SAFETY DATA SHEET



1. Identification

Product identifier ALKERAN INJECTION

Other means of identification

ALKERAN INJECTION 50 MG * ALKERAN IV INJECTION 50 MG * ALKERAN INJECTION 50 **Synonyms**

MG/10 ML * NDC NO. 0173-0130-93 * MELPHALAN HYDROCHLORIDE, FORMULATED

PRODUCT

Medicinal Product. Recommended use

> This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant

to medicinal use of the product. In this instance patients should consult prescribing

information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate

safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US

5 Moore Drive

Research Triangle Park, NC 27709 USA

US General Information (normal business hours): +1-888-825-5249

Email Address: msds@gsk.com Website: www.gsk.com

EMERGENCY PHONE NUMBERS -TRANSPORT EMERGENCIES:

US / International toll call +1 703 527 3887

available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
MELPHALAN HYDROCHLORIDE	GR 64466A 4-(BIS(2-CHLOROETHYL)AMINO)-L- PHENYLALANINE HYDROCHLORIDE	3223-07-2	71.27
POLYVINYLPYRROLIDONE	1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER POLY(N-VINYLPYRROLIDONE) POVIDONE PLASDONE PLASDONE K29/32	9003-39-8	< 30

SDS US 110531 Version #: 28 Revision date: 10-16-2015 Issue date: 10-16-2015

% **Chemical name CAS** number Common name and synonyms HYDROCHLORIC ACID HYDROCHLORIC ACID SOLUTIONS 7647-01-0 < 0.25 RTECS MW4025000 MURIATIC ACID AQUEOUS HYDROGEN CHLORIDE CHLOROHYDRIC ACID HCL

4. First-aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if

symptoms develop or persist. Under normal conditions of intended use, this material is not

expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse.

Get medical attention if irritation develops and persists.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large Ingestion

amount does occur, call a poison control center immediately. Do not induce vomiting without

advice from poison control center.

Most important

symptoms/effects, acute and delayed

Indication of immediate medical attention and special

treatment needed **General information** Accidental exposure or contact might produce: Nausea, vomiting., symptoms of hypersensitivity (such as skin rash, hives, itching), anaemia, diarrhoea.

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Following assessment, if the risk of exposure is considered significant then a health record should be maintained for exposed individuals to document periods of exposure. This record should be retained for at least 30 years after exposure ceases (or according local regulatory requirements if more stringent).

5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing media

Alcohol resistant foam. Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

None known.

Specific hazards arising from

the chemical

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

equipment/instructions

Specific methods

Move containers from fire area if you can do so without risk.

During fire, gases hazardous to health may be formed.

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up **Environmental precautions**

Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

^{*}Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store locked up. To maintain product quality, do not store in heat or direct sunlight. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

CCV

GSK Components	Туре	Value	Note	
MELPHALAN HYDROCHLORIDE (CAS 3223-07-2)	8 HR TWA	1 mcg/m3		
,	OHC	5	REPRODUCTIVE HAZARD	
		5	SKIN SENSITISER	
		5	CARCINOGEN	
Components	s for Air Contaminants (29 CFR 1910.1000) Type	Value		
HYDROCHLORIC ACID (CAS 7647-01-0)	Ceiling	7 mg/m3		
		5 ppm		
US. ACGIH Threshold Lim		Value		
Components	Туре			
HYDROCHLORIC ACID (CAS 7647-01-0)	Ceiling	2 ppm		
US. NIOSH: Pocket Guide				
Components	Туре	Value		
HYDROCHLORIC ACID (CAS 7647-01-0)	Ceiling	7 mg/m3		
		5 ppm		
iological limit values	No biological exposure limits noted for the	ingredient(s).		
xposure guidelines				
ppropriate engineering ontrols	General ventilation normally adequate.			
dividual protection measure Eye/face protection	s, such as personal protective equipment Not normally needed. If contact is likely, sa	afety glasses with side sh	nields are recommended.	
Skin protection Hand protection	Not normally needed. For prolonged or rep	eated skin contact use s	suitable protective gloves.	
Other	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.			
Respiratory protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.			
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.			
eneral hygiene onsiderations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.			

9. Physical and chemical properties

Appearance

Physical state Solid.

SDS US

Form Vial. Freeze dried powder.

and

Vial. Diluent.

Color Not available.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling Not available.

range

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

(%)

Explosive limit - lower (%)

Explosive limit - upper (%)

Vapor pressure

Vapor density

Relative density

Not available.

Not available.

Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoidContact with incompatible materials.

Incompatible materials Peroxides. Phenols.

incompatible materials — Peroxides. Phenois

Hazardous decomposition products

None known. Irritating and/or toxic fumes and gases may be emitted upon the product's

decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Health injuries are not known or expected under normal use.

Eye contact Health injuries are not known or expected under normal use.

Ingestion Health injuries are not known or expected under normal use. Very toxic if swallowed. However,

ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Nausea, vomiting., Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching), anaemia, diarrhoea.

Citatacteristics

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

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Components **Species Test Results**

HYDROCHLORIC ACID (CAS 7647-01-0)

Acute

Inhalation

LC50 Mouse 1108 ppm, 1 Hours

> Rat 3124 ppm, 1 Hours

LCL0 Guinea pig 4416 ppm, 30 minutes

> Human 3000 ppb, 5 minutes

> > 1300 ppm, 30 minutes 4416 ppm, 30 minutes

NOEL <= 1.8 ppm, 45 minutes No effect on Human

respiratory function in asthmatics.

Oral

LD50 Rabbit 900 mg/kg

Rabbit

Rat 700 mg/kg

Chronic

Inhalation

LOAEL Rat 10 ppm, 128 weeks

Subacute

Oral

LD Rat 34.1 mg/kg/day, 9 weeks LOEL Rat 10.2 mg/kg/day, 9 weeks

Subchronic

Inhalation

LOEC Rat 10 ppm, 3 months Inflammation of lips and

nasal cavity.

NOAEC 20 ppm, 3 months Rat

MELPHALAN HYDROCHLORIDE (CAS 3223-07-2)

Acute

Oral

LD50 Rat 4.7 mg/kg

POLYVINYLPYRROLIDONE (CAS 9003-39-8)

Acute

Oral

LD50 Rat > 5000 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Corrosivity

MELPHALAN HYDROCHLORIDE Literature search

Result: Mild irritant

HYDROCHLORIC ACID **OECD 404**

Result: Corrosive Species: Rabbit Test Duration: 1 Hours

Serious eye damage/eye Health injuries are not known or expected under normal use.

irritation

Eve

HYDROCHLORIC ACID **OECD 405**

Result: Corrosive effects/irritation

Species: Rabbit

MELPHALAN HYDROCHLORIDE Read across

Result: Mild irritant

Respiratory or skin sensitization

Respiratory sensitization Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin sensitization Health injuries are not known or expected under normal use.

Sensitization

MELPHALAN HYDROCHLORIDE Read across

Result: Positive

Germ cell mutagenicity Not expected to be genotoxic under occupational exposure conditions. Contains components that

produced genotoxicity in laboratory tests.

Mutagenicity

HYDROCHLORIC ACID <= 10 mmol/L Chromosomal Aberration Assay In Vitro, CHO

cells, IUCLID Result: Positive

MELPHALAN HYDROCHLORIDE Ames

Result: Positive
HYDROCHLORIC ACID
Ames, IUCLID
Result: Negative

MELPHALAN HYDROCHLORIDE Cytogenetic Analysis In Vivo

Result: Positive

HYDROCHLORIC ACID E coli Pol-A repair assay, IUCLID

Result: Negative

L5178Y mouse lymphoma thymidine kinase locus assay,

IUCLID

Result: Negative

MELPHALAN HYDROCHLORIDE Mouse Lymphoma Cell (L5178Y) Mutation Assay

Result: Positive

HYDROCHLORIC ACID Yeast Mutation Assay, IUCLID

Result: Negative

Carcinogenicity Carcinogenic effects are not expected as a result of occupational exposure.

HYDROCHLORIC ACID 10 ppm Inhalation

Result: Negative Species: Rat

Observation Period: 128 months

Notes: IUCLID

MELPHALAN HYDROCHLORIDE Clinical observation

Result: Positive Species: Human Clinical observation Result: Positive Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

HYDROCHLORIC ACID (CAS 7647-01-0)

3 Not classifiable as to carcinogenicity to humans.
POLYVINYLPYRROLIDONE (CAS 9003-39-8)

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

Reproductive toxicityComponents in this product have been shown to cause birth defects and reproductive disorders in

laboratory animals. May damage fertility or the unborn child. Health injuries are not known or

expected under normal use.

Reproductivity

HYDROCHLORIC ACID 302 ppm Embryo-foetal development, IUCLID

Result: Maternal toxicity, resorptions, foetal malformations.

Species: Rat

MELPHALAN HYDROCHLORIDE Fertility/foetal development

Result: Positive

Specific target organ toxicity - Not assigned.

single exposure

HYDROCHLORIC ACID Result: Respiratory irritation/corrosion.

Specific target organ toxicity - May cause damage to organs through prolonged or repeated exposure.

repeated exposure

MELPHALAN HYDROCHLORIDE Pharmacological effects.

Organ: Blood cell formation and bone marrow, gastro-intestinal

tract.

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Aspiration hazard Not likely, due to the form of the product.

Chronic effectsMay cause damage to organs through prolonged or repeated exposure. Prolonged inhalation may

be harmful. Prolonged exposure may cause chronic effects.

Further information Caution - Potent pharmaceutical agent. Occupational exposure to the substance or mixture may

cause adverse effects.

12. Ecological information

Ecotoxicity Contains a substance which causes risk of hazardous effects to the environment.

Test Results Components **Species** MELPHALAN HYDROCHLORIDE (CAS 3223-07-2) Acute IC50 Activated sludge > 112 mg/l, 3 hours Aquatic Acute Crustacea EC50 Water flea (Daphnia magna) > 11 mg/l, 48 hours POLYVINYLPYRROLIDONE (CAS 9003-39-8) Acute IC50 Activated sludge > 1000 mg/l, 3 hours Static test

Aquatic

Acute Crustacea

EC50 Water flea (Daphnia magna) 84 mg/l, 48 hours Static test

NOEC Water flea (Daphnia magna) 32 mg/l, 48 hours Static test

Persistence and degradability

Hydrolysis

Half-life (Hydrolysis-acidic)

MELPHALAN HYDROCHLORIDE 4.9 Hours, pH 5 Buffer Solution

Half-life (Hydrolysis-basic)

MELPHALAN HYDROCHLORIDE 3.9 Hours

Half-life (Hydrolysis-neutral)

MELPHALAN HYDROCHLORIDE 4.9 Hours, pH 7 Buffer Solution

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

POLYVINYLPYRROLIDONE 0 %, 28 days Modified MITI test, Activated sludge

Bioaccumulative potential

Bioconcentration factor (BCF)

MELPHALAN HYDROCHLORIDE 1 Estimated

Mobility in soil Not available.

Mobility in general

Volatility

Henry's law

MELPHALAN HYDROCHLORIDE 0 atm m^3/mol, 25 C Estimated

Distribution

Octanol/water distribution coefficient log DOW

MELPHALAN HYDROCHLORIDE -0.52, pH 7.4

Other adverse effects Not available.

13. Disposal considerations

Disposal instructionsCollect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not

discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable

regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

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^{*} Estimates for product may be based on additional component data not shown.

Waste from residues / unused

products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions). Avoid discharge into water courses or onto the ground.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied. Empty containers should be taken to an approved waste handling site for recycling or

disposal.

14. Transport information

DOT

UN3249 **UN number**

UN proper shipping name Medicine, solid, toxic, n.o.s. (MELPHALAN HYDROCHLORIDE)

Transport hazard class(es)

Class 6.1(PGI, II)

Subsidiary risk 6.1 Label(s) Packing group Ш

Special precautions for user Not available. T3, TP33 Special provisions Packaging exceptions 153 Packaging non bulk 212 242 Packaging bulk

IATA

UN number UN3249

Medicine, solid, toxic, n.o.s. (MELPHALAN HYDROCHLORIDE) **UN** proper shipping name

Transport hazard class(es) 6.1(PGI, II)

Subsidiary class(es) Packaging group П **Environmental hazards** No. Labels required 6.1 **ERG Code** 6L

Special precautions for user Not available.

Other information

Allowed with restrictions. Cargo aircraft only Passenger & cargo Allowed with restrictions.

IMDG

UN3249 **UN** number

MEDICINE, SOLID, TOXIC, N.O.S. (MELPHALAN HYDROCHLORIDE) **UN** proper shipping name Transport hazard class(es)

Class 6.1(PGI, II)

Subsidiary risk Label(s) 6.1 Packing group Ш **Environmental hazards**

Marine pollutant No. **EmS** F-A. S-A Special precautions for user Not available.

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

DOT



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IATA; IMDG



General information

Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

HYDROCHLORIC ACID (CAS 7647-01-0) Listed.

SARA 304 Emergency release notification

HYDROCHLORIC ACID (CAS 7647-01-0) 5000 LBS OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

> Delayed Hazard - Yes Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Chemical name **CAS** number Reportable **Threshold** Threshold **Threshold** quantity planning quantity planning quantity, planning quantity, lower value upper value **HYDROCHLORIC** 7647-01-0 5000 500 lbs

ACID

SARA 311/312 Hazardous No

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

HYDROCHLORIC ACID (CAS 7647-01-0)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

HYDROCHLORIC ACID (CAS 7647-01-0) Safe Drinking Water Act

(SDWA)

Not regulated.

Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2)

HYDROCHLORIC ACID (CAS 7647-01-0)

DEA Essential Chemical Code Number

HYDROCHLORIC ACID (CAS 7647-01-0) 6545

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

20 %WV HYDROCHLORIC ACID (CAS 7647-01-0)

DEA Exempt Chemical Mixtures Code Number

HYDROCHLORIC ACID (CAS 7647-01-0) 6545

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US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd.

(a))

HYDROCHLORIC ACID (CAS 7647-01-0)

US. Massachusetts RTK - Substance List

HYDROCHLORIC ACID (CAS 7647-01-0)

US. New Jersey Worker and Community Right-to-Know Act

HYDROCHLORIC ACID (CAS 7647-01-0)

US. Pennsylvania Worker and Community Right-to-Know Law

HYDROCHLORIC ACID (CAS 7647-01-0)

US. Rhode Island RTK

HYDROCHLORIC ACID (CAS 7647-01-0)

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

^{*}A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

Toxic Substances Control Act (TSCA) Inventory

16. Other information, including date of preparation or last revision

Issue date 10-16-2015 10-16-2015 **Revision date**

Version # 28

United States & Puerto Rico

HMIS® is a registered trade and service mark of the NPCA. **Further information**

Health: 2* **HMIS®** ratings Flammability: 1 Physical hazard: 0

Health: 2

NFPA ratings

Flammability: 1 Instability: 0

GSK Hazard Determination References

The information and recommendations in this safety data sheet are, to the best of our knowledge, Disclaimer

accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and

the suitability of the material or product for any particular purpose.

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Revision information

Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties:
Toxicological Information:

Ecological Information: Ecotoxicity
Transport Information: Proper Shipping Name/Packing Group
Regulatory Information: Risk Phrases - Class.

Material name: ALKERAN INJECTION 110531 Version #: 28 Revision date: 10-16-2015 Issue date: 10-16-2015