SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Issuing Date 11-Feb-2016 **Revision date** 15-Jan-2020 **Revision Number** 5

1. Identification

1.1. Product identifier

Product Name **Paclitaxel Injection**
NDC # 00703-4767-01, 45963-0613-56, 45963-0613-53, 45963-0613-59
CAS No. -
Pure substance/mixture Mixture
Contains Paclitaxel

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

Uses/ Identified uses Pharmaceutical
Uses advised against Use only as directed

1.3. Details of the supplier of the safety data sheet

Manufacturer

Teva Corporate Headquarters
5 Basel Street PO Box 3190
Petach Tikva, Israel

For further information, please contact
E-mail address SDS.TevaIL@teva.co.il

1.4. Emergency telephone number

Emergency Telephone United States/Canada/Puerto Rico: 1-800-424-9300 (Chemtrec) [24-hrs]
International: +1-703-741-5970 (Chemtrec) [24-hours]

2. Hazard(s) identification

2.1. Classification of the substance or mixture

Exempt from requirements - regulated as a medicinal product

2.2. Label elements

Exempt from requirements - regulated as a medicinal product

2.3. Other hazards

This product contains a material considered to be cytotoxic according to Teva's internal definition. See section 11.

3. Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH registration number
Paclitaxel	-	33069-62-4	Proprietary	Skin Sens. 1 (H317) Muta. 1B (H340)	No data available

				Repr. 1B (H360FD) STOT SE 3 (H335) STOT RE 1 (H372)	
Ethanol	EEC No. 200-578-6	64-17-5	> 30	Flam. Liq. 2 (H225)	01-2119457610-43
Excipients	-	-	Remainder	-	No data available

4. First-aid measures

4.1. Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air. If symptoms persist, call a physician.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area.

Skin contact Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Ingestion IF SWALLOWED. Rinse mouth thoroughly with water. Do NOT induce vomiting. Get medical attention if symptoms occur.

Self-protection of the first aider Remove all sources of ignition. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information.

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

Symptoms No information available.

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

Note to physicians Treat symptomatically.

5. Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical. Carbon dioxide (CO2). Water spray. Alcohol resistant foam.

Unsuitable extinguishing media CAUTION: Use of water spray when fighting fire may be inefficient.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

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.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material.

Other information Ventilate the area.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Refer to protective measures listed in Sections 7 and 8. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapor suppressing foam may be used to reduce vapors. Dike far ahead of spill to collect runoff

water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal.

Methods for cleaning up Take precautionary measures against static discharges. Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

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.

7. Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Use personal protection equipment. Avoid breathing vapors or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use with local exhaust ventilation. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.

General hygiene considerations Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Store locked up.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

8. Exposure controls/personal protection

8.1. Control parameters

Exposure Limits .

TEVA OEL Not Determined: Mixture: Mixture

Chemical Name	European Union	United Kingdom	France	Spain	Germany
Ethanol 64-17-5	-	TWA: 1000 ppm TWA: 1920 mg/m³ STEL: 3000 ppm STEL: 5760 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³ STEL: 5000 ppm STEL: 9500 mg/m³	STEL: 1000 ppm STEL: 1910 mg/m³	TWA: 500 ppm TWA: 960 mg/m³
Chemical Name	Italy	Portugal	Netherlands	Finland	Denmark
Ethanol 64-17-5	-	TWA: 1000 ppm	TWA: 260 mg/m³ STEL: 1900 mg/m³ H*	TWA: 1000 ppm TWA: 1900 mg/m³ STEL: 1300 ppm STEL: 2500 mg/m³	TWA: 1000 ppm TWA: 1900 mg/m³
Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
Ethanol 64-17-5	TWA: 1000 ppm TWA: 1900 mg/m³ STEL 2000 ppm STEL 3800 mg/m³	TWA: 500 ppm TWA: 960 mg/m³ STEL: 1000 ppm STEL: 1920 mg/m³	TWA: 1900 mg/m³	TWA: 500 ppm TWA: 950 mg/m³ STEL: 625 ppm STEL: 1187.5 mg/m³	STEL: 1000 ppm

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering controls	Provide a good standard of controlled ventilation (10 to 15 air changes per hour).
Personal protective equipment	
Eye/face protection	Tight sealing safety goggles.
Hand protection	Wear suitable gloves. Impervious gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron. Antistatic boots.
Respiratory protection	Use appropriate respiratory protection.
General hygiene considerations	Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.
Environmental exposure controls	No information available.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

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

Property	**Values**	**Remarks • Method**
pH	3.5	
Melting point / freezing point	No data available	None known
Boiling point / boiling range	77 °C	
Flash point	< 23 °C	
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	Miscible in water	
Solubility(ies)	No information available.	
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No information available	
Oxidizing properties	No information available	
Partition coefficient n-octanol /water (log KOW)	No information available	

9.2. Other information

Softening point	No information available
Molecular weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability
Stability Stable under normal conditions.
10.3. Possibility of hazardous reactions
Possibility of hazardous reactions None under normal processing.
10.4. Conditions to avoid
Conditions to avoid Heat, flames and sparks.
10.5. Incompatible materials
Incompatible materials None in particular.
10.6. Hazardous decomposition products
Hazardous decomposition products None known based on information supplied.

11. Toxicological information

11.1. Information on toxicological effects
Information on likely routes of exposure
Product Information .
Inhalation No known effects under normal use conditions.
Eye contact No known effects under normal use conditions.
Skin contact May be harmful in contact with skin.
Ingestion May be harmful if swallowed.

The following values are calculated based on chapter 3.1 of the GHS document
ATEmix (oral) 2,627.80 mg/kg
ATEmix (dermal) 3,000.00 mg/kg
ATEmix (inhalation-dust/mist) 374.10 mg/l

Unknown acute toxicity 94 % of the mixture consists of ingredient(s) of unknown toxicity.
94 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
94 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
94 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
94 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).
94 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Paclitaxel	2000 mg/kg (Rat)	2000 mg/kg (Rat)	
Ethanol	= 7060 mg/kg (Rat)		= 124.7 mg/L (Rat) 4 h

Delayed and immediate effects as well as chronic effects from short and long-term exposure
Skin corrosion/irritation No known effects under normal use conditions.

Serious eye damage/eye irritation No known effects under normal use conditions.

Respiratory or skin sensitization No known effects under normal use conditions.

Germ cell mutagenicity Classification based on data available for ingredients. Contains a known or suspected mutagen.

Carcinogenicity No known effects under normal use conditions.

Reproductive toxicity Classification based on data available for ingredients.

STOT - single exposure No known effects under normal use conditions.

STOT - repeated exposure No known effects under normal use conditions.

Aspiration hazard No known effects under normal use conditions.

Cytotoxicity Positive. According to Teva's internal policy, a compound is considered cytotoxic if it possesses the ability to interact directly with DNA or DNA-associated macromolecules, resulting in cell death. In addition, a cytotoxic agent causes such damage in an indiscriminate manner, affecting healthy cells in addition to abnormal (e.g., tumor) cells and causing serious systemic toxicity.

12. Ecological information

12.1. Toxicity

Ecotoxicity Harmful to aquatic life with long lasting effects.

Unknown aquatic toxicity Contains 93 % of components with unknown hazards to the aquatic environment.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Ethanol	275mg / l, 72h	13 g / l, 96h	-	12.34g / l, 48h

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

Chemical Name	Partition coefficient
Ethanol	-0.32

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
Ethanol	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Other adverse effects

Other adverse effects No information available.

13. Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Empty containers pose a potential fire and explosion hazard. Do not cut, puncture of weld containers.

14. Transport information

IMDG

14.1 UN number UN1170

14.2 UN proper shipping name Ethanol

14.3 Transport hazard class(es) 3

14.4 Packing group II

Description UN1170, Ethanol, 3, II, (23°C c.c.)

14.5 Marine pollutant Not applicable

14.6 Special Provisions 144

EmS-No. F-E, S-D

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code No information available

RID

14.1 UN number	UN1170
14.2 UN proper shipping name	Ethanol
14.3 Transport hazard class(es)	3
Labels	3
14.4 Packing group	II
Description	UN1170, Ethanol, 3, II
14.5 Environmental hazards	Not applicable
14.6	
Classification code	F1

ADR

14.1 UN number	UN1170
14.2 UN proper shipping name	Ethanol
14.3 Hazard class	3
Labels	3
14.4 Packing group	II
Description	UN1170, Ethanol, 3, II
14.5 Environmental hazards	Not applicable
14.6 Special Provisions	144, 601
Classification code	F1
Tunnel restriction code	(D/E)

IATA

14.1 UN number	UN1170
14.2 UN proper shipping name	Ethanol
14.3 Transport hazard class(es)	3
14.4 Packing group	II
Description	UN1170, Ethanol, 3, II
14.5 Environmental hazards	Not applicable
14.6	

15. Regulatory information

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

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical Name	French RG number	Title
Ethanol 64-17-5	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 does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU)

P5a - FLAMMABLE LIQUIDS
P5b - FLAMMABLE LIQUIDS
P5c - FLAMMABLE LIQUIDS

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

TSCA	Contact supplier for inventory compliance status
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AICS	Contact supplier for inventory compliance status

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 and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

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

H225 - Highly flammable liquid and vapor
H301 - Toxic if swallowed
H317 - May cause an allergic skin reaction
H335 - May cause respiratory irritation
H341 - Suspected of causing genetic defects
H360FD - May damage fertility. May damage the unborn child
H372 - Causes damage to organs through prolonged or repeated exposure

Legend

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Carcinogenicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

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Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

Region	Template name	Revision Note
European Union	EGHS	2.0

Key literature references and sources for data used to compile the SDS

ATSDR	Agency for Toxic Substances and Disease Registry (ATSDR)
CHEMVIEW not translate code	U.S. Environmental Protection Agency ChemView Database
EFSA not translate code	European Food Safety Authority (EFSA)
EPA not translate code	EPA (Environmental Protection Agency)
EPA_AEGL not translate code	Acute Exposure Guideline Level(s) (AEGL(s))
EPA_FIFRA not translate code	U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
EPA_HPV not translate code	U.S. Environmental Protection Agency High Production Volume Chemicals
FOOD_JOURN not translate code	Food Research Journal
HSDB not translate code	Hazardous Substance Database
IUCLID not translate code	International Uniform Chemical Information Database (IUCLID)
JAPAN_GHS not translate code	Japan GHS Classification
NICNAS not translate code	Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH not translate code	NIOSH (National Institute for Occupational Safety and Health)
NLM_CIP not translate code	National Library of Medicine's ChemID Plus (NLM CIP)
NLM_PUBMED not translate code	National Library of Medicine's PubMed database (NLM PUBMED)
NTP not translate code	National Toxicology Program (NTP)
NZ_CCID not translate code	New Zealand's Chemical Classification and Information Database (CCID)
OECD_EHSP not translate code	Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
OECD_HPV not translate code	Organization for Economic Co-operation and Development High Production Volume Chemicals Program
OECD_SIDS not translate code	Organization for Economic Co-operation and Development Screening Information Data Set
RTECS not translate code	RTECS (Registry of Toxic Effects of Chemical Substances)
WHO not translate code	World Health Organization

Component	WGK Classification (VwVwS)
Ethanol	class 1
64-17-5 (> 30)	

Sites Teva > UK > RidingsPoint Teva > Netherlands > Haarlem
NDC # 00703-4767-01, 45963-0613-56, 45963-0613-53, 45963-0613-59

Manufacturer
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CAS No. -
UN number UN1170
NDC # 00703-4767-01, 45963-0613-56, 45963-0613-53, 45963-0613-59
Teva Global ID (ONEGL) unknown