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 : Secure II, Medical Silicone Adhesive

Product Code : B-400, B-401, B-402, B-403, B-400N; BT-401, BT-401-1, BT-402, BT-404, BT-405.

Intended Use(s): This product is a pressure sensitive, silicone-based adhesive; intended for use with silicone prosthetics.

CONTACT INFORMATION FOR SUPPLIER OF SAFETY DATA SHEET

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SECTION 2: HAZARD(S) IDENTIFICATION

Hazard Classification: This material is hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29CFR 1910.1200.
Flammable liquids – Category 2
Specific target organ toxicity – single exposure – Category 3

Label Elements

Hazard Pictograms

Single Word: **DANGER!**

Hazards
Highly Flammable and vapour.
May cause drowsiness or dizziness.

Precautionary Statements

Prevention
Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
Keep container tightly closed.
Ground/bond container and receiving equipment.
Use explosion-proof electrical/ ventilating/ lighting equipment.
Use only non-sparking tools.
Take precautionary measures against static discharge.
Avoid breathing dust/ fumes/ gas/ mist/ vapours/ spray.
Use only outdoors or in well-ventilated area.
Wear protective gloves/eye protection/ face protection.

Response
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF USING AS ADHESIVE FOR PROSTHETIC: Make sure the solvent fully evaporates before placing on the skin.
IF INHALED: Remove person to fresh air and keep comfortable breathing for breathing.
Call a POISON CENTER/ doctor if you feel unwell.
In case of fire: Use water spray, alcohol-resistant foam, dry chemical, or carbon dioxide to extinguish.

Storage
Store in a well-ventilated place. Keep container tightly closed.
Store in a well-ventilated place. Keep cool.
Store locked up.

Disposal
Dispose of contents/ container to an approved waste disposal plant.

Other Hazards
Static- accumulating flammable liquid.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Nature: Silicone in solvent.
This product is a mixture.

Hazardous Ingredient	CAS Number	Concentration (%)
Ethyl Acetate	141-78-6	>=32.0 - <=38.0%

SECTION 4: FIRST AID MEASURES

Description of first aid measures
General advice:
First aid responders should pay attention to self-protection and use recommended protective clothing (chemical resistant gloves, splash protection). If potential for exposure exists refer to Section 8 for specific personal protective equipment.

Inhalation: move person to fresh air. If not breathing, give artificial respiration; if by mouth-to-mouth use rescuer protection (pocket mask, etc.). If breathing is difficult, oxygen should be administered by qualified personal.

Skin Contact: Wash off with plenty of water.
IF USING AS ADHESIVE FOR PROSTHETIC: Make sure the solvent fully evaporates before placing on the skin.

Eye Contact: Flush eye thoroughly with water for several minutes. Remove contact lenses after the initial 1-2 minutes and continue flushing for several minutes. If effects occur, consult a physician, preferably an ophthalmologist.

Ingestion: No emergency medical treatment necessary.

Most important symptoms and effects, both acute and delayed: Aside from the information found under "Description of first aid measures" (above) and "Indication of immediate medical attention and special treatment need" (below), any additional important symptoms and effects are described in Section 11: Toxicology Information.

Indication of any immediate medical attention and special treatment needed:
Notes to physician: Maintain adequate ventilation and oxygen of the patient. No specific antidote. Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient.

SECTION 5: FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray, Alcohol-resistant foam, Carbon dioxide (CO2), Dry chemical.

Unsuitable extinguishing media: High volume water jet; Do not use direct water stream.

Special hazards arising from the substance or mixture

Hazardous combustion products: Carbon oxides and silicone oxides.

Unusual Fire and Explosion Hazards: Flash back possible over a considerable distance. Exposure to combustion products may be a hazard to health.

Advice for Firefighters

Fire Fighting Procedures: Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Use water spray to cool fire exposed containers and fire affected zone until fire is out and danger of reignition has passed. Do not use a solid water stream as it may scatter and spread fire. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire are if it is safe to do so. Evacuate the area.

Special protective equipment for firefighters: in the event of a fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, protective equipment, and emergency procedures: Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Non-sparking tools should be used. Soak up with inert absorbent material. Supress (knock down) gasses/ vapours/ mists with a water spray jet. Local and national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, clean up remaining materials from spill with suitable absorbent. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
See sections: 7, 8, 11, 12, and 13.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Do not get on skin or clothing. **IF USING AS ADHESIVE FOR PROSTHETIC: Make sure the solvent fully evaporates before placing on the skin.** Do not breath vapours or spray mist. Do not swallow. Avoid contact with eyes. Keep container tightly closed. Keep away from heat and sources of ignition. Take precautionary measures against static discharge. Take care to prevent spills, waste and minimize release to the environment. Non-sparking tools should be used. Handle in accordance with good industrial hygiene and safety practice. Use with local exhaust ventilation. Use only in an area equipped with explosion proof exhaust ventilation. Ensure all equipment is electrically grounded before beginning transfer options. This material can accumulate static charge due to its inherent physical properties and can therefore cause an electrical ignition. Restrict flow velocity in order to reduce the accumulation of static electricity. Ground and bond container and receiving equipment.

Conditions for safe storage: keep in properly stored containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the national regulations. Keep away from heat and sources of ignition.

Do not store with the following product types: strong oxidizing agents. Organic peroxides. Flammable solids. Pyrophoric liquids. Pyrophoric solids. Self-heating substances and mixtures. Substances and mixtures, which in contact with water, emit flammable gasses. Explosives. Gasses.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters
If exposure limits exist, they are listed below, if no exposure limits are displayed, then no values are applicable.

Component	Regulation	Type of listing	Value/Notation
Ethyl Acetate	IHG	TWA	150ppm
	IHG	STEL	300ppm
	ACGIH	TWA	400ppm
	OSHA Z-1	TWA	1400 mg/m3 400ppm

Exposure controls
Engineering controls: use engineering controls to maintain airborne level below exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, use only with adequate ventilation. Local exhaust ventilation may be necessary for some operations.

Individual protection measures

Eye/ Face protection: Use safety glasses (with side shields).

Skin protection:

Hand protection: use gloves chemically resistant to this material when prolonged or frequently repeated contact can occur. Butyl rubber. Chlorinated polyethylene. Neoprene. Polyethylene. Ethyl vinyl alcohol laminate (“EVAL”). Polyvinyl alcohol (“PVA”). Examples of acceptable glove barrier materials include: Natural rubber (latex). Nitrile/butadiene rubber (“nitrile” or “NBR”). Polyvinyl chloride (“PVC” or “Vinyl”). Viton. **NOTICE:** the selection of a specific glove for a particular application and duration of use in a workplace should also take into account all relevant workplace factors such as, but not limited to: Other chemicals which may be handled,

physical requirements (cut/ puncture protection, dexterity, thermal protection), potential body reactions to glove materials, as well as the instructions/ specification provided by the glove supplier.

Other protection: Wear clean, body-covering clothing.

Respiratory protection: Respiratory protection should be worn when there is a potential to exceed the exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive-pressure supplied-air will depend on specific operation and the potential airborne concentration of the material. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: Organic vapour cartridge with a particulate pre-filter.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	
Physical State	Liquid
Color	Colorless to pale yellow
Odor	Solvent-like
Odor Threshold	No data available
pH	No data available
Melting point/ range	No data available
Freezing point	No data available
Boiling point (760mmHg)	77°C (171°F)
Flash Point	**closed cup** -4.44°C (24.01°F)
Evaporation Rate (Butyl Acetate = 1)	No data available
Flammability (solid, gas)	Not applicable
Lower explosion limit	No data available
Upper explosion limit	No data available
Vapor Pressure	125.29166hPa
Relative Vapor Density (air = 1)	3.04
Relative Density (water = 1)	1.02
Water solubility	No data available
Partition coefficient: n-octanol/ water)	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Dynamic Viscosity	4,000 cP
Kinematic Viscosity	No data available
Explosive properties	Not explosive
Oxidizing properties	The substance or mixture is not classified as oxidizing.
Molecular weight	No data available
Particle Size	Not applicable

NOTE: The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.

Chemical stability: Stable under normal conditions.

Possibility of hazardous reactions: Can react with strong oxidizing agents. When heated to temperatures above 150 °C (300 °F) in the presence of air, product can form formaldehyde vapours. Safe handling conditions may be maintained by keeping vapour concentrations within the occupational exposure limit for formaldehyde. Vapours may form explosive mixture with air. Highly flammable liquid vapour.

Conditions to avoid: Heat, flames, and sparks.

Incompatible materials: Oxidizing agents.

Hazardous decomposition products: Formaldehyde.

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicological information appears in this section when such data is available.

Acute Toxicity

Acute oral toxicity
Very low acute toxicity if swallowed. Harmful effects not anticipated from swallowing small amounts.

As product: Single dose oral LD50 has not been determined.

Based on information for component(s):
LD50, Rat, > 2,000 mg/kg Estimated.

Acute dermal toxicity
Prolonged skin contact is unlikely to result in absorption of harmful amounts.

As product: The dermal LD50 has not been determined.

Based on information for component(s):
LD50, Rabbit, >2,000 mg/kg Estimated.

Acute inhalation toxicity
Prolonged excessive exposure may cause adverse effects. Symptoms may include headache, dizziness, and drowsiness, progressing to incoordination and unconsciousness. May cause respiratory irritation and central nervous system depression.
As product: The LC50 has not been determined.

Skin corrosion/ irritation
Brief contact is essentially nonirritating to the skin.

Serious eye damage/ eye irritation
Essentially nonirritating to eyes.

Sensitization
Did not cause allergic skin reactions when tested in humans.

For Respiratory sensitization:
No relevant data found.

Specific Target Organ Toxicity (Single Exposure)
Contains component(s) which are classified as specific target organ toxicant, single exposure, Category 3.

Specific Target Organ Systemic Toxicity (Repeated Exposure)
Symptoms of excessive exposure may be anesthetic or narcotic effects; dizziness and drowsiness may be observed.
In animals, effects have been reported on the following organs:
-Liver.
-Respiratory Tract.

Carcinogenicity
Contains component(s) which did not cause cancer in laboratory animals.

Teratogenicity
No relevant data found.

Reproductive toxicity
No relevant data found.

Mutagenicity
Animal genetic toxicity studies were negative. In vitro genetic toxicity studies were predominantly negative.

Genetic Toxicity in vitro
Bacterial reverse mutation assay (AMES) – negative result: negative on basis of test data.

Aspiration Hazard
Based on physical properties, not likely to be an aspiration hazard.

COMPONENTS INFLUENCING TOXICOLOGY:

Ethyl Acetate

Acute inhalation toxicity
LC50, Rat, 4-hour, vapour, >28.6 mg/l.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicological information appears in this section when such data is available.

Toxicity

Ethyl Acetate

Acute toxicity to fish
Material is practically non-toxic to aquatic organisms on an acute basis, (LC50/EC50/EL50/LL50 > 100 mg/L in the most sensitive species tested).
LC50, Pimephales promelas (fathead minnow), 96 Hour, 230 mg/l.

Acute toxicity to aquatic invertebrates
EC50, Daphnia magna (water flea), 24 Hour, 3,090 mg/L, DIN 38412.

Acute toxicity to algae/ aquatic plants
NOEC, Pseudokirchneriella subcapitata (green algae), 72 Hour, >100 mg/L, OCED Test. Guideline 201
EbC50, alga Scenedesmus sp., static test, 48 Hour, Biomass, 3,300 mg/l

Toxicity to Bacteria
EC50, Photobacterium phosphoreum, 0.25 Hour, 5,870 mg/l

Chronic toxicity to fish
NOEC, Pimephales promelas (fathead minnow), 32 days, <9.65 mg/l

Chronic toxicity to aquatic invertebrates
NOEC, Daphnia magna (water flea), semi-static test, 21 d, number of offspring, 2.4 mg/l.

Persistence and Degradability

Ethyl Acetate

Biodegradability: Material is readily biodegradable. Passes OECD test(s) for ready biodegradability.
10 Day Window: Pass
Biodegradation: 100%
Exposure time: 28 days
Method: OECD Test Guideline 301D or Equivalent.

Theoretical Oxygen Demand: 1.82 mg/mg

Bioaccumulative Potential

Ethyl Acetate

Bioaccumulation: Bioconcentration potential is low (BCF < 100 or Log Pow < 3).
Partition coefficient: n-octanol/water (log Pow): 0.68 Measured.
Bioconcentration factor (BCF): 30 Fish Measured.

Mobility in soil

Ethyl Acetate

Potential for mobility in soil is very high (Koc between 0 and 50).
Partition coefficient (Koc): 3 Estimated.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Methods: DO NOT DUMP INTO ANY SEWERS, ON THE GROUND, OR INTO ANY BODY OF WATER. All disposal practices must be in compliance with all federal, state/ provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator. AS YOUR SUPPLIER, WE HAVE NO CONTROL OVER THE MANAGEMNET PRACTICES OR MANUFACTURING PROCESS OF PARTIES HANDLING OR USING THIS MATERIAL. THE INFORMATION PRESENTED HERE PERTAINS ONLY TO THE PRODUCT AS SHIPPED IN ITS INTENDED CONDITION AS DESCRIBED IN MSDS SECTION: Composition information. FOR UNUSED & UNCONTAIMINATED PRODUCT, the preferred options include sending to licensed, permitted: Recycler. Reclaimer. Incinerator or other thermal destruction device. For additional information, refer to: Handling and Storage Information, MSDS Section 7; Stability and Reactivity Information, MSDS Section 10; Regulatory Information, MSDS Section 15.

Treatment and disposal methods of used packaging: Empty containers should be recycled or otherwise disposed of by an approved waste management facility. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator. Do not re-use containers for any purpose.

SECTION 14: TRANSPORT INFORMATION

DOT

Proper shipping name	Ethyl Acetate Solution
UN Number	UN 1173
Class	3
Packing group	II
Reportable Quantity	Ethyl Acetate

Classification for SEA transport (IMO-IMDG)

Proper shipping name	Ethyl Acetate Solution
UN Number	UN 1173
Class	3
Packing group	II
Marine pollutant	No
Transport in bulk according to Annex I or II of MARPOL 73/78 and the IBC or IGC Code	Consult IMO regulations before transporting ocean bulk

Classification for AIR transport (IATA/ICAO)

Proper shipping name	Ethyl Acetate Solution
UN number	UN 1173
Class	3
Packing group	II

This information is not intended to convey all specific regulatory or operational requirements/ information relating to this product. Transportation classifications may vary by container volume and may be influenced by regional or country variations in regulations. Additional transportation system information can be obtained through an authorized sales or customer service representative. It is the responsibility of the transporting organization to follow all applicable laws, regulations and rules relating to the transportation of the material.

SECTION 15: REGULATORY INFORMATION

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-to-know Act of 1986) Sections 311 and 312
Flammable (gasses, aerosols, liquids, or solids)
Hazard not otherwise classified (physical hazards)
Specific target organ toxicity (single or repeated exposure)

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-to-Know of 1986) Section 313.
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) Section 103
Calculated RQ exceeds reasonably attainable upper limit.

Components	CASRN	RQ (RCRA Code)
Ethyl Acetate	141-78-6	5000 lbs. RQ
Ethyl Acetate	141-78-6	100 lbs. RQ (F003)
Ethyl Acetate	141-78-6	5000 lbs. RQ
Ethyl Acetate	141-78-6	100 lbs. RQ (F003)

Pennsylvania Right to Know
The following chemicals are listed because of the additional requirements of Pennsylvania law:

Components	CASRN
Trimethylated silica treated with dimethyl siloxane	68440-70-0
Ethyl Acetate	141-78-6

California Prop. 65
WARNING: this product can expose you to chemicals including Ethylbenzene (CAS#100-41-4), which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

United States TSCA Inventory (TSCA)
All components of this product are in compliance with the inventory listing requirements of the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

SECTION 16: OTHER INFORMATION

Hazard Rating System
NFPA

Health	Fire	Reactivity
0	3	0

HMIS

Health	Flammability	Physical Hazard
2/	3	0

Legend

ACGIH	USA. ACGIH Threshold Limit Values (TLV)
IHG	Industrial Hygiene Guideline
OSHA Z-1	USA. Occupational Exposure Limits (OSHA) – Table Z-1 Limits for Air Contaminants
STEL	Short term exposure limit
TWA	Time weighted average

Full text of other abbreviations

AICS – Australian Inventory of Chemical Substances; ASTM – American Society for the Testing of Materials; bw – Body Weight; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; CMR – Carcinogen, Mutagen or Reproductive Toxicant; DIN – Standard of the German Institute for Standardization; DOT – Department of Transportation; DSL – Domestic Substances List (Canada); ECx – Concentration associated with x% response; EHS – Extremely Hazardous Substance; ELx – Loading rate associated with x% response; EmS – Emergency Schedule; ENCS – Existing and New Chemical Substances (Japan); - ErCx – Concentration associated with x% growth rate response; ERG – Emergency Response Guide; GHS – Globally Harmonized System; GLP – Good Laboratory Practice; HMIS – Hazardous Materials Identification System; IARC – International Agency for Research on Cancer; IATA – International Air Transport Association; IBC – International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 – Half maximal inhibitory concentration; ICAO – International Civil Aviation Organization; IECSC – Inventory of Existing Chemical Substances in China; IMDG – International Maritime Dangerous Goods; IMO – International Maritime Organization; ISHL – Industrial Safety and Health Law (Japan); ISO – International Organization for Standardization; KECI – Korea Existing Chemicals Inventory; LC50 – Lethal Concentration to 50% of a test population; LD50 – Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL – International Convention for the Prevention of Pollution from Ships; MSHA – Mine Safety and Health Administration; n.o.s. – Not Otherwise Specified; NFPA – National Fire Protection Associations; NO(A)EC – No Observed (Adverse) Effect Concentration; NO(A)EL – No Observed (Adverse) Effect Level; NOELR – No Observable Effect Loading Rate; NTP – National Toxicology Program; NZIoC – New Zealand Inventory of Chemicals; OECD – Organization for Economic Co-operation and Development; OPPTS – Office of Chemical Safety and Pollution Prevention; PBT – Persistent, Bioaccumulative and Toxic substance; PICCS – Philippines Inventory of Chemicals and Chemical Substances; (Q) SAR – (Quantitative) Structure Activity Relationship; RCRA – Resource Conservation and Recovery Act; REACH – Regulation (EC) No 1907/2006 of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RQ – Reportable Quantity; SADT – Self-Accelerating Decomposition Temperature; SARA – Superfund Amendments and Reauthorization Act; SDS – Safety Data Sheet; TCSI – Taiwan Chemical Substance Inventory; TSCA – Toxic Substance Control Act (United States); UN – United Nations;UNRTDG – United Nations Recommendations on the Transport of Dangerous Goods; vPvB – Very Persistent and Very Bioaccumulative.

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IT IS RECOMMENDED THAT THE PURCHASER THOROUGHLY TEST ANY APPLICATION PRIOR TO FULL SCALE PRODUCTION OR

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