SAFETY DATA SHEET

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

1.1. Product identifier

Product Name Testosterone Cypionate Injection (Hospira, Inc.)

Product Code(s) PZ03047
Trade Name: Not applicable
Chemical Family: Mixture

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

Recommended Use Pharmaceutical product used for hormone replacement therapy

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
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.

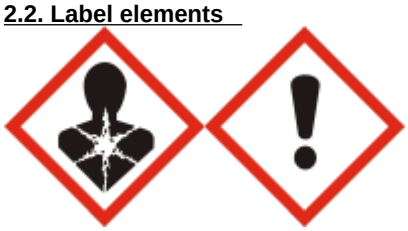
Acute toxicity - Oral	Category 4 - (H302)
Carcinogenicity	Category 1B - (H350)
Reproductive toxicity	Category 1A - (H360FD)
Endocrine disruption for human health	Category 1 - (EUH380)
Hazardous to the aquatic environment - acute	Category 2 - (H401)
Hazardous to the aquatic environment - chronic	Category 3 - (H412)
Endocrine disruption for the environment	Category 1 - (EUH430)

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



Signal word	Danger
Hazard statements	H302 - Harmful if swallowed H360FD - May damage fertility. May damage the unborn child H350 - May cause cancer H401 - Toxic to aquatic life H412 - Harmful to aquatic life with long lasting effects EUH380 - May cause endocrine disruption in humans EUH430 - May cause endocrine disruption in the environment
Precautionary Statements - EU (§28, 1272/2008)	P202 - Do not handle until all safety precautions have been read and understood P203 - Obtain, read and follow all safety instructions before use P270 - Do not eat, drink or smoke when using this product P273 - Avoid release to the environment P280 - Wear protective gloves/protective clothing/eye protection/face protection P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell P330 - Rinse mouth P308 + P313 - IF exposed or concerned: Get medical advice/attention P318 - IF exposed or concerned, get medical advice P405 - Store locked up P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable P264 - Wash face, hands and any exposed skin thoroughly after handling P273 - Avoid release to the environment

Unknown acute toxicity
20 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
20 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

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	Contains a known or suspected endocrine disruptor.
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)
Testosterone Cypionate (CAS #: 58-20-8)	20		200-368-4	Repr.1A (H360FD) Carc.1B (H350) ED HH 1 (EUH380) Aquatic Acute 1 (H400) Aquatic Chronic 2 (H411) ED ENV 1 (EUH430)	Not classified	1	No data available
BENZYL BENZOATE (CAS #: 120-51-4)	10 - 20		204-402-9 (607-085-00-9)	Acute Tox. 4 (H302) Aquatic Chronic 2 (H411)	Not classified	No data available	No data available
BENZYL ALCOHOL (CAS #: 100-51-6)	<1.0		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

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)
Cottonseed Oil (CAS #: 8001-29-4)	*		232-280-7	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
Cottonseed Oil 8001-29-4	89730	No data available	No data available	No data available	No data available

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
BENZYL BENZOATE 120-51-4	2000	4000	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

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

Additional information
* Proprietary
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

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

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. 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	Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. 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 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.

Testosterone Cypionate

Pfizer OEL TWA-8 Hr: 4 µg/m³, Skin

BENZYL ALCOHOL

Pfizer OEL TWA-8 Hr: 10 ppm

BENZYL BENZOATE

Russia	MAC: 5 mg/m³

BENZYL ALCOHOL

Bulgaria	TWA: 5.0 mg/m³;
Czech Republic	40 mg/m³ Ceiling: 80 mg/m³
Finland	TWA: 10 ppm; TWA: 45 mg/m³;
Germany DFG	TWA-MAK: 22 mg/m³; I(2); TWA-MAK: 5 ppm; I(2); Peak: 44 mg/m³; Peak: 10 ppm; Sk
Germany TRGS	TWA-AGW; 5 ppm (exposure factor 2); TWA-AGW; 22 mg/m³ (exposure factor 2); Sk
Ceiling Limit Value	25 mg/m³
Latvia	TWA: 5 mg/m³;
Poland	TWA-NDS: 240 mg/m³;
Russia	MAC: 5 mg/m³ Skin
Switzerland	TWA-MAK: 5 ppm; aerosol, vapour TWA-MAK: 22 mg/m³; aerosol, vapour Sk

Derived No Effect Level (DNEL) - Workers

Chemical name	Oral	Dermal	Inhalation
BENZYL BENZOATE 120-51-4	-	4 mg/kg bw/day [4] [6]	14.1 mg/m³ [4] [6] 70.5 mg/m³ [4] [7]

Derived No Effect Level (DNEL) - General Public

Chemical name	Oral	Dermal	Inhalation
BENZYL BENZOATE 120-51-4	1.42 mg/kg bw/day [4] [6]	-	2.48 mg/m³ [4] [6] 12.4 mg/m³ [4] [7]

Predicted No Effect Concentration (PNEC)

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
BENZYL BENZOATE 120-51-4	0.00322 mg/L	-	0.322 µg/L	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
BENZYL BENZOATE 120-51-4	2.0434 mg/kg sediment dw	0.204 mg/kg sediment dw	100 mg/L	0.4056 mg/kg soil dw	-

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.

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

Physical state	Liquid
Color	Clear
Odor	No information available.
Odor threshold	No information available

Property	**Values**
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	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
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 normal conditions.
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.

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 in this section describes the hazards of various forms of the active ingredient.
Long Term:	Adverse reproductive effects seen in repeat-dose animal studies are consistent with the

	pharmacologic action of this drug and are expected to be relevant to humans.
Known Clinical Effects:	Clinical use has caused effects on reproductive system, including prolonged erection (priapism), breast development in males (gynecomastia); loss of libido; decreased sperm count, impairment of male fertility, development of male characteristics (masculinization), development of male characteristics in the female fetus, impairment of female fertility. Clinical use of this drug has caused prostate cancer, liver cancer, kidney cancer.
Acute toxicity	Harmful if swallowed. Classification is based on mixture calculation methods based on component data.
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	May damage fertility. May damage the unborn child. 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	May cause cancer. Classification is based on mixture calculation methods based on component data.
Aspiration hazard	Based on available data, the classification criteria are not met.

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

Cottonseed Oil
Rat Oral LD50 > 90 ml/kg

BENZYL BENZOATE
Rat Oral LD50 1680 mg/kg

Testosterone Cypionate
Mouse Para-periosteal LD 50 > 1000 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

Testosterone
Rat (F) Para-periosteal LD50 325 mg/kg

Testosterone propionate
Rat Oral LD 50 1000 mg/kg
Mouse Oral LD 50 1350 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Cottonseed Oil	> 90 mL/kg (Rat)	-	-
BENZYL BENZOATE	> 2000 mg/kg (Rat)	= 4000 mg/kg (Rabbit)	-
BENZYL ALCOHOL	= 1230 mg/kg (Rat)	= 2 g/kg (Rabbit)	> 4178 mg/m³ (Rat) 4 h

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.

Unknown acute toxicity

20 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
20 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

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

BENZYL ALCOHOL
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Minimal
Skin Irritation Guinea Pig Moderate

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

Testosterone Cypionate
5 Day(s) Mouse Oral 200 mg/kg LOAEL Liver
Testosterone propionate
28 Day(s) Monkey Subcutaneous 2.7 mg/kg LOAEL None identified
5 Day(s) Mouse Oral 1000 mg/kg/day NOAEL None identified
28 Day(s) Monkey Subcutaneous 2.7 mg/kg/day LOAEL Endocrine system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Testosterone propionate
Embryo / Fetal Development Monkey Subcutaneous 1.25 mg/kg/day LOEL Teratogenic
Embryo / Fetal Development Rat Subcutaneous 0.4 mg/kg NOEL Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Testosterone Cypionate
Bacterial Mutagenicity (Ames) Negative
Testosterone
In Vivo Micronucleus Mouse Negative
In Vivo Mouse Spermatogonal Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Testosterone propionate
Not specified Rat Subcutaneous 80-100 mg LOEL Tumors, Male reproductive system
Carcinogenicity Androgenic (anabolic) steroids are classified as probable human carcinogens (IARC 2A) by the International Agency for Research on Cancer (IARC).
Testosterone Cypionate
IARC Group 2A

11.2. Information on other hazards
11.2.1. Endocrine disrupting properties
Endocrine disrupting properties This mixture contains a substance that has endocrine disrupting properties with respect to humans.

Chemical name	Endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100(3) or Commission Regulation (EU) 2018/605(4)
Testosterone Cypionate	health effects
Testosterone	health effects
Testosterone propionate	health effects

11.2.2. Other information
Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Toxic to aquatic organisms. Harmful to aquatic life with long lasting effects. Releases to the environment should be avoided. The information included in this section describes the potential hazards of various forms of the active ingredient.

12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)
BENZYL BENZOATE
Brachydanio rerio (Zebra fish) LC50 96 hours 1.34 mg/L

Algae EC50 72 0.475 mg/L
Shrimp LC50 96 hours 4.8 mg/L

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

Testosterone

Daphnia magna (Water Flea) OECD 202 NOEC 48 Hours > 6.2 mg/L
Scenedesmus subspicatus (Green Alga) OECD ErC50 72 hours 0.7 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Testosterone

Daphnia magna (Water Flea) OECD 211 21 Day(s) LOEC 0.31 mg/L
Daphnia magna (Water Flea) OECD 211 21 Day(s) NOEC 0.15 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

Testosterone

Activated sludge Mineralization (CO2 Evolution) 68 % After 72 Hour(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 Based on available data, the classification criteria are not met.

Chemical name	PBT and vPvB assessment
BENZYL BENZOATE	Not PBT/vPvB
BENZYL ALCOHOL	Not PBT/vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties This mixture contains a substance that has endocrine disrupting properties with respect to non-target organisms.

Chemical name	Endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100(3) or Commission Regulation (EU) 2018/605(4)
Testosterone Cypionate	Environmental effects
Testosterone	Environmental effects
Testosterone propionate	Environmental effects

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

Section 15: REGULATORY INFORMATION

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

Cottonseed Oil

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	232-280-7
AICS	Present

Testosterone Cypionate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Developmental Female Reproductive Male Reproductive
U.S. - DEA (Drug Enforcement Administration)	Schedule III Controlled Substance
EINECS	200-368-4
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

BENZYL BENZOATE

CERCLA/SARA Section 313 de minimus %	Not Listed

California Proposition 65 Not Listed
TSCA Present
EINECS 204-402-9
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

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)
Not applicable

TRGS 905

Chemical name	Carcinogenicity	Concentration limits (Classification thresholds)	Mutagenicity	Developmental effects	Fertility effects
Testosterone Cypionate 58-20-8	Category 2			Category 1B Category 2	Category 1A Category 2

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	-

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/NDSL - 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

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
H360FD - May damage fertility. May damage the unborn child. H350 - May cause cancer. H302 - Harmful if swallowed. H411 - Toxic to aquatic life with long lasting effects. H400 - Very toxic to aquatic life. H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. EUH380 - May cause endocrine disruption in humans. EUH430 - May cause endocrine disruption in the environment.

Classification procedure
Calculation method

Data Sources:	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 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.
Revision date	10-Jul-2025
Prepared By	Pfizer Global Environment, Health, and Safety

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