Kulzer GmbH • Leipziger Straße 2 • 63450 Hanau • Germany

Please pass on this
Urgent Safety Information to the
person responsible for occupational safety
in the Dental laboratory!

Kulzer GmbH
Leipziger Straße 2
63450 Hanau
Germany

Australia Product Management
Contact: Keren Masterson
:
E: Info.australia@kulzer-dental.com
www.kulzer.com

Urgent Safety Information

Revision of the Instructions for Use about occupational health and safety measures

...

Concerning

PalaXtreme

Sender:
See header.

Addressee:
Dental laboratories: owners, persons responsible for occupational health and safety, processing dental technicians

Identification of the medical devices concerned:
Denture base material PalaXtreme: all liquid batches as well as powder colours and batches

Description of the issue including the identified cause:
The occurrence of symptoms exclusively concerns only lab staff grinding the polymerized product in the dental laboratory. It does not affect any patients!

According to our current knowledge, approximately one in 100 dental technicians is affected by the symptoms described below. Approximately one in 1000 technicians has more severe symptoms associated with a proven allergic reaction to MMA and similar (Meth) Acrylates of the liquid component.

PalaXtreme is a densely cross-linked, high-impact denture base material. The chips left when grinding the cured material with conventional, used laboratory burs and grinders are particularly sharp-edged and abrasive.
When (frequently) grinding this polymer material without suitable protective clothing in accordance with occupational health and safety specifications, e.g. protective gloves, the abrasive chips may lead to skin lesions and micro-injuries on fingertips, between fingers, on palms and edges of the hands and even on forearms. The latter is especially the case, if the workplace is not cleaned regularly and no suitable protective clothing is worn that extends over the forearms. When grinding the work piece dental technicians tend to support themselves on work benches covered with those chips all over.
Therefore, non-allergic and/or allergic contact eczema may occur on the limbs. If there is also an MMA allergy acquired through regular contact with the liquid in the course of a working life, there may a delocalized allergic reaction occur in the form of redness and swelling on the neck and face.

Place of Business: Hanau • Registration Court: Local Court Hanau HRB 91228 • VAT-ID no. DE 812 593 096
Managing Directors/Geschäftsführer: Marc Berendes, Hiromi Hayashida • Chairman of the Supervisory Board: Hisayoshi Tanaka

What measures are to be taken by the addressee?

With this Urgent Safety Information, you will receive a revised version of the Instructions for Use with clear warning and safety instructions as well as recommendations for avoiding non-allergic and/or allergic contact eczema. Please, when working with PalaXtreme, observe the following necessarily!

- Wear a dust mask and suitable protective gloves.
- Wear protective goggles and long-sleeved protective clothing.
- Use table suction with a protective shield.
- It is recommended to work with a sanding box.
- Grinding particles can be sharp-edged and abrasive!
- Remove grinding chips from the work places and your body regularly!
- Grinding tools: We recommend grinding cutters with a crosscut,
  e.g.: FSQ cutters or diamond cutters; their grinding particles are shorter, fine-grained and less sharp-edged; they have a less abrasive effect onto the skin.
- In case of persistent skin irritations or rashes in connection with the processing of the product, clarify symptoms with a medical specialist regarding an MMA allergy; strictly avoid skin contact especially to the liquid.

Please use only this updated Instructions for Use on PalaXtreme.

Revise your operating instructions for the health protection of your staff

What you may do next?

If you are satisfied with the product, you may simply process it reliably and safely by further observing our relevant warnings and safety instructions.

If difficulties occur during grinding and working with PalaXtreme dentures, you may carefully follow our warnings, safety instructions and recommendations for the time being. If you are not satisfied, you may always return PalaXtreme free of charge to Kulzer or exchange it via your favorite dental specialist dealer to one of the tried and tested denture base materials of Kulzer.

In country Australia you get supported by Kulzer Australia local sales office.

Please, direct questions about this Urgent Safety Information to your Kulzer sales office, the local organization of KULZER AUSTRALIA Pty Ltd. Email: info.australia@kulzer-dental.com

PALA®

PalaXtreme®

DE Gebrauchsanweisung
GB Instructions for use
FR Mode d'emploi
ES Instrucciones de uso
IT Istruzioni per l'uso

KULZER
MITSUI CHEMICALS GROUP

Manufacturer:
Kulzer GmbH
Leipziger Straße 2
63450 Hanau (Germany)
Made in Romania

Distributed in USA/Canada exclusively by:
Kulzer, LLC
4315 South Lafayette Blvd.
South Bend, IN 46614-2517
1-800-431-1785

Caution: Federal law restricts this device to sale by or on the order of a dental professional.

Importado e Distribuído no Brasil por
Kulzer South América Ltda.
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Rua Cenno Sbrighi, 27 – cj. 42
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sac@kulzer-dental.com

Resp. Técnica: Dra. Regiane Marton – CRO 70.705
N° ANVISA: vide embalagem

CE 0197

MD

Medizinprodukt	Medisinsk utstyr	Flüssig	Pulver
Medical device	Ιατροτεχνολογικό προϊόν	Liquid	Powder
Dispositif médical	Orvostechnikai eszköz	Liquide	Poudre
Producto sanitario	Wyrób medyczny	Líquido	Pólvora
Dispositivo medico	Medicinski proizvod	Liquido	Polvere
Equipamento para saúde	Dispozitiv medical	Líquido	Pó
Medisch hulpmiddel	Zdravotnícka pomôcka	Vloeibaar	Poeder
Medicinteknisk produkt	Medicinski pripomoček	Flytande	Pulver
Medicinsk udstyr		Flydende	Pulver
		Flytende	Pulver
		ρευστό	πούντρα
		Folyékony	Por
		Płynny	Proszek
		Tekuć	Prašak
		Lichid	Pulbere
		Kvapalné	Prášok
		Tekoč	Prah

66087321/01

DE Gebrauchsanweisung PalaXtreme®

Medizinprodukt - Nur zur Anwendung durch dentales Fachpersonal.

Zweckbestimmung
Dieses Dentalmaterial ist für Patienten mit zahnmedizinischem Behandlungsbedarf entsprechend der nachfolgenden Indikationen geeignet unter Beachtung der Kontraindikationen. Bei Schwangeren und Stillenden sind aufgrund der besonderen Situation die Behandlungsrisiken zugunsten des Ungeborenen oder Säuglings sorgfältig gegenüber dem Nutzen der Behandlung abzuwägen. Medizinprodukte von KULZER sorgen für die Rehabilitation oraler Funktionen der natürlichen Bezahnung (Kauen, Sprechen sowie Ästhetik) und stabilisieren restaurativ oder prothetisch die Rest-Bezahnung und/oder den Kieferkamm.

Bestehend aus einer Pulverkomponente in verschiedenen Farben und Flüssigkeit.

Zusammensetzung
Pulverhauptkomponente:
Methylmethacrylat-Copolymer.
Flüssigkeitshauptkomponenten:
Methylmethacrylat, Dimethacrylate
PalaXtreme ist cadmiumfrei.

Indikationen
Gießverfahren:
– Totale OK- und UK-Prothesen
– Implantatprothetik
– Komplettierung von Modellgussprothesen bei einem oder mehreren Sätteln
– Schienenkonstruktionen

Injektionsverfahren:
– Totale OK- und UK-Prothesen
– Implantatprothetik

Kontraindikationen
Direkte Unterfütterungen mit PalaXtreme sind kontraindiziert. Bei bekannter oder vermuteter Allergie gegen Bestandteile des Produktes ist die Verwendung des Produktes kontraindiziert. Nicht anwenden bei bekannter oder vermuteter Allergie gegen (Meth-)Acrylat-Verbindungen oder Benzoylperoxid.

Nebenwirkungen
Überempfindlichkeiten gegen das Produkt oder seine Bestandteile können im Einzelfall nicht ausgeschlossen werden. Inhaltsstoffe sind im Verdachtsfall beim Hersteller zu erfragen. In Einzelfällen wurden Überempfindlichkeitsreaktionen (Allergien), örtliche Missempfindungen, Geschmacksirritationen und Reizungen der Mundschleimhaut beschrieben. Alle Prothesenwerkstoffe auf MMA/PMMA-Basis enthalten nach der Herstellung immer einen zulässigen, geringen Anteil Restmonomer (< 4,5 %). Zur weiteren Reduzierung des Risikos von Unverträglichkeitsreaktionen ist die Prothese vor dem Einsetzen für mindestens 12 Stunden in lauwarmem Wasser zu lagern.

Warn- und Sicherheitshinweise
Augen und Haut können gereizt werden. Berührung mit der Haut vermeiden. Sensibilisierung durch Hautkontakt möglich. Geeignete Schutzhandschuhe tragen. Bei Kontakt des Produktes mit der Haut sofort gründlich mit Wasser und Seife waschen. Berührung mit den Augen vermeiden. Bei Kontakt mit den Augen mehrere Minuten mit Wasser spülen. Eventuell vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen. Bei anhaltenden Beschwerden Augenarzt aufsuchen. Flüssigkeit und Dampf leicht entzündbar. Flammpunkt: 10°C. Von Hitze, heißen Oberflächen, Funken, offenen Flammen und anderen Zündquellen fernhalten - nicht rauchen. Kann die Atemwege reizen. Einatmen von Staub/Rauch/Gas/Nebel/Dampf/Aerosol vermeiden. Giftig für Wasserorganismen, mit langfristiger Wirkung. Bitte für ausreichende Absaugung der Schleifpartikel vom Arbeitsplatz sorgen. Wenn keine technischen Schutzmaßnahmen getroffen werden, können beim Schleifen von Prothesenkunststoffen Reizungen der Augen, Haut und Atmungsorgane auftreten. Bei anhaltenden Hautirritationen oder sonstigen Symptomen klären Sie mit einem Facharzt eine MMA-Allergie ab.

Anwendungshinweise
Vor Erstgebrauch des Produktes die Unversehrtheit der Primärverpackung prüfen. Beschädigte Produkte dürfen nicht eingesetzt werden. Kann in Verbindung mit Dubliergelen zu Weißverfärbungen führen. Bitte verwenden Sie Dubliersilikone. Bei der Zahnaufstellung in Wachs keine Isoliermittel auf Alkoholbasis (zum Trennen von Gips und Wachs) verwenden, da diese zu Weißverfärbungen auf der Basalfläche der Prothese führen können.
Die Flüssigkeit von PalaXtreme weist typischerweise ein milchiges Erscheinungsbild auf. Bitte beachten, das Produkt hat eine lange Gießphase und kurze plastische Phase.

Gießverfahren
Vorbereitende Arbeiten
Zur Modellherstellung wird ein Hartgips Typ 3 empfohlen. Die in Wachs aufgestellten Konfektionszähne werden durch Gips oder Silikon fixiert (Vorwall / Gießküvette). Nach Entfernen des Wachses mit heißem Wasser (ohne chemische Zusätze) wird das Gipsmodell mit Aislar® zweimal dünn isoliert (siehe Gebrauchsanweisung Aislar®). Nur so wird eine einwandfreie Oberflächengüte von PalaXtreme zum Modell hin sichergestellt. Zur Verbesserung des Verbundes zwischen PalaXtreme und den Konfektionszähnen werden die Basalflächen mit einem groben Diamant aufgeraut (Schleifstaub entfernen) und mit Palabond® benetzt. Palabond® mit einem Pinsel (ohne Metalleinfassung) zweimal auftragen und jeweils 30 sec einwirken lassen. Nach dem zweiten Auftrag bleibt der Haftvermittler ca. 10 min aktiv.

Dosierung und Verarbeitung
Empfohlenes Mischungsverhältnis für die Gießtechnik ist 10 g Pulver : 6 g Flüssigkeit. Die Flüssigkeit im Anmischbecher vorlegen, die entsprechende Pulvermenge zügig hinzufügen und 30 sec zu einem homogenen Teig verrühren. Blasenbildung vermeiden. Zum Entfernen von Luftblasen den Anmischbecher schwenken. Die Verarbeitungszeit ist von der Umgebungstemperatur abhängig. PalaXtreme ist nach Anmischen bei einer Raumtemperatur von 23°C (73°F) ca. 3 min gießbar, nach ca. 6 min wird eine plastische Phase von ca. 3 min Dauer erreicht.

Polymerisation
Die Polymerisation im Palamat® elite / Palamat® practic erfolgt frühestens in der 7. min, spätestens in der 13. min. Die Teigoberfläche soll stumpf aussehen. Polymerisationszeit im Druckgefäß **30 min,** Wassertemperatur **55°C (131°F),** Druck 2 bar.

Injektionsverfahren
Dosierung und Verarbeitung
PalaXtreme wird in einem Mischungsverhältnis von 20 g Pulver : 12 g Flüssigkeit angemischt. Die Flüssigkeit im Anmischbecher vorlegen, die entsprechende Pulvermenge zügig hinzufügen und 30 sec zu einem homogenen Teig verrühren. Dies entspricht der Menge einer totalen Prothese durchschnittlicher Größe. Der Injektionszeitpunkt ist erreicht, sobald der Teig beginnt eine stumpfe Oberfläche zu bilden. Die Wartezeit vor der Injektion ab Anmischbeginn bei 23°C (73°F) beträgt ca. 7 – 8 min. Die Wartezeiten sind von der Raumtemperatur und der angemischten Menge abhängig. Weitere Angaben zur Verarbeitung von PalaXtreme für das Injektionsverfahren bitte der Betriebsanleitung Palajet® entnehmen.

Polymerisation
Polymerisationszeit im Druckgefäß **30 min,** Wassertemperatur **55°C (131°F),** Druck 2 bar. Bei dickeren Stücken oder bei Verwendung der Duoflask empfehlen wir eine verlängerte Polymerisationszeit von ca. **40 min.**

Ausarbeitung und Politur für Injektions- und Gießverfahren
Nach dem Abkühlen und Reokkludieren wird die Prothese vorsichtig vom Modell entfernt und mit kreuzverzahnten Fräsern bearbeitet. Vor der Politur mit Bimsstein wird die Prothese mit Schmirgelpapier abnehmender Körnung geglättet.

Beim Ausarbeiten, bitte beachten! Schutzbrille, langärmlige Schutzkleidung, Staubschutzmaske und passende Schutzhandschuhe tragen. Tischabsaugung mit Schutzscheibe nutzen. Idealerweise mit Schleifbox arbeiten.
Schleifpartikel: Können scharfkantig, abrasiv sein! Schleifpartikel von Arbeitsfläche und Körper regelmässig entfernen! Ausarbeitungswerkzeuge: Empfehlenswert sind Fräser mit Querhieb z. B.: FSQ-Fräser oder Diamantschleifer, da Schleifpartikel kürzer, feinkörniger und weniger scharfkantig, abrasiv für die Haut sind.

Wiederherstellung
Arbeiten aus PalaXtreme können mit allen Pala-Autopolymerisaten wiederhergestellt und ergänzt werden.

Aufbewahrungshinweise
Nach Ablauf des Verfalldatums darf das Material nicht mehr verwendet werden. Direkte Sonneneinstrahlung vermeiden.
Bei Rückmeldungen zum Produkt bitte immer Chargenbezeichnung und Artikelnummer angeben. Gemäß EU Medizinprodukte-Verordnung sind Anwender / Patienten verpflichtet, schwerwiegende Ereignisse mit einem Medizinprodukt dem Hersteller und der zuständigen Behörde des Landes, in dem sie auftraten, zu melden.

Entsorgungshinweis
Empfehlung: Entsorgung gemäß den behördlichen Vorschriften. Inhalt und nicht restentleerte Verpackungen nicht mit dem Hausmüll entsorgen oder in die Kanalisation gelangen lassen. Europäischer Abfallkatalog: 180106 Chemikalien, die aus gefährlichen Stoffen bestehen oder solche enthalten.

Zur Entsorgung bitte Sicherheitsdatenblatt und nationale Vorschriften beachten. Sicherheitsdatenblätter und weitere Informationen finden Sie auf unserer Homepage www.kulzer.com

® = eingetragenes Warenzeichen der Kulzer GmbH

Stand: 2021-04

GB Instructions for use PalaXtreme®

Medical Device - for use by dental health care professionals only.

Intended purpose
This dental material is suitable for patients requiring dental treatment for the following indications with consideration of the contraindications. For pregnant and nursing women, the treatment risks must be weighed carefully against the benefits taking into consideration the unborn child or infant. KULZER medical devices ensure the rehabilitation of oral functions such as chewing, speaking and aesthetics. They stabilize the remaining dentition and/or the alveolar ridge restoratively or prosthetically.

Consisting of a powder component in various colours and liquid.

Composition
Major powder component:
Methyl methacrylate copolymer.
Major liquid components:
Methyl methacrylate, di-methacrylate
PalaXtreme is cadmium-free.

Indications
Pouring procedure:
– Full upper and lower dentures
– Implant supported denture
– Partial dentures. Several or single saddles.
– Dental splints

Injection procedure:
– Full upper and lower dentures
– Implant supported denture

Contraindications
Direct lining with PalaXtreme. is contraindicated. In case of known or suspected allergy to components of the product, its use is contraindicated. Do not use in case of known or suspected allergy against (meth)acrylate compounds or benzoyl peroxide.

Side effects
Hypersensitivities to the product or its components cannot be excluded in individual cases. In case of suspicion please contact the manufacturer for ingredients information. Hypersensitivity reactions (allergies), local sensory disturbances, taste disturbances and irritation of the oral mucosa have been described in isolated cases. After processing, all MMA/PMMA-based denture materials always contain a permitted, small proportion of residual monomer (< 4,5 %). For further risk reduction of intolerance reactions, the denture has to be stored in tepid water for at least 12 hours before placement.

Warnings and safety instructions
May cause skin and eye irritation. Avoid contact with skin. Skin contact may cause sensitization. Wear suitable protective gloves. In case of contact with skin, immediately wash with plenty of water and soap. Avoid contact with eyes. In case of contact with eyes, rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If symptoms persist, consult an eye specialist. Highly flammable liquid and vapour. Flash point: 10°C. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources - no smoking. May cause respiratory irritation. Avoid breathing dust/fume/gas/mist/vapours/spray. Toxic to aquatic life with long lasting effects. Please ensure sufficient extraction of the grinding particles from the workplace. If no technical protective measures are taken, irritation of the eyes, skin and respiratory organs may occur when grinding denture acrylics.In case of persistent skin irritation or other symptoms, clarify an MMA allergy with a specialist.

Application notes
Examine the integrity of the primary packaging before first use. Damaged products must not be used. May lead to white stains in combination with duplicating gels. Please use duplicating silicones. When positioning teeth in wax, do not use alcohol based separating agents (separation of gypsum and wax), as this may cause white discoloration on the basal surface of the prosthesis. The liquid of PalaXtreme typically has a milky appearance. Please note, the product has a long casting phase and short plastic phase.

Pouring procedure
Preparation
A type III dental stone is recommended for models. The teeth positioned in wax are fixed by a stone or silicone matrix (pouring procedure for partial denture). After removal of the wax with hot water (no chemical additives), the plaster cast is thinly coated twice with Aislar® (see Aislar® instructions for use). This is the only way to ensure a high quality contact between PalaXtreme and the master cast. To improve the bond between PalaXtreme and the prosthetic teeth, the basal surfaces are roughened with a coarse diamond (remove grinding residue) and wetted with Palabond®. Apply Palabond® twice with a brush (no metal ferrule) and leave for 30 sec after each coat. After the second coat, the adhesion promoter remains active for approx 10 min.

Dosage and processing
The recommended mixing ratio for the pouring technique is 10 g powder : 6 g liquid. Place the liquid in the mixing cup, add the specified volume of powder immediately, and stir for 30 sec to form a homogenous mass. Prevent bubble formation. Lightly tap the mixing cup to remove air bubbles. The processing time depends upon the ambient temperature. PalaXtreme can be poured about 3 min after mixing at room temperature of 23°C (73°F); after 6 min, a plastic phase, lasting approx 3 min, is reached.

Polymerisation
For polymerisation in the Palamat® elite or Palamat®, the prepared material should be mixed and allowed to bench cure for a minimum of 7 min, and a maximum time of 13 min. The surface of the mixture should have a dull appearance. Polymerisation time in the pressure vessel: **30 min**, water temperature: **55°C (131°F)**, pressure: 2 bar.

Injection procedure
Dosage and processing
PalaXtreme is placed in the dosage beaker in a mixing ratio of 20 g powder: 12 g liquid. Place the liquid in the mixing cup, add the specified volume of powder immediately, and stir to form a homogenous mass for a 30 sec. This volume is suitable for full dentures of average size. Inject when the mixture has a dull surface. The waiting time between mixing, start and injection at 23°C (73°F) is about 7 – 8 min. The times may vary depending on temperature and mixing volume. For more information on the preparation of PalaXtreme for injection, see the Palajet® instructions for use.

Polymerisation
Polymerisation time in the pressure vessel: **30 min**, water temperature: **55°C (131°F)**, pressure: 2 bar. We recommend a longer polymerisation time of **40 min** for thicker pieces or when Duoflask is used.

Processing and polishing for injection and pouring
After cooling and re-occlusion the prosthesis is carefully removed from the model and trimmed with cross-toothed cutters. Before polishing with pumice, the prosthesis should be made smooth with sandpaper of decreasing grain size.

When grinding, please note! Wear protective glasses, long-sleeved protective clothing, dust mask and fitting protective gloves. Use table extraction with protective screen. Ideally work with a sanding box.
Grinding particles: Can be sharp-edged, abrasive! Regularly remove grinding particles from the work surface and body! Finishing tools: We recommend cutters with a transverse cut, e.g. FSQ cutters or slide cutters: FSQ router or slide sander, as grinding particles are shorter, finer-grained and less sharp-edged, abrasive to the skin.

Repair
PalaXtreme can be relined, repaired and added to with all Pala auto-polymerisation materials.

Storage instructions
The material should not be used after the expiration date. Avoid direct exposure to sun.

When giving feedback on the product, please always state batch designation and article number. According to EU Medical Device Regulation users/ patients are obliged to report serious incidents with a medical device to the manufacturer and to the competent authority of the country, the incident occurred.

Disposal information
Recommendation: Dispose of in accordance with official regulations. Do not dispose of contents or partially emptied packaging in the household waste or allow them to enter the sewage system. European Waste Catalogue: 180106 Chemicals consisting of or containing hazardous substances.

For disposal please follow the instructions on the material safety data sheet and national regulations. Safety data sheets and more information are available at our website www.kulzer.com

® = registered trademark of Kulzer GmbH

Dated: 2021-04

FR Mode d'emploi PalaXtreme®

Dispositif médical - Réservé à l'usage exclusif des professionnels dentaires.

Usage
Ce matériau dentaire convient aux patients qui nécessitent un traitement dentaire pour les indications suivantes, en prenant en considération les contre-indications. Pour les femmes enceintes ou qui allaitent, les risques du traitement doivent être soigneusement mis en balance avec les bénéfices, en tenant compte de l'enfant à naître ou du nouveau-né. Les dispositifs médicaux KULZER assurent la réhabilitation des fonctions orales telles que la mastication, la parole et l'esthétique. Ils stabilisent la dentition restante et/ou la crête alvéolaire, au niveau de la restauration ou de la prothèse.

Description du produit
Résine acrylique pour prothèses dentaires très résistante à la rupture, à usage universel, pour la technique d'injection et la méthode coulée. Convient aux prothèses amovibles et permanentes, auto-polymérisation. Particulièrement recommandée pour les prothèses implanto-portées en raison de la résistance élevée à la rupture. Constitué d'un composant en poudre de coloris différents et d'un liquide.

Composition
Composant principal de la poudre :
copolymère de méthacrylate de méthyle.
Composants principaux du liquide :
méthacrylate de méthyle, di-méthacrylate.
PalaXtreme ne contient pas de cadmium.

Indications

Procédure de coulée :
- Prothèses dentaires complètes supérieures et inférieures
- Prothèses implanto-portées
- Prothèses partielles. Selles multiples ou uniques.
- Attèles de contention

Procédure d'injection :
- Prothèses dentaires complètes supérieures et inférieures
- Prothèses implanto-portées

Contre-indications
Les rebasages directs avec PalaXtreme sont contre-indiqués. L'utilisation de ce produit est contreindiquée en cas d'allergies connues ou présumées aux composants de ce produit. Ne pas utiliser en cas d'allergies connues ou suspectées aux composés de (méth)acrylate ou peroxyde de benzoyle.

Effet secondaires
Ce produit ou l'un de ses composants peut dans certains cas particuliers causer des réactions d'hypersensibilité. En cas de doute, des informations sur les composants peuvent être demandées au fabricant. Des réactions d'hypersensibilité (allergies) ainsi que des troubles sensoriels locaux, des troubles gustatifs et une irritation de la muqueuse orale ont été décrits chez des cas isolés. Après traitement, tous les matériaux de prothèse à base de MMA/PMMA contiennent toujours un faible pourcentage autorisé de monomère résiduel (< 4,5 %). Afin de réduire encore davantage le risque d'intolérance la prothèse doit être conservée dans de l'eau tiède pendant au moins 12 heures avant sa pose en bouche.

Avertissements et consignes de sécurité
Peut être irritant pour les yeux et la peau. Éviter le contact avec la peau. Peut entraîner une sensibilisation par contact avec la peau. Porter des gants de protection appropriés. Si le produit entre en contact avec la peau, laver immédiatement et soigneusement avec de l'eau et du savon. Éviter le contact avec les yeux. En cas de contact avec les yeux rincer à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. Contacter un médecin si des symptômes persistent. Liquide et vapeurs très inflammables. Point d'éclair : 10°C. Tenir à l'écart de la chaleur, des surfaces chaudes, des étincelles, des flammes nues et de toute autre source d'ignition - ne pas fumer. Peut irriter les voies respiratoires. Éviter de respirer les poussières/fumées/gaz/brouillards/vapeurs/aérosols. Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme. Veuillez assurer une extraction suffisante des particules issues du grattage de la prothèse sur le lieu de travail. Si aucune mesure technique de protection n'est prise, une irritation des yeux, de la peau et des organes respiratoires peut se produire lors du meulage des résines pour prothèses dentaires. En cas d'irritations cutanées persistantes ou d'autres symptômes, procédez à une recherche d'allergie au MMA avec un spécialiste médical.

Conseils pratiques
Examiner l'intégrité de l'emballage primaire avant la première utilisation. Il ne faut en aucun cas utiliser des produits endommagés. Peut provoquer des taches blanches en combinaison avec des gels de duplication. Veuillez utiliser des silicones de duplication. Lors du montage des dents sur cire, ne pas utiliser de produits isolants à base d'alcool (pour la séparation du plâtre et de la cire), ceux-ci pouvant entraîner des décolorations blanches sur l'intrados de la prothèse. Le liquide de PalaXtreme a généralement un aspect laiteux. Veuillez noter que le produit a une longue phase de coulée et une courte phase plastique.

Procédure de coulée

Préparation
Un plâtre de type III est recommandé pour fabriquer les modèles. Les dents positionnées dans la cire sont fixées par une matrice en plâtre ou en silicone (procédure de coulée pour une prothèse partielle). Après élimination de la cire à l'eau chaude (sans additif chimique), recouvrir l'empreinte au plâtre de deux fines couches d'Aislar® (voir le mode d'emploi d'Aislar®). C'est le seul moyen pour garantir une grande qualité de contact entre PalaXtreme et le maître-modèle. Afin d'améliorer la liaison entre PalaXtreme et les dents prothétiques, il convient de dépolir les intrados avec un diamant à gros grain (enlever la poussière de grattage) et de les humidifier avec l'agent de liaison Palabond®. Appliquer deux fois Palabond® avec un pinceau (sans manchon métallique) et laisser agir pendant 30 secondes après chaque couche. Après application de la deuxième couche, le promoteur d'adhésion reste actif pendant 10 minutes environ.

Dosage et mise en œuvre
Le rapport de mélange conseillé pour la méthode coulée est 10 g de poudre pour 6 g de liquide. Verser le liquide dans le godet de mélange, ajouter immédiatement la quantité de poudre correspondante et mélanger pendant 30 secondes jusqu'à l'obtention d'une pâte homogène. Éviter la formation de bulles d'air. Tapoter doucement le godet de mélange pour éliminer les bulles d'air. Le temps de manipulation dépend de la température ambiante. Il est possible de couler PalaXtreme environ 3 minutes après le mélange à une température ambiante de 23°C (73°F) ; après 6 minutes, une phase plastique, durant environ 3 minutes, est atteinte.

Polymérisation
Pour la polymérisation dans le Palamat® elite ou Palamat®, il convient de mélanger le matériau préparé et de le laisser durcir sur une paillasse pendant au moins 7 minutes et au maximum 13 minutes. La surface du mélange doit avoir un aspect mat. Le temps de polymérisation dans le récipient sous pression est de **30 minutes**, la température de l'eau de **55°C (131°F)** et la pression de 2 bars.

Procédure d'injection

Dosage et mise en œuvre
Verser PalaXtreme dans le bécher de dosage avec un rapport de mélange de 20 g de poudre pour 12 g de liquide. Verser le liquide dans le godet de mélange, ajouter immédiatement la quantité de poudre correspondante et mélanger pendant 30 secondes jusqu'à l'obtention d'une pâte homogène. Ce volume est adapté pour les prothèses dentaires complètes de taille moyenne. Procéder à l'injection lorsque le mélange a une surface mate. Le temps d'attente entre le mélange, le début et l'injection à une température de 23°C (73°F) est de 7 à 8 minutes environ. Les durées peuvent varier selon la température et le volume de mélange. Pour en savoir plus sur la préparation de PalaXtreme pour injection, voir le mode d'emploi de Palajet®.

Polymérisation
Le temps de polymérisation dans le récipient sous pression est de **30 minutes**, la température de l'eau de **55°C (131°F)** et la pression de 2 bars. Nous recommandons un temps de polymérisation plus long de **40 minutes** pour les pièces plus épaisses ou lors de l'utilisation du moufle Duoflask.

Traitement et polissage pour l'injection et la méthode coulée
Après refroidissement et vérification de l'occlusion, la prothèse est soigneusement retirée du modèle et grattée à l'aide de fraises à denture croisée. Avant de polir à l'aide d'une pierre ponce, lisser la prothèse avec du papier de verre de granulométrie décroissante.

Lorsque vous polissez ou grattez la prothèse, notez bien ! Porter des lunettes de protection, des vêtements de protection à manches longues, un masque anti-poussière et des gants de protection appropriés. Utiliser une extraction de table avec écran de protection. L'idéal est de travailler avec une boîte de ponçage. Particules issues de l'abrasion : peuvent être tranchantes, abrasives ! Enlevez régulièrement les particules abrasives du plan de travail et du corps ! Outils de finition : nous recommandons les fraises à coupe transversale, par exemple : la toupie FSQ ou la ponceuse à glissière, car les particules issues de l'abrasion sont plus courtes, à grain plus fin et moins tranchantes, moins abrasives pour la peau.

Réparations
PalaXtreme peut être rebasé, réparé ou faire l'objet d'ajouts avec tous les matériaux autopolymérisables Pala.

Consignes de stockage
Le matériau ne doit plus être utilisé après la date de péremption. Éviter l'exposition directe à la lumière du soleil. Veuillez rappeler le numéro de lot et le numéro de l'article dans toute correspondance à propos du produit. Conformément au règlement de l'UE sur les dispositifs médicaux, les utilisateurs / patients doivent notifier les incidents graves liés à un dispositif médical au fabricant et à l'autorité compétente du pays dans lequel ils sont survenus.

Consignes d'élimination:
Recommandation : Élimination conformément aux réglementations officielles. Ne pas jeter le contenu et les emballages qui n'ont pas été vidés avec les ordures ménagères et ne pas les laisser s'écouler dans les égouts. Catalogue européen des déchets : 180 106 produits chimiques à base de substances dangereuses ou qui en contiennent.
Respecter la fiche de données de sécurité et la législation en vigueur dans votre pays pour l'élimination du produit. Les fiches de données de sécurité et davantage d'informations sont disponibles sur notre site Web www.kulzer.com
® = marque déposée de Kulzer GmbH

Mise à jour de l'information : 2021-04

ES Instrucciones de uso PalaXtreme®

Producto sanitario - Solo para el uso por parte de profesionales dentales.

Finalidad de uso
Este material dental es adecuado para pacientes que requieren un tratamiento dental para las siguientes indicaciones, teniendo en cuenta las contraindicaciones. En el caso de mujeres embarazadas o en periodo de lactancia, deben valorarse cuidadosamente los riesgos del tratamiento con respecto a los beneficios, teniendo en cuenta la salud del feto o el bebé. Los productos sanitarios de KULZER garantizan la recuperación de las funciones bucales, como la masticación, el habla y la estética. Estabilizan las piezas dentales existentes o la cresta alveolar de forma restauradora o protésica.

Descripción del producto
Resina acrílica de uso universal con elevada resistencia a la rotura, para las técnicas de inyección o vertido. Adecuada para prótesis dentales fijas y removibles, autopolimerizable. Resulta especialmente recomendable para prótesis implantosoportadas debido a su gran resistencia a la rotura.

Consta de un componente en polvo de varios colores y líquido.

Composición
Componente principal del polvo:
copolímero de metacrilato de metilo.
Componentes principales del líquido:
metacrilato de metilo, dimetacrilato.
PalaXtreme no contiene cadmio.

Indicaciones

Procedimiento de vertido:
- Prótesis totales del maxilar superior e inferior.
- Prótesis implantosoportadas.
- Prótesis parciales. Monturas múltiples o simples.
- Férulas dentales.

Procedimiento de inyección:
- Prótesis totales del maxilar superior e inferior.
- Prótesis implantosoportadas.

Contraindicaciones
Están contraindicados los rebases directos con PalaXtreme. El uso de este producto está contraindicado en caso de alergia conocida o sospechada a los componentes de este producto. El producto no debe utilizarse en casos de alergia conocida o sospechada a los componentes del (met)acrilato o peróxido de benzoilo.

Efectos secundarios
En casos aislados, este producto o sus componentes pueden causar reacciones de hipersensibilidad. En caso de duda, puede solicitar información sobre los componentes al fabricante. En casos aislados se han descrito reacciones de hipersensibilidad (alergias), trastornos sensitivos locales, alteraciones del gusto e irritación de la mucosa bucal. Tras el procesamiento, todos los materiales de prótesis basadas en MMA/PMMA contendrán una pequeña proporción de monómero residual (dentro de los márgenes permitidos)(< 4,5 %). Para reducir aún más el riesgo de intolerancias, la prótesis debe almacenarse en agua templada durante al menos 12 horas antes de su colocación.

Advertencias e indicaciones de seguridad
Puede irritar los ojos y la piel. Evitar el contacto con la piel. Posibilidad de sensibilización al contacto con la piel. Utilizar guantes de protección adecuados. En caso de contacto del producto con la piel, lavarse inmediatamente con abundante agua y jabón. Evítese el contacto con los ojos. En caso de contacto con los ojos aclarar con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando. En caso de molestias persistentes, acudir al médico. Líquido y vapores muy inflamables. Punto de inflamación: 10°C. Mantener alejado del calor, superficies calientes, chispas llamas al descubierto y otras fuentes de ignición - no fumar. Puede irritar las vías respiratorias. Evitar respirar el polvo/el humo/el gas/la niebla/los vapores/el aerosol. Tóxico para los organismos acuáticos, con efectos nocivos duraderos. Por favor, tras el repasado asegúrese de eliminar las partículas resultantes del lugar de trabajo. Si no se toman medidas técnicas de protección, pueden producirse irritaciones en los ojos, la piel y los órganos respiratorios al repasar el acrílico de las prótesis. En caso de irritaciones cutáneas persistentes u otros síntomas, verifique si existe alergia al MMA con el médico especialista.

Instrucciones de uso
Examine la integridad del embalaje primario antes del primer uso. No utilizar productos dañados. En combinación con geles para duplicar, puede producir manchas blancas. Use siliconas para duplicado. Durante la colocación del diente en cera, no debe utilizarse ningún aislante a base de alcohol (para la separación de yesos y ceras), ya que pueden provocar decoloraciones blancas en la superficie basal de la prótesis.
El líquido de PalaXtreme suele tener un aspecto lechoso. Tenga en cuenta que el producto tiene una larga fase de fundición y una fase plástica corta.

Procedimiento de vertido

Preparación
Para la fabricación de los modelos, se aconseja un yeso duro de tipo 3. Los dientes acrílicos posicionados en cera se fijan por medio de yeso o silicona (procedimiento de vertido para prótesis parciales). Después de extraer la cera con agua caliente (sin aditivos químicos), debe aplicarse dos finas capas de Aislar® en el modelo de yeso (consulte las instrucciones de uso de Aislar®). Solo de este modo se garantizará una calidad de contacto adecuada entre PalaXtreme y el modelo maestro. Para mejorar la unión entre PalaXtreme y los dientes acrílicos, las superficies basales deben repasarse con una fresa de diamante gruesa (eliminar los restos tras el repasado) y humedecerse con Palabond®. Aplicar Palabond® dos veces con un pincel (sin borde de metal) y dejar actuar durante 30 segundos cada vez. Después de la segunda aplicación, el producto adhesivo está activo durante unos 10 min.

Dosificación y procesamiento
La proporción de mezcla recomendada para la técnica de vertido es de 10 g de polvo por 6 g de líquido. Introducir el líquido en el vaso de mezcla, añadir inmediatamente la cantidad de polvo correspondiente y removerlo durante 30 segundos hasta obtener una masa homogénea. Evitar la formación de burbujas. Para eliminar las burbujas, golpear suavemente el vaso de mezcla. El tiempo de procesamiento depende de la temperatura ambiente. Después de la mezcla, PalaXtreme puede verterse durante aproximadamente 3 min a una temperatura ambiente de 23°C (73°F); después de 6 minutos, se alcanza una fase plástica que dura unos 3 minutos.

Polimerización
Para la polimerización en Palamat® elite o Palamat®, el material preparado debe mezclarse y dejarse fraguar durante un mínimo de 7 minutos y un máximo de 13 minutos en el banco de trabajo. La superficie de la masa debe tener un aspecto mate. Tiempo de polimerización en el recipiente de presión: **30 minutos**; temperatura del agua: **55°C (131°F)**; presión: 2 bar.

Procedimiento de inyección

Dosificación y procesamiento
PalaXtreme se añade al vaso dosificador con una proporción de mezcla de 20 g de polvo por 12 g de líquido. Introducir el líquido en el vaso de mezcla, añadir inmediatamente la cantidad de polvo correspondiente y remover durante 30 segundos hasta obtener una masa homogénea. Esta cantidad es la correspondiente para una prótesis total de tamaño medio. El momento de la inyección llega cuando la superficie de la masa se mate. El tiempo de espera entre el comienzo de la mezcla y la inyección a 23°C (73°F) es de unos 7 – 8 minutos. Los tiempos pueden variar en función de la temperatura y el volumen de la mezcla. Para obtener más información acerca de la preparación de inyección de PalaXtreme, consultar las instrucciones de uso de Palajet®.

Polimerización
Tiempo de polimerización en el recipiente de presión: **30 minutos**; temperatura del agua: **55°C (131°F)**; presión: 2 bar. Recomendamos un tiempo de polimerización más prolongado, de **40 minutos**, para piezas más gruesas o cuando se utiliza Duoflask.

Elaboración y pulido para procedimientos de inyección y vertido
Tras el enfriamiento y el control de la oclusión, la prótesis se extrae con cuidado del modelo y se prepara con fresas con corte en cruz. Antes del pulido con piedra pómez, la prótesis se debe alisar con papel esmeril de granulado fino.

Durante el procesamiento, ¡tenga en cuenta! Utilizar gafas de protección, ropa de protección de manga larga, mascarilla antipolvo y guantes de protección adecuados. Utilizar la extracción de la mesa con la pantalla de protección. Lo ideal es trabajar con una caja de lijado. Partículas abrasivas: Pueden ser afiladas, abrasivas. Elimine regularmente las partículas abrasivas de la superficie de trabajo y del cuerpo. Herramientas de acabado: Recomendamos las fresas con corte transversal, por ejemplo Fresa FSQ o lijadora de corredera, ya que las partículas abrasivas son más cortas, de grano más fino y menos afiladas, abrasivas para la piel.

Reparación
PalaXtreme puede realinearse, repararse y complementarse con todos los materiales autopolimerizables Pala.

Conservación
El material no debe utilizarse después de la fecha de caducidad. Debe evitarse la radiación solar directa. Indique el número de lote y número de artículo en toda la correspondencia acerca del producto. De acuerdo con la normativa europea de regulación de productos sanitarios, los usuarios/pacientes están obligados a notificar los acontecimientos adversos graves con productos sanitarios al fabricante y a la autoridad competente del país en el que se hayan producido.

Eliminación de recursos:
Recomendación: Eliminación conforme a las normativas vigentes. No desechar el contenido ni los envases con restos de producto en la basura doméstica ni el alcantarillado. Lista europea de residuos: 180106 Productos químicos que consisten en, o contienen, sustancias peligrosas.

Para la eliminación de desechos, consultar la ficha de datos de seguridad y las normas nacionales. Hay hojas de datos de seguridad y más información disponibles en nuestro sitio web www.kulzer.com.
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Revisión: 2021-04

IT Istruzioni per l'uso PalaXtreme®

Dispositivo medico - Destinato all'uso solo da parte di personale odontotecnico specializzato.

Destinazione d'uso
Questo materiale dentale è adatto per pazienti che richiedono un trattamento dentale conforme alle seguenti indicazioni nell'osservanza delle contrindicazioni. Per le donne in gravidanza e che allattano, i rischi del trattamento devono essere considerati attentamente nei confronti dei benefici, tenendo conto del nascituro o del lattante. I dispositivi medici KULZER assicurano la riabilitazione delle funzioni orali come la masticazione, fonetica e l'estetica. Stabilizzano la dentizione rimanente e/o la cresta alveolare in modo conservativo o protesico.

Descrizione del prodotto
Resina per protesi di applicazione generale, con elevata resistenza alla frattura, per iniezione e colata. Adatta a protesi fisse e mobili, autopolimerizzante. Particolarmente raccomandata per protesi supportate da impianti, grazie all'elevata resistenza alla frattura.

Costituita da un componente in polvere di vari colori e un liquido.

Composizione
Principale componente in polvere:
copolimero del metacrilato di metile.
Principali componenti liquidi:
metacrilato di metile, dimetacrilato.
PalaXtreme è privo di cadmio.

Indicazioni

Procedura di colata:
- Protesi superiori e inferiori complete
- Protesi supportata da impianti
- Protesi parziale. Una o più selle edentule.
- Splint dentali

Procedura ad iniezione:
- Protesi superiori e inferiori complete
- Protesi supportata da impianti

Controindicazioni
Il ribasamento diretto con PalaXtreme. è controindicato. L'uso di questo prodotto è controindicato in caso di allergia nota o presunta verso i componenti di questo prodotto. Non utilizzare in caso di allergia nota o sospetta verso i composti a base di (met)acrilatio o perossido di benzoile.

Effetti collaterali
Questo prodotto o i suoi componenti possono causare reazioni di ipersensibilità in determinati casi. In caso di dubbio, rivolgersi al produttore per informazioni sui componenti. In casi isolati sono state descritte reazioni di ipersensibilità (allergie), nonché disestesie localizzate, alterazioni del gusto e irritazione della mucosa orale. Dopo la lavorazione, tutti i materiali per protesi a base di MMA/PMMA contengono sempre una piccola percentuale consentita di monometro residuo (< 4,5 %). Per ridurre il rischio di reazioni di incompatibilità, la protesi deve essere conservata in acqua tiepida per almeno 12 ore prima di inserirla nel cavo orale.

Avvertenze di pericolo e sicurezza
Può essere irritante per gli occhi e la pelle. Evitare il contatto con la pelle. Può provocare sensibilizzazione per contatto con la pelle. Indossare adeguati guanti protettivi. In caso di contatto con la pelle, lavarsi immediatamente ed abbondantemente con acqua e sapone. Evitare il contatto con gli occhi. In caso di contatto con gli occhi sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare. Se i disturbi persistono, consultare un medico. Liquido e vapori facilmente infiammabili. Punto di infiammabilità: 10°C. Tenere lontano da fonti di calore, superfici calde, scintille, fiamme libere o altre fonti di accensione - non fumare. Può irritare le vie respiratorie. Evitare di respirare la polvere/i fumi/i gas/la nebbia/i vapori/gli aerosol. Tossico per gli organismi acquatici con effetti di lunga durata. Si prega di assicurare una sufficiente aspirazione delle particelle di rifinitura dal luogo di lavoro. Se non si adottano misure tecniche di protezione, durante la fresatura degli acrilici per protesi possono verificarsi irritazioni agli occhi, alla pelle e agli organi respiratori. In caso di irritazioni cutanee persistenti o altri sintomi, valutare l'insorgenza di un all'allergia al MMA e consultare un medico specialista.

Avvertimenti per l'uso
Esaminare l'integrità della confezione principale prima del primo utilizzo. Non utilizzare i prodotti se sono danneggiati. Potrebbero verificarsi macchie bianche se utilizzata insieme a gel per duplicazione. Utilizzare siliconi per duplicazione. Durante la modellazione in cera non utilizzare isolanti a base alcolica (per separare il gesso dalla cera), poiché possono causare decolorazioni bianche sulla superficie basale della protesi.
Il liquido di PalaXtreme generalmente ha un aspetto lattiginoso. Si prega di notare che il prodotto ha una lunga fase di colata e una breve fase plastica.

Procedura di colata

Preparazione
Per la realizzazione dei modelli si consigliano i gessi di tipo 3. I denti posizionati nella cera vengono fissati mediante una matrice in gesso o silicone (procedura di colata per protesi parziale). Dopo la rimozione della cera con acqua calda (senza additivi chimici) il modello viene ricoperto con due strati sottili di Aislar® (vedere Aislar® istruzioni per l'uso). Questo è l'unico modo per garantire un contatto di alta qualità tra PalaXtreme e il modello master. Per migliorare il legame tra PalaXtreme e i denti protesici, le superfici basali vengono irruvidite con una fresa diamantata a grana grossa (eliminare i residui prodotti dalla fresatura) e bagnati con Palabond®. Applicare Palabond® due volte con una pennello (non utilizzare strumenti metallici) e lasciare asciugare per 30 secondi dopo l'applicazione di ogni strato. Una volta applicato il secondo strato, l'adesivo resta attivo per circa 10 minuti.

Dosaggio e lavorazione
Il rapporto di miscelazione raccomandato per la tecnica di colata è 10 g di polvere: 6 g di liquido. Versare il liquido nel recipiente di miscelazione, aggiungere rapidamente la quantità di polvere specificata e miscelare per 30 sec in modo da ottenere un impasto omogeneo. Evitare la formazione di bolle. Picchiettare lievemente il recipiente di miscelazione per eliminare le bolle d'aria. Il tempo di lavorazione dipende dalla temperatura ambiente. PalaXtreme può essere versato una volta trascorsi circa 3 minuti dalla miscelazione a una temperatura ambiente di 23°C (73°F); dopo 6 minuti si raggiunge la fase plastica, che dura circa 3 minuti.

Tecnica di polimerizzazione
Per la polimerizzazione nel Palamat® elite o nel Palamat®, il materiale preparato deve essere miscelato e lasciato riposare sul banco di lavoro per un tempo minimo di 7 minuti e massimo di 13 minuti. La superficie della miscela deve risultare opaca. Tempo di polimerizzazione nel polimerizzatore: **30 minuti**, temperatura dell'acqua: **55°C (131°F)**, pressione: 2 bar.

Procedura di iniezione

Dosaggio e lavorazione
PalaXtreme viene posizionato nel beaker di dosaggio con un rapporto di miscelazione di 20 g di polvere: 12 g di liquido. Versare il liquido nel recipiente di miscelazione, aggiungere rapidamente la quantità di polvere specificata e miscelare per 30 sec in modo da ottenere un impasto omogeneo. Questo volume è adatto a protesi complete di medie dimensioni. Iniettare quando la miscela presenta una superficie opaca. Il tempo di attesa tra la miscelazione, l'inizio e l'iniezione a 23°C (73°F) è di circa 7 – 8 min. I tempi possono variare in funzione della temperatura e del volume della miscela. Per ulteriori informazioni sulla preparazione di PalaXtreme per iniezione, consultare le istruzioni per l'uso di Palajet®.

Tecnica di polimerizzazione
Tempo di polimerizzazione nel polimerizzatore: **30 minuti**, temperatura dell'acqua: **55°C (131°F)**, pressione: 2 bar. Si raccomanda un tempo di polimerizzazione più lungo di **40 minuti** per le parti più spesse, quando viene utilizzata la muffola doppia Duoflask.

Lavorazione e lucidatura per iniezione e colata
Dopo il raffreddamento e il controllo dell'occlusione, togliere la protesi accuratamente dal modello e rifinirla con frese a taglio incrociato. Prima della lucidatura a pomice, la protesi deve essere levigata con carta abrasiva a dimensione decrescente della grana.

Quando ci si allena, attenzione! Indossare occhiali protettivi, abiti protettivi a maniche lunghe, maschera antipolvere e guanti protettivi adatti. Utilizzare l'estrazione da tavolo con schermo protettivo. L'ideale sarebbe lavorare con una scatola di levigatura.
Particelle abrasive: Può essere a spigoli vivi, abrasivo! Rimuovere regolarmente le particelle abrasive dalla superficie di lavoro e dal corpo! Utensili di finitura: raccomandiamo frese con un taglio trasversale, per esempio FSQ router o slide sander, poiché le particelle abrasive sono più corte, a grana più fine e meno spigolose, abrasive per la pelle.

Riparazione
PalaXtreme può essere ribasato, riparato e addizionato con tutti i materiali autopolimerizzanti.

Istruzioni per la conservazione
Il materiale non deve essere utilizzato dopo la data di scadenza. Evitare l'esposizione diretta al sole. Si prega di indicare il numero di lotto e il numero dell'articolo in tutta l'eventuale corrispondenza sul prodotto. Secondo il Regolamento UE sui dispositivi medici, gli utenti e/o i pazienti hanno l'obbligo di segnalare al produttore e alle autorità competenti locali i casi gravi legati a un dispositivo medico avvenuti nel relativo paese.

Avvertenze per lo smaltimento
Raccomandazione: Smaltire nel rispetto dei regolamenti ufficiali. Non smaltire il contenuto o confezioni parzialmente vuote insieme ai rifiuti domestici né permettere l'ingresso nel sistema fognario. Catalogo europeo dei rifiuti: 180106 Sostanze chimiche pericolose o contenenti sostanze pericolose.

Per lo smaltimento rispettare le schede dei dati di sicurezza e le normative nazionali. Schede di sicurezza e maggiori informazioni sono disponibili sul nostro sito web, all'indirizzo: www.kulzer.com
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Aggiornamento al: 2021-04

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 01.02.2021 *Version number 1* *Revision: 01.02.2021*

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

· **1.1 Product identifier**

· **Trade name:** **PalaXtreme Liquid**

· **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** Manufacture of dental prothesis

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Kulzer Australia Pty Ltd
Unit 20/53 Lorraine St, Peakhurst, NSW, 2210 Australia Tel.: +61 (02)9153 0311

· **Informing department:** E-Mail: info.australia@kulzer-dental.com
· **1.4** Poison Information: Australia: 13 11 26 and New Zealand: 0800 764 766

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**

Flam. Liq. 2	H225	Highly flammable liquid and vapour.
Skin Irrit. 2	H315	Causes skin irritation.
Eye Irrit. 2	H319	Causes serious eye irritation.
Skin Sens. 1	H317	May cause an allergic skin reaction.
STOT SE 3	H335	May cause respiratory irritation.

· **2.2 Label elements**
· **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:**
methyl methacrylate
· **Hazard statements**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
· **Precautionary statements**

P210	Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P241	Use explosion-proof electrical/ventilating/lighting/equipment.
P303+P361+P353	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321	Specific treatment (see on this label).
P405	Store locked up.

· **2.3 Other hazards** -

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· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**
· **Description:** -

· **Dangerous components:**		
CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-0000	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	75-90%
CAS: 63225-53-6 EINECS: 264-036-0	2-[[(butylamino)carbonyl]oxy]ethyl acrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	5-10%
CAS: 40220-08-4 EINECS: 254-843-6	(2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate Eye Dam. 1, H318	< 1%
CAS: 5137-55-3 EINECS: 225-896-2	methyltrioctylammonium chloride Acute Tox. 3, H301; Skin Corr. 1B, H314; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	< 1%

· **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 symptoms.
· **After skin contact**
Instantly wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
· **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.
· **After swallowing**
Rinse out mouth and then drink plenty of water.
In case of persistent symptoms consult doctor.
· **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **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** void
· **For safety reasons unsuitable extinguishing agents** Water with a full water jet.
· **5.2 Special hazards arising from the substance or mixture**
Can form explosive gas-air mixtures.
Formation of toxic gases is possible during heating or in case of fire.
· **5.3 Advice for firefighters**
· **Protective equipment:**
Wear self-contained breathing apparatus.
Wear full protective suit.

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· **Additional information** -

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 product to reach sewage system or water bodies.
Do not allow to enter the ground/soil.
Prevent material from reaching sewage system, holes and cellars.
· **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
Send for recovery or disposal in suitable containers.
· **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 information on disposal.
-

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**
Keep containers tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Ensure good interior ventilation, especially at floor level. (Fumes are heavier than air).
· **Information about protection against explosions and fires:**
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 containers:** Store in cool location.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Store in cool, dry conditions in well sealed containers.
· **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

· **8.1 Control parameters**

· **Components with critical values that require monitoring at the workplace:**	
80-62-6 methyl methacrylate	
WEL	Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm

· **DNELs**		
80-62-6 methyl methacrylate		
Dermal	worker industr., l.te., syst.	74.3 mg/Kg/d (human)
Inhalative	worker industr., l.te., syst.	210 mg/m3 (human)

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· **PNECs**	
80-62-6 methyl methacrylate	
freshwater	0.94 mg/l (aqua)

· **Additional information:** The lists that were valid during the compilation were used as basis.

· **8.2 Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Keep away from foodstuffs, beverages and food.
Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.
Avoid contact with the eyes and skin.
· **Breathing equipment:**
Not neccessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).
· **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.
Solvent resistant gloves
Check protective gloves prior to each use for their proper condition.
· **Material of gloves**
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 exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
Butyl rubber, BR
Nitrile rubber, NBR
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**
· **Form:** Fluid
· **Colour:** Colourless
· **Smell:** Ester-like
· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**
· **Melting point/Melting range:** Not determined
· **Boiling point/Boiling range:** 100 °C

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· **Flash point:**	10 °C
· **Inflammability (solid, gaseous)**	Not applicable.
· **Ignition temperature:**	430 °C
· **Decomposition temperature:**	Not determined.
· **Self-inflammability:**	Product is not selfigniting.
· **Danger of explosion:**	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
· **Critical values for explosion:**	
· **Lower:**	2.1 Vol %
· **Upper:**	12.5 Vol %
· **Steam pressure at 20 °C:**	47 hPa
· **Density**	Not determined
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **Water:**	Not miscible or difficult to mix
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
· **dynamic:**	Not determined.
· **kinematic:**	Not determined.
· **Solvent content:**	
· **Water:**	0.1 %
· **Solids content:**	0.1 %
· **9.2 Other information**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Conditions to be avoided:** No decomposition if used and stored according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** None
· **Additional information:** -

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 that are relevant for classification:**		
80-62-6 methyl methacrylate		
Oral	LD50	>5000 mg/kg (rat)

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Dermal	LD50	>5000 mg/kg (rab)
Inhalative	LC50/4 h	29.8 mg/l (rat)
63225-53-6 2-[[(butylamino)carbonyl]oxy]ethyl acrylate		
Inhalative	LC50/4 h	2000 mg/l (nd)
5137-55-3 methyltrioctylammonium chloride		
Oral	LD50	223 mg/kg (rat)

· **Primary irritant effect:**
· **Skin corrosion/irritation**
Causes skin irritation.
· **Serious eye damage/irritation**
Slight irritation possible
Causes serious eye irritation.
· **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
· **CMR effects (carcinogenity, 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 respiratory irritation.
· **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:**
Avoid transfer into the environment.
Do not allow product to reach ground water, water bodies or sewage system.
Danger to drinking water if even small quantities leak into soil.
· **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 not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.

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SECTION 14: Transport information

· **14.1 UN-Number**
· **ADR, IMDG, IATA** UN1993

· **14.2 UN proper shipping name**
· **ADR** 1993 FLAMMABLE LIQUID, N.O.S., special provision 640D (METHYL METHACRYLATE MONOMER, STABILIZED)
· **IMDG, IATA** FLAMMABLE LIQUID, N.O.S. (METHYL METHACRYLATE MONOMER, STABILIZED)

· **14.3 Transport hazard class(es)**

· **ADR**

· **Class** 3 (F1) Flammable liquids.
· **Label** 3

· **IMDG, IATA**

· **Class** 3 Flammable liquids.
· **Label** 3

· **14.4 Packing group**
· **ADR, IMDG, IATA** II

· **14.5 Environmental hazards:**
· **Marine pollutant:** No

· **14.6 Special precautions for user** Warning: Flammable liquids.
· **Kemler Number:** 33
· **EMS Number:** F-E,S-E
· **Stowage Category** B

· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

· **Transport/Additional information:** -

· **ADR**
· **Limited quantities (LQ)** 1L
· **Excepted quantities (EQ)** Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml
· **Transport category** 2
· **Tunnel restriction code** D/E

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· **IMDG**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **UN "Model Regulation":**	UN 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL PROVISION 640D (METHYL METHACRYLATE MONOMER, STABILIZED), 3, II

SECTION 15: Regulatory information

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

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** None of the ingredients is listed.
· **Seveso category** P5c FLAMMABLE LIQUIDS
· **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

These data are based on our present knowledge. However, they 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.
H301 Toxic if swallowed.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

· **Abbreviations and acronyms:**
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)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
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

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Acute Tox. 3: Acute toxicity – Category 3
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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

· **1.1 Product identifier**

· **Trade name:** **PalaXtreme Powder**

· **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** Manufacture of dental prothesis

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Kulzer Australia Pty Ltd
Unit 20 / 53 Lorraine St, Peakhurst, NSW, Australia Tel.: +61 (02)9153 0311

· **Informing department:** E-Mail: info.australia@kulzer-dental.com
· **1.4** Poison Information: Australia 13 11 26 and New Zealand 0800 764 766

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
The product is not classified according to the CLP regulation.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **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:** -

· **Dangerous components:** Void

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Supply fresh air; consult doctor in case of symptoms.
· **After skin contact** Instantly wash with water and soap and rinse thoroughly.
· **After eye contact** Rinse opened eye for several minutes under running water.
· **After swallowing**
Rinse out mouth and then drink plenty of water.
In case of persistent symptoms consult doctor.
· **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents**
CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
Use fire fighting measures that suit the environment.
· **5.2 Special hazards arising from the substance or mixture**
No further relevant information available.
· **5.3 Advice for firefighters**
· **Protective equipment:** No special measures required.
· **Additional information** -

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
· **6.2 Environmental precautions:** No special measures required.
· **6.3 Methods and material for containment and cleaning up:** Collect mechanically.
· **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 information on disposal.
-

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling** No special measures required.
· **Information about protection against explosions and fires:** No special measures required.
· **7.2 Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and containers:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.
· **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.
· **8.1 Control parameters**
· **Components with critical values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the compilation were used as basis.
· **8.2 Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
The usual precautionary measures should be adhered to in handling the chemicals.
· **Breathing equipment:** Not necessary if room is well-ventilated.
· **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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Check protective gloves prior to each use for their proper condition.

· ***Material of gloves***
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 exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· ***For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:***
Butyl rubber, BR
Nitrile rubber, NBR

· ***Eye protection:*** *Protective goggles are recommended.*

· ***Body protection:*** *Light weight protective clothing*

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
· **Form:**	Powder
· **Colour:**	White
· **Smell:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
· **Melting point/Melting range:**	Not determined
· **Boiling point/Boiling range:**	Not determined
· **Flash point:**	Not applicable
· **Inflammability (solid, gaseous)**	Not applicable.
· **Ignition temperature:**	
· **Decomposition temperature:**	Not determined.
· **Self-inflammability:**	Product is not selfigniting.
· **Danger of explosion:**	Product is not explosive.
· **Critical values for explosion:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Steam pressure:**	Not determined.
· **Density**	Not determined
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **Water:**	Insoluble
· **Partition coefficient (n-octanol/water):**	Not determined.

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· **Viscosity:**
· **dynamic:** Not determined.
· **kinematic:** Not determined.
· **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Conditions to be avoided:** No decomposition if used and stored according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** None
· **Additional information:** -

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.
· **Primary irritant effect:**
· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation**
Based on available data, the classification criteria are not met.
· **Respiratory or skin sensitisation**
Based on available data, the classification criteria are not met.
· **CMR effects (carcinogenity, 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** Based on available data, the classification criteria are not met.
· **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:** Avoid transfer into the environment.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects** No further relevant information available.

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SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**
Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage.

· **Uncleaned packagings:**
· **Recommendation:** *Packaging can be reused or recycled after cleaning.*

SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR, ADN, IMDG, IATA**	*Void*
· **14.2 UN proper shipping name**	
· **ADR, ADN, IMDG, IATA**	*Void*
· **14.3 Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	*Void*
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	*Void*
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	*No*
· **14.6 Special precautions for user**	*Not applicable.*
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	*Not applicable.*
· **Transport/Additional information:**	*-*
· **UN "Model Regulation":**	*Void*

SECTION 15: Regulatory information

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

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** *None of the ingredients is listed.*
· **15.2 Chemical safety assessment:** *A Chemical Safety Assessment has not been carried out.*

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **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)
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organisation
ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

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Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 01.02.2021 *Version number 1* *Revision: 01.02.2021*

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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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative