

Printing date 16.07.2015 Version number 4 Revision: 18.04.2015

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

- · 1.1 Product identifier
- Trade name: IPS Contrast Spray Chairside blue-lemon / creme-lemon
- · 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 Auxiliary for manufacture of dental prothesis
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent AG Bendererstrasse 2 FL-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, FL-9494 Schaan, Liechtenstein)

#### SECTION 2: Hazards identification

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

H229 Pressurised container: May burst if heated.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- · 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 Void
- · Signal word Warning
- · Hazard statements

H229 Pressurised container: May burst if heated.

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P251 Do not pierce or burn, even after use.

P260 Do not breathe spray.

P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

· Additional information:

Contains citrus oil. May produce an allergic reaction.

10.0 % by mass of the contents are flammable

- · 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.

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CAS: 431-89-0	heptafluorpropan	50-100%
	Press. Gas C, H280	
CAS: 64-17-5	ethanol	≤10%
EINECS: 200-578-	Flam. Liq. 2, H225	_ ]
CAS: 14807-96-6	Talc (Mg3H2(SiO3)4)	3-<10%
EINECS: 238-877-	Acute Tox. 4, H332; STOT SE 3, H335	- ]
CAS: 84929-31-7	citrus oil	0.3-<1%
EINECS: 284-515-	Flam. Liq. 3, H226; Asp. Tox. 1, H304; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Irrit. 2, H315; Skin Sens. 1, H317	

<sup>·</sup> Additional information: For the wording of the listed risk phrases refer to section 16.

#### SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · After inhalation:

Supply fresh air.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Rinse with water.

If skin irritation continues, consult a doctor.

- · 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.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

#### **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · For safety reasons unsuitable extinguishing agents: Water with full jet
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: Do not inhale explosion gases or combustion gases.
- · Additional information Cool endangered receptacles with water spray.

#### SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Ensure adequate ventilation

- · 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- $\cdot \textit{6.3 Methods and material for containment and cleaning up:} \\$

Absorb liquid components with liquid-binding material.

Dispose of the material collected according to regulations.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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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.

Keep away from heat and direct sunlight.

Open and handle receptacle with care.

Use only in well ventilated areas.

- · Information about fire and explosion protection: Keep ignition sources away Do not smoke.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:

Store in a cool location.

Store only in the original receptacle.

Observe official regulations on storing packagings with pressurised containers.

- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Protect from heat and direct sunlight.

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

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

#### SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

64-17-5 ethanol

WEL Long-term value: 1920 mg/m³, 1000 ppm

14807-96-6 Talc (Mg3H2(SiO3)4)

WEL Long-term value: 1 mg/m<sup>3</sup>

- · 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.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Do not inhale gases / fumes / aerosols.

· Respiratory protection:

Not necessary if room is well-ventilated.

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Protection of hands:



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After use of gloves apply skin-cleaning agents and skin cosmetics.

· 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

#### SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Aeroso

Colour: According to product specification

Odour: CharacteristicOdour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

**Melting point/Melting range:** Undetermined. **Boiling point/Boiling range:** ~ 78 °C

· Flash point: Not applicable, as aerosol.

· Flammability (solid, gaseous): Not determined.

· Self-igniting: Product is not selfigniting.

• Danger of explosion: Product does not present an explosion hazard.

· Explosion limits:

Lower:Not determined.Upper:Not determined.

· Vapour pressure at 20 °C: 4000 hPa

Density: Not determined.
 Relative density Not determined.
 Vapour density Not determined.
 Evaporation rate Not applicable.

· Solubility in / Miscibility with

water: Not miscible or difficult to mix.

· Partition coefficient (n-octanol/water): Not determined.

Viscosity:

**Dynamic:** Not determined. **Kinematic:** Not determined.

• 9.2 Other information No further relevant information available.

#### SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

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- 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 Danger of explosion.
- · 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

#### SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity
- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Additional toxicological information: No further relevant information available.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

#### SECTION 12: Ecological information

- · 12.1 Toxicity
- $\cdot \textbf{\textit{Aquatic toxicity:}} \ \textit{No further relevant information available}.$
- · 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.
- · Ecotoxical effects:
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water Do not allow product to reach ground water, water course or sewage system.

Harmful to aquatic organisms

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

#### **SECTION 13: Disposal considerations**

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system. Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

· European waste catalogue

16 05 04\* gases in pressure containers (including halons) containing dangerous substances

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

14.1 UN-Number ADR,RID,ADN, IMDG, IATA	UN1950
14.2 UN proper shipping name	
ADR/RID/ADN	1950 AEROSOLS
IMDG	AEROSOLS
IATA	AEROSOLS, non-flammable
14.3 Transport hazard class(es)	
ADR/RID/ADN	
,	
Class	2 5A Gases.
Label	2.2
IMDG, IATA	
Class	2.2
Label	2.2
14.4 Packing group ADR,RID,ADN, IMDG, IATA	Void
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Warning: Gases.
Danger code (Kemler):	-
EMS Number:	F- $D$ , $S$ - $U$
14.7 Transport in bulk according to Anno	ex II of
Marpol and the IBC Code	Not applicable.
Transport/Additional information:	
ADR/RID/ADN	
Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E0
· · · · · · ·	Not permitted as Excepted Quantity
Transport category	3
Tunnel restriction code	E
IMDG	
Limited quantities (LQ)	IL
Excepted quantities (EQ)	Code: E0
· · · ·	Not permitted as Excepted Quantity

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· UN "Model Regulation":

UN1950, AEROSOLS, 2.2

#### SECTION 15: Regulatory information

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

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

H280 Contains gas under pressure; may explode if heated.

H304 May be fatal if swallowed and enters airways.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

#### · Abbreviations and acronyms:

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

 $: Flammable\ aerosols,\ Hazard\ Category\ 3$ 

Press. Gas C: Gases under pressure: Compressed gas

Flam. Liq. 2: Flammable liquids, Hazard Category 2

Flam. Liq. 3: Flammable liquids, Hazard Category 3

Acute Tox. 4: Acute toxicity, Hazard Category 4

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

Asp. Tox. 1: Aspiration hazard, Hazard Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3