

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Trade name : 20/20 Syringe 3 gram Refill B3
Product code : 9006384

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

1.2.1. Relevant identified uses

Main use category : Industrial use
Use of the substance/mixture : Dental filling material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier

Henry Schein Inc.
135 Duryea Road
Melville, NY 11747
USA

Importer

Henry Schein UK Holdings Limited
Medcare House
Centurion Close, Gillingham Business Park, Gillingham,
Kent, United Kingdom, ME8 0SB
Tel No.: 01634 878750

Email competent person

sds@kft.de

1.4. Emergency telephone number

Emergency number : +49 (0)6132 84463 - GBK GmbH (24h 7d/w - 365d/a)

Country/Area	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Health Service (NHS) England / Scotland / Wales / Northern Ireland	-	England / Scotland: 111 Wales: 111 or 0845 46 47 Northern Ireland: call your local General Practitioner. For life-threatening emergencies: call 999 for an ambulance.	24 h medical helpline for general public

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to GB CLP (SI 2019:720 as amended)

Skin sensitisation, Category 1 H317
Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.

2.2. Label elements

Labelling according to GB CLP (SI 2019:720 as amended)

Hazard pictograms (GB CLP) :



GHS07

20/20 Syringe 3 gram Refill B3

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

Signal word (GB CLP)	: Warning
Contains	: Di-urethane dimethacrylate; tetramethylene dimethacrylate
Hazard statements (GB CLP)	: H317 - May cause an allergic skin reaction. H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements (GB CLP)	: P261 - Avoid breathing mist, vapours. P273 - Avoid release to the environment. P280 - Wear protective gloves. P333+P313 - If skin irritation or rash occurs: Get medical advice or attention. P321 - Specific treatment (see supplemental first aid instruction on this label). P501 - Dispose of contents and container to in accordance with local/regional/national/international regulations of disposal.

2.3. Other hazards

Component	
Substance(s) not meeting the PBT criteria of UK REACH regulation, in accordance with Annex XIII	Di-urethane dimethacrylate (41137-60-4), tetramethylene dimethacrylate (2082-81-7)
Substance(s) not meeting the vPvB criteria of UK REACH regulation, in accordance with Annex XIII	Di-urethane dimethacrylate (41137-60-4), tetramethylene dimethacrylate (2082-81-7)
Component	
Substance(s) not considered as endocrine disrupting. They are not included in the list established in accordance with Article 59(1) of UK REACH for having endocrine disrupting properties, nor identified as having endocrine disrupting properties in accordance with the criteria set out in GB BPR and GB PPP	Di-urethane dimethacrylate(41137-60-4), tetramethylene dimethacrylate(2082-81-7)

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to GB CLP (SI 2019:720 as amended)
Di-urethane dimethacrylate	CAS-No.: 41137-60-4	10 – 25	Skin Sens. 1B, H317 Aquatic Chronic 2, H411
tetramethylene dimethacrylate	CAS-No.: 2082-81-7 EC-No.: 218-218-1 UK Index-No.: 607-766-00-0	2.5 – 10	Skin Sens. 1B, H317

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
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4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
- Unsuitable extinguishing media : Strong water jet.

5.2. Special hazards arising from the substance or mixture

- Hazardous decomposition products in case of fire : Toxic fumes may be released. Carbon monoxide. Carbon dioxide.

5.3. Advice for firefighters

- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
- Other information : Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing mist, vapours.

6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid sub-soil penetration. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
- Other information : Disposal must be done according to official regulations.

6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing mist, vapours. Wear personal protective equipment.
- Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Close container tightly after use. Store in a well-ventilated place. Keep cool.
- Storage temperature : 10 – 25 °C
- Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

No additional information available

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

tetramethylene dimethacrylate (2082-81-7)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	4.2 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	14.5 mg/m ³
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	2.5 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	4.3 mg/m ³
Long-term - systemic effects, dermal	2.5 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.003 mg/l
PNEC aqua (marine water)	0.004 mg/l
PNEC aqua (intermittent, freshwater)	0.0003 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	0.12 mg/kg dwt
PNEC sediment (marine water)	0.012 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.022 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	20 mg/l

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing. EN ISO 13688. EN 13034

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Hand protection:

Chemically resistant protective gloves. ISO 374-1. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

Hand protection					
Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Chemically resistant protective gloves	Butyl rubber, Nitrile rubber	3 (> 60 minutes)	0,3	No additional information available	EN ISO 374-1
Chemically resistant protective gloves	Butyl rubber, Nitrile rubber	1 (> 10 minutes)	0,11	No additional information available	EN ISO 374-1

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Breathing apparatus with filter. P2. EN 143. . Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Viscous liquid.
Colour	: According to product specification.
Odour	: weak. characteristic.
Odour threshold	: Not available
pH	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: 251 °C
Flash point	: 101 °C
Explosive limits	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Relative vapour density at 20°C	: Not available
Relative density	: Not available
Density	: Not available
Solubility	: Insoluble.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Auto-ignition temperature	: 370 °C
Decomposition temperature	: Not available
Viscosity, kinematic	: Not available
Explosive properties	: Product is not explosive
Oxidising properties	: Non oxidizing.

9.2. Other information

Particle characteristics	: Not applicable
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SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerisation:

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Polymerisation with heat evolution may occur in the presence of radical forming substances, and/or heavy metals ions.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

Other information

Endocrine disrupting properties

No additional information available

Other information

Other information : Contains: 2,6-di-tert-butyl-p-cresol (128-37-0) (EU - Endocrine disruptor assessment list, Under development (SEV))

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Harmful to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

20/20 Syringe 3 gram Refill B3	
Persistence and degradability	No additional information available.

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

Di-urethane dimethacrylate (41137-60-4)	
Persistence and degradability	Not rapidly degradable

tetramethylene dimethacrylate (2082-81-7)	
Persistence and degradability	Readily biodegradable.
Biodegradation	84 % (28 d; (OECD 310 method))

12.3. Bioaccumulative potential

20/20 Syringe 3 gram Refill B3	
Bioaccumulative potential	No additional information available.

tetramethylene dimethacrylate (2082-81-7)	
Partition coefficient n-octanol/water (Log Pow)	3.1 (20 °C; (OECD 117 method))
Partition coefficient n-octanol/water (Log Kow)	3.1 (20 °C)
Bioaccumulative potential	Bioaccumulation unlikely.

12.4. Mobility in soil

20/20 Syringe 3 gram Refill B3	
Mobility in soil	No additional information available

12.5. Results of PBT and vPvB assessment

Component	
Di-urethane dimethacrylate (41137-60-4)	This product does not contain substances at $\geq 0.1\%$ that meet the PBT criteria of UK REACH regulation, annex XIII This product does not contain substances at $\geq 0.1\%$ that meet the vPvB criteria of UK REACH regulation, annex XIII
tetramethylene dimethacrylate (2082-81-7)	This product does not contain substances at $\geq 0.1\%$ that meet the PBT criteria of UK REACH regulation, annex XIII This product does not contain substances at $\geq 0.1\%$ that meet the vPvB criteria of UK REACH regulation, annex XIII

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.
Product/Packaging disposal recommendations	: Recycle or dispose of in compliance with current legislation.
HP Code	: HP13 - "Sensitising:" waste which contains one or more substances known to cause sensitising effects to the skin or the respiratory organs. HP14 - "Ecotoxic:" waste which presents or may present immediate or delayed risks for one or more sectors of the environment

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated for transport				
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
Transport document description				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

UK REACH Annex XVII (Restriction List)

UK restriction list (REACH Annex XVII)		
Reference code	Applicable on	Entry title or description
3(b)	20/20 Syringe 3 gram Refill B3 ; tetramethylene dimethacrylate	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10
3(c)	20/20 Syringe 3 gram Refill B3	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

UK REACH Annex XIV (Authorisation List)

This product contains no substance(s) listed on UK REACH Annex XIV (Authorisation List) equal to or above the 0.1% level of disclosure

UK REACH Candidate List (SVHC)

This product contains no substance(s) listed on the UK REACH Candidate List (SVHC) above the 0.1% level of disclosure

GB PIC regulation (Prior Informed Consent)

This product contains no substance(s) listed on the GB PIC List equal to or above the level of SDS disclosure

POP Regulation (Persistent Organic Pollutants)

This product contains no substance(s) listed on the GB POP List equal to or above the level of SDS disclosure

Ozone Regulation (S.I. No. 168 of 2015)

This product contains no substance(s) listed on the GB Ozone Depletion List equal to or above the level of SDS disclosure

Control of Poisons and Explosives Precursors Act

This product contains no substance(s) listed as a reportable poison on the Control of Poisons and Explosives Precursors Regulations equal to or above the level of SDS disclosure

This product contains no substance(s) listed as a regulated poison on the Control of Poisons and Explosives Precursors Regulations equal to or above the level of SDS disclosure

This product contains no substance(s) listed as a reportable explosive precursor on the Control of Poisons and Explosives Precursors Regulations equal to or above the level of SDS disclosure

This substance is not listed as a regulated poison on the Control of Poisons and Explosives Precursors Regulations

Drug Precursors Regulation (EC 273/2004)

This product contains no substance(s) listed on the GB Drug Precursors List equal to or above the level of SDS disclosure

15.1.2. Other Information

National regulations : Take note of Directive 94/33/EC on the protection of young people at work.

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CAS-No.	Chemical Abstract Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Data sources : MSDSs of the suppliers.
Department issuing data specification sheet: : KFT Chemieservice GmbH
Im Leuschnerpark 3
D-64347 Griesheim
Phone: +49 69 305 34 700
Fax: +49 69 305 86 500
SDS Service: +49 69 305 34 740
Contact person : Saskia Vetter

Full text of H- and EUH-statements:	
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1B	Skin sensitisation, category 1B
H317	May cause an allergic skin reaction.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method
Aquatic Chronic 3	H412	Calculation method

KFT SDS UK 06 - Version 24.2

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.