

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

Printing date 01.12.2023

Version number 4 (replaces version 3)

Revision: 01.12.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name: GRADIA DIRECT Flo****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** Auxillary 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

Further information obtainable from: Regulatory affairs**1.4 Emergency telephone number:**

National poison center for United Kingdom of Great Britain and Northern Ireland:

Belfast: +44 28 90 63 2032

Birmingham: +44 121 507 4123

Edinburgh: +44 131 242 1383

Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180

Penarth: +44 292 071 55 54

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

Skin Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 2 H411 Toxic 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 GB 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

GHS07 GHS09

Signal word Warning**Hazard-determining components of labelling:**

Urethane Dimethacrylate (UDMA)

2,2'-ethylenedioxydiethyl dimethacrylate

(Contd. on page 2)

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

Printing date 01.12.2023

Version number 4 (replaces version 3)

Revision: 01.12.2023

Trade name: GRADIA_DIRECT_Flo

(Contd. of page 1)

2-(2H-benzotriazol-2-yl)-p-cresol

Hazard statements

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards**Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****3.2 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:

| | | |
|--|--|-------------|
| CAS: 72869-86-4 EINECS: 276-957-5 | Urethane Dimethacrylate (UDMA) ----- Aquatic Chronic 2, H411; Skin Sens. 1B, H317 | 25-<50% |
| CAS: 109-16-0 EINECS: 203-652-6 | 2,2'-ethylenedioxydiethyl dimethacrylate ----- Skin Sens. 1, H317 | 5-<10% |
| CAS: 68611-44-9 EINECS: 271-893-4 | Silane, dichlorodimethyl-, reaction products with silica Nanoform: set including amorphous nanoforms surface-treated nanoforms Shape: Spheroidal Structure: amorphous forms Crystallinity: amorphous nanoform | 2.5-<5% |
| CAS: 1309-37-1 EINECS: 215-168-2 | Iron(III)oxide substance with a Community workplace exposure limit | 0.5-<1% |
| CAS: 13463-67-7 EINECS: 236-675-5 Index number: 022-006-00-2 | titanium dioxide ----- Carc. 2, H351 substance with a Community workplace exposure limit | 0.5-<1% |
| CAS: 1879-09-0 EINECS: 217-533-1 | 6-tert-butyl-2,4-xylenol ----- Acute Tox. 2, H310; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319 | ≥0.25-<0.5% |
| CAS: 2440-22-4 EINECS: 219-470-5 | 2-(2H-benzotriazol-2-yl)-p-cresol ----- Acute Tox. 3, H331; Aquatic Chronic 1, H410; Skin Sens. 1, H317 | ≥0.25-<0.5% |
| CAS: 7631-86-9 EINECS: 231-545-4 | silicon dioxide Nanoform: set including amorphous nanoforms non-surface-treated nanoforms Shape: Spheroidal Structure: amorphous forms Crystallinity: amorphous nanoform | 0.2-<0.5% |

(Contd. on page 3)

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

Printing date 01.12.2023

Version number 4 (replaces version 3)

Revision: 01.12.2023

Trade name: GRADIA_DIRECT_Flo

(Contd. of page 2)

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **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:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:**

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed 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, sand, extinguishing powder. Do not use water.

· **For safety reasons unsuitable extinguishing agents:** Water

· **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.

Avoid formation of dust.

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.

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to penetrate the ground/soil.

In case of seepage into the ground inform responsible authorities.

(Contd. on page 4)

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

Printing date 01.12.2023

Version number 4 (replaces version 3)

Revision: 01.12.2023

Trade name: GRADIA_DIRECT_Flo

(Contd. of page 3)

- **6.3 Methods and material for containment and cleaning up:**
Pick up mechanically.
Prevent formation of dust.
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.
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 dust.
Any unavoidable deposit of dust must be regularly removed.
Avoid contact with the eyes and skin.
- **Information about fire - and explosion protection:**
Protect against electrostatic charges.
Dust can combine with air to form an explosive mixture.
- **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:** None.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

1309-37-1 Iron(III)oxide

| | |
|-----|--|
| WEL | Short-term value: 10* mg/m ³ |
| | Long-term value: 5* 10** 4*** mg/m ³ |
| | *fume (as Fe), **total respirable, ***respirable |

13463-67-7 titanium dioxide

| | |
|-----|--|
| WEL | Long-term value: 10* 4** mg/m ³ |
| | *total inhalable **respirable |

- **DNELs**

13463-67-7 titanium dioxide

| | | |
|------------|-----------------|----------------------------|
| Inhalative | DNEL inhalation | 10 mg/m ³ (man) |
|------------|-----------------|----------------------------|

1879-09-0 6-tert-butyl-2,4-xylenol

| | | |
|------------|-----------------|------------------------------|
| Inhalative | DNEL inhalation | 0.14 mg/m ³ (man) |
|------------|-----------------|------------------------------|

- **Additional information:** The lists valid during the making were used as basis.

- **8.2 Exposure controls**

- **Appropriate engineering controls** No further data; see section 7.

(Contd. on page 5)

GB

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

Printing date 01.12.2023

Version number 4 (replaces version 3)

Revision: 01.12.2023

Trade name: **GRADIA_DIRECT_Flo**

(Contd. of page 4)

- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
Do not inhale dust / smoke / mist.
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
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **Hand protection**



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/face protection**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid
- **Colour:** Various colours
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Not determined.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Auto-ignition temperature:** Undetermined.
- **Decomposition temperature:** Not determined.
- **pH** Not applicable.
- **Viscosity:**
- **Kinematic viscosity** Not applicable.
- **Dynamic:** Not applicable.
- **Solubility**
- **water:** Insoluble.

(Contd. on page 6)

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

Printing date 01.12.2023

Version number 4 (replaces version 3)

Revision: 01.12.2023

Trade name: GRADIA_DIRECT_Flo

(Contd. of page 5)

| | |
|--|--|
| <ul style="list-style-type: none"> · <i>Partition coefficient n-octanol/water (log value)</i> · <i>Vapour pressure:</i> · <i>Density and/or relative density</i> · <i>Density:</i> · <i>Relative density</i> · <i>Vapour density</i> · <i>Particle characteristics</i> | <p><i>Not determined.</i></p> <p><i>Not applicable.</i></p> <p><i>Not determined.</i></p> <p><i>Not determined.</i></p> <p><i>Not applicable.</i></p> <p><i>SiO₂: Diameter particle structure = 2.5 - 50 nm (TEM, d50, number-based)</i></p> <p><i>Diameter agglomerate = 5 - 50 nm (laser diffraction dry module, d50, volume based)</i></p> <p><i>68611-44-9 Silane, dichlorodimethyl-, reaction products with silica:</i></p> <p><i>set including amorphous nanoforms</i></p> <p><i>surface-treated nanoforms</i></p> <p><i>Shape: Spheroidal</i></p> <p><i>Structure: amorphous forms</i></p> <p><i>Crystallinity: amorphous nanoform</i></p> <p><i>7631-86-9 silicon dioxide:</i></p> <p><i>set including amorphous nanoforms</i></p> <p><i>non-surface-treated nanoforms</i></p> <p><i>Shape: Spheroidal</i></p> <p><i>Structure: amorphous forms</i></p> <p><i>Crystallinity: amorphous nanoform</i></p> |
| <ul style="list-style-type: none"> · 9.2 Other information · <i>Appearance:</i> · <i>Form:</i> · Important information on protection of health and environment, and on safety. · <i>Ignition temperature:</i> · <i>Explosive properties:</i> · <i>Change in condition</i> · <i>Evaporation rate</i> | <p><i>Pasty</i></p> <p><i>Product is not selfigniting.</i></p> <p><i>Product does not present an explosion hazard.</i></p> <p><i>Not applicable.</i></p> |
| <ul style="list-style-type: none"> · Information with regard to physical hazard classes · <i>Explosives</i> · <i>Flammable gases</i> · <i>Aerosols</i> · <i>Oxidising gases</i> · <i>Gases under pressure</i> · <i>Flammable liquids</i> · <i>Flammable solids</i> · <i>Self-reactive substances and mixtures</i> · <i>Pyrophoric liquids</i> · <i>Pyrophoric solids</i> · <i>Self-heating substances and mixtures</i> · <i>Substances and mixtures, which emit flammable gases in contact with water</i> · <i>Oxidising liquids</i> · <i>Oxidising solids</i> · <i>Organic peroxides</i> · <i>Corrosive to metals</i> | <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> <p><i>Void</i></p> |

(Contd. on page 7)

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

Printing date 01.12.2023

Version number 4 (replaces version 3)

Revision: 01.12.2023

Trade name: GRADIA_DIRECT_Flo

(Contd. of page 6)

· *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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:****72869-86-4 Urethane Dimethacrylate (UDMA)**

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

1309-37-1 Iron(III)oxide

Oral LD50 >5,000 mg/kg (rat (f+m))

13463-67-7 titanium dioxide

Oral LD50 >5,000 mg/kg (mouse) (OECD 420)

Inhalative LC50/4 h >6.82 mg/l (rat male)

1879-09-0 6-tert-butyl-2,4-xylenol

Oral LD50 910 mg/kg (rat (f+m)) (OECD 401)

Dermal LD50 <200 mg/kg (rabbit) (OECD 402)

2440-22-4 2-(2H-benzotriazol-2-yl)-p-cresol

Oral LD50 10,000 mg/kg (rat (f+m))

Inhalative LC50/4 h 0.59 mg/l (rat (f+m))

7631-86-9 silicon dioxide

Oral LD50 10,000 mg/kg (rat (f+m))

· **Respiratory or skin sensitisation** May cause an allergic skin reaction.· **Additional toxicological information:**· **Repeated dose toxicity** No further relevant information available.· **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.· **11.2 Information on other hazards**· **Endocrine disrupting properties**

None of the ingredients is listed.

GB

(Contd. on page 8)

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

Printing date 01.12.2023

Version number 4 (replaces version 3)

Revision: 01.12.2023

Trade name: GRADIA_DIRECT_Flo

(Contd. of page 7)

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

| |
|--|
| 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

The product does not contain substances with endocrine disrupting properties.

· 12.7 Other adverse effects

· Additional ecological information:

· General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

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

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.

· Uncleaned packaging:

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

SECTION 14: Transport information

· 14.1 UN number or ID number

· ADR, IMDG, IATA

UN3077

· 14.2 UN proper shipping name

· ADR

3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Urethane Dimethacrylate (UDMA), 6-tert-butyl-2,4-xylenol)

· IMDG

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Urethane Dimethacrylate (UDMA), 6-tert-butyl-2,4-xylenol), MARINE POLLUTANT

· IATA

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Urethane Dimethacrylate (UDMA), 6-tert-butyl-2,4-xylenol)

(Contd. on page 9)

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

Printing date 01.12.2023

Version number 4 (replaces version 3)

Revision: 01.12.2023

Trade name: GRADIA_DIRECT_Flo

(Contd. of page 8)

· 14.3 Transport hazard class(es)

· ADR



· Class 9 (M7) Miscellaneous dangerous substances and articles.
· Label 9

· IMDG, IATA



· Class 9 Miscellaneous dangerous substances and articles.
· Label 9

· 14.4 Packing group

· ADR, IMDG, IATA

III

· 14.5 Environmental hazards:

· Marine pollutant:

No
Symbol (fish and tree)

· Special marking (ADR):

Symbol (fish and tree)

· Special marking (IATA):

Symbol (fish and tree)

· 14.6 Special precautions for user

Warning: Miscellaneous dangerous substances and articles.

· Hazard identification number (Kemler code):

90

· EMS Number:

F-A,S-F

· Stowage Category

A

· Stowage Code

SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.

· 14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

· Transport/Additional information:

· ADR

· Limited quantities (LQ)

5 kg

· Excepted quantities (EQ)

Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

· Transport category

3

· Tunnel restriction code

(-)

· IMDG

· Limited quantities (LQ)

5 kg

· Excepted quantities (EQ)

Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

· UN "Model Regulation":

UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (URETHANE DIMETHACRYLATE (UDMA), 6-TERT-BUTYL-2,4-

(Contd. on page 10)

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

Printing date 01.12.2023

Version number 4 (replaces version 3)

Revision: 01.12.2023

Trade name: GRADIA_DIRECT_Flo

(Contd. of page 9)

XYLENOL), 9, III

SECTION 15: Regulatory information

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

· Regulated explosives precursors

None of the ingredients is listed.

· Regulated poisons

None of the ingredients is listed.

· Reportable explosives precursors

None of the ingredients is listed.

· Reportable poisons

None of the ingredients is listed.

· Directive 2012/18/EU

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

· Seveso category E2 Hazardous to the Aquatic Environment

· Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t

· Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t

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

SECTION 16: Other information

· Relevant phrases

H302 Harmful if swallowed.

H310 Fatal in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H331 Toxic if inhaled.

H351 Suspected of causing cancer.

H373 May cause damage to organs through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

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

· Department issuing SDS: Regulatory affairs

· Contact: msds@gc.dental

· 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

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)

DNEL: Derived No-Effect Level (UK REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

(Contd. on page 11)

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

Printing date 01.12.2023

Version number 4 (replaces version 3)

Revision: 01.12.2023

Trade name: GRADIA_DIRECT_Flo

(Contd. of page 10)

*PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Acute Tox. 4: Acute toxicity – Category 4**Acute Tox. 2: Acute toxicity – Category 2**Acute Tox. 3: Acute toxicity – Category 3**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1**Skin Sens. 1B: Skin sensitisation – Category 1B**Carc. 2: Carcinogenicity – Category 2**STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2**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***Sources**

- ECHA (<http://echa.europa.eu/>)
- EnviChem (www.echemportal.org)

*** Data compared to the previous version altered.***This version replaces all previous versions.***Disclaimer:**

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