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

Printing date 30.06.2023

Version number 2 (replaces version 1)

Revision: 30.06.2023

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

· 1.1 Product identifier

Trade name:
<u>G2-BOND_Universal_1-PRIMER</u>

Nanoform

- 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 dental technology
- 1.3 Details of the supplier of the safety data sheet

• Manufacturer/Supplier: GC EUROPE N.V. Interleuvenlaan 33 B-3001 Leuven Tel. +32/(0)16/74.10.00 Fax +32/(0)16/40.26.84 msds@gc.dental

· Information department: Regulatory affairs

· 1.4 Emergency telephone number: International: +01-813-248-0585 (ChemTel Inc.)

SECTION 2: Hazards identification

• 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008		
Unst. Expl.	H200 Unstable explosives.	
Flam. Liq. 2	H225 Highly flammable liquid and vapour.	
Skin Corr. 1A	H314 Causes severe skin burns and eye damage.	
Eye Dam. 1	H318 Causes serious eye damage.	
Skin Sens. 1	H317 May cause an allergic skin reaction.	
STOT SE 3	H336 May cause drowsiness or dizziness.	
A muntie Character 2	II (1) $II = I = I = I = I = I = I = I = I = I$	

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 labeled according to the CLP regulation.

· Exemptions

The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).

· Hazard pictograms



· Signal word Danger

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List II

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· Hazard-determ	ining components of labeling:
acetone	6 I J 6
2,2'-ethylenedio	xydiethyl dimethacrylate
	hacrylate (UDMA)
Hazard stateme	
H200 Unstable	explosives.
H225 Highly fla	mmable liquid and vapour.
	vere skin burns and eye damage.
	e an allergic skin reaction.
	e drowsiness or dizziness.
	o aquatic life with long lasting effects.
Precautionary s	
P210	Keep away from heat/sparks/open flames/hot surfaces No smoking.
P260	Do not breathe dusts or mists.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P.	353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/
	shower.
P305+P351+P.	338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present
P310	and easy to do. Continue rinsing.
P321	Immediately call a poison center/doctor. Specific treatment (see on this label).
P362+P364	Take off contaminated clothing and wash it before reuse.
P373	DO NOT fight fire when fire reaches explosives.
P380	Evacuate area.
P401	Store in accordance with local/regional/national/international regulations.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international
1 501	regulations.
Additional info	0
	ins: Reportable explosives precursors. Making available, introduction, possession and use
	gulation (EU) 2019/1148, Article 9.
2.3 Other hazar	
	and vPvB assessment
PBT: Not applie	
vPvB: Not appli	
	of endocrine-disrupting properties

· Determination of endocrine-disrupting properties

128-37-0 Butylated hydroxytoluene

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterization: Mixtures

• Description:

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

· Dangerous	components:	
67-64-1	acetone	25-<50%
	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336, EUH066	
	·	(Contd. on page 3)

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1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane	≥10-<20%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
85590-00-7	methacryloyloxydecyl dihydrogen phosphate	5-<10%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
68611-44-9	Silane, dichlorodimethyl-, reaction products with silica	5-<10%
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	2.5-<5%
	Skin Sens. 1, H317	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	1-<2.5%
	<i>Repr. 2, H361f</i>	
128-37-0	Butylated hydroxytoluene	0.5-<1%
	Aquatic Acute 1, H400; Aquatic Chronic 1, H410 (II)	
1344-28-1	aluminium oxide	0.5-<1%
72869-86-4	Urethane Dimethacrylate (UDMA)	≥0.25-<0.5%
	Aquatic Chronic 2, H411; Skin Sens. 1B, H317	
· Additional i	<i>nformation:</i> For the wording of the listed hazard phrases refer to section 16.	

SECTION 4: First aid measures

• 4.1 Description of first aid measures

· General information:

Immediately remove any clothing soiled by the product. If symptoms persist consult doctor.

• After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. Take affected persons into fresh air and keep quiet.

• After skin contact:

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

If skin irritation continues, consult a doctor.

• After eye contact:

Protect unharmed eye.

Rinse opened eye for several minutes under running water.

Call a doctor immediately.

· 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 Allergic reactions

- 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, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire fighting measures that suit the environment.
- · For safety reasons unsuitable extinguishing agents: Water with full jet

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• 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire. No further relevant information available.

• 5.3 Advice for firefighters

· Protective equipment: Wear self-contained respiratory protective device.

• Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures
Remove persons from danger area.
Keep away from ignition sources
Avoid contact with the eyes and skin.
Wear protective clothing.
- 6.2 Environmental precautions:
Do not allow product to reach sewage system or any water course.
Do not allow to penetrate the ground/soil.
6.3 Methods and material for containment and cleaning up:
Ensure adequate ventilation.
Use neutralizing agent.
Absorb liquid components with liquid-binding material.
Dispose of the collected material 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. See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Avoid contact with the eyes and skin.
<i>Open and handle receptacle with care.</i>
Information about protection against explosions and fires:
Keep ignition sources away - Do not smoke.
Prevent impact and friction.
Do not spray on a naked flame or any incandescent material.
· 7.2 Conditions for safe storage, including any incompatibilities
· Storage:
• Requirements to be met by storerooms and receptacles: Store only in unopened original receptacles.
· Information about storage in one common storage facility: Store away from foodstuffs.
· Further information about storage conditions:
Keep receptacle tightly sealed.
Protect from heat and direct sunlight.
Store in a cool place.
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• 7.3 Specific end use(s) No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· Components with limit values that require monitoring at the workplace:

67-64-1 acetone

IOELV Long-term value: 1210 mg/m³, 500 ppm

· DNELs

128-37-0 Butylated hydroxytoluene

DermalDNEL dermal0.5 mg/kg bw/day (man)InhalativeDNEL inhalation3.5 mg/m3 (man)

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

· 8.2 Exposure controls

• Additional information about design of technical systems: No further data; see section 7.

· Personal protective equipment:

- General protective and hygienic measures:
- The usual precautionary measures for handling chemicals should be followed.
- Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

- Immediately remove all soiled and contaminated clothing.
- Breathing equipment: Suitable respiratory protective device recommended.
- Protection of hands:



Protective 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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.

• Eye protection:



Tightly sealed goggles

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
- · General Information
- · Physical state
- · Color:
- · Odor:
- Odor threshold:

Fluid Light yellow Acetone-like Not determined.

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Melting point/Melting range:	-95 °C
Boiling point/Boiling range:	55 °C
Flammability (solid, gaseous):	Not applicable.
Explosion limits:	11
Lower:	2.6 Vol % (67-64-1 acetone)
Upper:	13 Vol % (67-64-1 acetone)
Flash point:	-17 °C
Auto igniting:	Undetermined.
Decomposition temperature:	Not determined.
pH-value at 20 °C:	1.5-2
	1.3-2
Viscosity:	
Kinematic:	Not determined.
Dynamic:	Not determined.
Solubility in / Miscibility with	
Water:	Fully miscible.
Partition coefficient (n-octanol/water):	Not determined.
Vapor pressure:	Not determined.
Density and/or relative density	
Density at 20 °C:	$0.94 \ g/cm^3$
Relative density	Not determined.
Vapor density	Not determined.
Particle characteristics	SiO2: Diameter particle structure = $2.5 - 50$ nm (TE)
	d50, number-based)
	Diameter agglomerate = $5 - 50$ mm (laser diffraction d
	module, d50, volume based)
	Al2O3: Diameter particle structure = $2 - 100 \text{ nm}$ (d5
	number-based)
	68611-44-9 Silane, dichlorodimethyl-, reaction produc
	with silica: Spheroidal, amorphous nanoform, s
	including amorphous nanoforms, amorphous form
	surface-treated nanoforms
	1344-28-1 aluminium oxide: Spheroidal, crystallin
	nanoform, crystalline forms, non-surface-treate
	nanoforms
9.2 Other information	
Appearance:	
Form:	Liquid
I orm. Important information on protection of health (-

environment, and on safety.	Duo duot in not solficentities
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
	Risk of explosion by shock, friction, fire or other source
	of ignition.
Solvent content:	
Organic solvents:	33.0 %
Water:	24.0 %
VOC (EC)	400.6 g/l
Change in condition	· · · · · · · · · · · · · · · · · · ·
Evaporation rate	Not determined.
•	1101 Weiel minicu.
Information with regard to physical hazard classes	
Explosives	Unstable explosives.

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Flammable gases	Void	
Aerosols	Void	
Oxidising gases	Void	
Gases under pressure	Void	
Flammable liquids	Highly flammable liquid and vapour.	
Flammable solids	Void	
Self-reactive substances and mixtures	Void	
Pyrophoric liquids	Void	
Pyrophoric solids	Void	
Self-heating substances and mixtures	Void	
Substances and mixtures, which emit flammab	le gases	
in contact with water	Void	
Oxidising liquids	Void	
Oxidising solids	Void	
Organic peroxides	Void	
Corrosive to metals	Void	
Desensitised explosives	Void	

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

- · 10.2 Chemical stability
- 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 No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

• Acute toxicity: Based on available data, the classification criteria are not met.

· LD/LC50 values that are relevant for classification:

67-64-1 acetone

Oral LD50 5,800 mg/kg (rat (f+m))

Dermal LD50 20,000 mg/kg (rabbit)

128-37-0 Butylated hydroxytoluene

Oral LD50 >6,000 mg/kg (rat (f+m)) (OECD 401)

72869-86-4 Urethane Dimethacrylate (UDMA)

Oral LD50 > 5,000 mg/kg (rat female) (OECD 401)

• on the skin: Causes severe skin burns and eye damage.

• on the eye: Causes serious eye damage.

• Sensitization: May cause an allergic skin reaction.

• 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.*

• Specific target organ toxicity - single exposure May cause drowsiness or dizziness.

• Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

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- · Aspiration hazard Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

• *Repeated dose toxicity* No further relevant information available.

- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- No further relevant information available.

11.2 Information on other hazards

• Endocrine disrupting properties 128-37-0 Butylated hydroxytoluene

List II

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

128-37-0 Butylated hydroxytoluene

EC50/48h (static) 0.48 mg/l (daphnia magna) (OECD 202)

72869-86-4 Urethane Dimethacrylate (UDMA)

EC50/48h (static) >1.2 mg/l (daphnia magna) (OECD 202)

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

• 12.6 Endocrine disrupting properties For information on endocrine disrupting properties see section 11.

- · 12.7 Other adverse effects
- · Remark: Harmful to fish
- 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. Must not reach bodies of water or drainage ditch undiluted or unneutralized.

Harmful to aquatic organisms

Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation:

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

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

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· Recommended cleansing agent: Water, if necessary with cleansing agents.

SECTION 14: Transport information	
14.1 UN-Number	1011002
ADR, IMDG, IATA	UN1993
14.2 UN proper shipping name	
DOT	Flammable liquids, n.o.s. (Acetone)
ADR	1993 FLAMMABLE LIQUID, N.O.S. (ACETONE), speci
IMDG, IATA	provision 640D FLAMMABLE LIQUID, N.O.S. (ACETONE)
	TEAMMABLE EIGOID, N.O.S. (ACETONE)
14.3 Transport hazard class(es)	
ADR	
3	
Class Label	3 (F1) Flammable liquids 3
	,
IMDG, IATA	
3	
	2 Elanon abla linuida
Class Label	3 Flammable liquids 3
	5
14.4 Packing group	11
ADR, IMDG, IATA	II
14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for user	Warning: Flammable liquids
Hazard identification number (Kemler code):	33
EMS Number:	<i>F-E,<u>S-E</u></i>
Stowage Category	B
14.7 Transport in bulk according to Annex II o	
MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	IL
Excepted quantities $(\widetilde{E}Q)$	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	D/E

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· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S. (ACETONE), 3, II

SECTION 15: Regulatory information

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

· Section 355 (extremely hazardous substances):

None of the ingredient is listed.

Section 313 (Specific toxic chemical listings):

1344-28-1 aluminium oxide

· 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)

67-64-1 acetone

· TLV (Threshold Limit Value)

67-64-1 acetone 128-37-0 Butylated hydroxytoluene

1344-28-1 aluminium oxide

· MAK (German Maximum Workplace Concentration)

128-37-0 Butylated hydroxytoluene

1344-28-1 aluminium oxide

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

• *Directive 2012/18/EU*

· Named dangerous substances - ANNEX I None of the ingredients is listed.

· Seveso category Pla EXPLOSIVES

 \cdot Qualifying quantity (tonnes) for the application of lower-tier requirements 10 t

 \cdot Qualifying quantity (tonnes) for the application of upper-tier requirements 50 t

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• REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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• DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

• *REGULATION (EU) 2019/1148*

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

67-64-1 acetone

· Regulation (EC) No 273/2004 on drug precursors

67-64-1 acetone

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

67-64-1 acetone

• 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· Relevant phrases

- H225 Highly flammable liquid and vapour.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H336 May cause drowsiness or dizziness.
- H361f Suspected of damaging fertility.
- *H400 Very toxic to aquatic life.*
- *H410 Very toxic to aquatic life with long lasting effects.*
- *H411 Toxic to aquatic life with long lasting effects.*

EUH066 Repeated exposure may cause skin dryness or cracking.

· Classification according to Regulation (EC) No 1272/2008 Calculation method

- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental

• Date of previous version 30.06.2023

- · Version number of previous version: 1
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international 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

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)

VOC: Volatile Organic Compounds (USA, EU)

- DNEL: Derived No-Effect Level (REACH)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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(Contd. of page 11) NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health Unst. Expl.: Explosives – Unstable explosive Flam. Liq. 2: Flammable liquids – Category 2 Skin Corr. 1A: Skin corrosion/irritation - Category 1A Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Dam. 1: Serious eye damage/eye irritation – Category 1 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 Skin Sens. 1: Skin sensitisation - Category 1 Skin Sens. 1B: Skin sensitisation – Category 1B Repr. 2: Reproductive toxicity – Category 2 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1 Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3 · Sources • ECHA (http://echa.europa.eu/) • EnviChem (www.echemportal.org) • * Data compared to the previous version altered. This version replaces all previous versions. Disclaimer: The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.