SAFETY DATA SHEETS

This SDS packet was issued with item: 072157717

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

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Heraeus Kulzer Mitsu Chemidais Group

Aitsu: Chemidals Group Page 1/7

Safety Data Sheet acc. to OSHA HCS

Printing date 05/12	2/2015	Reviewed on 05/12/2015
1 Identificatio	00	
· Product ident	and the second	n an thai an a <u>ll an </u>
	ne: Gluma Desensitizer Powe	rGel
· Relevant iden	ntified uses of the substance or mixture evant information available.	
	want information available. I n of the substance / the mixture For de	sensitisation of teeth
• Manufactu Heraeus Ku	e supplier of the safety data sheet urer/Supplier: ulzer GmbH eg 11, D-63450 Hanau	Tel.: 0800 4372522
	on department:	
Marc Henn Tel. +1 (57 e-mail: mar • Emergency t e) 4) 2995444 / Fax: +1 (574) 2912542 rc.henn@kulzer-dental.com elephone number:	
Emerĝency CO GBK/Infotrac I	ONTACT (24-Hour-Number) ID 105860: (domestic) 1 800 535 5053 or	international (001) 352 323 3500
2 Hazard(s) i	dentification	
	n of the substance or mixture	
	I H334 May cause allergy or asthma sym	notoms or breathing difficulties if inhaled
	H318 Causes serious eye damage.	
	H302 Harmful if swallowed.	
okin dens. 1	H317 May cause an allergic skin reaction H227 Combustible liquid.	511.
Label elemen GHS label The produc Hazard		e Globally Harmonized System (GHS).
GHS05	5 GHS07 GHS08	
· Signal v	word Danger	
2-hydro: glutaral • Hazard	-determining components of labeling: xyethyl methacrylate statements stible liauid.	
	l if swallowed.	
Causes	skin irritation.	
Causes May oa	Serious eye damage.	sing difficultion if inholo-1
May Cau May cau	use allergy or asthma symptoms or breath use an allergic skin reaction.	ing amcuttes if innaled.
	tionary statements	
Keep av	way from heat/sparks/open flames/hot sur	faces No smoking.
In case	of inadequate ventilation wear respiratory	protection.
	reathing dust/fume/gas/mist/vapours/spra	у.
AVOID DI	YES Rineo contionaly with water for a	
IF IN E	YES: Rinse cautiously with water for s and easy to do. Continue rinsing.	everal minutes. Remove contact lenses, i

- 1. Describe major development programs
- 2. Assumed customer requirements
- 3. Breakdown of sales by top 10 customers and major product lines (next 3 vears)
- D. Products
 - 1. Applications/major customers for each
 - 2. Historical and projected growth rates for each
 - 3. Market share for each
 - 4. Cost structure/profitability
 - 5. New products/enhancements planned (timing for each)
 - 6.) QA/QC and testing programs in place KB = Serina
- E. Competition
 - 1. Market definition, size, growth rate
 - 2. Principal competitors by product and estimated competitors' market share
 - 3. Comparison to competitors
 - 4. Products, pricing, margins, technology, strengths and weaknesses, market perception
 - 5. Basis of competition
 - 6. Price, service, technology, distribution etc.
 - 7. Opportunities and risks in competitive environment
- F. Revenue Quality
 - 1. Level of recurring revenues (and trends)
 - 2. Nature of contracts (length, obligations of parties, cancellation terms)
 - 3. Customer attrition record
 - 4. Seasonality
 - 5. Cyclicality

G. Marketing and Sales

- 1. Strategy
 - Distribution channels 4e doc -
 - Description of selling process/marketing programs
 - Product positioning
 - Principal new business generation methods Ke
 - Ability to implement marketing/sales plan with projected budget

Mary to do saks diagram Trade shows

current non compliant

- 2. Sales force
- Organization/coverage Mergenary ness flan Mergenary ness flan Merez Price Errice Into
 - Compensation structure and quota/target plan
 - Productivity statistics
 - Experience/training profile (for both existing employees and future hires)

Heraeus Kulzer

Mitsul Chemicals Group Page 2/7

Safety Data Sheet acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Gluma Desensitizer PowerGel (Contd. of page 1) Specific treatment (see on this label). Dispose of contents/container in accordance with local/regional/national/international regulations. Classification system · NFPA ratings for USA (scale 0-4) Health = 2Fire = 2Reactivity = 0 · HMIS-Ratings (Scale 0-4) HEALTH *2 Health = *2 FIRE 2 Fire = 2Reactivity = 0 REACTIVITY 0 Results of PBT and vPvB assessment · PBT: Not applicable. · vPvB: Not applicable. 3 Composition/information on ingredients Chemical characterization: Mixtures Dangerous components: 868-77-9 2-hydroxyethyl methacrylate 25-50% 111-30-8 glutaral 2-8%

4 First-aid measures

· Description of first aid measures

· After inhalation Supply fresh air; consult doctor in case of complaints.

- · After skin contact Immediately wash with water and soap and rinse thoroughly.
- · After eye contact
- Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing
- Rinse out mouth and then drink plenty of water.
- Immediately call a 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 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
- Formation of toxic gases is possible during heating or in case of fire.
- Advice for firefighters

Protective equipment: Mount respiratory protective device.

(Contd. on page 3)

- 3. Discussion of sales cycle
- 4. Major Customers
 - Status of relationship/trends for each
 - Prospects for future growth and development
 - Current pipeline analysis (by product/market/segment)
- H. Research and Development
 - 1. Description of organization
 - Strategy/focus of program
 - Key personnel, including position and location
 - Major activities
 - Authorization/reporting structure
 - Budget/funding plan
 - 2. New product pipeline
 - Status and timing
 - Product development roadmap and cost
 - Critical technology/other factors necessary for implementation
 - Proprietary rights secured by Company?
- I. Key relationships
 - 1. List of top 20 customers (last 2 years and YTD)
 - Show revenue, % of sales, product/application for each
 - Position of key relationship/champion/buyer
 - Provide any executed agreements
 - 2. List of top 10 suppliers (last 2 years and YTD)
 - Describe product/service provided, % of COGS for each
 - List any product purchased not COTS (i.e. sole source, custom, etc.)
 - Provide any executed agreements
 - 3. Other strategic relationships
 - Consultants, referral sources, co-ops
 - Lawyers, bankers, accountants
 - 4. Describe significant changes in any key relationship (customer, supplier, other) over last 2 years, including reason for change and business impact
- III. <u>Production Process and Facilities</u>

N/A

IV. Management/Organization

- A. Organization chart
 - 1. Description of reporting relationships
 - 2. Headcounts by department, location, facility (current and projected)
- B. Employees

-leraeus Kulzer Milso, Chemicale Group

Safety Data Sheet acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 2)

Page 3/7

· Additional information -

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures
- Wear protective equipment. Keep unprotected persons away.
- Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up:

Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues). Dispose contaminated material as waste according to item 13.

Send for recovery or disposal in suitable receptacles.

- Reference to other sections
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

7 Handling and storage

· Precautions for safe handling

Wear protective equipment. Keep unprotected persons away.

Keep receptacles tightly sealed.

Ensure good ventilation/exhaustion at the workplace.

- Please observe the additional instructions in the product's instructions for use.
 - 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: No special requirements.
 - · Information about storage in one common storage facility: Not required.
 - · Further information about storage conditions: None.
- 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:

111-30-8 glutaral

- REL Short-term value: C 0.8 mg/m3, C 0.2 ppm
- TLV Short-term value: C 0.2 mg/m³, C 0.05 ppm

SEN

• Additional information: The lists that were valid during the creation were used as basis.

· Exposure controls

Personal protective equipment
General protective and hygienic measures
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Breathing equipment:
Not necessary with efficient local exhaust. If exposition to vapours is possible, use breathing
protective mask (filter A).
Protection of hands:
Protective gloves are recommended, if skin contact cannot be avoided.
(Contd. on page 4)

- 1. Dependence on key people
- 2. Employee/labor relations issues
 - 3. Turnover statistics (last 3 years) voluntary / mvoluntary
- 4. OSHA/other safety issues (last 5 years)
- 5. Personnel policy and procedures manual
- 6. Bankruptcy, criminal history of key employees
- C. Management

Sevena	Partrick	YE	3:0
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- Arthur + Ale 1. Resumes/bios of key management and technical personnel
 - Employment history
 - Age
 - Total service with company, including years in current position
- 2. Contracts/agreements in place (include copies) Julie + Alfanso
- 3. List all insider transactions (include directors) for last 5 years NIA
- D. Compensation

STÓ LIFE YOIK

- Health Ins 1. Benefit plans (including fringes) LTD
- 2. Incentive plans (equity and/or cash)
- 3. Total compensation detail for top 20 employees
- 4. Breakdown of salary vs. hourly and full-time vs. part-time

V. Other

NA

- A. List all intellectual property
 - 1. Patents, copyrights, licenses, trademarks (current and pending)

B. Litigation

- 1. Active or pending lawsuits against or initiated by company
 - Description of parties, claims, history, status, counsel
 - Maximum exposure/business impact

C. Board of Directors

- 1. Resumes, background, tenure, how/why joined Board
- 2. Show all Board presentations for last 3 years
- 3. Minutes of all meetings for last 3 years

D. Insurance

- 1. All policies P&C, key person, D&O, other Premiums, limits, claims experience
- 2. Current or anticipated material exposures

Heraeus Kulzer Milsoi Chemicals Group Page 4/7

Safety Data Sheet acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 3) The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Solvent resistant gloves

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. **Penetration time of glove material**

- The exact break trough time has to be found out by the manufacturer of the protective
- gloves and has to be observed.
 - For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable: Butyl rubber, BR

· Eye protection:

Before use, put on the protective goggles and cover the patient's eyes to protect against splashes of material.

· Body protection: Light weight protective clothing

9 Physical and chemical properties Information on basic physical and chemical properties **General Information** Appearance: Form: Viscous Color: Green · Odor: Aromatic · pH-value at 20 °C (68 °F): 3.66 · Change in condition Melting point/Melting range: Not applicable · Boiling point/Boiling range: 100 °C (212 °F) · Flash point: Not applicable Product is not selfigniting. · Auto igniting: · Danger of explosion: Product does not present an explosion hazard.

Density at 20 °C (68 °F): 1.11 g/cm³ (9.263 lbs/gal)
 Solubility in / Miscibility with

• Water: Partly soluble • Other information No further relevant information available.

10 Stability and reactivity

- · Possibility of hazardous reactions No dangerous reactions known
- Conditions to avoid No further relevant information available.
- Incompatible materials: No further relevant information available.
- Hazardous decomposition products: none Additional information: -

(Contd. on page 5)

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

- E. Material Contracts (and summary thereof)
- F. Legal
 - 1. Articles, By-laws, any other incorporation documents
 - 2. All previous equity financing documents
 - 3. Bank loan agreements
- G. Regulatory
 - 1. History/status with any governmental agency (SEC, IRS, EPA, etc.)
- H. References
 - 1. Provide 3 professional references for CEO (with name, contact info, context)
 - At least one person you worked for and one person who worked for you
 - May not all be from same job/organization/employer
- I. Miscellaneous
 - 1. Environmental issues (provide any Phase 1, Phase 2 reports)
 - 2. Any agreements with contingent payments?
 - 3. CEO's personal mission statement (Why are you doing this?)

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Mitro: Chemican Group Page 5/7

Safety Data Sheet acc. to OSHA HCS

Printing date 05/12/2015

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Reviewed on 05/12/2015

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 4)

Information Acute tox	on toxicological effects icity:
· LD/LC	50 values that are relevant for classification:
868-77-9 2-h	vdroxyethyl methacrylate
Oral	LD50 >5000 mg/kg (rat)
Dermal	LD50 >3000 mg/kg (rabbit)
Sensitization	Sensib. sensitizing (guinea pig)
· on t · on t	y irritant effect: t he skin: Irritant to skin and mucous membranes. the eye: Strong irritant with the danger of severe eye injury. I toxicological information:
· Carcin	ogenic categories
·IAR	C (International Agency for Research on Cancer)
Butyl-hydroxy	-toluol
· NTF	P (National Toxicology Program)
	gredients is listed.
· OSł	A-Ca (Occupational Safety & Health Administration)
None of the in	ngredients is listed.
	ngredients is listed.
12 Ecological Toxicity	information
12 Ecological Toxicity Aquatic to	information
12 Ecological Toxicity Aquatic to 868-77-9 2-hy	information
12 Ecological Toxicity Aquatic to 868-77-9 2-hy EC50/48h (sta	information xicity: ydroxyethyl methacrylate atic) 380 mg/l (daphnia) (OECD 202 Teil 1)
12 Ecological Toxicity Aquatic to 868-77-9 2-hy EC50/48h (sta EC50/72h	information xicity: ydroxyethyl methacrylate atic) 380 mg/l (daphnia) (OECD 202 Teil 1) 836 mg/l (algae) (OECD 201)
12 Ecological Toxicity Aquatic to 868-77-9 2-hg EC50/48h (sta EC50/72h LC50/96h	information xicity: ydroxyethyl methacrylate atic) 380 mg/l (daphnia) (OECD 202 Teil 1) 836 mg/l (algae) (OECD 201) >100 mg/l (fish)
12 Ecological Toxicity Aquatic to 868-77-9 2-hy EC50/48h (sta EC50/72h LC50/96h Persistence Bioaccumula Mobility in se Additiona Avoid ti Do not quantiti Dangei	information information ixicity: ydroxyethyl methacrylate atic) 380 mg/l (daphnia) (OECD 202 Teil 1) 836 mg/l (algae) (OECD 201 Teil 1) 836 mg/l (algae) (OECD 201) >100 mg/l (fish) and degradability No further relevant information available. ative potential information: al notes: ransfer into the environment. allow product to reach ground water, water course or sewage system, even in sm

Waste treatment methods

Recommendation Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

(Contd. on page 6)

Sue Sheaffer

From: Sent: To: Subject: Karla Gorsky Friday, October 23, 2015 8:49 AM Sue Sheaffer FW: American Interplex--Draft review

From: Patrick Anderson Sent: Friday, October 23, 2015 8:23 AM To: Jennifer Perry <jennifer.perry@gsmsds.com> Cc: Karla Gorsky <karla.gorsky@gsmsds.com> Subject: RE: American Interplex--Draft review

Section 1 must be changed

Protap Aerosol:

Section 1 – Please add the correct product number in SDSP

Section 2 - Please add the additional P statements in SDSP

Section 9 - Flash point is acceptable..lists a non-flammable value

Section 10 - All section 10 information is correct and should not be changed

Section 12 - All section 12 information is correct and should not be changed

Section 13 - Contains standardized section 13 reference to 49,CFR. No additional information necessary

Section 14 – It is hazard class 2 but subsection 2.2 which is for non-flammable compressed gas...proper pictogram is displayed

Protap

Section 1.1 – Please add the correct product number in SDSP

Section 2.2 - Please add the additional P statements in SDSP

Section 3.1 – SDSP default language...description in Section 1

Sections 3.2 & 3.3 - Correct information, do not change

Section 4 – The grammatical error is in the SDSP software...All information reported in section 4 is correct and should not be changed

Section 5 - All information correct as written

Section 6 – PPE information is already in Section 8. There is no reference in SDSP to other sections

Section 7 - All information correct as written

Section 8 – All information correct as written

Section 9 - All information correct as written - note - physical properties are from the customer...we cannot alter them

Section 10 - All information correct as written

Section 12 - Correct as written - SDSP default language

Section 13 - Contains standardized section 13 reference to 49,CFR. No additional information necessary

From: Jennifer Perry Sent: Wednesday, October 21, 2015 12:46 PM To: Patrick Anderson <patrick.anderson@gsmsds.com>

Safety Data Sheet acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

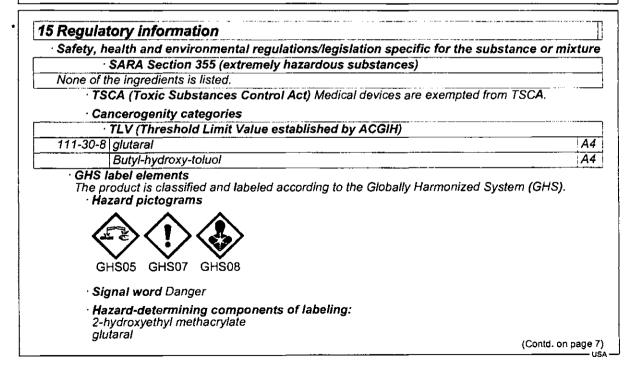
Trade name: Gluma Desensitizer PowerGel

(Contd. of page 5)

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 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 DOŤ. ĂDR. 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. · Transport/Additional information: . · UN "Model Regulation": -



. 4

Cc: Karla Gorsky <<u>karla.gorsky@gsmsds.com</u>> Subject: RE: American Interplex--Draft review

Hi Patrick,

I attached the "source" documents I was told to review against the new SDS....Meaning, the US versions attached to the email.

Thanks,

Jennifer Perry Senior Project Manager



GLOBAL SAFETY MANAGEMENT

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From: Patrick Anderson Sent: Wednesday, October 21, 2015 12:43 PM To: Jennifer Perry <<u>jennifer.perry@gsmsds.com</u>> Cc: Karla Gorsky <<u>karla.gorsky@gsmsds.com</u>> Subject: RE: American Interplex--Draft review

Jennifer:

What are you considering your "source" for your comments? In one item you say that your "source" states that carbon dioxide is highly flammable? Additionally, we do not repeat redundant P statements. Please enlighten me as to your point of reference

Patrick

From: Jennifer Perry Sent: Wednesday, October 21, 2015 12:38 PM To: Patrick Anderson <<u>patrick.anderson@gsmsds.com</u>> Cc: Karla Gorsky <<u>karla.gorsky@gsmsds.com</u>> Subject: American Interplex--Draft review Importance: High

Hi Patrick,

Heraeus Kulzer

Mitse: Chemicais Teocp Page 7/7

Safety Data Sheet acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 6) · Hazard statements Combustible liquid. Harmful if swallowed. Causes skin irritation. Causes serious eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. Precautionary statements Keep away from heat/sparks/open flames/hot surfaces. - No smoking. In case of inadequate ventilation wear respiratory protection. Avoid breathing dust/fume/gas/mist/vapours/spray. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Specific treatment (see on this label). Dispose of contents/container in accordance with local/regional/national/international regulations. Chemical safety assessment: A Chemical Safety Assessment has not been carried out. 16 Other information These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Date of preparation / last revision 05/12/2015 / -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 DOT: US Department of Transportation IATA: International Air Transport Association ACGIH: American Conference of Governmental Industrial Hygienists ACGN: American Contenence of Governmental Industrial Pytensis 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) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent : Flammable liquids, Hazard Category 4 Acute Tox. 4: Acute toxicity, Hazard Category 4 Skin Imit. 2: Skin corrosion/imitation, Hazard Category 2 Eye Dam, 1: Serious eye damage/eye irritation, Hazard Category 1 Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1 Skin Sens. 1: Sensitisation - Skin, Hazard Category 1 * Data compared to the previous version altered.

I pay close attention to detail with my current QC process in translation, so my comments may not apply. I defer to you and/or Karla to make that judgement. I have attached the US versions "source" information here for convenience.

You will see that on the Aerosol, I skip from Section 2 down to 9; upon review of this 2nd file (Liquid), I reviewed ALL sections to point out issues I saw when comparing against the source file of the US version dated 5/2015. I would tell you it is safe to assume the sections I did not mark up on Aerosol file, would be the same as those sections in the Liquid file. So please watch my comments (30 in Liquid file)....they probably all apply to the aerosol file as well.

Once revisions are completed, please notify me so I can pull revised PDFs down to T drive and send to Susie for client delivery.

Thank you,

Jennifer Perry Senior Project Manager



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Safety Data Sheet acc. to OSHA HCS

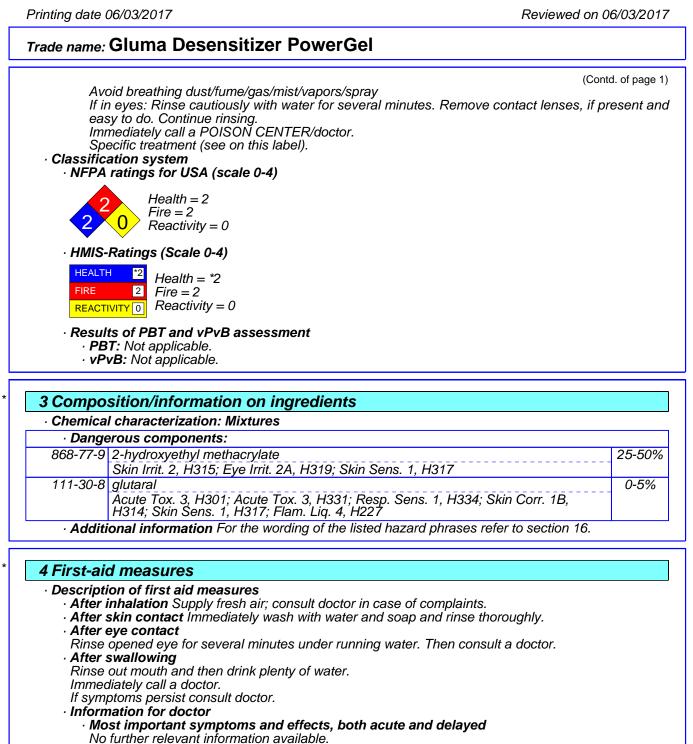
Reviewed on 06/03/2017 Printing date 06/03/2017 1 Identification · Product identifier · Trade name: Gluma Desensitizer PowerGel · Application of the substance / the mixture For desensitisation of teeth · Details of the supplier of the safety data sheet Manufacturer/Supplier: Kulzer GmbH Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522 Information department: Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545 e-mail: customer.servicehkna@kulzer-dental.com • Emergency telephone number: Emergency CONTACT (24-Hour-Number) GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500 2 Hazard(s) identification · Classification of the substance or mixture Flam. Lig. 4 H227 Combustible liquid. Acute Tox. 4 H302 Harmful if swallowed. Skin Irrit. 2 H315 Causes skin irritation. Eve Dam. 1 H318 Causes serious eye damage. Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. Skin Sens. 1 H317 May cause an allergic skin reaction. · Label elements GHS label elements The product is classified and labeled according to the Globally Harmonized System (GHS). Hazard pictograms GHS05 GHS07 GHS08 · Signal word Danger · Hazard-determining components of labeling: 2-hydroxyethyl methacrylate glutaral · Hazard statements Combustible liquid. Harmful if swallowed. Causes skin irritation. Causes serious eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. Precautionary statements Keep away from flames and hot surfaces. - No smoking. [In case of inadequate ventilation] wear respiratory protection. (Contd. on page 2)

USA



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Safety Data Sheet acc. to OSHA HCS



(Contd. on page 3)

USA -



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Safety Data Sheet acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Gluma Desensitizer PowerGel

• 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 Formation of toxic gases is possible during heating or in case of fire.
 Advice for firefighters
 - · Protective equipment: Mount respiratory protective device.
- · Additional information -

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.
- Environmental precautions: No special measures required.
 Methods and material for containment and cleaning up: Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues). Dispose contaminated material as waste according to item 13. Send for recovery or disposal in suitable receptacles.
- Reference to other sections
 See Section 8 for information on personal protection equipment.
 See Section 13 for disposal information.

7 Handling and storage

· Handling

· Precautions for safe handling

Wear protective equipment. Keep unprotected persons away.

Keep receptacles tightly sealed.

Ensure good ventilation/exhaustion at the workplace.

Please observe the additional instructions in the product's instructions for use.

· 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: No special requirements.
 - · Information about storage in one common storage facility: Not required.
 - Further information about storage conditions: None.

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

(Contd. on page 4)

HS4



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Safety Data Sheet acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 3)

-	re controls/personal protection
Addition	al information about design of technical systems: No further data; see item 7.
	parameters
	onents with limit values that require monitoring at the workplace:
111-30-8	
	rt-term value: C 0.8 mg/m³, C 0.2 ppm
	rt-term value: C 0.2 mg/m³, C 0.05 ppm
SEN	
· Ad	ditional information: The lists that were valid during the creation were used as basis.
Exposure	e controls
Perso	nal protective equipment
· Ge	neral protective and hygienic measures
Ke	ep awav from foodstuffs. beverages and feed.
Imi	nediately remove all soiled and contaminated clothing
	sh hands before breaks and at the end of work.
Do	not inhale gases / fumes / aerosols.
Ave	pid contact with the eyes and skin.
·Bre	eathing equipment:
No	t necessary with efficient local exhaust. If exposition to vapours is possible, use breathi
pro	tective mask (filter A).
	otection of hands:
	e glove material has to be impermeable and resistant to the product/ the substance/ t
	paration. Jaction of the alove material on consideration of the penetration times, rates of diffusion and t
do	ection of the glove material on consideration of the penetration times, rates of diffusion and t gradation
	kin contact cannot be avoided, protective gloves are recommended to
11 3	bid possible sensitization.
	lvent resistant gloves
	eck protective gloves prior to each use for their proper condition.
	ommended
	Material of gloves
	The selection of the suitable gloves does not only depend on the material, but also on furth
	marks of quality and varies from manufacturer to manufacturer. As the product is a preparat
	of several substances, the resistance of the glove material can not be calculated in advan
	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 glow
	and has to be observed.
	For the permanent contact of a maximum of 15 minutes gloves made of the followi
	materials are suitable:
	Butyl rubber, BR
	Nitrile rubber, NBR
	e protection:
	fore use, put on the protective goggles and cover the patient s eyes to protect against splash
of ı	naterial.
	(Contd. on page



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Safety Data Sheet acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Gluma Desensitizer PowerGel

· Body protection: Light weight protective clothing

9 Physical and chemical properti	ies
 Information on basic physical and ch General Information Appearance: 	emical properties
· Form:	Viscous
· Color:	Green
· Odor:	Aromatic
· Odor threshold:	Not determined.
· pH-value at 20 °C (68 °F):	3.66
 Change in condition Melting point/Melting range: Boiling point/Boiling range: 	Not applicable 100 °C (212 °F)
· Flash point:	Not applicable
 Flammability (solid, gaseous) 	Not applicable.
· Ignition temperature:	
 Decomposition temperature: 	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
• Explosion limits: • Lower: • Upper:	Not determined. Not determined.
· Vapor pressure:	Not determined.
 Density at 20 °C (68 °F): Relative density Vapor density Evaporation rate 	1.11 g/cm ³ (9.263 lbs/gal) Not determined. Not determined. Not determined.
Solubility in / Miscibility with Water:	Partly soluble
· Partition coefficient (n-octanol/wat	ter): Not determined.
 Viscosity: dynamic: kinematic: Other information 	Not determined. Not determined. No further relevant information available.

10 Stability and reactivity

Reactivity No further relevant information available.
 Possibility of hazardous reactions No dangerous reactions known

(Contd. on page 6)

- USA



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Safety Data Sheet acc. to OSHA HCS

Reviewed on 06/03/2017 Printing date 06/03/2017 Trade name: Gluma Desensitizer PowerGel (Contd. of page 5) Conditions to avoid No further relevant information available. · Incompatible materials: No further relevant information available. · Hazardous decomposition products: none · Additional information: -11 Toxicological information · Information on toxicological effects · Acute toxicity: LD/LC50 values that are relevant for classification: 868-77-9 2-hydroxyethyl methacrylate Oral LD50 5564 mg/kg (rat) Dermal LD50 >3000 mg/kg (can) · Primary irritant effect: • on the skin: Irritant to skin and mucous membranes. • on the eye: Strong irritant with the danger of severe eye injury. · Sensitization: No sensitizing effects known. Additional toxicological information: · Carcinogenic categories · IARC (International Agency for Research on Cancer) Butyl-hydroxy-toluol 3 · NTP (National Toxicology Program) None of the ingredients is listed. · OSHA-Ca (Occupational Safety & Health Administration) None of the ingredients is listed.

12 Ecological information

· Toxicity

· Aquatic toxicity:

868-77-9 2-hydroxyethyl methacrylate

LC50/96h 227 mg/l (fish)

• 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:
 - Avoid transfer into the environment.
 - Do not allow product to reach ground water, water course or sewage system, even in small quantities.

banger to drinking water if even extremely small quantities leak into the ground.

· Results of PBT and vPvB assessment

· PBT: Not applicable.

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Safety Data Sheet acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Gluma Desensitizer PowerGel

· vPvB: Not applicable.

· Other adverse effects No further relevant information available.

13 Disposal considerations

· Waste treatment methods

Recommendation

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packagings:

• Recommendation: Disposal must be made according to official regulations.

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 I MARPOL73/78 and the IBC Code 	Il of Not applicable.	
· Transport/Additional information:	-	
· UN "Model Regulation":	Void	

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.

· TSCA (Toxic Substances Control Act) Medical devices are exempted from TSCA.

· Cancerogenity categories

TLV (Threshold Limit Value established by ACGIH)

111-30-8 glutaral

(Contd. on page 8)

USA



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Safety Data Sheet acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Gluma Desensitizer PowerGel (Contd. of page 7) Butyl-hydroxy-toluol A4 · GHS label elements The product is classified and labeled according to the Globally Harmonized System (GHS). · Hazard pictograms GHS05 GHS07 GHS08 · Signal word Danger · Hazard-determining components of labeling: 2-hydroxyethyl methacrylate glutaral · Hazard statements Combustible liquid. Harmful if swallowed. Causes skin irritation. Causes serious eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. Précautionary statements Keep away from flames and hot surfaces. - No smoking. [In case of inadequate ventilation] wear respiratory protection. Avoid breathing dust/fume/gas/mist/vapors/spray If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. Specific treatment (see on this label). · Chemical safety assessment: A Chemical Safety Assessment has not been carried out. 16 Other information These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. • Relevant phrases H227 Combustible liquid. H301 Toxic if swallowed. H314 Causes severe skin burns and eye damage. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H331 Toxic if inhaled. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. · Date of preparation / last revision 06/03/2017 / 2 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

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Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Gluma Desensitizer PowerGel

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DOT: US Department of Transportation IATA: International Air Transport Association ACGIH: American Conference of Governmental Industrial Hygienists 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) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit Flam. Liq. 4: Flammable liquids – Category 4 Acute Tox. 3: Acute toxicity – Category 4 Skin Corr. 1B: Skin corrosion/irritation – Category 1B Skin Irrit. 2: Skin corrosion/irritation – Category 1 Eye Dam. 1: Serious eye damage/eye irritation – Category 1 Eye Irrit. 2A: Serious eye damage/eye irritation – Category 1 Eye Irrit. 2A: Serious eye damage/eye irritation – Category 1 Skin Sens. 1: Respiratory sensitisation – Category 1 Skin Sens. 1: Skin sensitisation – Category 1

USA -



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Printing date 10/25/2018

Reviewed on 10/25/2018

1 Identification	
· Product identifier	
Trade name: Gluma Desensitizer PowerGel	
 Application of the substance / the mixture For desensitisa 	ation of teeth
 Details of the supplier of the safety data sheet Manufacturer/Supplier: Kulzer GmbH Leipziger Straße 2, 63450 Hanau (Germany) 	Tel.: +49 (0)800 4372522
 Information department: Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545 e-mail: customer.servicehkna@kulzer-dental.com Emergency telephone number: Emergency CONTACT (24-Hour-Number) GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international content of the second s	
2 Hazard(s) identification	
· Classification of the substance or mixture	
 Flam. Liq. 4 H227 Combustible liquid. Skin Irrit. 2 H315 Causes skin irritation. Eye Dam. 1 H318 Causes serious eye damage. Resp. Sens. 1 H334 May cause allergy or asthma symptoms or br Skin Sens. 1 H317 May cause an allergic skin reaction. 	reathing difficulties if inhaled.
Label elements GHS label elements The product is classified and labeled according to the Globally H Hazard pictograms GHS05 GHS08	larmonized System (GHS).
· Signal word Danger	
 Hazard-determining components of labeling: 2-hydroxyethyl methacrylate glutaral Hazard statements Combustible liquid. Causes skin irritation. Causes serious eye damage. May cause allergy or asthma symptoms or breathing difficulti May cause an allergic skin reaction. Precautionary statements Avoid breathing dust/fume/gas/mist/vapors/spray Wear protective gloves/protective clothing/eye protection/face In case of inadequate ventilation wear respiratory protection. IF INHALED: Remove person to fresh air and keep comfortal If in eyes: Rinse cautiously with water for several minutes. I and easy to do. Continue rinsing. Specific treatment (see on this label). 	e protection. ble for breathing.
	(Contd. on page 2)



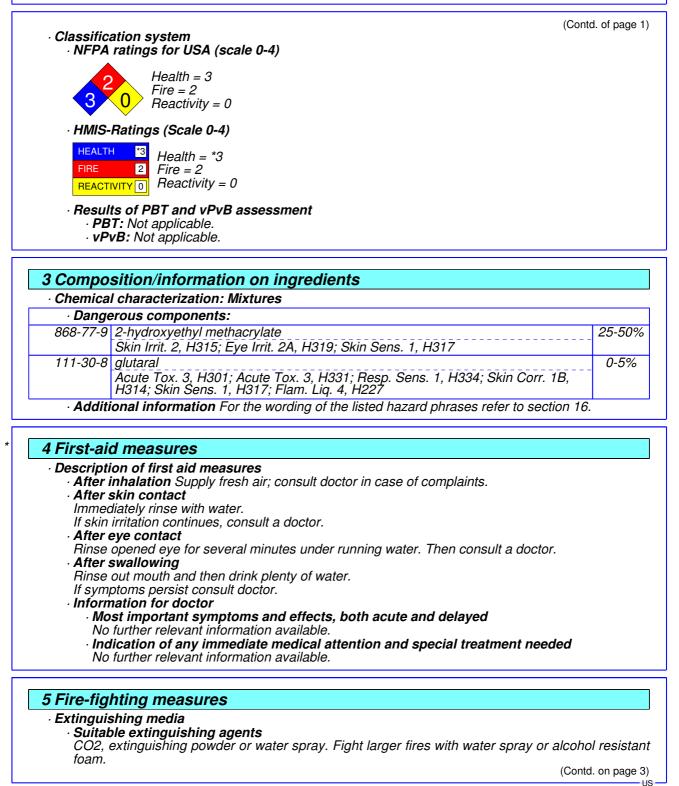
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Trade name: Gluma Desensitizer PowerGel





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Reviewed on 10/25/2018

Trade name: Gluma Desensitizer PowerGel

- · Special hazards arising from the substance or mixture
- Formation of toxic gases is possible during heating or in case of fire. • Advice for firefighters
- Protective equipment: Mount respiratory protective device.
- · Additional information -

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.
- Environmental precautions: No special measures required.
- **Methods and material for containment and cleaning up:** Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues). Dispose contaminated material as waste according to item 13. Send for recovery or disposal in suitable receptacles.
- **Reference to other sections** See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

7 Handling and storage

- · Handling
 - · Precautions for safe handling
 - Wear protective equipment. Keep unprotected persons away.
 - Keep receptacles tightly sealed.

Ensure good ventilation/exhaustion at the workplace.

- Please observe the additional instructions in the product's instructions for use.
- 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: No special requirements.
 - · Information about storage in one common storage facility: Not required.
- Further information about storage conditions: None.
- · 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:

111-30-8 glutaral

- REL Short-term value: C 0.8 mg/m³, C 0.2 ppm
- TLV Short-term value: C 0.2 mg/m³, C 0.05 ppm
 - SEN

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

· Exposure controls

- Personal protective equipment
 - General protective and hygienic measures Keep away from foodstuffs, beverages and feed.
 - Immediately remove all soiled and contaminated clothing

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Printing date 10/25/2018

Reviewed on 10/25/2018

Trade name: Gluma Desensitizer PowerGel

	(Contd. of page 3)
Wash hands before breaks	
Do not inhale gases / fumes	
Avoid contact with the eyes	
Breathing equipment:	
Not necessary with efficien	t local exhaust. If exposition to vapours is possible, use breathing
protective mask (filter A).	
· Protection of hands:	
The glove material has to l	be impermeable and resistant to the product/ the substance/ the
preparation.	
	rial on consideration of the penetration times, rates of diffusion and
the degradation	
If skin contact cannot be ave	oided, protective gloves are recommended to
avoid possible sensitization.	
Solvent resistant gloves	
Check protective gloves price	or to each use for their proper condition.
recommended	
 Material of gloves 	
The selection of the su	itable gloves does not only depend on the material, but also on
further marks of quality a	and varies from manufacturer to manufacturer. As the product is a
	substances, the resistance of the glove material can not be
	nd has therefore to be checked prior to the application.
 Penetration time of glo 	ve material
The exact break throug	h time has to be found out by the manufacturer of the protective
gloves and has to be obs	
	tact of a maximum of 15 minutes gloves made of the following
materials are suitable:	
Butyl rubber, BR	
_ Nitrile rubber, NBR	
Eye protection:	
	ptective goggles and cover the patient's eyes to protect against
splashes of material.	
 Body protection: Light weight 	ght protective clothing
0 Dhysical and shaminal new	neutice
9 Physical and chemical pro	perties
Information on basic physical a	nd chemical properties
· General Information	
· Appearance:	
· Form:	Viscous
Colori	

· Form:	Viscous	
· Color:	Green	
· Odor:	Aromatic	
 Odor threshold: 	Not determined.	
· pH-value at 20 ℃ (68 °F):	3,66	
Change in condition Melting point/Melting range: Boiling point/Boiling range:	Not applicable 100 ℃ (212 ℉)	
· Flash point:	Not applicable	
· Flammability (solid, gaseous)	Not applicable.	
· Ignition temperature:		
 Decomposition temperature: 	Not determined.	
		(Contd. on page 5

-US-



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Printing date 10/25/2018

Reviewed on 10/25/2018

Trade name: Gluma Desensitizer PowerGel

	Dredvet is not colfingities
· 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 ℃ (68 °F):	1,11 g/cm³ (9.26295 lbs/gal)
Relative density	Not determined.
· Vapor density	Not determined.
- Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Partly soluble
· Partition coefficient (n-octanol/w	vater): Not determined.
· Viscosity:	
· dynamic:	Not determined.
· kinematic:	Not determined.
Other information	No further relevant information available.
Stability and reactivity	
Reactivity No further relevant informa	ation available

- Conditions to avoid No further relevant information available.
- Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: none
- · Additional information: -

11 Toxicological information · Information on toxicological effects · Acute toxicity: · LD/LC50 values that are relevant for classification: LD50 >2,000 mg/kg (rat) Oral 868-77-9 2-hydroxyethyl methacrylate Oral LD50 >5,000 mg/kg (rat) LD50 Dermal >3,000 mg/kg (rabbit) Sensitization Sensib. (guinea pig) · Primary irritant effect: • on the skin: Irritant to skin and mucous membranes. • on the eye: Strong irritant with the danger of severe eye injury. • Sensitization: No sensitizing effects known. · Additional toxicological information: · Carcinogenic categories · IARC (International Agency for Research on Cancer) 128-37-0 2,6-di-tert-butyl-p-cresol 3 (Contd. on page 6)



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(Contd. of page 5)

Trade name: Gluma Desensitizer PowerGel

· NTP (National Toxicology Program)

None of the ingredients is listed.

• OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Toxicity	ormation		
· Aquatic toxici	ty		
-	xyethyl methacrylate		
EC50/72h	836 mg/l (algae) (OECD 201)		
	c) 380 mg/l (daphnia) (OECD 201)		
LC50/96h	380 mg/l (daphnia) (OECD 202 Teil 1) >100 mg/l (fish)		
Mobility in soi Additional ecolog General notes Avoid transfer Do not allow p quantities. Danger to drink Results of PBT a PBT: Not appli	: into the environment. product to reach ground water, water course or sewage system, even in sma king water if even extremely small quantities leak into the ground. nd vPvB assessment cable.		
3 Disposal cons			
· Waste treatment · Recommenda			
• Waste treatment • Recommenda Must not be dis system. • Uncleaned packa	tion sposed of together with household garbage. Do not allow product to reach sewag		
• Waste treatment • Recommenda Must not be dis system. • Uncleaned packa	tion sposed of together with household garbage. Do not allow product to reach sewag rgings: tion: Disposal must be made according to official regulations.		

· Transport hazard class(es)

· DOT, ADR, ADN, IMDG, IATA · Class

(Contd. on page 7)

Void



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Trade name: Gluma Desensitizer PowerGel

		(Contd. of page
· Packing group · DOT, ADR, IMDG, IATA	Void	
Environmental hazards: Marine pollutant:	No	
· Special precautions for user	Not applicable.	
 Transport in bulk according to Annex MARPOL73/78 and the IBC Code 	Il of Not applicable.	
· Transport/Additional information:	-	
UN "Model Regulation":	Void	

	15 Regul	latory inf	formation
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• Safety, health and environmental regulations/legislation specific for the substance or mixture • Sara

	SARA Section 355 (extremely hazardous substances)	
None of t	he ingredients is listed.	
	SARA Section 313 (specific toxic chemical listings)	
None of t	he ingredients is listed.	
· Pro	oposition 65	
	Prop 65 - Chemicals known to cause cancer	
None of t	he ingredients is listed.	
	Chemicals known to cause reproductive toxicity for females:	
None of t	he ingredients is listed.	
	Chemicals known to cause reproductive toxicity for males:	
None of t	he ingredients is listed.	
	Chemicals known to cause developmental toxicity:	
None of t	he ingredients is listed.	
· Ca	ncerogenity categories	
	EPA (Environmental Protection Agency)	
None of t	he ingredients is listed.	
	TLV (Threshold Limit Value established by ACGIH)	
111-30-8	glutaral	A4
128-37-0	2,6-di-tert-butyl-p-cresol	A4
	NIOSH-Ca (National Institute for Occupational Safety and Health)	
	7-7 Titanium dioxide	
· Chemica	I safety assessment: A Chemical Safety Assessment has not been carried out.	

16 Other information

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

H227 Combustible liquid.

H301 Toxic if swallowed.

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Printing date 10/25/2018

Reviewed on 10/25/2018

Trade name: Gluma Desensitizer PowerGel (Contd. of page 7) H314 Causes severe skin burns and eye damage. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H331 Toxic if inhaled. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. • **Date of preparation** / **last revision** 10/25/2018 / 3 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 DOT: US Department of Transportation IATA: International Air Transport Association ACGIH: American Conference of Governmental Industrial Hygienists 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) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic VPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit Flam. Liq. 4: Flammable liquids – Category 4 Acute Tox. 3: Acute toxicity – Category 3 Skin Corr. 1B: Skin corrosion/irritation – Category 1B Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Dam. 1: Serious eye damage/eye irritation – Category 1 Eve Irrit. 2A: Serious eye damage/eye irritation – Category 2 Eye Irrit. 2A: Serious eye damage/eye irritation - Category 2A Resp. Sens. 1: Respiratory sensitisation – Category 1 Skin Sens. 1: Skin sensitisation – Category 1 * * Data compared to the previous version altered. US