1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Hydrocortisone Sodium Succinate for Injection (Act-O-Vial)

Trade Name: Solu-Cortef
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anti-inflammatory

Details of the Supplier of the Safety Data Sheet

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number: Emergency telephone number:
Chemtrec (24 hours): 1-800-424-9300
International Chemtrec (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 2

Label Elements

Signal Word: Warning
Hazard Statements: H361d - Suspected of damaging the unborn child

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone Sodium Succinate</td>
<td>125-04-2</td>
<td>204-725-5</td>
<td>Repr. 2 (H361d)</td>
<td>5 - 10</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr.1A (H314)</td>
<td>**</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Acute Tox.4 (H302)</td>
<td>&lt;2</td>
</tr>
<tr>
<td>Sodium phosphate, monobasic</td>
<td>7558-80-7</td>
<td>231-449-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium phosphate, dibasic</td>
<td>7558-79-4</td>
<td>231-448-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:**
Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:**
Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:**
Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:**
Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**Symptoms and Effects of Exposure:**
For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:**
None known
Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products:
- Carbon dioxide, carbon monoxide

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. Avoid breathing dust. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product used as anti-inflammatory

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Hydrocortisone Sodium Succinate

Pfizer OEL TWA-8 Hr: 100 µg/m³, Skin

Sodium hydroxide
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ACGIH Ceiling Threshold Limit: 2 mg/m³
Australia PEAK 2 mg/m³
Austria OEL - MAKs 2 mg/m³
Bulgaria OEL - TWA 2.0 mg/m³
Czech Republic OEL - TWA 1 mg/m³
Estonia OEL - TWA 1 mg/m³
France OEL - TWA 2 mg/m³
Greece OEL - TWA 2 mg/m³
Hungary OEL - TWA 2 mg/m³
Japan - OELs - Ceilings 2 mg/m³
Latvia OEL - TWA 0.5 mg/m³
OSHA - Final PELS - TWAs: 2 mg/m³
Poland OEL - TWA 0.5 mg/m³
Slovakia OEL - TWA 2 mg/m³
Slovenia OEL - TWA 2 mg/m³
Sweden OEL - TWAs 1 mg/m³
Switzerland OEL - TWAs 2 mg/m³

Benzyl Alcohol
Bulgaria OEL - TWA 5.0 mg/m³
Czech Republic OEL - TWA 40 mg/m³
Finland OEL - TWA 10 ppm
45 mg/m³
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³
Poland OEL - TWA 240 mg/m³

Sodium phosphate, monobasic
Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Sodium phosphate, dibasic
Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Powder plus sterile diluent</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble: Water</td>
</tr>
<tr>
<td>pH</td>
<td>7-8 (solution)</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Hydrocortisone Sodium Succinate
No data available

Sodium phosphate, monobasic
No data available

Sodium phosphate, dibasic
No data available

Benzyl Alcohol
No data available

Sodium hydroxide
No data available

Water
No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:
- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under recommended storage conditions. Solutions are unstable after 4 hours.

Possibility of Hazardous Reactions
- Oxidizing Properties: No data available
10. STABILITY AND REACTIVITY

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause eye, skin and respiratory tract irritation (based on components). May be absorbed through the skin in harmful amounts. Central nervous system effects such as headache, dizziness, drowsiness, fatigue, and lack of muscular coordination can also occur. May cause stomach irritation, diarrhea, nausea, or vomiting.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects: Effects on vision have been seen during clinical use. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes. Clinical use may cause an increase in blood pressure (hypertension). Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Acute Toxicity: (Species, Route, End Point, Dose)

Hydrocortisone Sodium Succinate

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>5000 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>5000mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Subcutaneous</td>
<td>LD 50</td>
<td>449mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>LD 50</td>
<td>&gt;500mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>LD 50</td>
<td>150mg/kg</td>
</tr>
</tbody>
</table>

Benzyl Alcohol

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>1230 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Para-periosteal</td>
<td>LD50</td>
<td>53mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Inhalation</td>
<td>LC50</td>
<td>&gt;4.178mg/L</td>
</tr>
</tbody>
</table>

Sodium hydroxide

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>IP</td>
<td>LD50</td>
<td>40 mg/kg</td>
</tr>
</tbody>
</table>

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Hydrocortisone Sodium Succinate

| Eye Irritation | Rabbit | Minimal |

Benzyl Alcohol

| Eye Irritation | Rabbit | Severe |
| Skin Irritation | Rabbit | Minimal |
| Skin Irritation | Guinea Pig | Moderate |
11. TOXICOLOGICAL INFORMATION

Sodium hydroxide
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Hydrocortisone Sodium Succinate
7 Day(s)  Mouse  Oral  140 mg/kg/day  LOAEL  Thymus
4 Day(s)  Mouse  Subcutaneous  100 mg/kg/day  LOAEL  Liver
11 Day(s)  Mouse  Subcutaneous  62 mg/kg/day  LOAEL  Endocrine system
2 Week(s)  Mouse  Subcutaneous  560 mg/kg/day  LOAEL  Liver, Bone Marrow
85 Day(s)  Rat  Subcutaneous  175 mg/kg/day  LOAEL  Adrenal gland

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Hydrocortisone Sodium Succinate
Reproductive & Fertility-Females  Rat  Oral  210 mg/kg/day  LOAEL  Maternal toxicity
Embryo / Fetal Development  Mouse  Oral  10 mg/kg/day  LOAEL  Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Hydrocortisone Sodium Succinate
Bacterial Mutagenicity (Ames)  Salmonella  Negative
In Vivo In Vitro Direct DNA Damage  Rat, Mouse  Positive
In Vivo In Vitro Chromosome Aberration  Rat, Mouse  Positive
Cytogenetics  Mouse  Negative

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties of the formulation have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity:
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Benzyl Alcohol
Pimephales promelas (Fathead Minnow)  EPA  LC50  96 Hours  460 mg/L
Daphnia magna (Water Flea)  OECD  EC50  48 Hours  230 mg/L
Pseudokirchneriella subcapitata (Green Alga)  OECD  EC50  72 Hours  500 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Benzyl Alcohol
Daphnia magna (Water Flea)  OECD  21 Day(s)  EC50  66 mg/L  Reproduction

Persistence and Degradability:
Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Benzyl Alcohol
OECD  Activated sludge  Ready  92% After  14 Day(s)  Ready

Bio-accumulative Potential:  No data available
Mobility in Soil:  No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Hydrocortisone Sodium Succinate
CERCLA/SARA 313 Emission reporting  Not Listed
California Proposition 65  Not Listed
Australia (AICS):  Present
EU EINECS/ELINCS List  204-725-5

Sodium phosphate, monobasic
CERCLA/SARA 313 Emission reporting  Not Listed
California Proposition 65  Not Listed
Inventory - United States TSCA - Sect. 8(b)  Present
Australia (AICS):  Present
EU EINECS/ELINCS List  231-449-2
15. REGULATORY INFORMATION

Sodium phosphate, dibasic

| CERCLA/SARA 313 Emission reporting | Not Listed |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities | 5000 lb |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS) | Present |
| EU EINECS/ELINCS List | 231-448-7 |

Sodium hydroxide

| CERCLA/SARA 313 Emission reporting | Not Listed |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities | 1000 lb |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS) | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons | Schedule 5 |
| EU EINECS/ELINCS List | 215-185-5 |

Benzyl Alcohol

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS) | Present |
| EU EINECS/ELINCS List | 202-859-9 |

Water

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS) | Present |
| REACH - Annex IV - Exemptions from the obligations of Register | Present |
| EU EINECS/ELINCS List | 231-791-2 |

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information. Publicly available toxicity information.
SAFETY DATA SHEET

Material Name: Hydrocortisone Sodium Succinate for Injection (Act-O-Vial)
Revision date: 23-Oct-2019

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 23-Oct-2019
Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet