SAFETY DATA SHEET

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

1.1. Product identifier

Product Name Retacrit (epoetin alfa-epbx) Injection (MDV)

Product Code(s) PF00098
Synonyms Epoetin-alfa-epbx; Epoetin alfa-epbx Injection Multiple Dose Vial
Trade Name: RETACRIT
Chemical Family: Not determined

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

Recommended Use Pharmaceutical product

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
235 East 42nd Street
New York, New York 10017
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

Not classified as hazardous

2.2. Label elements

Signal word Not required

Hazard statements Not classified in accordance with international standards for workplace safety.

2.3. Other hazards

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

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	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
BENZYL ALCOHOL (CAS #: 100-51-6)	< 1		202-859-9	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	Not Listed	No data available	No data available
Sodium phosphate, dibasic (CAS #: 7558-79-4)	*		231-448-7	Not classified as hazardous	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC 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 as hazardous	Not Listed	No data available	No data available
Sucrose (CAS #: 57-50-1)	*	-	200-334-9	Not classified as hazardous	Not Listed	No data available	No data available
Sodium Phosphate Monobasic, Monohydrate (CAS #: 10049-21-5)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
Methionine (CAS #: 63-68-3)	*		200-562-9	Not classified as hazardous	Not Listed	No data available	No data available
Epoetin alfa (CAS #:	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

113427-24-0)							
Polysorbate 20 (CAS #: 9005-64-5)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	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
Sucrose 57-50-1	29700	No data available	No data available	No data available	No data available
BENZYL ALCOHOL 100-51-6	1230	2000	4.178	No data available	No data available
Methionine 63-68-3	36000	No data available	No data available	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
Polysorbate 20 9005-64-5	37000	No data available	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

Additional information

+ Substance with a Union workplace exposure limit
* 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.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

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 mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment 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

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area 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

Restrict access to work area. Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. 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.

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 drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

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

BENZYL ALCOHOL
Pfizer OEL TWA-8 Hr: 10 ppm

Sucrose

ACGIH TLV	10 mg/m³
Bulgaria	10.0 mg/m³
Estonia	10 mg/m³
France	10 mg/m³
Ireland	10 mg/m³
	STEL: 20 mg/m³
Latvia	5 mg/m³
Spain	10 mg/m³
OSHA PEL	15 mg/m³
	5 mg/m³
	(vacated) TWA: 15 mg/m³ total dust
	(vacated) TWA: 5 mg/m³ respirable fraction
United Kingdom	TWA: 10 mg/m³
	STEL: 20 mg/m³

BENZYL ALCOHOL

Bulgaria	5.0 mg/m³
Czech Republic	40 mg/m³
	Ceiling: 80 mg/m³
Finland	10 ppm
	45 mg/m³
Germany	22 mg/m³ can occur as vapor and aerosol at the same time
	5 ppm can occur as vapor and aerosol at the same time
	Ceiling / Peak: 44 mg/m³
	Ceiling / Peak: 10 ppm
	Skin
Germany	5 ppm
	22 mg/m³
	H*
Ceiling Limit Value	25 mg/m³
Latvia	5 mg/m³
Poland	240 mg/m³
Russia	MAC: 5 mg/m³
	Skin
Switzerland	5 ppm
	22 mg/m³
	H*

Methionine

Latvia	5 mg/m³

Sodium phosphate, dibasic

Russia	MAC: 10 mg/m³

Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m³
ACGIH TLV	Ceiling: 2 mg/m³
Austria	2 mg/m³
	STEL 4 mg/m³
Bulgaria	2.0 mg/m³
Czech Republic	1 mg/m³
	Ceiling: 2 mg/m³
Denmark	Ceiling: 2 mg/m³
Estonia	1 mg/m³
	STEL: 2 mg/m³
Finland	Ceiling: 2 mg/m³
France	2 mg/m³
Hungary	1 mg/m³
	STEL: 2 mg/m³
Ireland	STEL: 2 mg/m³
Ceiling Limit Value	2 mg/m³
Latvia	0.5 mg/m³
Poland	STEL: 1 mg/m³
	0.5 mg/m³
Romania	1 mg/m³
	STEL: 3 mg/m³
Slovakia	2 mg/m³
Spain	STEL: 2 mg/m³
Switzerland	2 mg/m³
	STEL: 2 mg/m³
OSHA PEL	2 mg/m³
	(vacated) Ceiling: 2 mg/m³
United Kingdom	STEL: 2 mg/m³

+ Hydrochloric Acid

ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	5 ppm
	8 mg/m³
	STEL 10 ppm
	STEL 15 mg/m³
Bulgaria	STEL: 10 ppm
	STEL: 15.0 mg/m³
	5 ppm
	8.0 mg/m³
Czech Republic	8 mg/m³
	Ceiling: 15 mg/m³
Denmark	Ceiling: 5 ppm
	Ceiling: 8 mg/m³
Estonia	5 ppm
	8 mg/m³
	STEL: 10 ppm
	STEL: 15 mg/m³
European Union	TWA: 5 ppm
	TWA: 8 mg/m³
	STEL: 10 ppm
	STEL: 15 mg/m³
Finland	STEL: 5 ppm
	STEL: 7.6 mg/m³
Germany	2 ppm
	3.0 mg/m³
	Ceiling / Peak: 4 ppm
	Ceiling / Peak: 6 mg/m³
Germany	2 ppm
	3 mg/m³
Hungary	8 mg/m³

	STEL: 16 mg/m³
Ireland	8 mg/m³
	5 ppm
	STEL: 10 ppm
	STEL: 15 mg/m³
Italy	5 ppm
	8 mg/m³
	STEL: 10 ppm
	STEL: 15 mg/m³
Ceiling Limit Value	2 ppm
	3.0 mg/m³
Latvia	5 ppm
	8 mg/m³
	STEL: 10 ppm
	STEL: 15 mg/m³
Netherlands	8 mg/m³
	STEL: 15 mg/m³
Poland	STEL: 10 mg/m³
	5 mg/m³
Romania	5 ppm
	8 mg/m³
	STEL: 10 ppm
	STEL: 15 mg/m³
Russia	MAC: 5 mg/m³
Slovakia	5 ppm
	8.0 mg/m³
Spain	5 ppm
	7.6 mg/m³
	STEL: 10 ppm
	STEL: 15 mg/m³
Switzerland	2 ppm
	3 mg/m³
	STEL: 4 ppm
	STEL: 6 mg/m³
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm
	7 mg/m³
OSHA PEL	(vacated) Ceiling: 5 ppm
	(vacated) Ceiling: 7 mg/m³
	Ceiling: 5 ppm
	Ceiling: 7 mg/m³
United Kingdom	TWA: 1 ppm
	TWA: 2 mg/m³
	STEL: 5 ppm
	STEL: 8 mg/m³

Pfizer Occupational Exposure Band (OEB) Statement: The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (ADI) range, based on available hazard data with appropriate safety factors applied. Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be used to achieve exposure control to the bottom of the band.

Sodium phosphate, dibasic

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

Epoetin alfa

Pfizer Occupational Exposure Band (OEB): B-OEB 5 (control exposure to <10 µg/day)

8.2. 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.
Environmental exposure controls	No information available.
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 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. (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.).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Color	Clear, colorless
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

Property	**Values**
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available

Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

9.2. Other information
No information available

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 data available.
10.2. Chemical stability
Stability Stable under normal conditions.
Explosion data
Sensitivity to Mechanical Impact No data available.
Sensitivity to Static Discharge No data 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 mists) may fuel fires/explosions. As a precautionary measure, keep away from 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	As with any protein, the possibility of allergic reactions exists.
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on blood cardiovascular system
Known Clinical Effects:	Adverse effects associated with therapeutic use include increase in blood pressure (hypertension), joint pain, muscle cramps, dizziness, respiratory infection, cough, effects on cardiovascular system.
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 Based on available data, the classification criteria are not met.
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)
Sucrose
Rat Oral LD 50 29,700 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)	-	-
Sucrose	= 29700 mg/kg (Rat)	-	-
BENZYL ALCOHOL	= 1230 mg/kg (Rat)	= 2 g/kg (Rabbit)	> 4178 mg/m³ (Rat) 4 h
Methionine	= 36 g/kg (Rat)	-	-
Sodium phosphate, dibasic	= 17 g/kg (Rat)	-	-
Epoetin alfa	= 20 kU/kg (Rat)	-	-
Polysorbate 20	= 37000 mg/kg (Rat)	-	> 5.1 mg/L (Rat) 4 h
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

Irritation / Sensitization: (Study Type, Species, Severity)
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
+ Hydrochloric Acid
Skin irritation Severe
Eye irritation Severe

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Epoetin alfa
Embryo / Fetal Development Rat Intravenous 500 mg/kg/day NOAEL Not teratogenic, Maternal toxicity
Embryo / Fetal Development Rabbit Intravenous 500 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Epoetin alfa
In Vitro Bacterial Mutagenicity (Ames) Not specified Negative
In Vitro HGPRT Forward Gene Mutation Assay Not specified Negative
In Vitro Chromosome Aberration Not specified Negative

In Vivo Micronucleus Mouse Negative
+ Hydrochloric Acid
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative

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

+ Hydrochloric Acid
IARC Group 3 (Not Classifiable)

11.2. Information on other hazards
11.2.1. Endocrine disrupting properties
Endocrine disrupting properties No information available.

11.2.2. Other information
Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

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.

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	The substance is not PBT / vPvB
Methionine	The substance is not PBT / vPvB
Sodium phosphate, dibasic	PBT assessment does not apply

Polysorbate 20	The substance is not PBT / vPvB PBT assessment does not apply
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
+ Hydrochloric Acid	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects
No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. 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 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

Special precautions for user: Not applicable

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

Sucrose
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **TSCA** Present
- **EINECS** 200-334-9

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 Monobasic, Monohydrate	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
AICS	Present
Methionine	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-562-9
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
Epoetin alfa	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4
Polysorbate 20	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	Not Listed
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
+ Hydrochloric Acid	
CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-595-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

France
Occupational Illnesses (R-463-3, France)

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

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
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	
+ Hydrochloric Acid - 7647-01-0	Use restricted. See item 75.	

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid - 7647-01-0	25	250

Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)
Sucrose - 57-50-1	Plant protection agent

EU - Biocides

Chemical name	EU - Biocides
+ Hydrochloric Acid - 7647-01-0	Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

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

Full text of H-Statements referred to under section 3

Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reason for revision New data sheet.

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Prepared By Pfizer Global Environment, Health, and Safety

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