



SAFETY DATA SHEET

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

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

Product Code(s) HYDROCORTISONE SODIUM SUCCINATE FOR INJECTION

Trade Name: Solu-Cortef

Item Code H000006008, H000006009, H000006010, H000013895, H000013943, H000013944, H000013945, H000400764, H000401059, H000401060, H000402211, H000402213, H000402215, H000402217, H000479720, H009402213, H009402215, H009402217

Chemical Family: Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as anti-inflammatory

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

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

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Reproductive toxicity Category 1B - (H360Df)

OSHA Classification

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

2.2. Label elements



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Signal word

Danger

Hazard statements

H360Df - May damage the unborn child. Suspected of damaging fertility

Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use

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

P280 - Wear protective gloves and protective clothing

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P405 - Store locked up

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

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Hydrocortisone Sodium Succinate (CAS #: 125-04-2)	5 - 10		204-725-5	Repr. 1B (H360Df)	Not classified	No data available	No data available
BENZYL ALCOHOL (CAS #: 100-51-6)	<2		202-859-9 (603-057-00-5)	Acute Tox. 4 (H302) Skin Sens. 1B (H317) Eye Irrit. 2 (H319)	Not classified	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5%	No data available	No data available

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					Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%		
--	--	--	--	--	--	--	--

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
Sodium phosphate, dibasic (CAS #: 7558-79-4)	*		231-448-7	Not classified	Not classified	No data available	No data available
Sodium phosphate, monobasic (CAS #: 7558-80-7)	*		231-449-2	Not classified	Not classified	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
BENZYL ALCOHOL 100-51-6	1200+ 1230	2000	4.178	No data available	No data available
Sodium phosphate, dibasic 7558-79-4	17000	No data available	No data available	No data available	No data available
Sodium phosphate, monobasic 7558-80-7	8290	7940	0.83	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59).

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. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

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Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
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.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO₂, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Carbon dioxide, carbon monoxide

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

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Methods for containment

Methods for cleaning up

Prevent further leakage or spillage if safe to do so.

Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated surface thoroughly.

Prevention of secondary hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections

See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Minimize dust generation and accumulation. Avoid contact with skin, eyes or clothing. Avoid breathing dust/fume/gas/mist/vapors/spray. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions

Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s)

Pharmaceutical product used as. anti-inflammatory.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

Hydrocortisone Sodium Succinate

Pfizer OEL TWA-8 Hr: 100 µg/m³, Skin

BENZYL ALCOHOL

Pfizer OEL TWA-8 Hr: 10 ppm

BENZYL ALCOHOL

Bulgaria

Czech Republic

Finland

Germany DFG

Germany TRGS

TWA: 5.0 mg/m³;

40 mg/m³

Ceiling: 80 mg/m³

TWA: 10 ppm;

TWA: 45 mg/m³;

TWA-MAK: 22 mg/m³; I(2);

TWA-MAK: 5 ppm; I(2);

Peak: 44 mg/m³;

Peak: 10 ppm;

Sk

TWA-AGW; 5 ppm (exposure factor 2);

TWA-AGW; 22 mg/m³ (exposure factor 2);

Sk

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Ceiling Limit Value	25 mg/m ³
Latvia	TWA: 5 mg/m ³ ;
Poland	TWA-NDS: 240 mg/m ³ ;
Russia	MAC: 5 mg/m ³
	Skin
Switzerland	TWA-MAK: 5 ppm; aerosol, vapour
	TWA-MAK: 22 mg/m ³ ; aerosol, vapour
	Sk

Sodium phosphate, dibasic

Russia

MAC: 10 mg/m³

Sodium phosphate, monobasic

Russia

MAC: 10 mg/m³

Sodium hydroxide

ACGIH OEL (Ceiling)

2 mg/m³

ACGIH TLV

Ceiling: 2 mg/m³

Austria

TWA-TMW: 2 mg/m³; inhalable fraction

Bulgaria

STEL-KZGW: 4 mg/m³ (8 X 5 min); inhalable fraction

Czech Republic

TWA: 2.0 mg/m³; alkaline aerosols

1 mg/m³

Ceiling: 2 mg/m³

Denmark

Ceiling: 2 mg/m³;

Estonia

TWA: 1 mg/m³;

STEL: 2 mg/m³;

Finland

Ceiling: 2 mg/m³;

France

2 mg/m³

Hungary

TWA-AK: 1 mg/m³;

STEL-CK: 2 mg/m³;

Ireland

STEL: 2 mg/m³;

Ceiling Limit Value

2 mg/m³

Latvia

TWA: 0.5 mg/m³;

Poland

TWA-NDS: 0.5 mg/m³;

STEL-NDSch: 1 mg/m³;

Romania

TWA: 1 mg/m³;

STEL: 3 mg/m³;

Slovakia

TWA: 2 mg/m³;

Spain

STEL (VLA-EC): 2 mg/m³;

Switzerland

TWA-MAK: 2 mg/m³; inhalable dust

STEL-KZGW: 2 mg/m³; inhalable dust

OSHA PEL

TWA: 2 mg/m³

(vacated) Ceiling: 2 mg/m³

United Kingdom

STEL: 2 mg/m³;

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

8.2. Exposure controls

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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.
Eye/face protection	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.).
Hand protection	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.).
Skin and body protection	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.).
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.).
Thermal hazards	No information available.
Environmental exposure controls	No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	plus sterile diluent
Physical state	Powder Liquid
Color	White to off-white
Odor	No information available.
Odor threshold	No information available

<u>Property</u>	<u>Values</u>
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	7-8
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available

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Solubility	Soluble Water
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

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

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

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.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

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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	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Classification is based on mixture calculation methods based on component data.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

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

Hydrocortisone Sodium Succinate

Rat Oral LD 50 5000 mg/kg

Mouse Oral LD 50 5000 mg/kg

Rat Subcutaneous LD 50 449 mg/kg

Mouse Subcutaneous LD 50 >500 mg/kg

Rat Intraperitoneal LD 50 150 mg/kg

BENZYL ALCOHOL

Rat Oral LD 50 1230 mg/kg

Mouse Oral LD 50 1360 mg/kg

Rabbit Dermal LD 50 2 gm/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
BENZYL ALCOHOL	= 1230 mg/kg (Rat)	= 2 g/kg (Rabbit)	> 4178 mg/m ³ (Rat) 4 h
Sodium phosphate, dibasic	= 17 g/kg (Rat)	-	-
Sodium phosphate, monobasic	= 8290 mg/kg (Rat)	> 7940 mg/kg (Rabbit)	> 0.83 mg/L (Rat) 4 h
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-

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

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

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

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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 & Development Toxicity: (Duration, 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

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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been thoroughly investigated. Releases to the environment should be avoided. The following information is available for the individual ingredients.

12.1. Toxicity

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

BENZYL ALCOHOL

Pimephales promelas (Fathead Minnow) EPA LC50 96 hours 460 - 770 mg/L
Daphnia magna (Water Flea) NPDES OECD EC50 48 Hours 230 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 hours 500 mg/L

12.2. Persistence and degradability

Persistence and degradability

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

BENZYL ALCOHOL

OECD Activated sludge Ready 92 % After 28 Day(s) Ready

12.3. Bioaccumulative potential

Bioaccumulation No information available.

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12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
BENZYL ALCOHOL	Not PBT/vPvB
Sodium phosphate, dibasic	PBT assessment does not apply
Sodium phosphate, monobasic	PBT assessment does not apply
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

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 wastewater 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.

Section 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.

UN number: Not applicable
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): Not applicable

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Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

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CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	204-725-5
AICS	Present

BENZYL ALCOHOL

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	202-859-9
AICS	Present

Sodium phosphate, dibasic

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-448-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

Sodium phosphate, monobasic

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-449-2
AICS	Present

Sodium hydroxide

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
BENZYL ALCOHOL 100-51-6	RG 84

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

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Not applicable

TRGS 905

Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable

Major Accidents Ordinance SR 814.012 Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
BENZYL ALCOHOL 100-51-6	75	-
Sodium hydroxide 1310-73-2	75	-

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

SAFETY DATA SHEET

Product Name Hydrocortisone Sodium Succinate for Injection
(Act-O-Vial)
Revision date 14-Jun-2025

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Version 5

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H314 - Causes severe skin burns and eye damage H302 - Harmful if swallowed H332 - Harmful if inhaled H360Df - May damage the unborn child. Suspected of damaging fertility

Data Sources:

Safety data sheets for individual ingredients. Pfizer proprietary drug development information. Publicly available toxicity information.

Reason for revision

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

Revision date

14-Jun-2025

Prepared By

Pfizer Global Environment, Health, and Safety

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