none

This information is based on our present state of knowledge. It should therefore not be construed as guaranteeing specific properties of the products described or their suitability for a particular application. We do not take any responsibility for possible sources of errors or sufficiency of this document. The user of the product accepts the sole responsibility to adhere to all herein mentioned regulations. It is the user's obligation to read this document carefully.

Safety data sheet in accordance with regulation (EC) no. 1907/2006



(amended by regulation (EU) no. 453/2010)

Date of issue 23.04.2015	Folidur N	Thermoforming Sheet 581-012-310
Date of revision 22.01.18	in all variations	581-012-048, 581-012-151, 581-012-300,
Valid from 01.01.15	of diameters	581-012-307, 581-012-301, 581-012-308,
Version: 2	round & square	Replaces Version: 1 581-012-302, 581-012-309, 581-012-303,
