



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: APREPITANT CAPSULES USP

SDS NO. : SDSGHS.054.00

EFFECTIVE DATE : 27/07/2016

PAGE No. : 1 of 18

Section 1. Identification

1.1 Substance Name: Aprepitant Capsules USP

1.2 Chemical Name: Not Known

1.3 Relevant identified uses of the substance or mixture and uses advised against:

For the prevention of acute and delayed chemotherapy-induced nausea and vomiting and for prevention of post-operative nausea and vomiting. In the treatment of cyclic vomiting syndrome. Taken by mouth. Generally given as part of a regime that includes corticosteroid and a 5-HT₃ antagonist. Aprepitant is classified as an NK₁ antagonist which is because it blocks signals given off by NK₁ receptors. While it successfully antagonises the NK₁ receptors it has very little affinity over other receptors such as serotonin, dopamine and corticosteroid. It is estimated that aprepitant is at least 3000 times more selective of NK₁ receptors compared to these other enzyme transporter, ion channels. NK₁ is a G protein coupled receptor and is located in the central nervous system and the peripheral nervous system. This receptor has a dominant ligand known as Substance P (SP). SP is a neuropeptide, comprising of 11 amino acids, which sends and receives impulses and messages from the brain. It is found in high concentrations in the vomiting center of the brain and when activated it results in a vomiting reflux occurring.

1.4 Company Identification: Glenmark Pharmaceuticals Inc., USA
750 Corporate Drive

Mahwah, NJ 07430

1.6 Emergency Contact details: (201) 684-8000

Section 2. Hazard Identification

2.1 Classification of the substance or mixture

Chemwatch Hazard Ratings

		Min	Max
Flammability	1	■	
Toxicity	1	■	
Body Contact	0		
Reactivity	1	■	



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Chronic **0**

0 = Minimum

1 = Low

2 = Moderate

3 = High

4 = Extreme

2.2 Label elements:

**GHS label
elements**

Not Applicable

2.3 Risk Phrase: Not Known

2.4 Safety Advice: Not Known

2.5 Other hazards: Not Known

Section 3- Composition/Information on Ingredients

3.1 Substances

COMPONENTS	CAS	CONCENTRATION (WT %)	EXPOSURE
Aprepitant	170729-80-3	27.66 to 30.78	N/E
ingredients determined not to be hazardous [Mfr]	-	Proprietary	N/E

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Section 4. First aid Measures

4.1 Inhalation:

- If fumes, aerosols or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

4.2 Skin: If skin or hair contact occurs:

- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

4.3 Eyes: If this product comes in contact with the eyes:

- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Seek medical attention without delay; if pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

4.4 Ingestion:

- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

4.5 Most important symptoms and effects, both acute and delayed

Treat symptomatically.

Single doses up to 600 mg of aprepitant were generally well tolerated in healthy subjects.

Aprepitant was generally well tolerated when administered as 375 mg once daily for up to 42 days to patients in non-CINV (chemotherapy induced nausea and vomiting) studies. In 33 cancer patients, administration of a single 375-mg dose of aprepitant on Day 1 and 250 mg once daily on Days 2 to 5 was generally well tolerated. Aprepitant is greater than 95% bound to plasma proteins. The mean apparent volume of distribution at steady state (V_{dss}) is approximately 70 L in humans. Aprepitant crosses the placenta in rats and rabbits and crosses the blood brain barrier in humans. Aprepitant undergoes extensive metabolism. In vitro studies using human liver

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microsomes indicate that aprepitant is metabolized primarily by CYP3A4 with minor metabolism by CYP1A2 and CYP2C19. Metabolism is largely via oxidation at the morpholine ring and its side chains. No metabolism by CYP2D6, CYP2C9, or CYP2E1 was detected. In healthy young adults, aprepitant accounts for approximately 24% of the radioactivity in plasma over 72 hours following a single oral 300-mg dose of [14C]-aprepitant, indicating a substantial presence of metabolites in the plasma. Seven metabolites of aprepitant, which are only weakly active, have been identified in human plasma. Excretion Following administration of a single IV 100-mg dose of [14C]-aprepitant prodrug to healthy subjects, 57% of the radioactivity was recovered in urine and 45% in feces. A study was not conducted with radiolabeled capsule formulation. The results after oral administration may differ. Aprepitant is eliminated primarily by metabolism; aprepitant is not renally excreted. The apparent plasma clearance of aprepitant ranged from approximately 62 to 90 mL/min. The apparent terminal half-life ranged from approximately 9 to 13 hours.

Section 5. Fire-fighting Measures

5.1 General Information:

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use water delivered as a fine spray to control fire and cool adjacent area.

5.2 Extinguishing Media:

- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

5.3 Fire/Explosion Hazard:

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions).

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- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.

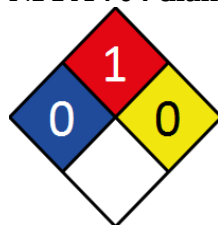
Combustion products include: carbon monoxide (CO), carbon dioxide (CO₂), hydrogen fluoride, nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material May emit poisonous fumes.

5.4 Fire Incompatibility:

- Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result

5.5 NFPA Rating:

NFPA 704 diamond



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Section 6. Accidental Release Measures

6.1 General Information: Personal Protective Equipment advice is contained in Section 8 of the SDS.

6.2 Minor Spills:

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.



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- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.

6.2 Major Spills: Moderate hazard.

- CAUTION: Advise personnel in area.
- Alert Emergency Services and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.

Section 7. Handling and Storage

7.1 Handling:

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions)
- Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.
- Establish good housekeeping practices.
- Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.

7.2 Storage:

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.

7.3 Storage Incompatibility:

- Avoid reaction with oxidizing agents

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Section 8. Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits (OEL):

Components	Type	Value
Aprepitant (CAS No. 170729-80-3)	TWA	-

Material Data

It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.

At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.

Note: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply.

Airborne particulate or vapour must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

8.2 Exposure controls:

Appropriate Engineering controls	Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/transferring quantities exceeding 500 mg.
Personal protection	

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Eye and face protection

When handling very small quantities of the material eye protection may not be required.
 For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:
 Chemical goggles.
 Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.

Skin protection

See Hand protection below

Hands/feet protection

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.
 The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.
 Suitability and durability of glove type is dependent on usage.

- Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.

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	• Double gloving should be considered. • PVC gloves. Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present. • polychloroprene. • nitrile rubber. • butyl rubber.
Body protection	See Other protection below
Other protection	• For quantities up to 500 grams a laboratory coat may be suitable. • For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. • For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
Thermal hazards	Not Available

Respiratory protection

Not Available

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1	-	PAPR-P1
up to 50 x ES	Air-line*	-	-
up to 100 x ES	Air-line**	P2	PAPR-P2
100+ x ES	-	P3	-
		Air-line*	-
	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

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A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

Section 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	:	Capsule
Appearance	:	Gelatin capsule
Colour	:	Not Known
pH Value	:	Not Known
Vapour Pressure	:	Not Known
Vapour Density	:	Not Known
Evaporation Rate	:	Not Known
<i>Other information</i>		
Flash point	:	Not Known



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Molecular Weight	:	Not Known
Melting point/range	:	Not Known
Boiling point/boiling range	:	Not Known
Density	:	Not Known
Viscosity	:	Not Known
Water solubility	:	Not Known
Solubility in other solvents	:	Not Known
Minimum ignition energy (MIE)	:	Not Known
Minimum ignition temperature (MIT)	:	Not Known
Layer ignition temperature (LIT)	:	Not Known
Flammability/explosivity	:	Not Known
Reactivity/exotherms	:	Not Known
Electrostatic nature	:	Not Known
Highly dusty material	:	Not Known
Any other properties which cause handling or processing difficulties	:	Not Known
Average PSD (particle size distribution (micron))	:	Not Known

9.2 Other Information: Not Known

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Section 10. Stability and Reactivity

10.1 Reactivity: Not known

10.2 Chemical stability:

- Unstable in the presence of incompatible materials.
- Product is considered stable.

10.3 Conditions to Avoid: Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result

10.4 Incompatibilities with Other Materials: Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result

10.5 Hazardous Decomposition Products: carbon monoxide (CO), carbon dioxide (CO₂), hydrogen fluoride, nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material May emit poisonous fumes.

10.6 Hazardous Polymerization: Will not occur

Section 11. Toxicological Information

11.1 Information on toxicological effects

Inhaled

The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result

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	in excessive exposures.	
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual. [Therapy may produce tiredness, weakness, nausea, constipation, diarrhea, loss of appetite, upset stomach, dizziness, headache and hiccups. Administration may reduce the efficacy of hormonal contraceptives	
Skin Contact	The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.	
Eye	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.	
Chronic	On the basis, primarily, of animal experiments, concern has been expressed by at least one classification body that the material may produce carcinogenic or mutagenic effects; in respect of the available information, however, there presently exists inadequate data for making a satisfactory assessment. Long term exposure to high dust concentrations may cause changes in lung function (i.e. pneumoconiosis) caused by particles less than 0.5 micron penetrating and remaining in the lung. A prime symptom is breathlessness. Lung shadows show on X-ray.	
Aprepitant for 100%	Toxicity	Irritation
	Subcutaneous (guinea pig) TDLO: 0.028 mg/kg Oral (guinea pig) TDLO: 0.085 mg/kg Oral (gerbil) TDLO: 0.06 mg/kg Intraperitoneal (Rat) TDLO: 10 mg/kg	Not Available



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Aprepitant

No significant acute toxicological data identified in literature search.

For substance P antagonists (SAP, NK1 antagonists):

Considerable progress has been made in understanding the neural circuits involved the antidepressant and anxiolytic efficacy of substance P (NK, receptor) antagonists (SPAs). Progress has been hampered by species differences in the pharmacology of the NK1 receptor, and the availability of NK1R-/- mice has been a particularly useful resource in overcoming this difficulty. Using neuroanatomical, behavioural, and electrophysiological techniques, studies have now established that pharmacological blockade or deletion of the NK1 receptor produces an antidepressant and anxiolytic-like profile in a range of behavioural assays that is distinct from that of established drugs. There is evidence from focal injection studies that some of these effects may be mediated directly by blockade of NK, receptors in the amygdala and its projections to the hypothalamus, periaqueductal gray, and reticulopontine nucleus.

Carcinogenicity studies, with aprepitant, were conducted in Sprague-Dawley rats and in CD-1 mice for 2 years. In the rat carcinogenicity studies, animals were treated with oral doses ranging from 0.05 to 1000 mg/kg twice daily. The highest dose produced a systemic exposure to aprepitant (plasma AUC_{0-24hr}) of 0.7 to 1.6 times the human exposure (AUC_{0-24hr} = 19.6 mcg_{hr}/mL) at the recommended dose of 125 mg/day. Treatment with aprepitant at doses of 5 to 1000 mg/kg twice daily caused an increase in the incidences of thyroid follicular cell adenomas and carcinomas in male rats. Aprepitant was not genotoxic in the Ames test, the human lymphoblastoid cell (TK6) mutagenesis test, the rat hepatocyte DNA strand break test, the Chinese hamster ovary (CHO) cell chromosome aberration test and the mouse micronucleus test. Aprepitant did not affect the fertility or general reproductive performance of male or female rats at doses up to the maximum feasible dose of 1000 mg/kg twice daily (providing exposure in male rats lower than the exposure at the recommended human dose and exposure in female rats at about 1.6 times the human exposure

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Section 12. Ecological Information

12.1 Toxicity:

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability: Not Known

12.3 Bioaccumulative potential: Not Known

12.4 Mobility in soil: Not Known

12.5 Other: Not Known.

Section 13. Disposal Considerations

13.1 Waste treatment methods

Product / Packaging disposal

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use.

- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.
- Recycle wherever possible.



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- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or Incineration in a licensed apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14. Transport Information

14. 1 Special precautions for user:

**Marine
Pollutant**

NO

Land transport (DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable



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Section 15. Regulatory Information

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

Aprepitant(170729-80-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS

- Not Applicable
Federal Regulations
Superfund Amendments and Reauthorization Act of 1986 (SARA)

SECTION 311/312 HAZARD CATEGORIES

Immediate (acute) health hazard	NO
Delayed (chronic) health hazard	NO
Fire hazard	NO
Pressure hazard	NO
Reactivity hazard	NO

US. EPA CERCLA HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES (40 CFR 302.4)

None Reported

State Regulations

US. CALIFORNIA PROPOSITION 65

None Reported

National Inventory	Status
Australia - AICS	N (aprepitant)
Canada - DSL	N (aprepitant)
Canada - NDSL	N (aprepitant)
China - IECSC	N (aprepitant)
Europe - EINEC / ELINCS / NLP	N (aprepitant)
Japan - ENCS	N (aprepitant)
Korea - KECI	N (aprepitant)
New Zealand - NZIoC	N (aprepitant)

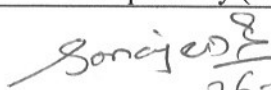
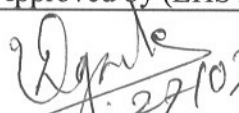
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Philippines - PICCS	N (aprepitant)
USA - TSCA	N (aprepitant)
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

Section 16. Additional Information**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 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.

Compiled By (R & D)	Approved by (EHS Head)
 26-07-2016	 27/07/2016
Signature /Date	Signature /Date