Universidade Estadual de Londrina

FERNANDA TRAMONTIN AGUIAR

# **ESTRATÉGIAS DE CIMENTAÇÃO PARA PINOS DE FIBRA DE VIDRO –** REVISÃO DE LITERATURA

Londrina
2025

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Trabalho de Conclusão de Curso apresentado ao Departamento de Odontologia Restauradora da Universidade Estadual de Londrina, como requisito parcial à obtenção do título de Residente em Dentística Restauradora.

Orientador: Prof. Dr. Alcides Gonini Júnior

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## RESUMO

Pinos pré-fabricados de fibra de vidro são indicados na reabilitação de dentes tratados endodonticamente que apresentam extensa perda coronária, a fim de obter um núcleo de preenchimento para retenção do material restaurador/protético. O sucesso do uso de pinos intrarradiculares fixados com cimento resinoso depende da qualidade de hibridização da dentina radicular e compatibilidade dos materiais adesivos. O objetivo deste trabalho é revisar a literatura acerca dos processos que envolvem a cimentação adesiva de pinos de fibra de vidro, avaliando estratégias e materiais utilizados. Foi realizada busca na base de dados PubMed, com os descritores “luting agente”, “glass fiber post”, “resin cements”, “post and core technique”, “dental bonding”, “hybrid layer” e “self-etch adesives”; além de estratégia de busca ((resin cements) AND (incompatibility)) AND (adhesive system). Informações do Safety Data Sheet dos materiais citados também foram utilizadas. A maior falha nos pinos de fibra de vidro é o seu descolamento, uma vez que a dentina radicular é passível de degradação por hidróllse e enzimas como as metaloproteinases de matriz. Foi observada uma tendência de inserção e uso de materiais simplificados que diminuam a quantidade de passos operatórios e sensibilidade técnica dos procedimentos. Ao combinar cimentos resinosos duais com adesivos simplificados há uma incompatibilidade da via química de polimerização dos cimentos com os monômeros acídicos presentes nos adesivos, que agem sobre a reação ácido-base e neutralizam parcialmente as aminas terciárias, além de criar um ambiente hipertônico que favorece a passagem de água em direção a interface adesiva, desafiando a qualidade e durabilidade dessa adesão. É imprescindível que ao optar pela cimentação adesiva de pinos de fibra de vidro observe-se a composição dos cimentos e sistemas adesivos disponíveis, uma vez que a compatibilidade entre estes é material dependente.



**Palavras-Chave:** cimentos resinosos, pino de fibra de vidro, adesivo dentinário

## ABSTRACT

Prefabricated fiberglass posts are indicated for the rehabilitation of endodontically treated teeth with extensive coronal loss, providing core retention of the restorative/prosthetic material. The success of intraradicular posts bonded with resin cement depends on the quality of root dentin hybridization and the compatibility of the adhesive materials. The objective of this study is to review the literature on the processes involved in the adhesive cementation of fiberglass posts, evaluating the strategies and materials used. A search was conducted in the PubMed database using the descriptors "luting agent," "glass fiber post," "resin cements," "post and core technique," "dental bonding,", "hybrid layer" and “self-etch adesives”; in addition to the search strategy ((resin cements) AND (incompatibility)) AND (adhesive system). Information from the Safety Data Sheets of the materials mentioned was also used. The main failure of fiberglass posts is debonding, as root dentin is susceptible to degradation by hydrolysis and enzymes such as matrix metalloproteinases. A tendency of insertion and use of simplified materials that reduce the number of operatory steps and technical sensitivity was observed. Combining dual-cured resin cements with simplified adhesives results in an incompatibility between the cements' chemical cured part and the acidic monomers in the adhesives, which act on the acid-base reaction and partially neutralize tertiary amines. This creates a hypertonic environment that favors the passage of water toward the adhesive interface, compromising the quality and durability of this bond. When choosing adhesive cementation for fiberglass posts, it is essential to consider the composition of the available cements and adhesive systems, as compatibility between them is material-dependent.



**Keywords:** resin cements, glass fiber post, adhesive system

## LISTA DE ABREVIATURAS E SIGLAS

| | |
|---|---|
| EDTA | Ácido etilenodiaminotetracético |
| HEMA | 2-hidroxietil metacrilato |
| MMP | Metaloproteinases de matriz |
| MMP-2 | Metaloproteinase da matriz 2 |
| MMP-9 | Metaloproteinase da matriz 9 |
| TEGDMA | Trietilenoglicol dimetacrilato |
| 10-MDP | 10-metacriloiloxidecil di-hidrogenofosfato |
| 4-META | Anidrido de 4-metacriloiloxietil trimelitato |

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# 1 INTRODUÇÃO

O tratamento endodôntico, em geral, é indicado quando a vitalidade ou o estado normal da polpa dos dentes naturais é alterado irremediavelmente, seja em decorrência da cárie dentária ou como consequência natural após um episódio de trauma. Em algumas situações específicas o tratamento pode se dar também por necessidades protéticas.

Em muitas destas situações, a perda de estrutura dentária está associada às causas que levaram ao comprometimento da vitalidade do tecido pulpar, sendo necessária a avaliação qualitativa e quantitativa do substrato dentário remanescente para que se proceda com o diagnóstico subsequente ao tratamento endodôntico, visando restaurar as funções naturais do elemento dentário comprometido.

Adicionalmente às causas que originaram a perda tecidual primária, ocorre uma perda secundária ou adicional de estrutura dentária, por ocasião do processo biomecânico como parte do tratamento endodôntico.

Gera-se, assim, uma demanda restauradora do dente tratado endodonticamente, que dependendo da indicação ou preferência do operador, pode se dar por via direta ou indireta, sendo indicado ou não um dispositivo intraradicular, com a única função de proporcionar maior retenção à futura restauração coronária (Bergoli *et al.*, 2018).

Acerca do diagnóstico e das indicações como um todo, o processo restaurador com estas possibilidades ainda é controverso e motivo para discussões entre clínicos, e na própria literatura.

Em parte, o que a literatura sugere é que os dispositivos intraradiculares, independentemente de sua natureza, podem ser indicados quando não há substrato coronário suficiente para proporcionar a retenção e sustentação necessária para o material restaurador, o que matematicamente se traduziria na presença de menos da metade da estrutura dentária coronária remanescente (Schwartz & Robbins, 2004). No entanto, em casos onde uma parcela maior de estrutura remanescente estiver presente, deve-se fazer a análise estratégica quanto a composição, localização e distribuição deste substrato, para considerá-lo efetivo, ou aventar a necessidade do dispositivo intraradicular.

Ainda assim, independentemente da opção restauradora, de forma direta ou indireta, associada ou não a um dispositivo intraradicular, deve estar claro para o

operador que o princípio que rege a retenção do material de escolha ao substrato dentário, coronário ou intraradicular, será de origem essencialmente mecânica, mais especificamente micromecânica. Em algumas ocasiões, entretanto, pode haver certo grau de interação química entre os substratos, a depender da natureza dos materiais restauradores, dos sistemas adesivos ou dos agentes de cimentação utilizados, o que pode somar-se ao processo adesivo micromecânico e proporcionar uma união mais estável e duradoura entre eles.

Quando se faz a opção pela restauração coronária sustentada por um dispositivo intraradicular, podem ser indicados os núcleos metálicos fundidos ou os pinos pré-fabricados, e dependendo do material constituinte, estes últimos podem ser de carbono, zircônia ou fibra de vidro.

Como vantagens, os núcleos metálicos fundidos têm se mostrado extremamente versátil, com resistência mecânica adequada e melhor adaptação às paredes intraradiculares com relação aos pinos pré-fabricados. No entanto, apresentam desvantagens, como a necessidade de duas sessões clínicas para sua cimentação, custo mais elevado, podendo desenvolver processo oxidativo a depender do material de escolha e da adaptação, promovem maior desgaste das paredes intraradiculares a fim de determinar um eixo único de inserção e remoção, e uma vez cimentados, podem trazer maior dificuldade para sua eventual remoção.

Já os pinos pré-fabricados, em especial os de fibra de vidro, apresentam como vantagem a possibilidade de serem cimentados em uma única sessão, são mais estéticos em relação aos primeiros, apresentam módulo de elasticidade próximo ao da dentina (Bergoli *et al.*, 2018), e, quando não apresentam fio metálico em seu interior, o que favorece a localização radiográfica, podem apresentar maior facilidade de remoção. Como desvantagem, os pinos pré-fabricados não permitem inclinações distintas de seu longo eixo para a constituição da porção coronária e necessitam de processo de cimentação criterioso para sua fixação à dentina.

Ao considerar as limitações clínicas inerentes a cada dispositivo intraradicular, verifica-se na literatura que, ao longo do tempo, os núcleos metálicos fundidos tendem a gerar mais fraturas catastróficas da estrutura dental remanescente em função de sua rigidez característica (Alirajpurwala *et al.*, 2022), o que ocorre em menor frequência com os pinos de fibra de vidro, devido ao seu módulo de elasticidade característico (Vichi *et al.*, 2001).

No entanto, os pinos de fibra de vidro sofrem mais falhas por decimentação

por conta do processo adesivo a que são submetidos, uma vez que o mecanismo ou técnica de cimentação pode apresentar fragilidades inerentes à natureza dos materiais utilizados, e decorrentes das características do substrato dentinário intraradicular.

Segundo a literatura, o sucesso da técnica de fixação dos pinos de fibra de vidro à dentina intraradicular, depende basicamente da qualidade da hibridização da dentina, e da adequada polimerização dos agentes de cimentação, o que propicia as melhores condições de adesão entre os substratos (Gomes *et al.*, 2011). Porém, sabe-se que a adesão à dentina radicular é crítica, e acontece em condições menos favoráveis ao processo quando comparada à dentina coronária (Ferrari *et al.*, 2000).

Quanto ao processo de fixação dos pinos mediante o uso de cimentos resinosos, são previstas algumas variáveis, a considerar a manipulação e manuseio do próprio cimento, em conjunto ou não com sistemas adesivos (Bergoli *et al.*, 2018), além do sistema de ativação dos cimentos, que podem ser quimicamente ativados, fotoativados ou de dupla ativação. Adicionalmente, ao se optar por cimentos resinosos fotoativáveis, a ativação de polimerização é prejudicada ao longo do terço apical do conduto radicular, uma vez que a intensidade da luz emitida na altura coronária ou cervical, diminui à medida que a distância da fonte de luz aumenta (Pulido, 2016). Por esta somatória de variáveis, a cimentação dos pinos de fibra de vidro à esta área específica, tornou-se um dos principais desafios em termos de protocolos quando da adoção da técnica adesiva (Gomes *et al.*, 2011).

A literatura ainda destaca outros fatores que podem afetar a retenção dos pinos de fibra de vidro, com destaque para a natureza dos materiais utilizados para o tratamento endodôntico, o método de aplicação do cimento resinoso, o preparo do pino previamente a cimentação, especialmente quando utilizado cimentos resinosos convencionais (Skupien *et al.*, 2015), além da adaptação do pino às paredes do conduto radicular. Os sistemas de adesão e cimentação escolhidos também são apontados como fatores que alteram a retenção dos pinos de fibra (Gomes *et al.*, 2011).

Apesar da literatura estar repleta de pesquisas a respeito das técnicas de cimentação dos pinos de fibra de vidro, muitos estudos descreverem diferentes protocolos, associando sistemas adesivos diversos com os pinos, tornando o processo inconclusivo quanto a definição da melhor estratégia clínica para a cimentação destes dispositivos. Portanto, o presente trabalho tem por objetivo

investigar a literatura pertinente ao tema, e apontar as estratégias mais eficientes de cimentação dos pinos pré-fabricados de fibra de vidro, em especial com relação a seleção do agente de cimentação, tendo como foco uma revisão de literatura narrativa.

# 2 OBJETIVOS

## 2.1. Objetivo Geral

Revisar a literatura acerca dos processos que envolvem a cimentação adesiva dos pinos de fibra de vidro.

## 2.2. Objetivos Específicos

1. Destacar fatores associados ao sucesso e insucesso da cimentação adesiva de pinos de fibra de vidro.

2. Subsidiar a tomada de decisão clínica quanto as estratégias e materiais utilizados na cimentação adesiva de pinos de fibra de vidro.

## 3 METODOLOGIA

O presente trabalho foi elaborado no formato de revisão de literatura narrativa, para flexibilizar a seleção da literatura disponível, visando assim, sintetizar e interpretar os dados da forma mais clínica possível.

A fim de manter a característica principal do formato escolhido, a revisão foi conduzida de forma exploratória, sem definição prévia de critérios rígidos de inclusão e exclusão.

Os trabalhos científicos considerados relevantes para a análise do tema foram selecionados a partir do ano de 1990 a 2025, desde que publicados em inglês ou português, e disponíveis, por meio do VNP institucional ou de forma gratuita, na base de dados *online* PubMed.

Foram adotados os descritores: “luting agent”, “glass fiber post”, “resin cements”, “post and core technique”, “dental bonding” e “hybrid layer”; intercalados com o operador booleano *AND* em diferentes combinações.

A seleção dos artigos foi orientada pelo julgamento crítico dos autores, considerando a pertinência do conteúdo para os objetivos do trabalho. Informações adicionais foram trazidas com base nos documentos denominados *Safety Data Sheet*, que são obrigatoriamente disponibilizados pelos fabricantes de materiais dentários comercializados nos Estados Unidos, os quais foram acessados via eletrônica.

No quesito específico sobra a possibilidade de incompatibilidade química entre os sistemas adesivos simplificados e cimentos resinosos, foi adotada a seguinte estratégia de busca nas plataformas já citadas: ((resin cements) *AND* (incompatibility)) *AND* (adhesive system), obtendo-se 15 resultados, dos quais 8 foram disponibilizados por meio de acesso gratuito na sua íntegra. Foram incluídos adicionalmente artigos similares ou citados em artigos selecionados previamente.

## 4 REVISÃO DE LITERATURA

Por princípio, a ligação que se estabelece entre materiais à base de resina composta e a dentina, seja ela coronária ou radicular, resulta de fenômenos físicos. Basicamente o fenômeno se estabelece pela formação da camada híbrida, descrita como uma zona de união micromecânica formada na dentina, resultante da interpenetração entre material resinoso e colágeno dentinário, após o condicionamento do substrato com ácido e aplicação subsequente de sistema adesivo (Nakabayashi *et al.*, 1991). Como função primordial, espera-se que a camada híbrida se converta numa interface estável ao longo do tempo, unindo o material restaurador (ou cimento resinoso) ao dente, proporcionando selamento para evitar microinfiltração e sensibilidade pós-operatória em dentes vitalizados.

Tecnicamente os eventos que oportunizam a formação da camada híbrida tem início com o condicionamento da dentina (primordialmente ácido fosfórico), que além de possibilitar a remoção da lama dentinária depositada sobre a superfície da dentina, desmineraliza este tecido superficialmente e em profundidade, expondo as fibras de colágeno. Uma vez que a substância adesiva do sistema tem características hidrofóbicas, sua infiltração na malha de colágeno exposta é facilitada pela impregnação prévia das fibras colágenas com *primer*, uma vez que este tem características hidrofílicas por natureza (Breschi *et al.*, 2018). Posteriormente, por meio do processo de ativação por luz, por exemplo, é obtida a fotopolimerização do adesivo, estabelecendo assim a camada híbrida.

Ao final, a camada híbrida pode expressar características de ambos os substratos, em decorrência de sua morfologia característica. Isto é resultado da sua composição, e das características individuais dos materiais componentes do sistema adesivo. O HEMA, por exemplo, componente do *primer*, permite a maior interação dos adesivos com o substrato dentinário, pois é uma molécula que conta com dois grupos funcionais, um hidrofílico e outro hidrofóbico, facilitando o processo de formação da camada híbrida. O primeiro grupo funcional proporciona afinidade com a superfície dentinária, enquanto o segundo, proporciona afinidade com o adesivo e a resina composta (Swift *et al.*, 1995).

Este mesmo *primer*, aplicado após o condicionamento ácido da dentina, promove o aumento da energia de superfície da dentina, aumentando o molhamento e a penetrabilidade da substância na rede de colágeno, resultando na maior

interação com o adesivo (Swift *et al.*, 1995; Pashley *et al.*, 2011). Porém, a infiltração do colágeno pelo adesivo, desnaturado nesta configuração pelo componente ácido, não é completa em profundidade, uma vez que a profundidade do condicionamento é maior do que a capacidade de penetração do adesivo resinoso, formando uma área frágil dentro do processo adesivo (Betancourt *et al.*, 2019).

O mecanismo de ação do sistema adesivo, assim configurado inicialmente, passou por evoluções em termos de composição e número de passos clínicos para sua aplicação, produzindo distintos modos de ação. Consideradas estas variáveis, Van Merbeek e colaboradores (2003) classificou os sistemas adesivos em 3 categorias essenciais: *etch-and-rinse*, *self-etch* e adesivos de ionômero de vidro modificados por resina. Os sistemas adesivos *etch-and-rinse* são aqueles em que se faz necessário o condicionamento ácido prévio da dentina, seguido da aplicação de *primer* e depois adesivo – três passos; ou da aplicação de um único produto que combina *primer* e adesivo em apenas um frasco – dois passos. Já os sistemas *self-etch* caracterizam-se pelo autocondiconamento, podendo ser de dois passos – com a aplicação de um *primer* acídico seguido do adesivo, ou de um único passo – os chamados "*all in one*", que contém o *primer* acídico e o adesivo no mesmo frasco; ocorrendo, neste sistema, a infiltração resinosa simultaneamente com o processo de condicionamento.

Por esta classificação, e estabelecidas as diferenças entre os sistemas adesivos, pode se esperar que os comportamentos clínicos sejam distintos. Nos sistemas simplificados, por exemplo, aqueles que são identificados por não possuírem o frasco individual com o adesivo propriamente dito, foi demonstrado por estudos laboratoriais, que sua performance clínica pode ser inferior quando comparados aos sistemas adesivos convencionais de 3 passos (Nagarkar *et al.*, 2019).

Ainda considerando os sistemas adesivos simplificados disponíveis, há aqueles denominados universais, por oferecem a possibilidade de uso na técnica *self-etch* ou *etch-and-rinse*, a depender da escolha do operador e do substrato dentário presente (Perdigão *et al.*, 2021; Cadenaro *et al.*, 2023), uma vez que o condicionamento seletivo adicional do esmalte apresenta uma performance melhorada (Rosa *et al.*, 2015; Ranjitha *et al.*, 2020). Devido à sua forma de apresentação e uso, os adesivos universais promovem naturalmente a redução da sensibilidade técnica operatória (Mirotti *et al.*, 2022), mesmo demonstrando

características morfológicas distintas da camada híbrida quando comparada ao sistema adesivo convencional.

Como fator coadjuvante ao processo microretentivo proporcionado pela formação da camada híbrida, monômeros funcionais de fosfato e/ou carboxilato, como por exemplo o 10-MDP e o 4-META respectivamente, quando adicionados à composição dos sistemas adesivos, foram capazes de desencadear ligações químicas, adicionais em termos retentivos, com o cálcio presente na hidroxiapatita da matriz mineral dentária, mantendo a interação mecânica característica (Perdigão *et al.*, 2013).

Apesar de ser esperada estabilidade do sistema restaurador com a formação da camada híbrida, percebe-se que não é uma estrutura morfológica estável ao longo do tempo em dadas circunstâncias, resultando, às vezes, em instabilidade que pode resultar na decimentação característica dos pinos pré-fabricados cimentados com cimentos à base de resina composta. Dependendo das condições locais prévias ou que se estabelecem após a constituição da camada híbrida, o processo adesivo pode estar sujeito a deficiências (Tjäderhane *et al.*, 2013).

Um exemplo disto é que a camada híbrida é passível de degradação por hidrólise em decorrência da presença de água no meio. Mesmo a presença de monômeros hidrofílicos como o HEMA, que são componentes essenciais para a infiltração do adesivo em um substrato naturalmente úmido como a dentina, podem causar alta sorção de água pelas redes de resina, transformando a camada híbrida em uma membrana permeável (Tay *et al.*, 2002; Pashley *et al.*, 2004; Frassetto *et al.*, 2016). A movimentação de água resultante do processo, transitando na interface dos substratos dentário e restaurador, cria canais de água que degradam a parte hidrofílica do adesivo, facilitando sua lixiviação, expondo a matriz colágena não infiltrada e tornando-a vulnerável a ação de enzimas proteolíticas endógenas, presentes naturalmente no substrato dentinário (Tay *et al.*, 2002; Pashley *et al.*, 2004).

Como exemplos de enzinas proteolíticas, tem-se as metaloproteinases de matriz (MMP) que são zinco e cálcio dependentes, capazes de degradar diversos componentes da matriz extracelular dentinária (Mazzoni *et al.*, 2015). Sintetizadas por odontoblastos, as MMP participam no desenvolvimento do órgão dentário, assim como no processo de formação e desenvolvimento da lesão cariosa, e como sugerido, na degradação da camada híbrida na interface dentina-resina (Perdigão *et*

*al.*, 2013).

Apesar de identificadas cerca de 20 tipos de MMP, pesquisas apontaram que as denominadas de MMP-2 e MMP-9, possuem atividade colagenolítica específica, e quando não inibidas, podem ser capazes de clivar moléculas de colágeno tipo I, presentes na dentina (Perdigão *et al.*, 2013). Durante procedimentos restauradores, infelizmente tais MMP podem ser ativadas se expostas a meios com pH baixos, o que pode ocorrer pelo contato de componentes ácidos presentes no procedimento adesivo, provenientes do condicionamento ácido (Mazzoni *et al.*, 2006), ou pelo uso de adesivos autocondicionantes com monômeros acídicos presentes em sua composição. (Pergidão *et al.*, 2013; Mazzoni *et al.*, 2015).

Mesmo quando as MMP não são totalmente infiltradas por adesivo resinoso após sua ativação, podem degradar lentamente as fibras de colágeno da interface adesiva que não foram totalmente infiltradas e inseridas na camada híbrida, diminuindo a longevidade das restaurações adesivas (Mazzoni *et al.*, 2006; Perdigão *et al.*, 2013). Essa atividade enzimática foi identificada na parte inferior da camada híbrida, correlacionando com as camadas e graus de desmineralização e colágeno não completamente infiltrado (Pashley *et al.*, 2004; Mazzoni *et al.*, 2015), sugerindo que as MMP possuem papel determinante na degradação de camadas híbridas com infiltração resinosa inadequada (Pashley *et al.*, 2011; Mazzoni *et al.*, 2013).

Como alternativa, e estrategicamente limitar a ação das MMP nos contextos descritos, pode-se fazer uso de inibidores de MMP, como a clorexidina e o EDTA por exemplo, a fim de aumentar a longevidade das restaurações adesivas (Mazzoni *et al.*, 2015).

Além das características apontadas até o momento, há outras variáveis possíveis e pertinentes ao processo de cimentação de pinos de fibra de vidro, que podem interferir na formação da camada híbrida. Assim, deve-se considerar, além da natureza dos sistemas adesivos, a natureza dos cimentos resinosos sujeitos também a um sistema de classificação próprio (Pereira *et al.*, 2020).

Estes, podem ser classificados conforme fatores específicos. Com relação ao método de cura, podem ser classificados como quimicamente ativados (autopolimerizados), fisicamente ativados (fotoativados) e de dupla polimerização (duais), sendo este último a combinação das reações de polimerização anteriores, química e física (Dal Paz, 2021). Estes últimos foram desenvolvidos a fim de combinar as características favoráveis das curas química e fotoativada em um único

cimento, proporcionando como vantagens o tempo de trabalho estendido, e capacitando a polimerização em locais onde a incidência de luz ativadora da reação de polimerização é dificultada, visando permitir que se obtenha compósitos com maior grau de conversão monomérica, uma vez que estes, apresentam melhores propriedades mecânicas, ainda que não sejam o único fator a influenciá-las (Braga *et al.*, 2002).

Outro fator que dita a classificação dos cimentos resinosos diz respeito ao pré-tratamento das estruturas dentárias e protéticas, e os divide em: cimentos resinosos convencionais, autocondicionantes e autoadesivos (Dal Paz, 2021). Para o uso de cimentos resinosos convencionais, está indicado e se faz necessário o condicionamento ácido do substrato dentário associado ao emprego de determinado sistema adesivo, enquanto os cimentos resinosos autocondicionantes não exigem condicionamento ácido prévio, preconizando o uso de sistema adesivo autocondicionante anteriormente. Já os cimentos resinosos autoadesivos não apresentam necessidade de utilizar sistemas adesivos previamente ao seu uso (Radovic *et al.*, 2008; Dal Paz, 2021).

Apesar da dupla ativação, os cimentos resinosos duais exibem maior influência da fotoativação, passo indispensável para a dureza final característica do material, uma vez que a via química, normalmente induzida pelo sistema peróxido-amina, não garante sua polimerização completa (Araújo *et al.*, 2024). No entanto, a via química tem ação prolongada após a fotoativação, garantindo a polimerização em locais de difícil alcance de luz, proporcionando resistência adesiva aos cimentos resinosos e segurança na polimerização dentro do canal radicular, por exemplo (Araújo *et al.*, 2024; Khan *et al.*, 2020).

No caso da cimentação adesiva de pinos de fibra de vidro, cimentos resinosos duais são os mais utilizados, a fim de compensar a falta de exposição à luz em locais inacessíveis (Carek *et al.*, 2022; Aguiar *et al.*, 2015).

Além da dificuldade de penetração da luz no interior do canal radicular e a passagem de luz ineficiente pelo pino de fibra de vidro, o ambiente úmido do conduto radicular também dificulta a obtenção de uma interface adesiva ideal, de forma a contribuir para a degradação precoce da camada híbrida que será formada (Monticelli *et al.*, 2008). Mesmo com o uso de pinos de fibra de vidro translúcidos, a transmissão de luz é reduzida no terço apical e a reação química de polimerização não acontece adequadamente (Pulido *et al.*, 2016).

Quando a via física é comprometida, a via química assume maior relevância e, embora ela continue após a exposição do material à luz fotoativadora, geralmente não alcança o mesmo grau de conversão fornecido pela luz isoladamente, devido a influência de fatores como concentração de iniciadores químicos, e inibição por monômeros ácidos que retardam a formação de radicais livres (Nima *et al.*, 2022). O comprometimento da conversão dos monômeros resulta em propriedades mecânicas inferiores e risco elevado de falha adesiva e degradação do cimento ao longo do tempo (Goracci *et al.*, 2005; Radovic *et al.*, 2008), facilitando os meios para a decimentação.

A fim de diminuir a quantidade de passos operatórios e a sensibilidade da técnica, certos fabricantes indicam a combinação de cimentos resinosos duais com sistemas adesivos simplificados para cimentação de peças protéticas ou pinos intrarradiculares. Sanares, em 2001, atribuiu uma relação inversa entre a acidez de adesivos de frasco único e a resistência micromecânica de compósitos de cura química.

Um estudo *in vitro* (Michaud & MacKenzie, 2016) avaliou a adesão resultante da combinação de cimentos resinosos de polimerização dual e diferentes categorias de sistemas adesivos, concluindo que existem incompatibilidades a depender da composição dos materiais, indicando que alguns tipos de cimentos são mais sensíveis aos monômeros acídicos do que outros. Os autores também destacaram que aqueles de polimerização dual não devem ser combinados com sistemas adesivos de outros fabricantes a não ser que a compatibilidade já tenha sido comprovada.

Quando cimentos resinosos duais são associados a sistemas adesivos simplificados, monômeros acídicos residuais e não polimerizados presentes na camada inibida pelo oxigênio do sistema adesivo permanecerão em contato direto com o cimento resinoso, reagindo com a amina terciária aromática presente em cimentos com cura química, neutralizando-a parcialmente e comprometendo a formação da rede polimérica (Sanares *et al.*, 2001; Suh *et al.*, 2003; Tay *et al.*, 2003; Malaquias *et al.*, 2020). Além de agir sobre a reação ácido-base entre os monômeros acídicos e aminas terciárias, levando a uma interação que compete com a reação redox comum entre a amina terciária e o peróxido de benzoíla (Franco *et al.*, 2005), há a criação de um ambiente hipertônico, que por meio de osmose move o fluido presente na dentina hidratada através da camada adesiva permeável (Tay *et*

*al.*, 2002; Malaquias *et al.*, 2020). O fluido que migra para a interface entre resina e adesivo permanece preso pela camada hidrofóbica adjacente como bolhas de água que intensificam o estresse entre estes materiais, comprometendo suas propriedades mecânicas (Malaquias *et al.*, 2020). Assim, a permeabilidade de adesivos de 1 passo à água pode acelerar a taxa de sorção de água e lixiviação dos componentes resinosos, desafiando a durabilidade de adesão produzida por esses adesivos com a dentina (Tay *et al.*, 2002).

A passagem de água através da camada adesiva já curada pode ocorrer quando essa região apresenta substâncias em alta concentração. Isso inclui íons inorgânicos dissolvidos, monômeros hidrofílicos remanescentes que não polimerizaram totalmente e permanecem solúveis em água, além de derivados de colágeno e proteoglicanos presentes na camada de inibição por oxigênio do adesivo polimerizado. Isso cria um ambiente hipertônico que movimenta água por osmose da região de dentina hidratada (baixa concentração) para a interface adesiva (alta concentração) (Tay *et al.*, 2002).

Em contraste, quando adesivos *etch-and-rinse* de 3 passos ou *self-etch* de 2 passos são utilizados, uma camada hidrofílica neutra de resina adesiva é aplicada sobre a dentina previamente condicionada e preparada com o primer, separando e impedindo o contato entre o cimento resinoso ou resina composta com o monômero ácido presente na camada inibida por oxigênio (Michaud & MacKenzie, 2016).

Adesivos de um frasco, assim como os primers autocondicionantes ou sistemas adesivos "*all in one*" apresentam maior acidez devido à sua capacidade de condicionamento (Sanares *et al.*, 2001; Franco *et al.*, 2005); combinando monômeros hidrofílicos e ácidos, monômeros diluentes, fotoiniciadores, outras moléculas ácidas e solventes (Perdigão; Lopes, 1999).

Para garantir uma correta polimerização em áreas onde a irradiação de luz é comprometida, sistemas adesivos fotopolimerizáveis podem ser associados a um ativador autopolimerizável, com a intenção de prevenir a incompatibilidade química com cimentos resinosos de cura química (Nunes *et al.*, 2009). Porém, estudos sugerem que essa incompatibilidade não necessariamente é solucionada pela adição de um iniciador no procedimento adesivo (Hagge & Lindemuth, 2001; Moll *et al.*, 2007), sendo material dependente (Gutierrez *et al.*, 2017).

A mistura de um ativador autopolimerizável com o adesivo pode ter revertido a desativação do iniciador de amina terciária aromática, mantendo monômeros

ácidos na camada inibida por oxigênio dos sistemas adesivos com baixo pH (Sanares *et al.*, 2001), melhorando a compatibilidade química entre adesivos universais específicos e o compósito usado para construção de núcleo de preenchimento, resultando em maior resistência adesiva (Malaquias *et al.*, 2020).

Em 2005, uma revisão sistemática apontou que a maioria dos adesivos e primers autocondicionantes disponíveis eram a base de metacrilato, com pH entre 1.5 e 2.5. Em condições como essa, ésteres como HEMA e TEDGMA são hidrolisados, além de apresentarem alta sorção de água e formação de *water trees* na interface adesiva (Moszner *et al.*, 2005). No mesmo ano, um estudo em vitro que buscava investigar o efeito do pH de diferentes sistemas adesivos na polimerização de uma resina composta quimicamente ativada sugeriu que o pH dos sistemas adesivos exerce impacto direto tanto na reação de polimerização quanto na resistência de união de materiais resinosos de cura química. No estudo, os adesivos simplificados com pH mais baixo mostraram-se incompatíveis com a resina de polimerização química, prejudicando a união. Em contraste, os sistemas adesivos convencionais de três passos não demonstraram efeitos negativos sobre a resistência de união da resina composta (Franco *et al.*, 2005).

Porém, o estudo de Chen e Suh (2013), que avaliou a compatibilidade entre cimentos resinosos duais e adesivos simplificados de um frasco, mostrou que adesivos simplificados com o mesmo pH, mas diferentes níveis de hidrofilicidade (10-30% de HEMA na sua composição), mostraram comportamentos diferentes quanto à adesão à dentina. Onde o uso de adesivos mais hidrofóbicos, portanto com menor porcentagem de HEMA, não resultou em diminuição da resistência de união quando usado com um cimento resinoso de cura dupla, seja ele de cura química ou fotopolimerizável. Corroborando com o estudo experimental de Van Landuyt e colaboradores (2008), que concluiu que uma pequena quantidade de HEMA (10%) melhorou a resistência adesiva de um sistema adesivo autocondicionante de um passo, mas em concentrações mais elevadas, seu efeito benéfico é perdido devido ao aumento da osmose, formando gotículas que levam a redução da conversão de polimerização e das propriedades físico-mecânicas da interface adesiva resultante.

A fim de melhorar a estabilidade hidrolítica, fabricantes introduziram adesivos simplificados menos hidrofílicos e menos permeáveis à água (Moszner *et al.*, 2005), a adição de 10-MDP oferece maior hidrofobicidade aos adesivos universais devido a sua longa cadeia carboxílica, por exemplo (Malaquias *et al.*, 2020).

De acordo com Yoshida (2004), dentre os monômeros funcionais capazes de interagir ionicamente através de um grupo carboxílico/fosfórico/fosfônico com o cálcio da hidroxiapatita, o 10-MDP apresenta a ligação mais eficaz. Isso foi atribuído a formação de sais de MPD-cálcio e a sua auto-organização em uma estrutura nano-laminada (Yoshihara *et al.*, 2011).

Um estudo em vitro (Yoshida *et al.*, 2012) avaliou os efeitos do HEMA na ligação química do 10-MDP com a hidroxiapatita e concluiu que o HEMA reduziu significamente a formação da estrutura nano-laminada, uma vez que diminuiu a taxa de desmineralização da hidroxiapatita, dificultando a formação dos sais de MDP-cálcio, mas não inibindo de forma completa sua interação, sendo necessários maiores estudos para definição do impacto clínico.

A quantidade aumentada de solventes nos sistemas adesivos também pode afetar a adesão de forma negativa, já que haverá mais solvente residual retido na camada híbrida e interface adesiva, impedindo a formação de um polímero com maior número de ligações (Loguercio *et al.*, 2009).

Em contrapartida, um estudo experimental (Malaquias *et al.*, 2020) avaliou a resistência de união por microcisalhamento e nanoinfiltração de três adesivos universais utilizados em restaurações de compósitos com diferentes modos de polimerização, utilizando-os no modo *etch-and-rinse*. A conclusão foi que nenhum adesivo universal foi significamente afetado pelo modo de cura em relação a resistência de união por microcisalhamento, algumas interações foram observadas para a nanoinfiltração, porém classificadas como material específica, sugerindo que pode não haver incompatibilidade entre adesivos universais e resinas compostas (Malaquias *et al.*, 2020).

## 5 DISCUSSÃO

Devido a melhor uniformidade de distribuição do estresse oclusal pela raiz, os pinos de fibra de vidro proporcionam menores e mais favoráveis fraturas radiculares que frequentemente possibilitam reparos (Akkayan & Gülmez, 2002; Angnanon *et al.*, 2023). Porém, a ocorrência de falhas adesivas entre o pino e a dentina radicular representa a maior preocupação em relação a esta técnica (Rodrigues *et al.*, 2017; Angnanon *et al.*, 2023).

Inúmeros fatores podem influenciar, mais ou menos, na longevidade e resistência da interface adesiva entre o cimento resinoso e a dentina intrarradicular, considerando a dificuldade de realizar o tratamento de superfície apropriado, quando necessário, controle de umidade, evaporação dos solventes dos adesivos, inserção do cimento resinoso sem entrada de ar, assim como a correta fotopolimerização dos cimentos de presa física (Ubaldini *et al.*, 2017).

Por muito tempo, assumiu-se que compósitos resinosos tem boa adesão aos adesivos dentinários, e que a fragilidade adesiva ocorria apenas entre o adesivo e a dentina; porém, com o advento dos adesivos simplificados contemporâneos, isso pode não ser mais válido (Tay *et al.*, 2002).

Nas últimas décadas, a fim de simplificar a técnica adesiva e da necessidade de união em substratos de dentina úmida, houve a incorporação de maiores concentrações de monômeros resinosos hidrofílicos em adesivos convencionais, em especial os de 2 passos, e autocondicionantes; para simultaneamente condicionar e aderir ao esmalte e à dentina (Mazzoni *et al.*, 2006). Criando, assim, uma matriz resinosa potencialmente permeável e instável, propensa à sorção de água e hidrólise ao longo do tempo (Ito *et al.*, 2005; Mazzoni *et al.*, 2006).

Na classe dos adesivos simplificados, alguns adesivos autocondicionantes, ao se comportarem como uma membrana permeável após sua polimerização (Tay *et al.*, 2002; Mazzoni *et al.*, 2006), permitem a passagem de fluidos para a camada híbrida, o que pode explicar sua menor força adesiva e durabilidade quando comparados aos adesivos *etch-and-rinse* (Michaud & MacKenzie, 2016). Ainda que os *etch-and-rinse* tenham melhores resultados em adesão, uma revisão de literatura (Peumans *et al.*, 2005) demonstrou que adesivos *etch-and-rinse* de 3 passos apresentam a menor taxa anual de falhas, porém adesivos *etch-and-rinse* de 2 passos apresentaram uma taxa anual de falhas mais alta devido à maior

sensibilidade operatória quanto ao controle da umidade dentinária.

A molécula HEMA é frequentemente adicionado aos sistemas adesivos a fim de melhorar a molhabilidade da dentina e aumentar sua resistência adesiva, prevenindo a separação de fases ao homogeneizar as fases hidrofóbica e hidrofílica; mas oferece desvantagens promovendo a absorção de água e, consequentemente, a hidrólise na interface adesiva, afetando a durabilidade adesiva (Van Landuyt *et al.*, 2008).

No uso de cimentos resinosos que requerem o condicionamento ácido da dentina radicular, o ácido fosfórico provoca a desmineralização da dentina, podendo liberar e ativar as MMPs, enzimas presentes de forma latente na dentina humana mineralizada (Mazzoni *et al.*, 2006). A ativação das MMPs está associada à degradação do colágeno e à formação de camadas híbridas menos estáveis. Quando ativadas pelo uso do ácido fosfórico, as MMPs podem ser inativadas pelo uso subsequente de adesivos, se corretamente infiltradas (Mazzoni *et al.*, 2006). Ainda, quando usados adesivos ácidos de sistemas autocondicionantes, a depender do seu pH, estes podem ativar as MMPS (Perdigão *et al.*, 2013). Porém, como a descalcificação dentinária e a penetração do ácido e co-monômeros ocorre na mesma profundidade, a camada híbrida não possui áreas de nanoinfiltração, resultando em menor sensibilidade pós-operatória (Moszner *et al.*, 2005).

Sobre os passos pré-operatórios, a irrigação com clorexidina não afeta a adesão (Santos *et al.*, 2006) e promove a inibição das MMPs (Mazzoni *et al.*, 2015) tornando-se uma alternativa viável para irrigação após a preparação do conduto para o pino radicular; assim como o EDTA, que ao reagir com íons íons Zn+2 e Ca+2, tem ação quelante que preserva a camada híbrida (Zehnder, 2006) inativando as MMPs (Mazzoni *et al.*, 2015).

Diversos estudos reintegram que quando adesivos simplificados são utilizados com compósitos resinosos com cura química, haverá uma interação entre os monômeros ácidos residuais na camada inibida por oxigênio do adesivo e a reação peróxido-amina, o que interfere de forma negativa no procedimento adesivo (Sanares *et al.*, 2001; Tay *et al.*, 2003; Tay *et al.*, 2002; Rueggeberg & Margeson, 1990; Franco, 2005).

Já os cimentos resinosos autoadesivos contêm monômeros ácidos e hidrofílicos capazes de desmineralizar e se infiltrar de forma simultânea, tanto em esmalte como em dentina, sem a necessidade de tratamentos prévios na superfície

dentária (Ferracane *et al.*, 2011). Esses cimentos contêm moléculas de ácido fosfórico metacrilato funcional ou ésteres carboxílicos que interagem quimicamente com a hidroxiapatita (Ubaldini *et al.,* 2017). Uma revisão sistemática da literatura de estudos in vitro demonstrou que os pinos de fibra cimentados com cimento resinoso autoadesivo apresentaram maior retenção à dentina (Sarkis-Onofre *et al.*, 2014).

Uma revisão sistemática e metanálise (Angnanon *et al.*, 2023) concluiu que cimentos autoadesivos tendem a apresentar adesão mais efetiva entre o pino de fibra de vidro e a dentina radicular, enquanto os cimentos duais convencionais, que requerem condicionamento ácido, demonstraram a menor força adesiva a curto e longo prazo.

## 6 CONCLUSÃO

Os cimentos resinosos são a melhor opção para cimentação de pinos de fibra de vidro, sendo necessária a cura química. Quando se opta pelo uso de cimentos resinosos duais, deve-se analisar a compatibilidade com o sistema adesivo selecionado, principalmente quando simplificados, garantindo que ocorrerá uma adequada polimerização, promovendo melhores propriedades mecânicas. Os cimentos resinosos autoadesivos têm menor sensibilidade técnica e operatória, garantindo propriedades mecânicas similares aos convencionais, sendo também uma boa opção de escolha para cimentação de pinos pré-fabricados de fibra de vidro.

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# APÊNDICES

Tabela 1 – Composição dos cimentos resinosos de acordo com os fabricantes.

| CIMENTO | COMPOSIÇÃO | CLASSIFICAÇÃO |
|---|---|---|
| Allcem CORE<br>(FGM) | Dimetacrilato de trietilenoglicol (TEGDMA) (5-20%)<br>Dimetacrilato de bisfenol A etoxilado (EBPADMA) (5-20%)<br>Bisfenol A-glicidil metacrilato (BIS-GMA) (5-20%)<br>1,12-dodecanediyl bismethacrylate (1-10%)<br>Vidro (30-70%)<br>Peróxido de Benzoíla (0,1-3,0%)<br>N,N-Bis(2-Hydroxyethyl)-p-Toluidine (0,1-3%) | Cimento resinoso convencional dual |
| Allcem<br>(FGM) | Dimetacrilato de trietilenoglicol (TEGDMA) (5-20%)<br>Dimetacrilato de bisfenol A etoxilado (EBPADMA) (5-20%)<br>Bisfenol A-glicidil metacrilato (BIS-GMA) (5-20%)<br>1,12-dodecanediyl bismethacrylate (1-10%)<br>Vidro (30-70%)<br>Peróxido de Benzoíla (0,1-3,0%)<br>N,N-Bis(2-Hydroxyethyl)-p-Toluidine (0,1-3%) | Cimento resinoso convencional dual |
| RelyX U200<br>(Solventum) | **Pasta Catalisadora:**<br>Dimetacrilato alternativo (10-30%)<br>1,12-dodecane dimethycrylate (<5%)<br>Vidro modificado (50-70%)<br>Sílica tratada com silano (<%5)<br>Derivado de ácido barbitúrico (<5%)<br>Derivado de ácido propenóico (<2%)<br>**Pasta Base:**<br>Dimetacrilato de trietilenoglicol (TEGDMA) (10-20%)<br>Vidro modificado (45-55%)<br>Produtos químicos de óxido de vidro (<3%)<br>Sílica tratada com silano (1-10%)<br>tert-butyl peroxy-3,5,5-trimethylhexanoate (<0.5%)<br>Derivado de ácido propenóico (20-30%)<br>Ácido acético (<0.1%) | Cimento resinoso autoadesivo dual |
| RelyX ARC<br>(Solventum) | **Pasta A:**<br>2-hidroxietilmetacrilato (HEMA) (10-30%)<br>Dimetacrilato de glicerila (GDMA) (1-5%)<br>Dimetacrilato de etilenoglicol (EGDMA) (<0.5%) Cerâmica tratada com silano (30-40%)Butil-hidroxitolueno (BHT) (<0.5%)<br>Copolímeros dos ácidos acrílico e itacônico (10-30%)<br>Água (5-15%)<br>Difosfato de potássio (1-5%)<br>Persulfato de potássio (1-5%)<br>**Pasta B:**<br>2-hidroxietilmetacrilato (HEMA) (<10%)<br>Vidro tratado com silano (70-80%)<br>Sílica tratada com silano (<2%)<br>4-(dimethylamino)-benzeneethanol (<1%)<br>Água (10-20%) | Cimento resinoso convencional dual |
| Calibra Universal<br>(Dentsply) | **Pasta Base:**<br>Dimetacrilato de uretano (UDMA) (<10%)<br>*Outros (resinas de trimetacrilato e dimetacrilato polimerizáveis)*<br>**Pasta Catalisadora:**<br>Dimetacrilato de uretano (UDMA) (<10%)<br>UDMA modificado por Bis-GMA (<10%)<br>Resinas de dimetacrilato polimerizáveis (<15%)<br>Fosfato de penta-acrilato de dipentaeritritol (<10%) | Cimento Resinoso Autoadesivo |
| Multilink Automix<br>(Ivoclar) | **Pasta Base:**<br>Trifluoreto de itérbio (≥20-≤30%)<br>Bisfenol A-glicidil metacrilato (BIS-GMA) (≥10-≤13%)<br>2-hidroxietilmetacrilato (HEMA) (3-7%)<br>Metacrilato de 2-dimetilaminoetila (≥0.1-≤1%)<br>**Pasta Catalisadora:**<br>Bisfenol A etoxilado dimetacrilato (BIS-EMA) (10-<25%)<br>Trifluoreto de itérbio (10-<25%)<br>Dimetacrilato de uretano (UDMA) (3-<10%) | Cimento Resinoso Convencional Dual |

| | | |
|---|---|---|
| | 2-hidroxietilmetacrilato (HEMA) (3-<10%)<br>Peróxido de benzoíla (1-<2.5%) | |
| Variolink II<br>(Ivoclar) | **Pasta Base:**<br>Bisfenol A-glicidil metacrilato (BIS-GMA) (10-25%)<br>Dimetacrilato de uretano (UDMA) (2.5-10%)<br>TEGDMA (2.5-10%)<br>**Pasta Catalisadora:**<br>Bisfenol A-glicidil metacrilato (BIS-GMA) (50-100%)<br>Dimetacrilato de uretano (UDMA) (2.5-10%)<br>Dimetacrilato de trietilenoglicol (TEGDMA) (2.5-10%)<br>Peróxido de benzoíla (≤2.5%) | Cimento Resinoso<br>Convencional Dual |
| NX3 Nexus<br>(Kerr) | Dimetacrilato de trietilenoglicol (TEGDMA) (5-10%)<br>2-hidroxietilmetacrilato (HEMA) (5-10%)<br>3-trimetoxissililpropil metacrilato (0.1-1%)<br>Dimetacrilato de bisfenol A etoxilado (5-10%)<br>d1,1,3,3-tetrametilbutil hidroperóxido (0.1-1%) | Cimento Resinoso<br>Autocondicionante Dual |
| Maxcem Elite<br>(Kerr) | Vidro borossilicato de bário e alumínio (30-60%)<br>Fluoreto de itérbio (10-30%)<br>1,6-hexanodiol dimetacrilato (5-10%)<br>Dimetacrilato de glicerila (GDMA) (5-10%)<br>Dimetacrilato de uretano (UDMA) (1-5%)<br>3-trimetoxissililpropil metacrilato (1-5%)<br>Sílica pirogênica (1-5%) | Cimento Resinoso<br>Autocondicionante Dual |

Tabela 2 – Uso associado dos cimentos resinosos e sistemas adesivos conforme instruções dos fabricantes.

| Cimento | Classificação | Adesivo | pH (Adesivo) | Composição (Adesivo) |
|---|---|---|---|---|
| Allcem CORE (FGM) | Cimento resinoso convencional dual | Ambar (FGM) | ≥ 5 | Dimetacrilato de uretano (UDMA) (10-30%)<br>Dimetacreilato de glicerina (10-30%)<br>2-hidroxietilmetacrilato (HEMA) (10-30%)<br>10-metacriloiloxidecil di-hidrogenofosfato (10-MDP) (1-10%)<br>Etil 4-(dimetilamino)benzoato (EDMAB) (0,1-2%)<br>Etanol (10-25%)<br>Monômero adesivo (0,1-1%)<br>Antioxidante (<1%)<br>Canforquinona (<1%) |
| Allcem (FGM) | Cimento resinoso convencional dual | Ambar (FGM) ou **Ambar Universal APS (FGM)** | 3.01 | Bismetacrilato de 2-hidroxi-1,3-propanodiilo (20-35%)<br>Dimetacrilato de uretano (UDMA) (20-35%)<br>2-hidroxietilmetacrilato (HEMA) (20-35%)<br>10-metacriloiloxidecil di-hidrogenofosfato (10-MDP) (5-15%)<br>Etanol (3-10%)<br>Monômero adesivo PMDM (0.5-2%)<br>Etil 4-(dimetilamino)benzoato (EDMAB) (0.5-2%)<br>hexafluorofosfato de difeniliodônio (0.5-2%)<br>Fotoiniciador 819 (0.1-2%)<br>Hidroxitolueno butilado (<1%) |
| RelyX U200 (Solventum) | Cimento resinoso autoadesivo dual | Não se aplica | Não se aplica | Não se aplica |
| RelyX ARC (Solventum) | Cimento resinoso convencional dual | Adapter Single Bond 2 (3M) | Não disponível | Dimetacrilato de Éter Diglicidílico de Bisfenol A (BIS-GMA) (10-20%)<br>2-hidroxietil metacrilato (HEMA) (5-15%)<br>Dimetacrilato de Diuretano (UDMA) (<5%)<br>Etil 4-(dimetilamino)benzoato (EDMAB) (<0.3%)<br>Glicerol 1,3-Dimetacrilato (5-10%)<br>Hexafluorofosfato de difeniliodônio (<1%)<br>Copolímero de Ácido Acrílico e Ácido Itacônico (<5%)<br>Álcool Etílico (25-35%)<br>Sílica tratada com silano (10-20%)<br>Água (<10%) |
| Calibra (Dentsply) | Cimento resinoso autoadesivo dual | Não se aplica | Não se aplica | Não se aplica |
| Multilink Automix (Ivoclar) | Cimento resinoso convencional dual | Multillink Primer (A e B) | Não disponível | A: N,N-Bis(2-hidroxietil)-p-toluidina (2.5-10%)<br>B: ácido acrílico fosfônico (25-50%)<br>2-hidroxietil metacrilato (HEMA) (25-50%) |
| Multilink N (Ivoclar) | Cimento resinoso convencional dual | ExciTE F DSC | 2.5 | Etanol (10-<25%)<br>2-hidroxietil metacrilato (HEMA) (10-<25%)<br>Ácido acrílico fosfônico (10-<25%)<br>Óxido de trimetilbenzoíla difenilfosfina (<2.5%)<br>Etil 4-dimetilaminobenzoato (<2.5%)<br>Fluoreto de potássio (<2.5%)<br>Hidroxitolueno butilado (<2.5%) |
| NX3 Nexus (Kerr) | Cimento resinoso autocondicionante dual | Compatibilidade com qualquer sistema adesivo | Não se aplica | Não se aplica |
| Maxcem Elite (Kerr) | Cimento resinoso autocondicionante dual | Optibond Universal | Não disponível | Acetona (30-60%)<br>2-hidroxietil metacrilato (HEMA) (7-13%)<br>Etanol (5-10%)<br>Dimetacrilato de glicerila (GDMA) (1-5%) |

# ANEXOS

## 1. Safety Data Sheet – Allcem CORE (FGM)

FICHA DE DATOS DE SEGURIDAD
DE PRODUCTOS QUÍMICOS

ALLCEM CORE

ID: SDS-0021
Revisión: 00
Fecha: 21/01/2021
Página **1** de **6**

### 1. *IDENTIFICACIÓN DEL PRODUCTO*

| | |
|---|---|
| **Nombre del producto:** | Allcem Core |
| **Principales usos recomendados:** | Fijación definitiva de: coronas, puentes, inlays, onlays, postes intrarradiulares e núcleo de llenado (muñion) adhesivo en dientes vitales o no vitales. |
| **Nombre de la Empresa:** | Dentscare LTDA |
| **Domicilio:** | Avenida Edgar Nelson Meister, 474 – Joinville, SC - Brasil |
| **Teléfono:** | +55 47 3441-6100 (Brasil) |
| **Teléfono de emergencia:** | 0800 644 6100 (Brasil) |
| **Correo electrónico:** | cr@fgm.ind.br (Brasil) |

### 2. *IDENTIFICACIÓN DE PELIGROS*

| | |
|---|---|
| **Clasificación de Peligro del producto:** | Corrosión/Irritación a la piel – Categoría 2<br>Lesiones Oculares – Categoría 2A<br>Sensibilización Respiratoria o de la Piel: Categoría 1<br>Peligros para el médio ambiente acuático agudo – Categoría 2<br>Peligros para el médio ambiente acuático crónico – Categoría 3 |
| **Sistema de Clasificación Adoptado:** | Globally Harmonized System of Classification – Eighth revised edition |
| *ELEMENTOS DE ROTULADO*<br>**Pictogramas:** |  |
| **Palabra de Advertencia:** | Atención |
| **Frases de Peligro:** | H315 – Provoca Irritación a la Piel<br>H319 - Provoca irritación ocular grave<br>H317 – Puede provocar reacciones alérgicas en la piel<br>H402 – Tóxico para los organismos acuáticos<br>H412 - Nocivo para los organismos acuáticos, con efectos duraderos |
| *FRASES DE PRECAUCIÓN*<br>**Prevención:** | P261 - Evite inhalar los polvos/humos/gases/nieblas/vapores/aerosoles.<br>P264 – Lave cuidadosamente después del manoseo<br>P272 - La ropa de trabajo contaminada no puede salir del local de trabajo.<br>P280 - Use guantes de protección/ropa de protección/protección ocular/protección facial.<br>P273 – Evitar su liberación al medio ambiente |

**Respuesta a la emergencia:** EN CASO DE CONTACTO CON LA PIEL: Lave con agua y jabón en abundancia. En caso de irritación o erupción cutánea: Consulte un médico. Quite toda la ropa contaminada y lávela antes de usarla nuevamente.

EN CASO DE CONTACTO CON LOS OJOS: Enjuague cuidadosamente con agua durante varios minutos. En el caso de uso de lentillas de contacto, quíteselas, si fuera fácil. Siga enjuagando. Caso la irritación ocular persista: consulte a un médico.

**Almacenamiento:** No aplicable

**Disposición:** P501 - Deseche el contenido/recipiente conforme legislación vigente.

## 3. *COMPOSICIÓN E INFORMACIONES SOBRE LOS INGREDIENTES*

**Nombre Químico Común o técnico:** **Cemento Resinoso Dual**

INGREDIENTES O IMPUREZAS QUE CONTRIBUYEN PARA EL PELIGRO:

| Componente | Número de CAS | Rango de Concentración (%) |
|---|---|---|
| Triethylene Glycol Dimethacrylate | 109-16-0 | 5 - 20 |
| Ethoxylated Bisphenol A Dimethacrylate | 41637-38-1 | 5 - 20 |
| 1,12-dodecanediyl bismethacrylate | 72829-09-5 | 1 - 10 |
| Bisphenol A-glycidyl methacrylate | 1565-94-2 | 5 - 20 |
| Inert Glass | Property | 30 - 70 |
| Antioxadant | Property | < 1,0 |
| Benzoyl Peroxide | 9436-0 | 0,1 – 3,0 |
| N,N-Bis(2-Hydroxyethyl)-p-Toluidine | 3077-12-1 | 0,1 – 3,0 |
| Stabilizer | Property | < 2,0 |

*Informaciones confidenciales retenidas.

## 4. *MEDIDAS DE PRIMEROS AUXILIOS:*

**Inhalación:** Saque a la persona para local ventilado y manténgala en descanso en una posición que no le dificulte la respiración. Si los síntomas persisten, busque a un médico.

**Contacto con la piel:** Quítese inmediatamente toda la ropa contaminada. Enjuáguese la piel con agua y jabón en abundancia. Lave la ropa contaminada antes de usarla nuevamente. En caso de irritación o erupción cutánea: Consulte a un médico.

**Contacto con los ojos:** Enjuague los ojos cuidadosamente con agua durante varios minutos. En el caso de uso de lentillas de contacto, quíteselas, si fuera fácil. Siga enjuagando. Si los síntomas persisten, busque a un médico.

**Ingestión:** Enjuague bien la boca, NO induzca vómito. Si los síntomas persisten, busque a un médico.

| | |
|---|---|
| Síntomas y efectos más importantes, agudos o tardíos: | No disponible |
| Protección del prestador de auxilios y/o notas para el médico: | No disponible |

## 5. *MEDIDAS DE COMBATE A INCENDIO:*

| | |
|---|---|
| Medios de Extinción: | Agua neblina espuma, $CO_2$ y polvo seco |
| Peligros específicos de la mixtura: | El producto puede descomponerse en CO y CO2 durante la combustión. |
| Medidas de protección del equipo de combate a incendio: | Utilizar aparatos de protección y de respiración autónoma en casos de incendio. Vestir equipo de protección individual. Colocar a las personas en seguridad. Evitar contacto con los ojos y piel. |

## 6. *MEDIDAS DE CONTROL PARA DERRAME O PÉRDIDA:*

*6.1. Precauciones personales, equipos de protección y procedimientos de emergencia:*

| | |
|---|---|
| 6.1.1. Para personal que no forma parte de los servicios de emergencia: | Evitar contacto con el producto. Evacuar al personal para áreas seguras, alejar a las personas y mantenerlas en una dirección contraria al viento respecto al derrame. |
| 6.1.2 . Para personal del servicio de emergencia: | Utilice equipos de protección individuales. |
| 6.2. Precauciones al medio ambiente: | No enviar el producto para red de aguas residuales. |
| 6.3. Métodos y materiales para la contención y limpieza: | Recoger los residuos sin levantar polvos. Mantener en recipientes cerrados adecuados, para eliminación. |

## 7. *MANIPULACIÓNUSEIO Y ALMACENAMIENTO:*

| | |
|---|---|
| Precauciones para el almacenamiento Seguro: | Medidas Técnicas: manipule de acuerdo con la buena higiene industrial y práctica de seguridad. Requiere buena ventilación en el local de trabajo. Cuando opere con el producto, no se alimente, no beba y no fume. Minimice el contacto del producto con la piel y ojos.<br><br>En la operación de carga y descarga se debe evitar caídas de los embalajes, bajadas de rampas sin protección y rodamiento en terreno accidentado para evitar hoyos o cualquier daño al embalaje. |
| Condiciones de almacenamiento seguro, incluyendo cualquier incompatibilidad: | Recipientes conteniendo el producto deben ser almacenados sobre estrados o ripas de madera, al abrigo de luz y calor. El descargado de los embalajes más pesados debe ser hecho a través de máquina elevadora.<br><br>Los recipientes deben estar bien cerrados y almacenados en local ventilado e identificado, evitar: exposición del producto bajo sol, lluvia y temperaturas elevadas. Almacenar entre 5 ° C y 25 ° C, protegido de la luz directa. |

## 8. CONTROL DE EXPOSICIÓN Y PROTECCIÓN INDIVIDUAL:

*8.1Parámetros de Control específicos*

| | |
|---|---|
| 8.1.1 Límite de Exposición ocupacional: | No disponible |
| 8.1.2 Medida de control de ingeniería: | No disponible |

*8.2 Medidas de Protección personal*

| | |
|---|---|
| 8.2.1 Protección de los ojos/rostro: | Utilizar gafas de protección |
| 8.2.3 Protección de la piel y cuerpo: | Utilizar guantes |
| 8.2.4 Protección respiratoria: | Utilizar máscara |

## 9. PROPIEDADES FÍSICAS Y QUÍMICAS:

| | |
|---|---|
| Estado Físico: | Sólido (pastoso) |
| Color: | Incoloro y ligeramente amarillo (color de los dientes) |
| Olor: | Característico |
| pH: | No disponible |
| Punto de fusión: | No disponible |
| Punto de ebullición: | No disponible |
| Punto de fulgor: | No disponible |
| Tasa de evaporación: | No disponible |
| Límite inferior/superior de inflamabilidad o explosividad: | No disponible |
| Presión de vapor: | No disponible |
| Densidad relativa: | No disponible |
| Solubilidad: | No disponible |
| Temperatura de descomposición: | No disponible |
| Viscosidad: | No disponible |

## 10. ESTABILIDAD Y REACTIVIDAD:

| | |
|---|---|
| Reactividad: | No disponible |
| Estabilidad Química: | Producto estable en condiciones recomendadas de almacenamiento. |
| Posibilidad de reacciones peligrosas: | No disponible |
| Condiciones a ser evitadas: | La exposición directa al sol y/o altas temperaturas puede causar degradación del producto, evite dejar el embalaje abierto después del uso. |
| Materiales Incompatibles: | Materiales altamente oxidantes. |
| Productos peligrosos de descomposición: | El producto puede descomponerse en CO y CO2 durante la combustión. |

## 11. INFORMACIONES TOXICOLÓGICAS:

| | |
|---|---|
| Toxicidad aguda: | Producto no clasificado con toxicidad aguda por vía oral. |
| Corrosión/irritación a la piel: | El producto contiene monómeros metacrílicos que pueden provocar reacciones alérgicas o irritantes leves en pacientes sensibles a estas sustancias. |

| | |
|---|---|
| Lesiones oculares graves/irritación ocular: | Puede causar daño. |
| Sensibilización respiratoria o a la piel: | Puede causar sensibilización a la piel. |
| Mutagenicidad en células germinativas: | No disponible |
| Carcinogenicidad: | No disponible |
| Toxicidad a la reproducción: | No disponible |
| Toxicidad para órganos-blanco específicos – Exposición única: | No disponible |
| Toxicidad para órganos-blanco específicos – Exposición repetida | No disponible |
| Peligro por aspiración: | No disponible |

## *12. INFORMACIONES ECOLÓGICAS:*

| | |
|---|---|
| Ecotoxicidad: | No disponible |
| Persistencia y degradabilidad: | No disponible |
| Potencial bioacumulación: | No disponible |
| Movilidad en el suelo: | No disponible |
| Otros efectos adversos: | No disponible |

## *13. CONSIDERACIONES SOBRE DESTINACIÓN FINAL:*

| | |
|---|---|
| Producto y Restos del producto: | Agotar siempre las posibilidades de reaprovechamiento del producto en el proceso de fabricación. En el caso de no ser posible, incineración o aterramiento de acuerdo con reglamentación federal o regional. |
| Embalaje usado: | Desechar el embalaje conforme las normas locales y nacionales. |

## *14. INFORMACIONES SOBRE TRANSPORTE:*

Reglamentaciones **Brasil:**

Este producto no es clasificado como peligroso para el transporte, de acuerdo con la Resolución 204 del Ministerio de Transporte, 20/05/1997

Reglamentaciones Internacionales:

Este producto no es considerado como producto peligroso para el transporte terrestre, marítimo y aéreo de acuerdo con los respectivos reglamentos (ADR, IMDG, IATA – DGR).

## *15. INFORMACIONES SOBRE REGLAMENTACIONES:*

No disponible

*16. OTRAS INFORMACIONES:*

SOLAMENTE USO PROFESIONAL.

Las informaciones utilizadas en el desarrollo de esa SDS son provenientes de las SDS de las materias primas utilizadas en el desarrollo del producto.

Dentscare Ltda no se responsabiliza por la precisión de esas informaciones o por la necesidad de informaciones adicionales.

## 2. Safety Data Sheet – Allcem (FGM)



### 1. *IDENTIFICAÇÃO DO PRODUTO*

| | |
|---|---|
| **Nome do produto:** | Allcem |
| **Principais usos recomendados:** | Cimentação de coroas e pontes de porcelana puras ou fundidas a partes de metais preciosos, semi-preciosos ou não preciosos (metalo-cerâmicas).<br>Cimentação de inlays, onlays ou coroas protéticas confeccionadas em porcelana ou resina laboratorial.<br>Cimentação de pinos radicalares de fibra de vidro, fibra de carbono, cerâmicos ou metálicos.<br>Cimentação de pontes de Maryland (próteses adesivas). |
| **Nome da Empresa:** | Dentscare LTDA |
| **Endereço:** | Avenida Edgar Nelson Meister, 474 – Joinville, SC - Brasil |
| **Telefone:** | +55 47 3441-6100 (Brasil) |
| **Telefone de emergência:** | 0800 644 6100 (Brasil) |
| **E-mail:** | cr@fgm.ind.br (Brasil) |

### 2. *IDENTIFICAÇÃO DE PERIGOS*

| | |
|---|---|
| **Classificação de Perigo do Produto:** | Corrosão/Irritação a pele – Categoria 2<br>Lesões Oculares – Categoria 2A.<br>Sensibilização Respiratória ou da Pele: Categoria 1<br>Perigos ao ambiente Aquático Agudo – Categoria 2 |
| **Sistema de Classificação Adotado:** | ABNT NBR 14725 |

*ELEMENTOS DE ROTULAGEM*

**Pictogramas:**



| | |
|---|---|
| **Palavra de Advertência:** | Atenção |
| **Frases de Perigo:** | H315 – Provoca Irritação a Pele<br>H319 - Provoca irritação ocular grave<br>H317 – Pode provocar reações alérgicas na pele<br>H401 – Tóxico para os organismos aquáticos |

*FRASES DE PRECAUÇÃO*

| | |
|---|---|
| **Prevenção:** | P261 - Evite inalar as poeiras/fumos/gases/névoas/vapores/aerossóis.<br>P264 – Lave cuidadosamente após manuseio<br>P272 - A roupa de trabalho contaminada não pode sair do local de trabalho.<br>P280 - Use luvas de proteção/roupa de proteção/proteção ocular/proteção facial.<br>P273 – Evite a liberação para o meio ambiente |

**Resposta à emergência:** EM CASO DE CONTATO COM A PELE: Lave com água e sabão em abundância. Em caso de irritação ou erupção cutânea: Consulte um médico. Retire toda a roupa contaminada e lave-a antes de usá-la novamente.

EM CASO DE CONTATO COM OS OLHOS: Enxágue cuidadosamente com água durante vários minutos. No caso de uso de lentes de contato, remova-as, se for fácil. Continue enxaguando. Caso a irritação ocular persista: consulte um médico.

**Armazenamento:** Não Aplicável

**Disposição:** P501 - Descarte o conteúdo/recipiente conforme legislação vigente.

## 3. *COMPOSIÇÃO E INFORMAÇÕES SOBRE OS INGREDIENTES*

**Nome Químico Comum ou técnico:** Cimento Resinoso Dual

INGREDIENTES OU IMPUREZAS QUE CONTRIBUEM PARA O PERIGO:

| Componente | Número de CAS | Faixa de Concentração (%) |
|---|---|---|
| Triethylene Glycol Dimethacrylate | 109-16-0 | 5 - 20 |
| Ethoxylated Bisphenol A Dimethacrylate | 41637-38-1 | 5 - 20 |
| 1,12-dodecanediyl bismethacrylate | 72829-09-5 | 1 - 10 |
| Bisphenol A-glycidyl methacrylate | 1565-94-2 | 5 - 20 |
| Vidro Inerte | Propriedade | 30 - 70 |
| Antioxidante | Propriedade | < 1,0 |
| Peróxido de Benzoila | 9436-0 | 0,1 – 3,0 |
| N,N-Bis(2-Hydroxyethyl)-p-Toluidine | 3077-12-1 | 0,1 – 3,0 |
| Estabilizante | Propriedade | < 2,0 |

*Informações confidenciais retidas.

## 4. *MEDIDAS DE PRIMEIROS SOCORROS:*

**Inalação:** Remova a pessoa para local ventilado e a mantenha em repouso numa posição que não dificulte a respiração. Se os sintomas persistirem, procure um médico.

**Contato com a pele:** Retire imediatamente toda a roupa contaminada. Enxágue a pele com água e sabão em abundância. Lave a roupa contaminada antes de usá-la novamente. Em caso de irritação ou erupção cutânea: Consulte um médico.

**Contato com os olhos:** Enxágue os olhos cuidadosamente com água durante vários minutos. No caso de uso de lentes de contato, remova-as, se for fácil. Continue enxaguando. Se os sintomas persistirem, procure um médico.

**Ingestão:** Enxague bem a boca, NÃO induza vômito. Se os sintomas persistirem, procure um médico.

| | |
|---|---|
| Sintomas e efeitos mais importantes, agudos ou tardios: | Não disponível |
| Proteção do prestador de socorros e/ou notas para o médico: | Não disponível |

## 5. *MEDIDAS DE COMBATE A INCÊNDIO:*

| | |
|---|---|
| Meios de Extinção: | Água neblina espuma, $CO_2$ e pó seco |
| Perigos específicos da mistura: | O produto pode se decompor em CO e CO2 durante a combustão. |
| Medidas de proteção da equipe de combate a incêndio: | Utilizar aparelhos de proteção e de respiração autônoma em casos de incêndio. Vestir equipamento de proteção individual. Colocar as pessoas em segurança. Evitar contato com os olhos e pele. |

## 6. *MEDIDAS DE CONTROLE PARA DERRAMAMENTO OU VAZAMENTO:*

### 6.1. *Precauções pessoais, equipamentos de proteção e procedimentos de emergência:*

| | |
|---|---|
| 6.1.1. Para pessoal que não faz parte dos serviços de emergência: | Evitar contato com o produto. Evacuar o pessoal para áreas seguras, afastar as pessoas e mantê-las numa direção contrária ao vento em relação ao derramamento. |
| 6.1.2 . Para pessoal do serviço de emergência: | Utilize equipamentos de proteção individuais. |
| 6.2. Precauções ao meio ambiente: | Não enviar o produto para rede de águas residuais. |
| 6.3. Métodos e materiais para a contenção e limpeza: | Apanhar os resíduos sem levantar poeiras. Manter em recipientes fechados adequados, para eliminação. |

## 7. *MANUSEIO E ARMAZENAMENTO:*

| | |
|---|---|
| Precauções para o armazenamento Seguro: | Medidas Técnicas: manuseie de acordo com a boa higiene industrial e prática de segurança. Requer boa ventilação no local de trabalho. Quando operar com o produto, não se alimente, não beba e não fume. Minimize o contato do produto com a pele e olhos.<br><br>Na operação de carga e descarga deve-se evitar quedas das embalagens, descidas de rampas sem proteção e rolamento em terreno acidentado para evitar furos ou qualquer dano a embalagem. |
| Condições de armazenagem seguro, incluindo qualquer incompatibilidade: | Recipientes contendo o produto devem ser armazenados sobre estrados ou ripas de madeira, ao abrigo de luz e calor. O descarregamento das embalagens mais pesadas deve ser feito por meio de empilhadeiras.<br><br>Os recipientes devem estar bem fechados e armazenados em local ventilado e identificado, evitar: exposição do produto sob sol, chuva e temperaturas elevadas. Armazenar entre 5°C e 25°C, protegido da incidência direta de luz. |

## 8. CONTROLE DE EXPOSIÇÃO E PROTEÇÃO INDIVIDUAL:

| | |
|---|---|
| Parâmetros de Controle específicos | |
| Limite de Exposição ocupacional: | Não disponível |
| Medida de controle de engenharia: | Não disponível |
| *Medidas de Proteção pessoal* | |
| Proteção dos olhos/face: | Utilizar óculos de proteção |
| Proteção da pele e corpo: | Utilizar luvas |
| Proteção respiratória: | Utilizar máscara |

## 9. PROPRIEDADES FÍSICAS E QUÍMICAS:

| | |
|---|---|
| Estado Físico: | Sólido (pastoso) |
| Cor: | Incolor e Levemente amarelado (cor de dente) |
| Odor: | Característico |
| pH: | Não disponível |
| Ponto de fusão: | Não disponível |
| Ponto de ebulição: | Não disponível |
| Ponto de fulgor: | Não disponível |
| Taxa de evaporação: | Não disponível |
| Limite inferior/superior de inflamabilidade ou explosividade: | Não disponível |
| Pressão de vapor: | Não disponível |
| Densidade relativa: | Não disponível |
| Solubilidade: | Não disponível |
| Temperatura de decomposição: | Não disponível |
| Viscosidade: | Não disponível |

## 10. ESTABILIDADE E REATIVIDADE:

| | |
|---|---|
| Reatividade: | Não disponível |
| Estabilidade Química: | Produto estável em condições recomendadas de armazenamento. |
| Possibilidade de reações perigosas: | Não disponível |
| Condições a serem evitadas: | A exposição direta ao sol e/ou altas temperaturas pode causar degradação do produto, evite deixar a embalagem aberta após o uso. |
| Materiais Incompatíveis: | Materiais altamente oxidantes. |
| Produtos perigosos de decomposição: | O produto pode se decompor em CO e CO2 durante a combustão. |

## 11. INFORMAÇÕES TOXICOLÓGICAS:

| | |
|---|---|
| Toxicidade aguda: | Produto não classificado com toxidade aguda por via oral. |
| Corrosão/irritação a pele: | O produto contém monômeros metacrílicos que podem provocar reações alérgicas ou irritativas leves em pacientes sensíveis a essas substâncias. |
| Lesões oculares graves/irritação ocular: | Pode causar dano. |
| Sensibilização respiratória ou à pele: | Pode causar sensibilização a pele. |
| Mutagenicidade em células germinativas: | Não disponível |
| Carcinogenicidade: | Não disponível |
| Toxicidade à reprodução: | Não disponível |

| | |
|---|---|
| **Toxicidade para órgãos-alvo específicos – Exposição única:** | Não disponível |
| **Toxicidade para órgãos-alvo específicos – Exposição repetida** | Não disponível |
| **Perigo por aspiração:** | Não disponível |

## *12. INFORMAÇÕES ECOLÓGICAS:*

| | |
|---|---|
| **Ecotoxicidade:** | Não disponível |
| **Persistência e degradabilidade:** | Não disponível |
| **Potencial bioacumulativo:** | Não disponível |
| **Mobilidade no solo:** | Não disponível |
| **Outros efeitos adversos:** | Não disponível |

## *13. CONSIDERAÇÕES SOBRE DESTINAÇÃO FINAL:*

| | |
|---|---|
| **Produto e Restos do produto:** | Esgotar sempre as possibilidades de reaproveitamento do produto no processo de fabricação. No caso de não ser possível, incineração ou aterramento de acordo com regulamentação federal ou regional. |
| **Embalagem usada:** | Descartar a embalagem conforme as normas locais e nacionais. |

## *14. INFORMAÇÕES SOBRE TRANSPORTE:*

**Regulamentações Nacionais:**

Este produto não é classificado como perigoso para o transporte, de acordo com a Portaria 204 do ministério dos Transportes, 20/05/1997

**Regulamentações Internacionais:**

Este produto não é considerado como produto perigoso para o transporte terrestre, marítimo e aéreo de acordo com os respectivos regulamentos (ADR, IMDG, IATA – DGR).

## *15. INFORMAÇÕES SOBRE REGULAMENTAÇÕES:*

Não disponível

## *16. OUTRAS INFORMAÇÕES:*

APENAS USO PROFISSIONAL.

As informações utilizadas no desenvolvimento dessa SDS são provenientes das SDS das matérias-primas utilizadas no desenvolvimento do produto.

A Dentscare Ltda não se responsabiliza pela precisão dessas informações ou pela necessidade de informações adicionais.

# 3. Safety Data Sheet – RelyX U200 (3M)



## Safety Data Sheet

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| | | | |
|---|---|---|---|
| **Document Group:** | 29-3018-8 | **Version Number:** | 1.01 |
| **Issue Date:** | 04/15/15 | **Supercedes Date:** | 02/25/11 |

**Product identifier**
3M™ ESPE™ RelyX™ U200 Sample Kit A2

**Recommended use**
Dental Product, Dental cement.
**Restrictions on use**
For use only by dental professionals.

**Supplier's details**

| | |
|---|---|
| **MANUFACTURER:** | 3M |
| **DIVISION:** | 3M ESPE Dental Products |
| **ADDRESS:** | 3M Center, St. Paul, MN 55144-1000, USA |
| **Telephone:** | 1-888-3M HELPS (1-888-364-3577) |

**Emergency telephone number**
1-800-364-3577 or (651) 737-6501 (24 hours)

**This product is a kit or a multipart product which consists of multiple, independently packaged components. A Safety Data Sheet (SDS), Article Information Sheet (AIS), or Article Information Letter (AIL) for each of these components is included. Please do not separate the component documents from this cover page. The document numbers for components of this product are:**

29-2267-2, 29-2269-8

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# Safety Data Sheet

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| | | | |
|---|---|---|---|
| **Document Group:** | 29-2269-8 | **Version Number:** | 8.00 |
| **Issue Date:** | 03/18/22 | **Supercedes Date:** | 10/23/18 |

## SECTION 1: Identification

**1.1. Product identifier**
3M™ RelyX™ U200 Catalyst

**1.2. Recommended use and restrictions on use**

**Recommended use**
Dental Product, Cement
**Restrictions on use**

For use only by dental professionals.

**1.3. Supplier's details**

| | |
|---|---|
| **MANUFACTURER:** | 3M |
| **DIVISION:** | Oral Care Solutions Division |
| **ADDRESS:** | 3M Center, St. Paul, MN 55144-1000, USA |
| **Telephone:** | 1-888-3M HELPS (1-888-364-3577) |

**1.4. Emergency telephone number**
1-800-364-3577 or (651) 737-6501 (24 hours)

## SECTION 2: Hazard identification

This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.

**2.1. Hazard classification**
Serious Eye Damage/Irritation: Category 2A.
Skin Sensitizer: Category 1.

**2.2. Label elements**
**Signal word**
Warning

**Symbols**
Exclamation mark |

**Pictograms**



**Hazard Statements**
Causes serious eye irritation.
May cause an allergic skin reaction.

**Precautionary Statements**

**Prevention:**
Wear protective gloves and eye/face protection.
Wash thoroughly after handling.
Contaminated work clothing must not be allowed out of the workplace.

**Response:**
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse.

**Disposal:**
Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

## SECTION 3: Composition/information on ingredients

| Ingredient | C.A.S. No. | % by Wt |
|---|---|---|
| Glass powder (65997-17-3), surface modified with 2-propenoic acid, 2 methyl-.3-(trimethoxysilyl)propyl ester (2530-85-0), bulk material | None | 50 - 70 Trade Secret * |
| SUBSTITUTED DIMETHACRYLATE | 27689-12-9 | 10 - 30 Trade Secret * |
| 1,12-DODECANE DIMETHYCRYLATE | 72829-09-5 | < 5 Trade Secret * |
| 2,4,6(1H,3H,5H)-Pyrimidinetrione, 5-phenyl-1-(phenylmethyl)-, calcium salt (2:1) | 945012-02-2 | < 5 Trade Secret * |
| SILANE TREATED SILICA | 68909-20-6 | < 5 Trade Secret * |
| 2-Propenoic acid, 2-methyl-, [(3-methoxypropyl)imino]di-2,1-ethanediyl ester | 93962-71-1 | < 2 Trade Secret * |
| CALCIUM HYDROXIDE | 1305-62-0 | < 2 Trade Secret * |
| SODIUM P-TOLUENESULFINATE | 824-79-3 | < 2 Trade Secret * |
| NUC - Titanium Dioxide | 13463-67-7 | < 0.5 Trade Secret * |

*The specific chemical identity and/or exact percentage (concentration) of this composition has been withheld as a trade secret.

## SECTION 4: First aid measures

**4.1. Description of first aid measures**

**Inhalation:**
Remove person to fresh air. If you feel unwell, get medical attention.

**Skin Contact:**
Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

**Eye Contact:**
Immediately flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. Get medical attention.

**If Swallowed:**
Rinse mouth. If you feel unwell, get medical attention.

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

Allergic skin reaction (redness, swelling, blistering, and itching).

**4.3. Indication of any immediate medical attention and special treatment required**
Not applicable

## SECTION 5: Fire-fighting measures

**5.1. Suitable extinguishing media**
In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

**5.2. Special hazards arising from the substance or mixture**
None inherent in this product.

**Hazardous Decomposition or By-Products**

| Substance | Condition |
|---|---|
| Carbon monoxide | During Combustion |
| Carbon dioxide | During Combustion |
| Irritant Vapors or Gases | During Combustion |

**5.3. Special protective actions for fire-fighters**
No special protective actions for fire-fighters are anticipated.

## SECTION 6: Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**
Evacuate area. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapors, in accordance with good industrial hygiene practice. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

**6.2. Environmental precautions**
Avoid release to the environment.

**6.3. Methods and material for containment and cleaning up**
Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. Seal the container. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

## SECTION 7: Handling and storage

**7.1. Precautions for safe handling**
Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wash contaminated clothing before reuse. Do not get in eyes. A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. If product

contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove.

**7.2. Conditions for safe storage including any incompatibilities**
Store away from heat.

## SECTION 8: Exposure controls/personal protection

**8.1. Control parameters**

**Occupational exposure limits**
If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

| Ingredient | C.A.S. No. | Agency | Limit type | Additional Comments |
|---|---|---|---|---|
| CALCIUM HYDROXIDE | 1305-62-0 | ACGIH | TWA:5 mg/m3 | |
| CALCIUM HYDROXIDE | 1305-62-0 | OSHA | TWA(as total dust):15 mg/m3;TWA(respirable fraction):5 mg/m3 | |
| NUC - Titanium Dioxide | 13463-67-7 | ACGIH | TWA:10 mg/m3 | A4: Not class. as human carcin |
| NUC - Titanium Dioxide | 13463-67-7 | OSHA | TWA(as total dust):15 mg/m3 | |
| SILICA, AMORPHOUS | 68909-20-6 | OSHA | TWA:20 millions of particles/cu. ft.;TWA concentration:0.8 mg/m3 | |

ACGIH : American Conference of Governmental Industrial Hygienists
AIHA : American Industrial Hygiene Association
CMRG : Chemical Manufacturer's Recommended Guidelines
OSHA : United States Department of Labor - Occupational Safety and Health Administration
TWA: Time-Weighted-Average
STEL: Short Term Exposure Limit
CEIL: Ceiling

**8.2. Exposure controls**

**8.2.1. Engineering controls**
Use in a well-ventilated area.

**8.2.2. Personal protective equipment (PPE)**

**Eye/face protection**

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:
Safety Glasses with side shields

**Skin/hand protection**
See Section 7.1 for additional information on skin protection.

**Respiratory protection**
None required.

## SECTION 9: Physical and chemical properties

**9.1. Information on basic physical and chemical properties**

**Appearance**

| | |
|---|---|
| **Physical state** | Solid |
| **Color** | Tooth |

| | |
|---|---|
| **Specific Physical Form:** | Paste |
| **Odor** | Slight Acrylic |
| **Odor threshold** | *No Data Available* |
| **pH** | *Not Applicable* |
| **Melting point** | *No Data Available* |
| **Boiling Point** | *No Data Available* |
| **Flash Point** | No flash point |
| **Evaporation rate** | *No Data Available* |
| **Flammability (solid, gas)** | Not Classified |
| **Flammable Limits(LEL)** | *No Data Available* |
| **Flammable Limits(UEL)** | *No Data Available* |
| **Vapor Pressure** | *No Data Available* |
| **Vapor Density** | *No Data Available* |
| **Density** | 2 - 2.2 g/cm3 |
| **Specific Gravity** | 2 - 2.2 [*Ref Std:*WATER=1] |
| **Solubility in Water** | Nil |
| **Solubility- non-water** | *No Data Available* |
| **Partition coefficient: n-octanol/ water** | *No Data Available* |
| **Autoignition temperature** | *No Data Available* |
| **Decomposition temperature** | *No Data Available* |
| **Viscosity** | *No Data Available* |
| **Molecular weight** | *No Data Available* |
| **Percent volatile** | *No Data Available* |

## SECTION 10: Stability and reactivity

**10.1. Reactivity**
This material may be reactive with certain agents under certain conditions - see the remaining headings in this section.

**10.2. Chemical stability**
Stable.

**10.3. Possibility of hazardous reactions**
Hazardous polymerization will not occur.

**10.4. Conditions to avoid**
Heat

**10.5. Incompatible materials**
None known.

**10.6. Hazardous decomposition products**

| Substance | Condition |
|---|---|
| None known. | |

Refer to section 5.2 for hazardous decomposition products during combustion.

## SECTION 11: Toxicological information

**The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be**

**reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.**

**This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.**
**The information below represents toxicological information associated with the individual components of the uncured product. Once properly mixed and/or cured, the product is safe for its intended use.**

**11.1. Information on Toxicological effects**

**Signs and Symptoms of Exposure**

**Based on test data and/or information on the components, this material may produce the following health effects:**

**Inhalation:**
This product may have a characteristic odor; however, no adverse health effects are anticipated.

**Skin Contact:**
Mild Skin Irritation: Signs/symptoms may include localized redness, swelling, itching, and dryness. Allergic Skin Reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

**Eye Contact:**
Severe Eye Irritation: Signs/symptoms may include significant redness, swelling, pain, tearing, cloudy appearance of the cornea, and impaired vision.

**Ingestion:**
May be harmful if swallowed.
Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

**Additional Health Effects:**

**Carcinogenicity:**
Exposures needed to cause the following health effect(s) are not expected during normal, intended use:
Contains a chemical or chemicals which can cause cancer.

| Ingredient | CAS No. | Class Description | Regulation |
|---|---|---|---|
| Titanium dioxide | 13463-67-7 | Grp. 2B: Possible human carc. | International Agency for Research on Cancer |

**Toxicological Data**
If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

**Acute Toxicity**

| Name | Route | Species | Value |
|---|---|---|---|
| Overall product | Dermal | | No data available; calculated ATE >5,000 mg/kg |
| Overall product | Ingestion | | No data available; calculated ATE >2,000 - ≤5,000 mg/kg |
| Glass powder (65997-17-3), surface modified with 2-propenoic acid, 2 methyl-.3-(trimethoxysilyl)propyl ester (2530-85-0), bulk material | Dermal | | LD50 estimated to be > 5,000 mg/kg |
| Glass powder (65997-17-3), surface modified with 2-propenoic acid, 2 methyl-.3-(trimethoxysilyl)propyl ester (2530-85-0), bulk material | Ingestion | | LD50 estimated to be 2,000 - 5,000 mg/kg |
| SUBSTITUTED DIMETHACRYLATE | Dermal | Professional | LD50 estimated to be > 5,000 mg/kg |

| | | | |
|---|---|---|---|
| | | judgement | |
| SUBSTITUTED DIMETHACRYLATE | Ingestion | Rat | LD50 > 17,600 mg/kg |
| 1,12-DODECANE DIMETHYCRYLATE | Dermal | Professional judgement | LD50 estimated to be 2,000 - 5,000 mg/kg |
| 1,12-DODECANE DIMETHYCRYLATE | Ingestion | similar compounds | LD50 2000-5000 mg/kg |
| 2,4,6(1H,3H,5H)-Pyrimidinetrione, 5-phenyl-1-(phenylmethyl)-, calcium salt (2:1) | Dermal | Professional judgement | LD50 estimated to be 2,000 - 5,000 mg/kg |
| 2,4,6(1H,3H,5H)-Pyrimidinetrione, 5-phenyl-1-(phenylmethyl)-, calcium salt (2:1) | Ingestion | Rat | LD50 > 2,000 mg/kg |
| SILANE TREATED SILICA | Dermal | Rabbit | LD50 > 5,000 mg/kg |
| SILANE TREATED SILICA | Inhalation-Dust/Mist (4 hours) | Rat | LC50 > 0.691 mg/l |
| SILANE TREATED SILICA | Ingestion | Rat | LD50 > 5,110 mg/kg |
| SODIUM P-TOLUENESULFINATE | Dermal | Professional judgement | LD50 estimated to be 2,000 - 5,000 mg/kg |
| CALCIUM HYDROXIDE | Dermal | Rabbit | LD50 > 2,500 mg/kg |
| CALCIUM HYDROXIDE | Ingestion | Rat | LD50 7,340 mg/kg |
| SODIUM P-TOLUENESULFINATE | Ingestion | Rat | LD50 3,200 mg/kg |
| 2-Propenoic acid, 2-methyl-, [(3-methoxypropyl)imino]di-2,1-ethanediyl ester | Dermal | Professional judgement | LD50 estimated to be > 5,000 mg/kg |
| 2-Propenoic acid, 2-methyl-, [(3-methoxypropyl)imino]di-2,1-ethanediyl ester | Ingestion | Rat | LD50 > 1,600 mg/kg |
| NUC - Titanium Dioxide | Dermal | Rabbit | LD50 > 10,000 mg/kg |
| NUC - Titanium Dioxide | Inhalation-Dust/Mist (4 hours) | Rat | LC50 > 6.82 mg/l |
| NUC - Titanium Dioxide | Ingestion | Rat | LD50 > 10,000 mg/kg |

ATE = acute toxicity estimate

**Skin Corrosion/Irritation**

| Name | Species | Value |
|---|---|---|
| Glass powder (65997-17-3), surface modified with 2-propenoic acid, 2 methyl-.3-(trimethoxysilyl)propyl ester (2530-85-0), bulk material | Professional judgement | No significant irritation |
| SUBSTITUTED DIMETHACRYLATE | Rabbit | No significant irritation |
| SILANE TREATED SILICA | Rabbit | No significant irritation |
| CALCIUM HYDROXIDE | Human | Corrosive |
| NUC - Titanium Dioxide | Rabbit | No significant irritation |

**Serious Eye Damage/Irritation**

| Name | Species | Value |
|---|---|---|
| Glass powder (65997-17-3), surface modified with 2-propenoic acid, 2 methyl-.3-(trimethoxysilyl)propyl ester (2530-85-0), bulk material | Professional judgement | No significant irritation |
| SUBSTITUTED DIMETHACRYLATE | Rabbit | Mild irritant |
| SILANE TREATED SILICA | Rabbit | No significant irritation |
| CALCIUM HYDROXIDE | Rabbit | Corrosive |
| NUC - Titanium Dioxide | Rabbit | No significant irritation |

**Skin Sensitization**

| Name | Species | Value |
|---|---|---|
| SUBSTITUTED DIMETHACRYLATE | Guinea pig | Not classified |
| 2,4,6(1H,3H,5H)-Pyrimidinetrione, 5-phenyl-1-(phenylmethyl)-, calcium salt (2:1) | Mouse | Not classified |
| SILANE TREATED SILICA | Human and animal | Not classified |
| 2-Propenoic acid, 2-methyl-, [(3-methoxypropyl)imino]di-2,1-ethanediyl ester | Professional judgement | Sensitizing |
| NUC - Titanium Dioxide | Human and animal | Not classified |

**Respiratory Sensitization**

For the component/components, either no data are currently available or the data are not sufficient for classification.

**Germ Cell Mutagenicity**

| Name | Route | Value |
|---|---|---|
| SUBSTITUTED DIMETHACRYLATE | In Vitro | Not mutagenic |
| 2,4,6(1H,3H,5H)-Pyrimidinetrione, 5-phenyl-1-(phenylmethyl)-, calcium salt (2:1) | In Vitro | Not mutagenic |
| SILANE TREATED SILICA | In Vitro | Not mutagenic |
| NUC - Titanium Dioxide | In Vitro | Not mutagenic |
| NUC - Titanium Dioxide | In vivo | Not mutagenic |

**Carcinogenicity**

| Name | Route | Species | Value |
|---|---|---|---|
| SILANE TREATED SILICA | Not Specified | Mouse | Some positive data exist, but the data are not sufficient for classification |
| NUC - Titanium Dioxide | Ingestion | Multiple animal species | Not carcinogenic |
| NUC - Titanium Dioxide | Inhalation | Rat | Carcinogenic |

**Reproductive Toxicity**

**Reproductive and/or Developmental Effects**

| Name | Route | Value | Species | Test Result | Exposure Duration |
|---|---|---|---|---|---|
| SILANE TREATED SILICA | Ingestion | Not classified for female reproduction | Rat | NOAEL 509 mg/kg/day | 1 generation |
| SILANE TREATED SILICA | Ingestion | Not classified for male reproduction | Rat | NOAEL 497 mg/kg/day | 1 generation |
| SILANE TREATED SILICA | Ingestion | Not classified for development | Rat | NOAEL 1,350 mg/kg/day | during organogenesis |

**Target Organ(s)**

**Specific Target Organ Toxicity - single exposure**

| Name | Route | Target Organ(s) | Value | Species | Test Result | Exposure Duration |
|---|---|---|---|---|---|---|
| 2,4,6(1H,3H,5H)-Pyrimidinetrione, 5-phenyl-1-(phenylmethyl)-, calcium salt (2:1) | Ingestion | nervous system | Not classified | Rat | NOAEL 2,000 mg/kg | |
| CALCIUM HYDROXIDE | Inhalation | respiratory irritation | May cause respiratory irritation | Human | LOAEL 2.5 mg/m3 | 20 minutes |

**Specific Target Organ Toxicity - repeated exposure**

| Name | Route | Target Organ(s) | Value | Species | Test Result | Exposure Duration |
|---|---|---|---|---|---|---|
| SILANE TREATED SILICA | Inhalation | respiratory system \| silicosis | Not classified | Human | NOAEL Not available | occupational exposure |
| NUC - Titanium Dioxide | Inhalation | respiratory system | Some positive data exist, but the data are not sufficient for classification | Rat | LOAEL 0.01 mg/l | 2 years |
| NUC - Titanium Dioxide | Inhalation | pulmonary fibrosis | Not classified | Human | NOAEL Not available | occupational exposure |

**Aspiration Hazard**
For the component/components, either no data are currently available or the data are not sufficient for classification.

**Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.**

## SECTION 12: Ecological information

**Ecotoxicological information**

Please contact the address or phone number listed on the first page of the SDS for additional ecotoxicological information on this material and/or its components.

**Chemical fate information**

Please contact the address or phone number listed on the first page of the SDS for additional chemical fate information on this material and/or its components.

## SECTION 13: Disposal considerations

**13.1. Disposal methods**
Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Dispose of waste product in a permitted industrial waste facility. As a disposal alternative, incinerate in a permitted waste incineration facility.

**EPA Hazardous Waste Number (RCRA):** Not regulated

## SECTION 14: Transport Information

For Transport Information, please visit http://3M.com/Transportinfo or call 1-800-364-3577 or 651-737-6501.

## SECTION 15: Regulatory information

### 15.1. US Federal Regulations
Contact 3M for more information.

**EPCRA 311/312 Hazard Classifications:**

| Physical Hazards |
|---|
| Not applicable |

| Health Hazards |
|---|
| Respiratory or Skin Sensitization |

| |
|---|
| Serious eye damage or eye irritation |

### 15.2. State Regulations
Contact 3M for more information.

### 15.3. Chemical Inventories
This material contains one or more substances not listed on the TSCA Inventory. Commercial use of this material is regulated by the FDA.

Contact 3M for more information.

### 15.4. International Regulations
Contact 3M for more information.

**This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.**

## SECTION 16: Other information

**NFPA Hazard Classification**
**Health:** 2 **Flammability:** 1 **Instability:** 0 **Special Hazards:** None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

| | | | |
|---|---|---|---|
| **Document Group:** | 29-2269-8 | **Version Number:** | 8.00 |
| **Issue Date:** | 03/18/22 | **Supercedes Date:** | 10/23/18 |

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# Safety Data Sheet

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|---|---|---|---|
| **Document Group:** | 29-2267-2 | **Version Number:** | 4.01 |
| **Issue Date:** | 01/18/18 | **Supercedes Date:** | 02/25/16 |

## SECTION 1: Identification

**1.1. Product identifier**
3M™ ESPE™ RelyX™ U200 Base Paste

**1.2. Recommended use and restrictions on use**

**Recommended use**
Dental Product, Cement
**Restrictions on use**
For use only by dental professionals.

**1.3. Supplier's details**

| | |
|---|---|
| **MANUFACTURER:** | 3M |
| **DIVISION:** | Oral Care Solutions Division |
| **ADDRESS:** | 3M Center, St. Paul, MN 55144-1000, USA |
| **Telephone:** | 1-888-3M HELPS (1-888-364-3577) |

**1.4. Emergency telephone number**
1-800-364-3577 or (651) 737-6501 (24 hours)

## SECTION 2: Hazard identification

This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.

**2.1. Hazard classification**
Skin Sensitizer: Category 1.

**2.2. Label elements**
**Signal word**
Warning

**Symbols**
Exclamation mark |

**Pictograms**



**Hazard Statements**
May cause an allergic skin reaction.

**Precautionary Statements**

**Prevention:**
Wear protective gloves.
Contaminated work clothing must not be allowed out of the workplace.

**Response:**
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse.

**Disposal:**
Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

## SECTION 3: Composition/information on ingredients

| Ingredient | C.A.S. No. | % by Wt |
|---|---|---|
| Glass powder (65997-17-3), surface modified with 2-propenoic acid, 2 methyl-.3-(trimethoxysilyl)propyl ester (2530-85-0) and phenyltrimethoxy silane (2996-92-1), bulk material | None | 45 - 55 Trade Secret * |
| 2-PROPENOIC ACID, 2-METHYL-, 1,1'-[1-(HYDROXYMETHYL)-1,2-ETHANEDIYL] ESTER, REACTION PRODUCTS WITH 2-HYDROXY-1,3-PROPANEDIYL DIMETHACRYLATE AND PHOSPHORUS OXIDE | 1224866-76-5 | 20 - 30 Trade Secret * |
| TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA) | 109-16-0 | 10 - 20 Trade Secret * |
| SILANE TREATED SILICA | 68909-20-6 | 1 - 10 Trade Secret * |
| OXIDE GLASS CHEMICALS (non-fibrous) | 65997-17-3 | < 3 Trade Secret * |
| SODIUM PERSULFATE | 7775-27-1 | < 3 Trade Secret * |
| TERT-BUTYL PEROXY-3,5,5-TRIMETHYLHEXANOATE | 13122-18-4 | < 0.5 Trade Secret * |
| Acetic acid, copper(2+) salt, monohydrate | 6046-93-1 | < 0.1 Trade Secret * |

*The specific chemical identity and/or exact percentage (concentration) of this composition has been withheld as a trade secret.

## SECTION 4: First aid measures

**4.1. Description of first aid measures**

**Inhalation:**
Remove person to fresh air. If you feel unwell, get medical attention.

**Skin Contact:**
Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

**Eye Contact:**
Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

**If Swallowed:**
Rinse mouth. If you feel unwell, get medical attention.

**4.2. Most important symptoms and effects, both acute and delayed**
See Section 11.1. Information on toxicological effects.

**4.3. Indication of any immediate medical attention and special treatment required**
Not applicable

## SECTION 5: Fire-fighting measures

**5.1. Suitable extinguishing media**
In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

**5.2. Special hazards arising from the substance or mixture**
None inherent in this product.

**Hazardous Decomposition or By-Products**

| Substance | Condition |
|---|---|
| Carbon monoxide | During Combustion |
| Carbon dioxide | During Combustion |
| Irritant Vapors or Gases | During Combustion |

**5.3. Special protective actions for fire-fighters**
No special protective actions for fire-fighters are anticipated.

## SECTION 6: Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**
Evacuate area. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapors, in accordance with good industrial hygiene practice. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

**6.2. Environmental precautions**
Avoid release to the environment.

**6.3. Methods and material for containment and cleaning up**
Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. Seal the container. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

## SECTION 7: Handling and storage

**7.1. Precautions for safe handling**
A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate

commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wash contaminated clothing before reuse. Do not get in eyes.

**7.2. Conditions for safe storage including any incompatibilities**
Store away from heat.

## SECTION 8: Exposure controls/personal protection

**8.1. Control parameters**

**Occupational exposure limits**
If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

| Ingredient | C.A.S. No. | Agency | Limit type | Additional Comments |
|---|---|---|---|---|
| COPPER COMPOUNDS | 6046-93-1 | ACGIH | TWA(as Cu dust or mist):1 mg/m3;TWA(as Cu, fume):0.2 mg/m3 | |
| SILICA, AMORPHOUS | 68909-20-6 | OSHA | TWA concentration:0.8 mg/m3;TWA:20 millions of particles/cu. ft. | |
| PERSULFATE COMPOUNDS | 7775-27-1 | ACGIH | TWA(as persulfate):0.1 mg/m3 | |

ACGIH : American Conference of Governmental Industrial Hygienists
AIHA : American Industrial Hygiene Association
CMRG : Chemical Manufacturer's Recommended Guidelines
OSHA : United States Department of Labor - Occupational Safety and Health Administration
TWA: Time-Weighted-Average
STEL: Short Term Exposure Limit
CEIL: Ceiling

**8.2. Exposure controls**

**8.2.1. Engineering controls**
Use in a well-ventilated area.

**8.2.2. Personal protective equipment (PPE)**

**Eye/face protection**

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:
Safety Glasses with side shields

**Skin/hand protection**
See Section 7.1 for additional information on skin protection.

**Respiratory protection**
None required.

## SECTION 9: Physical and chemical properties

**9.1. Information on basic physical and chemical properties**

| | |
|---|---|
| **General Physical Form:** | Solid |
| **Specific Physical Form:** | Paste |

| | |
|---|---|
| **Odor, Color, Grade:** | toothcolored paste with slight acrylic odor |
| **Odor threshold** | *No Data Available* |
| **pH** | *Not Applicable* |
| **Melting point** | *No Data Available* |
| **Boiling Point** | *No Data Available* |
| **Flash Point** | No flash point |
| **Evaporation rate** | *No Data Available* |
| **Flammability (solid, gas)** | Not Classified |
| **Flammable Limits(LEL)** | *No Data Available* |
| **Flammable Limits(UEL)** | *No Data Available* |
| **Vapor Pressure** | *No Data Available* |
| **Vapor Density** | *No Data Available* |
| **Density** | 2 - 2.2 g/cm3 |
| **Specific Gravity** | 2 - 2.2 [*Ref Std:*WATER=1] |
| **Solubility in Water** | Negligible |
| **Solubility- non-water** | *No Data Available* |
| **Partition coefficient: n-octanol/ water** | *No Data Available* |
| **Autoignition temperature** | *No Data Available* |
| **Decomposition temperature** | *No Data Available* |
| **Viscosity** | *No Data Available* |
| **Molecular weight** | *No Data Available* |
| **Percent volatile** | *No Data Available* |

## SECTION 10: Stability and reactivity

**10.1. Reactivity**
This material may be reactive with certain agents under certain conditions - see the remaining headings in this section.

**10.2. Chemical stability**
Stable.

**10.3. Possibility of hazardous reactions**
Hazardous polymerization will not occur.

**10.4. Conditions to avoid**
Heat

**10.5. Incompatible materials**
None known.

**10.6. Hazardous decomposition products**

| Substance | Condition |
|---|---|
| None known. | |

Refer to section 5.2 for hazardous decomposition products during combustion.

## SECTION 11: Toxicological information

**The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labeling, an ingredient may not be available for exposure, or the data may not be**

**relevant to the material as a whole.**

**This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.**
**The information below represents toxicological information associated with the individual components of the uncured product. Once properly mixed and/or cured, the product is safe for its intended use.**

**11.1. Information on Toxicological effects**

**Signs and Symptoms of Exposure**

**Based on test data and/or information on the components, this material may produce the following health effects:**

**Inhalation:**
This product may have a characteristic odor; however, no adverse health effects are anticipated.

**Skin Contact:**
Mild Skin Irritation: Signs/symptoms may include localized redness, swelling, itching, and dryness. Allergic Skin Reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

**Eye Contact:**
Contact with the eyes during product use is not expected to result in significant irritation.

**Ingestion:**
May be harmful if swallowed.
Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

**Toxicological Data**
If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

**Acute Toxicity**

| Name | Route | Species | Value |
|---|---|---|---|
| Overall product | Ingestion | | No data available; calculated ATE2,000 - 5,000 mg/kg |
| Glass powder (65997-17-3), surface modified with 2-propenoic acid, 2 methyl-.3-(trimethoxysilyl)propyl ester (2530-85-0) and phenyltrimethoxy silane (2996-92-1), bulk material | Dermal | | LD50 estimated to be > 5,000 mg/kg |
| Glass powder (65997-17-3), surface modified with 2-propenoic acid, 2 methyl-.3-(trimethoxysilyl)propyl ester (2530-85-0) and phenyltrimethoxy silane (2996-92-1), bulk material | Ingestion | | LD50 estimated to be 2,000 - 5,000 mg/kg |
| 2-PROPENOIC ACID, 2-METHYL-, 1,1'-[1-(HYDROXYMETHYL)-1,2-ETHANEDIYL] ESTER, REACTION PRODUCTS WITH 2-HYDROXY-1,3-PROPANEDIYL DIMETHACRYLATE AND PHOSPHORUS OXIDE | Dermal | | LD50 estimated to be > 5,000 mg/kg |
| 2-PROPENOIC ACID, 2-METHYL-, 1,1'-[1-(HYDROXYMETHYL)-1,2-ETHANEDIYL] ESTER, REACTION PRODUCTS WITH 2-HYDROXY-1,3-PROPANEDIYL DIMETHACRYLATE AND PHOSPHORUS OXIDE | Ingestion | Rat | LD50 > 2,000 mg/kg |
| TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA) | Dermal | Professional judgement | LD50 estimated to be > 5,000 mg/kg |
| TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA) | Ingestion | Rat | LD50 10,837 mg/kg |
| SILANE TREATED SILICA | Dermal | Rabbit | LD50 > 5,000 mg/kg |
| SILANE TREATED SILICA | Inhalation-Dust/Mist (4 hours) | Rat | LC50 > 0.691 mg/l |

| | | | |
|---|---|---|---|
| SILANE TREATED SILICA | Ingestion | Rat | LD50 > 5,110 mg/kg |
| OXIDE GLASS CHEMICALS (non-fibrous) | Dermal | | LD50 estimated to be > 5,000 mg/kg |
| OXIDE GLASS CHEMICALS (non-fibrous) | Ingestion | | LD50 estimated to be 2,000 - 5,000 mg/kg |
| SODIUM PERSULFATE | Dermal | Rabbit | LD50 > 10,000 mg/kg |
| SODIUM PERSULFATE | Inhalation-Dust/Mist (4 hours) | Rat | LC50 > 47.93 mg/l |
| SODIUM PERSULFATE | Ingestion | Rat | LD50 895 mg/kg |
| TERT-BUTYL PEROXY-3,5,5-TRIMETHYLHEXANOATE | Dermal | Rat | LD50 > 2,000 mg/kg |
| TERT-BUTYL PEROXY-3,5,5-TRIMETHYLHEXANOATE | Inhalation-Dust/Mist (4 hours) | Rat | LC50 > 0.8 mg/l |
| TERT-BUTYL PEROXY-3,5,5-TRIMETHYLHEXANOATE | Ingestion | Rat | LD50 12,905 mg/kg |

ATE = acute toxicity estimate

**Skin Corrosion/Irritation**

| Name | Species | Value |
|---|---|---|
| Glass powder (65997-17-3), surface modified with 2-propenoic acid, 2 methyl-.3-(trimethoxysilyl)propyl ester (2530-85-0) and phenyltrimethoxy silane (2996-92-1), bulk material | Professional judgement | No significant irritation |
| 2-PROPENOIC ACID, 2-METHYL-, 1,1'-[1-(HYDROXYMETHYL)-1,2-ETHANEDIYL] ESTER, REACTION PRODUCTS WITH 2-HYDROXY-1,3-PROPANEDIYL DIMETHACRYLATE AND PHOSPHORUS OXIDE | Rabbit | Minimal irritation |
| TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA) | Guinea pig | Mild irritant |
| SILANE TREATED SILICA | Rabbit | No significant irritation |
| OXIDE GLASS CHEMICALS (non-fibrous) | Professional judgement | No significant irritation |
| TERT-BUTYL PEROXY-3,5,5-TRIMETHYLHEXANOATE | Rabbit | No significant irritation |

**Serious Eye Damage/Irritation**

| Name | Species | Value |
|---|---|---|
| Overall product | | No significant irritation |
| Glass powder (65997-17-3), surface modified with 2-propenoic acid, 2 methyl-.3-(trimethoxysilyl)propyl ester (2530-85-0) and phenyltrimethoxy silane (2996-92-1), bulk material | Professional judgement | No significant irritation |
| 2-PROPENOIC ACID, 2-METHYL-, 1,1'-[1-(HYDROXYMETHYL)-1,2-ETHANEDIYL] ESTER, REACTION PRODUCTS WITH 2-HYDROXY-1,3-PROPANEDIYL DIMETHACRYLATE AND PHOSPHORUS OXIDE | Rabbit | Corrosive |
| TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA) | Professional judgement | Moderate irritant |
| SILANE TREATED SILICA | Rabbit | No significant irritation |
| OXIDE GLASS CHEMICALS (non-fibrous) | Professional judgement | No significant irritation |
| TERT-BUTYL PEROXY-3,5,5-TRIMETHYLHEXANOATE | Rabbit | No significant irritation |

**Skin Sensitization**

| Name | Species | Value |
|---|---|---|
| 2-PROPENOIC ACID, 2-METHYL-, 1,1'-[1-(HYDROXYMETHYL)-1,2-ETHANEDIYL] ESTER, REACTION PRODUCTS WITH 2-HYDROXY-1,3-PROPANEDIYL DIMETHACRYLATE AND PHOSPHORUS OXIDE | Guinea pig | Not classified |
| TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA) | Human and animal | Sensitizing |

| | | |
|---|---|---|
| SILANE TREATED SILICA | Human and animal | Not classified |
| TERT-BUTYL PEROXY-3,5,5-TRIMETHYLHEXANOATE | Guinea pig | Sensitizing |

**Respiratory Sensitization**
For the component/components, either no data are currently available or the data are not sufficient for classification.

**Germ Cell Mutagenicity**

| Name | Route | Value |
|---|---|---|
| 2-PROPENOIC ACID, 2-METHYL-, 1,1'-[1-(HYDROXYMETHYL)-1,2-ETHANEDIYL] ESTER, REACTION PRODUCTS WITH 2-HYDROXY-1,3-PROPANEDIYL DIMETHACRYLATE AND PHOSPHORUS OXIDE | In Vitro | Not mutagenic |
| TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA) | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| SILANE TREATED SILICA | In Vitro | Not mutagenic |

**Carcinogenicity**

| Name | Route | Species | Value |
|---|---|---|---|
| TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA) | Dermal | Mouse | Not carcinogenic |
| SILANE TREATED SILICA | Not Specified | Mouse | Some positive data exist, but the data are not sufficient for classification |

**Reproductive Toxicity**

**Reproductive and/or Developmental Effects**

| Name | Route | Value | Species | Test Result | Exposure Duration |
|---|---|---|---|---|---|
| TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA) | Ingestion | Not classified for female reproduction | Mouse | NOAEL 1 mg/kg/day | 1 generation |
| TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA) | Ingestion | Not classified for male reproduction | Mouse | NOAEL 1 mg/kg/day | 1 generation |
| TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA) | Ingestion | Not classified for development | Mouse | NOAEL 1 mg/kg/day | 1 generation |
| SILANE TREATED SILICA | Ingestion | Not classified for female reproduction | Rat | NOAEL 509 mg/kg/day | 1 generation |
| SILANE TREATED SILICA | Ingestion | Not classified for male reproduction | Rat | NOAEL 497 mg/kg/day | 1 generation |
| SILANE TREATED SILICA | Ingestion | Not classified for development | Rat | NOAEL 1,350 mg/kg/day | during organogenesis |

**Target Organ(s)**

**Specific Target Organ Toxicity - single exposure**
For the component/components, either no data are currently available or the data are not sufficient for classification.

**Specific Target Organ Toxicity - repeated exposure**

| Name | Route | Target Organ(s) | Value | Species | Test Result | Exposure Duration |
|---|---|---|---|---|---|---|
| TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA) | Dermal | kidney and/or bladder \| blood | Not classified | Mouse | NOAEL 833 mg/kg/day | 78 weeks |
| SILANE TREATED SILICA | Inhalation | respiratory system \| silicosis | Not classified | Human | NOAEL Not available | occupational exposure |

**Aspiration Hazard**
For the component/components, either no data are currently available or the data are not sufficient for classification.

**Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.**

## SECTION 12: Ecological information

**Ecotoxicological information**

Please contact the address or phone number listed on the first page of the SDS for additional ecotoxicological information on this material and/or its components.

**Chemical fate information**

Please contact the address or phone number listed on the first page of the SDS for additional chemical fate information on this material and/or its components.

## SECTION 13: Disposal considerations

**13.1. Disposal methods**
Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Incinerate in a permitted waste incineration facility.

**EPA Hazardous Waste Number (RCRA):** Not regulated

## SECTION 14: Transport Information

For Transport Information, please visit http://3M.com/Transportinfo or call 1-800-364-3577 or 651-737-6501.

## SECTION 15: Regulatory information

**15.1. US Federal Regulations**
Contact 3M for more information.

**EPCRA 311/312 Hazard Classifications:**

| Physical Hazards |
|---|
| Not applicable |

| Health Hazards |
|---|
| Respiratory or Skin Sensitization |

**15.2. State Regulations**
Contact 3M for more information.

**15.3. Chemical Inventories**
This material contains one or more substances not listed on the TSCA Inventory. Commercial use of this material is regulated by the FDA.

Contact 3M for more information.

**15.4. International Regulations**
Contact 3M for more information.

**This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.**

## SECTION 16: Other information

**NFPA Hazard Classification**
**Health:** 2 **Flammability:** 1 **Instability:** 1 **Special Hazards:** None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

| | | | |
|---|---|---|---|
| **Document Group:** | 29-2267-2 | **Version Number:** | 4.01 |
| **Issue Date:** | 01/18/18 | **Supercedes Date:** | 02/25/16 |

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# 4. Safety Data Sheet – RelyX ARC (3M)



## Safety Data Sheet

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| | | | |
|---|---|---|---|
| **Document Group:** | 29-6283-5 | **Version Number:** | 3.00 |
| **Issue Date:** | 04/07/20 | **Supercedes Date:** | 02/21/18 |

**Product identifier**
3M™ RelyX™ Luting Plus Automix Cement (3535/3535TK/3535SK)

**ID Number(s):**

70-2010-8554-8, 70-2010-8555-5, 70-2010-8557-1

7000128981, 7000128982, 7000128984

**Recommended use**
Dental product, Dental luting cement
**Restrictions on use**
For use only by dental professionals

**Supplier's details**

| | |
|---|---|
| **MANUFACTURER:** | 3M |
| **DIVISION:** | Oral Care Solutions Division |
| **ADDRESS:** | 3M Center, St. Paul, MN 55144-1000, USA |
| **Telephone:** | 1-888-3M HELPS (1-888-364-3577) |

**Emergency telephone number**
1-800-364-3577 or (651) 737-6501 (24 hours)

**This product is a kit or a multipart product which consists of multiple, independently packaged components. A Safety Data Sheet (SDS), Article Information Sheet (AIS), or Article Information Letter (AIL) for each of these components is included. Please do not separate the component documents from this cover page. The document numbers for components of this product are:**

29-6280-1, 29-6234-8

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# Safety Data Sheet

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| | | | |
|---|---|---|---|
| **Document Group:** | 29-6280-1 | **Version Number:** | 3.04 |
| **Issue Date:** | 06/22/22 | **Supercedes Date:** | 04/03/20 |

## SECTION 1: Identification

**1.1. Product identifier**
3M™ RelyX™ Luting Plus Cement Paste B

**Product Identification Numbers**
LE-F100-0969-8

**1.2. Recommended use and restrictions on use**

**Recommended use**
Dental Product, Luting cement
**Restrictions on use**

For use only by dental professionals

**1.3. Supplier's details**

| | |
|---|---|
| **MANUFACTURER:** | 3M |
| **DIVISION:** | Oral Care Solutions Division |
| **ADDRESS:** | 3M Center, St. Paul, MN 55144-1000, USA |
| **Telephone:** | 1-888-3M HELPS (1-888-364-3577) |

**1.4. Emergency telephone number**
1-800-364-3577 or (651) 737-6501 (24 hours)

## SECTION 2: Hazard identification

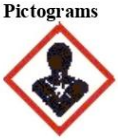
This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.

**2.1. Hazard classification**
Serious Eye Damage/Irritation: Category 2A.
Respiratory Sensitizer: Category 1.
Skin Sensitizer: Category 1.

**2.2. Label elements**
**Signal word**
Danger

**Symbols**
Health Hazard |

**Pictograms**



**Hazard Statements**
Causes serious eye irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.

**Precautionary Statements**

**Prevention:**
Avoid breathing dust/fume/gas/mist/vapors/spray.
In case of inadequate ventilation wear respiratory protection.
Wear protective gloves and eye/face protection.
Wash thoroughly after handling.
Contaminated work clothing must not be allowed out of the workplace.

**Response:**
IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse.

**Disposal:**
Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

88% of the mixture consists of ingredients of unknown acute inhalation toxicity.

## SECTION 3: Composition/information on ingredients

| Ingredient | C.A.S. No. | % by Wt |
|---|---|---|
| Silane Treated Ceramic | 444758-98-9 | 30 - 40 Trade Secret * |
| 2-Hydroxyethyl Methacrylate (HEMA) | 868-77-9 | 10 - 30 Trade Secret * |
| Copolymer Of Acrylic And Itaconic Acids | 25948-33-8 | 10 - 30 Trade Secret * |
| Water | 7732-18-5 | 5 - 15 Trade Secret * |
| Glycerol 1,3 Dimethacrylate | 1830-78-0 | 1 - 5 Trade Secret * |
| Potassium Diphosphate | 7778-77-0 | 1 - 5 Trade Secret * |
| Potassium Persulfate | 7727-21-1 | 1 - 5 Trade Secret * |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | 128-37-0 | < 0.5 Trade Secret * |
| Ethylene Dimethacrylate (EGDMA) | 97-90-5 | < 0.5 Trade Secret * |

*The specific chemical identity and/or exact percentage (concentration) of this composition has been withheld as a trade secret.

## SECTION 4: First aid measures

**4.1. Description of first aid measures**

**Inhalation:**
Remove person to fresh air. If you feel unwell, get medical attention.

**Skin Contact:**
Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

**Eye Contact:**
Immediately flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. Get medical attention.

**If Swallowed:**
Rinse mouth. If you feel unwell, get medical attention.

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

Allergic respiratory reaction (difficulty breathing, wheezing, cough, and tightness of chest). Allergic skin reaction (redness, swelling, blistering, and itching).

**4.3. Indication of any immediate medical attention and special treatment required**
Not applicable

## SECTION 5: Fire-fighting measures

**5.1. Suitable extinguishing media**
In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

**5.2. Special hazards arising from the substance or mixture**
None inherent in this product.

**Hazardous Decomposition or By-Products**

| Substance | Condition |
|---|---|
| Carbon monoxide | During Combustion |
| Carbon dioxide | During Combustion |

**5.3. Special protective actions for fire-fighters**
Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

## SECTION 6: Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**
Evacuate area. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapors, in accordance with good industrial hygiene practice. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

**6.2. Environmental precautions**
Avoid release to the environment.

**6.3. Methods and material for containment and cleaning up**
Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. Seal the container. Dispose of collected material as soon as possible in accordance with

applicable local/regional/national/international regulations.

## SECTION 7: Handling and storage

**7.1. Precautions for safe handling**
A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. Avoid breathing dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not get in eyes.

**7.2. Conditions for safe storage including any incompatibilities**
Store away from heat.

## SECTION 8: Exposure controls/personal protection

**8.1. Control parameters**

**Occupational exposure limits**
If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

| Ingredient | C.A.S. No. | Agency | Limit type | Additional Comments |
|---|---|---|---|---|
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | 128-37-0 | ACGIH | TWA(inhalable fraction and vapor):2 mg/m3 | A4: Not class. as human carcin |
| PERSULFATE COMPOUNDS | 7727-21-1 | ACGIH | TWA(as persulfate):0.1 mg/m3 | |

ACGIH : American Conference of Governmental Industrial Hygienists
AIHA : American Industrial Hygiene Association
CMRG : Chemical Manufacturer's Recommended Guidelines
OSHA : United States Department of Labor - Occupational Safety and Health Administration
TWA: Time-Weighted-Average
STEL: Short Term Exposure Limit
CEIL: Ceiling

**8.2. Exposure controls**

**8.2.1. Engineering controls**
Use in a well-ventilated area.

**8.2.2. Personal protective equipment (PPE)**

**Eye/face protection**

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:
Safety Glasses with side shields

**Skin/hand protection**
See Section 7.1 for additional information on skin protection.

**Respiratory protection**
None required.

## SECTION 9: Physical and chemical properties

**9.1. Information on basic physical and chemical properties**

| | |
|---|---|
| **Appearance** | |
| **Physical state** | Solid |
| **Color** | Transparent Yellow |
| **Specific Physical Form:** | Paste |
| **Odor** | Characteristic Odor |
| **Odor threshold** | *No Data Available* |
| **pH** | *No Data Available* |
| **Melting point** | *Not Applicable* |
| **Boiling Point** | *Not Applicable* |
| **Flash Point** | No flash point |
| **Evaporation rate** | *No Data Available* |
| **Flammability (solid, gas)** | Not Classified |
| **Flammable Limits(LEL)** | *No Data Available* |
| **Flammable Limits(UEL)** | *No Data Available* |
| **Vapor Pressure** | *No Data Available* |
| **Vapor Density** | *No Data Available* |
| **Density** | 1.5 g/cm3 |
| **Specific Gravity** | 1.5 [*Ref Std:*WATER=1] |
| **Solubility in Water** | Negligible |
| **Solubility- non-water** | *No Data Available* |
| **Partition coefficient: n-octanol/ water** | *No Data Available* |
| **Autoignition temperature** | *No Data Available* |
| **Decomposition temperature** | *No Data Available* |
| **Viscosity** | *No Data Available* |
| **Molecular weight** | *Not Applicable* |
| **Volatile Organic Compounds** | *Not Applicable* |

## SECTION 10: Stability and reactivity

**10.1. Reactivity**
This material may be reactive with certain agents under certain conditions - see the remaining headings in this section.

**10.2. Chemical stability**
Stable.

**10.3. Possibility of hazardous reactions**
Hazardous polymerization will not occur.

**10.4. Conditions to avoid**
Heat

**10.5. Incompatible materials**
None known.

**10.6. Hazardous decomposition products**

| **Substance** | **Condition** |
|---|---|
| None known. | |

Refer to section 5.2 for hazardous decomposition products during combustion.

## SECTION 11: Toxicological information

**The information below may not be consistent with the material classification in Section 2 if specific ingredient**

**classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.**

**This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.**
**The information below represents toxicological information associated with the individual components of the uncured product. Once properly mixed and/or cured, the product is safe for its intended use.**

**11.1. Information on Toxicological effects**

**Signs and Symptoms of Exposure**

**Based on test data and/or information on the components, this material may produce the following health effects:**

**Inhalation:**
Respiratory Tract Irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

Allergic Respiratory Reaction: Signs/symptoms may include difficulty breathing, wheezing, cough, and tightness of chest.

**Skin Contact:**
Mild Skin Irritation: Signs/symptoms may include localized redness, swelling, itching, and dryness. Allergic Skin Reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

**Eye Contact:**
Severe Eye Irritation: Signs/symptoms may include significant redness, swelling, pain, tearing, cloudy appearance of the cornea, and impaired vision.

**Ingestion:**
Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

**Toxicological Data**
If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

**Acute Toxicity**

| Name | Route | Species | Value |
|---|---|---|---|
| Overall product | Inhalation-Dust/Mist(4 hr) | | No data available; calculated ATE >12.5 mg/l |
| Overall product | Ingestion | | No data available; calculated ATE >5,000 mg/kg |
| Silane Treated Ceramic | Dermal | | LD50 estimated to be > 5,000 mg/kg |
| Silane Treated Ceramic | Ingestion | | LD50 estimated to be 2,000 - 5,000 mg/kg |
| Copolymer Of Acrylic And Itaconic Acids | Ingestion | Rat | LD50 > 5,000 mg/kg |
| Copolymer Of Acrylic And Itaconic Acids | Dermal | similar health hazards | LD50 estimated to be > 5,000 mg/kg |
| 2-Hydroxyethyl Methacrylate (HEMA) | Dermal | Rabbit | LD50 > 5,000 mg/kg |
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Rat | LD50 5,564 mg/kg |
| Glycerol 1,3 Dimethacrylate | Ingestion | Rat | LD50 > 2,000 mg/kg |
| Potassium Diphosphate | Dermal | Rabbit | LD50 > 4,640 mg/kg |
| Potassium Diphosphate | Ingestion | Rat | LD50 > 4,640 mg/kg |
| Potassium Persulfate | Dermal | Rabbit | LD50 > 10,000 mg/kg |
| Potassium Persulfate | Inhalation-Dust/Mist | Rat | LC50 > 10.7 mg/l |

| | | | |
|---|---|---|---|
| | (4 hours) | | |
| Potassium Persulfate | Ingestion | Rat | LD50 1,130 mg/kg |
| Ethylene Dimethacrylate (EGDMA) | Dermal | Professional judgement | LD50 estimated to be 2,000 - 5,000 mg/kg |
| Ethylene Dimethacrylate (EGDMA) | Ingestion | Rat | LD50 3,300 mg/kg |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Dermal | Rat | LD50 > 2,000 mg/kg |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | Rat | LD50 > 2,930 mg/kg |

ATE = acute toxicity estimate

**Skin Corrosion/Irritation**

| Name | Species | Value |
|---|---|---|
| Silane Treated Ceramic | similar compounds | No significant irritation |
| 2-Hydroxyethyl Methacrylate (HEMA) | Rabbit | Minimal irritation |
| Glycerol 1,3 Dimethacrylate | Rabbit | No significant irritation |
| Ethylene Dimethacrylate (EGDMA) | Professional judgement | Mild irritant |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Human and animal | Minimal irritation |

**Serious Eye Damage/Irritation**

| Name | Species | Value |
|---|---|---|
| Silane Treated Ceramic | similar compounds | Mild irritant |
| 2-Hydroxyethyl Methacrylate (HEMA) | Rabbit | Moderate irritant |
| Glycerol 1,3 Dimethacrylate | In vitro data | Severe irritant |
| Ethylene Dimethacrylate (EGDMA) | Not available | Moderate irritant |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Rabbit | Mild irritant |

**Skin Sensitization**

| Name | Species | Value |
|---|---|---|
| Silane Treated Ceramic | similar compounds | Not classified |
| 2-Hydroxyethyl Methacrylate (HEMA) | Human and animal | Sensitizing |
| Glycerol 1,3 Dimethacrylate | Mouse | Not classified |
| Ethylene Dimethacrylate (EGDMA) | Guinea pig | Sensitizing |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Human | Not classified |

**Respiratory Sensitization**

For the component/components, either no data are currently available or the data are not sufficient for classification.

**Germ Cell Mutagenicity**

| Name | Route | Value |
|---|---|---|
| 2-Hydroxyethyl Methacrylate (HEMA) | In vivo | Not mutagenic |
| 2-Hydroxyethyl Methacrylate (HEMA) | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Ethylene Dimethacrylate (EGDMA) | In Vitro | Some positive data exist, but the data are not |

| | | |
|---|---|---|
| | | sufficient for classification |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | In Vitro | Not mutagenic |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | In vivo | Not mutagenic |

**Carcinogenicity**

| Name | Route | Species | Value |
|---|---|---|---|
| Silane Treated Ceramic | Inhalation | similar compounds | Some positive data exist, but the data are not sufficient for classification |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | Multiple animal species | Some positive data exist, but the data are not sufficient for classification |

**Reproductive Toxicity**

**Reproductive and/or Developmental Effects**

| Name | Route | Value | Species | Test Result | Exposure Duration |
|---|---|---|---|---|---|
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for female reproduction | Rat | NOAEL 1,000 mg/kg/day | premating & during gestation |
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for male reproduction | Rat | NOAEL 1,000 mg/kg/day | 49 days |
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for development | Rat | NOAEL 1,000 mg/kg/day | premating & during gestation |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | Not classified for female reproduction | Rat | NOAEL 500 mg/kg/day | 2 generation |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | Not classified for male reproduction | Rat | NOAEL 500 mg/kg/day | 2 generation |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | Not classified for development | Rat | NOAEL 100 mg/kg/day | 2 generation |

**Target Organ(s)**

**Specific Target Organ Toxicity - single exposure**

| Name | Route | Target Organ(s) | Value | Species | Test Result | Exposure Duration |
|---|---|---|---|---|---|---|
| Copolymer Of Acrylic And Itaconic Acids | Ingestion | nervous system | Not classified | Rat | NOAEL 5,000 mg/kg | |
| Ethylene Dimethacrylate (EGDMA) | Inhalation | respiratory irritation | May cause respiratory irritation | official classification | NOAEL Not available | |

**Specific Target Organ Toxicity - repeated exposure**

| Name | Route | Target Organ(s) | Value | Species | Test Result | Exposure Duration |
|---|---|---|---|---|---|---|
| Silane Treated Ceramic | Inhalation | pulmonary fibrosis | Not classified | similar compounds | NOAEL Not available | |
| Copolymer Of Acrylic And Itaconic Acids | Ingestion | endocrine system \| hematopoietic system \| liver | Not classified | Rat | NOAEL 200 mg/kg/day | 28 days |
| Copolymer Of Acrylic And Itaconic Acids | Ingestion | heart \| bone, teeth, nails, and/or hair \| immune system \| muscles \| nervous system \| eyes \| kidney and/or bladder \| respiratory system \| vascular system | Not classified | Rat | NOAEL 2,000 mg/kg/day | 28 days |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | liver | Some positive data exist, but the data are not sufficient for | Rat | NOAEL 250 mg/kg/day | 28 days |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | classification | | | |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | kidney and/or bladder | Not classified | Rat | NOAEL 500 mg/kg/day | 2 generation |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | blood | Not classified | Rat | LOAEL 420 mg/kg/day | 40 days |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | endocrine system | Not classified | Rat | NOAEL 25 mg/kg/day | 2 generation |
| 2,6-Di-Tert-Butyl-P-Cresol (BHT) | Ingestion | heart | Not classified | Mouse | NOAEL 3,480 mg/kg/day | 10 weeks |

**Aspiration Hazard**
For the component/components, either no data are currently available or the data are not sufficient for classification.

**Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.**

## SECTION 12: Ecological information

### Ecotoxicological information

Please contact the address or phone number listed on the first page of the SDS for additional ecotoxicological information on this material and/or its components.

### Chemical fate information

Please contact the address or phone number listed on the first page of the SDS for additional chemical fate information on this material and/or its components.

## SECTION 13: Disposal considerations

**13.1. Disposal methods**
Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Dispose of waste product in a permitted industrial waste facility. As a disposal alternative, incinerate in a permitted waste incineration facility.

**EPA Hazardous Waste Number (RCRA):** Not regulated

## SECTION 14: Transport Information

For Transport Information, please visit http://3M.com/Transportinfo or call 1-800-364-3577 or 651-737-6501.

## SECTION 15: Regulatory information

### 15.1. US Federal Regulations
Contact 3M for more information.

**EPCRA 311/312 Hazard Classifications:**

| **Physical Hazards** |
|---|
| Not applicable |

| **Health Hazards** |
|---|
| Respiratory or Skin Sensitization |
| Serious eye damage or eye irritation |

### 15.2. State Regulations
Contact 3M for more information.

### 15.3. Chemical Inventories
This material contains one or more substances not listed on the TSCA Inventory. Commercial use of this material is regulated by the FDA.

Contact 3M for more information.

### 15.4. International Regulations
Contact 3M for more information.

**This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.**

## SECTION 16: Other information

**NFPA Hazard Classification**
**Health:** 2 **Flammability:** 1 **Instability:** 0 **Special Hazards:** None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

| | | | |
|---|---|---|---|
| **Document Group:** | 29-6280-1 | **Version Number:** | 3.04 |
| **Issue Date:** | 06/22/22 | **Supercedes Date:** | 04/03/20 |

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# Safety Data Sheet

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| | | | |
|---|---|---|---|
| **Document Group:** | 29-6234-8 | **Version Number:** | 2.03 |
| **Issue Date:** | 04/22/21 | **Supercedes Date:** | 04/03/20 |

## SECTION 1: Identification

**1.1. Product identifier**
3M™ RelyX™ Luting Plus Cement Paste A

**Product Identification Numbers**
LE-F100-0969-1

**1.2. Recommended use and restrictions on use**

**Recommended use**
Dental Product, Luting cement
**Restrictions on use**
For use only by dental professionals

**1.3. Supplier's details**

| | |
|---|---|
| **MANUFACTURER:** | 3M |
| **DIVISION:** | Oral Care Solutions Division |
| **ADDRESS:** | 3M Center, St. Paul, MN 55144-1000, USA |
| **Telephone:** | 1-888-3M HELPS (1-888-364-3577) |

**1.4. Emergency telephone number**
1-800-364-3577 or (651) 737-6501 (24 hours)

## SECTION 2: Hazard identification

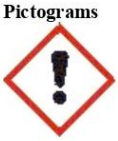
This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.

**2.1. Hazard classification**
Skin Sensitizer: Category 1.

**2.2. Label elements**
**Signal word**
Warning

**Symbols**
Exclamation mark |

**Pictograms**



**Hazard Statements**
May cause an allergic skin reaction.

**Precautionary Statements**

**Prevention:**
Wear protective gloves.
Contaminated work clothing must not be allowed out of the workplace.

**Response:**
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse.

**Disposal:**
Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

72% of the mixture consists of ingredients of unknown acute oral toxicity.

## SECTION 3: Composition/information on ingredients

| Ingredient | C.A.S. No. | % by Wt |
|---|---|---|
| Silane Treated Glass | None | 70 - 80 Trade Secret * |
| Water | 7732-18-5 | 10 - 20 Trade Secret * |
| 2-Hydroxyethyl Methacrylate (HEMA) | 868-77-9 | < 10 Trade Secret * |
| Silane Treated Silica | 68909-20-6 | < 2 Trade Secret * |
| 4-(Dimethylamino)-Benzeneethanol | 50438-75-0 | < 1 Trade Secret * |
| Allylthiourea | 109-57-9 | < 0.5 Trade Secret * |
| Titanium Oxide | 13463-67-7 | < 0.5 Trade Secret * |

*The specific chemical identity and/or exact percentage (concentration) of this composition has been withheld as a trade secret.

## SECTION 4: First aid measures

**4.1. Description of first aid measures**

**Inhalation:**
Remove person to fresh air. If you feel unwell, get medical attention.

**Skin Contact:**
Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

**Eye Contact:**
Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

**If Swallowed:**
Rinse mouth. If you feel unwell, get medical attention.

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

Allergic skin reaction (redness, swelling, blistering, and itching).

**4.3. Indication of any immediate medical attention and special treatment required**
Not applicable

## SECTION 5: Fire-fighting measures

**5.1. Suitable extinguishing media**
In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

**5.2. Special hazards arising from the substance or mixture**
None inherent in this product.

**Hazardous Decomposition or By-Products**

| Substance | Condition |
|---|---|
| Carbon monoxide | During Combustion |
| Carbon dioxide | During Combustion |

**5.3. Special protective actions for fire-fighters**
Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

## SECTION 6: Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**
Evacuate area. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapors, in accordance with good industrial hygiene practice. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

**6.2. Environmental precautions**
Avoid release to the environment.

**6.3. Methods and material for containment and cleaning up**
Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. Seal the container. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

## SECTION 7: Handling and storage

**7.1. Precautions for safe handling**
A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not get in eyes.

**7.2. Conditions for safe storage including any incompatibilities**
Store away from heat.

## SECTION 8: Exposure controls/personal protection

**8.1. Control parameters**

**Occupational exposure limits**
If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

| Ingredient | C.A.S. No. | Agency | Limit type | Additional Comments |
|---|---|---|---|---|
| Titanium Oxide | 13463-67-7 | ACGIH | TWA:10 mg/m3 | A4: Not class. as human carcin |
| Titanium Oxide | 13463-67-7 | OSHA | TWA(as total dust):15 mg/m3 | |
| SILICA, AMORPHOUS | 68909-20-6 | OSHA | TWA:20 millions of particles/cu. ft.;TWA concentration:0.8 mg/m3 | |

ACGIH : American Conference of Governmental Industrial Hygienists
AIHA : American Industrial Hygiene Association
CMRG : Chemical Manufacturer's Recommended Guidelines
OSHA : United States Department of Labor - Occupational Safety and Health Administration
TWA: Time-Weighted-Average
STEL: Short Term Exposure Limit
CEIL: Ceiling

**8.2. Exposure controls**

**8.2.1. Engineering controls**
Use in a well-ventilated area.

**8.2.2. Personal protective equipment (PPE)**

**Eye/face protection**

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:
Safety Glasses with side shields

**Skin/hand protection**
See Section 7.1 for additional information on skin protection.

**Respiratory protection**
None required.

## SECTION 9: Physical and chemical properties

**9.1. Information on basic physical and chemical properties**

| | |
|---|---|
| **Appearance** | |
| **Physical state** | Solid |
| **Color** | Off-White, Yellow |
| **Specific Physical Form:** | Paste |
| **Odor** | Characteristic Odor |
| **Odor threshold** | *No Data Available* |
| **pH** | *No Data Available* |
| **Melting point** | *No Data Available* |
| **Boiling Point** | *No Data Available* |
| **Flash Point** | No flash point |
| **Evaporation rate** | *No Data Available* |
| **Flammability (solid, gas)** | Not Classified |
| **Flammable Limits(LEL)** | *No Data Available* |

| | |
|---|---|
| **Flammable Limits(UEL)** | *No Data Available* |
| **Vapor Pressure** | *No Data Available* |
| **Vapor Density** | *No Data Available* |
| **Density** | 1.5 g/cm3 |
| **Specific Gravity** | 1.5 [*Ref Std:*WATER=1] |
| **Solubility in Water** | Negligible |
| **Solubility- non-water** | *No Data Available* |
| **Partition coefficient: n-octanol/ water** | *No Data Available* |
| **Autoignition temperature** | *No Data Available* |
| **Decomposition temperature** | *No Data Available* |
| **Viscosity** | *No Data Available* |
| **Molecular weight** | *Not Applicable* |
| **Volatile Organic Compounds** | *No Data Available* |

## SECTION 10: Stability and reactivity

**10.1. Reactivity**
This material is considered to be non reactive under normal use conditions.

**10.2. Chemical stability**
Stable.

**10.3. Possibility of hazardous reactions**
Hazardous polymerization will not occur.

**10.4. Conditions to avoid**
Heat

**10.5. Incompatible materials**
None known.

**10.6. Hazardous decomposition products**

| Substance | Condition |
|---|---|
| None known. | |

Refer to section 5.2 for hazardous decomposition products during combustion.

## SECTION 11: Toxicological information

**The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.**

**This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.**
**The information below represents toxicological information associated with the individual components of the uncured product. Once properly mixed and/or cured, the product is safe for its intended use.**

**11.1. Information on Toxicological effects**

**Signs and Symptoms of Exposure**

**Based on test data and/or information on the components, this material may produce the following health effects:**

**Inhalation:**
This product may have a characteristic odor; however, no adverse health effects are anticipated.

**Skin Contact:**
Contact with the skin during product use is not expected to result in significant irritation. Allergic Skin Reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

**Eye Contact:**
Contact with the eyes during product use is not expected to result in significant irritation.

**Ingestion:**
Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

**Additional Health Effects:**

**Carcinogenicity:**
Exposures needed to cause the following health effect(s) are not expected during normal, intended use:
Contains a chemical or chemicals which can cause cancer.

| Ingredient | CAS No. | Class Description | Regulation |
|---|---|---|---|
| Titanium Oxide | 13463-67-7 | Grp. 2B: Possible human carc. | International Agency for Research on Cancer |

**Toxicological Data**
If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

**Acute Toxicity**

| Name | Route | Species | Value |
|---|---|---|---|
| Overall product | Ingestion | | No data available; calculated ATE >5,000 mg/kg |
| 2-Hydroxyethyl Methacrylate (HEMA) | Dermal | Rabbit | LD50 > 5,000 mg/kg |
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Rat | LD50 5,564 mg/kg |
| Silane Treated Silica | Dermal | Rabbit | LD50 > 5,000 mg/kg |
| Silane Treated Silica | Inhalation-Dust/Mist (4 hours) | Rat | LC50 > 0.691 mg/l |
| Silane Treated Silica | Ingestion | Rat | LD50 > 5,110 mg/kg |
| Titanium Oxide | Dermal | Rabbit | LD50 > 10,000 mg/kg |
| Titanium Oxide | Inhalation-Dust/Mist (4 hours) | Rat | LC50 > 6.82 mg/l |
| Titanium Oxide | Ingestion | Rat | LD50 > 10,000 mg/kg |
| Allylthiourea | Ingestion | Rat | LD50 200 mg/kg |

ATE = acute toxicity estimate

**Skin Corrosion/Irritation**

| Name | Species | Value |
|---|---|---|
| 2-Hydroxyethyl Methacrylate (HEMA) | Rabbit | Minimal irritation |
| Silane Treated Silica | Rabbit | No significant irritation |
| Titanium Oxide | Rabbit | No significant irritation |
| Allylthiourea | Professional judgement | Minimal irritation |

**Serious Eye Damage/Irritation**

| Name | Species | Value |
|---|---|---|
| 2-Hydroxyethyl Methacrylate (HEMA) | Rabbit | Moderate irritant |
| Silane Treated Silica | Rabbit | No significant irritation |
| Titanium Oxide | Rabbit | No significant irritation |
| Allylthiourea | Professional judgement | Mild irritant |

**Skin Sensitization**

| Name | Species | Value |
|---|---|---|
| 2-Hydroxyethyl Methacrylate (HEMA) | Human and animal | Sensitizing |
| Silane Treated Silica | Human and animal | Not classified |
| Titanium Oxide | Human and animal | Not classified |
| Allylthiourea | Professional judgement | Sensitizing |

**Respiratory Sensitization**

For the component/components, either no data are currently available or the data are not sufficient for classification.

**Germ Cell Mutagenicity**

| Name | Route | Value |
|---|---|---|
| 2-Hydroxyethyl Methacrylate (HEMA) | In vivo | Not mutagenic |
| 2-Hydroxyethyl Methacrylate (HEMA) | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Silane Treated Silica | In Vitro | Not mutagenic |
| Titanium Oxide | In Vitro | Not mutagenic |
| Titanium Oxide | In vivo | Not mutagenic |
| Allylthiourea | In Vitro | Not mutagenic |

**Carcinogenicity**

| Name | Route | Species | Value |
|---|---|---|---|
| Silane Treated Silica | Not Specified | Mouse | Some positive data exist, but the data are not sufficient for classification |
| Titanium Oxide | Ingestion | Multiple animal species | Not carcinogenic |
| Titanium Oxide | Inhalation | Rat | Carcinogenic |
| Allylthiourea | Ingestion | Rat | Some positive data exist, but the data are not sufficient for classification |

**Reproductive Toxicity**

**Reproductive and/or Developmental Effects**

| Name | Route | Value | Species | Test Result | Exposure Duration |
|---|---|---|---|---|---|
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for female reproduction | Rat | NOAEL 1,000 mg/kg/day | premating & during gestation |
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for male reproduction | Rat | NOAEL 1,000 mg/kg/day | 49 days |
| 2-Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for development | Rat | NOAEL 1,000 mg/kg/day | premating & during |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | gestation |
| Silane Treated Silica | Ingestion | Not classified for female reproduction | Rat | NOAEL 509 mg/kg/day | 1 generation |
| Silane Treated Silica | Ingestion | Not classified for male reproduction | Rat | NOAEL 497 mg/kg/day | 1 generation |
| Silane Treated Silica | Ingestion | Not classified for development | Rat | NOAEL 1,350 mg/kg/day | during organogenesis |

**Target Organ(s)**

**Specific Target Organ Toxicity - single exposure**
For the component/components, either no data are currently available or the data are not sufficient for classification.

**Specific Target Organ Toxicity - repeated exposure**

| Name | Route | Target Organ(s) | Value | Species | Test Result | Exposure Duration |
|---|---|---|---|---|---|---|
| Silane Treated Silica | Inhalation | respiratory system \| silicosis | Not classified | Human | NOAEL Not available | occupational exposure |
| Titanium Oxide | Inhalation | respiratory system | Some positive data exist, but the data are not sufficient for classification | Rat | LOAEL 0.01 mg/l | 2 years |
| Titanium Oxide | Inhalation | pulmonary fibrosis | Not classified | Human | NOAEL Not available | occupational exposure |
| Allylthiourea | Ingestion | endocrine system | Not classified | Rat | NOAEL 23 mg/kg/day | 15 months |

**Aspiration Hazard**
For the component/components, either no data are currently available or the data are not sufficient for classification.

**Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.**

## SECTION 12: Ecological information

**Ecotoxicological information**

Please contact the address or phone number listed on the first page of the SDS for additional ecotoxicological information on this material and/or its components.

**Chemical fate information**

Please contact the address or phone number listed on the first page of the SDS for additional chemical fate information on this material and/or its components.

## SECTION 13: Disposal considerations

**13.1. Disposal methods**
Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Dispose of completely cured (or polymerized) material in a permitted industrial waste facility. As a disposal alternative, incinerate uncured product in a permitted waste incineration facility. If no other disposal options are available, waste product that has been completely cured or polymerized may be placed in a landfill properly designed for industrial waste.

## SECTION 14: Transport Information

For Transport Information, please visit http://3M.com/Transportinfo or call 1-800-364-3577 or 651-737-6501.

## SECTION 15: Regulatory information

### 15.1. US Federal Regulations
Contact 3M for more information.

**EPCRA 311/312 Hazard Classifications:**

| Physical Hazards |
|---|
| Not applicable |

| Health Hazards |
|---|
| Respiratory or Skin Sensitization |

### 15.2. State Regulations
Contact 3M for more information.

### 15.3. Chemical Inventories
This material contains one or more substances not listed on the TSCA Inventory. Commercial use of this material is regulated by the FDA.

Contact 3M for more information.

### 15.4. International Regulations
Contact 3M for more information.

**This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.**

## SECTION 16: Other information

**NFPA Hazard Classification**
**Health:** 2 **Flammability:** 1 **Instability:** 0 **Special Hazards:** None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

| | | | |
|---|---|---|---|
| **Document Group:** | 29-6234-8 | **Version Number:** | 2.03 |
| **Issue Date:** | 04/22/21 | **Supercedes Date:** | 04/03/20 |

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# 5. Safety Data Sheet – Calibra Universal (Dentsply)

**DENTSPLY/International**
**DENTSPLY/Caulk**
**Safety Data Sheet** **507806**

## 1. Identification

| | |
|---|---|
| Product Name<br>Calibra® Universal | SDS Code Number<br>507806 |
| Substance Identity<br>Calibra® Universal Self-Adhesive Resin Cement | Date of Last Revision<br>02/14/15 |
| Manufacturer:<br>DENTSPLY Caulk | Address<br>38 West Clarke Avenue<br>Milford DE 19963-1805<br>http://www.caulk.com http://www.dentsply.com |
| Grades or Minor Variant Identities<br>Not Applicable | Information Telephone Number<br>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |
| Product Use (for Canada)<br>Dual Curing Dental Luting Cement | Emergency Telephone Number<br>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |

## 2. Hazard(s) Identification



**WARNING**
**MAY CAUSE AN ALLERGIC SKIN**

Wash hands thoroughly after handling.
Wear protective gloves
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation occurs: Get Medical Advice/attention.
Take off contaminated clothing and wash before reuse.

## 3. Composition/Information on Ingredients – Base Paste

| Hazardous Components | C.A.S. Number | Exposure Limits | % |
|---|---|---|---|
| Urethane Dimethacrylate Resin | 105883-40-7 | Not Established | < 10 |
| Polymerizable trimethacrylate resin | 3290-92-4 | Not Established | < 10 |
| Polymerizable dimethacrylate resin | 41637-38-1 | Not Established | < 10 |
| Polymerizable dimethacrylate resin | 109-16-0 | Not Established | < 5 |
| Polymerizable dimethacrylate resin | 868-77-9 | Not Established | < 10 |
| Polymerizable dimethacrylate resin | 1709-71-3 | Not Established | < 5 |

Other Information: Colorants are inorganic iron oxides.

## 3. Composition/Information on Ingredients – Catalyst Paste

| Hazardous Components | C.A.S. Number | Exposure Limits | % |
|---|---|---|---|
| Urethane Dimethacrylate Resin | 105883-40-7 | Not Established | < than 10 |
| Urethane Modified Bis-GMA Dimethacrylate Resin | 41637-38-1 | Not Established | < than 10 |
| Polymerizable Dimethacrylate Resins | 3290-92-4/109-16-0 | Not Established | < than 15 |
| Dipentaerythritol Pentaacrylate Phosphate | 87699-25-0 | Not Established | < than 10 |

## 4. First Aid Measures

| Routes of Exposure | First Aid Instructions | Immediate Medical Attention | Delayed Effects |
|---|---|---|---|
| Eye | Rinse opened eye for several minutes under running water.<br>If symptoms persist consult physician | Not Applicable | Not Applicable |
| Skin | Immediately wash with soap and water and rinse thoroughly | Not Applicable | Not Applicable |
| Inhalation | Not Applicable | Not Applicable | Not Applicable |
| Ingestion | Not Applicable | Not Applicable | Not Applicable |
| Mucosa | Rinse tissue for several minutes under running water.<br>If symptoms persist consult physician | Not Applicable | Not Applicable |
| Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically. | | | |

## 5. Fire Fighting Measures

| | | | |
|---|---|---|---|
| Flame Propagation or Burning Rate (for Solids) Not Applicable | Properties Contributing to Fire Intensity Not Applicable | Flammability Classification: Not Applicable | Other: Not Applicable |
| Extinguishing Media: $CO_2$, extinguishing powder, foam carbon dioxide or water spray. Fight larger fires with water spray or alcohol resistant foam. | | Extinguishing Media to Avoid: Water with full jet. | |
| Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices. | | | |
| Unusual Fire and Explosion Hazards: Formation of toxic, irritating gases is possible from the decomposition of the dimethacrylate resins. Product does not present an explosion hazard. | | | |

## 6. Accidental Release Measures

| | | |
|---|---|---|
| Containment Techniques: Material is a paste and as such will not flow. | | |
| Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation. | | |
| Evacuation Procedures: Not Applicable | Special Instructions: Not Applicable | Reporting Requirements: Not Applicable |

## 7. Handling and Storage

| |
|---|
| Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. |
| Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages. |

## 8. Exposure Control / Personal Protection



| | | |
|---|---|---|
| Occupational Exposure Limits: Not Applicable | | |
| Engineering Controls: Not Applicable | | |
| Individual Protection Measures | Personal Protective Equipment for Normal Use | Personal Protective Equipment for Emergencies |
| Eye/Face | Safety Glasses | Not Applicable |
| Skin | The glove material has to be impermeable and resistant to the product. | Not Applicable |
| Inhalation | Not Required | Not Applicable |
| Body Protection | Protective work clothing | Not Applicable |

## 9. Physical and Chemical Characteristics

| | | |
|---|---|---|
| Appearance: Creamy viscous paste. Multiple shades. | | Odor: Characteristic sweet acrylic ester odor. |
| Normal Physical State: High Viscosity Liquid (Paste) | | Melting Point: Not Applicable |
| Specific Gravity: 1.8-1.9 g/cm$^3$ | Solubility in Water: Not soluble | pH: Not Applicable |
| Vapor Pressure (mm Hg): Not Applicable | Vapor Density (AIR=1): Not Applicable | Evaporation Rate (Butyl Acetate =1): Not Applicable |
| Flashpoint Method: Not Applicable | Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable | Autoignition Temperature: Not Applicable, Product will not autoignite. |
| Other: Not Applicable | | |

## 10. Stability and Reactivity Data

| | |
|---|---|
| Incompatibility (Materials to Avoid): Strong Oxidizing materials. | |
| Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use. | |
| Hazardous Polymerization: ☐May Occur ☒May Not Occur | Conditions to Avoid: None known |
| Stability? ☒Stable ☐Unstable | Conditions to Avoid: None known |

## 11.Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:
Product is an irritant to the skin and mucous membranes. The unpolymerized product may be an irritant to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: Repeated or prolonged contact with the unpolymerized material may cause sensitization for persons allergic to acrylates and methacrylates. This product shows the following dangers according to internally approved calculation methods for composite materials: Irritant.

Emergency Overview Material is irritating to eyes, respiratory system and skin.

| Routes of Exposure | Signs and Symptoms | Single, Repeated, or Lifetime Exposure | Severity (Mild, Moderate, Severe) | Acute and Chronic Health Effect(s) | Target Organ(s) |
|---|---|---|---|---|---|
| Eye | Material can cause irritation. | Single | Moderate | Irritation and possible corneal damage | Not Applicable |
| Skin | Material may be an irritant | Single & Repeated | Moderate | Irritation or possible allergic response. Severe allergic response may result in breathing difficulties. | Not Applicable |
| Inhalation | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable |

| | | | | | |
|---|---|---|---|---|---|
| Ingestion | Material is not harmful if swallowed using clinically relevant quantities | Not Applicable | Mild | Not Applicable | Not Applicable |
| Mucosa | Material can cause irritation. | Single | Mild | Inflammation of the mucosa | Not Applicable |
| Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. Individuals with known sensitivity to methacrylates, acrylates, or urethane dimethacrylate resin used in Dental restorative products. | | | | | |
| Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory. | | | | | |
| Potential Environmental Effects Do not allow to enter sewers/ surface or ground water. | | | | | |
| NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 0 | | | | | |

## 12.Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.

## 13.Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations

Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

## 14.Transport Information

| | | |
|---|---|---|
| Regulated for Shipping: No. Not Regulated | DOT Shipping Name: Not Regulated | Packing Group: Not Applicable |
| Do Changes in Quantities, packaging, or shipment method change product classification? No | DOT Hazard Class: Not Applicable | UN Number: Not Applicable |

## 15.Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.

U.S. Federal Regulations: CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.

U.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California Proposition 65 list.

International Regulations: Canadian Environmental Protection Act:
This product is a medical device and not subject to chemical notification requirements.

European Community Labeling: Not a dangerous preparation.

European Inventory of New and Existing Chemicals Substances (EINECS):
This product is a medical device and not subject to chemical notification requirements.

Other: Not Applicable

## 16.Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex.
All components are synthetically produced; none are derived from animal products.
This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship.
The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

# 6. Safety Data Sheet – Multilink Automix (Ivoclar)



**Safety Data Sheet**
**according to HPR, Schedule 1**

Printing date 07/22/2019 Version number 7 Reviewed on 06/03/2019

## 1 Identification

· **Product identifier**

· **Trade name: Multilink Automix (Base)**

· **Application of the substance / the mixture**
Self-curing resin-based dental luting material with light-curing option

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102

· **Information department:** Quality Assurance / Regulatory Affairs
· **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

## 2 Hazard identification

· **Classification of the substance or mixture**

| | |
|---|---|
| Skin Irritation - Category 2 | H315 Causes skin irritation. |
| Eye Irritation - Category 2A | H319 Causes serious eye irritation. |
| Skin Sensitizer - Category 1 | H317 May cause an allergic skin reaction. |
| Specific Target Organ Toxicity - Single Exposure - Category 3 | H335 May cause respiratory irritation. |

· **Label elements**
· **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**
Bis-GMA
ytterbium trifluoride

(Contd. on page 2)

**Safety Data Sheet**
**according to HPR, Schedule 1**

Printing date 07/22/2019 Version number 7 Reviewed on 06/03/2019

**Trade name: Multilink Automix (Base)**

(Contd. of page 1)

2-hydroxyethyl methacrylate
2-dimethylaminoethyl methacrylate
· **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.
· **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wash thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of water.
Specific treatment (see on this label).
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Call a poison center/doctor if you feel unwell.
Take off contaminated clothing and wash it before reuse.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Store in a well-ventilated place. Keep container tightly closed.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.
· **Additional information:**
Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).
· **Classification system:**
· **NFPA ratings (scale 0 - 4)**




Health = 2
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

| | |
|---|---|
| HEALTH | 2 |
| FIRE | 0 |
| REACTIVITY | 0 |

Health = 2
Fire = 0
Reactivity = 0

* 
## 3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with nonhazardous additions.

| · **Dangerous components:** | | |
|---|---|---|
| CAS: 13760-80-0 | ytterbium trifluoride | ≥20-≤30% w/w * |
| CAS: 36425-15-7 | Bis-GMA | ≥10-≤13% w/w * |
| CAS: 868-77-9 | 2-hydroxyethyl methacrylate | 3-7% w/w * |
| CAS: 2867-47-2 | 2-dimethylaminoethyl methacrylate | ≥0.1-<1% w/w * |

* Actual concentration ranges are withheld as a trade secret.

CA

(Contd. on page 3)

**Safety Data Sheet**
**according to HPR, Schedule 1**

Printing date 07/22/2019 Version number 7 Reviewed on 06/03/2019

**Trade name: Multilink Automix (Base)**

(Contd. of page 2)

## 4 First aid measures

· **Description of first aid measures**
· **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** Rinse with water.
· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

## 5 Firefighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

## 6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Not required.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

## 7 Handling and storage

· **Handling:**
· **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Protect from exposure to the light.
Protect from heat and direct sunlight.
Keep receptacle tightly sealed.

(Contd. on page 4)

**Safety Data Sheet**
**according to HPR, Schedule 1**

Printing date 07/22/2019 Version number 7 Reviewed on 06/03/2019

**Trade name: Multilink Automix (Base)**

(Contd. of page 3)

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

## 8 Exposure controls/ Personal protection

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

· **Control parameters**
· **Components with limit 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 creation were used as basis.

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the eyes and skin.
· **Breathing equipment:** Not required.
· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
After use of gloves apply skin-cleaning agents and skin cosmetics.
· **Material of gloves**
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Not suitable are gloves made of the following materials:**
Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
· **Eye protection:** Safety glasses

## 9 Physical and chemical properties

| | |
|---|---|
| · **Information on basic physical and chemical properties** | |
| · **General Information** | |
| · **Appearance:** | |
| **Form:** | Pasty |
| **Color:** | According to product specification |
| · **Odor:** | Characteristic |
| · **Odor threshold:** | Not determined. |
| · **pH-value:** | Not determined. |
| · **Change in condition** | |
| **Melting point/Melting range:** | Undetermined. |
| **Boiling point/Boiling range:** | Undetermined. |
| · **Flash point:** | Not applicable. |

(Contd. on page 5)

**Safety Data Sheet**
**according to HPR, Schedule 1**

Printing date 07/22/2019 Version number 7 Reviewed on 06/03/2019

**Trade name: Multilink Automix (Base)**

(Contd. of page 4)

| | |
|---|---|
| · **Flammability (solid, gaseous):** | Not applicable. |
| · **Auto igniting:** | Product is not selfigniting. |
| · **Danger of explosion:** | Product does not present an explosion hazard. |
| · **Explosion limits:** | |
| **Lower:** | Not determined. |
| **Upper:** | Not determined. |
| · **Vapor pressure:** | Not determined. |
| · **Density at 20 °C:** | 2.05 g/cm³ |
| · **Relative density** | Not determined. |
| · **Vapor density** | Not determined. |
| · **Evaporation rate** | Not determined. |
| · **Solubility in / Miscibility with** | |
| **Water:** | Nearly insoluble. |
| · **Partition coefficient (n-octanol/water):** | Not determined. |
| · **Viscosity:** | |
| **Dynamic:** | Not determined. |
| **Kinematic:** | Not determined. |
| · **Other information** | No further relevant information available. |

## 10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
Photoreactive (Danger of polymerization).
Stable under normal handling and storage conditions.
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** None under normal conditions of storage and use.

## 11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
· **Sensitization:** Sensitization possible through skin contact.
· **Additional toxicological information:** No further relevant information available.

· **Carcinogenic categories**

| · **NTP (National Toxicology Program)** |
|---|
| None of the ingredients is listed. |



(Contd. on page 6)

**Safety Data Sheet**
**according to HPR, Schedule 1**

Printing date 07/22/2019 Version number 7 Reviewed on 06/03/2019

**Trade name: Multilink Automix (Base)**

(Contd. of page 6)

## 15 Regulatory information

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

· **Sara**

| · **Section 355 (extremely hazardous substances):** |
|---|
| None of the ingredients is listed. |

| · **Section 313 (Specific toxic chemical listings):** |
|---|
| None of the ingredients is listed. |

| · **TSCA (Toxic Substances Control Act):** | |
|---|---|
| CAS: 13760-80-0 | ytterbium trifluoride |
| CAS: 1565-94-2 | Bis-GMA |
| CAS: 868-77-9 | 2-hydroxyethyl methacrylate |
| CAS: 2867-47-2 | 2-dimethylaminoethyl methacrylate |

· **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**
Bis-GMA
ytterbium trifluoride
2-hydroxyethyl methacrylate
2-dimethylaminoethyl methacrylate
· **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.
· **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wash thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of water.
Specific treatment (see on this label).
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Call a poison center/doctor if you feel unwell.
Take off contaminated clothing and wash it before reuse.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Store in a well-ventilated place. Keep container tightly closed.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 8)

**Safety Data Sheet**
**according to HPR, Schedule 1**

Printing date 07/22/2019 Version number 7 Reviewed on 06/03/2019

**Trade name: Multilink Automix (Base)**

(Contd. of page 7)

· **National regulations:**
· **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16 Other information

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

· **Date of the latest revision of the safety data sheet** 07/22/2019 / 6
· **Abbreviations and acronyms:**
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
· *** Data compared to the previous version altered.**

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

*Printing date 22.07.2019* *Version number 6* *Revision: 03.06.2019*

* 

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

· **1.1 Product identifier**

· **Trade name: Multilink Automix (Catalyst)**

· **Article number:** NGC
· **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**
Self-curing resin-based dental luting material with light-curing option

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Ivoclar Vivadent AG
Bendererstrasse 2
9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35
Fax: +423 235 33 60

· **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
· **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

## SECTION 2: Hazards identification

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

| | |
|---|---|
| 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. |
| Aquatic Chronic 4 | H413 May cause long lasting harmful effects to aquatic life. |

· **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**



GHS07

· **Signal word** Warning

· **Hazard-determining components of labelling:**
urethane dimethacrylate
ytterbium trifluoride
2-hydroxyethyl methacrylate
dibenzoyl peroxide
· **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

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H335 May cause respiratory irritation.
H413 May cause long lasting harmful effects to aquatic life.
· **Precautionary statements**
P263 Avoid contact during pregnancy and while nursing.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
· **Additional information:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.
· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

* 

## SECTION 3: Composition/information on ingredients

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

| · **Dangerous components:** | | |
|---|---|---|
| CAS: 13760-80-0<br>EINECS: 237-354-2 | ytterbium trifluoride<br>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | 10-<25% |
| CAS: 41637-38-1<br>Reg.nr.: 01-2119980659-17-xxxx | Bis-EMA<br>Aquatic Chronic 4, H413 | 10-<25% |
| CAS: 72869-86-4<br>EINECS: 276-957-5 | urethane dimethacrylate<br>Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412 | 3-<10% |
| CAS: 868-77-9<br>EINECS: 212-782-2 | 2-hydroxyethyl methacrylate<br>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | 3-<10% |
| CAS: 94-36-0<br>EINECS: 202-327-6 | dibenzoyl peroxide<br>Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317 | 1-<2.5% |

· **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 and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** Rinse with water.
· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist 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, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **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.

## SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
· **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **6.3 Methods and material for containment and cleaning up:** Pick up 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 disposal information.

## SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
· **Information about fire - and explosion protection:** No special measures required.

· **7.2 Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Protect from exposure to the light.
Protect from heat and direct sunlight.
Keep container tightly sealed.
· **7.3 Specific end use(s)** No further relevant information available.

## SECTION 8: Exposure controls/personal protection

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

· **8.1 Control parameters**
· **Ingredients with limit values that require monitoring at the workplace:**
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 valid during the making were used as basis.

· **8.2 Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the eyes and skin.
· **Respiratory protection:** Not required.

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· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
After use of gloves apply skin-cleaning agents and skin cosmetics.

· **Material of gloves**
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Safety glasses

## SECTION 9: Physical and chemical properties

| | |
|---|---|
| · **9.1 Information on basic physical and chemical properties** | |
| · **General Information** | |
| · **Appearance:** | |
| **Form:** | Pasty |
| **Colour:** | According to product specification |
| · **Odour:** | Characteristic |
| · **Odour threshold:** | Not determined. |
| · **pH-value:** | Not determined. |
| · **Change in condition** | |
| **Melting point/freezing point:** | Undetermined. |
| **Initial boiling point and boiling range:** | Undetermined. |
| · **Flash point:** | Not applicable. |
| · **Flammability (solid, gas):** | Not applicable. |
| · **Auto-ignition temperature:** | Product is not selfigniting. |
| · **Explosive properties:** | Product does not present an explosion hazard. |
| · **Explosion limits:** | |
| **Lower:** | Not determined. |
| **Upper:** | Not determined. |
| · **Vapour pressure:** | Not determined. |
| · **Density at 20 °C:** | 2.05 g/cm³ |
| · **Relative density** | Not determined. |
| · **Vapour density** | Not determined. |
| · **Evaporation rate** | Not determined. |
| · **Solubility in / Miscibility with** | |
| **water:** | Nearly insoluble. |
| · **Partition coefficient: n-octanol/water:** | Not determined. |
| · **Viscosity:** | |
| **Dynamic:** | Not determined. |
| **Kinematic:** | Not determined. |

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· **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** Stable under normal handling and storage conditions.
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known.
· **10.4 Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

* 

## SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.
· **Skin corrosion/irritation**
Causes skin irritation.
· **Serious eye damage/irritation**
Causes serious eye irritation.
· **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
· **Additional toxicological information:** No further relevant information available.
· **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:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects** No further relevant information available.



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## SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

| · **European waste catalogue** | |
|---|---|
| 18 01 06* | chemicals consisting of or containing dangerous substances |

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

## SECTION 14: Transport information

| | |
|---|---|
| · **14.1 UN-Number**<br>· **ADR/RID/ADN, ADN, IMDG, IATA** | Void |
| · **14.2 UN proper shipping name**<br>· **ADR/RID/ADN, ADN, IMDG, IATA** | Void |
| · **14.3 Transport hazard class(es)**<br>· **ADR/RID/ADN, ADN, IMDG, IATA**<br>· **Class** | Void |
| · **14.4 Packing group**<br>· **ADR/RID/ADN, IMDG, IATA** | Void |
| · **14.5 Environmental hazards:**<br>· **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:** | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · **UN "Model Regulation":** | Void |

* 

## SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **National regulations:**
· **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

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

· **Relevant phrases**
H241 Heating may cause a fire or explosion.

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*H315 Causes skin irritation.*
*H317 May cause an allergic skin reaction.*
*H319 Causes serious eye irritation.*
*H335 May cause respiratory irritation.*
*H412 Harmful to aquatic life with long lasting effects.*
*H413 May cause long lasting harmful effects to aquatic life.*

· **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)*
*PBT: Persistent, Bioaccumulative and Toxic*
*vPvB: very Persistent and very Bioaccumulative*
*Org. Perox. B: Organic peroxides – Type B*
*Skin Irrit. 2: Skin corrosion/irritation – Category 2*
*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 Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3*
*Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4*

· ***Data compared to the previous version altered.***

7. Safety Data Sheet – Variolink II (Ivoclar)



ivoclar vivadent:

**Safety Data Sheet**
**acc. to OSHA HCS**

*Printing date 09/19/2013* *Version number 6* *Reviewed on 09/19/2013*

## 1 Identification

· **Product identifier**

· **Trade name: Variolink II (Base)**

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
· **Application of the substance / the preparation** Dual-curing/light-curing resin based dental luting material

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102

· **Information department:** Quality Assurance / Regulatory Affairs
· **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General MSDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

## 2 Hazard(s) identification

· **Classification of the substance or mixture**

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Irritant
Irritating to eyes. May cause sensitisation by skin contact.
· **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· **Label elements**

· **Labelling according to EU guidelines:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· **Code letter and hazard designation of product:**



Irritant

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**Trade name: Variolink II (Base)**

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· **Hazard-determining components of labeling:**
triethyleneglycol dimethacrylate
urethane dimethacrylate

· **Risk phrases:**
Irritating to eyes.
May cause sensitisation by skin contact.

· **Safety phrases:**
Avoid contact with skin.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Wear suitable gloves.
This material and its container must be disposed of as hazardous waste.
· **Classification system:**
· **NFPA ratings (scale 0 - 4)**




Health = 1
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**




Health = 1
Fire = 0
Reactivity = 0

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

## 3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with nonhazardous additions.

| · **Dangerous components:** | | |
|---|---|---|
| 1565-94-2 | Bis-GMA | 10-25% |
| 72869-86-4 | urethane dimethacrylate | 2.5-10% |
| 109-16-0 | triethyleneglycol dimethacrylate | 2.5-10% |

## 4 First-aid measures

· **Description of first aid measures**
· **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** Rinse with water.
· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:** If symptoms persist consult doctor.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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**Trade name: Variolink II (Base)**

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· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

## 5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

## 6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Not required.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

## 7 Handling and storage

· **Handling:**
· **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Protect from exposure to the light.
Protect from heat and direct sunlight.
Keep receptacle tightly sealed.
· **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

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

· **Control parameters**
· **Components with limit 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 creation were used as basis.

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**Trade name: Variolink II (Base)**

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· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
Usual hygienic measures for dental practice.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
· **Breathing equipment:** Not required.
· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· **Material of gloves**
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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses

## 9 Physical and chemical properties

| | |
|---|---|
| · **Information on basic physical and chemical properties** | |
| · **General Information** | |
| · **Appearance:** | |
| **Form:** | Pasty |
| **Color:** | According to product specification |
| · **Odor:** | Characteristic |
| · **Odour threshold:** | Not determined. |
| · **pH-value:** | Not applicable. |
| · **Change in condition** | |
| **Melting point/Melting range:** | Undetermined. |
| **Boiling point/Boiling range:** | Undetermined. |
| · **Flash point:** | Not applicable. |
| · **Flammability (solid, gaseous):** | Not determined. |
| · **Auto igniting:** | Product is not selfigniting. |
| · **Danger of explosion:** | Product does not present an explosion hazard. |
| · **Explosion limits:** | |
| **Lower:** | Not determined. |
| **Upper:** | Not determined. |

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**Trade name: Variolink II (Base)**

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| | |
|---|---|
| · **Vapor pressure:** | Not applicable. |
| · **Density at 20 °C (68 °F):** | 2.23 g/cm³ (18.609 lbs/gal) |
| · **Relative density** | Not determined. |
| · **Vapour density** | Not applicable. |
| · **Evaporation rate** | Not applicable. |
| · **Solubility in / Miscibility with Water:** | Nearly insoluble. |
| · **Partition coefficient (n-octanol/water):** | Not determined. |
| · **Viscosity:** | |
| **Dynamic:** | Not applicable. |
| **Kinematic:** | Not applicable. |
| · **Other information** | No further relevant information available. |

## 10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
Stable under normal handling and storage conditions.
Photoreactive (Danger of polymerization).
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** None under normal conditions of storage and use.

## 11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** Irritating effect.
· **Sensitization:** Sensitization possible through skin contact.
· **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

· **Carcinogenic categories**

| · **NTP (National Toxicology Program)** |
|---|
| None of the ingredients is listed. |

## 12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.

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**Trade name: Variolink II (Base)**

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· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

## 13 Disposal considerations

· **Waste treatment methods**
· **Recommendation:**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

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

## 14 Transport information

| | |
|---|---|
| · **UN-Number** | |
| · **DOT, ADR, ADN, IMDG, IATA** | Void |
| · **UN proper shipping name** | |
| · **DOT, ADR, ADN, IMDG, IATA** | Void |
| · **Transport hazard class(es)** | |
| · **DOT, ADR, ADN, IMDG, IATA** | |
| · **Class** | Void |
| · **Packing group** | |
| · **DOT, ADR, IMDG, IATA** | Void |
| · **Environmental hazards:** | |
| · **Marine pollutant:** | No |
| · **Special precautions for user** | Not applicable. |
| · **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** | Not applicable. |

## 15 Regulatory information

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

· **Sara**

· **Section 355 (extremely hazardous substances):**
None of the ingredients is listed.

(Contd. on page 7)

**Safety Data Sheet**
**acc. to OSHA HCS**

*Printing date 09/19/2013* *Version number 6* *Reviewed on 09/19/2013*

**Trade name: Variolink II (Base)**

(Contd. of page 6)

· **Section 313 (Specific toxic chemical listings):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**
All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

| | | |
|---|---|---|
| 13760-80-0 | ytterbium trifluoride | A4 |

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Product related hazard informations:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· **Hazard symbols:**



Irritant

· **Hazard-determining components of labeling:**
triethyleneglycol dimethacrylate
urethane dimethacrylate

· **Risk phrases:**
Irritating to eyes.
May cause sensitisation by skin contact.

· **Safety phrases:**
Avoid contact with skin.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Wear suitable gloves.
This material and its container must be disposed of as hazardous waste.

(Contd. on page 8)

**Safety Data Sheet**
**acc. to OSHA HCS**

*Printing date 09/19/2013* *Version number 6* *Reviewed on 09/19/2013*

**Trade name: Variolink II (Base)**

(Contd. of page 7)

· **National regulations:**
· **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16 Other information

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

**Safety Data Sheet**
**acc. to OSHA HCS**

*Printing date 09/19/2013* *Version number 6* *Reviewed on 09/19/2013*

**Trade name: Variolink II (Catalyst)**

(Contd. of page 1)

· **Hazard-determining components of labeling:**
triethyleneglycol dimethacrylate
urethane dimethacrylate

· **Risk phrases:**
Irritating to eyes and skin.
May cause sensitisation by skin contact.

· **Safety phrases:**
Avoid contact with skin.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Wear suitable gloves.
This material and its container must be disposed of as hazardous waste.
· **Classification system:**
· **NFPA ratings (scale 0 - 4)**




Health = 1
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**




Health = 1
Fire = 0
Reactivity = 0

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

## 3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with nonhazardous additions.

| · **Dangerous components:** | | |
|---|---|---|
| 1565-94-2 | Bis-GMA | 50-100% |
| 72869-86-4 | urethane dimethacrylate | 2.5-10% |
| 109-16-0 | triethyleneglycol dimethacrylate | 2.5-10% |
| 94-36-0 | dibenzoyl peroxide | ≤ 2.5% |

## 4 First-aid measures

· **Description of first aid measures**
· **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** Rinse with water.
· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:** If symptoms persist consult doctor.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

(Contd. on page 3)

**Safety Data Sheet**
**acc. to OSHA HCS**

*Printing date 09/19/2013* *Version number 6* *Reviewed on 09/19/2013*

**Trade name: Variolink II (Catalyst)**

(Contd. of page 2)

· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

## 5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

## 6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Not required.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

## 7 Handling and storage

· **Handling:**
· **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Store in a cool place.
Protect from exposure to the light.
Protect from heat and direct sunlight.
Keep receptacle tightly sealed.
· **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

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

· **Control parameters**
· **Components with limit 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 creation were used as basis.

(Contd. on page 4)

**Safety Data Sheet**
**acc. to OSHA HCS**

Printing date 09/19/2013 Version number 6 Reviewed on 09/19/2013

**Trade name: Variolink II (Catalyst)**

(Contd. of page 6)

· **Section 313 (Specific toxic chemical listings):**

| | |
|---|---|
| 94-36-0 | dibenzoyl peroxide |

· **TSCA (Toxic Substances Control Act):**
All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

| | | |
|---|---|---|
| 13760-80-0 | ytterbium trifluoride | A4 |
| 94-36-0 | dibenzoyl peroxide | A4 |

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Product related hazard informations:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· **Hazard symbols:**



Irritant

· **Hazard-determining components of labeling:**
triethyleneglycol dimethacrylate
urethane dimethacrylate

· **Risk phrases:**
Irritating to eyes and skin.
May cause sensitisation by skin contact.

· **Safety phrases:**
Avoid contact with skin.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Wear suitable gloves.
This material and its container must be disposed of as hazardous waste.

(Contd. on page 8)

**Safety Data Sheet**
**acc. to OSHA HCS**

Printing date 09/19/2013 Version number 6 Reviewed on 09/19/2013

**Trade name: Variolink II (Catalyst)**

(Contd. of page 7)

· **National regulations:**
· **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16 Other information

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

8. Safety Data Sheet – NX3 Nexus (Kerr)

# SAFETY DATA SHEET

NX3 Nexus® Third Generation Dual Cure Base and Catalyst

## Section 1. Identification

**GHS product identifier** : NX3 Nexus® Third Generation Dual Cure Base and Catalyst

**Other means of identification** : Not available.

**Product type** : Paste.

**Relevant identified uses of the substance or mixture and uses advised against**

**Product use** : Dental product: Permanent cement

**Area of application** : Professional applications.

**Manufacturer** : **Kerr Corporation**
1717 West Collins Avenue
Orange, CA 92867-5422
Telephone no.: 1-800-KERR-123

**e-mail address of person responsible for this SDS** : edwin.varela@kavokerrgroup.com

**Emergency telephone number (with hours of operation)** : CHEMTREC® (24 hours) U.S. : 1-800-424-9300 International: +1-703-527-3887

## Section 2. Hazards identification

**OSHA/HCS status** : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Health effects are based on the uncured material.

**Classification of the substance or mixture** : SKIN IRRITATION - Category 2
EYE IRRITATION - Category 2A
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 43%

**GHS label elements**

**Hazard pictograms** :



**Signal word** : Warning

**Hazard statements** : Causes serious eye irritation.
Causes skin irritation.
May cause respiratory irritation.

**Precautionary statements**



**United States**

## Section 2. Hazards identification

**Prevention** : Wear protective gloves. Wear eye or face protection. Use only outdoors or in a well-ventilated area. Avoid breathing vapor. Wash hands thoroughly after handling.

**Response** : IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or physician if you feel unwell. IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.

**Storage** : Store locked up.

**Disposal** : Dispose of contents and container in accordance with all local, regional, national and international regulations.

**Hazards not otherwise classified** : None known.

## Section 3. Composition/information on ingredients

**Substance/mixture** : Mixture

**Other means of identification** : Not available.

**CAS number/other identifiers**

**CAS number** : Not applicable.

**Product code** : Not available.

| Ingredient name | Other names | % | CAS number |
|---|---|---|---|
| Poly(oxy-1,2-ethanediyl), α,α'-[(1-methylethylidene)di-4,1-phenylene]bis[ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]- | Not available. | 5-10 | 41637-38-1 |
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate | 7,7,9(or 7,9,9)-trimethyl-4, 13-dioxo-3,14-dioxa-5, 12-diazahexadecane-1, 16-diyl bismethacrylate | 5-10 | 72869-86-4 |
| 2,2'-ethylenedioxydiethyl dimethacrylate | 2,2'-ethylenedioxydiethyl dimethacrylate | 5-10 | 109-16-0 |
| 2-hydroxyethyl methacrylate | 2-hydroxyethyl methacrylate | 5-10 | 868-77-9 |
| 3-trimethoxysilylpropyl methacrylate | 3-trimethoxysilylpropyl methacrylate | 0.1-1 | 2530-85-0 |
| 1,1,3,3-tetramethylbutyl hydroperoxide | 1,1,3,3-tetramethylbutyl hydroperoxide | 0.1-1 | 5809-08-5 |

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

**There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health and hence require reporting in this section.**

# Section 4. First aid measures

## Description of necessary first aid measures

**Eye contact** : No special measures are required. In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if symptoms occur.

**Inhalation** : No special measures required. If inhaled, remove to fresh air. Get medical attention if symptoms occur.

**Skin contact** : No special measures required. In case of contact, immediately flush skin with plenty of water. Get medical attention if symptoms occur.

**Ingestion** : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Get medical attention if adverse health effects persist or are severe.

## Most important symptoms/effects, acute and delayed

### Potential acute health effects

**Eye contact** : Causes serious eye irritation.

**Inhalation** : May cause respiratory irritation.

**Skin contact** : Causes skin irritation.

**Ingestion** : No known significant effects or critical hazards.

### Over-exposure signs/symptoms

**Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness

**Inhalation** : Adverse symptoms may include the following:
respiratory tract irritation
coughing

**Skin contact** : Adverse symptoms may include the following:
irritation
redness

**Ingestion** : No specific data.

## Indication of immediate medical attention and special treatment needed, if necessary

**Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

**Specific treatments** : No specific treatment.

**Protection of first-aiders** : In case of major fire and large quantities: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

**See toxicological information (Section 11)**

## Section 5. Fire-fighting measures

**Extinguishing media**

**Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.

**Unsuitable extinguishing media** : Do not use water jet.

**Specific hazards arising from the chemical** : In a fire or if heated, a pressure increase will occur and the container may burst.

**Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
phosphorus oxides
halogenated compounds
metal oxide/oxides

**Special protective actions for fire-fighters** : In case of major fire and large quantities: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

**Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**

**For non-emergency personnel** : Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely

**For emergency responders** : Low release. See also the information in "For non-emergency personnel".

**Environmental precautions** : Low release. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

**Methods and materials for containment and cleaning up**

**Small spill** : Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

**Large spill** : Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

## Section 7. Handling and storage

**Precautions for safe handling**

**Protective measures** : No special measures are required for small quantities under normal and intended conditions of product use. For professional use only. Put on appropriate personal protective equipment (see Section 8). Handle with care and dispose in a safe manner.

**Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

## Section 7. Handling and storage

**Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

## Section 8. Exposure controls/personal protection

**Control parameters**

**Occupational exposure limits**

None.

**Appropriate engineering controls** : No special measures are required for small quantities under normal and intended conditions of product use.

**Environmental exposure controls** : No special measures are required for small quantities under normal and intended conditions of product use.

**Individual protection measures**

**Hygiene measures** : No special measures are required for small quantities under normal and intended conditions of product use.

**Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

**Skin protection**

**Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

**Body protection** : No special measures are required for small quantities under normal and intended conditions of product use.

**Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Respiratory protection** : No special measures are required for small quantities under normal and intended conditions of product use.

## Section 9. Physical and chemical properties

**Appearance**

**Physical state** : Liquid. [Paste.]

**Color** : Various

**Odor** : Fruity ester-like

**Odor threshold** : Not available.

**pH** : Not available.

## Section 9. Physical and chemical properties

| | | |
|---|---|---|
| **Melting point** | : | Not available. |
| **Boiling point** | : | Not available. |
| **Flash point** | : | Not available. |
| **Evaporation rate** | : | Not available. |
| **Flammability (solid, gas)** | : | Not applicable. |
| **Lower and upper explosive (flammable) limits** | : | Not available. |
| **Vapor pressure** | : | Not available. |
| **Vapor density** | : | Not available. |
| **Relative density** | : | 2 to 2.5 [Water = 1] |
| **Solubility** | : | Insoluble in the following materials: cold water and hot water. |
| **Solubility in water** | : | Not available. |
| **Partition coefficient: n-octanol/water** | : | Not available. |
| **Auto-ignition temperature** | : | Not available. |
| **Decomposition temperature** | : | Not available. |
| **SADT** | : | Not available. |
| **Viscosity** | : | Not available. |

## Section 10. Stability and reactivity

| | | |
|---|---|---|
| **Reactivity** | : | No specific test data related to reactivity available for this product or its ingredients. |
| **Chemical stability** | : | The product is stable. |
| **Possibility of hazardous reactions** | : | Hazardous reactions or instability may occur under certain conditions of storage or use.<br>Hazardous polymerization may occur under certain conditions of storage or use. |
| **Conditions to avoid** | : | Keep away from heat and direct sunlight. Heat can cause polymerization with rapid release of energy. |
| **Incompatible materials** | : | Reactive or incompatible with the following materials: oxidizing materials and reducing materials.<br>Amines. Peroxide. |
| **Hazardous decomposition products** | : | Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

## Section 11. Toxicological information

**Information on toxicological effects**

**Acute toxicity**

## Section 11. Toxicological information

| Product/ingredient name | Result | Species | Dose | Exposure |
|---|---|---|---|---|
| 2,2'-ethylenedioxydiethyl dimethacrylate | LD50 Oral | Rat | 10837 mg/kg | - |
| 2-hydroxyethyl methacrylate | LD50 Oral | Rat | 4230 mg/kg | - |
| 3-trimethoxysilylpropyl methacrylate | LD50 Oral | Rat | 23504 mg/kg | - |

**Conclusion/Summary** : Based on the criteria of the protocol, this product is considered non-cytotoxic per ISO 10993-5.

**Irritation/Corrosion**

| Product/ingredient name | Result | Species | Score | Exposure | Observation |
|---|---|---|---|---|---|
| 3-trimethoxysilylpropyl methacrylate | Eyes - Mild irritant | Rabbit | - | 24 hours 500 milligrams | - |
| | Skin - Mild irritant | Rabbit | - | 24 hours 500 milligrams | - |

**Sensitization**

Not available.

**Conclusion/Summary**

**Skin** : Kligman score: Grade I (weak sensitizer)

**Mutagenicity**

Not available.

**Carcinogenicity**

Not available.

**Reproductive toxicity**

Not available.

**Teratogenicity**

Not available.

**Specific target organ toxicity (single exposure)**

| Name | Category | Route of exposure | Target organs |
|---|---|---|---|
| Poly(oxy-1,2-ethanediyl), α,α'-[(1-methylethylidene)di-4,1-phenylene]bis[ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]- | Category 3 | Not applicable. | Respiratory tract irritation |
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5, 12-diazahexadecane-1,16-diyl bismethacrylate | Category 3 | Not applicable. | Respiratory tract irritation |
| 2,2'-ethylenedioxydiethyl dimethacrylate | Category 3 | Not applicable. | Respiratory tract irritation |
| 2-hydroxyethyl methacrylate | Category 3 | Not applicable. | Respiratory tract irritation |
| 1,1,3,3-tetramethylbutyl hydroperoxide | Category 3 | Not applicable. | Respiratory tract irritation |

**Specific target organ toxicity (repeated exposure)**

Not available.

**Aspiration hazard**

Not available.

## Section 11. Toxicological information

**Information on the likely routes of exposure** : Routes of entry anticipated: Oral, Dermal, Inhalation.

**Potential acute health effects**

**Eye contact** : Causes serious eye irritation.

**Inhalation** : May cause respiratory irritation.

**Skin contact** : Causes skin irritation.

**Ingestion** : No known significant effects or critical hazards.

**Symptoms related to the physical, chemical and toxicological characteristics**

**Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness

**Inhalation** : Adverse symptoms may include the following:
respiratory tract irritation
coughing

**Skin contact** : Adverse symptoms may include the following:
irritation
redness

**Ingestion** : No specific data.

**Delayed and immediate effects and also chronic effects from short and long term exposure**

**Short term exposure**

**Potential immediate effects** : Not available.

**Potential delayed effects** : Not available.

**Long term exposure**

**Potential immediate effects** : Not available.

**Potential delayed effects** : Not available.

**Potential chronic health effects**

Not available.

**General** : No known significant effects or critical hazards.

**Carcinogenicity** : No known significant effects or critical hazards.

**Mutagenicity** : No known significant effects or critical hazards.

**Teratogenicity** : No known significant effects or critical hazards.

**Developmental effects** : No known significant effects or critical hazards.

**Fertility effects** : No known significant effects or critical hazards.

**Numerical measures of toxicity**

**Acute toxicity estimates**

| Route | ATE value |
|---|---|
| Oral | 53278.7 mg/kg |

## Section 11. Toxicological information

## Section 12. Ecological information

### Toxicity

| Product/ingredient name | Result | Species | Exposure |
|---|---|---|---|
| 2-hydroxyethyl methacrylate | Acute LC50 227000 µg/l Fresh water | Fish - Pimephales promelas - Juvenile (Fledgling, Hatchling, Weanling) | 96 hours |

### Persistence and degradability

| Product/ingredient name | Test | Result | Dose | Inoculum |
|---|---|---|---|---|
| 2-hydroxyethyl methacrylate | 301C Ready Biodegradability - Modified MITI Test (I) | 92 to 100 % - 14 days | - | - |

| Product/ingredient name | Aquatic half-life | Photolysis | Biodegradability |
|---|---|---|---|
| 2-hydroxyethyl methacrylate | - | - | Readily |

### Bioaccumulative potential

| Product/ingredient name | $LogP_{ow}$ | BCF | Potential |
|---|---|---|---|
| Poly(oxy-1,2-ethanediyl), α,α'-[(1-methylethylidene)di-4,1-phenylene]bis[ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]- | 3.43 to 5.62 | 2372 | high |
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate | 3 | - | low |
| 2,2'-ethylenedioxydiethyl dimethacrylate | 1.88 | - | low |
| 2-hydroxyethyl methacrylate | 0.42 | - | low |
| 3-trimethoxysilylpropyl methacrylate | 2.1 | - | low |
| 1,1,3,3-tetramethylbutyl hydroperoxide | 2.9 | - | low |

### Mobility in soil

**Soil/water partition coefficient ($K_{OC}$)** : Not available.

**Other adverse effects** : No known significant effects or critical hazards.

## Section 13. Disposal considerations

**Disposal methods** : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

## Section 14. Transport information

| | DOT Classification | IMDG | IATA |
|---|---|---|---|
| **UN number** | Not regulated. | Not regulated. | Not regulated. |
| **UN proper shipping name** | - | - | - |
| **Transport hazard class(es)** | - | - | - |
| **Packing group** | - | - | - |
| **Environmental hazards** | No. | No. | No. |
| **Additional information** | - | - | - |

**Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** : Not available.

## Section 15. Regulatory information

**U.S. Federal regulations** : **TSCA 8(a) PAIR**: mequinol

**United States inventory (TSCA 8b)**: All components are listed or exempted.

**Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)** : Listed

**Clean Air Act Section 602 Class I Substances** : Not listed

**Clean Air Act Section 602 Class II Substances** : Not listed

**DEA List I Chemicals (Precursor Chemicals)** : Not listed

**DEA List II Chemicals (Essential Chemicals)** : Not listed

**SARA 302/304**

# Section 15. Regulatory information

## Composition/information on ingredients

| Name | % | EHS | SARA 302 TPQ | | SARA 304 RQ | |
|---|---|---|---|---|---|---|
| | | | (lbs) | (gallons) | (lbs) | (gallons) |
| ethylene oxide | <0.0106 | Yes. | 1000 | - | 10 | - |

**SARA 304 RQ** : 104821.8 lbs / 47589.1 kg [5587.4 gal / 21150.7 L]

## SARA 311/312

**Classification** : Immediate (acute) health hazard

## Composition/information on ingredients

| Name | % | Fire hazard | Sudden release of pressure | Reactive | Immediate (acute) health hazard | Delayed (chronic) health hazard |
|---|---|---|---|---|---|---|
| Poly(oxy-1,2-ethanediyl), α,α'-[(1-methylethylidene)di-4,1-phenylene]bis[ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]- | 5-10 | No. | No. | No. | Yes. | No. |
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate | 5-10 | No. | No. | Yes. | Yes. | No. |
| 2,2'-ethylenedioxydiethyl dimethacrylate | 5-10 | Yes. | No. | No. | Yes. | No. |
| 2-hydroxyethyl methacrylate | 5-10 | No. | No. | No. | Yes. | No. |
| 3-trimethoxysilylpropyl methacrylate | 0.1-1 | No. | No. | No. | Yes. | No. |
| 1,1,3,3-tetramethylbutyl hydroperoxide | 0.1-1 | No. | No. | Yes. | Yes. | No. |

## SARA 313

Not applicable.

## State regulations

**Massachusetts** : The following components are listed: MINERAL WOOL FIBER

**New York** : None of the components are listed.

**New Jersey** : The following components are listed: FLUORIDES

**Pennsylvania** : None of the components are listed.

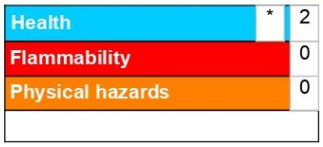
## California Prop. 65

**WARNING:** This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm. This product may contain trace amounts of the compound listed below.

| Ingredient name | Cancer | Reproductive | No significant risk level | Maximum acceptable dosage level |
|---|---|---|---|---|
| ethylene oxide | Yes. | Yes. | Yes. | Yes. |

## Section 16. Other information

**Hazardous Material Information System (U.S.A.)**




**Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks Although HMIS® ratings are not required on SDSs under 29 CFR 1910. 1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.**

**The customer is responsible for determining the PPE code for this material.**

**National Fire Protection Association (U.S.A.)**




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**Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.**

**History**

| | | |
|---|---|---|
| **Date of issue/Date of revision** | : | 05/15/2015 |
| **Date of previous issue** | : | No previous validation |
| **Version** | : | 1 |
| **Key to abbreviations** | : | ATE = Acute Toxicity Estimate<br>BCF = Bioconcentration Factor<br>GHS = Globally Harmonized System of Classification and Labelling of Chemicals<br>IATA = International Air Transport Association<br>IBC = Intermediate Bulk Container<br>IMDG = International Maritime Dangerous Goods<br>LogPow = logarithm of the octanol/water partition coefficient<br>MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)<br>UN = United Nations |
| **References** | : | HCS (U.S.A.)- Hazard Communication Standard<br>International transport regulations |

**Indicates information that has changed from previously issued version.**

**Notice to reader**

## Section 16. Other information

**To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.**
**Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.**

# 9. Safety Data Sheet – Maxcem Elite (Kerr)



**SAFETY DATA SHEET**

## Section 1. Product And Company Identification

**Product Name: Maxcem Elite**
**Product Use:** Dental product: Permanent cement

**Manufacturer:** Kerr Corporation
1717 W. Collins Ave.
Orange, CA 92867-5422
U.S.A.

**Information Phone Number**: 1-800-841-1428 (Customer Service)

**Chemical Emergency Phone Number** (Chemical Spills, Leaks, Fire, Exposure or Accident only):
CHEMTREC 1-800-424-9300 (in the US) 1-703-527-3887 (Outside the US)

**SDS Date of Preparation/Revision:** April 12, 2019

## Section 2. Hazards Identification

**GHS Classification:**
Skin Irritation Category 2
Eye Irritation Category 2A
Specific Target Organ Toxicity Single Exposure Category 3

**Label Elements:**
Warning!



**Hazard Phrases**
Causes skin irritation.
Causes serious eye irritation.
May cause respiratory irritation.

**Precautionary Phrases:**
Avoid breathing vapors.
Wash hands thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves and eye or face protection.
IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention.
Take off contaminated clothing and wash it before reuse.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.

Store locked up.
Dispose of contents and container in accordance with local and national regulations.

## Section 3. Composition/Information on Ingredients

| Component | CAS No. | Amount |
|---|---|---|
| Barium aluminoborosilicate glass | 65997-17-3 | 30-60% |
| Ytterbium fluoride | 13760-80-0 | 10-30% |
| 1,6-hexanediyl bismethacrylate | 6606-59-3 | 5-10% |
| 2-hydroxy-1,3-propanediyl bismethacrylate | 1830-78-0 | 5-10% |
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate | 72869-86-4 | 1-5% |
| 3-trimethoxysilylpropyl methacrylate | 2530-85-0 | 1-5% |
| Fumed silica | 68909-20-6 | 1-5% |

## Section 4. First Aid Measures

**Inhalation:** Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if you feel unwell.

**Skin Contact:** Remove contaminated clothing and shoes. Flush skin thoroughly with water for several minutes. Get medical attention if irritation or rash occurs. Launder clothing before re-use.

**Eye Contact:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. Get medical attention if irritation occurs and persists.

**Ingestion:** If swallowed, rinse mouth with water (only if the person is conscious). Call a POISON CENTER or doctor if you feel unwell.

**Most important symptoms and effects, acute and delayed:** Causes skin irritation and serious eye irritation. Inhalation may cause respiratory irritation. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure. Ingestion may be irritating to mouth, throat and stomach.

**Indication of immediate medical attention and special treatment, if needed:** Treat symptomatically.

## Section 5. Fire Fighting Measures

**Suitable (and Unsuitable) Extinguishing Media:** Use any media appropriate for the surrounding fire. Cool fire exposed containers with water.

**Specific Hazards Arising from the Chemical:** Combustion may produce carbon dioxide, carbon monoxide, nitrogen oxides, phosphorus oxides, halogenated compounds, and metal oxides.

**Special Protective Equipment and Precautions for Fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for fires in areas where chemicals are used or stored. Cool fire-exposed containers with water. Contain water used in firefighting from entering sewers or natural waterways.

## Section 6: Accidental Release Measures

**Personal precautions, Protective equipment, and Emergency procedures:** Evacuate spill area and keep unprotected personnel away. Avoid contact with eyes, skin and clothing. Wear appropriate protective clothing and equipment. Avoid breathing dust and vapors from dried paste.

**Environmental Precautions:** Avoid releases to the environment. Report spill as required by local and federal regulations.

**Methods and Materials for Containment and Cleaning up:** Prompt cleanup and removal are necessary. Absorb spills with an inert material and place in an appropriate waste disposal container.

## Section 7. Handling and Storage

**Precautions for Safe Handling:** Prevent contact with eyes, skin and clothing. Always wear impervious gloves, chemical safety goggles and protective clothing when handling this material. Wash thoroughly with soap and water after handling. Do not eat, drink or smoke in the work area. Do not breathe dust or vapors. Use with adequate ventilation. Remove and wash contaminated clothing before reuse.

Empty containers retain product residues which can be hazardous. Follow all SDS precautions when handling empty containers.

**Conditions for Safe Storage, Including any Incompatibilities:** Store in a cool, dry, well-ventilated area away from direct sunlight. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers.

## Section 8. Exposure Controls / Personal Protection

**Exposure Limits**

| Chemical | Exposure Limit |
|---|---|
| Barium aluminoborosilicate glass | 10 mg/m$^3$ TWA ACGIH TLV (total)<br>5 mg/m$^3$ TWA ACGIH TLV (inhalable fraction) |
| Ytterbium fluoride | 2.5 mg/m$^3$ TWA ACGIH TLV |
| 1,6-hexanediyl bismethacrylate | None Established |
| 2-hydroxy-1,3-propanediyl bismethacrylate | None Established |
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate | None Established |
| 3-trimethoxysilylpropyl methacrylate | None Established |
| Fumed silica (as amorphous silica) | 10 mg/m$^3$ TWA ACGIH TLV (inhalable)<br>3 mg/m$^3$ TWA ACGIH TLV (respirable) |

**Appropriate Engineering Controls:** Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits.

**Respiratory Protection:** None under normal use conditions with adequate ventilation. For operations where the occupational exposure limits are exceeded, an approved respirator with particulate cartridges

is recommended. Equipment selection depends on contaminant type and concentration. Select in accordance with applicable regulations and good industrial hygiene practice. For firefighting, use self-contained breathing apparatus.

**Hand protection:** Impervious gloves are suggested to prevent skin contact. Contact your glove supplier for selection assistance.

**Eye Protection:** Chemical safety goggles are recommended if contact is possible.

**Skin Protection:** Wear protective clothing as needed to avoid skin contact and contamination of personal clothing.

**Hygiene measures:** Suitable eye and skin washing facilities should be available in the work area.

## Section 9. Physical and Chemical Properties

| | | | |
|---|---|---|---|
| **Appearance:** | Various colored paste | **Odor:** | Slight peppermint-like |
| **Odor Threshold:** | Not available | **pH:** | Not available |
| **Melting/Freezing Point:** | Not available | **Boiling Point/Range:** | Not available |
| **Flash Point:** | Not flammable | **Evaporation Rate:** | Not available |
| **Flammability: (Solid, Gas)** | Not applicable | **Flammability Limits:** | LEL: Not applicable<br>UEL: Not applicable |
| **Vapor Pressure:** | Not available | **Vapor Density:** | Not available |
| **Relative Density:** | 2 | **Solubilities:** | Insoluble in water |
| **Partition Coefficient: (N-Octanol/Water)** | Not available | **Autoignition Temperature:** | Not available |
| **Decomposition Temperature:** | Not available | **Viscosity:** | Not available |

## Section 10. Stability and Reactivity

**Reactivity:** The product is not expected to be reactive.
**Chemical Stability:** Stable under normal storage and handling conditions.
**Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
**Conditions to avoid:** Avoid heat and direct sunlight. Heat can cause polymerization with rapid release of energy.
**Incompatible Materials:** Oxidizing materials, reducing materials, peroxides, and amines.
**Hazardous decomposition products:** None if stored normally.

## Section 11. Toxicological Information

**Potential Health Effects:**
**Inhalation:** May cause respiratory irritation. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
**Skin Contact:** Causes skin irritation.
**Eye Contact:** Causes serious eye irritation.
**Ingestion:** May be irritating to mouth, throat and stomach.

**Chronic Hazards:** None expected.

**Skin Sensitization:** Product is categorized in Grade I (weak sensitizer) in Kligman test.

**Respiratory Sensitization:** No data available. This product is not expected to cause respiratory sensitization.

**Germ Cell Mutagenicity:** None of the components have shown mutagenic activity in animal studies.

**Carcinogen:** None of the components are listed as a carcinogen or potential carcinogen by IARC, NTP, ACGIH, or OSHA.

**Developmental / Reproductive Toxicity:** None of the components have been shown to cause reproductive or developmental toxicity.

**Specific Target Organ Toxicity (Single Exposure):** Single exposure to 1,6-hexanediyl bismethacrylate, 2-hydroxy-1,3-propanediyl bismethacrylate, and 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate may cause respiratory tract irritation.

**Specific Target Organ Toxicity (Repeated Exposure):** No data available.

**Aspiration Toxicity:** Not an aspiration hazard.

**Acute Toxicity Values:**
Ytterbium fluoride: Oral rat LD50: >2000 mg/kg
3-trimethoxysilylpropyl methacrylate: LD50 Oral rat: 23504 mg/kg
Fumed silica: Oral rat LD50: >5000 mg/kg, Inhalation rat LC0: >0.139 mg/L/4hr (no mortality), Skin rat LD50: >5000 mg/kg

## Section 12. Ecological Information

**Toxicity:**
Ytterbium fluoride: 48 hr EC50 Daphnia magna: >0.52 mg/L
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate: 72 hr EC50 Desmodesmus subspicatus 0.6 mg/L; 48 hr EC50 Daphnia magna 1.2 mg/L

**Persistence and degradability:** Biodegradation is not applicable to inorganic substances.

**Bioaccumulative Potential:**
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate: log $P_{ow}$ 3, potential for bioaccumulative is low.
3-trimethoxysilylpropyl methacrylate: log $P_{ow}$ 2.1, potential for bioaccumulative is low.

**Mobility in Soil:** No data available.

**Other Adverse Effects:** No data available.

## Section 13. Disposal Considerations

**Disposal:** For unused product, dispose of in accordance with Federal and local regulations.

**Container Disposal:** Dispose of empty container in accordance with Federal and local regulations.

## Section 14. Transport Information

| | UN Number | UN Proper Shipping Name | Hazard Class(s) | Packing Group | Environmental Hazards |
|---|---|---|---|---|---|
| **US DOT** | None | Not Regulated | None | None | None |
| **EU ADR/RID** | None | Not Regulated | None | None | None |
| **IMDG** | None | Not Regulated | None | None | None |
| **IATA/ICAO** | None | Not Regulated | None | None | None |

**Special Precautions for User:** None identified

**Transport in Bulk According to Annex II MARPOL 73/78 and the IBC Code:** Not applicable – product is transported only in packaged form.

## Section 15. Regulatory Information

**U.S. Federal Regulations:**

**EPA SARA 311/312 Hazard Classification:** Refer to Section 2 for OSHA Hazard Classification.

**EPA SARA 313: This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372):** None

**Protection Of Stratospheric Ozone:** This product is not known to contain or to have been manufactured with ozone depleting substances as defined in 40 CFR Part 82, Appendix A to Subpart A.

**CERCLA SECTION 103:** This product is not subject to CERCLA reporting requirements; however, many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

**International Inventories**

**US EPA TSCA Inventory**: All of the components of this product are listed on the Toxic Substances Control Act (TSCA) Chemical Substances Inventory or exempt.

**Canada CEPA**: All of the components of this material are listed on the DSL or exempt.

## Section 16. Other Information

**Effective Date:** April 12, 2019
**Supersedes Date:** October 27, 2014
**Revision Summary:** All Sections – New SDS format

The information and recommendations set forth herein are taken from sources believed to be accurate as of the date of preparation, however, KERR Corporation makes no warranty with respect to the accuracy or suitability of the recommendations, and assumes no liability to any use thereof.