



Factor II, Incorporated

The Art, Science and Technology of
Silicones and Prosthetics...

Safety Data Sheet

A-330-GOLD

Date of Issue: 05/26/2015

Revision Date: 11/13/2019

Factor II Inc. encourages the end user to read this document entirely and understand all sections of this SDS sheet prior to use. There is important information regarding this product. The end user is expected to follow all precautions outlined in this SDS.

SECTION 1: IDENTIFICATION

PRODUCT IDENTIFIER

Product Name : Platinum Primer

Product Code : A-330-GOLD

Intended Use(s) : For professional use only.

CONTACT INFORMATION FOR SUPPLIER OF SAFETY DATA SHEET

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928- 368-7502

SECTION 2: HAZARD(S) IDENTIFICATION

Classification of substance or mixture:

Classification according to Regulation (EC) No 1272/2008:

Flam. Liq. 2, H225 Highly Flammable liquid and vapor.

Eye Irrit. 2, H319 causes serious eye irritation.

STOT SE 3, H336 May cause drowsiness or dizziness.

Information concerning particular hazards for human and environment:

The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

Label elements

Labeling according to Regulation (EC) 1272/2008:

Hazard Pictograms





Single word

Danger

Hazard statements

H225 Highly flammable liquid vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

Precautionary statements

P210 Keep away from heat/sparks/open flames/hot surfaces – No smoking.

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

Labeling according to EU guidelines:

Medical Devices as defined in Directive 93/43/EEC, and which are invasive or used in direct physical contact with the human body; are expected from provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

Other Hazards:

Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical characterization :

Description of mixture : Solution of polyacrylate in ethylacetate.

Hazardous components :

CAS-No. [141-78-6], EC-No.2005-500-4 Ethylacetate GHS02, GHS07, H225, H319, H336

SECTION 4: FIRST-AID MEASURES

General information: no special measure required

After skin contact: wash with plenty of water and soap.

After inhalation: fresh air

After eye contact: rinse opened eye for several minutes under running water and consult with a doctor.

After swallowing: Caution if victim vomits. Risk of aspiration. Keep airways free. Consult a physician. Subsequently administer: Activated charcoal (20-40 g in 10% slurry). Laxative: Sodium sulfate (1 tablespoon/ ¼ l water).

SECTION 5: FIRE-FIGHTING MEASURES

Extinguishing media:

CO₂, powder, water spray.

Use extinguishing method and media suitable to surrounding fire.

Special hazards arising from the substance or mixture: No further relevant information available.

Protective equipment: Wear self-contained respiratory protective equipment.

**SECTION 6: ACCIDENTAL RELEASE MEASURES****Personal precautions, protective equipment and emergency procedures:**

Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms.

Environmental precautions:

Do not allow to enter drains/surface water/ groundwater.

Methods for cleaning up:

Absorb with liquid binding material. Clean up affected area.

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**Handling:**

This product should only be supplied to and handled by professionals in the industry.

Precautions for safe handling:

Observe normal care for working with chemicals.

Information about fire and explosion protection:

No special measures required.

Storage:

Requirements at storerooms and containers: Store only in the original containers

Further information on storage conditions:

Store in well ventilated place at 15 °C to 25 °C, protected from light. Store away from food stuffs. Store tightly closed. Keep away from heat and sources of ignition.

Specific end uses: No further relevant information available.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**Components with limits of values to be supervised at the workplace:**

CAS-No	Name	Art	Value	Unit
141-78-6	Ethylacetate	TRGS900	400	ml/m ³
		or	1500	mg/m ³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties****Appearance:**

Form: Liquid

Color: Slightly Yellow

Odor: Sweetish

Safety – Relevant basic data



	Value	Unit	Method
Melting Point/ melting range	N.A		
Boiling Point/ boiling range	Approx. 77	°C	
Flash Point	-4	°C	DIN 51755
Ignition Temperature	No	Information	Available
Danger of Explosion	Lower limit of explosion		2.1 Vol% Kühn
Density	Upper limit of explosion		11.5 Vol% Birett
Vapor Pressure	c.a. 0.9	20°C g/cm ³	
Solubility in/ Miscibility with	n.d		
Water	Soluble		
Content of Solvents			
Organic Solvents	Ethylacetate		

SECTION 10: STABILITY AND REACTIVITY

Thermal decomposition / conditions to be avoided.

Possibility of hazardous reactions: no information available.

Conditions to avoid: Heat, direct sunlight and radical stars. This product is stable by proper use. Avoid contact with alkali metals, hydrides, oxidizing agents, radical initiators.

Hazardous decomposition products: No information available.

SECTION 11: TOXICOLOGICAL INFORMATION**Acute Toxicity: (Ethylacetate)**

LD₅₀ (oral, rat) 5600 mg/kg

LD₅₀ (dermal, rabbit) >18000 mg/kg

LD₅₀ (inhal., rat) 5,86 mg/l (8h)

Primary irritation:

Skin: repeated exposure may cause skin dryness or cracking.

Eye: strong irritating effect.

Inhalation and swallowing: irritation of mucous membranes, loss of appetite, headache, drowsiness.

Additional toxicological information: Allergic reactions to acrylates after long-term exposure are possible. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.



SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Aquatic toxicity: No further relevant information found.

Persistence and degradability: No further relevant information found.

Behavior in environmental systems

Bioaccumulative potential: No further relevant information found.

Mobility in soil: No further relevant information found.

General information: Do not flush into surface water or sanitary sewer system.

SECTION 13: DISPOSAL CONSIDERATIONS

Product Recommendation:

Use proper landfill disposal or incineration in accordance with local, state, and federal regulations.

Uncleaned Packaging Recommendation:

Disposal must be made according to official regulations.

SECTION 14: TRANSPORT INFORMATION

Land transport ADR/RID and GGVS/GGVE (Germany): UN1173 ETHYL ACETATE, 3, II.

See transport ICAO-TI and IATA-DGR: UN 1173 ETHYL ACETATE, 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.

SECTION 15: REGULATORY INFORMATION

Classification According to EC-guidelines:

The product is a medical device according to EC-directive 93/42 EEC.

Chemical safety assessment:

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Factor II, Inc. urges each customer or recipient of this SDS to study it carefully to become aware of and understand the hazards associated with the product. The reader should consider consulting reference works or individuals who are experts in ventilation, toxicology and/or fire prevention as necessary or appropriate to the use and understanding of the data contained in this SDS. To promote safe handling each customer or recipient should 1) notify and furnish its employees, agents, contractors, customers and/or others whom it knows or believes will use this material of the information regarding hazards or safety, and 2) request its customers to notify their employees, customers and other users of the product of this information

This is to certify that the above designated material has been tested and did comply with the listed specifications (with listed exceptions) when supplied in original container. The material is subject to the conditions listed on the invoice. The above is a copy of information on file. The lot acceptance data are available for examination. This is a



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