

**SECTION 1: IDENTIFICATION**
**1.1. Product Identifier**

**Product Form:** Mixture

**Product Name:** TYENNE® (tocilizumab-aazg) injection, for intravenous or subcutaneous use

**1.2. Intended Use of the Product**

Immunosuppressive Agent. Treatment For Rheumatoid Arthritis (RA), Systemic Juvenile Idiopathic Arthritis (SJIA), Polyarticular Juvenile Idiopathic Arthritis (PJIA)

**1.3. Name, Address, and Telephone of the Responsible Party**
**Distributor**

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

<http://www.fresenius-kabi.com/us/>

**1.4. Emergency Telephone Number**

**Emergency Number : VelocityEHS**

(800)255-3924 (North America)

+1 (813)248-0585 (International)

**SECTION 2: HAZARDS IDENTIFICATION**
**2.1. Classification of the Substance or Mixture**
**GHS-US/CA Classification**

Reproductive toxicity Category 2

H361

Specific target organ toxicity (repeated exposure) Category 2

H373

**2.2. Label Elements**
**GHS-US/CA Labeling**

**Hazard Pictograms (GHS-US/CA)** :



GHS08

**Signal Word (GHS-US/CA)** :

Warning

**Hazard Statements (GHS-US/CA)** :

H361 - Suspected of damaging fertility or the unborn child (unborn child, oral exposures).

H373 - May cause damage to organs (liver, immune system) through prolonged or repeated exposure (oral).

**Precautionary Statements (GHS-US/CA)** :

P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P260 - Do not breathe vapors, mist, or spray.

P280 - Wear protective gloves, protective clothing, and eye protection.

P314 - Get medical advice/attention if you feel unwell.

P405 - Store locked up.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

**2.3. Other Hazards**

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

**2.4. Unknown Acute Toxicity (GHS-US/CA)**

No additional information available

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### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	AQUA	(CAS-No.) 7732-18-5	95.78	Not classified.
Tocilizumab	tocilizumab	(CAS-No.) 375823-41-9	2	Repr. 2, H361 STOT RE 2, H373
L-Arginine	L-Arginine / ARGININE / (S)-2-Amino-5- [(aminoiminomethyl)amino]pentanoic acid / arginine / Arginine, L- / Arginine L- / Arginine	(CAS-No.) 74-79-3	1.74	Comb. Dust
L-Histidine	Glyoxaline-5-alanine / Histidine / Histidine, L- / L- Histidine / L-(-) Histidine / HISTIDINE	(CAS-No.) 71-00-1	0.31	Comb. Dust
L-Lactic acid	Propanoic acid, 2-hydroxy-, (S)- / (S)-2- Hydroxypropanoic acid / (S)-Lactic acid / (S)-(+)-Lactic acid / L-(+)-Lactic acid / (+)-Lactic acid / Lactic acid, L- / Propanoic acid, 2-hydroxy-, (2S)- / Sarcosine / (S)- (+)-2-Hydroxypropanoic acid / (+)-2-Hydroxypropanoic acid / L-2-Hydroxypropanoic acid / L-(+)-lactic acid / Lactic acid, L-	(CAS-No.) 79-33-4	0.09	Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 3, H402
Sodium chloride	Sodium salt of hydrochloric acid / Salt / SEA SALT / SODIUM CHLORIDE / Sodium chloride (NaCl) / Sea salt	(CAS-No.) 7647-14-5	0.06	Not classified.
Sorbitan, mono-(9Z)-9- octadecenoate, poly(oxy- 1,2-ethanediyl) derivatives	Polyoxyethylene sorbitan monooleate / Polysorbate 80 / Sorbitan monooleate, ethoxylated / Sorbitan, mono-9- octadecenoate, poly(oxy-1,2-ethanediyl) derivatives, (Z)- / Polyoxyethylene (5) sorbitan monooleate / PEG-3 SORBITAN OLEATE / Polyoxyethylene (20) sorbitan monooleate / Polyethylene glycol sorbitan monooleate / PEG-20 SORBITAN OLEATE / PEG sorbitan oleate / Sorbitan monooleate, ethoxylated (1-6.5 moles ethoxylated) / POLYSORBATE 80 / POLYSORBATE 81 / PEG-6 sorbitan oleate / PEG-40 sorbitan oleate / PEG-20 sorbitan oleate / PEG-40 SORBITAN OLEATE / PEG-6 SORBITAN OLEATE	(CAS-No.) 9005-65-6	0.02	Not classified.

\*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%). Full text of H-statements: see section 16.

### SECTION 4: FIRST AID MEASURES

#### 4.1. Description of First-aid Measures

**General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

**Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**Skin Contact:** Remove contaminated clothing. Wash with plenty of soap and water. If exposed or concerned: Get medical advice/attention.

**Eye Contact:** Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical advice.

**Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

#### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**General:** Suspected of damaging the unborn child (oral). May cause damage to organs (liver, immune system) through prolonged or repeated exposure (oral).

**Inhalation:** Prolonged exposure may cause irritation.

**Skin Contact:** Prolonged exposure may cause skin irritation.

**Eye Contact:** May cause slight irritation to eyes.

**Ingestion:** Ingestion may cause adverse effects.

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**Chronic Symptoms:** Suspected of damaging the unborn child (oral). May cause damage to organs (liver, immune system) through prolonged or repeated exposure (oral).

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Solutions do not burn. Use extinguishing media appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** None known.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Product is not flammable.

**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** None expected under normal conditions of use. Under fire conditions, product may produce: Carbon and nitrogen oxides. Sodium oxides. Chlorine compounds.

**Other Information:** No additional information available.

### 5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray. Avoid all contact with skin, eyes, or clothing. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

#### 6.1.1. For Non-Emergency Personnel

**Protective Equipment:** Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Material may be biologically contaminated with pathogenic organisms during use.

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing. Do NOT breathe (dust, vapor, mist, gas). Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with EC Directive 2010/32/EU.

**Handling Temperature:** 8 – 30 °C (46 - 86 °F). Tyenne can be stored for a single period of up to 14 days at room temperature at or below 25°C (77°F). Please verify if extended stability temperature goes up to 30 °C (86 °F). Do not use material exposed to

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temperature greater than 30 °C (86 °F).

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

**Incompatible Materials:** Strong acids, strong bases, strong oxidizers.

**Storage Temperature:** Tyenne can be stored for a single period of up to 14 days at room temperature at or below 25°C (77°F).

Please verify if extended stability temperature goes up to 30 °C (86 °F). Do not use material exposed to temperature greater than 30 °C (86 °F).

### 7.3. Specific End Use(s)

Immunosuppressive Agent. Treatment For Rheumatoid Arthritis (RA), Systemic Juvenile Idiopathic Arthritis (SJIA), Polyarticular Juvenile Idiopathic Arthritis (PJIA)

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

### 8.2. Exposure Controls

**Appropriate Engineering Controls:** Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

**Personal Protective Equipment:** Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



**Materials for Protective Clothing:** Chemically resistant materials and fabrics.

**Hand Protection:** Wear protective gloves.

**Eye and Face Protection:** Chemical goggles or safety glasses.

**Skin and Body Protection:** Wear suitable protective clothing.

**Respiratory Protection:** If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

**Other Information:** When using, do not eat, drink or smoke. Pregnant or possibly pregnant women must use special care while handling this material. Needle sticks should be reported immediately.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear, colorless to pale-yellow liquid
Odor	: No data available
Odor Threshold	: No data available
pH	: ≈ 6
Evaporation Rate	: No data available
Melting Point	: ≈ 0 °C (32 °F)
Freezing Point	: ≈ 0 °C (32 °F)
Boiling Point	: ≈ 100 °C (212 °F)
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available

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Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Specific Gravity	: No data available
Solubility	: Water: Soluble/miscible
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

### 10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

### 10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

### 10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

### 10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

### 10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Carbon and nitrogen oxides. Sodium oxides. Chlorine compounds.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects - Product

Likely routes of exposure: Dermal. Eye contact. Ingestion. Inhalation.

Acute Toxicity (Oral): Not classified.

Acute Toxicity (Dermal): Not classified.

Acute Toxicity (Inhalation): Not classified.

#### LD50 and LC50 Data:

No additional information available

Skin Corrosion/Irritation: Not classified.

pH: ≈ 6

Eye Damage/Irritation: Not classified.

pH: ≈ 6

Respiratory or Skin Sensitization: Not classified.

Germ Cell Mutagenicity: Not classified.

Carcinogenicity: Not classified.

Specific Target Organ Toxicity (Repeated Exposure): May cause damage to organs (liver, immune system) through prolonged or repeated exposure (oral).

Reproductive Toxicity: Suspected of damaging the unborn child (oral).

Specific Target Organ Toxicity (Single Exposure): Not classified.

Aspiration Hazard: Not classified.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging the unborn child (oral). May cause damage to organs (liver, immune system) through prolonged or repeated exposure (oral).

### 11.2. Information on Toxicological Effects - Ingredient(s)

#### LD50 and LC50 Data:

L-Histidine (71-00-1)	
LD50 Oral Rat	> 15 g/kg (Source: NLM_CIP)
L-Lactic acid (79-33-4)	
LD50 Oral Rat	3730 mg/kg (Source: IUCLID)
LD50 Dermal Rabbit	> 2000 mg/kg (Source: NICNAS)
LC50 Inhalation Rat	7.9 mg/l/4h