SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Substance name : DOXIL
CAELYX
Pegylated liposomal doxorubicin hydrochloride

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

Use of the Substance/Mixture : Finished Pharmaceutical Product, Pharmacotherapeutic group: Cytostatics, This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use).This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component. A safety data sheet is not required for this product under Article 31 of REACH. This SDS has been created on a voluntary basis (to pass on relevant information required under Article 32). Since an SDS is not required, this document may not contain all of the information that is required for substance and mixture SDS's under REACH.

1.3 Details of the supplier of the safety data sheet

Company : JanssenPreservation &Material Protection
Division of Janssen Pharmaceutica NV
1125 Trenton-Harbourton Rd
08560 Titusville NJ
US

Telephone : +16097302000
Telefax :
E-mail address
Responsible/issuing person : SDSJanssen@its.jnj.com

1.4 Emergency telephone number +32 14 60 24 44

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity , Category 4	H302: Harmful if swallowed.
Skin corrosion/irritation , Category 2	H315: Causes skin irritation.
Serious eye damage , Category 1	H318: Causes serious eye damage.
, Category 3	H335: May cause respiratory irritation.
Carcinogenicity , Category 2	H351: Suspected of causing cancer.
Reproductive toxicity , Category 2	H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.

Classification (67/548/EEC, 1999/45/EC)

Harmful	R22: Harmful if swallowed.
Irritant	R38: Irritating to skin.
Irritant	R37: Irritating to respiratory system.
Irritant	R41: Risk of serious damage to eyes.
Carcinogenic	R40: Limited evidence of a carcinogenic effect.
Toxic to reproduction	R62: Possible risk of impaired fertility.
Teratogenic	R63: Possible risk of harm to the unborn child.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements :

H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H351	Suspected of causing cancer.

Precautionary statements :

Prevention:

P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

2.3 Other hazards

Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidently leaking, broken or crushed.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Liquid

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration [%]
DOXORUBICIN HYDROCHLORIDE	25316-40-9 246-818-3	T; R45 T; R60-R61 Xn; R22	Acute Tox.4; H302 Carc.1B; H350 Repr.2; H361fd	< 0,3

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled : If breathed in, move person into fresh air.
Consult a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off immediately with plenty of water.
If symptoms persist, call a physician.
Wash contaminated clothing before re-use.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Remove contact lenses.
Consult a physician.

If swallowed : Rinse mouth with water.
Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Ingestion may provoke the following symptoms:
Also harmful if swallowed.
Danger of very serious irreversible effects.
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment	:	Treat symptomatically. Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	:	Water spray jet

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products	:	No hazardous combustion products are known.

5.3 Advice for firefighters

Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus.
Further information	:	In the event of fire, cool tanks with water spray.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Evacuate personnel to safe areas. In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.

6.2 Environmental precautions

Environmental precautions	:	Should not be released into the environment.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up	:	Large spills: Dam up. Soak up with inert absorbent material. Keep in properly labelled containers. Small spills: Gently cover the spill with an absorbent towel or pad. Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

6.4 Reference to other sections

For disposal information, see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	:	To avoid thermal decomposition, do not overheat. For personal protection see section 8. Do not break, crush or spill this Finished Pharmaceutical Product. Avoid inhalation, ingestion and contact with skin and eyes.
Advice on protection against fire and explosion	:	no data available
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	To maintain product quality, do not store in heat or direct sunlight. Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat and sources of ignition. Keep locked up.
Storage temperature	:	2 - 8 °C
Other data	:	Do not freeze.

7.3 Specific end use(s)

Specific use(s)	:	Consult the technical guidelines for the use of this substance/mixture., Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Update	Basis
DOXORUBICIN HYDROCHLORIDE	25316-40-9	PBOEL-HHC	4		J&J OEL/PBOEL HHC
DOXORUBICIN HYDROCHLO	25316-40-9	TWA	0,00047 mg/m3		J&J OEL/PBOEL HHC

RIDE					
Further information	J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 4. This means that the OEL is estimated to be less than 0.5 µg/m3				
Further information	Notation REPRO: has the potential to have adverse effects on reproduction and fetal development				
Further information	Notation CAR: has carcinogenic properties.				

8.2 Exposure controls

Engineering measures

All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment

Eye protection : No special precautions required.

Hand protection

Remarks : Skin protection required for pregnant women or women of child bearing age. Gloves are recommended as a good hygiene measure if there is direct contact with the tablets.

Skin and body protection : Preventive skin protection

Respiratory protection : Engineering controls should always be the primary method of controlling exposures.
If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.
No personal respiratory protective equipment normally required.

Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.

Environmental exposure controls

General advice : Should not be released into the environment.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	Vial
Colour	:	red
Odour	:	no data available
Odour Threshold	:	no data available
pH	:	no data available
Melting point/range	:	no data available
Boiling point/boiling range	:	no data available
Flash point	:	no data available
Upper explosion limit	:	no data available
Lower explosion limit	:	no data available
Vapour pressure	:	no data available
Relative vapour density	:	no data available
Relative density	:	no data available
Density	:	no data available
Solubility(ies)		
Water solubility	:	no data available
Partition coefficient: n-octanol/water	:	no data available
Thermal decomposition	:	no data available
Viscosity		
Viscosity, dynamic	:	no data available
Viscosity, kinematic	:	no data available
Explosive properties	:	no data available

9.2 Other information

Conductivity	:	no data available
Molecular Weight	:	579,99 g/mol

SECTION 10: Stability and reactivity

10.1 Reactivity

None reasonably foreseeable.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Conditions to avoid : To avoid thermal decomposition, do not overheat.

10.5 Incompatible materials

Materials to avoid : None known.

10.6 Hazardous decomposition products

Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product

Acute oral toxicity : LD50 mouse: 698 mg/kg

Components:

DOXORUBICIN HYDROCHLORIDE :

Acute oral toxicity : LD50 mouse: 570 mg/kg

Acute inhalation toxicity : no data available

Acute dermal toxicity : no data available

Acute toxicity (other routes of administration) : no data available

Skin corrosion/irritation

Product

Result: Irritating to skin.

Components:

DOXORUBICIN HYDROCHLORIDE :

no data available

Serious eye damage/eye irritation

Product

Result: Severe eye irritation

Components:

DOXORUBICIN HYDROCHLORIDE :
Result: Lachrymation
Eye irritation

Respiratory or skin sensitisation

Components:

DOXORUBICIN HYDROCHLORIDE :
no data available

Germ cell mutagenicity

Components:

DOXORUBICIN HYDROCHLORIDE :

Genotoxicity in vitro	:	no data available
Germ cell mutagenicity-Assessment	:	Animal experiments showed mutagenic and teratogenic effects.

Carcinogenicity

Components:

DOXORUBICIN HYDROCHLORIDE :
Remarks: carcinogenic effects

Carcinogenicity - Assessment	:	Sufficient evidence of carcinogenicity in animal experiments

Reproductive toxicity

Toxicity to reproduction/fertility

Components:

DOXORUBICIN HYDROCHLORIDE :
no data available

Reprod.Tox./Development/Teratogenicity

Components:

DOXORUBICIN HYDROCHLORIDE :
Species: rat
Did show teratogenic effects in animal experiments.

Teratogenicity - Assessment	:	Potential embryo-foetal toxicity and teratogenicity., Limited evidence of adverse effects on development in animal studies and/ or human studies.

STOT - single exposure

Components:

DOXORUBICIN HYDROCHLORIDE :
Remarks: no data available

STOT - repeated exposure

no data available

Repeated dose toxicity

Components:
DOXORUBICIN HYDROCHLORIDE :

Remarks: no data available

Aspiration toxicity

no data available

SECTION 12: Ecological information

12.1 Toxicity

Components:
DOXORUBICIN HYDROCHLORIDE :

Toxicity to fish	:	no data available
Toxicity to daphnia and other aquatic invertebrates	:	no data available
Toxicity to algae	:	no data available

12.2 Persistence and degradability

Components:
DOXORUBICIN HYDROCHLORIDE :

Biodegradability	:	no data available

12.3 Bioaccumulative potential

Product:

Partition coefficient: n-octanol/water	:	no data available

Components:
DOXORUBICIN HYDROCHLORIDE :

Bioaccumulation	:	no data available
Partition coefficient: n-octanol/water	:	no data available

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

no data available

12.6 Other adverse effects

no data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	In accordance with National, Federal, State and Local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number

ADN
Not dangerous goods
ADR
Not dangerous goods
RID
Not dangerous goods
IMDG
Not dangerous goods
IATA
Not dangerous goods

14.2 Proper shipping name

ADN
Not dangerous goods
ADR
Not dangerous goods
RID
Not dangerous goods
IMDG
Not dangerous goods
IATA
Not dangerous goods

14.3 Transport hazard class

ADN
Not dangerous goods
ADR
Not dangerous goods
RID

Not dangerous goods
IMDG
Not dangerous goods
IATA
Not dangerous goods

14.4 Packing group

ADN
Not dangerous goods
ADR
Not dangerous goods
RID
Not dangerous goods
IMDG
Not dangerous goods
IATA
Not dangerous goods

14.5 Environmental hazards

ADN
Not dangerous goods
ADR
Not dangerous goods
RID
Not dangerous goods
IMDG
Not dangerous goods
IATA
Not dangerous goods

14.6 Special precautions for user

For personal protection see section 8.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

SECTION 15: Regulatory information

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

Major Accident Hazard Legislation
96/82/EC : Update: 2003
Directive 96/82/EC does not apply

Other regulations : According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.
Restricted to professional users.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment is not applicable (mixture)

SECTION 16: Other information

Full text of R-Phrases

R22	Harmful if swallowed.
R45	May cause cancer.
R60	May impair fertility.
R61	May cause harm to the unborn child.

Full text of H-Statements

H302	Harmful if swallowed.
H350	May cause cancer.
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.

Full text of other abbreviations

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012-12-31
Numbers:	123456,78	as	12 345,67

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.