

Material Safety Data Sheet
according to Regulation (EC) No. 1272 / 2008

Revision: 5

Revised on: August 20, 2021 SW

1. Product and company name**Name of the product:**

ANA Fulfill Flow

Use of the product (intended use):

Flowable, radiopaque composite filling material for repairs of bis-acrylic materials and for fillings of cavity classes III, IV and V.

Manufacturer / Supplier:

dent a pharm Prod.gesell.mbH

Street:

Schusterring 35

Nat. no. / ZIP/postal code / city

D-25355 Barmstedt

Contact point for technical information

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Emergency information (24 hours):

Dr. Wolfgang Willmann

Tel: 0170-4053052

2. Possible dangers**Hazard designation:****Classification of the mixture**

according to Regulation (EC) No. 1272/2008:

H317 **May cause allergic skin reactions.****H318** **Causes severe eye damage.****Labeling elements****Danger****H317** **May cause allergic skin reactions**

P261 Avoid inhalation of dust/fume/gas/mist/vapor/aerosol.

P272 Do not wear contaminated work clothing outside the workplace.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302 + P352 ON CONTACT WITH THE SKIN: Wash with plenty of water/...

P333 + P313 For skin irritation or rash: Get medical advice/
attention.

P321 Special handling (see ... on this identification label).

P362 + P364 Remove contaminated clothing and wash before wearing again.

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P501 Dispose of contents/container to ...

H318 **Causes serious eye damage**
P305+P351+P338 IF IN EYES: Rinse cautiously with water
for several minutes. Remove contact lenses, if present and easy to do. Continue
rinsing.
P310 Immediately call POISON CONTROL CENTER/physician/....

3. Composition / information on ingredients

Chemical characterization

Hazardous substances in the mixture that lead to labeling

Substance	CAS No./EINECS No./EC No.	Content in %	Classification according to CLP Regulation
1,4-butanediol dimethacrylate	2082-81-7 218-218-1	3-8	H315 - Skin Irrit. 2 H317 - Skin Sense 1 H319 - Eye Irrit. 2 H335 - STOT SE 3
2,2-Bis-(4-(3'-methacryloyloxy-2'-hydroxy)propoxyphenyl)propane	1565-94-2 216-367-7	10-20	H317 - Skin Sens. 1 H318 - Eye Dam. 1
Butylated hydroxytoluene	128-37-0 204-881-4	<0.1	H413 - Aquatic Chronic 4
2-(2H-benzotriazol-2-yl)-p-cresol	2440-22-4 219-470-5	<0.1	H317 - Skin Sense 1 H413 - Aquatic Chronic 4
Camphorquinone	10373-78-1	<0.1	H302 - Acute Tox. 4 H334 - Resp. Sens. 1
2-ethylhexyl 4-(dimethylamino)benzoate	21245-02-3 244-289-3	<0.1	H360 - Repr. 1B H319 - Eye Irrit. 2 H400 - Aquatic Acute
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8 278-355-8	0,1-0,3	H361 - Repr. 2 H412 - Aquatic Chronic 3
2-(2H-benzotriazol-2-yl)-p-cresol	2440-22-4 219-470-5	<0.1	H317 - Skin Sens. 1 H413 - Aquatic chronic 4

4. First aid measures

General notes:

none

After inhalation:

does not apply, as the product boils above 250°C

After contact with the skin:

Product is applied in small portions into tooth cavities, after skin contact with water and Soap wash .

After contact with the eyes:

In case of contact with eyes, rinse thoroughly with water, seek medical advice if irritation persists.

After swallowing:

Induce vomiting and consult physician if symptoms persist.

5. Fire-fighting measures

Suitable extinguishing media:

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Water spray, foam, extinguishing powder, carbon dioxide

Extinguishing media unsuitable for safety reasons:

Water in full jet.

Special protective equipment:

Breathing apparatus

Special protective equipment for firefighting:

Stay in the hazardous area only with suitable chemical protective clothing and self-contained breathing apparatus.

6. Measures in case of accidental release

Personal precautions:

none

Environmental protection measures:

none

Procedure for cleaning/soaking up:

Pick up mechanically, cure in the light and dispose of

7. Handling and storage

Handling

Instructions for safe handling:

None

Notes on fire and explosion protection:

none

Storage

Requirement for storage rooms and containers:

Protected from light, not above 25° C

Storage together instructions:

None

Storage time:

3 years at temperatures below 25° C

Further information on storage conditions: none

8. Exposure controls and personal protective equipment

Occupational exposure limits and / or biological limits

Occupational exposure limit values (OEL) Germany

PNCE and DNCL values as they have to be determined in a possibly to be prepared chemical safety report.

Additional notes on the design of technical installations: no further details, see 7.

Components with limit values that require monitoring at the workplace: none

Personal protective equipment:

General protective and hygienic measures:

observe professional hygiene

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Respiratory protection:
not required**Eye protection:**
Safety goggles when machining the cured material**Hand protection:**
not required**Skin and body protection:**
occupational safety clothing**9. Physical and chemical properties**

Appearance:
Form: flowable paste
Color: yellowish tooth colored
Odor: characteristic of methacrylates

Changes of state
Setting point: -20°C
Boiling point: 250°C

Safety-relevant data
Ignition temperature: not determined
Flash point: > 150°C
Autoflammability: no
Explosion limits: none
Explosion hazard: non-explosive
Vapor pressure: < 1 hPa at 20°C
Density: 2.1 g/cc
Solubility in water: practically insoluble
pH: not applicable

10. Stability and reactivity

Thermal decomposition
/Conditions to avoid:
No decomposition when used as directed.

Hazardous reactions:
None, slow polymerization when exposed to light

Hazardous decomposition products:
None if used as intended.

11. Toxicology data

Acute oral toxicity (LD 50):
16555 mg/kg, species rat, method FDA Guideline

Skin irritation: Non-irritant, exposure duration: 24h, Species: Rabbit, Method: occlusive, FDS Draise

Sensitization: non-sensitizing, species guinea pig, method GPMT

Toxicokinetics: In accordance with the new safety data sheet according to REACH data on toxicokinetics, metabolism and distribution of the substance in the body must be listed here. We do not have any data on this.

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Further toxicological information: not carcinogenic according to Anh. II GefStoffV (German Hazardous Substances Ordinance), not mentioned in Annex III of TRGS 900. According to the available experience and information, the product does not cause any adverse health effects if handled and used properly.

12. Environmental information

Ecotoxic effects:

Biological effects:	not specified
Toxicity to fish:	not specified
Aquatic organisms:	not specified
Bacterial toxicity:	not specified

General notes:

Do not allow to enter waters.

Bioaccumulation potential:

No data available

Result of the PTB and vPvB assessment determination:

Endocrine disruption potential

Whether the material triggers or prevents hormonal effects is not known.

German Water Hazard Class (WGK)

WGK 1 (after estimation on the basis of the contents)

13. Notes on disposal

Substance / Preparation

Dispose of properly in accordance with local regulations.

Do not allow to enter drains.

Product uncured:

Waste code according to the Waste Catalogue Ordinance (AVV)

16 03 05 (organic wastes containing dangerous substances)

Product cured:

In compliance with the respective applicable local/national regulations as a rule without special treatment.

Packing:

The syringe is made of polyester and is disposed of with household waste.

14. Transport data

Land Transport

ADR, RID and GGVS/GGVE (cross-border/country):

ADR/RID:	No dangerous goods
GGVS/GGVE:	No dangerous goods
Post Germany:	approved

Sea transport

IMDG, GGVSee

No dangerous goods

Air transport

ICAO-TI and IATA-DGR

ICAO-II/IATA-DGR:	No dangerous goods
UN/ID number:	1247
Transport/further information:	No dangerous goods in the sense of the above regulations

15. Legislation

Labeling according to EC Directive:

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Code letter(s) and hazard designations of the product

**Classification of the mixture
according to Regulation (EC) No. 1272/2008**



Danger

H317 May cause allergic skin reactions
H318 Causes severe eye irritation

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P310 Immediately call POISON CONTROL CENTER/physician/...

Safety assessments

Safety assessments for substances in this preparation have not been

National regulations

German Water Hazard Class (WGK): **WGK 1** (slightly hazardous to water) (self-classification)

16. Other information

Applicable EC directives

Preparations Directive (1999/45/EC), as last amended by Directive 2006/8/EC
Substances Directive (67/548/EEC), as last amended by Directive 2006/121/EC.
REACH Regulation (EC) No 1907/2006, as amended by REACH Regulation (EC) No 1272/2008.

Limitation of use recommended by the manufacturer

For dental use only.

Changes compared to the last version

Adaptation according to REACH Regulation (EC) No. 1272/2008

Data sheet issuing area

Dr. rer. nat. Wolfgang Willmann (Tel: 0 41 23 - 92 28 0)

Other notes:

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Sources: ¹ <http://www.baua.de>

² <http://www.arbeitssicherheit.de>

Some of the information given here and conclusions drawn from it

come from sources that are not determined from direct test data of the product itself.

The contents and formats of this safety data sheet comply with the European Commission Regulation (EC) No. 1272 / 2008.

Warranty limitations

The information in this safety data sheet has been obtained from sources we believe to be reliable. Nevertheless, this information is provided without any express or implied warranty as to its accuracy. The conditions or methods of handling, storage, use or disposal of this product are beyond our control, and may be outside of our knowledge.

For this and other reasons, we expressly assume no responsibility for loss, damage to the product, or other costs incurred in connection with the use, storage or disposal of the product.

This safety data sheet has been prepared specifically and expressly for this product only and shall be used expressly for this purpose only.

If this product is used as a component of another product, this information is not applicable.