

DIE HARDENER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 12/4/2015 Revision date: 2/1/2018 Supersedes: 1/27/2023 Version: 2.0
SDS No: 11294-0001



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

1.1. Product identifier

Product form : Mixture
Product name : DIE HARDENER
UFI : U300-P0FG-800V-GV7T
Other means of identification : Article number:
540-0001,
540-0001M,
540-0006,
540-0018,
540-0250,
540-6018

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Gypsum hardener for dental use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

YETI Dentalprodukte GmbH
Industriestrasse 3
78234 Engen
Germany
T +49 7733-9410-0 - F +49 7733-9410-22
sdb@yeti-dental.com
E-mail address of competent person responsible for the SDS: sds@gbk-ingelheim.de

1.4. Emergency telephone number

Emergency number : +49 7733-9410-0 (Mo-Do 8:00 - 16:30, Fr 8:00 - 15:00)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable liquids, Category 2	H225
Serious eye damage/eye irritation, Category 2	H319
Specific target organ toxicity – Single exposure, Category 3, Narcosis	H336

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

Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour. May cause drowsiness or dizziness. Causes serious eye irritation.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



Signal word (CLP) : Danger
Contains : Butanone

DIE HARDENER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 11294-0001

Hazard statements (CLP)	: H225 - Highly flammable liquid and vapour. H319 - Causes serious eye irritation. H336 - May cause drowsiness or dizziness.
Precautionary statements (CLP)	: P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 - If eye irritation persists: Get medical advice/attention. P403+P233 - Store in a well-ventilated place. Keep container tightly closed. P501 - Dispose of contents and container to Dispose of contents/container in accordance with local and national regulations.
EUH-statements	: EUH066 - Repeated exposure may cause skin dryness or cracking.
Extra phrases	: For professional users only.

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Butanone Substance with a Community workplace exposure limit	CAS-No.: 78-93-3 EC-No.: 201-159-0 EC Index-No.: 606-002-00-3 REACH-no: 01-2119457290-43	$\geq 75 - < 80$	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 EUH066

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	: Call a poison center or a doctor if you feel unwell. Take off immediately all contaminated clothing.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash off immediately with soap and plenty of water. Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Do not induce vomiting. Rinse mouth. Drink plenty of water. Call a physician immediately.

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

Symptoms/effects	: May cause drowsiness or dizziness.
Symptoms/effects after skin contact	: Repeated exposure may cause skin dryness or cracking.
Symptoms/effects after eye contact	: Eye irritation.

DIE HARDENER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 11294-0001

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 : Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media : Do not use a solid water stream as it may scatter and spread fire.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Highly flammable liquid and vapour.
Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information : The vapours are denser than air and may travel along the ground. Distance ignition possible.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : In case of vapour formation use adequate respirator. Ensure adequate ventilation, especially in confined areas. No flames, no sparks. Eliminate all sources of ignition.

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. No open flames, no sparks, and no smoking. Avoid breathing Vapours, gas. Avoid contact with skin and eyes.

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 release to the environment. Prevent liquid from entering sewers, watercourses, underground or low areas. Explosive.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public waters.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". Information for disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapours may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Use only outdoors or in a well-ventilated area. Avoid breathing vapours, gas. Avoid contact with skin and eyes.

DIE HARDENER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 11294-0001

Hygiene measures : 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

Technical measures : Ground/bond container and receiving equipment.
Storage conditions : Store in a well-ventilated place. Keep cool. Keep out of direct sunlight. Keep container tightly closed. Store locked up.
Incompatible materials : oxidizing materials.

7.3. Specific end use(s)

See Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Butanone (78-93-3)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Butanone
IOEL TWA	600 mg/m ³ 600 mg/m ³
IOEL TWA [ppm]	200 ppm
IOEL STEL	900 mg/m ³ 900 mg/m ³
IOEL STEL [ppm]	300 ppm 300 ppm
Regulatory reference	COMMISSION DIRECTIVE 2000/39/EC COMMISSION DIRECTIVE 2000/39/EC

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

No additional information available

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:

Protective goggles (EN 166). Eyewash bottle with clean water (EN 15154)

8.2.2.2. Skin protection

Skin and body protection:

Antistatic clothing. Wear suitable protective clothing. General protective and hygienic measures

DIE HARDENER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 11294-0001

Hand protection:

Chemically resistant protective gloves. Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves

Hand protection					
Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Splash protection	Butyl rubber	5 (> 240 minutes)	0,7		EN ISO 374

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Respiratory protection			
Device	Filter type	Condition	Standard
Full face mask	Type A		

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless.
Odour	: Solvent-like.
Odour threshold	: Not available
Melting point	: -86 °C
Freezing point	: Not available
Boiling point	: ≈ 80 °C
Flammability (solid, gas)	: Highly flammable liquid and vapour
Explosive properties	: Explosive vapour/air mixtures may be formed.
Explosive limits	: Not available
Lower explosive limit (LEL)	: 1.8 vol %
Upper explosive limit (UEL)	: 11.5 vol %
Flash point	: ≈ 4 °C DIN 51755
Auto-ignition temperature	: 514 °C DIN 51794
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Water: 292 g/l (20 °C)
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: 105 hPa @ 20 °C
Vapour pressure at 50°C	: Not available
Density	: 0.805 g/cm ³
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

DIE HARDENER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 11294-0001

9.2.2. Other safety characteristics

VOC content : 100 %

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapour.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

Oxidizing agent.

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 hazard classes as defined in Regulation (EC) No 1272/2008

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)

Butanone (78-93-3)	
LD50 oral	2737 mg/kg
LD50 dermal	6480 mg/kg

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation : Causes serious eye irritation.
Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)
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 : May cause drowsiness or dizziness.

Butanone (78-93-3)	
STOT-single exposure	May cause drowsiness or dizziness.

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)

11.2. Information on other hazards

No additional information available

DIE HARDENER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 11294-0001

SECTION 12: Ecological information

12.1. Toxicity

- Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
- 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) : Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

- Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions. The waste code/waste name refers to the end product. To be defined by the customer in agreement with appropriate waste disposal company.
- Product/Packaging disposal recommendations : Empty receptacle completely. Must not be disposed together with household garbage.
- Additional information : Flammable vapours may accumulate in the container.
- European List of Waste (LoW) code : 16 05 08* - discarded organic chemicals consisting of or containing dangerous substances

SECTION 14: Transport information






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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
UN 1193	UN 1193	UN 1193	UN 1193	UN 1193
14.2. UN proper shipping name				
ETHYL METHYL KETONE (METHYL ETHYL KETONE)	ETHYL METHYL KETONE (METHYL ETHYL KETONE)	Ethyl methyl ketone	ETHYL METHYL KETONE (METHYL ETHYL KETONE)	ETHYL METHYL KETONE (METHYL ETHYL KETONE)

DIE HARDENER

Safety Data Sheet

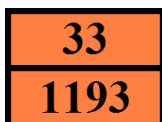
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 11294-0001

ADR	IMDG	IATA	ADN	RID
Transport document description				
UN 1193 ETHYL METHYL KETONE (METHYL ETHYL KETONE), 3, II, (D/E)	UN 1193 ETHYL METHYL KETONE (METHYL ETHYL KETONE), 3, II (-1°C c.c.)	UN 1193 Ethyl methyl ketone, 3, II	UN 1193 ETHYL METHYL KETONE (METHYL ETHYL KETONE), 3, II	UN 1193 ETHYL METHYL KETONE (METHYL ETHYL KETONE), 3, II
14.3. Transport hazard class(es)				
3	3	3	3	3
				
14.4. Packing group				
II	II	II	II	II
14.5. Environmental hazards				
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No	Dangerous for the environment: No	Dangerous for the environment: No
No supplementary information available				

14.6. Special precautions for user

Overland transport

Classification code (ADR) : F1
Limited quantities (ADR) : 1I
Excepted quantities (ADR) : E2
Packing instructions (ADR) : P001, IBC02, R001
Mixed packing provisions (ADR) : MP19
Transport category (ADR) : 2
Hazard identification number (Kemler No.) : 33
Orange plates :



Tunnel restriction code (ADR) : D/E

Transport by sea

Limited quantities (IMDG) : 1 L
Excepted quantities (IMDG) : E2
Packing instructions (IMDG) : P001
IBC packing instructions (IMDG) : IBC02
Tank instructions (IMDG) : T4
Tank special provisions (IMDG) : TP1
EmS-No. (Fire) : F-E
EmS-No. (Spillage) : S-D
Stowage category (IMDG) : B
Flash point (IMDG) : -1°C c.c.

Air transport

PCA Excepted quantities (IATA) : E2
PCA Limited quantities (IATA) : Y341
PCA limited quantity max net quantity (IATA) : 1L
PCA packing instructions (IATA) : 353
PCA max net quantity (IATA) : 5L
CAO packing instructions (IATA) : 364
CAO max net quantity (IATA) : 60L

DIE HARDENER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 11294-0001

ERG code (IATA) : 3L

Inland waterway transport

Classification code (ADN) : F1
Limited quantities (ADN) : 1 L
Excepted quantities (ADN) : E2
Carriage permitted (ADN) : T
Equipment required (ADN) : PP, EX, A
Ventilation (ADN) : VE01
Number of blue cones/lights (ADN) : 1

Rail transport

Classification code (RID) : F1
Limited quantities (RID) : 1L
Excepted quantities (RID) : E2
Packing instructions (RID) : P001, IBC02, R001
Transport category (RID) : 2
Hazard identification number (RID) : 33

14.7. Maritime transport in bulk according to IMO instruments

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

REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)		
Reference code	Applicable on	Entry title or description
40.	DIE HARDENER ; Butanone	Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or not.

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

VOC Directive (2004/42)

VOC content : 100 %

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

DIE HARDENER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 11294-0001

Drug Precursors Regulation (273/2004)

Contains substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

Name	CN designation	CAS-No.	CN code	Category	Threshold	Annex
Methylethylketone	Butanone	78-93-3	2914 12 00	Category 3		Annex I

Seveso Directive (Disaster Risk Reduction)

Seveso III Part I (Categories of dangerous substances)	Qualifying quantity (tonnes)	
	Lower-tier	Upper-tier
P5c FLAMMABLE LIQUIDS Flammable liquids, Categories 2 or 3 not covered by P5a and P5b	5000	50000

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

All chapters have been modified since the previous version.

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
BCF	Bioconcentration factor
ATE	Acute Toxicity Estimate
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
DOT	Department of Transport
TDG	Transportation of Dangerous Goods
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
IARC	International Agency for Research on Cancer
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships

DIE HARDENER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 11294-0001

Abbreviations and acronyms:	
ADG	Transport of Australian Dangerous Goods
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
ED	Endocrine disrupting properties

Other information

: Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

Full text of H- and EUH-statements:	
EUH066	Repeated exposure may cause skin dryness or cracking.
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis

DIE HARDENER

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 11294-0001

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Flam. Liq. 2	H225	On basis of test data
Eye Irrit. 2	H319	Calculation method
STOT SE 3	H336	Calculation method

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 therefore not be construed as guaranteeing any specific property of the product.