Safety Data Sheet according to Regulation 1907/2006/EC Article 31

Revision Date: 30.01.2013 Version: 1

Date of Print: 13.05.2013

1. Product identification/preparation/company undertaking

Trade name:

GO easy! F-Mix

Use of the preparation:

Dental varnish

Manufacturer/supplier:

First Scientific Dental Materials GmbH

D-25335 Elmshorn, Germany mail@f-scientific-dm.com

Emergency information:

++49 (0) 4121 90 95 08

2. Hazards identification

Classification of substance

Classification according to Directive

R10 Flammable

67/548/EEC or Directive 1999/45/EEC

Classification system:

Classification corresponds to actual EC guidelines,

however completed with details from technical

literature and company data.

Labeling according to EU guidelines:

As a medical device the product is not subject to

labeling regulations under directive 1272/2008/EC

Safety phrases:

S7 Keep container tightly closed

S16 Keep away from sources of ignition - No

smoking

S23 Do not breathe fumes/aerosols

3. Composition/Information of Ingredients

Chemical characterization:

Slurry of potassiumfluoride, calciumfluoride and

fluorapatite in ethanol

Description:

Hazardous components:

CAS-No.

<u>Name</u>

R-classification

64-17-5

Ethanol

F. R11

7789-23-3

Potassium fluoride

T, R23,24,25

4. First-aid measures

General information:

Seek medical advice, if symptoms occur, which can

be caused by the product.

after skin contact:

Wash with plenty of water and soap.

after eye contact: after swallowing:

Rinse with plenty of water and consult a physician.

Seek medical advice immediately.

5. Fire fighting measures

Extinguishing media:

CO₂, water spray, powder.

Protective equipment:

Chose in dependence to surrounding fire.

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6. Accidental release measures

Personal precautions: Wear protective equipment

Environmental precautions: Do not allow to enter sewerage system.

Methods for cleaning up: Wipe out with absorbent material.

Additional information: None.

7. Handling and storage

Handling: The product should only be supplied to or handled by

dentists or dental technicians or upon their

instructions.

Handling procedures: no procedures, if correctly handled

Recommendation for fire and keep aw

explosion protection:

keep away from heat and fire. Take measure to

Store at dry place, at room temperature

prevent electrostatic charge

Storage: Requirements at storerooms and

containers:

Store away from food stuffs.

Requirements for storage with other

products:

Keep containers closed.

Additional storage conditions:

8. Exposure controls/personal protection

Additional information for technical

plants:

Components with limits of values to be supervised at the workplace:

CAS-No. Name art value unit

The product contains no relevant quantities of components with limits of values to be supervised at the workplace.

Additional information:

Personal protective equipment:

General measures of protection and

Normal hygienic measures.

hygiene:

respiration:

Not required

hands:

Not required

eyes:

Not required

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9.	Physical	and	chemical	properties

Appearance

Form:

gel

Color:

white-transparent

Odor:

mint-like

iiiit-iikc

Value Unit Method

Information on change in the physical state

Melting point/melting range:

n.a.

Boiling point/boiling range: Flash point:

n.a.

Autoignition temperature:

Product is not selfigniting

Danger of explosion:

Product does not present an explosion hazard

Density:

ca. 1.1 g/cm³

Viscosity:

n.d.

nH:

n.a.

Solubility in/miscibility with:

Water:

Not miscible or difficult to mix

Content of solvents:

Organic solvents:

Ethanol

Water:

Content of solids:

10. Stability and reactivity

No decomposition if used according to

specifications.

Incompatibility with other

Acids

substances:

Hazardous decomposition products:

Not known.

11. Toxicological information

Acute toxicity:

Potassium fluoride: LD50 rat (oral): 245 mg/kg

Primary irritation:

skin:

No irritating effect No irritating effect

eye: Sensitization of product:

No sensitizing effect known

Additional toxicological information:

The product is not subject to classification according

to the calculation method of general EU

Classification Guidelines for Preparations as issued

in the latest version.

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12. Ecological information

General information: Do not allow undiluted product or large quantities of

it to reach groundwater, water course or sewage

system

Classification of water endangerment:

(self estimation)

WGK=1 (German Regulation) (slightly polluting

substance).

13. Disposal consideration

Product:

Recommendation:

Use proper landfill disposal or incineration in

accordance with local, state and federal regulations.

Disposal key number:

Uncleaned packaging:

Handle contaminated packaging in the same way as

the substance itself.

Recommendation:

14. Transport information

Land transport ADR/RID and GGVS/GGVE

(Germany)

UN 1993

ENTZÜNDBARER FLÜSSIGER STOFF N.A:G.

(Ethanol) 3,II

Sea transport IMDG

UN 1993

FLAMMABLE LIQUID, N.O.S.

(Ethanol) 3, II EmS: F-E S-D

Air transport ICAO-TI and IATA-DGR

UN 1993

FLAMMABLE LIQUID, N.O.S.

(Ethanol) 3, II

The transport regulations are cited according to international regulations and in the form applicable in Germany. Possible national

deviations in other countries are not considered.

15. Regulatory information

Labeling according to

EC-guidelines:

As a medical device the product is not subject to labeling regulations under directive 1272/2008/EC

16. Other information:

Changes compared with the previous

version:

The above information is based on our present day knowledge and relates solely to the safety

requirements of the product. The data do not signify any warranty with regards to products properties.

However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.