

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 03.11.2020



Version number 3

Revision: 04.03.2020

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

- **1.1 Product identifier**
- **Trade name:** APK primer
- **Article number:** 004APK25
- **1.2 Relevant identified uses of the substance or mixture and uses advised against:**  
No further relevant information available.
- **Application of the substance / the mixture:** Primer.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
bredent GmbH & Co.KG  
Weißenhorn Str. 2  
89250 Senden  
Tel: +49 (0) 7309/872-0  
Fax: +49 (0) 7309/872-24
- **Further information obtainable from:**  
R & D  
e-mail: R.D@bredent.com
- **1.4 Emergency telephone number:** (001) 352 323 3500

### SECTION 2: Hazards identification

- **Remark**  
The device is a medical device pursuant to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. No safety data sheet is required for the device, so no claim is made to full compliance with the relevant statutory requirements.
- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
- 
**GHS02 flame**  
  
 Flam. Liq. 2 H225 Highly flammable liquid and vapour.
- 
**GHS07**  
  
 Eye Irrit. 2 H319 Causes serious eye irritation.  
 STOT SE 3 H336 May cause drowsiness or dizziness.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
Medical products and medical devices within the meaning of Directives 90/385/EEC and 93/42/EEC used in an invasive manner or in direct contact with the body as well as medical products and medical devices falling under Directive 98/79/EC are fully exempt from the provisions of the CLP Regulation and therefore do not need to be classified, packaged or labelled.  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** GHS02, GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**  
butanone
- **Hazard statements**  
H225 Highly flammable liquid and vapour.  
H319 Causes serious eye irritation.  
H336 May cause drowsiness or dizziness.
- **Precautionary statements**  
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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- P261* Avoid breathing dust/fume/gas/mist/vapours/spray.  
*P303+P361+P353* IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  
*P304+P340* IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
*P305+P351+P338* IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
*P403+P233* Store in a well-ventilated place. Keep container tightly closed.  
*P403+P235* Store in a well-ventilated place. Keep cool.
- **2.3 Other hazards**
  - **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

#### · **Dangerous components:**

CAS: 78-93-3	butanone	50-100%
EINECS: 201-159-0	 Flam. Liq. 2, H225  Eye Irrit. 2, H319; STOT SE 3, H336	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** If skin irritation continues, consult a doctor.
- **After eye contact:**  
 Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** Rinse out mouth and then drink plenty of water.
- **4.2 Most important symptoms and effects, both acute and delayed**  
 Coughing  
 Dizziness  
 Dizziness  
 Breathing difficulty  
 Nausea
- **4.3 Indication of any immediate medical attention and special treatment needed**  
 No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** CO<sub>2</sub>, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture**  
 Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
- **Protective equipment:**  
 Wear self-contained respiratory protective device.  
 Wear fully protective suit.
- **Additional information**  
 Cool endangered receptacles with water spray.

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Collect contaminated fire fighting water separately. It must not enter the sewage system.

### SECTION 6: Accidental release measures

#### · 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

#### · 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

#### · 6.3 Methods and material for containment and cleaning up:

Send for recovery or disposal in suitable receptacles.

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Ensure adequate ventilation.

Do not flush with water or aqueous cleansing agents

#### · 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### SECTION 7: Handling and storage

#### · 7.1 Precautions for safe handling

Keep receptacles tightly sealed.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

#### · Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

#### · 7.2 Conditions for safe storage, including any incompatibilities

##### · Storage:

· Requirements to be met by storerooms and receptacles: Store in a cool location.

· Information about storage in one common storage facility: Not required.

· Further information about storage conditions:

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

#### · 7.3 Specific end use(s) No further relevant information available.

### SECTION 8: Exposure controls/personal protection

· Additional information about design of technical facilities: No further data; see item 7.

#### · 8.1 Control parameters

##### · Ingredients with limit values that require monitoring at the workplace:

##### 78-93-3 butanone (50-100%)

WEL (Great Britain)	Short-term value: 899 mg/m <sup>3</sup> , 300 ppm
	Long-term value: 600 mg/m <sup>3</sup> , 200 ppm
	Sk, BMGV

##### · Ingredients with biological limit values:

##### 78-93-3 butanone (50-100%)

BMGV (Great Britain)	70 µmol/L
	Medium: urine
	Sampling time: post shift
	Parameter: butan-2-one

· Additional information: The lists valid during the making were used as basis.

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**· 8.2 Exposure controls****· Personal protective equipment:****· General protective and hygienic measures:***The usual precautionary measures are to be adhered to when handling chemicals.**Keep away from foodstuffs, beverages and feed.**Immediately remove all soiled and contaminated clothing**Wash hands before breaks and at the end of work.**Avoid contact with the eyes and skin.***· Respiratory protection:***Not necessary if room is well-ventilated.**Filter A/P2**In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.***· Protection of hands:***The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.**Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.**Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation***· Material of gloves***Butyl rubber, BR**Recommended thickness of the material:  $\geq 0.7$  mm**The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.***· Penetration time of glove material***The penetration time has to be at least 240 minutes (Permeation according to EN 374 Part 3: Level 5).**The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.***· Eye protection:***Tightly sealed goggles*

## SECTION 9: Physical and chemical properties

**· 9.1 Information on basic physical and chemical properties****· General Information****· Appearance:**

<b>Form:</b>	<i>Fluid</i>
<b>Colour:</b>	<i>Colourless</i>
<b>· Odour:</b>	<i>Solvent-like</i>
<b>· Odour threshold:</b>	<i>Not determined.</i>

**· pH-value:** *Not determined.***· Change in condition**

<b>Melting point/freezing point:</b>	<i>-86.3 °C</i>
<b>Initial boiling point and boiling range:</b>	<i>79 °C</i>

**· Flash point:** *-4 °C***· Flammability (solid, gas):** *Not applicable.***· Ignition temperature:** *514 °C*

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· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· <b>Explosion limits:</b>	
Lower:	1.8 Vol %
Upper:	11.5 Vol %
· <b>Vapour pressure at 20 °C:</b>	105 hPa
· <b>Density at 20 °C:</b>	0.804-0.807 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water at 20 °C:</b>	290 g/l
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic:	Not determined.
Kinematic:	Not determined.
· <b>Solvent content:</b>	
Organic solvents:	95.0 %
· <b>9.2 Other information</b>	No further relevant information available.

## SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions**  
Violent reaction with concentrated alkali and oxidising agents.  
Reacts with peroxides.  
Reacts with strong acids.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

## SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

### · LD/LC50 values relevant for classification:

#### 78-93-3 butanone

Oral	LD50	3300 mg/kg (rat)
Dermal	LD50	5000 mg/kg (rabbit)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Repeated or permanent exposure may irritate the skin.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.

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- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure**  
May cause drowsiness or dizziness.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.


### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must be specially treated adhering to official regulations.  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |   |                          |
|---|--------------------------|
| · <b>14.1 UN-Number</b>   |                          |
| · <b>ADR, IMDG, IATA</b>  | UN1193                   |
| · <b>14.2 UN proper shipping name</b>   |                          |
| · <b>ADR</b>  | 1193 ETHYL METHYL KETONE |
| · <b>IMDG, IATA</b>   | ETHYL METHYL KETONE      |
| · <b>14.3 Transport hazard class(es)</b>  |                          |
| · <b>ADR, IMDG, IATA</b>  |                          |
|  |                          |
| · <b>Class</b>  | 3 Flammable liquids.     |
| · <b>Label</b>  | 3                        |

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· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	II
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b> · <b>Danger code (Kemler):</b> · <b>EMS Number:</b> · <b>Stowage Category</b>	Warning: Flammable liquids. 33 F-E,S-D B
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b> · <b>Limited quantities (LQ)</b> · <b>Excepted quantities (EQ)</b>	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>Transport category</b> · <b>Tunnel restriction code</b>	2 D/E
· <b>IMDG</b> · <b>Limited quantities (LQ)</b> · <b>Excepted quantities (EQ)</b>	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN 1193 ETHYL METHYL KETONE, 3, II

\*

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** GHS02, GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**  
butanone
- **Hazard statements**  
H225 Highly flammable liquid and vapour.  
H319 Causes serious eye irritation.  
H336 May cause drowsiness or dizziness.
- **Precautionary statements**  
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P403+P233 Store in a well-ventilated place. Keep container tightly closed.  
P403+P235 Store in a well-ventilated place. Keep cool.
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category** P5c FLAMMABLE LIQUIDS

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- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5.000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50.000 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

- **Relevant phrases**

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

- **Department issuing SDS:** R & D

- **Contact:** R & D

- **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

- **\* Data compared to the previous version altered.**

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