

ACU-flow™
Thixotropic Silicone Material

PRODUCT INFORMATION SHEET

Description and Indication of Material:

A Vinyl poly siloxane material used as a medical device to create via impression taking a reproduction of tooth and gum structure. Acu-flow Silicone Material is an addition impression silicone easily removed from the mouth providing a highly detailed reproduction as well as unlimited shelf life as compared to alginate.

Technical data in accordance to Din EN ISO 4823:

Consistency: medium viscosity-Type2 . Working Time: 1.00min (+-30sec) Intra=oral Set Time:1.30min (+-30sec). The work /set times refer to a room temperature of 23C/73F with a relative humidity of 50%. Higher temperatures shorten and lower temperatures prolong these times.

Additional Important Information:

Do not use Acu-flow Silicone Material in combination with condensation impression materials. Remove by water spray any residues from hemostatic agents prior to taking impression. Use of latex gloves,creams,cleaning agents,resins,etc may inhibit Polymerization. Available in our convenient 50ml automix cartridges. Keep away from Children. For Dental Use Only. US Law restricts this device to sale by or to order of , a dentist.

Cartridge Mixing:

Insert the 50ml cartridge into the dispensing gun and attach the proper size mixing tip. The mixing is done automatically within the mixing tip. Always bleed the cartridge before each use and reattach cartridge cover tip to seal the material after each use.

Impression Tray:

The impression tray whether plastic,metal,perforated or non perforated,should be cleaned and carefully dried .Using a VPS tray adhesive is recommended.

Pouring and Storage:

Acu-flow Quick Set Silicone material's thixotropic and non gagging formulation provides exact replication and remains stable for years and can be poured immediately or at your convenience. You can also pour multiple times as required. After removal from the mouth, store impression at room temperature.(15-28C/59-82F)

Disinfecting:

After removing the impression from the mouth it should be rinsed with the water for 15 seconds. The Impression should then be immersed in disinfecting solution for 10-15 minutes. The use of a 2% glutaraldehyde solution is recommended .Make sure that the solution is compatible with the addition reaction silicones. Rinse the impression again with water for another 15 seconds.

Warranty:

Rainbow Specialty & Health Products Inc (Rainbow). will replace free of charge any product proven to be defective when stored and used according to recommendations mentioned herein. Rainbow does not accept liability for any loss or damage direct or otherwise arising out of use of or the inability to use this product. Users assume all risks and liability whatsoever in connection therewith.

REV:08/13/2015

ACU-flow™ - Thixotropic Silicone Material MSDS - Material Safety Data Sheet

SECTION 1 - PRODUCT IDENTIFICATION & INFORMATION

MATERIAL NAME: ACU-flow™ Thixotropic Silicone Material

COMPANY: Rainbow Specialty & Health Products Inc.
3400 – 14th Ave. Unit 22

Markham, Ontario Canada L3R 0H7

TELEPHONE: For Emergencies or Product

Information Call: 1-800-268-3384 or 905-947-0124

FOR PROFESSIONAL DENTAL USE ONLY

SECTION 2 - COMPOSITION/DATA ON COMPONENTS

Chemical Characterization

DESCRIPTION: Mixture of substances listed below with non-hazardous additions.

Dangerous Components:

1344-09-8 Silicic acid, sodium salt ≤2.5%

Additional Information: For the wording of the listed risk phrases, refer to section 16.

SECTION 3 - HAZARDS IDENTIFICATION

Hazard Description: Not applicable

Information Pertaining to Particular Dangers for Man and Environment:

The product does not have to be labeled due to the calculation procedure of the "General Classification Guideline for Preparations of the EU" in the latest valid version.

Classification System: The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

NFPA Ratings (Scale 0-4)

Health = 0 Fire = 1 Reactivity = 0

HMIS Ratings (Scale 0-4)

Health = 0 Fire = 1 Reactivity = 0

SECTION 4 - FIRST AID MEASURES

General Information: No special measures required.

After Inhalation: Supply fresh air; consult doctor in case of complaints.

After Skin Contact: Generally the product does not irritate the skin.

After Eye Contact: Rinse opened eye for several minutes under running water.

After Swallowing: If symptoms persist consult doctor.

SECTION 5 - FIRE FIGHTING MEASURES

Suitable Extinguishing Agents: Use fire fighting measures that suit the environment.

Protective Equipment: No special measures required.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Person-related Safety Precautions: Avoid contact with skin and eyes.

Measures for Environmental Protection: Do not allow to enter sewers/surface or ground water.

Measures for cleaning/collecting: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Additional Information: No dangerous substances are released.

SECTION 7 - HANDLING AND STORAGE

Information for Safe Handling: When using do not eat, drink, or smoke.

Information about Protection Against Explosions and Fire: No special measures required.

Storage Requirements to be met by Storerooms and Receptacles: Keep container tightly sealed.

Information about Storage in One Common Storage Facility: Not required.

Further Information about Storage Conditions: None

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Additional Information about Design of Technical Systems: No further data, see item 7.

Components with limit Values that Require Monitoring at the Workplace:

14464-46-1 Cristobalite

REL 0.05* mg/m3 * respirable dust

TLV 0.025 R mg/m3

Additional Information: The lists valid during the making were used as basis.

Personal Protective Equipment

General Protective and Hygienic Measures: The usual precautionary measures for handling chemicals should be followed.

Breathing Equipment: Not required.

Protection of Hands: The glove material had to be impermeable and resistant to the product/the substance/the preparation. Due to missing tests, no recommendation to the glove material can be given for the product/the preparation/the chemical mixture. Selection of the glove material should be based on the penetration times, rates of diffusion, and the degradation.

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: Goggles are recommended during refining.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

General Information

Form: Viscous

Color: Pink

Odor: Characteristic

Change in Condition

Melting Point/Melting Range: Undetermined

Boiling Point/Boiling Range: 275°C (527°F)

Flash Point: 130°C (266°F)

Ignition Temperature: 375°C (707°F)

Auto-igniting: Product is not self-igniting

Danger of Explosion: Product does not present an explosion hazard.

Vapor Pressure at 20°C (68°F): 100 hPa (75mm Hg)

Density: Not determined

Solubility in/Miscibility with Water: Not miscible or difficult to mix.

SECTION 10 - STABILITY AND REACTIVITY

Thermal Decomposition/Conditions to be Avoided: No decomposition if used according to specifications.

Dangerous Reactions: No dangerous reactions known.

Dangerous Products of Decomposition: No dangerous decomposition products known.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Primary Irritant Effect: -----

On the Skin: No irritant effect.

On the Eye: No irritant effect.

Sensitization: No sensitizing effects known.

Additional Toxicological Information: The product is not subject to classification according to internally approved calculation methods for preparations.

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

SECTION 12 - 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 sewer system.

SECTION 13 - DISPOSAL CONSIDERATIONS

Product

Recommendation: Disposal must be made according to official regulations.

Uncleaned Packaging

Recommendation: Disposal must be made according to official regulations.

SECTION 14 - TRANSPORT INFORMATION

DOT Regulations:

Hazard Class: -

Land Transport ADR/RID (Cross-Border):

ADR/RID Class: -

Maritime Transport IMDG:

IMDG Class: -

Marine Pollutant: No

Air Transport ICAO-TI and IATA-DGR:

ICAO/IATA Class: -

SECTION 15 - REGULATIONS SARA

Section 355 (Extremely Hazardous Substances): None of the ingredients are listed.

Section 313 (Specific Toxic Chemical Listings): None of the ingredients are listed.

TSCA (Toxic Substances Control Act): All ingredients are listed.

PROPOSITION 65

Chemicals Known to Cause Cancer: None of the ingredients are listed.

Chemicals Known to Cause Reproductive Toxicity for Females: None of the ingredients are listed.

Chemicals Known to Cause Reproductive Toxicity for Males: None of the ingredients are listed.

Chemicals Known to Cause Developmental Toxicity: None of the ingredients are listed.

CANCEROGENICITY CATEGORIES

EPA (Environmental Protection Agency): None of the ingredients are listed.

IARC (International Agency for Research on Cancer):

14464-46-1 Cristobalite

1318-02-1 Sodium Aluminium Silicate

NTP (National Toxicity Program):

14464-46-1 Cristobalite

TLV (Threshold Limit Value Established by ACGIH): None of the ingredients are listed.

MAK (German Maximum Workplace Concentration): 14464-46-1 Cristobalite

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

14464-46-1 Cristobalite

OSHA-Ca (Occupational Safety & Health Administration):

None of the ingredients are listed.

Product Related Hazard Information: Observe the general safety regulations when handling chemicals.

The product is not subject to identification regulations according to directives on hazardous materials.

NATIONAL REGULATIONS:

Water Hazard Class: Water Hazard Class 1 (Self-assessment): Slightly hazardous for water.

SECTION 16 - OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish and legally valid contractual relationship.