

MATERIAL SAFETY DATA SHEET

SECTION 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Commercial name: HARMONY

Relevant use of product: Vinyl polysiloxane impression materials

Product references: HM-100, HLN-100, HLF-100, HPN-600, HPF-600, HPF-760, HPN-760, HHB-760, HMP-760, HM-20, HLN-20, HLF-20.

Information concerning safety data sheet supplier:

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SECTION 2 – HAZARDS IDENTIFICATION

2.1 Classification of the mixture

The mixture meets the criteria for classification of Regulation 1272/2008 / EC amending Directives 67/548 / EEC and 1999/ 45 / EC and regulation 1907/2006 / EC (CLP). The mixture requires security sheet according to the requested requirements.

2.1.1 Classification according to regulation (EC) N° 1272/2008 (CLP):

The mixture is not considered as dangerous

2.1.2 Classification according to the directive N° 67/548/CEE:

The mixture is not considered as dangerous

2.1.3 Additional Informations

The full text of the classes and categories of danger: hazards H and R phrases are mentioned in Section 16.

2.2 Label elements

The labeling is not mandatory according to Regulation (EC) No 1272/2008 (CLP)

Pictogram: N/A

Signal word: N/A

H statements: N/A

P statements: N/A

Additional hazards information: N/A

2.3 Other hazards: the mixtures do not contain PBT or vPvP.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Products

EC designation : N/A

EEC classification : Class I

3.2 Mixture of substances listed below

Mixture of paste : polyvinyle fluids, inorganics fillers

SECTION 4 - FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation: N/A in normal condition of use

Swallowing: Seek medical advice

Skin contact: Wash with water and soap.

Eye contact: Wash with water and seek medical advice.

Other measure: Remove contaminated clothes.

4.2 Most important symptoms and effects, both acute and delayed: None available

4.3 Indication of any immediate medical attention and special treatment needed: None available

SECTION 5 - FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing media: Water in spray

Non-suitable Extinguishing media: N/A

Melting point: N/A

Necessary special protection gear: No

Explosion limits in air: N/A

Self-ignition temperature: N/A

Flammability: NO

Flash point: N/A

5.2 Special hazards arising from the substance or mixture: N/A

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with eyes and skin. Wash with water and soap.

6.2 Environmental precautions:

Large amount: Remove the product following nationals, federals, regional or locals current laws (by incineration). Remove the content the same way.

6.3 Methods and material for containment and cleaning up:

N/A

6.4 Reference to other sections

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

No special precautions necessary.

7.2 Conditions for safe storage, including any incompatibilities

No special precautions necessary.

7.3 Specific end use(s): Dental professional use only. Use only plastic or steel utensils to mix. The product vulcanizes by a polyaddition reaction and could inhibit if expose to the following products:

- Heavy metal salts
- amine
- sulfur and derivative
- Catalyst of epoxy resins

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Respiratory and ventilating protection: Not necessary in normal condition of use.

Personal protective equipment: Disposable glooves

Specific hygiene measure: Not necessary in normal condition of use

SECTION 9 - PHYSICAL & CHEMICAL PROPERTIES

9.1 Information regarding the physicals and chemicals properties

Appearance: Paste

Odour: Variable

Boiling point: N/A

Melting point: N/A

Solubility in water: Insoluble

Reactivity in water: N/A

PH: N/A

Explosive properties: N/A

Auto flammability: N/A

Oxidant properties: No

Flash point: N/A

Vapour density: N/A

Colour: variable

Specific gravity: Variable

SECTION 10 - STABILITY & REACTIVITY

10.1 Reactivity: N/A.

10.2 Chemical stability: Stable in normal condition of use

10.3 Possibility of hazardous reactions: No dangerous reactions known in normal condition of use

10.4 Conditions to avoid: Unknown

10.5 Incompatible materials: Unknown

10.6 Hazardous decomposition products: Unknown in normal condition of use

10.7 Uncontrolled polymerization: N/A

SECTION 11 – TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity for health: LD50 5000mg/kg Rat.

Chronic toxicity: Unknown in normal condition of use

Signs and symptoms of exposure: None irritating.

11.2 Other Information: N/A

SECTION 12 – ECOLOGICAL INFORMATION

12.1 Toxicity

No ecological or environmental impact known, in the quantity of a regular packaging. Do not pour into the sink, the drain or into the aquatic environment

12.2 Persistence and degradability: N/A

12.3 Bioaccumulative potential: N/A

12.4 Mobility in soil: N/A

12.5 Results of PBT and vPvB assessment: N/A

12.6 Other adverse effects: N/A

SECTION 13 - DISPOSAL MEASURES

13.1 Waste treatment methods

Large quantity:

Disposal must be made according to local, state and federal regulations. Do not pour into the sink.

Small quantity: Remove by the classical system after polymerization.

SECTION 14 - TRANSPORT INFORMATION

The transportation requirements followed the international transportation requirements.

No restriction for the road, boat or plane transportation. Avoid high temperatures during transportation.

SECTION 15 - REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture: Class I medical device according to the Directive 93/42 / EEC

15.2 Chemical safety assessment: N/A

SECTION 16 - OTHER INFORMATION

N/A : Non applicable

R phrases

R 52: Dangerous for aquatic organism

S phrases

H phrases

H412: In the long term, can be dangerous for the aquatic organism

P phrases:

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P302 + P352: IF ON SKIN: Wash with plenty of soap and water.

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