

NO - NORSK

BRUKSANVISNING

CHAMP® TETNINGSMASSE FOR GROPER OG SPREKKER

Champ er ment å forsegle groper og sprekker i tannemaljen for å bidra til å forebygge karies.

BRUKSANVISNING:

- Rengjør emaljeflatene grundig med oljefri rengjøringspasta. Fjern alt rusk.
- Skyll godt, og fjern alle rester av pasta fra hull og sprekker i emaljen.
- Isoler behandlingsområdet, og tork lett med oljefri trykkluft.
- Påfør etsende gel med fosforsyre på den rene tannoverflaten i 15 sekunder. Skyll godt.
- Tork lett, og fjern overflødig vann med en bomullspletlet eller ren trykkluft. La tannoverflatene være litt fuktige. Champ fester seg til overflater som er litt fuktige, men det er best å ikke la spytt kontaminere behandlingsområdet.
- Åpne:
 - Hvis du bruker Champ Lollipack® enkeltdose, tar du tak i folien og trekker sakte av baksiden, slik at børsten og tetningsmassen kommer godt til syne.
 - Hvis du bruker Champ-sprøyten , fjerner du hetten og skrur på applikatorspissen.
- Påfør en tynn film med Champ på behandlingsområdet. Påfør materialet fra tyggeforhøyning til tyggeforhøyning, men ikke dekk til ytterkantene.
- Lysherding. Champ herdes i alle typer lys. Herdetiden for en halogenlampe med en utgangsintensitet på minst 300 mW/cm2 er 20 sekunder. Kraftigere lys herder raskere.
- Kontroller og juster okklusjonen om nødvendig.
- Kast all emballasje og en Lollipack enkeltdose så snart prosedyren er fullført.

KONTRAINDIKASJONER:

Champ er kontraindisert hos pasienter som er allergisk overfor noen av bestanddelene i dette legemidlet. Skal ikke brukes på karies.

FI - FINNISH

KÄYTTÖOHJEET

CHAMP® PIT & FISSURE SEALANT -TÄYTEAINE

Champ on tarkoitettu hammaskiilteessä olevien kuoppien ja halkeamien täyttämiseen karieksen ehkäisemiseksi.

KÄYTTÖOHJE:

- Puhdista killepinta huolellisesti öljyttömällä puhdistustahnulla. Poista kaikki irtoaines.
- Poista hammaskiilteen kuoppiin ja halkeamiin jäänyt tahna huuhtelemalla huolellisesti.
- Eristä hoitoalue ja kuivaa kevyesti öljyttömällä paineilmalla.
- Levitä hampaan puhtaalle pinnalle fosforihappoa sisältävää etsausgeeliä 15 sekunniksi. Huuhtele huolellisesti.
- Kuivaa kevyesti ja poista ylimääräinen vesi vanutulla tai puhtaalla paineilmalla. Jätä hampaan pinnat hieman kosteiksi. Champ kiinnittyy pintoihin, jotka ovat hieman kosteat, mutta syljen ei saisi antaa kontaminoida valmisteltua aluetta.
- Avaaminen:
 - Käytettäessä Champ Lollipack® -kerta-annosta tartu kalvopiintaan ja irrota se hitaasti, kunnes levityssivellin ja täyteaine tulevat kokonaan esiin.
 - Käytettäessä Champ-ruiskua irrota korkki ja kiinnitä levityspää.
- Levitä hoitoalueelle ohut kalvo Champ-täyteainetta. Levitä ainetta kuspista kusiin, mutta älä peitä reunaharjuja.
- Koveta valolla. Champ voidaan kovettaa millä tahansa valolla. Kovettamisaika halogeenivalolla on 20 sekuntia tehon ollessa vähintään 300 mW/cm2. Tehokkaammalla valolla kovettuminen tapahtuu nopeammin.
- Tarkista purenta ja korjaa tarvittaessa.
- Hävitä kaikki pakkausmateriaalit ja Lollipack-kerta-annos, kun toimenpide on valmis.

VASTA-AIHEET:

Champ on vasta-aiheinen potilailla, jotka ovat allergisia jollekin sen ainesosalle.

Ei saa käyttää hammaskariekseen.

DK - DANSK

BRUGSANVISNING

CHAMP® FORSEGLINGSMIDDEL TIL GRUBER OG SPRÆKKER

Champ er beregnet til at forsegle gruber og sprækker i tandemalje for at hjælpe med at forebygge caries.

BRUGSANVISNING:

- Rengør emaljefader grundigt med oljefri rengøringspasta. Fjern alt rusk.
- Skyll grundigt, og fjern al resterende pasta fra gruber og sprækker i emaljen.
- Isoler behandlingsområdet, og tør det let med oljefri trykluft.
- Påfør fosforsyre-ætsegel på tandens rene overflade i 15 sekunder. Skyll grundigt.
- Tør forsigtigt overskydende vand af med en vatrondel eller ren trykluft. Lad tandfladerne være let fugtige. Champ binder til overflader, der er let fugtige, men det er bedst ikke at lade spyt forurene klargøringsområdet.
- Sådan åbnes emballagen:
 - Hvis du bruger Champ Lollipack® enkeltdosisemballage, skal du tage fat i folieindpakningen og langsomt trække den tilbage, så du eksponerer penselapplikatoren og tetningsmidlet.
 - Hvis du bruger Champ-sprøtjen, skal du tage hæften af og skrue applikatorspidsen på.
- Påfør en tynd film af Champ på behandlingsområdet. Påfør materialet fra tyggeknude til tyggeknude, men dæk ikke de marginale kanter.
- Hærd ved hjælp af lys. Champ hærdes ved alle typer lys. Hærdningstid for halogenlys med en minimal lysstyrke på 300 mW/cm2 er 20 sekunder. Kraftigere lys vil gøre hærdningen hurtigere.
- Kontroller og juster om nødvendigt okklusjonen.
- Bortskaf al emballage og Lollipack enkeltdosispakken når proceduren er fuldført.

KONTRAINDIKATIONER:

Champ er kontraindiceret hos patienter, der er allergiske over for nogen af dens indholdsstoffer. Må ikke anvendes på tandcaries.

PL – JĘZYK POLSKI

INSTRUKCJA UŻYTKOWANIA

USZCZELNIACZ STOMATOLOGICZNY CHAMP® DO ZABEZPIECZANIA UBYTKÓW I USZKODZEŃ ZĘBÓW

Produkt Champ jest wskazany do stosowania jako uszczelniacz ubytków i uszkodzeń szkliwa w zapobieganiu rozwoju próchnicy zębów.

INSTRUKCJA UŻYTKOWANIA

- Starannie oczyścić powierzchnię szkliwa za pomocą pasty niezawierającej olejów. Usunąć wszelkie zanieczyszczenia.
- Dokładnie przepłukać, usuwając pozostałości pasty z ubytków i uszkodzeń szkliwa zębów.
- Wyodrębnić leczony obszar i delikatnie osuszyć sprężonym powietrzem bez oleju.
- Aby oczyścić powierzchnię zęba, należy nałożyć na nią kwas fosforowy w postaci żelu i pozostawić do wytrawiania przez 15 sekund. Dokładnie przepłukać.
- Delikatnie osuszyć, usuwając nadmiar wilgoci przy pomocy bawełnianego wacika lub czystego, sprężonego powietrza. Pozostawić powierzchnię zęba nieznacznie zwilżoną. rodukt Champ dobrze wiąże się z powierzchniami, które są zwilżone, należy jednak uważać, aby na leczony obszar nie dostała się ślina.
- Otwieranie:
 - W przypadku używania produktu w opakowaniu z pojedynczą dawką Champ Lollipack® chwycić opakowanie i ostrożnie odkleić folię, odstaniając aplikator w postaci szczoteczki i uszczelniacz.
 - W przypadku używania produktu Champ ze strzykawką usunąć nakrętkę i przykręcić końcówkę aplikatora.
- Nałożyć cienką warstwę produktu Champ na leczony obszar. Materiał nakładać na obszar pomiędzy guzkami zębowymi. Nie okładać listewek brzożnych.
- Utwardzić światłem. Produkt Champ ulega utwardzenia pod wpływem każdego rodzaju światła. Czas utwardzania w przypadku światła halogenowego o minimalnym natężeniu 300 mW/cm2 wynosi 20 sekund. Światło o wyższym natężeniu sprawia, że utwardzanie przebiega szybciej.
- Sprawdzić i, w razie potrzeby, dostosować zwarcie zębów.
- Po ukończeniu procedury wyrzucić wszystkie opakowania / opakowanie z pojedynczą dawką Lollipack.

PRZECIWWSKAZANIA:

Produktu Champ nie należy stosować u pacjentów, którzy są uczuleni na którykolwiek z jego składników.

Nie stosować bezpośrednio na zmiany próchnicowe zębów.

SAFETY DATA SHEET (SDS)

In accordance with Hazard Communication Standard (HCS), 29CFR 1910.1200(g), 2012 revision

SECTION I - PRODUCT / COMPANY IDENTIFICATION

REF - See Above

Company: Centrix Inc., 770 River Road, Shelton, CT 06484

Emergency / Information Telephone Numbers: 203-929-5582

Toll Free: 800-235-5862 (USA & Canada)

SECTION II – HAZARDOUS INGREDIENTS/IDENTITY INFORMATION

Classification: Irritant

Adverse human health effects: May be irritating to eyes, respiratory system and skin. May cause sensitization by skin contact.

Hazard Class	Hazard Category	Hazard Statement
Eye Irritation	2	H319
STOT SE	3	H335
Skin irritation	2	H315
Skin sensitization	1	H317

SECTION III - COMPOSITION

Chemical characterization of the preparation: Acrylate ester monomers in a glass-filled, light-cured paste. Hazardous ingredients

CAS Number	Name of the Ingredient	%	Classification per 67/548/EEC	Classification per Regulation (EC) No. 1278/2008 (CLP)
Proprietary R 3637//38 - 43	Uncured acrylate Eye Irritation, 2, H319	55-60%	Irritant; Xi	ester monomers <p>STOT SE 3, H335 Skin irritation, 2, H315</p>
112945-52-5	Silica, amorphous	5%	Irritant; Xi, R 36/37/38	Skin sensitization, 1, H317 Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315

SECTION IV - FIRST AID MEASURES

General Information: May be irritating to eyes, respiratory system and skin. Do not inhale vapors. Avoid contact with eyes and skin. May cause sensitization by skin contact. Show this safety data sheet to medical personnel.

Get medical attention in case of uncertainty.

Inhalation: Move to fresh air. If necessary, administer oxygen and/or artificial respiration. Seek medical attention.
Skin Contact: Take off contaminated clothing. Wash skin thoroughly with soap and running water for 15 minutes.

Eye Contact: Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention.

Ingestion: Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes. Never give anything by mouth to an unconscious person.

Precautions for first responders: Ventilate the area. Wear eye and skin protection. Information for physicians
Symptoms: Irritation or redness in eyes, throat or on skin.

Hazards: May be irritating to eyes, respiratory system and skin. May cause sensitization by skin contact.

Treatment: As above under First Aid.

SECTION V - FIRE-FIGHTING MEASURES

Suitable extinguishing media: Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool.

Extinguishing media to avoid: Do not use direct water stream

Special exposure hazards in a fire: Heat may cause polymerization with rapid release of energy.

Special protective equipment for fire-fighters: A self-contained breathing apparatus should be worn by fire fighting personnel. Cool exposed containers with water spray to prevent polymerization under fire conditions.

SECTION VI - ACCIDENTAL RELEASE MEASURES

Personal precautions: Wear safety glasses, gloves and lab coat.

Environmental precautions: Avoid releasing large amounts of uncured material into the environment. Cured / set-up material is, to our knowledge, inert.

Method for clean up: Contain spilled material. Absorb or wipe up spill with suitable material (paper towels or cloths). Collect for disposal in a covered container. Wash area of spill with alcohol or soap and water.

SECTION VII - HANDLING AND STORAGE

Handling: For use only by dental professionals. Follow good hygiene practices. Do not smoke, eat or drink while using. Avoid direct / strong light sources, extremes of temperature, contamination, and cross contamination of two-part materials. Recap immediately after use.

Storage: Keep containers tightly closed. Store product in original container at cool room temperature (< 25°C) and in a dry, well ventilated area. Avoid direct, strong light, sources of ignition and extremes of temperature. Shelf life for unopened product is two years from date of manufacture, provided that the material has been stored properly.

Specific uses: Dental material

SECTION VIII - EXPOSURE CONTROLS / PERSONAL PROTECTION

Eye protection, hands protection, Engineering controls or other equipment: None required

SECTION IX - PHYSICAL AND CHEMICAL PROPERTIES

Color / Physical state: Natural tooth shade or off-white thin paste.

Odor: Faint, characteristic

Vapor pressure:< 1 mm HgPH

Solubility in water: Nil

Specific gravity: 1.575

SECTION X - STABILITY AND REACTIVITY

Conditions to avoid: Heat (> 38°C), light, contamination.

Materials to avoid: Reducing and oxidizing agents, peroxides, amines.

Hazardous decomposition products: Under fire conditions and with amounts greater than that supplied in this product, hazardous polymerization may occur with heat build up and release of carbon monoxide, carbon dioxide, and oxides of nitrogen.

Further information: Stable material if stored and used as directed. Polymerization will occur when light-cured material is exposed to direct light.

SECTION XI - TOXICOLOGICAL INFORMATION

Acute toxicity: Not toxic. Minimal health hazard under normal conditions of use.

Local effects: Eye irritant, mucous membranes or skin on contact or with prolonged exposure. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.

SECTION XII - ECOLOGICAL INFORMATION

Avoid release of uncured material into the environment. To the best of our knowledge, polymerized material is inert. No other information is available. Follow all government regulations.

SECTION XIII - DISPOSAL CONSIDERATIONS

Dispose in accordance with federal, state and local regulations

SECTION XIV - TRANSPORT INFORMATION

DOT- Not regulated

SECTION XV - REGULATORY INFORMATION

Champ Pit and Fissure Sealant is a Class IIA Medical Device under the Medical Devices Directive 93/42/EEC.

Hazard symbol:	Xi
Hazardous ingredient:	Uncured acrylate ester monomers
Risk phrases R36/37/38:	Irritating to eyes, respiratory system and skin.
R43:	Sensitizing by skin contact
Safety phrases: S24/25:	Avoid contact with skin and eyes.
S3/9/49:	Keep only in the original container in a cool, well ventilated place.

SECTION XVI - OTHER INFORMATION

List of relevant R phrases: R36/37/38: Irritating to eyes, respiratory system and skin.
R43: Sensitizing by skin contact.

Training advice: Champ Pit and Fissure Sealant is for use by dental professionals only.

Restrictions on use: Champ Pit and Fissure Sealant is to be sold to and used by dental professionals only.

Further information: The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Centrix, Inc. bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate. Sources of key data: National Institute for Occupational Safety (NIOSH) US Occupational Safety and Health Administration (OSHA)Eur-Lex European Union Law. Information which has been added, deleted or revised: This Safety Data Sheet has been revised to meet the requirements of Regulation (EC) No. 1907/2006 (REACH).

	
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