SECTION 1: IDENTIFICATION

PRODUCT IDENTIFIER

Product Name : Factor 2 Secure Adhesive (silicone in solvent)

Product Code : B-400, B-401, BT-401, B-460, B-461, BT-460,

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

CONTACT INFORMATION FOR SUPPLIER OF SAFETY DATA SHEET

Company name:	Technovent Ltd
Street:	Unit 5 York Park Bridgend CF31 3TB
Place:	UK
Telephone:	+44 1656 768566
e-mail:	info@technovent.com
Internet:	www.technovent.com

EMERGENCY TELEPHONE NUMBERS

Emergency number: +44 1656768566

This number is only obtainable during office hours
(Monday - Thursday 9.00 am - 5.00 pm, Friday 9.00 am - 4.00 pm)

SECTION 2: HAZARD(S) IDENTIFICATION

GHS Classification

Hazard class : Flammable liquids,
Category 2 Eye irritation,
Category 2A
Specific target organ systemic toxicity - single exposure, Category 3

Hazard Pictogram(s) :

Signal word : Danger

Hazard statement(s) : H225 Highly flammable liquid and vapor

H319 Causes serious eye irritation
H336 May cause drowsiness or dizziness

Precautionary statement(s) : **Prevention**

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P233 Keep container tightly closed
P240 Ground/bond container and receiving equipment
P241 Use explosion-proof electrical/ventilating/lighting equipment P242 Use only non-sparking tools
P243 Take precautionary measures against static discharge P261 Avoid breathing mist or vapors
P264 Wash skin thoroughly after handling
P271 Use only outdoor or in a well-ventilated area
P280 Wear protective gloves/eye protection/face protection

Response

P303 + P361 + P353 IF ON SKIN (or hair): Immediately remove all contaminated clothing. Rinse skin with water/ shower.
P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
P305 + P351 + P338 IF IN EYES: Rise cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists, seek medical advice/ attention.

Storage

P403 + P235 Store in a well-ventilated area and keep cool. P405 Store locked up.

Disposal

P501 Dispose of contents/container to an approved waste disposal plant.

Other hazard(s) : Static-accumulating flammable liquid.
Repeated exposure may cause skin dryness or cracking. Vapors may form explosive mixture with air.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	Concentration (%)
Ethyl Acetate	141-78-6	>=30 – <50

SECTION 4: FIRST-AID MEASURES

In the case of accident or if you feel unwell, see medical attention immediately. When symptoms persist, or in all cases of doubt, seek medical attention.

First-aid instructions by relevant routes of exposure include:

Inhalation : Remove victim to fresh air. Seek medical attention if symptoms occur.

Skin contact : Immediately flush skin with plenty of water. Seek medical attention if symptoms occur.

Eye contact : Flush eyes with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do. Seek medical attention.

Ingestion : DO NOT induce vomiting. Rinse mouth thoroughly with water. Seek medical attention if symptoms occur.

Most important symptoms and effects, both acute and delayed : Causes serious eye irritation. May cause drowsiness or dizziness. Prolonged or repeated contact may dry skin and cause irritation.

First aid responders : First aid responders should pay attention to self-protection and use the recommended personal protective equipment when the potential for exposure exists.

Note to physician : Treat symptomatically and supportively.

SECTION 5: FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray, alcohol-resistant foam, dry chemical, carbon dioxide (CO2)

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire : Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides, silicon oxides, formaldehyde

Specific extinguishing methods : 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 area if safe to do so. Evacuate area.

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

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions and emergency procedures : Remove all sources of ignition and ventilate the area. 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 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 cleanup procedures : Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapors/mist with a water spray jet. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.

Local or 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. See Sections 13 and 15 of this SDS for information regarding certain local or national requirements.

SECTION 7: HANDLING AND STORAGE

Technical measures : Ensure all equipment is electrically grounded before beginning transfer operations. This material can accumulate static charge due to its inherent physical properties and can therefore cause an electrical ignition source to vapors. In order to prevent a fire hazard, as bonding and grounding may be insufficient to remove static electricity, it is necessary to provide an inert gas purge before beginning transfer operations. Restrict flow velocity in order to reduce the accumulation of static electricity.

Local/total ventilation : Use with local exhaust ventilation. Use only in an area equipped with explosion proof exhaust ventilation.

Precautions for safe handling : Do not get on skin or clothing. Do not breathe vapors or spray mist. Do not swallow. Do not get in eyes. Handle in accordance with good industrial hygiene and safety practice. Non-sparking tools should be used. Keep container tightly closed. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

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

Materials to avoid : 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 gases, explosives or gases.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENTS WITH WORKPLACE CONTROL PARAMETERS

Ingredients	CAS Number	Value type (Form of exposure)	Control parameters/ Permissible concentration	Basis
Ethyl acetate	141-78-6	TWA	400 ppm	ACGIH
		TWA	400 ppm 1,400 mg/m3	NIOSH REL
		TWA	400 ppm 1,400 mg/m3	OSHA Z-1

Engineering Controls : Processing may form hazardous compounds (see Section 10). Minimize workplace exposure concentrations. Use only in an area equipped with explosion proof exhaust ventilation. Use with local exhaust ventilation.

Personal Protective Equipment
Pictograms :

Respiratory : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Eye/Face : Use safety goggles as a minimum when working with chemicals.

Hands : Antistatic, impervious, flame retardant gloves. Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, clarify the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Skin/Body : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Wear the following personal protective equipment: flame retardant antistatic protective clothing. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc.).

Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. These precautions are for room temperature handling. Use at elevated temperature or aerosol/spray applications may require added precautions. For further information regarding the use of silicones/organic oils in consumer aerosol applications, please refer to the guidance document regarding the use of these type of materials in consumer aerosol applications that has been developed by the silicone industry (www.SEHSC.com).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Liquid

Color	:	Colorless to pale yellow
Upper/lower flammability or explosive limits	:	No data available
Odor	:	Solvent
Vapor pressure	:	No data available
Odor threshold	:	No data available
Vapor density	:	No data available
pH	:	No data available
Relative density	:	1.02
Melting point/freezing point	:	No data available
Solubility(ies)	:	No data available
Initial boiling point and boiling range	:	> 95°F / > 35°C
Flash point	:	24°F / -4.44°C (Method: closed cup)
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Partition coefficient n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	3,000 mPa.s
Explosive properties	:	Not explosive
Oxidizing properties	:	Substance or mixture is not classified as oxidizing
Molecular weight	:	No data available

SECTION 10: STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard

Chemical stability : Stable under normal conditions

Hazardous reactions : Highly flammable liquid and vapor. Vapors may form explosive mixture with air. Can react with strong oxidizing agents. When heated to temperatures above 300°F (150°C) in the presence of air, product can form formaldehyde vapors. Safe handling conditions may be maintained by keeping vapor concentrations within the occupational exposure limit for formaldehyde.
Formaldehyde may cause cancer. It is also toxic by inhalation, skin absorption and ingestion, corrosive to skin and eyes and may cause skin sensitization and respiratory irritation. See OSHA formaldehyde standard, 29 CFR 1910.1048. Hazardous decomposition products will be formed at elevated temperatures.

Conditions to avoid : Avoid handling operations that can promote accumulation of static charges. Avoid heat, flames and sparks.

Incompatible materials : Oxidizing agents

Hazardous thermal decomposition products : Formaldehyde

SECTION 11: TOXICOLOGICAL INFORMATION

INFORMATION ON LIKELY ROUTES OF EXPOSURE - Inhalation, skin contact, ingestion, eye contact

ACUTE TOXICITY - Not classified based on available information

Product

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Ingredients

Ethyl acetate

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 420

Acute inhalation toxicity : LC50 (Rat): > 29.3 mg/l
Exposure time: 4 h
Test atmosphere:
vapor
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

SKIN CORROSION/IRRITATION – Not classified based on available information

Ingredients

Ethyl acetate

Result : No skin irritation
Species : Rabbit
Assessment : Repeated exposure may cause skin dryness or cracking

SERIOUS EYE DAMAGE/EYE IRRITATION – Causes serious eye irritation

Ingredients

Ethyl acetate

Result : Irritation to eyes, reversing within 21 days
Remarks : Based on harmonized classification in EU regulation 1272/2008, Annex VI

RESPIRATORY AND SKIN SENSITIZATION – Not classified based on available information

Ingredients

Ethyl acetate

Test type : Maximization Test
(GPMT) Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : Negative

GERM CELL MUTAGENICITY - Not classified based on available information

Ingredients

Ethyl acetate

Genotoxicity in vitro

Test Type : Bacterial reverse mutation assay (AMES)
Result : Negative

Genotoxicity in vivo

Test Type : Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species : Hamster
Application route :
Ingestion
Result :
Negative

CARCINOGENICITY - Not classified based on available information

IARC : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA : No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP : No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

REPRODUCTIVE TOXICITY – Not classified based on available information

Ingredients

Ethyl acetate

Effects on fertility

Test type : Two-generation reproduction toxicity study
Species :
Mouse
Application route :

Ingestion

Result : Negative

Effects on fetal development

Test type : Embryo-fetal development
Species : Rat
Application route : Inhalation
Result : Negative

STOT-SINGLE EXPOSURE - May cause drowsiness or dizziness

Ingredients

Ethyl acetate

Assessment : May cause drowsiness or dizziness

STOT-REPEATED EXPOSURE – Not classified based on available information

REPEATED DOSE TOXICITY

Ingredients

Ethyl acetate

Species : Rat
NOAEL : 900
mg/kg Application route : Inhalation
Exposure time : 90 d

ASPIRATION TOXICITY - Not classified based on available information

SECTION 12: ECOLOGICAL INFORMATION

Ethyl acetate

Toxicity to fish
LC50 : Pimephales promelas (fathead minnow) 220 mg/l
Exposure time : 96 h

Toxicity to daphnia and other aquatic invertebrates EC50 : > 100 mg/l
Exposure time : 48 h

Toxicity to algae
NOEC : Desmodesmus subspicatus (green algae) > 100 mg/l
Exposure time : 72 h
Method : OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (chronic toxicity) NOEC : Daphnia magna (water flea) 2.4 mg/l
Exposure time : 24 d

Toxicity to bacteria
EC50 : Photobacterium phosphoreum 5,870 mg/l

Exposure time : 0.25 h

PERSISTENCE AND DEGRADABILITY

Ingredients
Ethyl acetate
Biodegradability
Result : Readily biodegradable
Biodegradation : 69%
Exposure time : 20 d

BIOACCUMULATIVE POTENTIAL

Ingredients
Ethyl acetate
Bioaccumulation
Species : Leuciscus idus (Golden orfe) Bioconcentration factor : 30
Exposure time : 3 d

Partition coefficient n-0.68 octanol/water : log Pow

MOBILITY IN SOIL - No data available

OTHER ADVERSE EFFECTS - No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Resource Conservation And Recovery Act (RCRA) : When a decision is made to discard this material as supplied, it is classified as a RCRA hazardous waste.

Waste Code : D001 Ignitability

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Dispose of as unused product. Do not re-use empty containers. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not burn, or use a cutting torch on, the empty drum.

SECTION 14: TRANSPORT INFORMATION

UNRTDG
Proper shipping name : Ethyl acetate

solution UN number : UN1173
Hazard class(es) : 3

Packing group : II
Labels : 3

IATA-DGR

Proper shipping name : Ethyl acetate
solution UN number : UN1173
Hazard class(es) : 3
Packing group : II
Labels : Flammable liquids
Packing instructions : Passenger/Cargo aircraft – 353

IMDG-Code

Proper shipping name : Ethyl acetate
solution UN number : UN1173
Hazard class(es) : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : No

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code – not applicable for the product as supplied

DOMESTIC REGULATION – 49 CFR

Proper shipping name : Ethyl acetate
solution UN number : UN1173
Hazard class(es) : 3
Packing group : II
Labels : Flammable liquids
ERG Code : 129
Marine pollutant : No

SECTION 15: REGULATORY INFORMATION

EPCRA - EMERGENCY PLANNING AND COMMUNITY RIGHT-TO-KNOW

CERCLA Reportable Quantity

Ingredients	CAS Number	Component RQ (lbs)	Calculated Product RQ (lbs)
Ethyl acetate	141-78-6	5,000	12500
Xylene	1330-20-7	100	*
Ethylbenzene	100-41-4	1,000	*

* Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 Hazards : Fire hazard
Acute health hazard

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 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.

US STATE REGULATIONS

Pennsylvania Right To Know

Trimethylated silica treated with dimethyl siloxane	68440-70-0	50 – 70%
Ethyl acetate	171-78-6	30 – 50%

New Jersey Right To Know

Trimethylated silica treated with dimethyl siloxane	68440-70-0	50 – 70%
Ethyl acetate	171-78-6	30 – 50%

California Prop 65 WARNING – This product contains a chemical know in the State of California to cause cancer. Ethylbenzene 100-41-4

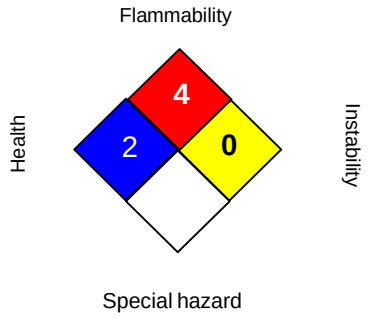
The ingredients of this product are reported in the following inventories:

REACH	All ingredients (pre-) registered or exempt
TSCA	All chemical substances in this material are included on or exempted from listing on the TSCA Inventory of Chemical Substances
AICS	All ingredients listed or exempt
IECSC	All ingredients listed or exempt
ENCS/ISHL	All components are listed on ENCS/ISHL or exempted from inventory listing
DSL	All chemical substances in this product comply with the CEPA 1999 and NSNR and are on or exempt from listing on the Canadian Domestic Substances List (DSL)

Inventories: AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), NECSI (Taiwan), TSCA (USA)

SECTION 16: OTHER INFORMATION

NFPA:



HMIS III:

HEALTH	2
FLAMMABILITY	4
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight, 2 = Moderate, 3 = High 4 = Extreme, * = Chronic

FULL TEXT OF OTHER ABBREVIATIONS

ACGIH	:	USA. ACGIH Threshold Limit Values
(TLV) NIOSH REL Limits	:	USA. NIOSH Recommended Exposure
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average

DISCLAIMER / STATEMENT SDS to OF LIABILITY:

Factor II, Inc. urges each customer or recipient of this 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.